NBS TECHNICAL NOTE 777

# Cost Analysis of Blood Banking Alternatives

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Sponsored by
Office of the Assistant Secretary for
Planning and Evaluation, Department
of Health, Education, and Welfare
HEW North Building, Washington, D.C.
20201

U.S. DEPARTMENT OF COMMERCE, Frederick B. Dent, *Secretary*
NATIONAL BUREAU OF STANDARDS, Richard W. Roberts, *Director*

Issued September 1973

National Bureau of Standards Technical Note 777

Nat. Bur. Stand. (U.S.), Tech. Note 777, 121 pages (Sept. 1973)

CODEN: NBTNAE

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For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402
(Order by SD Catalog No. C13.46:777). Price $1.35

## Executive Summary

The purpose of this analysis has been to establish base line data on the national blood banking system and to project the cost impact and health risk associated with changes to the current system of blood banking through adoption of alternative legislative, technological, and operational policies. Reliable data on nonmilitary blood use and the ancillary problem of post-transfusion reaction due to poor quality blood are not readily available. Thus, a major portion of the study has been directed to the compilation and, where needed, estimation of operational and cost data.

In 1971, an estimated 7.3 million units of blood were collected by nonprofit and for-profit organizations. Of these about 6.2 million units were actually used for whole blood transfusions for about 2 million Americans. Approximately 3,000 of those transfused died of complications directly attributable to blood-induced reactions; and a substantially larger number remained in hospitals or underwent an extended convalescence, primarily due to hepatitis reaction. Hepatitis risk is several times higher when blood is obtained from a paid donor.

Currently, there are only about 62 million eligible donors, of whom 8% gave one or more units of blood last year. While this resource is capable of providing all blood needed now and even the estimated 7.7 million units projected to be required in 1976, unpaid volunteer donors presently account for only 75% of whole blood collected. There is a 20% annual turnover rate in the volunteer donor population; adverse reactions experienced during the donation process are a major cause of the high turnover rate. These factors point to the need for stronger donor recruitment and retention programs and for improvements in "blood letting" techniques.

The physician, not the blood recipient, controls the demand for blood. Many medical schools do not give sufficient instruction in proper blood utilization practices, and as a result, many physicians are using blood improperly. Frequently whole blood is transfused when packed red cells would be medically superior. This is a major cause of shortages in blood components and derivatives. Also many single unit transfusions are given needlessly. Improved physician training and education appear to be in order; peer review of transfusion practices is a possible first step in achieving improved blood use.

A second factor hindering more efficient blood utilization is the lack of cooperative and structured procedures for distribution and control of blood among collectors and users. Regional coordination of banking facilities is frequently lacking. As a consequence, outdating, shortages, and stockpiling occur more frequently than is necessary and greater reliance is placed on the paid donor.

There is risk associated with any transfusion and while most are unaffected, the few that contract hepatitis or cytomegalovirus or sustain an allergic reaction will pay a heavy price physically and economically.

Hospitalization, disability or death resulting from blood-related adverse reactions represent a major component of cost to the public. If the risk is to be reduced, efficiencies must be realized which will serve either to eliminate the paid donor from the system or to satisfactorily screen out all hepatitis carriers. A more effective Hepatitis Associated Antigen test is needed and alternative procedures described in the report require consideration if the Nation is to move to an all volunteer blood banking system.

Presently three Federal agencies, four national organizations, and at least eight states impose regulations on the blood industry. The nature of the regulatory controls, their degree of coverage and their manner of enforcement differ widely. There are deficiencies in Federal standards development, and administration; however, the principal gaps lie in the lack of (1) full coverage of the industry and (2) uniformity among licensing agencies.

The report includes a cost analysis of the current blood banking system and nine alternative system structures, namely:

(1) Tax Incentive - Adoption of a policy which provides a $25 tax deduction to blood donors (proposed legislation).
(2) Regional Coordination - Organization of the banking system on a regional basis with establishment of blood inventory control system.
(3) Regional Coordination (28 day life) - Like (2) above with the added assumption that use of CPD as a blood preservative (in lieu of ACD) will permit extension of blood "shelf life" to 28-days.
(4) "Milwaukee" Donor and Coordination Programs - A regionally operated banking system augmented by establishment of blood inventory control, donor registry and call-up procedures, and limited donor education programs.
(5) Transfusion Review Board - Adoption of peer review of blood utilization procedures to regulate and reduce improper blood use practices.
(6) Frozen Blood - Conversion of the existing banking program to a regionally controlled program involving transfusion of almost all red blood cells only if they have been frozen during processing.
(7) Legislative Elimination of Paid Donors - Elimination of all whole blood paid donors through Federal and State legislative means.
(8) "Milwaukee" Plus 28-Day Life - A combination of alternatives (3) and (4) above.
(9) "Milwaukee" Plus Transfusion Review - A combination of alternatives (4) and (5) above.

The analysis of costs indicates that alternatives 5, 8, and 9 are particularly advantageous.

Figure 1 shows the range of values over which these alternatives are preferred as a function of the cost associated with death and the level of HAA test effectiveness. This figure shows, for example, that at the

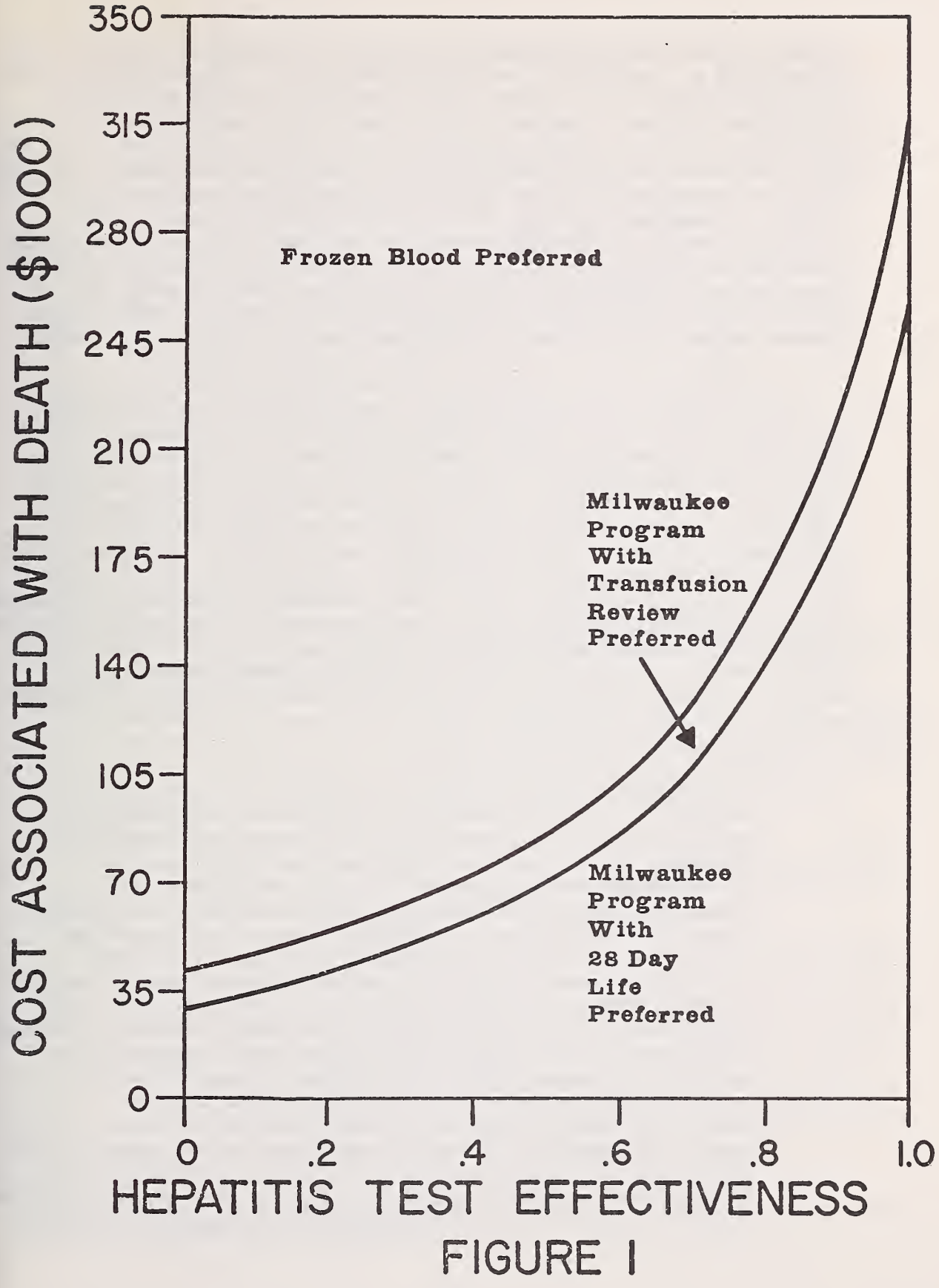
350
315
280
245
210
175
140
105
70
35
0
COST ASSOCIATED WITH DEATH ($1000)
Frozen Blood Preferred
Milwaukee Program With Transfusion Review Preferred
Milwaukee Program With 28 Day Life Preferred
0
.2
.4
.6
.8
1.0
HEPATITIS TEST EFFECTIVENESS

FIGURE 1

current 30% HAA test effectiveness, a decision maker would conclude that frozen blood is preferred if he feels that the cost associated with death exceeds $65,000. If he chooses a cost associated with death between $50,000 and $65,000, he would conclude that the Milwaukee program with transfusion review is preferred at this test effectiveness level. If he feels that a cost of less than $50,000 is associated with death, then the Milwaukee program with 28-day life would be preferred at this level. Analysis of uncertainty in the cost estimates reveals that it would probably be unwise to use unit cost as a criterion of choice between the Milwaukee alternatives. A choice might be based on the fact that "Transfusion Review" should improve blood utilization, thus reducing the average cost of health care to the patient. The regional frozen blood program results in a minimum of transfusion related disease and death, but at a higher cost per unit for preparation and storage.

*The findings of the study suggest the feasibility of an effective department approach involving minimum Federal control, but with Federal support of developmental efforts which will lead to adoption of an effective blood banking system. At the moment, a frozen blood system or a regional donor registry and call-up system administered by presently organized or chartered organizations such as the ANRC and AABB or a combination seem to be the principal candidate systems. Regional groups would develop and operate a comprehensive information system to foster the use of on-call volunteer donors and to reduce blood wastage associated with overcollection, maldistribution and outdating. Complementary actions in which DHEW has a greater or lesser involvement include donor recruitment and retention programs; development of improved standards for collection, processing, and storage; and professional education programs.*

Specific findings of the study are:

1. *The standards promulgated and enforced by the Division of Biological Standards should be strengthened and broadened to achieve a scope and comprehensiveness consistent with the standards of the American Association of Blood Banks.*
2. *The DHEW can assume responsibility for development and/or adaptation of a model state standard which serves to regulate the operations of blood handlers not engaged in interstate commerce and not licensed/accredited by the AABB or ANRC. Joint participation of a DHEW agency and state agencies should be considered as a feasible approach to standards development. Adaptation of the model standard by all states lacking equivalent legislation might be fostered and promoted by appropriately revising or strengthening DHEW policies vis-a-vis Medicaid reimbursement, categorical fund distribution, etc.*
3. *Methods of streamlining DBS procedures should be examined and means considered to promote research necessary to establish the safety and stability of blood derivatives and blood products.*
4. *Economic loss and health risk to a patient from post-transfusion hepatitis argues for continuation of the strong National Heart*

*and Lung Institute-sponsored research efforts on improved HAA testing.**

5. *Research on the approved use of CPD as a "28-day" blood additive and of blood derivatives from CPD-stored blood should be initiated in FY 73.*
6. *Peer/utilization review might be desirable as a means to establish and maintain higher standards of blood utilization.*
7. *Consideration should be given to JCAH-HEW cooperative efforts which would result in an added request for hospital review of transfusion as a requirement for JCAH-Medicare certification.*
8. *There is evidence that the use of tax incentives, monetary payment and other economic rewards to obtain blood may be counterproductive and should not be furthered without careful study of the likely effects.*
9. *A regional computerized donor registry and call-up system, supplemented with donor recruitment through advertising and other means, offers a way to increase blood supplies from unpaid volunteers. Central development and distribution of quality media advertising will be more efficient than many independent local efforts. Improved donor retention is crucial.*
10. *Elimination of the paid donor from the system concurrent with (9) is desirable from a cost standpoint in the absence of a highly effective HAA test or if the frozen blood concept is not adopted for nationwide use.*
11. *The physiological and psychological effects of blood donation and alternative procedures for collection of blood should be further analyzed and evaluated.*
12. *A regional system is preferred from a cost standpoint. Successful programs in a number of cities indicate that adequate administration can be exercised by organizations that have current responsibility for blood collection. An important feature that should be included in the regional control system is a donor registry and call-up system.*
13. *Carefully developed decision rules for inventory control, priority of blood use, collection quotas, etc., are also important features of an efficient system. These rules should replace the arbitrary and sometimes erroneous procedures currently in use.*
14. *Reduction in post-transfusion complications is a dominant consideration in seeking blood banking system improvement. A nationwide frozen blood system would provide the most equitable distribution of costs and the greatest reduction in patient risk, but would not require elimination of the paid donor. If frozen blood is judged to be too costly, the poorly screened paid donor should be eliminated through legislation, regulation, economic boycott or other means but only in conjunction with establishment of a regionally-controlled donor registry, call-up recruitment system and either transfusion review or 28-day CPD certification programs.*

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*This conclusion is warranted until such time as a nationwide frozen blood program is adopted and implemented.

15. *Transition to a frozen blood system must be accompanied by recruitment or retraining of technicians to staff the facilities.*

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This report provides a description of the current blood banking system and of the collection and derivation of quantitative information concerning system operation and blood cost. A reasonably accurate but somewhat incomplete profile of practices, attitudes, and likely costs of present and alternative systems has been developed. Among the topics presented are: (1) a discussion of the blood collection process including statistics on present use and future needs; (2) information relating to donor motivation, attitudes and incentives; (3) a brief summary of demonstration programs in the U.S. and national blood programs in other countries which provides some insight concerning means for improving blood quality and availability; (4) a description of blood processing, storage and distribution procedures; (5) narrative and statistical information relating to blood utilization practices; (6) discussions of post-transfusion reactions and frozen blood programs; (7) a discussion of current governmental and professional standards, regulations and controls which influence many, but not all, concerns involved in blood collection and processing.

This information serves as the basis for the selection of alternatives analyzed in a cost effectiveness analysis of eight apparently viable alternatives to the current system. Because of the possible variation which might be ascribed to many of the parameters used as a basis for costing alternatives, the sensitivity analysis is crucial in the comparison of alternatives.

Key words: Blood banks; blood utilization statistics; cost benefit analysis; donor profiles; peer review; regulatory activities; sensitivity analysis.

## 1. Introduction

The present report documents the results of three months of analysis of the national blood banking system and specifically addresses alternatives or actions which should be considered as a means for improving the current banking system.

The fundamental contribution of this report is the description of the current banking system and the collection and derivation of quantitative information concerning system operation and blood cost. As a result of extensive literature search and discussions with medical practitioners, researchers, knowledgeable blood banking officials, blood

donors, etc., a reasonably accurate but somewhat incomplete profile of practices, attitudes, and likely costs of present and alternative systems has been developed.

Chapter 2 of this report presents an overview of the perceived and real problems attributed to the current banking system and briefly describes several legislative proposals which influenced the thrust of some of the cost analyses reported in later chapters of the report.

Chapter 3 describes the current system in some detail. Among the topics presented are: (1) a discussion of the blood collection process, including statistics on present use and future needs; (2) information relating to donor motivation, attitudes and incentives; (3) a brief summary of demonstration programs in the U.S. and of national blood programs in Canada and overseas, which provides some insight concerning means for improving blood quality and availability; (4) a description of blood processing, storage and distribution procedures; (5) narrative and statistical information relating to blood utilization practices; and (6) subsections on post-transfusion reactions and frozen blood programs. This information serves as the basis for the selection of alternatives analyzed in a cost-effectiveness analysis.

Chapters 4 and 5 describe the methodology for and results of a cost analysis of eight alternatives regarded to be viable alternatives to the current system. Of particular importance are the results of a sensitivity analysis summarized in Chapter 5.11 and described in detail in Appendix B. This analysis was deemed to be necessary because of uncertainty about the numerical values which might be ascribed to many of the parameters used as a basis for costing alternatives.

Chapter 7 summarizes current governmental and professional standards, regulations and controls which influence many, but not all, concerns involved in blood collection and processing. Gaps in existing regulatory and control functions are also discussed.

Chapter 8 summarizes the results of the analysis and presents findings pertaining to (1) standards, (2) research, (3) professional education, (4) donor recruitment and retention, (5) system operation, (6) storage methods,and (7) financing and cost.

# 2. Background

## 2.1. Problems

The United States blood banking program has been severely and justly criticized on several grounds. Foremost among the criticisms are:

1. A lack of integration and communication between the various agencies involved in the procurement, processing, distribution,

and utilization of blood. Symptomatic of this problem are:
(a) unnecessary duplication of effort;
(b) high cost associated with collection and processing;
(c) waste due to stockpiling, poor management practices, and other causes.

2. A significant health risk associated with the transfusion process. While hepatitis is recognized as a principal problem, other infectious diseases (e.g., malaria, mononucleosis, cytomegalovirus) can be transmitted through transfusion.
3. A lack of uniform standards for blood collected and processed; only 15-20% of the blood collected is subject to Federal regulatory control as a product in interstate commerce and few states (less than a dozen) have any laws directed to blood quality or standards. Up to 80% of the whole blood is collected by agencies which are federally licensed. The residual, estimated at more than 1.4 million units annually, is collected or processed by concerns which are not required to adhere to any recognized standard of quality.
4. Unlike England, where 100% of the blood is donated, the United States must obtain about 25% of its blood (excluding plasmapheresis programs and the like) from paid donors whose blood has a higher than average health risk.
5. Transfusions of a single unit of blood are often given needlessly, thereby increasing the risk of disease transmission and placing an unnecessary drain on the blood supply. This unnecessary drain is furthered by many health professionals who, despite recent educational efforts by the AMA, continue to use whole blood when blood components are known to be preferable from a medical as well as a safety standpoint.

## 2.2. Policy Issues

These problems have led to the formulation of several policy issues which relate to the acquisition and distribution of whole blood. These issues are currently under study within DHEW, and are discussed in some detail in a DHEW internal working document of March 20, 1972, entitled "Revised Outline for Options on Blood Program." The issues relate to six topics:

1. Donor Incentives and Donor Selection.
2. Management of the Blood Delivery System.
3. Regulation and Standards.
4. Costs of Blood Products.
5. Component Therapy.
6. Blood Derivatives.

Each of these topics is discussed explicitly or implicitly in later sections of this report.

## 2.3. Proposed Legislation

Several legislative measures dealing with blood banking in the U.S. have been proposed during the last six months.

Congressman Victor Veysey (R-Calif.) proposes a multiple attack on the problem (H.R. 11828), including strong Federal initiatives to require licensing and inspection of all those who collect, process, and administer blood; encouragement of voluntary blood donation; and the labeling of paid donor blood. This bill would provide $10 million annually to fund an Office of National Blood Bank Programs.

A bill introduced by Congressman Edward Koch (D-N.Y.) (H.R. 11853) addresses the problem of blood supply and blood quality by offering a $25 tax deduction to unpaid blood donors. This proposal resembles H.R. 6416 (1961), which proposed a $50 tax deduction for unpaid blood donors.[1, 2] Senator Walter Mondale (D-Minn.) has introduced a bill (S1.3046) which would provide funds for research into causes, prevention, diagnosis, and treatment of blood disease, and for the improvement of blood banking programs at a rate of approximately $50 million annually (i.e., FY 1972-$50M; FY 1973-$55M; FY 1974-$55M; FY 1975-$50M; and FY 1976-$45M).

## 2.4. Need for Analysis

These criticisms, issues, and initiatives serve to illustrate the complexity of the blood banking problem. They also suggest a partial set of alternative courses of action which might be taken to reduce the cost and improve the quality, availability, and utilization of whole blood as a medical product. Basic questions must be asked and answered with regard to the cost and effectiveness of various changes, as well as the identification of the Federal Government's role in this process in the immediate future.

The technical approach employed in the analysis has been chosen to provide a basis for discriminating among a number of viable alternatives for change. The main variable is the cost of blood, but considerations of quality, quantity, and use are implicitly recognized and treated within the context of the analysis. As a starting point, the operational and economic character of the present blood system is described.

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[1]H.R. 11853 suggests a $125 maximum deduction; H.R. 6416 suggests a $200 maximum.

[2]For a discussion of H.R. 6416, see "Science, Economics, Politics, and Blood," Transfusion, Vol. 1, No. 5, 1961.

# 3. The Existing System

## 3.1. Collection

### 3.1.1. Some Statistics

Accurate information has not generally been maintained on the number of units of whole blood collected and transfused. The American National Red Cross (ANRC) compiles and publishes an annual record of its activities. Members of the American Association of Blood Banks and the commercial blood banks have not, in general, done so. Periodic attempts to obtain national statistics have provided incomplete and sketchy results. For example, only 7,060 of 10,443 facilities responded to a 1968 poll conducted by the American Medical Association. A recent poll by the American Hospital Association provided accurate data on units transfused in the first six months of 1971. From this data, ANRC annual collection reports and information obtained in personal interviews with AABB and Veterans Administration personnel, a fairly complete set of statistics on nonmilitary blood collection and transfusion was derived for 1971.

Using this information and U.S. Census data, the probable nonmilitary transfusion requirements during the next five years have been projected and the number of units transfused during the past five years have been estimated. Appendix A details the analysis and the major results are summarized below.

In 1971, 7.3 million units were collected; 6.2 million units were transfused; 15% of the collected units exceeded the 21-day legal age limit and were outdated. Donors were paid for 25.5% of the units collected and 28.9% of the units transfused came from paid donors.

In 1971, 1,500 AABB institutional members (including seven commercial blood banks) collected over 3.3 million units of blood, accounting for an estimated 45.4% of total collections.[3] Almost 2.9 million of these units were transfused (46.2% of total transfused units); the remaining 13.4% outdated. Donors were paid for about 36% of AABB collections and for 40% of the units which were actually transfused.[4] An unknown percentage of the unpaid donations were used to fulfill blood replacement obligations of those receiving AABB blood for which a cash fee would otherwise have been charged.

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[3]An additional 200,000 units were collected by a Los Angeles blood bank which the AABB feels is primarily an ANRC collector.

[4]About 30% of noncommercial collections came from paid donors.

Commercial blood banks, including the seven AABB members, supplied about 885,000 units, 12.1% of 1971 blood collections; 851,000 of these units were transfused, accounting for 13.7% of all transfused units. Less than 4% of the commercial blood outdated. All commercial blood is obtained from paid donors.

Another 3.2 million units (43.6%) were collected by the 59 ANRC regional blood centers which coordinate the activities of 1,700 individual chapters throughout the United States.[5] Only 2.6 million of these units were administered (41.5% of all units transfused); an estimated 19% of collections outdated. ANRC collections in 1971 were obtained from over 2.3 million unpaid volunteer donors; an average of 1.37 donations per donor were drawn during the year. These donors and their families were guaranteed a free blood supply for one year through their donations. Eighty-five percent of ANRC collections each year are obtained by mobile vehicles. The percentage of mobile collections is much lower among the other collectors.

A telephone survey was conducted in an effort to estimate average donor payments. Seventeen paying blood banks in 14 cities were contacted. Fees were found to range from $5 to $25 with an average of about $8. In many areas, a higher payment was offered for less common blood types.

The survey included hospital blood banks which maintain panels of medically screened donors who are willing to respond to telephoned requests for donation, community blood banks which screen their donors less carefully, and commercial blood banks which may draw blood from poorly screened donors. An example of the latter group is a blood bank whose Chicago branch pays $5 in voucher, redeemable only at a nearby liquor store. The store requires either a purchase or payment of 10¢ as the cashing fee. An official of this blood bank explains the voucher system:

> "There is a currency exchange three blocks away (from the drawing station), but some of these guys (paid donors) would have a hard time finding it."[6]

Estimates of demand in the recent past and the immediate future were based on per capita blood utilization rates and population estimates as described in Appendix A. The U.S. Census Bureau gives four estimates of future population; the demand for blood was projected for Population Series B and D. Table 1 contains estimates from 1967 through 1976.

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[5]An additional 200,000 units were collected in New York by a community blood bank which we feel is primarily an AABB collector.

[6]"Blood Banks: Pay Stations of Winos, Addicts," Chicago Tribune, September 14, 1971.

Table 1. Estimates of Number of Units of Blood Transfused

| Year | Population (1000's) | Units Transfused (1000's) |
|---|---|---|
| 1967 | 198,629 | 5,899 |
| 1968 | 200,619 | 5,958 |
| 1969 | 202,599 | 6,017 |
| 1970 | 204,800 | 6,083 |
| 1971 | 207,006 | 6,148 |

Future Estimate Based on Population Series B

| Year | Population (1000's) | Units Transfused (1000's) |
|---|---|---|
| 1972 | 209,484 | 6,222 |
| 1973 | 212,155 | 6,301 |
| 1974 | 215,053 | 6,387 |
| 1975 | 218,177 | 6,480 |
| 1976 | 221,519 | 6,579 |

Future Estimate Based on Population Series D

| Year | Population (1000's) | Units Transfused (1000's) |
|---|---|---|
| 1972 | 209,181 | 6,213 |
| 1973 | 211,530 | 6,282 |
| 1974 | 213,999 | 6,356 |
| 1975 | 216,561 | 6,432 |
| 1976 | 219,239 | 6,511 |

Thus we estimate that blood utilization increased by 250,000 units between 1967 and 1971 or about 60,000 units per year (1.1% per annum). Depending on which population series is used, blood utilization is projected to increase between 360,000 and 430,000 units by 1976. The average increase is about 80,000 units per year (1.3% per annum).

### 3.1.2 Donor Population: Attitudes and Motivation

Blood donor eligibility, attitudes, and motivation are extremely important considerations for determining the effect of programs designed to alter the donor population. At the start of this study, it was anticipated that only the results of a literature search on these topics would be reported; however, the paucity of information in this area, some obviously erroneous, required that limited survey work and analysis be performed. Consideration of incentive programs which have been tried in the U.S. or other economically developed nations proved another valuable source of insight into these questions.

The volunteer donor in the U.S. is on the average older than the paid donor, better educated and more likely to have church affiliations. Eighty percent of the volunteers are men. About 80% of all volunteers are employed and less than 20% are students or nonworking women.[7] The main reasons cited for voluntary donor participation are the benefits of a protection plan, replacement for a friend, altruism and social pressure. Volunteers expect no recompense for participation, except possibly membership in a protection plan or cancellation of another's debt. Many give three or more times a year; these people have largely altruistic motives.[8] Some consider payment for blood to be immoral, but it is not clear what portion of the donor population holds this view.[9] It follows that those who feel strongly about the morality of selling blood might be lost to the system if blood is treated as a commodity.

Blood banking organizations generally state that there are 100 million eligible blood donors in the U.S. but that only 2-4% of those available actually donate.[10] This leads to the conclusion that there is a vast untapped resource of donors who could, if motivated, satisfy all conceivable national blood needs. However, if a random sample of

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[7]S. Condie and N. Maxwell, "Voluntary and Paid Donors," Transfusion, Vol. 10, No. 2, pp. 84-88, 1970.

Korzekawa, Jordan, and Alsever, "The Blood Donor: I. Who Are Our Donors? An Analysis of Social and Other Characteristics of 12,759 Donors," The American Journal of the Medical Sciences, Vol. 240, July 1960, pp. 36-46.

[8]Condie and Maxwell, "Social Psychology of Blood Donors," Transfusion, Vol. 10, No. 2, 1970, pp. 79-83.

London and Hemphill, "The Motivations of Blood Donors," Transfusion, Vol. 5, No. 6, 1965, pp. 559-568.

H. Grace, "Blood Donor Recruitment: A Case Study in the Psychology of Communications," The Journal of Social Psychology, Vol. 46, pp. 269-276, 1957.

[9]T. Ireland and J. Koch, "The Political Economy of Blood," presented at the 1972 Meeting of the Public Choice Society, Pittsburgh, May 3-6, 1972.

[10]See e.g., Supply, Demand, and Human Life, AABB, 1970.

mature individuals is polled regarding participation, it is likely that a good many more, perhaps 20-25%, have attempted to donate blood at one time or another. In fact, the number of units drawn at most installations which are visited by an ANRC mobile unit is between 15 and 25% of the number of people in the organization. These anomalies, together with other data appearing in the literature, indicate that many more eligible donors may be currently participating, or have previously participated, in blood collection programs.

An analysis was performed using available data in an effort to estimate the situation with respect to donor eligibility and participation. The analysis is reported in Appendix B and is summarized here.

While there were 114,525,000 residents in the U.S. and its territories during 1970 who were between the ages of 18 and 65, and therefore age-eligible to donate blood, many were ineligible to do so because of health disorders, pregnancies, weight conditions, etc.[11, 12] For example, about 11 million of the 114 were ineligible because of heart disease. During 1970, about 4 million otherwise eligible women were pregnant. Another 24 million men and women were ineligible on the basis of weight or anemia. Active allergies or asthma accounted for another 11 million. In summary, age, health, or health-related problems reduced the number of eligible male donors to about 35 million and the number of females to less than 27 million giving an estimated 62 million eligible donors nationwide during 1970.

Based on other information reported in Appendix B, it appears that of the 5.45 million units donated by unpaid donors, about 1.1 million come from "first-time" donors and the remaining 4.35 million from approximately 2.9 million individuals who were already in the program. The 1.85 million paid units were obtained from about .95 million individuals. Thus, it is estimated that to satisfy 1971 blood needs about 8% of the eligible population were involved. Moreover, because of the relative stability of donors entering and leaving donor programs over the last decade, it appears that approximately 25% of the eligible population has given one or more units since 1960. The turnover is estimated to be approximately 20% per year.[13]

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[11]Many areas do not allow donation after age 60.

[12]According to Blood Center Operations for the Year Ended June 30, 1971, the ANRC exempts about 12.0% of prospective donors each year. However, the majority of medically exempted donors never again attempt to donate; many others do not attempt an initial donation because a recruiter informs them that they would be rejected. The percentage of age-eligibles who are medically exempt is, therefore, probably much higher.

[13]The ANRC's Blood Center Operations, states that 20% of ANRC donors were first-time donors in both 1970 and 1971. Those exempted for medical reasons are not counted as donors. Since our estimates indicate an annual increase in collections of only about 1%, almost 20% of the donors who give in any year must never give again.

The next question that must be asked is: what causes this stable, but high, turnover of blood donors? Of the 4 million who participate in some form of voluntary blood donation during any year, only about 3.2 million ever give again. A portion would be expected to drop out due to ineligibility (e.g., age, health defect), but a 20% loss rate indicates that part of the solution to satisfying blood needs with healthy donors may lie with the retention and not the initial recruitment of such donors.

Some studies have been undertaken on the psychology of the blood donor. For example, London and Hemphill investigated the extend to which blood donations in San Francisco might be increased through education concerning the blood banking system. The study involved previous donors who would be expected to have a greater knowledge of the blood banking system than those who had not participated in any program.

While the authors concluded that more education would be beneficial, several collateral findings of this study, not necessarily related to the primary study objective, are of greater interest. In the course of interviewing their donor sample, London and Hemphill found that there was a great deal of concern about the "blood letting" process. Twenty-nine percent of those donors interviewed felt that most people might feel weak after a blood donation, and 46% indicated that most people might feel faint or dizzy after giving blood. Since these were donors, it seems reasonable to hypothesize that their responses were based, at least in part, on their personal reactions or on observation of other donors in the process of giving blood. A study by Condie and Maxwell reaffirms that there are psychological, if not physiological, drawbacks to giving blood, even among veteran donors. Seventeen percent of veteran donors in their study anticipated more than a little difficulty in donating, and 30% were bothered by the feel of the needle.[14] The U.S. Army has found that 6.7% of their donors reacted on the donor bed, and an additional 3.8% reacted after leaving the bed but before leaving the donor area. Seventeen percent of the donors who were questioned expected difficulty. Twenty-three percent of those expecting difficulty and 8% of those not expecting difficulty had reactions.[15]

The literature provides little information concerning donor habits; the effectiveness of education programs; incentives for obtaining or retaining donors; or the reasons that people choose not to donate. The only other finding of interest from the literature survey is that there is no significant correlation between number of blood units collected and the socio-economic characteristics of the community.[16] The donor turnover

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[14]"Social Psychology," loc. cit.

[15]C. Shields, "Quality Control Approach to Improve Donor Care," Transfusion, Vol. 10, No. 5, 1970, pp. 272-278.

[16]T. Rockwell and R. Hanlon, "The Effect of Community and Chapter Characteristics on Blood Donations," Transfusion, Vol. 3, No. 5, pp. 401-407, 1963.

rate (as measured by the percentage of repeat donors), the donor reaction rate, and the number of replacement donations also have no effect on the collection rate. However, the rate of volunteer donation is highly correlated with the size and concentration of the age-eligible donor population and the amount of blood used in a region. It thus appears that the rate of donation is determined by the demand in the immediate area and by the availability of eligible donors. These factors probably influence the level of donor recruitment activity, but verification of this hypothesis has not been attempted.

Because of the limited information in the open literature, a very limited survey was designed and carried out to (1) obtain further information on blood donor reaction and (2) determine the reason for nonparticipation of those who do not donate. Fifty-two male and 42 female Federal employees were arbitrarily selected and interviewed. Each had the opportunity to donate at mobile red cross collection units which arrived periodically, and each was aware of an active donor recruitment program. The males interviewed were on average older and better educated than the females. The results of the survey are not conclusive; however, responses did tend to support the fundamentals of London and Hemphill in San Francisco and to provide some new information on non-donor attitudes.

Twenty-seven of the 52 males and 23 of the 42 females had at one time volunteered to give blood; 14 of the males and nine of the females continue to give blood. More than half of those who stopped giving did so after donating more than once.

The majority of those who had donated blood at least once indicated that they had some adverse reaction such as weakness, dizziness, fainting, pain, or hematoma during or after at least one donation. In most cases, this reaction occurred after the donor left the collection area and was not reported to the ANRC. This implies that published nonmilitary figures which show a 4.5% donor reaction rate probably underestimate the situation. Twenty-eight percent of those interviewed (eight women and six men) had stopped future donations due to adverse reaction. An additional 30% (eight women and seven men) no longer donated because of medical ineligibility. Three other individuals had stopped donating because they believed blood was no longer in short supply.

Non-donors represented about 47% of the random sample selected from this agency. Lack of participation was usually attributed to one of four reasons: Over 45% (seven men and 13 women) indicated that they had not tried because they believed they were disqualified from doing so for medical reasons. Another 23% (six men and four women) indicated that fear of adverse reactions, such as fainting in front of others or pain of the needle, was the primary reason for nonparticipation. An additional four men and two women had not given because they knew they would have an adverse reaction if they gave. Seven men indicated that failure to participate was primarily due to lack of interest or any incentive to "get involved"; many of these individuals may have been unwilling to admit that they were "scared" to donate.

It would appear, then, that retention rates among mobile unit donors are low because of medical disqualifications and adverse reactions to donating. Anticipation of medical disqualification, anticipation of a recurrence of adverse reaction, and primal fear of donating are major causes of nonparticipation.

It appears that donations can be increased by a more intensive recruitment campaign or by efforts to reduce donor reactions. We hypothesize a higher payoff from increased efforts to reduce donor reactions than from additional efforts to recruit new donors. However, we cannot test this hypothesis because the scope of this study is not broad enough to permit accurate definition of the relationship between amount of blood collected and efforts exerted. The data problems that would be encountered in attempting to develop this relationship from published ANRC data are illustrative: (1) Practices at local chapters within a region vary widely and only regional totals are readily available. (2) Canteen cost is the only readily available surrogate for donor retention efforts. Other expenditures for donor retention may not correlate with the canteen cost, and if they do, total retention expenditures are assumed to be higher than canteen costs. (3) Volunteer workers do much of the recruitment and canteen work. No measure for the amount of volunteer work is readily available. (4) It is difficult to cost vacation time and other recruitment incentives donated by employers.

A rough analysis using the available ANRC data[17] was, nevertheless, attempted. It was possible to explain 86% of the variation in regional collections (at statistically significant levels) as a linear function of regional population, regional canteen expenditure and regional recruitment cost. Despite the extreme limitations of the data, this crude analysis gives further credence to the hypothesis that there is greater cost benefit in retaining donors rather than recruiting new ones.

A number of American cities have recently adopted new recruitment tactics, accompanied by installation of a management information system and regional control of blood resources. Most notable are: (1) an AABB-coordinated demonstration program in the Passaic Valley of New Jersey; and (2) a project supported by the NHLI in Milwaukee, Wisconsin.

The Passaic Valley program seems rather drastic. Except in emergencies and extreme hardship cases, patients in area hospitals are expected to supply donors at the blood bank in advance to fill their anticipated surgical blood requirements. "If the blood was not administered to the patient, either a credit of $15 for each pint (but not more than $30 total) was applied to the patient's hospital bill or the blood was held as a credit for the patient.... Once the policy had become firmly established, it was rarely necessary to delay admission

[17] Blood Center Operations for Year Ended June 30, 1971.

until donors were provided."[18] Not surprisingly, donations received through blood assurance programs have increased considerably since this policy was adopted, and the need for paid blood donors has been almost completely eliminated.

In Milwaukee, five donor retention strategies have been instituted: (1) Voluntary donors have been "offered the opportunity to complete a form expressing their willingness to become an on-call donor for cardiac surgery." Approximately 1,000 donors, about 8% of those who gave blood during the first four months of the program, completed the form. (2) Donor club membership lists are being placed on computer files. When a mobile unit visit to a club is planned, special appeals are sent to those who have blood types which are in short supply. (3) Members of the blood assurance plan are automatically called by blood type at peak demand periods. Although these donors need only give once a year to maintain coverage, if possible they must respond when called. (4) First time donors are called after their donation and encouraged to return. Questions relating to procedures or problems that were encountered are answered for these donors. (5) A public relations firm was hired to prepare media and news campaigns intended to increase the number of assurance plan and replacement donors.[19]

The effect of these strategies has been spectacular. At the start of the program over 40% of the units came from paid, on-call donors. Eighteen months later, all paid donors had been eliminated. Many of the on-call donors continued to give without payment. About 4,500 phone calls are currently made each month in attempts to obtain blood. Approximately 20% of these calls result in a donation within 24 hours. The success of this program is partially the result of a quality mass media campaign which recently won a Public Relations Society award. The cost of donor recruitment, including fees paid to the public relations firm, three telephone operators, and an additional staff of three full time employees, adds less than $.80 to each unit of blood collected.[20]

A review of donor incentive programs in foreign countries is informative. Notable are programs in the U.S.S.R., Canada, Great Britain, Sweden, and Japan.

In the U.S.S.R., about 50% of the donors are paid, but many areas supply all their blood needs by voluntary donations. Most blood is

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[18]J. Churg, P. Steindaut, R. Brilly, J. Gannon, A. Ellis, H. Sobel, and I. Weiss, "Passaic Valley Blood Program," Transfusion, Vol. 11, No. 2, pp. 102-105, 1971.

[19]S. Masouredis, D. Roseth, R. Stelloh, J. Perine, I. Nehama, T. Hurst, A. Rimm, G. Becker, E. Strei, S. Krenz, and R. Aster, "Development of an Automated Blood Inventory and Information System for a Regional Transfusion Service," Transfusion, Vol. 10, No. 3, pp. 182-193, 1970.

[20]Personal communication with Mr. T. Hurst, MBC.

donated in mobile units, and a special effort is made to provide a warm and attentive atmosphere. All donors receive a day off from work to give their donation. They also receive written thanks for each donation, a "Drop of Blood" badge for the first donation and special badges for the fifth, tenth, and fifteenth donations. Paid donors receive 60 rubles per liter of blood. This amounts to between 15 and 25 rubles for an average donation (16-27 dollars). Voluntary donors are given a free meal and an additional day off from work.

All donors in the U.S.S.R. are thoroughly examined by a physician who determines how much blood the patient will be allowed to give. "The usual initial donation is 250 ml rising at subsequent donations by 50 ml to a maximum of 450 ml."[21] A waiting period of eight weeks is required between donations.

The British and Canadian blood donation systems have always been completely voluntary, and there has never been a charge for blood products. There is a transfusion fee, but in most areas, the national government pays all costs of hospitalization so the fee is not directly assessed on the patient. In Canada, over 30% of collections outdate before they can be used. An average of .0325 units are transfused per person each year[22] which is slightly higher than a comparable figure for the U.S.

The Canadian Red Cross (CRC) has an "overwhelmingly positive public image," and carries out massive recruitment campaigns.[23] Recruitment costs are about $1.80 per unit collected and account for over 20% of total CRC expenses. This is a considerably larger amount than the ANRC presently spends on recruitment. Recruitment methods used include spot ads "on the radio, in newspapers, and to a lesser extent on TV"; scheduling of collection clinics for most employers and organized groups (recruitment of donors is handled by group members); and telephone scheduling of donations from those who have previously donated. A special program is conducted in the high schools to obtain donations from males over the age of 16. Finally, personal appeals to recruit donors are made to all those receiving transfusions.

In British Columbia, 13.7% of the units were obtained from new donors in 1971, 8.4% of them from high school students. Collections in 1971 totaled 95,000 units; 200,000 donors (probably about 20% of the eligible population) have given in the past five years. There is thus an average

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[21]"The Public Health Service and the Blood Donor Problem - Abstract," Transfusion, Vol. 6, No. 3, p. 276, 1966, and J. Vaughn, "Blood Transfusion in the U.S.S.R.," Transfusion, Vol. 7, No. 3, pp. 219-229, 1967.

[22]Canadian population estimates used in analyzing this data from Information Please Almanac 1967.

[23]Much of the raw material on the CRC is based on findings in internal working documents of the DHEW Task Force on Blood Banking.

of only 2.5 units per participating donor over the five year period, indicating that the CRC, like the ANRC, has donor retention problems.

In Great Britain, blood donations take on the aspect of a social function. Retention in the English system appears to be very high although the percentages are not available.[24] Employers are cooperative, and it is not unusual for an employee to call in and report that he is taking the morning off to give blood. To enhance the social aspect of the donation, the atmosphere at the blood bank is warm and pleasant. Surprisingly, 40% of British donors are women. Donations are limited to two per person per year. In many areas, danger of shortage occurs several times a year; special media appeals are used to recruit during these periods.[25]

In Sweden, all blood donors are paid. Such payment serves as a reimbursement for community service and an incentive for the young to participate. Donors are given annual physical examinations. Extensive health records are maintained and all cases of transfusion-related disease are traced back to the carrier. Recruitment drives are held at most places of work. Attempts are made to schedule donations about one month before a mobile vehicle or blood bank visit. The system is augmented by soliciting emergency donations from registered donors via telephone and maintaining supplies of frozen blood as protection against shortages. Donors are encouraged to give blood four times a year.

In Japan, until recently, almost all blood was obtained commercially, There was a large population of professional donors who had no other source of income. To increase their donation frequency, these donors reportedly drank a mixture of sea water, iodine, and iron filings which was intended to raise their hemoglobin level. The majority of these donors had hepatitis. When U.S. Ambassador Reischauer contracted a much-publicized case of serum hepatitis during surgery in Japan in 1970, the Japanese Government initiated a program designed to eliminate paid donations.[26] No further information is available on the results of this action.

### 3.2. Processing

After collection, each unit of blood is tested for group, type, antibodies, venereal disease (VDRL test), and hepatitis associated antigens (HAA). If the VDRL and the HAA tests are negative, the unit is labeled by group and type, screened for antibodies, and refrigerated.

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[24]R. Titmuss, The Gift Relationship, Random House, 1971.

[25]Personal communication with Mr. Raymond Ward, English management consultant and former director of the Local Government Operations Research Unit, Royal Institute of Public Administration.

[26]C. Holden, "Blood Banking: Tangled System Resists Swift Change," Science, Vol. 175, pp. 1444-1446, March 31, 1972.

To save time and money, the ANRC frequently pools samples from several units of blood for the antibody screening.

Upon receipt of requested blood units from the processing agency, the hospital laboratory will often repeat the group, type, antibody screen, and HAA test to verify the original work of the processing agency. This process is normally done on six to ten units at a time, and takes one medical technologist 1-1/2 to 2 hours. After verification of the lab work, the unit is inventoried for use.

When a transfusion is needed, the laboratory performs a group, type, and antibody screen of the patient's blood, then does a major screen cross-match. Finally, the correct unit in inventory is pulled, verified to still have satisfactory salinity and albumin levels, and again rechecked for group and type. This process takes a technologist approximately 45 minutes. It is estimated that for every 2.7 times a unit is cross-matched, processed, and reserved for an operation, only one unit is actually transfused.[27] Consequently, a pint of blood will normally be processed several times before it is transfused or its maximum legal storage date is reached.

The processing at the time of collection, receipt by hospital, and prior to transfusion is usually, but not always, done in accordance with Public Health Service Regulations or AABB Standards for Transfusion Services.

### 3.3. Storage

Whole blood is normally stored at approximately 4°C in either an acid citrate dextrose (ACD) or a citrate phosphate dextrose (CPD) anti-coagulant solution. CPD is a newer solution which is claimed to ensure shelf life up to 28 days.[28] (Canada presently allows 28-day storage in CPD.) After this amount of time, the unit is considered unusable because less than 70% of the red cells can be expected to survive transfusion. The Division of Biologic Standards (DBS) has placed a shelf life of 21

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[27]O'Hara and Josephson, "Automated Data Processing System for Blood Banks," Transfusion, Vol. 10, No. 4, p. 220, 1970.

Confirmed by personal communication with Col. Peak, Congressional Liaison Representative of AABB, who estimated a 3-1 ratio.

[28]See, for example, Dawson, Ellis, Kocholaty and Shields, The Hemoglobin Function of Blood Stored at 4°C, U.S. Army Medical Research Laboratory Report No. 836, or Bowman, "Red Cell Preservation in Citrate-Phosphate-Dextrose and in Acid-Citrate-Dextrose," Transfusion, Vol. 3, No. 5, 1963, p. 364.

days on both ACD and CPD until more conclusive tests can be made.[29] In addition to permitting storage in solutions of ACD and CPD, DBS permits blood to be stored in heparin solution.

Another means of extending shelf life is to freeze the red cell portion of the blood. At present there are two major processes by which this can be done. The first involves a very rapid freeze in a solution which has not received DBS approval because it is partially retained in the body. The second method involves a much slower freezing in an anti-coagulant solution of ACD and glycerol. During the post-thaw period, the red cells must be washed to remove the glycerol. There are two slow freeze methods which have been in use for over ten years.[30] No upper bound on shelf life has been established for the Cohn fractionator slow freezing techniques through which at least 11 years storage is achievable.[31] DBS has approved a three-year shelf life for blood frozen by the Huggin's slow freeze technique.

## 3.4. Distribution

Distribution systems within the United States vary widely. Their characteristics are influenced by the size of the region served and by sources of the blood supply available for transfusions. Some areas have a single supplier. For example, in Connecticut, a state-wide collection and distribution system has been established by the Red Cross. There are virtually no paid donors, and user organizations deal directly with a central Red Cross facility to obtain their supplies of blood. The city of Milwaukee also has a highly centralized and fully volunteer collection and distribution system. Blood is processed and stored by the Milwaukee Blood Center and is requisitioned, on the basis of need, by hospitals in the area. Since blood is readily available and the source is centralized, there is less stockpiling in user facilities. This is reflected by substantially less outdating and wasted blood than is found in other metropolitan areas.

Unfortunately, these examples appear to be the exception rather than the rule. In many areas, particularly large cities, the ANRC, the AABB and various commercial blood banks co-exist. A hospital will normally deal with a single supplier such as the ANRC; however, when blood is scarce or a less common blood type is needed, a commercial bank may be

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[29]The U.S. Army has developed methods using ACD with two additional additives, adenine and inosine, which allow safe storage for up to 42 days, but the additives are partially retained in the body. Further research on their long-term effects is required before a decision can be reached on their safety.

[30]Valeri and Runck, "Long Term Frozen Storage of Human Red Blood Cells," Transfusion, Vol. 9, No. 1, 1969.

[31]Tullis, Transfusion, Vol. 11, No. 2.

contacted or a hospital donor registry used to fill the gap. In areas where there is no recognized single source of supply or a clearinghouse to maintain records of inventories, a great deal of blood waste by outdating apparently occurs.

Regional coordination has been attempted in a number of areas. The ANRC has developed a computerized management information system which costs about $.40 per collected unit to operate. This system has been tried in many ANRC regions. Some regions have encountered difficulty in convincing hospitals to report their inventories fully. The main problem is with the reporting of rare blood units which the hospitals fear they might be unable to replace if the need arose.[32]

The AABB is presently operating pilot regional clearinghouse programs in the San Francisco area, the Passaic Valley, New Jersey area and in the Washington, D. C. area. All of these programs are based on frequent telephone checks of hospital inventory levels. Special recruiting policies exist in all programs, and paid donors have been virtually eliminated.

In San Francisco, all blood is supplied by the Irwin Memorial Blood Bank. The majority of blood is distributed in accordance with preassigned quotas which are reviewed every six months. In addition, inventory checks are made four times a day, and blood is redistributed as necessary. Since blood is on consignment until transfused, the central blood bank encounters no difficulty in obtaining cooperation from the hospitals. The outdating rate is estimated to be between 6 and 8%.[33]

In the Passaic Valley region, each hospital collects its own blood. The AABB Clearinghouse functions as an exchange center and accounting agent. To date, no problems of cooperation have been reported. To reduce outdating, the AABB-endorsed policy which suggests that blood transfers between hospitals should be restricted to units less than five days old has been replaced by a policy of transferring the oldest unit first. Outdating has averaged less than 5% since 1967.[34]

In Washington, D. C., the majority of the blood is drawn by the ANRC. Control of the remaining supply is coordinated by the Metropolitan Washington Blood Plan. The MWBP polls inventories at 13 area hospitals twice each day, and units are redistributed as necessary. The only charge to the hospital for this service is $1 per unit transported. The total cost is not clear because additional funds are obtained through an

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[32]Personal communication with Dr. William Sherwood, Philadelphia ANRC.

[33]Internal working documents of the DHEW Task Force on Blood Banking.

[34]Churg, et al., op. cit.

annual blood protection plan membership for $10 per family. Figures on outdating are not available.[35]

The Lockheed Missiles and Space Co. has done extensive developmental work on systems for regional control of blood inventories. The system developed by Lockheed, like the AABB clearinghouse pilot projects, relies on telephone monitoring of hospital inventories. The Oakland demonstration project is illustrative. Oakland has a central blood bank facility.

In Oakland, five control policies were adopted:

(1) Blood in a hospital which has a low utilization rate is moved to a hospital with a high utilization rate if it is not transfused within ten days after collection.
(2) If a unit which has been cross-matched is not used or released within two days, the reservation is reconfirmed with the requesting physician.
(3) If the average inventory in a hospital is several times the weekly utilization (computed over a 13-week period), an attempt is made to convince the ordering pathologist to change his ordering policy.
(4) Blood presently in the system is checked before on-call paid donors are contacted.
(5) The performance of all participating hospitals is rated and the ratings are distributed.

These policies have resulted in reduction of outdating from a 13% level to a 5% level, 30% reduction in blood bank inventories, and a major reduction in shortages at the central blood bank. The service costs about $.45 per unit.[36]

A similar system in Milwaukee was developed with the assistance of former Lockheed personnel. There is again a central blood bank, the Milwaukee Blood Center (MBC). The control policies, many of which are based on an analysis of early system operations, are:

(1) The central blood bank sends the oldest blood in stock first. Blood less than four or five days old is normally sent out only for special orders, such as cardiovascular surgery where a very high percentage is transfused within one or two days. Such usage constitutes about 22% of total blood transfused in the Milwaukee region. Blood over 19 days old is normally only sent to hospitals with immediate transfusion needs.

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[35]Personal communication with Mr. Kenneth Staffa, Executive Director MWBP.

[36]Catassi and Peterson, "Blood Inventory System - Helping Blood Bank Management Through Computerized Inventory Control," Transfusion, Vol. 7, No. 1, pp. 60-68, 1967.

(2) If a unit of AB positive, AB negative or B negative blood is held at a hospital for more than three days, the hospital is called to verify that the need is still imminent. If it is not, the unit is recalled to the central bank.
(3) The performance of all participating hospitals is rated, and the ratings are distributed.

Little control is exerted over order and return policies for units of common blood types because MBC personnel fear that an attempt to exercise such control would hinder cooperation. Recently published results show that the probability of a unit outdating at a hospital with a low volume of transfusions need not exceed that at a hospital with a higher volume. The key indicator of unnecessary outdating is an average daily inventory level which exceeds nine times the average daily number of transfusions[37]

Introduction of inventory control in the Milwaukee area has reduced outdating from 7% to 6%. The percentage of blood obtained from paid on-call donors has been reduced from 40% to zero.[38]

Regional coordination efforts, to date, are deficient in two respects. First, as J. B. Jennings points out, with the partial exception of the Milwaukee system, regional inventory control systems seem to be based on arbitrary rules of thumb.[39] To find the best decision rules, analysis of data from the existing systems will be required. Secondly, all of the systems use the percentage of paid donors, shortage rate and outdate rate as performance measures. This set of performance measures does not allow for consideration of blood potency. Many policies intended to reduce outdating, for example the policy of transfusing oldest blood first, lead to the use of the least potent product available in order to assure sufficient supply. Such policies may be unwise if supply can be maintained by calling in medically screened paid donors. Cost, shortage rate, average age of transfused blood, and percentage of paid donors would probably be a preferable set of inventory system performance measures.

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[37]D. Yahnke, A. Rimm, C. Mundt, R. Aster, and T. Hurst, "Analysis and Optimization of a Regional Blood Bank Distribution Process: I. Introduction and Descriptive Analysis," Transfusion, Vol. 12, No. 2, pp. 111-118, 1972.
Personal communication with Mr. T. Hurst.

[38]Masouredis et al., op. cit.
Yahnke et al., op. cit.
Personal communication with Mr. Hurst.

[39]J. B. Jennings, Inventory Control in Regional Blood Banking Systems, Technical Report No. 53, MIT Operations Research Center, July 1970.

## 3.5. Utilization

A unit of blood can be transfused or it can be split into components. If the unit is split into components, it is first separated as plasma and packed red cells. Further separation of the plasma into cryoprecipitate, platelets, leucocytes, and a residuum is possible. The residuum is usually processed to obtain a number of blood derivatives. These include serum albumin, gamma globulin, fibrinogen, and various immune serums. Most of the derivatives can be recovered from outdated blood and this is often done if blood is returned to a component processing facility.

During FY 1971, the ANRC prepared the following amounts of whole blood and blood products for medical use:[40]

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|---|---|
| Whole Blood | 2,921,258 units |
| Red Cells | 483,934 |
| Cryoprecipitate | 248,107 |
| Fresh Frozen Plasma | 183,048 |
| Platelet Concentrate | 201,707 |
| Platelet Rich Plasma | 5,268 |

Common situations which require the use of whole blood are severe blood loss, exchange transfusion and open heart surgery. However, pathologists agree that less than 15% of those patients receiving transfusions need whole blood. Seventy-five percent currently receive this type of transfusion, although in most cases, packed red cells would have been preferred.[41]

There are many advantages to using packed red cells rather than whole blood. The reduced volume of fluid minimizes the possibility of circulatory overload and cardiovascular failure; the lower concentrations of sodium, acid, potassium, ammonium, and citrate are preferable for some medical conditions; and post-transfusion reactions are minimized because of the decreased amounts of plasma.

Unlike packed red cells, which are generally useful in situations where transfusion is required, most components and derivatives of whole blood have specialized applications. Cryoprecipitate, fibrinogen, platelets, and fresh frozen plasma are all used in treating clotting deficiencies. Serum albumin is available in a 5% buffered saline solution or a 25% "salt-poor" form. Both solutions may be used interchangeably for the treatment of shock due to hemorrhage, trauma, infection, or operation. Gamma globulin and leucocytes relate to the body's ability to fight

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[40]ANRC, 1971 Annual Report of the American National Red Cross.

[41]Committee on Plasma and Plasma Substitutes of the National Academy of Sciences-National Research Council, An Evaluation of the Utilization of Human Blood Resources in the United States, 10/70.

disease.[42] Since many of the blood components and derivatives are in short supply, increased use of packed red cells instead of whole blood would make more plasma available for fractionation and thus ease the shortage.

Both the American Medical Association and the National Academy of Sciences have initiated education campaigns to encourage physicians to use components in lieu of whole blood. The AABB, since 1967, has sponsored a series of component therapy workshop programs. In some areas, most notably in Massachusetts, the percentage of transfusions performed with packed red cells has increased dramatically as a result. Some hospitals now use packed red cells in 80% of all transfusions.[43]

On the other hand conversion to component therapy has been ardently resisted by many physicians, as the NAS-NRC report on blood utilization points out:

> In many communities, the physician, even if he is aware of the benefits ascribed to component therapy, continues to regard whole blood in an almost mystical light and is reluctant to deny his patient any of its potential restorative powers. He may acknowledge that red cell preparations alone can restore oxygen transport and that albumin alone can restore blood volume; but he still believes that the natural combination is best for his own patients. Neither the surgeon, with his attention focused on his patient undergoing surgery, nor the internist, dealing with his patient with anemia, is likely to be moved by economic considerations or by the need of other patients for products present in the plasma of the blood about to be transfused.

The NAS-NRC report goes on to discuss the effects of the physician's educational process:

> That process has three main components: formal medical education, continuing education by peers, and experience and circumstances. Most physicians now in practice were taught very little in medical school about the use of blood and have since acquired little knowledge of component therapy, primarily because the papers concerned with it have usually been directed at hematologists and those involved in blood banking. Interns and residents learn from the attending staffs of their hospitals; because the staffs are representative of the practitioners referred to above, there is little opportunity for house staffs to acquire familiarity with the concept of component therapy. It does not appear that the present generation of medical

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[42] AABB, Physician's Handbook of Blood Component Therapy, 1969.

[43] Committee on Plasma Substitutes, op. cit.

students will stimulate wider acceptance of the concept. The competition for curriculum hours and the trend away from required subjects in favor of early electives do not favor any attempt to teach component therapy to the student. In one Eastern medical school last year, only 50% of the students were exposed to hematology, and the one scheduled period covering component therapy was canceled because of the visit of a distinguished lecturer.

In lieu of straightforward education, it has been demonstrated that a measure of control over access to blood products within a hospital can alter usage patterns. In a few hospitals, the director of the blood services is permitted in some circumstances to request justification of orders for whole blood, as opposed to red cell preparations. In some cases, rules require that a specific proportion of blood given to a single patient be in the form of red cell preparations. This type of action, taken in the interest of conservation of blood as well as in patient welfare, may be construed by some as infringing on the privileges of the practitioner. However, it should be noted that, where it has been taken, a genuine acceptance of the concept of component therapy has ultimately been achieved.[44]

Yet, the trend toward component therapy appears to be on the upswing, as illustrated by statistics on blood usage in "short-term" hospitals which are members of the American Hospital Association.[45]

| Number of Patients (1000's) Receiving | 1969 | 1970 | 1971 |
|---|---|---|---|
| Whole Blood | 1,510 | 1,222 | 1,151 |
| Packed Red Cells | | 376 | 464 |
| % Packed/Total Transfusions | | 23.5% | 28.7% |

In addition to component therapy, a number of other aspects of blood utilization merit discussion. These include the average number of units used per transfusion and the total number of patients transfused.

A blood utilization study[46] on hospital patients under Medicare during 1970 states that 487,000 Medicare patients (7.5% of all Medicare

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[44]Committee on Plasma and Plasma Substitutes, National Academy of Sciences-National Research Council, An Evaluation of the Utilization of Human Blood Resources in the United States, 10/70.

[45]Commission on Hospital and Professional Activities, Hospital Record Study, Volumes for 1969, 1970, and 1971.

[46]Henry L. Savitt, "Blood Utilization by Hospital Inpatients Under Medicare, 1969 and 1970," Health Insurance Statistics, DHEW, 7/22/71.

patients) received 1,590,000 units of blood, an average of 3.3 units per patient. The number of units transfused per transfusion episode was broken down as follows:

| Number of Units Transfused Per Episode | Percentage of Patients | Units of Blood |
|---|---|---|
| 1 pint | 24% | 117,000 |
| 2 pints | 31.7 | 309,000 |
| 3 pints | 15.0 | 219,000 |
| 4 or more pints | 29.2 | 945,000 |

Assuming the Medicare ratio (3.3 units per episode) to be representative of the general United States population, it is estimated that there were almost 1.9 million transfusion episodes in 1971. (6.2 million units transfused/3.3 units per transfusion.) However, some adjustment must be made because Medicare patients are believed to have a higher incidence of serious operations than the population as a whole and therefore utilize more units of blood per operation. Red Cross data in Massachusetts indicate an average of 3.0 units per transfusion episode in 1970.[47] Using 3.1 units per episode[48] gives an estimate that there were 2 million transfusion episodes in 1971.

The data on blood transfused to Medicare patients reveals a facet of blood utilization which should be highlighted. Single unit transfusions represent a significant proportion of the total patients transfused; in this instance about 24%. While there may be instances where one unit of blood is needed, many believe that the vast majority of such transfusions are either unnecessary or not worth the inherent risks. Education and training of health professionals in the effectiveness-versus-risk aspects of single-unit transfusions is needed, particularly as regards patients over 40 for whom the mortality rate associated with post-transfusion hepatitis is substantially greater. The AABB has recommended that hospital transfusion committees review all single unit transfusions and many hospitals have implemented this recommendation. A one-third reduction in single unit transfusions has been achieved at many hospitals where transfusions are occasionally reviewed.[49] However, single unit transfusions still persist in most areas. For larger transfusions, evaluation of physician decisions on the number of units to transfuse is extremely rare. One study which reviewed multiple unit transfusions

[47]D. Kinloch and A. Kliman, "Blood Misuse in Massachusetts," New England Journal of Medicine, Vol. 284, pp. 446-447, 2/25/71.

[48]E. Diethrich, "Evaluation of Blood Transfusion Therapy," Transfusion, Vol. 5, No. 1, 1965, pp. 82-88.

[49]See e.g., J. Morton, "Surgical Transfusion Practices, 1967," Surgery, Vol. 65, No. 3, pp. 407-416, 1969.

found no justification for 13% of the surgical transfusions, 22% of the medical transfusions, and 33% of transfusions for obstetrics and gynecology.[50]

A 1960 study provides data on likely effects of transfusion review. Physicians involved in this study were forewarned that the study would be performed. Even then, 6.5% needless transfusions were detected during the study. In addition, 16% fewer units were transfused than during comparable periods with no review.[51]

### 3.6. Post-Transfusion Reaction

A good deal of attention has been given to the problem of post-transfusion hepatitis and the means whereby this infectious disease can be detected or eliminated from the transfusion process. Other post-transfusion reactions can also result in extended hospital stay and even death. These include syphillis, malaria, and cytomegalovirus.

In addition to the diseases transmitted by transfusion, there are four major classes of noninfectious post-transfusion reactions: (1) allergic reaction to donor plasma; (2) allergic reaction to donor leucocytes (white cells); (3) reaction to an excess of antibodies present in the donor blood (due, for example, to a cold or an active allergy); and (4) reaction to an increase in the circulating amount of a chemical constituent (e.g., sodium or potassium). Allergic reactions frequently manifest themselves shortly after the start of a transfusion and may force interruption of the transfusion if a fever develops.

A large number of antibodies are present in the plasma portions of blood, including anti-A, anti-B, anti-Rh-positive, and anti-Kell-positive. An allergic reaction occurs when a blood antigen and its antibody mix. Fevers as high as 106° and urticaria develop fairly frequently. This is commonly referred to as a febrile reaction.

Allergic reactions to transfused blood are not uncommon. Although most allergic reactions are not life threatening, they may impede the recovery of the patient.[52] In rare instances, an allergic reaction and the attendant transfusion interruption have been contributory factors in the death of a patient.

A severe allergic reaction may cause the red cells to break down and release hemoglobin. The effects and symptoms of mild hemolytic reactions are basically the same as for other febrile reactions but can be fatal.

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[50]Diethrich, op. cit.

[51]C. Graham-Stewart, "A Clinical Survey of Blood Transfusion," Lancet, Volume 2 for 1960, p. 421.

[52]From Physician's Handbook of Blood Component Therapy, AABB, 1969, pp. 9-10.

A post-transfusion reaction may also become evident several days after the transfusion by the appearance of jaundice and increasing anemia. Such reactions are usually severe.[53]

### 3.7. Frozen Blood

Frozen packed red cells reconstituted in 5% albumin saline solution have proven to be a satisfactory replacement for whole blood.

The Washington, D. C., ANRC states that frozen blood should be used "for specialized surgery and for other instances when reaction-free transfusions are required."[54] Mr. Henry, the Director of the ANRC blood program, states that "all of us in blood banking have had in the backs of our minds an all frozen program, but we very quickly discarded it because we couldn't afford it." Dr. Meryman, of the ANRC Research Laboratory, states that "barring unforeseen circumstances, we can expect to see freezing of all blood administered within this decade."[55] Conversion to a frozen system is impeded in part because most users have several blood suppliers and each supplier hesitates to be the first to adopt the more expensive system.

The statements that have been made about frozen blood suggest various advantages and disadvantages of using red cells which have been frozen, thawed, and thoroughly washed. These are:

A. Advantages[56]

1. The hepatitis virus is virtually eliminated by slow-freezing methods if the red cells are not reconstituted in plasma.
2. The cleansing of plasma virtually eliminates one type of febrile reaction, and makes Type O blood truly universal.
3. The removal of leucocytes eliminates almost all other febrile reactions.

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[53]Standards for Blood Banks and Transfusion Services, Fifth Edition, AABB, 1970.

[54]D.C. Red Cross Annual Report, June, 1971.

[55]Personal communication with Mr. Henry and Dr. Meryman.

[56]Sources for 1 through 7 include:
B. Hurn, Storage of Blood, 1968.
A. Turner, Frozen Blood, A Review of the Literature, 1949-1968, 1970.
Personal communication with Dr. C. E. Huggins of Massachusetts General Hospital and with Dr. Meryman of the ANRC.
J. L. Tullis, J. Hinman, M. T. Sproul, and R. J. Nickerson, "Incidence of Posttransfusion Hepatitis in Previously Frozen Blood," Journal of the American Medical Association, Vol. 214, 1970, p. 719.

4. Since outdating is virtually eliminated, storage of uncommon blood types is simplified.
5. Since frozen blood can be shipped for long distances, distribution can be centralized and greater control established.
6. Preparation for freezing includes splitting the blood into components; therefore, use of frozen blood promotes a far more adequate supply of plasma products and less requirement for plasmapheresis.[57]
7. Since frozen blood is reconstituted in an artificial medium, it can be tailored to meet specific requirements. For example, low potassium blood can be reconstituted for the treatment of burn patients.
8. Exchange transfusions for newborns with erythroblastosis are improved. The use of frozen blood minimizes concern over electrolyte and pH changes which may occur if citrated blood is used.
9. Massive transfusions in children can be given without the danger of citrate toxicity.[58]

B. Disadvantages

1. The direct cost of frozen blood is, at present, substantially higher than that commonly charged for whole blood.
2. Few facilities are currently equipped to process and thaw blood for transfusion. The Red Cross is opening 18 frozen blood centers in the country this year. They expect that the frozen blood will be used in kidney and open-heart surgery virtually as fast as it is produced.[59]
3. Extra time is required while thawing proceeds. Dr. Huggins of Massachusetts General Hospital suggests an emergency procedure. Small samples of recently frozen blood are refrigerated for about 15 days. While a cross-match is being performed on a sample (a 45 minute procedure), the blood can be thawed simultaneously, (a 30-60 minute procedure). If transfusion must be started immediately, O blood of the appropriate type which has been thawed for a forthcoming operation can be used. Most frozen blood researchers agree that it is possible to store a few thawed units for at least one week in case an emergency occurs.

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[57]Plasmapheresis is the process of drawing blood and removing plasma, then reinfusing the red cells and other blood components. Approximately 2,000,000 liters are collected and processed annually. The reactions associated with plasma collected by pheresis are not discussed in this report.

[58]The source for 8 and 9 is:
Becker, Pribor, and Remington, "Routine Use of Frozen Blood in a Community Hospital, Economic Dream or Reality?," Transfusion, Vol. 11, No. 5, 1971, p. 293.

[59]Personal communication with ANRC headquarters personnel.

## 4. Description of the Cost Analysis

### 4.1. Need for Cost Analysis

It has been argued that blood is a gift, not a commodity, indicating that cost analysis is not applicable.[60] This concept is open to criticism for the following reasons:

1. Not all blood is donated as a gift (i.e., without cost) by the donor.
2. Even blood that is donated (as a gift by the donor) has associated with it direct costs of collection, processing, storage, and transfusion. These costs are at least partially paid for by the blood recipient.
3. In addition to these direct costs, the total cost to the patient/user includes indirect costs of disease, reaction, and shortage that cannot be reflected in the price charged per unit and, in specific instances, can be substantial.

### 4.2. Costing Methodology

The fee a recipient pays for whole blood and its administration by the health practitioner is generally cited as the cost of blood to a patient. However, indirect costs (such as the cost of an extra pre-operative day spent in the hospital because blood was not available on the scheduled operation day and the cost of continued hospitalization for post-transfusion hepatitis) should also be considered. Similarly, cost subsidies provided from charitable or Federal contributions are costs of the system which must be included in a cost analysis of a set of alternatives if the results are expected to reflect the relative cost of each alternative to society. Therefore, this report estimates the total cost of a unit of blood as the sum of indirect costs and direct costs, whether or not the payment of such costs is subsidized. The total cost does not include artificial user penalties which are related to donor recruitment philosophies and do not relate to the actual cost of system operation. It also does not include costs of time spent by volunteers and incentives provided by employers because sufficient data on the magnitude of these costs is not available. Fortunately, there is no reason to expect that the alternatives considered in this report will greatly affect the level of such activities, and therefore, the effect of this omission on the ranking of alternatives should be trivial.

Major cost related problems for which cost estimates have been considered in this analysis are: outdating of blood which has been collected; delay of operations due to blood shortage; allergic or febrile reaction to transfused blood; transmission of serum hepatitis by transfusion; and transmission of cytomegalovirus or mononucleosis by transfusion.

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[60] R. Titmuss, The Gift of Blood, Pantheon Books-Random House, 1971.

## 4.3. The Direct Costs and Charges

Direct charges to the user include a processing fee and a transfusion fee, and sometimes, a replacement fee and a donor payment.

Most members of the American Association of Blood Banks adopt the policy that blood donations would be encouraged by charging a high price to any recipient who does not replace blood used, usually on a two-for-one basis. Those who do not replace blood are commonly charged $25/unit. Their payments are sometimes used to defray the $15 processing charge for those recipients who provide replacement donors. The replacement fee is not charged for units supplied by the ANRC. Since the replacement fee is an artificial user penalty, it will not be counted as a cost factor in subsequent analysis. The processing, transfusion, and replacement fees are actual costs.

The processing cost has risen rapidly in the past five years. The $15.10 per unit average ANRC processing cost for 1971 is used in our analysis. Approximately $5 per unit was subsidized by community contributions, to the ANRC, but this subsidy is not included in the analysis. The components of the $15.10 fee are:

| | |
|---|---|
| Laboratory Supplies | $2.45 |
| Overhead and Amortization | 2.00 |
| Labor | 7.00 |
| Distribution | .35 |
| National Administrative and Research Program | 1.90 |
| Recruitment, Canteen, and Mobile Unit Operation | 1.40[61] |

Using community contributions, the ANRC also absorbs the processing cost of blood which outdates. Average cost due to outdating of processed units in 1971 was approximately $2.65 per transfused unit (7.3 million units collected x 15% outdate rate x $15.10 processing cost/(7.3 million units collected x 85% transfused)).

A telephone survey of hospitals in several areas indicated that the average transfusion fee is around $25 per unit. This fee covers costs of transportation (approximately $2), laboratory work, tranfusion, and administration of the hospital blood program.

In 1971, about 25.2% of the blood was obtained from paid donors who are paid an average of $8 per unit. The donor payments are a direct cost factor which currently average $2.40 per unit transfused (7.3 million units collected x 25.5% paid x $8 payment/(7.3 million units collected x 85% transfused)). The price charged by a commercial firm for blood includes

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[61] Blood Center Operations for the Year Ended June 30, 1971, and the ANRC Annual Report for FY 71. This cost factor ignores the "costs" of time spent by donors, donor incentives provided by employers, etc.

the processing fee and the firm's profit. In this analysis it has been assumed that the firm's profit is approximately equivalent to recruitment costs for a volunteer donor. Donor recruitment costs for paid non-commercial and unpaid donors are assumed to be approximately equal.

## 4.4. The Indirect Costs

### Shortage Cost

It is estimated that approximately 3% of the operations for which blood is reserved (whether or not it is actually transfused) are postponed for at least one day before enough blood of the correct type is available.[62] Such delays are infrequent for common blood types (e.g., O positive and A positive) but occur frequently for rarer types such as AB and B negative. The cost of such delays, including hospital fee, tests, and lost earnings, is estimated to be $110/day.[63] (This is made up of an average hospital cost per day of $90 plus lost wages conservatively estimated at $20 per day.) In addition, such delays can contribute to hospital overcrowding or place an unnecessary burden on hospital staffs.

### Febrile and Hemolytic Reaction Costs

Febrile reactions are estimated to occur for 2.5% of all units transfused.[64] The cost of treatment for febrile reaction is negligible. However, there are also costs associated with discontinuing a transfusion and with the effects that fever, urticaria, or related reactions will have on a seriously ill individual. It is estimated that 10% of the febrile reactions which occur result in a one day average prolongation of hospital stay and that 90% will have negligible effect. Further, it is estimated

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[62]Estimates of this value range from 1-8% based on hospital management practices and other factors. A national average of 3% has been used for the purposes of this cost analysis. This is consistent with figures in J. B. Jennings, "An Analysis of Hospital Blood Bank Whole Blood Inventory Control Policies," Transfusion, Vol. 8, 1968, p. 335.

[63]Basic Facts on the Health Industry Prepared for the Committee on Ways and Means, 1971 - adjusted for 1970 and 1971 hospital cost increases.

[64]Kevy, Schmidt, McGinniss, and Workman, "Febrile, Nonhemolytic Transfusion Reactions and the Limited Role of Leukoagglutinins in Their Etiology," Transfusion, Vol. 2, No. 1, 1962, pp. 7-16 found an incidence of 2.5% of all units transfused. Personal communication with Lt. Col. Charles E. Shields, Army Medical Research Laboratories, Ft. Knox, Ky. reveals that the U. S. Army also experiences a 2.5% incidence. "Evaluation of Blood Transfusion Therapy," loc. cit. cites a per unit incidence of 2.8%.

that febrile reaction is a contributory cause of death in .01 percent of transfusion episodes.[65]

A serious hemolytic reaction which involves a potential direct life hazard occurs to about one of every 2,500 patients (.04%). One in four people experiencing a serious hemolytic reaction dies as a direct result. Treatment in an intensive care ward is usually required, and an average additional hospital expense of $3,000 is estimated for those patients who suffer serious hemolytic reactions. This estimate does not include the patient's wage loss.

## Disease

Diseases which are known to be transmittable through transfusion include serum hepatitis, mononucleosis, syphilis, malaria, and cytomegalovirus. A rapid and reliable test for syphilis exists, and a four-day incubation period appears to totally mitigate transmission of the disease. Malaria was relatively uncommon prior to the Vietnam conflict and donors who have had the disease are rejected. Despite a massive research effort, the best approved hepatitis screening test is reported to be only 25-30% effective. There are, in addition, about .2% false positives. For the purpose of the cost analysis provided in Chapter 5, the effectiveness of hepatitis testing has been parameterized since a 50-60% effective test exists which has not been fully tested yet.

Post-transfusion hepatitis is sufficiently common that many hospitals require patients to sign a form releasing the hospital from responsibility before performing an operation in which blood may be required. Before any HAA test became available, it was estimated that 1.5% of the patients receiving transfusions were later hospitalized for overt (icteric) serum hepatitis.[66] Approximately 10% of those hospitalized for the disease die.[66] The average hospital stay is estimated to be 28 days. Hospitalization is followed by a one-month convalescence period if the patient recovers.[66] Costs of medical care and lost wages during convalescence are assumed to be $750.

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[65]Consensus arrived at through personal communication with most of the physicians who have published information on febrile incidence.

[66]NAS-NRC, op. cit.
Dr. Sam Gibson, JAMA, Vol. 186, p. 272, 1963.
Chalmers, Koff, and Grady, "A Note on Fatality in Serum Hepatitis," Gastroenterology, Vol. 49, pp. 22-26, 1965
Internal working documents of the DHEW Task Force on Blood Banking.
Personal communication with Dr. Huggins.

Incidence of anicteric (no overt symptoms) hepatitis has been shown to be approximately four times the incidence of icteric hepatitis.[67] Anicteric hepatitis can become chronic, but no costs have been assigned for it in this report.

There has been considerable public discussion of the fact that commercially purchased blood involves a much higher risk of serum hepatitis. Studies have produced widely varying estimates of the difference, but a common figure is ten times the risk associated with freely donated blood. Hepatitis incidence in blood obtained from paid donors by nonprofit groups is between these extremes, although some have even claimed that paid registry donors are safer than volunteers.[68] In the subsequent analysis, we assume that blood from paid donors has five times as high an incidence as blood from unpaid donors. To determine the volunteer incidence, y, we observe that pre-HAA incidence with 25.5% paid donors is $1.5\% = .745y + .255(5y) \approx 2y$. Thus, volunteer incidence is .75% and paid incidence is 3.75%.

Cytomegalovirus is a disease in which interest has recently been shown. In its mild form, cytomegalovirus results in fever, anarexia, and malaise; more severe reactions frequently involve hemolytic anemia and mild hepatitis. Incidence of the disease is largely unstudied, but appears to be significant. Furthermore, a close relative of cytomegalovirus, the Epstein Barr virus, has been identified as the cause of heterophile positive mononucleosis, and has been tentatively associated with a number of other very serious diseases. This family of viruses is clearly dangerous, and cytomegalovirus may prove to be as costly as febrile reaction or hepatitis.

A very recent study shows that leucocyte poor blood significantly reduces cytomegalovirus risk, but the mechanism involved is unknown. For the purpose of this cost analysis, it is postulated that cytomegalovirus results in an average two day increase in hospitalization. Almost no data is available on the post-transfusion incidence of cytomegalovirus, but a small sample of major surgery patients evidenced a 32% incidence of mild attacks of the virus. Figures from open-heart and renal surgery indicate that fifty to seventy-five percent of the patients whose operations require blood pumps contract the disease. At least ten thousand

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[67]Since the average transfusion involves in excess of three pints, the incidence of hepatitis per unit of blood is less than 1/3 of this figure. Personal communication with the ANRC indicates that they have found 1.3 positives per hundred units tested by a 25% effective HAA test. This implies that 5.2 volunteer units in every hundred carry hepatitis. The detection rate has been reduced to 0.85 per hundred through use of a donor registry.

[68]See e.g., J. Alsever, "The Blood Donor II. Blood Donors Associated with Homologous Serum Hepatitis: An Analysis of 211 Donors Involved in 70 Cases," The American Journal of the Medical Sciences, Vol. 240, July 1960, pp. 48-56.

such operations are performed each year. In about 5% of these operations, a severe case of cytomegalovirus develops, requiring an average of 15 days additional hospitalization. Approximately one percent of these reactions cause terminal complications.[69]

### 4.5. Summary of the Cost Factors

The cost factors of importance are:

Direct

| | |
|---|---|
| Processing fee: | $15.10 |
| Transfusion fee: | $25.00 |
| Outdating: | Processing fee x % outdate/% transfused |
| Donor payment: | $8 x % paid/% transfused |

Indirect

| | |
|---|---|
| Hepatitis Hospitalization: | .75% of patients ((100% - % paid) + 5 x % paid) x % test effectiveness x 28 days x $110 per day |
| Hepatitis Convalescence: | .75% (100% + 4 x % paid) x % test effectiveness x 90% recover x $750 convalescence |
| Hepatitis Death: | .75% (100% + 4 x % paid) x % test effectiveness x 10% die x cost associated with death |
| Shortage: | 2.7 million delayable operations x % of operations delayed x 1 day of delay x $110 per day |
| Febrile Reaction: | 2.5% of units x 10% serious x 1 day of hospitalization x $110 per day |
| Febrile Death: | .01% of episodes x cost associated with death |
| Serious Hemolytic Reaction: | .04% of episodes x $3000 treatment |
| Serious Hemolytic Death: | .04% of episodes x 25% die x cost associated with death |

[69]This section is largely based on private communication with researchers in the field, largely with Dr. David Lang of Duke University. Also see Kantor and Johnson, "Latent Cytomegalovirus Infection and Blood Transfusion," Annals of Internal Medicine, Vol. 73, No. 2, pp. 333-334.

Indirect (continued)

| | |
|---|---|
| Minor Cytomegalovirus Reaction: | 10K operations x 50% minor reactions x 2 days of hospitalization x $110 per day |
| Major Cytomegalovirus Reaction: | 10K operations x 5% serious reactions x 15 days of hospitalization x $110 per day |
| Cytomegalovirus Death: | 10K operations x 5% serious reactions x 1% die x cost associated with death |

## 5. Analysis of Alternatives

This chapter presents a cost analysis of seven alternative concepts for a blood banking system. These alternatives are representative of certain legislative proposals discussed in Chapter 2 of this report or other possible choices suggested by the debate on blood banking. The alternatives are:

(1) current system
(2) tax incentive
(3) regional coordination
(4) regional coordination with 28-day blood life
(5) Milwaukee donor and coordination programs
(6) transfusion review board
(7) frozen blood
(8) legislative elimination of paid donors.

Based on the analysis, cost-efficient combinations of the alternatives are developed. Details of the alternatives appear in the appropriate sections. To facilitate comparison, Table 2 lists the values for outdate rate; number of units to be collected and transfused; and percentage of paid units, which were ascribed to the alternatives. The estimated percentages of paid units were based upon the assumption that a reduction in collection requirements would not affect the availability of blood given voluntarily. Data relating to disease incidence, effect, and cost are extremely limited; therefore, it must be cautioned that the analysis which follows has been based on estimates or judgments that could be inaccurate. The basic data developed and used is not intended to be precise but is believed to have value for ranking the relative cost of blood banking alternatives. Concern with data reliability and the possible implications of selecting an improper parameter value necessitated the sensitivity analysis. This is reported in Section 5.11.

As the cost of contracting hepatitis is a major component of indirect cost, each alternative has been evaluated at three different levels of hepatitis test effectiveness (30%, 60%, and 90%). A 30% effective hepatitis test is assumed for the current system. Graphs in

Section 5.10 show direct, indirect, and total cost for these levels and permit interpolation for other test effectiveness levels.

Table 2

| Alternative | Number of Units Collected (Millions) | Percentage of Units from Paid Donors | Outdate Rate (%) | Number of Units Transfused (Millions) |
|---|---|---|---|---|
| Current System | 7.3 | 25.5 | 15 | 6.2 |
| Tax Incentive (Mean Effect) | 7.3 | 12.75 | 15 | 6.2 |
| Regional Coordination (RC) | 6.6 | 18.5 | 6 | 6.2 |
| RC with 28-Day Life | 6.4 | 14.8 | 3 | 6.2 |
| Transfusion Review Board | 7.3 | 22.3 | 15 | 5.96 |
| Milwaukee Control Program (MCP) | 6.6 | 3.0 | 6 | 6.2 |
| MCP with 28-Day Life | 6.4 | 0.0 | 3 | 6.2 |
| MCP with Transfusion Review | 6.35 | 0.0 | 6 | 5.96 |
| Frozen Blood | 6.25 | 12.8 | 1 | 6.2 |

The cost analysis uses estimated 1971 figures which have been discussed in previous chapters. Some of these are restated here to facilitate the understanding of the next sections.

- 7.3 million units of blood were collected in 1971
- 5.45 million units were collected from volunteers in 1971
- 6.2 million units of blood were transfused in 1971
- 2 million persons were transfused in 1971
- blood was cross-matched and held for 2.7 million delayable operations in 1971
- blood was actually transfused in 1 million of these operations
- 10 thousand open-heart and renal operations were performed in 1971
- $110 per day is the average cost of hospitalization and lost wages.

In addition, some number is needed to represent the value of a human life. Although the cost of a life depends on the person's age and many other specific factors, data limitations almost always restrict cost considerations to the use of a single average value. The most commonly cited dollar value of a human life is the $45,000 figure estimated and publicized by the National Safety Council in July 1971. The National Highway Traffic Safety Administration, in attempting to determine the cost-benefit ratio of a proposed safety standard for large trucks, cited the NSC's calculated per life estimate of worth but used its own "preliminary estimate" of $200,000 per life. The highest value of human

life used in conventional cost-benefit analysis was a Federal Aviation Administration estimate of $300,000. Another air travel related estimate, contained in a 1968 report entitled "Aviation Safety" which was written by Gary Fromm, then of Duke University, and reprinted by the Brookings Institution, concluded that "a conservative estimate...of the value of life based only on lost productive services and resources expended would be $275,000."[70] We will use the conservative $45,000 as a base value in this analysis and subsequently parameterize it for the interesting alternatives.

## 5.1. The Current System

### Direct Cost of Transfused Units

Direct costs associated with a transfused unit total $45.15. The direct cost components are:

| | |
|---|---|
| Processing: | $15.10 |
| Transfusion: | 25.00 |
| Outdating: 15% outdated x $15.10 processing fee/85% transfused[71] | 2.65 |
| Donor Payment: 7.3 million collected x 25.5% paid x $8 average payment/6.2 million units transfused | 2.40 |
| Total | $45.15 |

### Indirect Cost

Aggregate indirect costs for all units transfused are:

| | |
|---|---|
| Operation Delay: 2.7M operations x 3% delay x 1 day of delay x $110 per day | $ 8.9M |
| Febrile Reaction: 6.2M units transfused x 2.5% febrile reaction x 10% serious x 1 day of hospitalization x $110 per day | 1.7M |
| Febrile Death: 2M transfusion episodes x .01% febrile deaths x $45K per death | 9.0M |
| Hemolytic Reaction: 2M transfusion episodes x .04% hemolytic reaction x $3K per reaction | 2.4M |
| Hemolytic Death: 2M transfusion episodes x .04% hemolytic x 25% die x $45K per death | 9.0M |

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[70]This discussion was based on an article entitled, "Worth of Life, Dollar Estimates Vary Widely," Status Report, Insurance Institute for Highway Safety, Vol. 7, No. 4, 2/28/72, p. 4.

[71]Fifteen percent outdated x $15.10 x 7.3 million collected/(85% x 7.3 million collected).

Indirect Cost (continued)

| | |
|---|---|
| Icteric Hepatitis Reaction: 2M transfusion episodes x 1.5% hepatitis x 70% ineffective hepatitis test x 28 days of hospitalization x $110 per day | 64.7M |
| Icteric Hepatitis Convalescence: 2M transfusion episodes x 1.5% hepatitis x 70% ineffective test x 90% recover x $750 per convalescent | 14.2M |
| Icteric Hepatitis Death: 2M transfusion episodes x 1.5% hepatitis x 70% ineffective test x 10% die x $45K per death | 94.5M |
| Major Cytomegalovirus Reaction: 10K open-heart and renal operation x 5% major reactions x 15 days of hospitalization x $110 per day | .8M |
| Cytomegalovirus Death: 10K operations x 5% major x 1% die x $45K per death | .2M |
| Minor Cytomegalovirus Reaction: 10K operations x 50% minor reactions x 2 days of hospitalization x $110 per day | 1.1M |
| Total | 206.5M |

M = million K = thousand

Indirect costs per unit transfused total $206.5M/6.2M units or $33.30/unit.

Currently, the average cost of a unit of blood is estimated to be $78.45. If hepatitis testing became 60% effective (which will probably cost $1 more than the $.50 cost of the current HAA test), the total cost per unit would be $67.45 and the hepatitis attack rate would be 0.6%; if it became 90% effective (a 0.15% attack rate), total cost would be $55.45.

The estimated 2,505 transfusion-related deaths for 1971 are broken down as follows:

| | | |
|---|---|---|
| Febrile: | 2M x .01% | 200 |
| Hemolytic: | 2M x .04% x .25 | 200 |
| Hepatitis: | 2M x 1.5% x .7 x 10% | 2,100 |
| Cytomegalovirus: | 10K x 5% x 1% | 5 |
| Total | | 2,505 |

With more effective hepatitis testing, total projected deaths drop to:

| | |
|---|---|
| 60% effective | 1,605 |
| 90% effective | 705. |

## 5.2. Tax Incentive

Under this alternative, proposed by Rep. Edward Koch, (D-NY), each person who gave a pint of blood would receive a $25 income tax exemption, up to a maximum of $125 per year. According to an estimate made by the Internal Revenue Service, this program would be the equivalent of a $3.10

Federal subsidy per voluntarily donated unit.[72] The ANRC and the AABB point out that a tax write-off could tempt donors to withhold pertinent health facts, thus contributing towards contamination of blood quality. Furthermore, ANRC studies show that an increase in donations is mainly achieved by personal appeals, not minor monetary incentives. Since the monetary incentive is small, it is unlikely that employer attitudes about the charitable nature of blood donation will be significantly affected.

We assume that the tax incentive will not affect current outdating and shortage rates. The only cost factors which will differ from the current system are the hepatitis incidence, the subsidy cost, and the average donor payment. Assuming that hepatitis incidence is five times as high with paid blood, all of these costs become functions of the percentage of paid donors. Therefore, the key to estimating the cost of blood after institution of a tax incentive program is to determine what percentage of paid donors will be eliminated. In this analysis, the costs for three possibilities were investigated:

(1) All paid donors are eliminated.
(2) 50% of current paid donors are eliminated.
(3) No paid donors are eliminated.

The tax subsidy is treated as a direct cost.

All Eliminated

In this case, the hepatitis incidence is expected to be reduced by 50%[73], and the hepatitis costs become:

| | | |
|---|---|---|
| Reaction: | 2M x .75% x .7 x 28 x $110 | $32.3M |
| Convalescence: | 2M x .75% x .7 x 90% x $750 | 7.1M |
| Death: | 2M x .75% x .7 x 10% x $45K | 47.3M |
| Total Hepatitis: | | 86.7M |

Since indirect costs other than the hepatitis costs are $32.1M, total indirect costs are $119.8M or $19.30/unit transfused.

The average donor payment of $2.40 is eliminated in this instance, and the subsidy of $3.10 is paid for all units collected. Average subsidy per unit transfused is thus $3.65 (7.3M units collected x $3.10 subsidy per unit/6.2 million units transfused). Total direct costs including subsidies therefore increase to $46.40 per unit transfused.

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[72]Range of the estimate was between $2.50 and $3.75 tax loss per donation.

[73]If all volunteer incidence is X, incidence with 25.5% paid donors is .745X + .255(5X) $\approx$ 2X. The reduction in incidence is X/2X or 50%.

Total cost per unit transfused in a tax incentive system with no paid donors is $65.70. The cost with a 60% effective hepatitis test would be $60.70/unit. With a 90% effective hepatitis test, the cost would be $54.70/unit.

The number of hepatitis deaths is expected to be halved, and total projected deaths become:

| | |
|---|---|
| 30% effective test | 1,455 |
| 60% effective test | 1,005 |
| 90% effective test | 555. |

50% Eliminated

In this case, the hepatitis incidence is expected to be reduced by 25%[74], and the hepatitis costs become:

| | | |
|---|---|---|
| Reaction: | 2M x 1.125% x .7 x 28 x $110 | $48.5M |
| Convalescence: | 2M x 1.125% x .7 x 90% x $750 | 11.8M |
| Death: | 2M x 1.125% x .7 x 10% x $45K | 70.9M |
| Total Hepatitis: | | 131.2M |

Total indirect costs are thus $164.3M or $26.45/unit transfused.

The average donor payment becomes $1.20 (7.3M x 12.75% paid x $8/6.2M) and the average subsidy per unit transfused is $3.20 (7.3M x 87.25% unpaid x $3.10/6.2M). Total direct costs, including subsidies, therefore increase to $47.15 per unit transfused.

Total cost per unit transfused is $73.60. The cost with a 60% effective hepatitis test would be $65.55/unit. With a 90% effective hepatitis test, the cost would be $56.50/unit.

The number of hepatitis deaths is expected to be reduced by 25%, and total projected deaths become:

| | |
|---|---|
| 30% effective test | 1,980 |
| 60% effective test | 1,305 |
| 90% effective test | 630. |

None Eliminated

If the tax incentive did not reduce the current number of paid donors, the indirect costs would not change. The direct costs would increase by the amount of the subsidy. The subsidy is $2.70/unit

[74]If all volunteer incidence is X, incidence with 25.5% paid donors is 2X and incidence with 12.75% paid donors is .8725X + .1275(5X) ≈ 1.5X. The reduction in incidence is .5X/2X or 25%.

transfused (7.3M x 74.5% unpaid x $3.10/6.2M). Direct costs are $47.85, and total costs are $81.15. Total projected deaths are the same as projections for the current system.

## 5.3. Regional Coordination

This alternative assumes nationwide implementation of a regional management information and inventory control system. Such a system costs about $.45/unit collected.[75]

Regional coordination has cut outdating from 15% to 6% and shortage from 3% to 1% in a number of regions.[76] With 6% outdating, 6.6M units of blood are required. Since approximately 5.45M unpaid units are assumed to be collected, 1.15M paid units will be required (18.5% of total collections). Commonly two to five years will be required before a coordination program reaches operational efficiency.

When the coordination program is in operation, the hepatitis incidence is expected to be reduced by 12.5%[77], and the hepatitis costs become:

| | | |
|---|---|---|
| Reaction: | 2M x 1.3125% x .7 x 28 x $110 | $56.6M |
| Convalescence: | 2M x 1.3125% x .7 x 90% x $750 | 12.4M |
| Death: | 2M x 1.3125% x .7 x 10% x $45K | 82.7M |
| Total Hepatitis: | | 151.7M |

The shortage cost becomes:

| | | |
|---|---|---|
| Operation Delay: | 2.7M x 1% x 1 x $110 | 3.0M |

Costs of cytomegalovirus and febrile and hemolytic reaction remain at $24.2M. Indirect costs total $178.9M or $28.85/unit transfused.

Direct costs are $43.05/unit broken down as follows:

| | |
|---|---|
| Processing: | $15.10 |
| Added Processing Cost for Program Operation; | .45 |
| Transfusion: | 25.00 |

---

[75]Personal communication with ANRC on cost of their system. See also e.g., Masouredis, op. cit.

[76]J.B. Jennings,"An Analysis for Hospital Blood Bank Whole Blood Inventory Control Policies," Transfusion, Vol. 8, 1968, p. 335.

[77]If all volunteer incidence is X, incidence with 25.5% paid donors is 2X and incidence with 12.75% paid donors is .815X + .185(5X) = 1.75X. The reduction in incidence is .25X/2X or 12.5%.

| | | |
|---|---|---|
| Outdating: | 6% x $15.55/99% | 1.00 |
| Donor Payment: | 1.15M paid x $8 payment/6.2M units transfused | 1.50 |

Total cost is thus $71.90/unit with regional control and a 30% effective hepatitis test. The cost with a 60% effective hepatitis test would be $62.40/unit. With a 90% effective hepatitis test, the cost would be $51.90/unit.

The number of hepatitis deaths is expected to be reduced by one-eighth, and total projected deaths become:

| | |
|---|---|
| 30% effective test | 2,275 |
| 60% effective test | 1,485 |
| 90% effective test | 695. |

### 5.4. Regional Control and 28-Day Blood Life

Here the assumption is that a regional control program which allows paid donor participation is coupled with use of the CPD blood additive to extend shelf life to 28 days. The cost increase is $.45/unit collected.[78] A one week extension in blood life with regional control is estimated to result in a reduction of outdating from 15% to 3% and to eliminate shortage. With 3% outdating, 6.4M units of blood are required. Since 5.45M unpaid units are assumed to be collected, .95 paid units are required (14.8% of total collections). At least one year would be required in order to obtain approval for the increase in legal blood life with CPD storage. Two to five more will probably be required before the control program reaches operational efficiency.

When the coordination program is in operation, the hepatitis incidence is expected to be reduced by 20%[79], and the hepatitis costs become:

| | | |
|---|---|---|
| Reaction: | 2M x 1.2% x .7 x 28 x $110 | $51.8M |
| Convalescence: | 2M x 1.2% x .7 x 90% x $750 | 11.3M |
| Death: | 2M x 1.2% x .7 x 10% x $45K | 75.6M |
| Total Hepatitis: | | 138.7M |

Costs of cytomegalovirus and febrile and hemolytic reaction remain at $24.2M. Indirect costs thus total $162.9M or $26.25/unit transfused.

---

[78] In large quantities, ACD and CPD are equal in cost and the regional control program is the only anticipated cost increase.

[79] If all volunteer incidence is X, incidence with 25.5% paid donors is 2X and incidence with 12.75% paid donors is .852X + .148(5X) $\approx$ 1.6X. The reduction in incidence is .4X/2X or 20%.

Direct costs are $42.25/unit broken down as follows:

| | | |
|---|---|---|
| Processing: | | $15.10 |
| Added Processing Cost for Program Operation: | | .45 |
| Transfusion: | | 25.00 |
| Outdating: | 3% x $15.55/99% | .50 |
| Donor Payment: | .95M paid x $8 payment/6.2M units transfused | 1.20 |

Total cost is thus $68.50/unit with regional control and a 30% effective hepatitis test. The cost with a 60% effective hepatitis test would be $59.90/unit. With a 90% effective hepatitis test, the cost would be $50.30/unit.

The number of hepatitis deaths is expected to be reduced by one-fifth, and total projected deaths become:

| | |
|---|---|
| 30% effective test | 2,085 |
| 60% effective test | 1,365 |
| 90% effective test | 645. |

### 5.5. Milwaukee Donor and Coordination Programs

This alternative assumes nationwide adoption of the regional coordination, donor recruitment and donor retention programs now in use in Milwaukee. The cost of these programs is about $2.90/unit collected (including all costs of donor recruitment, canteen, and mobile unit operations—the processing cost therefore increases by $1.50/unit).

The Milwaukee system cuts outdating to 6% and shortage to 1%. With 6% outdating, 6.6M units of blood are required. As a result of the donor programs, the paid noncommercial donors will be replaced on a one-for-one basis by unpaid donors. Since 6.4M noncommercial units are assumed to be collected, only .2M commercial units will be required (3.0% of total collections). Once again, two to five years will probably be required before the coordination programs reach anticipated operational efficiency.

With the Milwaukee program in operation, the hepatitis incidence is expected to be reduced by 44%[80], and hepatitis costs become:

| | | |
|---|---|---|
| Reaction: | 2M x .84% x .7 x 28 x $110 | $36.2M |
| Convalescence: | 2M x .84% x .7 x 90% x $750 | 7.9M |
| Death: | 2M x .84% x .7 x 10% x $45K | 52.9M |
| Total Hepatitis: | | 97.0M |

The shortage cost becomes

| | | |
|---|---|---|
| Operation Delay: | 2.7M x 1% x 1 x $110 | 3.0M |

[80]If all volunteer incidence is X, incidence with 25.5% paid donors is 2X and incidence with 3% paid donors is .97X + .03(5X) = 1.12X. The reduction in incidence is .88X/2X or 44%.

Costs of cytomegalovirus and febrile and hemolytic reaction remain at $24.4M. Indirect costs thus total $124.2M or $20/unit transfused.

Direct costs are $42.90/unit broken down as follows:

| | | |
|---|---|---|
| Processing: | | $15.10 |
| Added Processing for Program Operation: | | 1.50 |
| Transfusion: | | 25.00 |
| Outdating: | 6% x $16.60/94% | 1.05 |
| Donor Payment: | .2M paid x $8/6.2M | .25 |

Total cost is thus $62.90/unit with the Milwaukee program and a 30% effective hepatitis test. The cost with a 60% effective hepatitis test would be $57.20/unit. With a 90% effective hepatitis test, the cost would be $50.50/unit.

The number of hepatitis deaths is expected to be reduced by 44% and projected deaths become:

| | |
|---|---|
| 30% effective test | 1,580 |
| 60% effective test | 1,075 |
| 90% effective test | 570. |

## 5.6. Transfusion Review Board

Under this alternative, peer review of physician decisions in a 5% sample of all transfusion episodes would become a requirement for Medicare certified hospitals.[81] It is estimated that approximately one hour of physician time (at $35 per hour) will be required for each review. The review is assumed to eliminate all of the unnecessary single unit transfusions. Currently, an estimated 20% of all transfusion episodes involve a single unit; at least 60% of these transfusions are now considered unnecessary. Using these proportions, peer review is assumed to reduce the demand for blood by 240,000 units (2M transfusion episodes x 20% single unit x 60% unnecessary) and the number of transfusion episodes by an equal amount. Assuming continuation of the existing 15% outdate rate, 7.0M units must be collected so that 5.96M units can be transfused. The number of paid collections required is reduced to 1.56M units (22.3% of total collections).

Total direct cost is $45.35 broken down as:

| | | |
|---|---|---|
| Processing: | | $15.10 |
| Transfusion: | | 25.00 |
| Outdating: | 15% x $15.10/85% | 2.65 |
| Donor Payment: | 1.56M x $8/5.96M | 2.10 |
| Transfusion Review: | 1.76M transfusion episodes x 5% reviewed x $35 per review/5.96M units transfused | .50 |

[81]This will cover about 85% of the hospitals. However, it is assumed that the AHA certification committee will follow suit.

The hepatitis incidence is expected to be reduced by 5%.[82] The indirect cost equations parallel those for the current system. Aggregate indirect costs for all units transfused are:

| | | |
|---|---|---|
| Operation Delay[83]: | 2.7M x 3% x 1 x $110 | $8.9M |
| Febrile Reaction: | 5.96M x 2.5% x 10% x 1 x $110 | 1.6M |
| Febrile Death: | 1.76M x .01% x $45K | 7.9M |
| Hemolytic Reaction: | 1.76M x .04% x $3K | 2.1M |
| Hemolytic Death: | 1.76M x .04% x 25% x $45K | 7.9M |
| Icteric Hepatitis Reaction: | 1.76M x 1.425% x 70% x 28 x $110 | 54.1M |
| Icteric Hepatitis Convalescence: | 1.76M x 1.425% x 70% x 90% x $750 | 11.8M |
| Icteric Hepatitis Death: | 1.76M x 1.425% x 70% x 10% x $45K | 79.0M |
| Major Cytomegalovirus Reaction: | 10K x 5% x 15 x $110 | .8M |
| Cytomegalovirus Death: | 10K x 5% x 1% x $45K | .2M |
| Minor Cytomegalovirus Reaction: | 10K x 50% x 2 x $110 | 1.1M |
| Total | | $175.4M |

Indirect costs per unit transfused total $175.4M/5.96M units or $29.40/unit.

Total cost per unit transfused is $74.75 with a transfusion review board and a 30% effective hepatitis test. The cost with a 60% effective hepatitis test would be $65.35/unit. With a 90% effective hepatitis test, the cost would be $54.95/unit.

Total projected deaths are expected to be:

| | |
|---|---|
| 30% effective hepatitis test[84] | 2,110 |
| 60% effective hepatitis test | 1,355 |
| 90% effective hepatitis test | 605. |

## 5.7. Frozen Packed Red Blood Cells

Under this alternative, except in cases of dire emergency, red cells would always be frozen after collection. Dr. Meryman of the ANRC Research Laboratory estimates the added costs of processing frozen blood in

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[82] If all volunteer incidence is X, incidence with 25.5% paid donors is 2X and incidence with 22.3% paid donors is .777X + .223(5X) ≈ 1.9X. The reduction in incidence is .1X/2X or 5%.

[83] We assume that the number of operations delayed for a single unit transfusion is negligible.

[84]

| | | |
|---|---|---|
| Febrile: | 1.76M x .01% | 175 |
| Hemolytic: | 1.76M x .04% x 25% | 175 |
| Hepatitis: | 1.76M x 1.425% x 70% x 10% | 1,755 |
| Cytomegalovirus: | 10K x 5% x 1% | 5 |

comparison to current processing techniques is $19.15.[85] This is made up of:

| | |
|---|---|
| Bag | $2.00 |
| Solutions | 5.55 |
| Plastic Tubing and Disposable Wash Bowl | 7.60 |
| Technician Time (6 Units Per Hr. Freeze - 3 Per Hr. Thaw) | 3.50 |
| Amortization of Equipment | 2.00[86] |
| Material Not Used, But Used in Current Nonfrozen Processing | -1.50[87] |
| Total | 19.15 |

Frozen blood banking has been shown to reduce outdating to 1%. With 1% outdating, only 6.25M units are required. Since 5.45M unpaid units are assumed to be collected, only .8M paid units will be required (12.8% of total collections). Before implementing a frozen blood system, it would be necessary to obtain DBS sanction for an increase in approved thawed blood life from the current 24 hours to one week.

Direct costs for frozen red cells total $60.65 broken down as follows:

| | |
|---|---|
| Current Processing: | $15.10 |
| Added Processing Cost: | 19.15 |
| Transfusion: | 25.00 |
| Outdating: 1% outdated x $34.25 processing fee/99% transfused | .35 |
| Donor Payment: .8M paid x $8 payment/6.2M transfused | 1.05 |
| Total | 60.65 |

As stated in Section 3.7, frozen blood effectively reduces hepatitis risk to zero and results in almost no febrile and hemolytic reactions. Although it appears that frozen blood does not transmit cytomegalovirus, this has not been scientifically demonstrated as yet, and we will ignore the possibility. Frozen blood banking virtually eliminates shortages. Thus, the only indirect cost is cytomegalovirus at $2.2M/6.2M units or $.35/unit. The cost of frozen blood is thus estimated at $61 unit for all hepatitis testing levels (i.e., hepatitis risk is eliminated at all levels).

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[85]Personal communications with Dr. Meryman. Figures obtained from Dr. Huggins are consistent with these. See also Becker, Pribor, and Remington, "Routine Use of Frozen Blood in a Community Hospital, Economic Dream or Reality?" Transfusion, Vol. 11, No. 5, 1971, p. 293. Becker's calculations do not assume widespread adoption of blood freezing.

[86]Based on the equipment requirements calculated in Section 6.4. Freezing equipment has a 15-year life and washing equipment has a five-year life.

[87]Blood bag: $1.40, materials for minor crossmatch exempted by DBS: $0.10.

Total projected deaths are expected to be five people at all levels of hepatitis testing. There are several differences between this alternative and those discussed previously:

(1) The cost of the system is distributed evenly among all blood recipients. Those unfortunates who have rare blood types, allergic constitutions, or bad luck are not forced to bear a disproportionate share of the costs.
(2) The quality of the blood is higher.
(3) Since most blood antibodies are eliminated, O blood becomes truly universal.
(4) A wide spectrum of blood derivatives will become less scarce because components separated in preparation for freezing (such as plasma) and not used for transfusion can be diverted for other purposes. As these products have economic value, component sale has the effect of spreading blood cost over several users, i.e., the average cost of any individual component is reduced. Becker estimates that in today's blood market, component separation and sale could reduce the average cost of a unit of frozen blood by more than $10.[88]

The reader is referred to Section 3.7 for a discussion of additional uncosted benefits of frozen blood banking.

## 5.8. Outlawing of the Paid Donor

In costing the seven alternatives, it was assumed that an adequate supply of blood could only be made available by using some paid donors. The projected number of deaths and the cost per unit proved highly sensitive to the percentage of paid donors. In this section, the choice between an inadequate supply with no paid donors and an adequate supply with paid donors is analyzed. The specific question which is addressed here is:

> Given that a 30% effective HAA test is in use, is it ever cost effective to outlaw the paid donor?

The unit of measure will be the cost per unit required for transfusion.

We assume the case that blood unavailability will be absorbed by transfusing one less unit than the attending physician considered desirable. The effects of such a policy would probably be less harmful than the effects of alternative policies. For example, under this policy, unavailability of 100,000 units means that 100,000 transfusions will be one unit short rather than that 30,000 transfusions will not be performed.

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[88]Becker, Pribor, and Remington, "Routine Use of Frozen Blood in a Community Hospital - Economic Dream or Reality?" Transfusion, Vol. 11, No. 5, 1971, p. 292.

The effects of unit unavailability under the chosen policy are assumed to be that 3% of those shorted die, 48.5% are hospitalized for two extra days, and 48.5% are hospitalized for ten extra days. It is quite possible that the effects would be more drastic.

On the basis of the assumptions, an equation is derived in Appendix C which expresses the maximum percentage of paid donors which could be cost-effectively eliminated as a function of the outdating rate before and after the paid donor is eliminated. This equation shows that being short a unit is worse than using a paid unit. Thus, if the outdate rate does not drop, it is never cost effective to outlaw the paid donor.

Table 3 shows the percentage of paid donors which could potentially be replaced by strategies designed to reduce outdating. These values were obtained by using the initial outdating rates in the alternatives and a final outdating rate of zero. In general, if a decrease in outdating is achieved, the percentage decrease is approximately equal to the percentage of paid donors which can be cost-effectively eliminated.

Table 3

| Initial Outdating (%) | Maximum Achievable Reduction in % Paid Donors |
|---|---|
| 1% | 1.04% |
| 3% | 3.11% |
| 6% | 6.23% |
| 15% | 15.53% |

Thus, among the alternatives that have been considered, the strategy of reducing outdating could only potentially eliminate all paid donors in the Milwaukee control program. It is difficult to estimate the chance of eliminating all paid donors from the tax incentive alternative by an outdate reduction stragegy. Similar estimates of potential payoff can be anticipated when considering strategies intended to reduce the demand for blood.

## 5.9. Combinations of Alternatives

Since the cost equations are sensitive to the percentage of paid donors and even more sensitive to blood unavailability, alternatives which provide fully adequate supplies of blood from unpaid donors are desirable. Situations which do not require paid units will result from two combinations of the alternatives which were previously considered:

(1) Milwaukee control program with 28-day blood life.
(2) Milwaukee control program with transfusion review.

As before, it is expected that two to five years will be required before the "Milwaukee program" reaches operational efficiency and that a decision on licensing of CPD will require at least a year.

The Milwaukee program can be expected to provide 6.4M unpaid units. 6.4M units will be required with 28-day blood life and 6.34M units will be required with transfusion review. Therefore, no paid units will be required for either alternative. As shown on page 38, the hepatitis incidence is expected to be halved.

28-Day Life

The hepatitis costs become:

| | | |
|---|---|---|
| Reaction: | 2M x .75% x 70% x 28 x $110 | $32.3M |
| Convalescence: | 2M x .75% x 70% x 90% x $750 | 7.1M |
| Death: | 2M x .75% x 70% x 10% x $45K | 47.3M |
| Total Hepatitis | | 86.7M |

Cost of cytomegalovirus and febrile and hemolytic reaction remain at the current level of $24.2M. It is assumed that there will be no shortage with 28-day blood life. Indirect costs total $110.9M or $17.85/unit transfused.

Direct costs are $42.15/unit broken down as follows:

| | |
|---|---|
| Processing: | $15.10 |
| Added Processing for Program Operation: | 1.50 |
| Transfusion: | 25.00 |
| Outdating: 3% x $16.60/97% | .55 |

Total cost is thus $60/unit with a 30% effective hepatitis test. The cost with a 60% effective hepatitis test would be $55/unit. With a 90% effective hepatitis test, the cost would be $49/unit.

The number of hepatitis deaths is halved and total projected deaths are expected to be:

| | |
|---|---|
| 30% effective test | 1,355 |
| 60% effective test | 955 |
| 90% effective test | 555. |

Transfusion Review

The hepatitis costs become:

| | | |
|---|---|---|
| Reaction: | 1.76M x .75% x 28 x $110 | $28.5M |
| Convalescence: | 1.76M x .75% x 70% x 90% x $750 | 6.2M |
| Death: | 1.76M x .75% x 70% x 10% x $45K | 41.6M |
| Total Hepatitis | | 80.3M |

Costs of cytomegalovirus and febrile and hemolytic reaction are $21.6M as calculated in Section 5.6. The Milwaukee program reduces shortages to 1%, and the shortage cost becomes:

| | | |
|---|---|---|
| Operation Delay: | 2.7M x 1% x $110 | 3.0M |

Indirect costs total $100.9M or $16.90/unit transfused.

Direct costs are $43.15/unit broken down as follows:

| | | |
|---|---|---|
| Processing: | | $15.10 |
| Added Processing for Program Operation: | | 1.50 |
| Transfusion: | | 25.00 |
| Outdating: | 6% x $16.60/94% | 1.05 |
| Transfusion Review: | 1.76M x 5% x 1 x $35/5.96M | .50 |

Total cost is thus $60.05/unit with a 30% effective hepatitis test. The cost with a 60% effective hepatitis test would be $55.55/unit. With a 90% effective hepatitis test, the cost would be $50.05/unit.

Total projected deaths are:

| | |
|---|---|
| 30% effective test | 1,280 |
| 60% effective test | 885 |
| 90% effective test | 485. |

## 5.10. Comparison of Costs

Eight alternative concepts for a revised blood banking system have been presented:

(1) Tax incentive (50% of current paid donors eliminated gives the mean effect).
(2) Regional coordination.
(3) Regional coordination with 28-day blood life.
(4) Transfusion review board.
(5) Milwaukee donor and coordination programs.
(6) Milwaukee programs with 28-day blood life.
(7) Milwaukee programs with transfusion review board.
(8) Frozen blood.

Table 4 lists the direct, indirect, and total costs separately for each alternative for three levels of effectiveness of hepatitis testing. When comparing these figures, it is important to consider that direct costs are borne by all blood recipients whereas indirect costs are average costs of reactions which strike at random and affect only a small segment of blood recipients. Average cost figures mask the fact that very high costs are borne by a few. Thus, the inequity of a situation increases as the indirect costs increase. Figures A, B, and C show graphs of total, indirect, and direct costs for each alternative.

Table 4. Costs of Alternatives for Different Levels of Hepatitis Test Effectiveness

| Alternative | Direct Cost | | | Indirect Costs | | | Total Cost | | |
|---|---|---|---|---|---|---|---|---|---|
| | 30% Effective HAA Test | 60% | 90% | 30% | 60% | 90% | 30% | 60% | 90% |
| Current System | $45.15 | $46.15 | $46.15 | $33.30 | $21.30 | $ 9.30 | $78.45 | $67.45 | $55.45 |
| Tax Incentive (Mean Effect) | 47.15 | 48.15 | 48.15 | 26.45 | 17.40 | 8.35 | 73.60 | 65.55 | 56.50 |
| Regional Coordination (RC) | 43.05 | 44.05 | 44.05 | 28.85 | 18.35 | 7.85 | 71.90 | 62.40 | 51.90 |
| RC with 28-Day Life | 42.25 | 43.25 | 43.25 | 26.25 | 16.65 | 7.05 | 68.50 | 59.90 | 50.30 |
| Transfusion Review Board | 45.90 | 46.90 | 46.90 | 29.40 | 19.00 | 8.60 | 74.75 | 65.35 | 54.95 |
| Milwaukee Control Program (MCP) | 42.90 | 43.90 | 43.90 | 20.00 | 13.30 | 6.60 | 62.90 | 57.20 | 50.50 |
| MCP with 28-Day Life | 42.15 | 43.15 | 43.15 | 17.85 | 11.85 | 5.85 | 60.00 | 55.00 | 49.00 |
| MCP with Transfusion Review | 43.70 | 44.70 | 44.70 | 16.90 | 11.40 | 5.90 | 60.05 | 55.55 | 50.05 |
| Frozen Blood | 60.65 | 60.65 | 60.65 | .35 | .35 | .35 | 61.00 | 61.00 | 61.00 |

Note: Start-up costs not included. See page 82 for a summary of start-up costs.

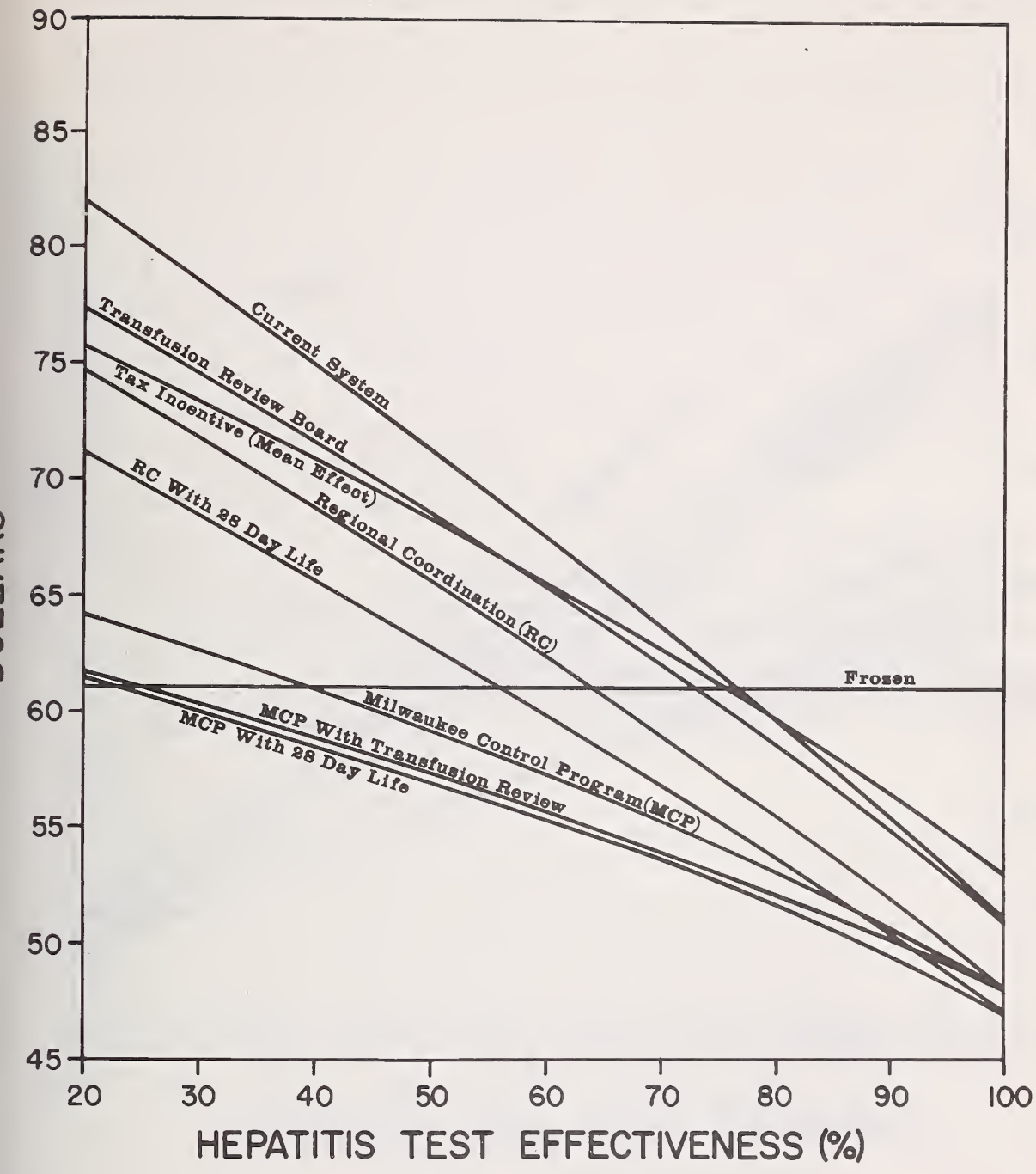


FIGURE A – TOTAL COST

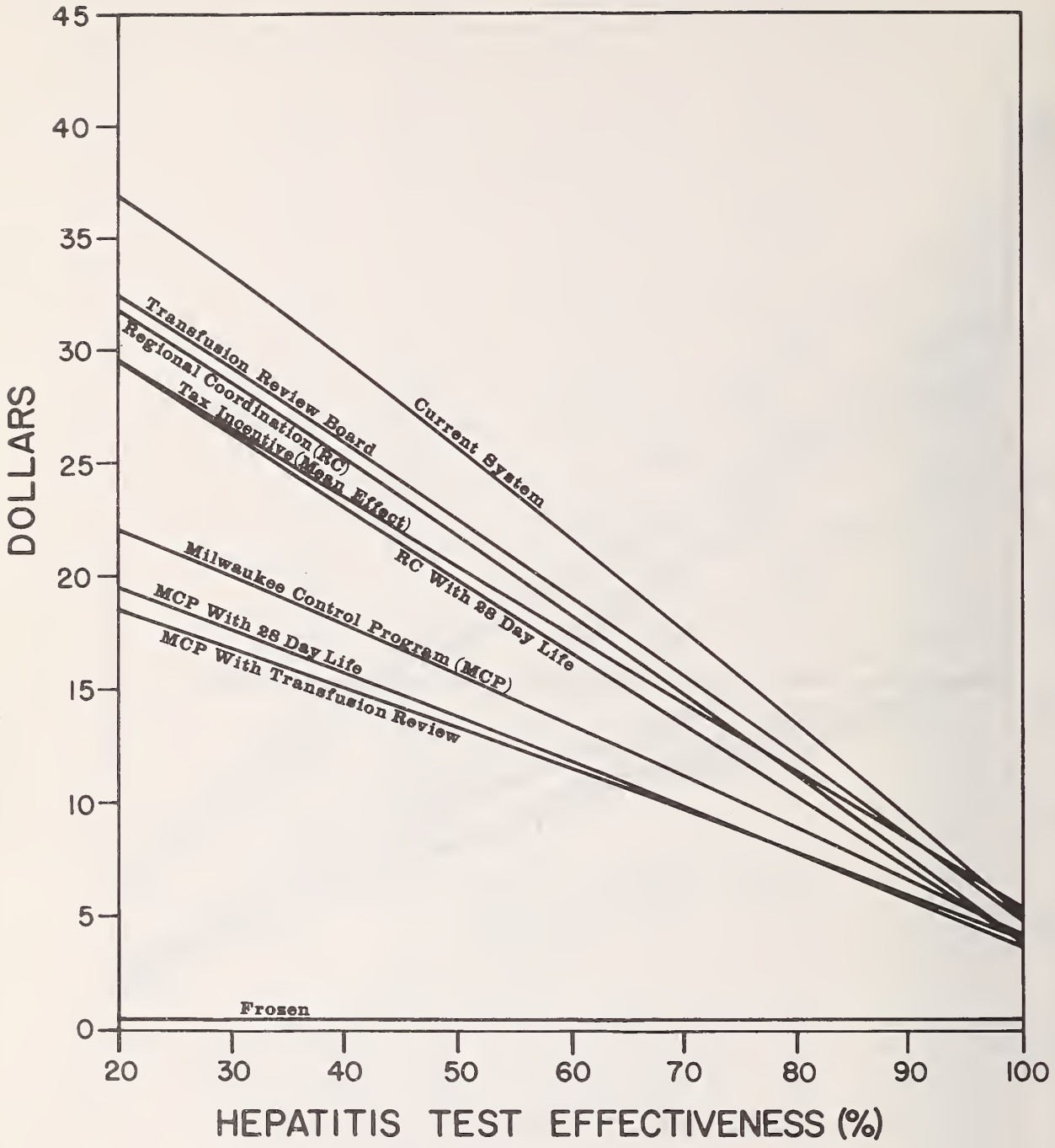


FIGURE B – INDIRECT COST

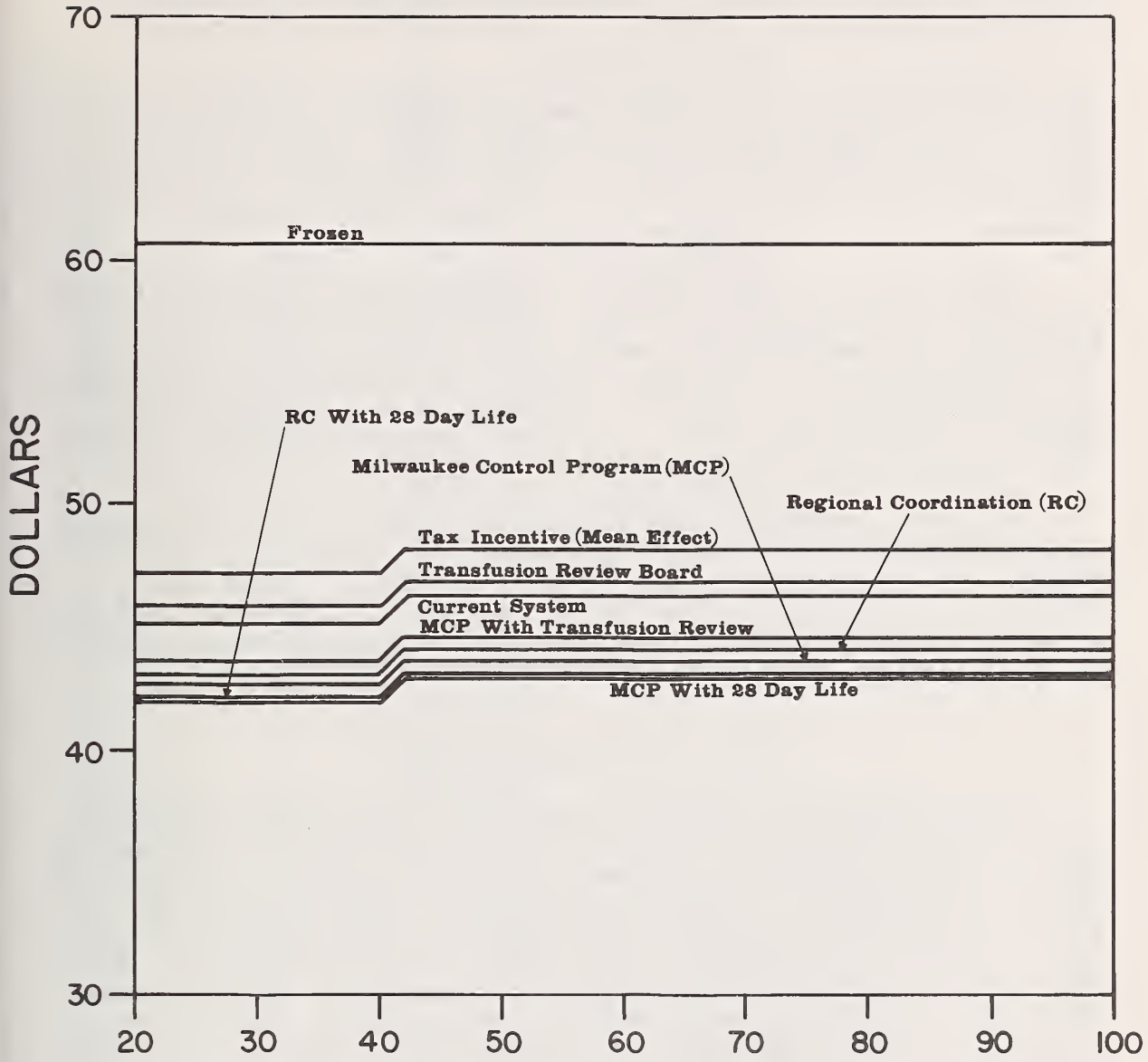


FIGURE C – DIRECT COST

It is evident that, for liquid-stored blood, there is little variation among the alternatives in direct cost per unit of blood transfused. Frozen blood costs are higher. Note that the difference in direct costs of liquid storage alternatives decreases considerably as HAA test effectiveness increases.

The indirect cost of frozen blood is virtually nil; this is the only alternative in which costs are uniformly distributed among blood recipients. The Milwaukee control program yields lower indirect cost than other liquid storage alternatives which were considered. Differences in indirect cost are reduced as the effectiveness of the hepatitis test increases.

Total costs show some similarity among the alternatives. Costs for the current system are highest with the tax incentive system and the transfusion review board close behind. Costs with regional control are intermediate, and the alternatives involving the Milwaukee control program are considerably lower in cost. Frozen blood cost is comparable with Milwaukee control program cost with 30% HAA test effectiveness; with 90% effectiveness, frozen blood becomes the most expensive alternative.

For each alternative, Table 5 shows the number of units transfused, the percentage of units from paid donors and the projected number of deaths at each level of hepatitis test effectiveness. Frozen blood results in fewer deaths than any other alternative. The number of deaths in liquid-storage alternatives decreases as the number of units transfused and/or the percentage of units from paid donors decrease.

## 5.11. Sensitivity Analysis

Eight feasible blood banking systems have been costed. Identification of the least costly system will be difficult because of the high level of uncertainty in the components of the cost equation (Table 6) and the small differences in cost between systems. This identification problem is partially resolved by noting that, although the parameters are uncertain, they will assume the same values for all alternatives. As a result, some alternatives will always dominate others. Analysis reveals that MCP is superior to regional control, tax incentive, and current systems; and that 28-day life is cost effective in situations where blood is not frozen. Thus, despite the high uncertainties, it is possible to state that the only alternatives which might prove optimal are MCP with 28-day life; MCP with TR and 28-day life; and FB.

Several methods were considered for distinguishing between these three remaining alternatives. Since the estimated costs are close and the possible errors are large, evaluation of the uncertainty range of the estimates on a percent error basis would only reveal that any of the three alternatives might be optimal. Therefore, some form of sensitivity analysis will be necessary. One form of sensitivity analysis would begin with evaluation of the cost equation at, for example, ten levels of each uncertain parameter. In one sub-type of this form of sensitivity

Table 5

| Alternative | Number of Units Transfused (Millions) | Percentage of Units from Paid Donors | Deaths | | |
|---|---|---|---|---|---|
| | | | 30% Effective HAA Test | 60% | 90% |
| Current System | 6.2 | 25.5 | 2,505 | 1,605 | 705 |
| Tax Incentive (Mean Effect) | 6.2 | 12.75 | 1,980 | 1,300 | 630 |
| Regional Coordination (RC) | 6.2 | 18.5 | 2,275 | 1,485 | 695 |
| RC with 28-Day Life | 6.2 | 14.8 | 2,085 | 1,365 | 645 |
| Transfusion Review Board | 5.96 | 22.3 | 2,110 | 1,355 | 605 |
| Milwaukee Control Program (MCP) | 6.2 | 3.0 | 1,580 | 1,075 | 570 |
| MCP with 28-Day Life | 6.2 | 0.0 | 1,355 | 955 | 555 |
| MCP with Transfusion Review | 5.96 | 0.0 | 1,280 | 885 | 485 |
| Frozen Blood | 6.2 | 12.8 | 5 | 5 | 5 |

Table 6. Range of Variation in Parameters of Possible Least Cost Alternatives

| Variable | MCP with 28-Day Life | | MCP with Transfusion Review | | Frozen | |
|---|---|---|---|---|---|---|
| | Value Used | Range | Value Used | Range | Value Used | Range |
| Outdate % | 3% | 2-4 | 6 | 5-7 | 1 | .5-3 |
| Average Donor Payment | $8 | 5-11 | 8 | 5-11 | 8 | 5-11 |
| % Paid Donors | 0% | 0-1 | 0 | 0-.9 | 12.8 | 10.8-14.8 |
| Average No. Units Per Transfusion | 3.1 | 2.75-3.45 | 3.395 | 2.895-3.895 | 3.1 | 2.75-3.45 |
| % Operation Delay | 0% | 0-.6 | 1 | .7-1.3 | 0 | 0 |
| # Days/Operation Delay | 1 | .5-3 | 1 | .5-3 | -- | |
| Cost Hospitalization/Day | $110 | 90-130 | 110 | 90-130 | | |
| % Febrile Reaction | 2.5% | 2.0-3.0 | 2.5 | 2.2-2.8 | 0 | 0 |
| % Serious Febrile | 10% | 7.5-12.5 | 10 | 7.5-12.5 | -- | |
| % Febrile Death | .01% | .008-.012 | .01 | .008-.012 | -- | |
| # Days Hosp./Serious Febrile | 1 | .5-1.5 | 1 | .5-1.5 | -- | |
| Cost of Death | $45K | 25K-100K | 45K | 25K-100K | 45K | 25K-100K |
| % Hemolytic Reaction | .04% | .02-.06 | .04 | .02-.06 | 0 | 0 |
| % Hemolytic Death | 25% | 20-30 | 25 | 20-30 | -- | |
| Cost Hemolytic Reaction | $3000 | 1500-4500 | 3000 | 1500-4500 | -- | |
| % Hepatitis Assuming No Paid Donors | .75% | .65-.85 | .75% | .65-.85 | 0 | 0 |
| # Days Hospitalization | 28 | 20-36 | 28 | 20-36 | -- | |
| Cost Convalescence Hep. | $750 | 600-900 | $750 | 600-900 | -- | |
| % Die Hep. | 10% | 5-15 | 10 | 5-15 | -- | |
| Cost Transfusion Review | -- | | $1.75 | 1.00-2.50 | -- | |
| Cost Added Frozen Processing | -- | | -- | | $19.15 | 15.00-30.00 |

analysis, the end result is the identification of the range of the parameters in which each alternative is optimal. This would be of little value here since there is no hope of obtaining accurate parameter values in the near future, and action decisions are imminent. In a second subtype, a count would be kept of the number of times that each alternative was considered optimal, and a probability of optimality would be developed. However, use of this complete enumeration method with 22 uncertain parameters would require $10^{22}$ calculations of the cost equation, a prohibitively large task even on a computer. A second form of sensitivity analysis could be attempted in which the uncertain parameters are defined as random numbers, and the cost equations are repeatedly evaluated for numbers sampled from the parameter distributions. When a sufficient sample size is achieved, the probability of optimality of each alternative can be estimated accurately. Since the distribution of the parameters is unknown, it would be necessary to perform this analysis for two different distributions selected in a manner which would yield bounds on the optimality probabilities. Sensitivity analysis is often performed by this randomized technique, but the process is bulky and time consuming.

Because of the time and effort that would be required to use the randomized approach, an attempt was made to develop closed-form equations which would yield the optimality probability bounds. Appendix D contains the theoretical mathematical development. The application of the results is reported here.

A further explanation of Table 6 is helpful in understanding the implications of the sensitivity analysis which was performed. In the earlier cost analysis, $19.15 was used as the increased cost of storing blood in frozen rather than liquid form. It is reasonable to believe that, if frozen blood use becomes widespread, unit costs will be reduced through bulk purchase of equipment, reductions in technician time, refinement in techniques, and cost savings which accrue in blood component preparation. These features may also reduce disposable equipment costs. Similarly, for one or more reasons, the processing cost could be an underestimate despite the fact that the ANRC currently anticipates these costs for limited applications. For example, in areas of low population, unit costs may increase because equipment and technicians are not kept busy. To account for these contingencies, a range of frozen processing costs should be considered; therefore, a low estimate of $15 per unit and a high estimate of $30 per unit were used in the sensitivity analysis. Any value within this range was considered equally likely to be correct.

Because the distribution of possible costs for any alternative is unknown, it is impossible to exactly determine the probability (as a function of HAA test effectiveness) that a decision maker would be correct in concluding that a unit of blood will cost less if the Milwaukee donor program with transfusion review is adopted than if the Milwaukee donor program with 28-day life is adopted. However, limits on this probability can be calculated. Figure D illustrates the range in which this probability lies. Because of the magnitude of uncertainty in the cost factors, the unit cost preference between these alternatives is never as much as 80% certain, and over much of the likely HAA effectiveness

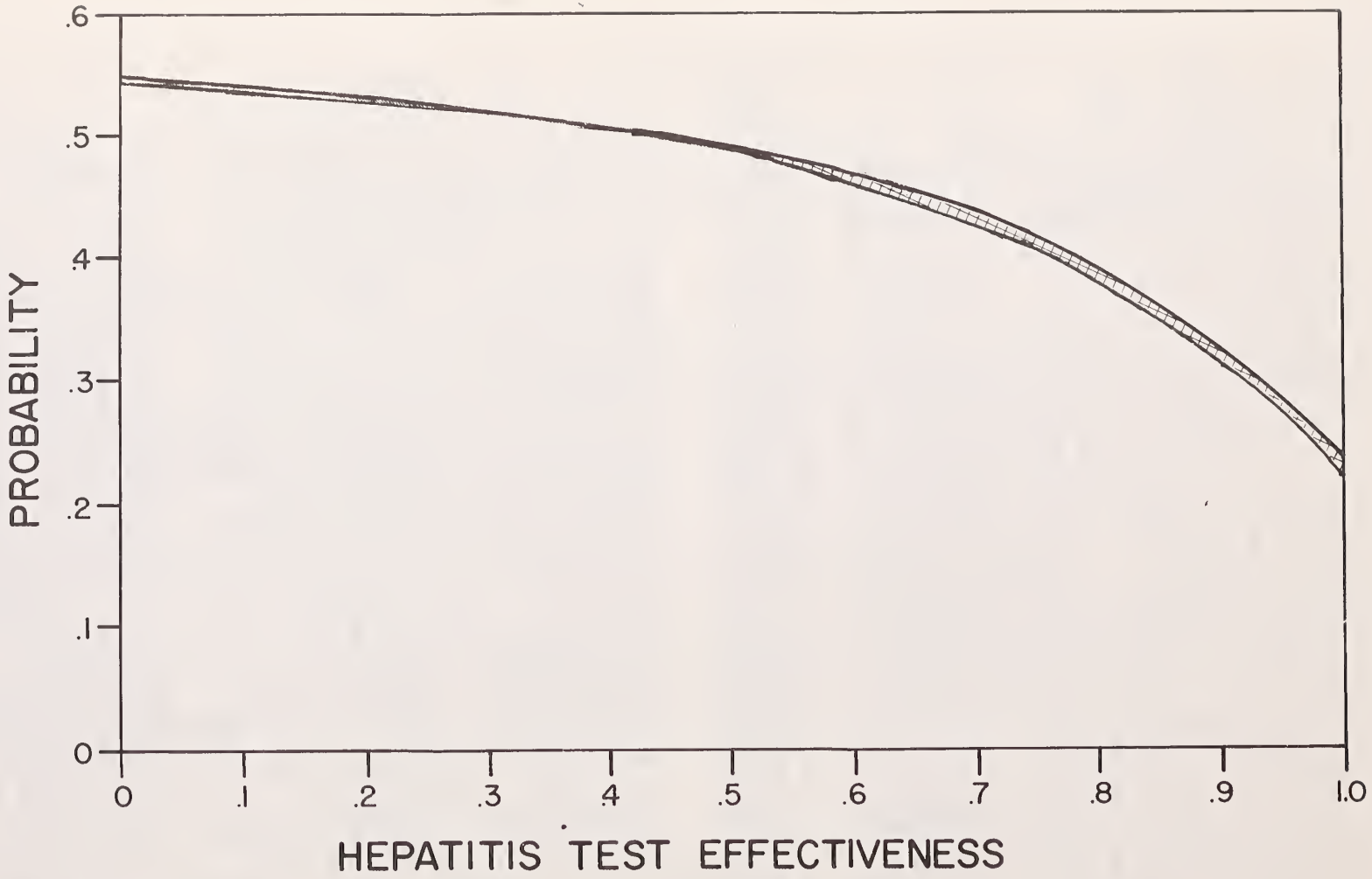


FIGURE D- RANGE OF THE PROBABILITY THAT A DECISION MAKER WOULD BE CORRECT IN CONCLUDING THAT THE MILWAUKEE CONTROL PROGRAM WITH TRANSFUSION REVIEW COSTS LESS THAN THE MILWAUKEE CONTROL PROGRAM WITH 28 DAY LIFE

range, the two alternatives are nearly equal in unit cost preference. Above 75% HAA effectiveness, there is a 60% certainty that 28-day life is slightly more likely to be the least costly. A choice between these alternatives could, perhaps, be based on the fact that transfusion review will reduce the number of units transfused, and therefore, result in a lower total cost of the system. Figure E illustrates the range of the probability that a decision maker would be correct in concluding that a unit of frozen blood will be less costly than a unit from either Milwaukee program. There is a 30% probability that frozen blood might be less costly with a hepatitis test which is 60% effective, but the likelihood decreases rapidly as testing becomes more effective.

The principle reason for the high uncertainty is that there is no agreed value of a human life to use in the cost computations. The substitution of a range of equally probable values with mean of $62,500 increases the attractiveness of the transfusion review and frozen blood alternatives over the initial analysis which used a $45,000 value. Figure F shows which of these three alternatives is the probable least cost alternative as a function of the hepatitis test effectiveness level and the average cost associated with death. Above a $315,000 average cost associated with death, frozen blood is preferred regardless of HAA test effectiveness. With a 30% effective HAA test, the Milwaukee programs have smaller total cost per unit of blood if the cost associated with death is valued at $65,000 or less.

## 6. Capital Cost for a Frozen Blood Program

### 6.1. Introduction

Previous chapters of this report contrasted the costs and benefits which accrue to various blood banking alternatives. Federal actions required for implementation seem relatively straightforward for most of the alternatives. (Suggested Federal actions are discussed in Chapter 8.) This is not true of the frozen blood alternative. Estimation of the cost of this alternative requires the adoption of several assumptions and the use of some tenuous data. The results are, nevertheless, suggestive.

### 6.2. Alternatives

Three alternatives for Federal participation are compared. These are as follows:

1. The Federal Government fully subsidizes the equipment costs associated with freezing, storage, and reconstitution of whole blood, under the provision that it specifies where this equipment will be located.
2. The Federal Government fully subsidizes the equipment cost associated with the freezing, storage, and reconstitution of whole blood by providing funds to the American Red Cross,

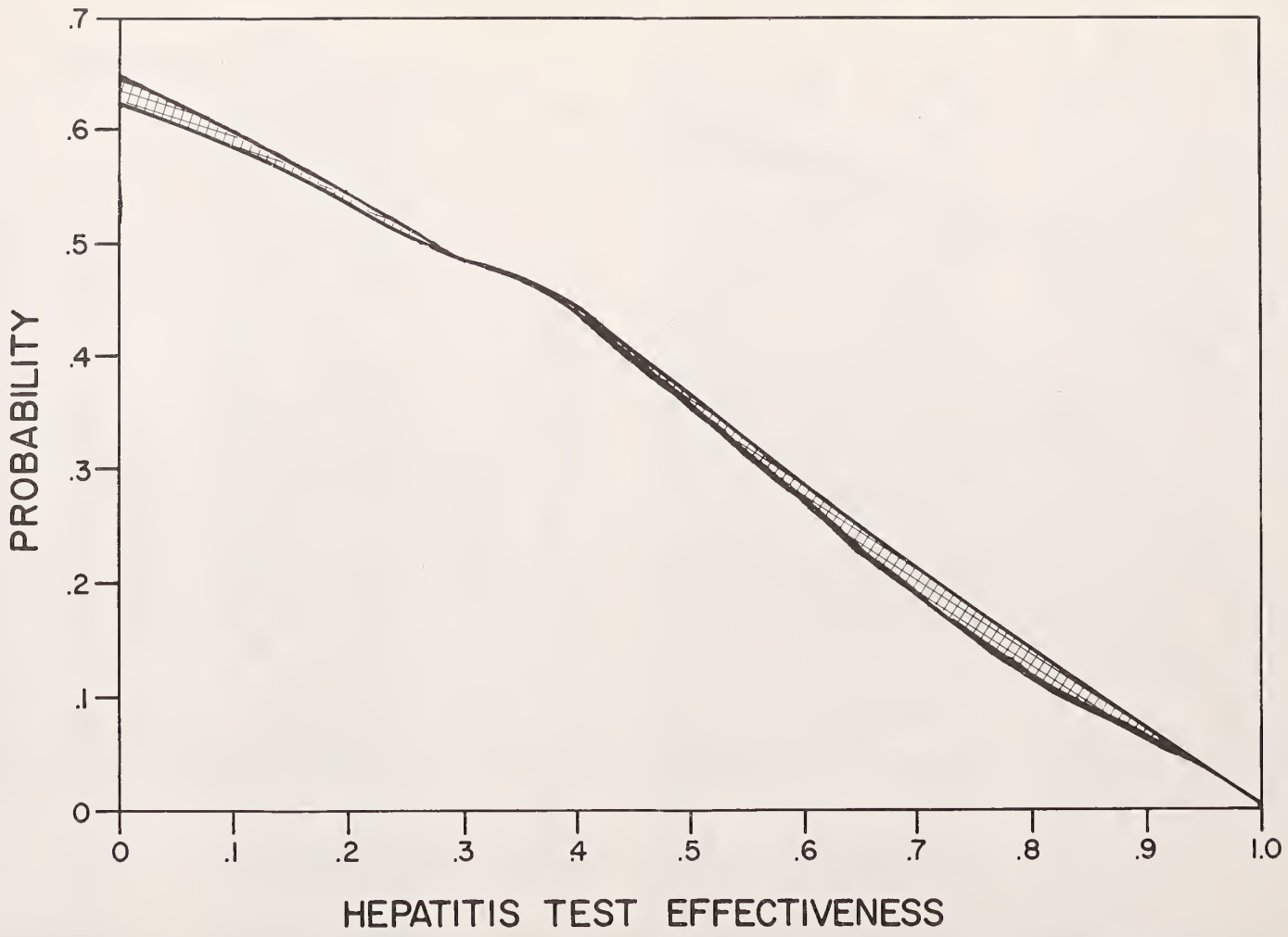


FIGURE E – RANGE OF THE PROBABILITY THAT A DECISION MAKER WOULD BE CORRECT IN CONCLUDING THAT FROZEN BLOOD COSTS LESS THAN EITHER MILWAUKEE CONTROL PROGRAM ALTERNATIVE

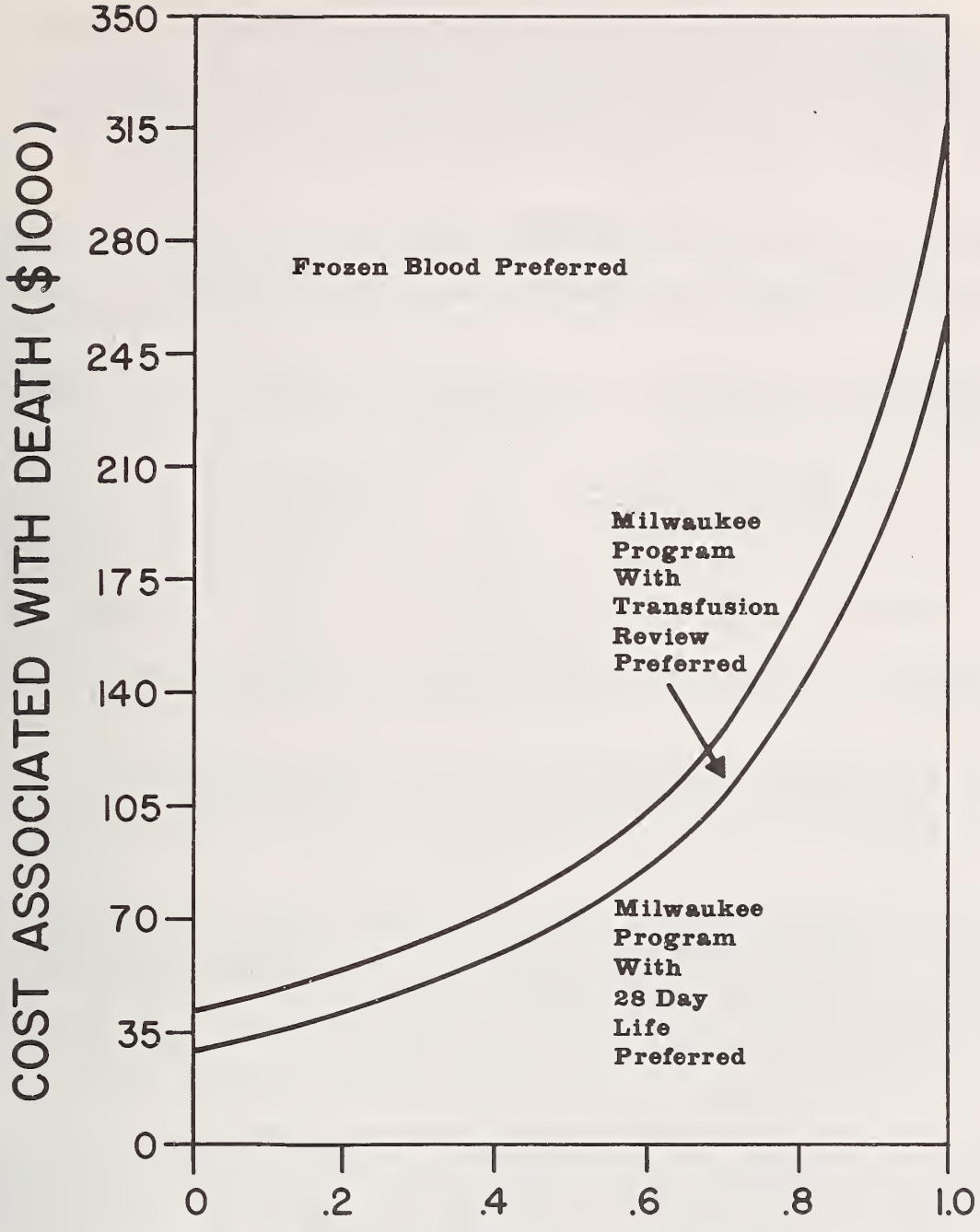
350
315
280
245
210
175
140
105
70
35
0
COST ASSOCIATED WITH DEATH ($1000)
Frozen Blood Preferred
Milwaukee Program With Transfusion Review Preferred
Milwaukee Program With 28 Day Life Preferred
0
.2
.4
.6
.8
1.0
HEPATITIS TEST EFFECTIVENESS

FIGURE F

nonprofit members of AABB and a few public hospitals currently engaged in blood collection and distribution.
3. The Federal Government provides long-term interest free loans which are repaid over a five-year period, to all organizations engaged in blood collection and distribution.

## 6.3. Equipment Costs

There are two partially automated means for freezing blood. These are the Fenwal variation of the Huggins method and the Meryman method.

The wash unit for either system costs about $15,000. Freezer sizes currently available and estimated volume prices are:[89]

| | |
|---|---|
| 1,100 unit capacity | $12,000/freezer |
| 288 unit capacity | 6,500/freezer |
| 168 unit capacity | 5,800/freezer. |

## 6.4. Federally Subsidized-Locations Chosen by Federal Government

In order to estimate the requirements for freezing and washing equipment for the first alternative, the following data are needed:[90]

1. The average freezer requirements per hundred population.
2. Freezer capacity needed for cities of a given size.
3. Additional blood bank centers needed to insure service to rural areas.

In 1971, approximately 7.3 million units of blood were drawn from a total U.S. population of approximately 207 million people, an annual average of 3.55 units per hundred population. Dr. Meryman of the ANRC Research Lab states that their initial experience dictates a freezer capacity equal to five times the projected average monthly usage. Using a monthly average of 0.3 units per hundred population (3.55/12) this equates to a freezer capacity of 1.5 units/hundred population.

On this basis, the freezer requirements for urban places with a population of 250,000 or more were obtained by multiplying the population in hundreds of thousands by 1.5. (This procedure allows for at least 100 units of slack in each freezer.) For places between 50,000 and 250,000, two 1,100 unit freezers per hundred thousand population were assumed to be necessary (areas in this size range will usually require one and a

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[89]Private communications with Mr. Edward Sweeney of Harris Manufacturing Co. and Dr. Meryman of the ANRC Research Laboratory. These prices reflect recent cost reduction which resulted from increased equipment sales volume.

[90]The interest expense for Federal Government funds has not been included in the analysis.

a fraction freezers and a whole freezer must be purchased whenever a fraction is needed). One 1,100 unit freezer will be allocated for each area of 25,000-50,000 people, and areas with 10,000-25,000 population will each be allocated one 288 unit freezer. The use of the 168 unit freezers was not contemplated.

Total freezer requirements are therefore projected to be 3,151 (1,767 of the 1,100 unit freezers and 1,384 freezers capable of handling 288 units at one time):

| Urban Place Size[91] | # of Places | Total Population (1,000's) | # of 1,100 Unit Freezers | # of 288 Unit Freezers |
|---|---|---|---|---|
| >1M | 6 | 18,742 | 281 | |
| 500K-1M | 20 | 12,967 | 195 | |
| 250K-500K | 30 | 10,442 | 152 | |
| 100K-250K | 100 | 14,285 | 285 | |
| 50K-100K | 240 | 16,724 | 335 | |
| 25K-50K | 519 | 17,820 | 519 | |
| 10K-25K | 1,384 | 21,414 | | 1,384 |
| Total | 2,299 | 112,394 | 1,767 | 1,384 |

Total freezer cost of $30.2 million is determined as follows:

1,767 x $12K = 21.2M
1,384 x $6.5K = 9.0M.

One wash unit, used eight hours per day, five days per week, can handle 500 units per month. The monthly throughput of an 1,100 unit freezer is 220 units, but demand is not uniform and therefore, one wash unit per freezer was allowed, even though there will be some installations with two or three freezers. Wash unit cost is thus computed to be 3,151 x $15K or $47.3 million.

It is assumed that many rural areas will be served by centralized facilities, probably located in a nearby city. In fact, 9.75 million units of freezer capacity and almost 19.0 million units of washer capacity have been allocated to areas with population of 10,000 or over. However, it is also recognized that some provision must be made to serve elements of the population who live in extremely remote rural areas which are served by small hospitals in towns of less than 10,000 population.

To provide a margin of safety in the estimate, we have arbitrarily provided for 500 centers in rural locations. The additional cost is

[91] Statistical Abstract of the United States, 1971, U.S. Bureau of the Census, p. 17.

approximately $10.4M (500 x ($15K + $5800)). Total cost for this alternative is therefore $87.9M.

### 6.5. Federally Subsidized—No Federal Location Preference

A basic assumption for this alternative is that each major blood collection organization will have its own freezing and washing equipment. For example, a city having one ANRC chapter, two AABB members and one commercial firm would probably maintain four separate freezer and washer installations.

Currently there are 1,700 ANRC chapters and 1,500 AABB members. The number of commercial blood bank locations in the United States was estimated as follows: (a) the average commercial installation is assumed to collect 85 units per week, (b) roughly 885 thousand commercial units were collected in 1971, equal to approximately 17,020 units collected per week, (c) an estimate of approximately 200 commercial blood banks is derived by dividing 17,020 by 85. Predicated on this reasoning the total freezer requirements would be as follows:

| | |
|---|---|
| | 1,700 ANRC |
| | 1,500 AABB Members |
| | 200 Commercial |
| Total | 3,400 |

It is assumed that each AABB member and commercial blood collector will have one 1,100 unit capacity freezer. According to Dr. Meryman, the ANRC will attempt to centralize its washing and long-term storage facilities. Some chapters will, therefore, require only a 288 unit freezer to handle daily collections which are shipped to a central facility.

An estimate of the total number of ANRC chapters needing freezing and washing equipment, was prepared by dividing the total regional collections by the number of blood units that an 1,100 unit freezer can handle. According to Dr. Meryman, ANRC experience to date is that a freezer capacity of five times the average monthly throughput is needed. Therefore an 1,100 unit freezer would adequately handle 2,500 units collected annually.

The ANRC has tabulated their collection information on a chapter and regional basis.[92] For example, the St. Paul region, which has 92 chapters, collected 109,546 units in 1971. Dividing 109,546 by 2,500 results in 43 plus (rounded up to 44) chapters which would have complete facilities, leaving 48 chapters needing only the 288 unit freezer used for freezing units after collection. According to this estimation procedure, approximately 525 of the ANRC chapters will only require small freezers.

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[92]ANRC, Blood Center Operations for the Year Ended June 30, 1971.

Equipment requirements are therefore projected to be:

| | Freezers | | Washers |
|---|---|---|---|
| | 1,100 unit ($12K) | 288 unit ($6.5K) | ($15K) |
| ANRC | 1,175 | 525 | 1,175 |
| AABB | 1,500 | | 1,500 |
| Commercial | 200 | | 200 |
| Total | 2,875 | 525 | 2,875 |

The total cost of this system is determined by adding the three costs involved: (a) 2,875 @ $12K = $34.5M, (b) 525 @ $6.5K = $3.4M, (c) 2,875 @ $15K = 43.1M. The total cost is $81.0M. To insure a high level of service in rural areas, we will again allow for 500 additional centers, resulting in a total cost of $91.4M ($81.0M + $10.4M). The Federal expenditure could be held to $86.0M by requiring the commercial blood banks to assume their costs of $5.4M (200 washers @ 15K plus 200 freezers @ 12K). Thus the reduction in Federal expense for this alternative, compared with the first case cited, is $1.9M ($87.9M - $86.0M).

### 6.6. Long-Term Low-Interest or Interest-Free Federal Loans

The scenario for this alternative is that the Federal Government provides low-interest or interest-free loans to all organizations engaged in blood collection and distribution.[93] It is assumed that: (1) loans are made for a five-year period, (2) the usable life span for the wash equipment is five years and of the freezers is 15 years, (3) the industry will replace outdated equipment with monies accrued through the sale of whole blood and components, (4) the average demand for blood over the next five years will be 6.4 million units, and (5) increased equipment costs due to inflation will be matched by interest accrued to the depreciation fund.

To get an upper estimate of equipment replacement costs, it is assumed that at the end of five years the blood banking industry would need to replace all washers and have accumulated one-third of the cost of the freezers in a depreciation fund. This will be a high estimate because washers will be used at less than capacity in many places and will consequently last longer than five years.

After five years the depreciation fund is $62.4M consisting of $50.6M for the washers and one-third of the cost of the freezers ($35.4M/3 or $11.8M). In addition to this cost, the blood banks need to repay the five-year loan of $86.0M for the cost of the equipment. The total $148.4M would be generated through the transfusion of approximately

[93]For this alternative, the total equipment cost is projected to be $86.0M, equal to the cost of Federal subsidy without location preference.

32 million units of blood (based on the projections shown in Table 1, page 7). The cost of frozen blood cited in Section 5.7 included $2 per unit for equipment amortization. Under this alternative the cost to the blood recipient during the five-year start-up period would increase by $2.65/unit ($48.4M/32M - $2). The loan alternative includes interest expense to the Federal Government. Assuming a 5% interest rate, interest would amount to approximately $12.8M for the loan alternative. The administrative costs will be ignored for the loan alternative.

In summary, expenses incurred by the Federal Government and commercial firms would be:

| | | |
|---|---|---|
| 1. | Federal Control | $87.9M |
| 2. | Federal Subsidy | |
| | a. to existing organizations | $75.6M |
| | b. adding 500 blood centers | $86.0M |
| | c. commercial expenditure | $ 5.4M |
| 3. | Interest Free Loan | $12.8M |

## 7. Standards and Regulations—An Overview

### 7.1. Introduction

A cursory examination of the standards and regulations governing the blood banking process reveals several problems, some gaps, areas of duplication, and a general lack of a coordinated approach to standardization. At present the Division of Biologic Standards, the Center for Disease Control, the Food and Drug Administration, the American Association of Blood Banks, the American National Red Cross, the Joint Committee on Accreditation of Hospitals, the College of American Pathologists and eight individual states have some form of blood licensing and/or inspection programs. Over the years standards have been developed in response to a specific need or problem. As the "industry" has grown, no central governing body has emerged. Thus, a number of organizations share the responsibility for safeguarding the Nation's blood banking operations.

### 7.2. DBS

The Division of Biologic Standards (DBS) of the National Institutes of Health is responsible for regulation of the interstate shipment of biological products. DBS has primary responsibility for regulation of blood, blood derivatives and components, as specified in Section 351 of the Public Health Service Act (42 USC 262). DBS issues mandatory standards for blood banks and other manufacturers of biological products who are engaged in interstate commerce. It also issues product and establishment licenses. Each establishment is inspected annually by an "officer of the

Public Health Service having special knowledge of the methods used in the manufacture and control of products."[94] At present there are 72 DBS licensed blood products and 165 licensed blood collection and processing establishments in the U.S. Many of the establishments operate several facilities (e.g., the American National Red Cross has one license to operate 1,700 chapters engaged in blood collection). Approximately 80% of the blood collected in the U.S. is processed as a product licensed by DBS.

The DBS standards for blood and blood products cover (a) physical equipment (facility) and personnel; (b) donor criteria; (c) collection of blood; (d) processing for storage and identification; and (e) production of red blood cells, cryoprecipitate and immune serum. Of the aforementioned, the only standards unique to DBS are those prescribing dating periods and/or storage methods for specific products and formulas for admissible anticoagulants. The dating periods are "based on data relating to usage, clinical experience or laboratory tests that establish the period beyond which the product cannot be expected, beyond reasonable doubt, to yield its specific results and retain its safety, purity, and potency."[95] Table 7 shows the currently enforced dating periods for various blood products.

DBS must necessarily receive considerable experimental evidence of the safety and utility of a blood derivative or additive before it will issue a license. As a consequence, many years of research effort may be involved in satisfying DBS licensing requirements, and submissions for Federal licensure may be rejected on the basis of inconclusive evidence. Conversely, DBS has no direct responsibility for initiation or continuance of studies required for licensure of a new product. Because the initiative lies with the product developer, a useful component may be in experimental use for several years before initiation of studies aimed at obtaining a Federal license are attempted. This subject is discussed further in Section 7.6.

## 7.3. AABB and ANRC

The AABB and ANRC have developed voluntary standards/directives which are, in many ways, the most comprehensive and most stringently enforced. It must be stressed that these are voluntary standards; it is thus possible for those blood banks not engaged in interstate commerce to be in operation without regard to any recognized standard.

The AABB program was initiated in 1955 when the AABB Committee on Standards first prepared the Standards for Blood Banks and Transfusion

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[94] PHS Regulations for Manufacture of Biological Products, Title 42, Part 73, Section 73.400, U.S. GPO, 1971.

[95] PHS Regulations, Title 42, Part 73, Section 73.870.

Table 7. DBS Dating Periods for Human Blood Products

| Product Name | Storage Time | Labeling Required | Temperature |
|---|---|---|---|
| 1. Cryoprecipitated Antihemophilic Factor | 12 Months | Yes | Below - 19°C |
| 2. Fibrinogen | Five Years | - | - |
| 3. Normal Plasma | | | |
| a. Liquid | Three Years | Yes | 15 - 30°C |
| b. Dried | Seven Years | Yes | Below 38°C |
| 4. Normal Serum | | | |
| a. Liquid | 18 Months | - | - |
| b. Dried | Five Years | - | - |
| c. Frozen | Three Years | Yes | Below - 19°C |
| Thawed | One Year | | |
| 5. Plasma Protein Fraction | | | |
| a. Either | Five Years | - | 5°C for one year |
| b. Or | Three Years | Yes | Below 31°C for Two Years and 5°C One Year |
| 6. Red Blood Cells | | | |
| a. Fresh | 21 Days | Yes | Between 1-10°C |
| b. Frozen | Three Years | Yes | Below - 66°C |
| Thawed | 24 Hours | Yes | Between 1-10°C |
| 7. Resuspended Red Blood Cells | Ten Days | | |
| 8. Single Donor Plasma | | | |
| a. Either | Five Years | Yes | Below - 19°C |
| b. If Used in Coagulation Defects | One Year | Yes | Below - 19°C |
| 9. Whole Blood | | | |
| a. In ACD Solution | 21 Days | Yes | Between 1-10°C |
| b. In Heparin Solution | 48 Hours | Yes | Between 1-10°C |
| c. In CPD Solution | 21 Days | Yes | Between 1-10°C |

Services. The purposes of the standards were "to provide maximum safety for those individuals involved in the transfusion service," to be a "measure of protection afforded the physician who orders the transfusion," and to "form the basis on which the Inspection and Accreditation Program has been established."[96] This program is administered by the AABB Committee on Inspection and Accreditation comprised of 13 physicians and approximately 270 professionals who serve as voluntary inspectors. AABB members may participate without any fee payment and accreditation is granted for a three-year period. Non-AABB members pay an inspection fee and accreditation is granted for one year. Currently, approximately 1,400 establishments have AABB accreditation. The only non-AABB members participating in the program are commercial blood banks.[97]

The Standards Committee meets yearly to consider any necessary changes to standards. Frequently, such changes seem to reflect practice and experience of the members rather than scientific evidence. This was illustrated in 1966 when a letter to the editor in Transfusion (the AABB Journal) questioned the one-year waiting period for a donor who received a rabies vaccination. The reply stated one reason, but added, "how valid these observations are I do not know, but this is probably the origin of the one-year timing." The reply then cited another reason and concluded, "inasmuch as this is all more or less hypothetical, the one-year interval must have been arrived at on a purely arbitrary basis (emphasis added); ...I have a feeling that three months is a much more realistic figure than one-year, but that it is mostly a matter of foreseeing possible legal problems..."[98, 99]

The AABB is the only organization with standards which encompass the total collection, storage, distribution, and blood administration processes. Standards are provided for all components in common use even if they have not been licensed by DBS.

Standards dealing with the actual transfusion are unique to the AABB and are designed to insure patient safety. The requirements for labeling and testing of blood are detailed and specific. The standards provide for verification of all information before a transfusion is performed. The standards do not require the attending physician to specify why the blood is needed, or to provide a justification for the request. Following a transfusion, there are no requirements for recording of amount of blood

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[96]J. R. Jennings, "Standards and Accreditation Programs of the American Association of Blood Banks," Transfusion, Vol. 5, No. 2, 1965.

[97]Personal communication with Col. Peak, AABB representative in Washington, D.C.

[98]"Questions and Answers—Donation After Rabies Vaccination," Transfusion, Vol. 6, No. 4, 1966.

[99]The current AABB standards require a 24-hour wait after a prophylactic rabies vaccine.

requested and amount of blood utilized or for review of the physician's transfusion decision.

The ANRC, through 59 regional centers, administers the activities of 1,700 Red Cross chapters currently engaged in the collection of blood. The ANRC is licensed by the DBS and adheres to DBS standards. In addition, however, the ANRC publishes, "Blood Program Directives." The directives are divided into six subject areas: (1) Organization and Administration, (2) Budget and Finance, (3) Supplies and Equipment, (4) Medical, (5) Nursing, and (6) Technical. Generally, the Directives may be thought of as a complete handbook for the organization and administration of the Red Cross National Blood Program. As such, the Directives also contain the standards necessary for quality control within the operation of the program.

The Medical Director of the National Blood Program, ANRC, is responsible for "establishing goals and standards and developing criteria to measure medical, nursing, and technical effectiveness of the program." The Administrator of the Blood Program is responsible for "insuring that standards established by the Red Cross Blood Program are followed and maintained."[100] The ANRC standards program is supported by contributions to the ANRC; no part of the cost is passed on to the blood user.

For many years the ANRC has operated an internal inspection program to monitor quality control. In 1970, a proficiency testing program administered by National Headquarters was added. This program is intended to meet the inspection requirements of a number of new State and Federal laws including the Clinical Laboratories Improvement Act of 1967 administered by the Center for Disease Control, DHEW. "When the program is in full operation (the ANRC plans)...to obtain the necessary approvals for acceptance of (their)...testing program by State and National Regulatory Agencies."[101] The testing consists of two parts: proficiency of technical skills and testing of center produced products. Each center receives four sets of blood samples at intervals throughout each year. The samples are processed within ten days of receipt, and copies of the results are sent to National Headquarters. Periodic tests and assays are performed on all products; samples are shipped to National Headquarters upon request. A report of the findings is returned to the center where it is kept on file in a loose-leaf notebook which is available for public review.

All three organizations promulgate standards or directives for (a) physical equipment/facility/personnel, (b) donor criteria, (c) blood collection, and (d) processing for identification and storage. Frequently, DBS develops the base standard or minimum requirement, the AABB upgrades and adds further qualifications for performance of the standard, while the ANRC provides the level of detail in management and organization

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[100]Blood Program Directive 1.2, ANRC, July 1971.

[101]Blood Program Directive 6.14, ANRC, April 1970.

necessary to achieve a given performance level. The ANRC directives tend to be more exacting than either DBS or AABB standards.

To illustrate the relationships, DBS standards include ten criteria for donor selection:

(1) Minimum of eight weeks between donations.
(2) Normal body temperature.
(3) Normal systolic and diastolic blood pressure.
(4) Hemoglobin level of at least 12.5 per 100 ml. of blood.
(5) Free from acute respiratory diseases.
(6) Free from any disease transmissible by blood.
(7) Free from infectious skin disease at phlebotomy site.
(8) Free from indications of narcotic addiction.
(9) No history of or close contact with person having viral hepatitis.[102]
(10) A minimum of six months after last transfusion with human whole blood or any blood derivative which can transmit viral hepatitis.

Both the AABB and ANRC further detail the ten criteria listed (e.g., body temperature, taken orally, shall not exceed 99.6°F) plus adding a substantial number of criteria. Most of the additional criteria (e.g., minimum weight requirements, exclusion of pregnant women and the requirement that male hemoglobin level be at least 13.5 per 100 ml. of blood) provide for increased donor safety. Other additional restrictions (e.g., on drawing from those with active allergies and on waiting periods after vaccinations and immunizations) protect the recipient. The ANRC directives are more detailed and specify more restrictions than the AABB standards (e.g., on those under medication).

## 7.4. Other Standards and Regulatory Bodies

Two other Federal agencies, the Food and Drug Administration and the Center for Disease Control, are also tangentially concerned with assuring the safety and quality of our national blood delivery system through regulatory action. The Federal Food, Drug, and Cosmetic Act has authority over interstate commerce of misbranded or adulterated food, drugs, device, or cosmetic. A drug is defined to include, "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals."[103] Thus, the FDA regulates the quality of packaging and labeling of blood products,[104] and requires that those who manufacture, prepare, propagate, compound or process blood products shall

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[102]Public Health Service Regulations for the Manufacture of Biological Products, Title 42, Part 73, Subpart D, Section 73.3001, Revised 6/1/71, pp. 83-84.

[103]Food, Drug, and Cosmetics Act, as amended January 1971, Section 201 (321) (g) (1) (B).

[104]Ibid., Section 502 (352) (a, h).

annually register "name, places of business, and all such establishments" with the Secretary of HEW.[105]

The Center for Disease Control (CDC) establishes standards for and inspects and tests those clinical laboratories which are engaged in interstate commerce and which examine material from the human body. Their standards encompass the hematological portion of the lab work, which may include cross-matching and processing. CDC is concerned primarily with clinical laboratories. Its effect on blood services is incidental, and reflects only on those standards involving hematological processes.

The Joint Committee on Accreditation of Hospitals and the College of American Pathologists have inspection and accreditation programs which include standards on blood banking procedures carried out in hospitals and clinical laboratories, respectively. JCAH standards and CAP standards are based on the AABB standards.

## 7.5. State Regulation

Eight states currently have a licensing and/or inspection program for blood banks. The states of California, Georgia, New Jersey, New York, Massachusetts, and Illinois have very detailed regulations covering the complete blood collection process. Where standards exist, these tend to parallel those of the AABB. For example, the Clinical Laboratory Licensure Law of Georgia states that the criteria for donor selection and the methods for collection, storage, processing, and transfusion shall conform with current AABB standards. Florida's law primarily covers clinical laboratory operations although it does state that the same regulations apply to blood banks. Commercial blood banking has been outlawed in Wisconsin, while Massachusetts requires that all blood usage be reported.

## 7.6. Problems and Deficiencies

It was pointed out previously that DBS requires sound and conclusive evidence in order to license blood derivatives or additives. Such clinical testing is necessary to protect against unsafe products and there are instances where failure to obtain sufficient evidence could have had severe consequences.[106] Unfortunately, licensing procedures and attendant gathering of conclusive scientific evidence also serve to restrict the adoption of new techniques and have slowed distribution and utilization of new products. As examples:

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[105] Food, Drug, and Cosmetics Act, as amended January 1971, Section 510 (360) (a) (1) (c).

[106] The most effective plasma substitute discovered to date (high molecular weight-polyglucine) has been shown to result in liver and kidney damage: precipitous licensing of this product could have been catastrophic.

stored in ACD but not CPD (an additive regarded to be superior), because of lack of clinical evidence to support licensure. As a result, CPD has not come into common use and many potential benefits of this additive including increase in blood survival[107] and ability to recover fractional units of blood[108] have not been realized.

(2) Platelets, a blood derivative, have been widely accepted for therapeutic use, but have not as yet been licensed by DBS. Because of the interstate commerce constraint, the Philadelphia Red Cross charges $10 for a unit of platelets used in Pennsylvania but supplies the unit free of charge if used in New Jersey, thereby adding to variance in blood pricing.[109]

(3) Blood freezing techniques have been the subject of considerable technological development aimed at achieving longer shelf life and increasing blood quality. Almost every advancement has resulted in a slight change in the processing technique and, from the view of DBS, in a new product. Considerable experimental work is carried out in testing each new technique, but DBS requirements are exacting, and sufficient evidence for licensing has only been submitted for one technique to date. The approved technique is generally regarded to be obsolete.

Another perceived problem encountered in the study of regulatory activities affecting blood is the reactive rather than active character of control and enforcement practices. DBS, the AABB and the ANRC appear to wait for a crisis situation to develop before establishing regulations. For example, there is much current interest in transmission of hepatitis through transfusion. The problem has long been recognized, but it has only recently become controversial. The current AABB standards contain no mention of methods for dealing with the problem.[110] In July 1971, the ANRC ordered hepatitis testing for all donor blood.[111] On November 1, 1971, DBS amended part 73 of the Public Health Service Regulations to provide: (1) that all human blood in interstate commerce be tested for hepatitis associated antigen; (2) that the blood container label indicate test results; and (3) that all donors with positive results be permanently deferred. Although donor registries are finding increasing use in hepatitis prevention, only the ANRC standards mention them.

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[107]See footnote 28, page 16.

[108]Orlina et al., "Transportation and Red Cell Survival," Transfusion, Vol. 8, No. 3, 1968.

[109]Personal communication with Dr. William Sherwood, Philadelphia ANRC.

[110]"Blood Use in Massachusetts," New England Journal of Medicine, Vol. 284, p. 447, 2/25/71.

[111]ANRC Blood Program Directive 4.29.

Similarly, when a published standard is found insufficient, imprecise or confusing, change is often slow in coming. For example, the ANRC is the only group which has a standard on the volume of blood to collect. They prescribe a standard unit of 450 ml. However, any unit containing 405 ml. to 495 ml. of blood is considered acceptable. Since the containers are packaged with 50 ml. of anticoagulant, the concentration of anticoagulant varies.[112] The resultant problems were discussed in a letter to the editor of Transfusion in 1964, but no change has, as yet, been made.[113]

Another more obvious deficiency lies with gaps and variations in the present standards. Those blood banks which conform only to DBS standards are subject to less stringent rules than those which conform to AABB regulations. For example, many of the donors excluded as unhealthy under AABB and ANRC standards can give in blood banks licensed by DBS. Most state laws have apparently been motivated as much by a desire to tighten the DBS-imposed standards for interstate blood banks as to set standards for intrastate blood banks. For example, blood bank regulations which were recently enacted in Illinois are largely the result of unfavorable publicity received by a DBS-licensed blood bank.[114]

There is a small segment of the blood collection and distribution system that can operate without adherence to any of the standards and regulations previously discussed. These groups need not adopt AABB/ANRC quality standards, test for hepatitis, operate donor registers, or properly screen donors unless it suits their purpose to do so.

This is not to suggest that there are a large number of organizations who operate in an objectionable manner; in fact, the industry will usually drive such organizations out of the market.[115] Nevertheless, some undesirables do exist, often in areas where demand for blood exceeds noncommercial supply and the consideration of availability outweighs the question of blood quality.

This latter factor must be considered when suggesting changes to the current blood banking system; more stringent regulatory action could influence both the availability and cost of blood. Fear of curbing

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[112]ANRC Blood Program Directive 4.11, April 1969.

[113]"Letters to the Editor," Transfusion, Vol. 4, No. 1, 1964, p. 60.

[114]Personal communication with M. Clune, Illinois Department of Public Health.

[115]The most famous example of a DBS-licensed but unsanitary commercial blood bank which was driven out of the market occurred in Kansas City. In that case, the Federal Trade Commission ruled that the methods used violated antitrust laws; this ruling was eventually overturned by the U.S. Supreme Court.

blood availability is one reason for current DBS policy. Dr. Sam Gibson, former Assistant Director of DBS, says, "we have the obligation not to make regulations so strict that the blood supply dries up."[116] If availability is curtailed, it is reasonable to believe that quality could suffer unless: (1) the regulatory actions are extended to include all blood banking participants and/or (2) another mechanism is employed, such as donor education and incentives, to increase blood resources.

The evident inertia and the gaps in standards appear to be natural functions of a system which encompasses a weak Federal regulatory system and two large private organizations with different philosophies of proper system structure and donor recruitment methods. No one has assumed the role of leadership for the regulatory process; each organization guards and administers its own area of responsibility. In short, the regulatory and standardization activity is best represented as a group of detached segments working more or less toward common objectives but without general direction and continuity.

### 8. Policy Alternatives and Suggested Courses of Action

There are many aspects of the blood banking system that would benefit from change. Increases in blood supply, improvements in blood quality and a reduction, or redistribution of user costs are all desirable and technically feasible.

To move toward achieving these goals, modifications in the present system should be considered. These modifications are related to seven topical areas of system organization and operation. Subsections which follow highlight the results of study in these seven areas and suggest certain actions which should have a positive influence on components of the blood banking system. Some of these actions are within the purview of DHEW and might be undertaken unilaterally without direct assistance from state agencies, organizations or individuals within the private sector. For the most part, however, implementation of suggested actions will require the cooperation and direct participation of both governmental and private organizations, as it is the latter that have responsibility for and greatest vested interest in the national blood banking system.

It appears possible to develop a department approach involving minimum Federal control, but with Federal support of developmental efforts which will lead to adoption of an effective blood banking system. At the moment a frozen blood system or regional donor registry and call-up systems administered by presently organized or chartered organizations such as the ANRC and AABB or a combination seem to be the principal candidate systems. Regional groups would develop and operate a comprehensive information system to foster the use of on-call volunteer donors

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[116]"Blood Banking: Money Is at Root of System's Evils," Science, Vol. 175, No. 4028, 3/24/72, p. 1346.

and to reduce blood wastage associated with overcollection, maldistribution, and outdating. Complementary actions in which DHEW has a greater or lesser involvement include donor recruitment and retention programs; development of improved standards for collection, processing and storage; and professional education programs.

## 8.1. Standards, Regulations, and Surveillance

An analysis of regulations and standards pertaining to blood collection, processing, storage and administration indicate that there are at least three actions which may have a positive influence on blood quality.

1. *The standards promulgated and enforced by the Division of Biological Standards should be strengthened and broadened to achieve a scope and comprehensiveness consistent with the standards of the American Association of Blood Banks.*
2. *The DHEW can assume responsibility for development and/or adaptation of a model state standard which serves to regulate the operations of blood handlers not engaged in interstate commerce. Joint participation of a DHEW agency and state agencies should be considered as a feasible approach to standards development. Adoption of the model standard by all states lacking equivalent legislation might be fostered and promoted by appropriately revising or strengthening DHEW policies vis-a-vis Medicaid reimbursement, categorical fund distribution, etc.*
3. *Methods of streamlining DBS procedures should be examined and means considered to promote research necessary to establish the safety and stability of blood derivatives and blood products.*

## 8.2. Research

Viewed within the context of present problems, there are several areas of research that can lead to better blood quality and blood availability.

Dominant in this category is the development of an effective (> 95%) Hepatitis Associated Antigen (HAA) test.

A second area involves definitive determination of allowable storage periods for CPD-stored blood and blood products.

There are a number of other research activities, which could have pronounced impact if technological breakthroughs are achieved and if the results of research can be implemented by a large segment of the blood banking or medical community. These are:

(1) Further improvement in techniques for component preparation and component therapy.

(2) Development of improved blood expanders and blood substitutes.
(3) Development of techniques to reduce donor reaction rate.
(4) Development of blood sterilization techniques.
(5) Improvement in blood storage equipment and techniques.

It is inappropriate for this report to judge research priorities or to propose a level of effort for the research potentials in this area. However, two actions relating to blood research and additive testing deserve strong consideration:

4. *Economic loss and health risk to a patient from post-transfusion hepatitis argues for continuation of the strong National Heart and Lung Institute-sponsored research efforts on improved HAA testing.*[117]
5. *Research on the approved use of CPD as a "28-day" blood additive and of blood derivatives from CPD-stored blood should be initiated in FY 73.*

## 8.3. Professional Education

There is general consensus that use of packed red cells is generally safer and a preferred alternative to whole blood transfusion. It is also pointed out that there are a large number of transfusions (mainly single unit) which need not be administered; unnecessary transfusions are estimated to consume over 4% of all blood collections and thereby increase the requirements for paid blood.

The doctor or surgeon is often inadvertently doing a disservice to his patient when blood is transfused, primarily because the inherent risk of the transfusion process has not been fully recognized and because of the physician's natural hesitancy to convert to component therapy techniques. In fairness to the physician, the magnitude of medical problems associated with blood transfusions has only recently been widely publicized. Yet the chance of mismatching, allergic reaction, disease, etc., have long been recognized and should, in themselves, mitigate against the single unit practice.

There are few, if any, review procedures that would identify if a physician is using blood properly. Death and Tissue Boards have been established at most hospitals to serve as peer review committees to judge and advise the physician. This has proved to be an effective technique for maintaining high quality care if the review program is properly administered. Perhaps a similar review procedure should be established for transfusion review.

In addition, the NAS-NRC reports that medical schools are not providing sufficient training in such subjects as component therapy, blood

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[117]This conclusion is warranted until such time as a nationwide frozen blood program is adopted and implemented.

expanders and general blood utilization. The suggestion has been made that the Federal Government might exert pressure on medical schools in order to have this sort of training provided, but many medical schools view direct Federal intervention in their curriculum as improper. Feedback from practicing professionals who are worried about transfusion review requirements may be a less controversial and equally effective means of achieving curriculum changes.

The previous discussion suggests that:

6. *Peer/utilization review might be desirable as a means to establish and maintain higher standards of blood utilization.*
7. *That consideration should be given to JCAH-HEW cooperative efforts which would result in an added request for hospital review of transfusion as a requirement for JCAH-Medicare certification.*

### 8.4. Donor Recruitment and Retention

The examples of blood banking systems such as those in Canada and Milwaukee indicate that stronger donor recruitment and retention will yield more adequate blood supplies. The Milwaukee system involves a computer registry used for telephone call-up of donors, quality media advertising and follow-up contact with first-time donors. It is also noted that the registry serves a second important function since it provides a means for detection and elimination of disease carriers.

Establishment of an effective donor recruitment and retention program on a nationwide basis appears to be both feasible and cost effective. It is expected that the operational costs of the registry and call-up system, supplemented by limited advertising and recruitment programs, would not exceed $1.50 per unit after the program becomes operational. There is, however, a nontrivial start-up cost to establish and maintain computer regional registers. Based on an estimated five million donor population, total start-up costs are estimated to range between $7.5 and ten million dollars. These costs could be passed on to the blood recipient or various means of Federal subsidization might be considered. Partial or full Federal subsidization might be advantageous in that such an arrangement would permit limited government involvement which could be helpful in speeding implementation. The cost of donor registry and the use of call-up procedures have been found to significantly reduce the need for blood obtained from paid donors. Indirect costs of health care associated with post-transfusion hepatitis should also be curtailed accordingly.

The cost of a quality media campaign is clearly subject to economies of scale. An advertising campaign, developed under Federal contract, could serve the entire nation; otherwise, perhaps 60 regions will have to develop their own campaigns at a cost of about $100,000/region/year.

Limited data on behavioral response to blood donation supplemented by survey data collected as a part of this study corroborates the finding

that a large percentage of donors are lost to the system because of adverse reaction. These reactions appear to be of two types:

(1) The donor experienced pain, discomfort or hematoma due to procedural practices, or other causes.
(2) Weakness and/or dizziness occurred during or several hours after donation.

Both problems can strike even veteran donors.

It would appear that more research is needed on the physiological and psychological aspects of blood donation with a view toward identifying and correcting those factors that discourage individuals from first or subsequent donations. For example, many donors complain of a stinging sensation during blood draw. This is usually caused by the unnecessary presence of anticoagulant in the needle.[118] Similarly, dizziness, weakness, and hematoma caused by search for a second vein if the first vein collapses might be alleviated by drawing less blood or by adjusting the quantity drawn on the basis of patient characteristics and/or prior donation record. This practice is standard in the USSR and offers other advantages in that minimum weight and hemoglobin levels might be lowered if smaller amounts of blood are drawn. Conversely unit costs of blood and risk of transfusion-related reaction would be increased if less than standard amounts of blood are taken.

The previous discussion and related analysis elsewhere in this report indicate that:

8. *There is evidence that the use of tax incentives, monetary payment and other economic rewards to obtain blood may be counterproductive and should not be furthered without careful study of the likely effects.*
9. *A regional computerized donor registry and call-up system, supplemented with donor recruitment through advertising and other means, offer a way to increase blood supplies from unpaid volunteers. Central development and distribution of quality media advertising will be more efficient than many independent local efforts. Improved donor retention is crucial.*
10. *Elimination of the paid donor from the system concurrent with (9) is desirable from a cost standpoint in the absence of a highly effective HAA test or if the frozen blood concept is not adopted for nationwide use.*
11. *The physiological and psychological effects of blood donation and alternative procedures for collection of blood should be further analyzed and evaluated.*

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[118]Personal communication with Dr. Paul Schmidt of the NIH Blood Bank indicates that this is a common problem because it is easier for the manufacturer to sterilize the blood bag if there is anticoagulant in the needle. The NIH blood bank does not allow the manufacturer to put anticoagulant in the needle of its blood bags.

## 8.5. Regional Coordination

The Federal Government has a major role to perform in developing and fostering regulatory and control measures for donor selection and blood collection, processing, storage, and use.

The Federal Government can also serve as a catalyst to further cooperation between competing organizations. However, it is considered desirable that responsibility for operation of the system remain with those organizations who have a present vested interest in these programs.

Successful demonstration programs point to the fact that a coordinated activity at the regional level can significantly reduce outdating, shortage, and the need for paid donors, even in large metropolitan areas like New York City. Coordination activities and donor registry and call-up are easily interrelated and are most beneficial in combination.

Adaptation of a regional coordination concept places a high degree of reliance on the establishment of a cooperative program in which all existing and competing blood collection agencies participate. Since, in principle, a program aimed at reducing the risk of disease will result in the elimination of some of the initial participants (i.e., commercial blood banks) it is questionable how much support can be expected from this quarter. (The frozen blood alternative discussed in Section 8.6, which follows, does not create this problem.) A catalyst may be needed, and Federal support of some aspects of a responsive system (e.g., donor registry) may be a viable course of action to achieve majority acceptance and joint implementation.

12. *A regional system is preferred from a cost standpoint. Successful programs in a number of cities indicate that adequate administration can be exercised by organizations that have current responsibility for blood collection. An important feature that should be included in the regional control system is a donor registry and call-up system.*
13. *Carefully developed decision rules for inventory control, priority of blood use, collection quotas, etc., are also important features of an efficient system. These rules should replace the arbitrary and sometimes erroneous procedures currently in use.*

## 8.6. Blood Storage Methods

The results of the cost analysis presented in this report suggest that a Milwaukee control type program with an effective, low cost transfusion review probably represents the least costly solution to blood banking of all alternatives considered. The Milwaukee program coupled with 28-day blood life has an equally low unit cost, but requires more units. There is over a 30% chance that frozen blood will have an even lower cost per unit if hepatitis testing is less than 65% effective. Considerations relating to cost equity (especially when human life values are included) argue for the preferability of the frozen blood alternative

since the principal advantage of frozen blood is the expected reduction in numbers of transfusion-related diseases and deaths. There are other advantages including:

virtually unlimited blood life (in particular with respect to rare blood types); and
retention of the commercial blood bank and paid donor as active components of the blood banking system.

The principal drawbacks of the frozen blood concept are: (1) high start-up cost, (2) high unit cost, and (3) requirement for additional technician staff.[119]

Unless rapid conversion to an all frozen blood system or a 95% effective HAA test is imminent, it appears that some form of regional control and donor recruitment/retention programs in conjunction with other programs designed to eliminate the paid donor is the most attractive approach to take. It should be cautioned that major reduction or elimination of the paid donor category should not be attempted before start-up of regional inventory control, and the establishment of donor registry and call-up systems.

Either of two possible supplements to the control and call-up system appear to substantially eliminate the need for the paid donor. These are:

(1) extension of the legal CPD storage period from 21 to 28 days; or
(2) institution of an adequate transfusion review process.

Transfusion review will result in less transfusions and less transfusion-related deaths, and is probably the preferred choice. Consequently, the findings of this study indicate that:

14. *Reduction in post-transfusion complications is a dominant consideration in seeking blood banking system improvement. A nationwide frozen blood system would provide the most equitable distribution of costs and the greatest reduction in patient risk, but would not require elimination of the paid donor. If frozen blood is judged to be too costly, the poorly screened paid donor should be eliminated through legislation, regulation, economic boycott or other means but only in conjunction with establishment of a regionally-controlled donor registry, call-up recruitment system and either transfusion review or 28-day CPD certification programs.*
15. *Transition to a frozen blood system must be accompanied by recruitment or retraining of technicians to staff the facilities.*

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[119]Labor costs of technicians have been included in the cost analysis of alternatives in this report.

## 8.7. Financing and Cost

Several alternative means for system change are described in the report. Four of these alternatives (two of which involve the frozen blood concept) are regarded as best candidates for selection.

a. Alternative 1: Adaptation of regional systems administered by existing blood organizations including the establishment of donor registries, call-up and retention procedures, media advertising, inventory control procedures, and use of CPD to extend blood storage life to 28 days.
b. Alternative 2: Adaptation of regional systems administered by existing blood organizations including the establishment of donor registries, call-up and retention procedures, media advertising, inventory control procedures, and transfusion review.
c. Alternative 3: Adoption of frozen blood nationwide in conjunction with (1) establishment of regional inventory control; (2) full Federal subsidization of start-up costs.
d. Alternative 4: Adoption of frozen blood nationwide in conjunction with (1) establishment of regional inventory control; (2) low interest five-year loans to nonprofit and for-profit organizations to cover start-up costs.

| Alternative[120] | Deaths (Annually) | Total Cost to Federal Gov't. (Millions) | Total Average Annual Costs to User—1st 3 years (M) | Total Annual Cost 1st 3 years (M) |
|---|---|---|---|---|
| Current System | 2,285 | - | 418 | 418 |
| Alternative 1 | 995 | 11 | 341 | 345 |
| Alternative 2 | 885 | 11 | 330 | 334 |
| Alternative 3 | 5 | 88 | 378 | 407 |
| Alternative 4 | 5 | -[121] | 395 | 395 |

It will be noted that current system cost exceeds all alternatives for the first year even when start-up costs for frozen blood and regional controls are fully amortized in the first three years.

Alternatives 1 and 2 appear to be favored over alternatives 3 and 4 because of the high start-up costs of either a fully subsidized or non-subsidized frozen blood program. Whereas alternatives 1 and 2 are less expensive in terms of average patient payment, there are approximately 900 more deaths associated with these alternatives. The question of whether the expense involved in saving these lives is too high is largely a policy consideration.

[120]Assumes 60% HAA test effectiveness.

[121]Lost opportunity costs to government associated with low interest loans have not been treated in this comparison.

## Postscript

Since the completion of this report, two major events have impacted on the blood banking system. The more significant event resulted from the transfer of the Division of Biologic Standards from the National Institutes of Health to the Food and Drug Administration, where it was renamed the Bureau of Biologics (BOB). Since its relocation, BOB has been able to apply a broader interpretation to existing laws governing blood banks. The new interpretation has allowed BOB to regulate and inspect all American blood banks, whether or not they are engaged in interstate commerce. Thus, the problem addressed in recommendation 2 of this report has been resolved.

The second significant event is that 21 American National Red Cross (ANRC) Blood Centers are now engaged in red cell freezing operations. Large ANRC equipment orders have resulted in a considerable decrease from the estimates of capital costs for red cell freezing equipment given in the report. Freezing equipment now is $10,000 per unit rather than $12,000 and thaw-wash equipment for the Meryman technique now costs roughly $3,800 rather than $15,000. The capital equipment purchase program described in Chapter 6 of the report would thus cost:

Federally subsidized—locations chosen by Federal Government: $42.5 million
Federally subsidized—no Federal location preference: $44.1 million Federal expenditure plus $2.8 million commercial expenditure
Interest free loan: $6.1 million.

Furthermore, the report's claim of technical feasibility for this alternative appears to have been confirmed. Dr. Meryman of the ANRC Research Laboratories has stated that the ANRC would convert its 40% of the blood supply to an all-frozen red cell system within three years if ten million dollars were made available for equipment purchases. The 1973 ANRC budget for purchase of red cell freezing equipment is on the order of one-half million dollars.

In retrospect, it would appear that the alternative MCP with transfusion review should also have included 28-day life. This inclusion would reduce the direct cost of that alternative by $.50 at all levels of hepatitis testing and would slightly expand the range over which this alternative is preferred to MCP with 28-day life and frozen blood.

## Appendix A. Derivation of Statistics on Blood Supply and Demand

The literature contains a broad range of estimates on the number of units of blood currently collected and transfused. However, in no instance do these estimates derive from hard analytical evidence. This appendix contains the results of an analytic approach to the derivation of estimates of nonmilitary blood use during the period 1967-1971 and the prediction of probable levels of nonmilitary blood use during the period 1972-1976.

Red cells are the only blood component which cannot be obtained by plasmapheresis. Therefore, for purposes of estimation, the number of units of blood needed for patient transfusion is defined as the sum of the whole blood needs and packed red cell needs.

The estimates of future usage assume that current transfusion practices will be continued. However, a number of factors could change current practice. Notable are:

1. Increased effectiveness of education programs aimed at ending single unit transfusions.
2. A change in attitude towards and/or technology for blood substitutes and expanders.
3. The possibility of blood utilizing or saving medical breakthroughs (e.g., the recently announced "cure" for childhood leukemia).

These events have not been included in the projection of future blood requirements because it is unlikely, given the current situation, that factors of this nature will have a major effect on usage in a period as short as four or five years.

In order to arrive at past and future requirements for whole blood, two estimation procedures were considered:

1. Estimation of current use and future need based on (a) longitudinal data on the number of units transfused per capita and (b) Census Bureau estimates of population increase during 1967-1976.
2. Direct estimation based on blood usage during the last several years.

### Method 1

Only limited data are available to support the first estimation method because national statistics on per capita blood utilization are not available. However, the ANRC has supplied all of Connecticut's blood requirements for several years and these data are available for four years. As these data are almost complete and deal with a known population, they have been used as a basis for the first estimation method. U. S. Census and ANRC data can be used to compute the ratio of the number of units transfused in Connecticut to the population of Connecticut for the years 1967-71. The data and results are shown in Table A1.

Table A1

| Year | Units Transfused[122] | Population[123] | Ratio |
|---|---|---|---|
| 1967 | 88,815 | 2,935,000 | .00303 |
| 1968 | Not Available | | |
| 1969 | 88,548 | 3,000,000 | .00295 |
| 1970 | 88,319 | 3,032,000 | .00291 |
| 1971 | 91,316 | 3,065,000 | .00298 |

The annual per capita transfusion rate in Connecticut is stable, (.00297 ± .0006) based on four years of data. If these results are assumed to be representative of the Nation, blood usage can be obtained by applying a utilization rate of .00297 to U.S. population estimates for 1967-1971 and projections for 1972-1976. This assumption of representativeness can be investigated by deriving an estimate of 1971 blood usage from other data sources and comparing it to the estimate obtained by using the Connecticut data. If the two estimates agree, the assumption gains credence. The U.S. Census Bureau gives four estimates of future population; the demand for blood was projected using Population Series B and D. The results are contained in Table A2.

The method predicts that approximately 6.15 million units of blood were transfused in 1971. Blood utilization increased by 250,000 units between 1967 and 1971 or about 60,000 units per year (1.1% per annum over the 1967 estimate). Depending on which population series is used, blood utilization will increase between 360,000 and 430,000 units by 1976. This is about a 1.3% per year increase over the 1971 estimate.

[122] 1967 figure from the AMA's Directory of Blood Banking and Transfusion Facilities and Services, 1969. All other figures from ANRC's Blood Center Operations reports as product of accountable supply used and sum of whole blood and red blood cells retained by civilian and military hospitals or sent to other blood banks.

[123] 1971 Statistical Abstract of the U.S.

Table A2

| | Population (1000's)[124] | Units Transfused (1000's) |
|---|---|---|
| 1967 | 198,619 | 5,899 |
| 1968 | 200,619 | 5,958 |
| 1969 | 202,599 | 6,017 |
| 1970 | 204,800 | 6,083 |
| 1971 | 207,006 | 6,148 |

| | Population Series B[124] | | Population Series D[124] | |
|---|---|---|---|---|
| | Population (1000's) | Units Trans. (1000's) | Population (1000's) | Units Trans. (1000's) |
| 1972 | 209,484 | 6,222 | 209,181 | 6,213 |
| 1973 | 212,155 | 6,301 | 211,530 | 6,282 |
| 1974 | 215,053 | 6,389 | 213,991 | 6,356 |
| 1975 | 218,177 | 6,480 | 216,561 | 6,432 |
| 1976 | 221,519 | 6,579 | 219,239 | 6,511 |

If an outdate and wastage rate of 15% is applied to the estimated total units transfused, then it appears that about 1.25 million units were collected but not used in 1971.

Method 2

Use of the second estimation method proves to be difficult because of lack of data on blood utilization nationwide. AMA statistics on units transfused, published every four years, suffer from severe underreporting. ANRC statistics report on collections and on transfusions where the ANRC was involved. The AABB records only collections. Reasonably complete national data on the number of units transfused and their source is only available for transfusions in Veteran's Administration hospitals and from a special AHA Survey of transfusions in "short-term" nonfederal hospitals during the first six months of 1971.

Consequently, if the second method is employed, calculations must be based on six months of utilization data, and unsupported assumptions concerning blood used in "long-term" hospitals must be made. Thus, the second estimation method can, at best, be used as a reliability check of

[124]U.S. Bureau of the Census, Current Population Reports, Series P-25, No. 476, "Demographic Projections for the United States," 1972.

the first method. It does, however, provide insight on sources and usage in 1971 (e.g., collection agency, % paid donors).

Table A3 contains the AHA data on sources and quantities of blood transfused in short-term nonfederal hospitals between January 1, 1971 and June 30, 1971.[125] Table A4 contains data on sources and quantities of blood obtained by Veteran's Administration (V.A.) hospitals in 1971. Of the 253,000 units collected, 230,000 were transfused and 23,000 were outdated.[126]

Additional reliable data available for 1971 are:

The ANRC collected 3,182,000 units;[127]
AABB members collected 3,312,000 units;[128]
Those commercial blood banks which are AABB members collected 284,000 units.[129]

To prepare a detailed estimate of the current situation from this raw data, a number of arbitrary, but plausible, assumptions must be made as follows:

1. Blood use in short-term nonfederal hospitals was the same in the first and second halves of 1971.
2. Blood is used at the same rate per bed in long-term nonfederal and in V.A. hospitals.
3. Blood is obtained from the same sources by short and long-term nonfederal hospitals.
4. Blood obtained from all sources outdates at the same rate in V.A. hospitals.
5. All non-V.A. units from paid donors outdate at the same rate (3.6%)[130] as blood collected by Blood Services, a multi-state community blood banking operation which pays over 75% of its donors.

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[125]American Hospital Association News, press release of December 8, 1971. Based on a special National Hospital Panel Survey released October 12, 1971.

[126]Personal communication with Mr. Lee Johnson of the Veteran's Administration.

[127]ANRC, Blood Center Operations for the Year Ended June 30, 1971. Another 223,000 units were collected by the Greater New York Blood Program which we feel is primarily an AABB collector.

[128]Personal communication with Col. Ben Peake, AABB Congressional liaison. Another 194,000 units were collected by a Los Angeles blood bank which the AABB feels is primarily an ANRC collector.

[129]Personal communication with Col. Peake.

[130]Internal working documents of the DHEW Task Force on Blood Banking.

Table A3

| Source | # of Units Transfused ('000s) | % of Units Transfused |
|---|---|---|
| All | 2,943 | 100.0 |
| Drawn by Hospital from Voluntary Donors | 171 | 5.8 |
| Drawn by Hospital from Replacement Donors | 280 | 9.5 |
| Drawn by Hospital from Paid Donors | 162 | 5.5 |
| Drawn by ANRC | 1,192 | 40.5 |
| Drawn by Community Blood Bank | 603 | 20.5 |
| Drawn by Commercial Blood Bank | 400 | 13.6 |
| Transfer from Other Hospital | 50 | 1.7 |
| Other | 85 | 2.9 |

Table A4

| Source | # of Units Obtained ('000s) | % of Units Obtained |
|---|---|---|
| All | 253 | 100.0 |
| Drawn by Hospital from Voluntary Donors | 32 | 12.5 |
| Drawn by Hospital from Paid Donors[131] | 4 | 1.6 |
| Drawn by ANRC | 174 | 68.7 |
| Drawn by Commercial Blood Bank[131] | 43 | 17.2 |

[131]The breakdown between these two categories is only an estimate.

6. All non-V.A. volunteer blood outdates at the ANRC outdate rate.
7. Donors are paid for one-half of all transfused blood obtained from community blood banks.
8. All units collected from replacement donors and all units transferred between blood banks were collected by AABB members.
9. The percentage of total collections which were made by AABB members is the same for each of the following categories in Table A3: hospital paid; hospital volunteer; community; and other.

Using assumption 2 and the fact that there were 38% as many V.A. beds as long-term hospital beds in 1965,[132] we estimate that about 87,000 units were transfused in long-term hospitals in 1971. The sources of the 87,000 units transfused by long-term nonfederal hospitals can be calculated using assumption 3 and the percentages shown in Table A3. Similarly, the sources of the 230,000 units used in transfusions by the V.A. can be calculated from assumption 4 and the data in Table A4. Using assumption 1 and the data in Table A3, the sources of all units transfused in short-term, nonfederal hospitals in 1971 can be calculated. Table A5 shows the estimated sources of all transfused units which derive from those calculations. These estimates are the sum of the estimated quantities transfused by short-term, long-term and V.A. sources. The estimated number of units transfused is within 1% (57,000 units) of the estimate made by the first estimation method. This lends greater credence to the assumption that utilization in Connecticut was representative of U.S. blood utilization.

Estimates of collections by source and of AABB activities can also be prepared for 1971. Table A5 shows that 2,577,000 of the 3,182,000 units collected by the ANRC were transfused; this indicates that approximately 19% outdated or was wasted. Using the data in Tables A4 and A5 and assumptions 5 and 6, it is possible to estimate the collections by source. These are listed in Table A6. The overall outdate rate is 15% ((7303-6204)/7303).

An estimate of the sources of the 3,312,000 units of blood supplied by AABB members can also be made. Recall that 284,000 commercial units were collected by AABB members. According to assumption 8, 827,000 units were obtained from replacement donors and hospital transfers. 2,201,000 AABB units are unaccounted for and must have been supplied by four sources: hospital paid, hospital volunteer, community, and other.

This accounts for 92.5% of collections by these sources. Assumption 9 provides that these units were divided equally between these sources. Table A7 summarizes blood collection and disposition by AABB members.

The salient results of this analysis are discussed in detail in the text.

[132] H. Herman and M. McKay, Community Health Service, ICMA Municipal Management Series, 1968, p. 106. Data from the AHA.

Table A5

| Source | # of Units Transfused ('000s) | % of Units Transfused |
|---|---|---|
| All | 6,204 | 100.0 |
| Hospital-Voluntary Donor | 375 | 6.0 |
| Hospital-Paid Donor | 333 | 5.4 |
| Hospital-Replacement Donor | 568 | 9.2 |
| ANRC | 2,577 | 41.5 |
| Community-Paid Donor[133] | 612 | 9.9 |
| Community-Voluntary Donor[133] | 613 | 9.9 |
| Commercial | 851 | 13.7 |
| Hospital Transfer | 102 | 1.6 |
| Other | 173 | 2.8 |
| Paid | 1,796 | 28.9 |
| Unpaid | 4,408 | 71.1 |
| AABB[134] | 2,867 | 46.2 |

[133]Distribution based on assumption 7.

[134]From Table A7.

Table A6

| Source | # of Units Collected ('000s) | % of Units Collected |
|---|---|---|
| All | 7,303 | 100.0 |
| Hospital-Voluntary Donor | 459 | 6.3 |
| Hospital-Paid Donor | 345 | 4.7 |
| Hospital-Replacement Donor | 701 | 9.6 |
| ANRC | 3,182 | 43.6 |
| Community-Paid Donor | 645 | 10.4 |
| Community-Voluntary Donor | 756 | 8.7 |
| Commercial | 875 | 12.1 |
| Hospital Transfer | 126 | 1.7 |
| Other | 214 | 2.9 |
| Paid | 1,865 | 25.5 |
| Unpaid | 5,438 | 74.5 |
| AABB | 3,312 | 45.4 |

Table A7

| Source | # of Units Collected ('000s) | # of Units Transfused ('000s) |
|---|---|---|
| All AABB | 3,312 | 2,867 |
| Hospital-Voluntary Donor | 396 | 321 |
| Hospital-Paid Donor | 316 | 305 |
| Hospital-Replacement Donor | 701 | 568 |
| Community-Paid Donor | 589 | 568 |
| Community-Voluntary Donor | 701 | 568 |
| Commercial | 284 | 274 |
| Hospital Transfer | 126 | 102 |
| Other | 199 | 161 |
| Paid | 1,189 | 1,147 |
| Unpaid | 2,123 | 1,720 |
| % Paid | 35.9 | 40.0 |
| Noncommercial Total | 3,028 | 2,593 |
| Noncommercial Paid | 905 | 873 |
| % Noncommercial Paid | 29.9 | 33.7 |

## Appendix B. Analysis on Eligible Donors

In 1970, there were 114,525,000 residents of the U.S. and its territories who were between the ages of 18 and 65. The analysis reported in this Appendix was used to estimate how many of these people would be able to meet donor acceptability standards as published by the ANRC.

Using ANRC criteria;[135] acceptable donors must satisfy a large number of requirements including the following:

1. systolic blood pressure less than 200;
2. diastolic blood pressure less than 100;
3. no donation during or six months after pregnancy;
4. no major surgery or transfusion within six months;
5. not suffering from active allergy or asthma;
6. not in a mental or penal institution;
7. not suffering from diabetes controlled by medication;
8. not suffering from heart disease or active rheumatoid arthritis;
9. females must weigh at least 110 pounds and males 130 pounds; and
10. female hemoglobin must be at least 12.5 g/100 ml and male at least 13.5 g/100 ml.

For the most part, these criteria reflect an attempt to further define and quantify the basic criteria that blood donors must be in overall good health and capable of donating a full unit of blood without deleterious effects.

There are two factors which had to be recognized and resolved before an analysis could be conducted. First, levels of health vary considerably with age and sex. Therefore, all computations had to be done using data which related to these factors. Second, once a person contracts an exemptable health problem, the probability that he will contract another exemptable health problem is much greater than that of a normal person. The most notable example of this relationship is the correlation between the incidence of hypertension (high blood pressure), diabetes, and heart disease. Important data on multiple disease incidence in the general population is not available and therefore some assumption had to be made on disease relationships. To avoid double counting of ineligible donors, it was assumed that those persons with hypertension, those having undergone major surgery and those institutionalized would not be classified as ineligible because it was felt that their ineligibility would be manifested in another category. Conversely, it was assumed that there is independence among the other disease categories considered (e.g., heart disease and anemia).

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[135] ANRC Blood Program Directive 4.12, September, 1971.

The 1971 Statistical Abstract provided data on pregnancy, heart disease, and rheumatoid arthritis.[136] Data on incidence of anemia (hemoglobin level); allergy and asthma; diabetes; and underweight were obtained from two sources. These were: (1) observations made on 8,420 males and 15,207 females who underwent a free multiphasic screening examination at the Public Health Service demonstration center in Brookdale Hospital, Brooklyn, New York;[137] (2) data from the Metropolitan Life Insurance Company which recently screened its home office employees for health information.[138] The groups involved in the two studies had obvious differences in population characteristics; yet the results were similar. This indicated to us that the data might be generally applicable to the total donor population.

Table B1 contains the data by age, group, and sex, used in the analysis to estimate the total number of eligible donors. The table starts with a total of 114,525,000 age-eligible donors in the U.S. The size of the group is then systematically reduced to account for those persons who do not meet the ANRC blood donor qualifications.

Heart disease and active rheumatoid arthritis resulted in the elimination of 10,987,000 persons from the age-eligible sample. These conditions affect mainly those over 45 years old.

Pregnancy, according to ANRC criteria, results in a 15-month period of blood donor ineligibility. To estimate the number of persons affected by this restriction we have assumed that the percent decrease in eligible women is 1.25 times the annual birth rate. The incidence of miscarriage was not included in the estimation. Pregnancy, thus reduced the size of the potential donor population by approximately 4 million females.

The inability to meet the minimum weight criteria affects approximately 6,300,000 men and women, thereby excluding them from the potential donor population.

Anemia, which occurs most often in women who have not reached menopause, reduces the potential donor population by an additional 19 million individuals.

Of the remaining potential donors about 11 million are eliminated because they suffer from asthma or active allergies, and another 1 million are ineligible because they take insulin.

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[136] 1971 Statistical Abstract, Washington, D. C., U.S. Government Printing Office, 1971.

[137] Unpublished material obtained from Multiphasic Systems, Inc. of Norristown, Pennsylvania.

[138] Bulletin of the Metropolitan Life Insurance Co., July 2, 1970.

Table B1

| | 18 - 19 | 20 - 24 | 25 - 34 | 35 - 44 | 45 - 54 | 55 - 65 | Total |
|---|---|---|---|---|---|---|---|
| Initial No. of Male Donors by Age (1,000's) | 3,749 | 8,562 | 12,439 | 11,335 | 11,209 | 8,790 | 56,083 |
| Heart Disease or Rheumatoid Arthritis - incidence | 30 | 70 | 284 | 889 | 1,511 | 2,213 | |
| Donors Remaining | 3,719 | 8,492 | 12,155 | 10,446 | 9,698 | 6,577 | 51,087 |
| % Underweight (<130#) - incidence | 19.6 | 13.0 | 5.0 | 2.6 | 2.0 | 3.0 | |
| Donors Remaining | 2,990 | 7,388 | 11,547 | 10,174 | 9,504 | 6,380 | 47,983 |
| % Anemic (HGB<13.5) - incidence | 18.1 | 16.1 | 11.2 | 10.9 | 11.4 | 14.7 | |
| Donors Remaining | 2,449 | 6,199 | 10,254 | 9,065 | 8,421 | 5,442 | 41,830 |
| % Asthma & Hay Fever - incidence | 16.0 | 16.0 | 16.0 | 16.0 | 14.0 | 12.0 | |
| Donors Remaining | 2,057 | 5,207 | 8,613 | 7,615 | 7,242 | 4,789 | 35,523 |
| % Taking Insulin - incidence | 0.1 | 0.4 | 0.7 | 1.6 | 3.0 | 5.5 | |
| Male Donors Remaining | 2,055 | 5,186 | 8,553 | 7,502 | 7,025 | 4,526 | 34,847 |
| Initial No. of Female Donors by Age (1,000's) | 3,639 | 8,454 | 12,693 | 11,849 | 12,013 | 9,793 | 58,442 |
| Heart Disease or Rheumatoid Arthritis - incidence | 30 | 75 | 294 | 1,003 | 1,781 | 2,807 | |
| Donors Remaining | 3,609 | 8,379 | 12,399 | 10,846 | 10,232 | 6,986 | 52,451 |
| 1.25 x % Births - incidence | 8.3 | 20.9 | 13.5 | 5.6 | .14 | | |
| Donors Remaining | 3,309 | 6,628 | 10,731 | 10,542 | 10,218 | 6,986 | 48,414 |
| % Underweight (<110#) - incidence | 24.4 | 19.0 | 9.3 | 4.5 | 3.8 | 4.1 | |
| Donors Remaining | 2,502 | 5,369 | 9,733 | 10,068 | 9,830 | 6,700 | 44,202 |
| % Anemic (HGB<12.5) - incidence | 37.9 | 36.8 | 35.0 | 30.0 | 22.2 | 18.4 | |
| Donors Remaining | 1,554 | 3,393 | 6,326 | 7,048 | 7,648 | 5,467 | 31,436 |
| % Asthma & Hay Fever - incidence | 11.0 | 12.0 | 17.0 | 19.0 | 13.5 | 12.5 | |
| Donors Remaining | 1,383 | 2,936 | 5,251 | 5,709 | 6,616 | 4,784 | 26,729 |
| % Taking Insulin - incidence | 0.1 | 0.4 | 0.5 | 0.6 | 1.8 | 4.0 | |
| Female Donors Remaining | 1,382 | 2,974 | 5,225 | 5,675 | 6,497 | 4,593 | 26,346 |

The analysis indicates that of an initial 56,083,000 male donors between the ages of 18 and 65, 34,847,000 are eligible. The comparable reduction for females is from 58,442,000 to 26,729,000. The total donor base has been reduced by 46.6%; the female base was reduced by 55%, and the male base by 37.9%. Of the 48.8% of those under 35 ruled ineligible, 61.3% were women.

We have estimated that 7.3 million units of blood were drawn in 1971. 5.45 million units came from unpaid volunteers. Several studies indicate that approximately 20% of all volunteer units are drawn from donors who are giving for the first time.[139] Based on this, an estimate of 1.1 million "first-time" donors will be used for 1970. Sixty percent of the remaining volunteer donors and 25% of the paid donors give only once a year. The remaining donors give approximately 2.25 times a year.[140]

Thus, it is estimated that in order to achieve the 7.3 million units of blood, approximately 4.0 million volunteers and .95 million paid donors (about 8% of all eligible donors) gave blood.[141] Of special note is the figure of 1.1 million "first-time" donors each year. This implies that in any given year, about 1.75% of all eligible donors will give for the first time. Over a ten-year period, as many as 25% of all eligible donors will have given blood.

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[139]Condie and Maxwell, "Social Psychology of Blood Donors," Transfusion, Vol. 10, No. 2, 1970, pp. 79-83.

London and Hemphill, "The Motivations of Blood Donors," Transfusion, Vol. 5, No. 6, 1965, pp. 559-568.

Korzekawa, Jordan and Alsever, "The Blood Donor: I. Who Are Our Donors? An Analysis of Social and Other Characteristics of 12,759 Donors," The American Journal of the Medical Sciences, Vol. 240, July 1960, pp. 36-46.

[140]London and Hemphill, loc. cit.

Greater New York Blood Program data cited in internal working documents of the DHEW Task Force on Blood Banking.

[141]To check the reasonableness of this estimate, paid and unpaid collections were divided by the average number of units collected per ANRC donor in 1971(1.37). This calculation showed that there would be 4.0 million volunteers and 1.35 million paid donors.

## Appendix C. Derivation of Equation Relating Percentage of Paid Donors to Outdate Rates

In this appendix, an equation is derived which expresses the maximum percentage of paid donors which could be cost-effectively eliminated as a function of outdating rates before and after their elimination is effected.

Make the following definitions:

R = fraction of donors who are paid
T = number of units required for transfusion
N = current fraction of collections which is transfused
L = fraction of collections which would be transfused if shortage occurred.

Cost factors affected by shortage or the percentage of paid donors are the donor payment, the hepatitis cost, and the outdating cost. With a fraction R of paid donors, these costs are:

Payment: \$8 average payment per unit x R paid x # collected/(# collected x N transfused) = \$8R/N

Hepatitis: (.75% unpaid incidence x (1 - R) unpaid + 3.75% paid incidence x R paid) x 70% test ineffectiveness x (28 days of hospitalization for hepatitis x \$110 per day + 90% survive x \$750 convalescence + 10% die x \$45K per death) (# units transfused/3.1 units per episode)/# units transfused = (1 + 4R) (\$13.98)

Outdating: \$15.10 processing x (1 - N) outdate x # units collected/(N transfused x # units collected) = \$15.10 (1 - N)/N.

With paid donors outlawed, total collections will be T(1 - R)/N and requirements for transfusion will be T/L. Thus, the shortage is T/L - T(1 - R)/N, and T - LT(1 - R)/N units will not be available when required for transfusion. The shortage cost per unit required for transfusion will be ((T - LT(1 - R)/N) short x 3% die x \$45K per death + 48.5% serious effect x 10 days hospitalization x \$110 per day + 48.5% minor effect x 2 days hospitalization x \$110 per day)/T units transfused = ((N - L + LR)/N (\$2,038.20)). Outdating cost will be \$15.10 (1 - L)/L and unit hepatitis cost will be \$13.98 since R = 0.

Outlawing of the paid donor is cheaper when \$13.98 + \$15.10 (1 - L)/L + \$2,038.20 (N - L + LR)N $\leq$ \$13.98 (1 + 4R) + \$15.10 (1 - N)/N + \$8R/N, i.e., when R $\leq$ (\$2,038.20 $\mp$ \$15.10/L) (L - N)/(\$2,038.20 L - 55.92 + 8). Since L $\geq$ N, we have $R_{max}$ = (\$2,038.20 + 15.10/L) (L - N)/(\$2,038.20 L - 55.92 + 8). Thus, we see that if the outdating rate is not reduced, L - N = 0, $R_{max}$ = 0, and outlawing of the paid donor is not cost effective. The maximum percentage paid will occur if there is no outdating when shortage occurs. The expression becomes $R_{max}$ = (2053.3) (1 - N)/(2030.2 - 55.92N). Table 2 in Section 5.8 of the text was prepared by evaluating this expression for appropriate values of N.

## Appendix D. Sensitivity Analysis Derivation

### D1. Analysis for Figures D and E

The cost of each alternative is computed from many values which are "best estimates." Any set of estimates of these values can be considered to be a vector of cost parameters. Call the vector which contains the "best estimates" of these parameters the mean cost vector, and define the mean cost of the alternative as the cost which is calculated from the mean cost vector. Table 6 in Section 5.11 shows the range of values which are estimated to be equally likely to be the actual values.[142] Call any cost vector which contains one or more of these equally likely, but not "best," cost parameters a possible cost vector. Define the set of possible costs of an alternative to be the costs calculated from possible cost vectors. Obviously, there are an infinite number of these vectors since many of the cost parameters are "continuous variables" which might assume any of an infinite set of real-number values.

For the sake of simplicity, the cost comparisons made in Section 5.10 relied exclusively on mean costs. Since each possible cost of an alternative represents a cost estimate which one might consider to be the actual cost of that alternative if the exact values of the incidence parameters were known, a decision on the relative cost ranking of two alternatives based on their mean cost values will not be a good one if rankings based on possible cost values are likely to differ from the mean-cost-based ranking. The purpose of the present sensitivity analysis is to bound the likelihood of such reversals in ranking, between the lowest mean cost alternative and each of the two other alternatives which have mean costs close to the lowest mean cost. This type of analysis is particularly important because some of the parameters (e.g., cost associated with death) have no "true" value—the value of a life is perceived differently by different individuals. A high likelihood of reversal in rankings indicates that many people would not concur with a decision based on the mean cost ranking. Such disagreements are of particular concern to political decision makers.

The technical part of the discussion involves the costs, X and Y, of two alternatives. The associated mean costs are denoted $\bar{X}$ and $\bar{Y}$. The first of the alternatives is assumed to be that with lowest mean cost, so that

$$\bar{X} < \bar{Y}. \qquad (1)$$

The possible values of X are taken as ranging from a minimum value $X_{min}$ to a maximum value $X_{max}$ (where conceivably $X_{min} = -\infty$ and/or $X_{max} = \infty$),

[142] More precisely, the actual value is regarded as having a "uniform distribution" over its associated range.

and similarly for Y; therefore

$$X_{min} < X < X_{max}, \tag{2}$$

$$Y_{min} < Y < Y_{max}. \tag{3}$$

A reversal of the ranking based on mean costs of the two alternatives will occur precisely when (in contrast with (1))

$$Y < X. \tag{4}$$

Our uncertainty about the values of X and Y is represented by regarding them as random variables, with distributions (probability density functions) f(X) and g(Y). Moreover, they will be regarded as independent random variables. At first, this may seem incorrect: the total costs of the two alternatives may involve certain common uncertain cost elements (e.g., the basic processing fee), whose presence would, in general, imply dependence of X and Y. However, such common elements would "drop out" in comparing X and Y as in (4), and therefore are assumed to have been subtracted off in advance.

The aim of this analysis is to bound the probability of a reversal, denoted P(R). From the material in the last two paragraphs, it follows that

$$\begin{aligned} P(R) &= \text{Prob}(Y < X) \\ &= \iint_A f(X)\, g(Y)\, dX\, dY \end{aligned} \tag{5}$$

where A is the region in the (X,Y) plane defined by the three conditions (2), (3), and (4). This double integral can be converted into an iterated integral, with the integration over X performed first. For this purpose, note that for fixed Y, (2) yields $X > X_{min}$ and (4) yields $X > Y$, so that both conditions together yield $X > \max(Y, X_{min})$. Next, (3) yields $Y < Y_{max}$ while (2) and (4) together yield $Y < X < X_{max}$, so that all three conditions yield $Y < \min(Y_{max}, X_{max})$. It follows from these considerations and from (5) that

$$P(R) = \int_{Y_{min}}^{\min(Y_{max},X_{max})} g(Y) \int_{\max(Y,X_{min})}^{X_{max}} f(x)\, dX\, dY. \tag{6}$$

Figure D1. Possible Configurations of X-Interval and Y-Interval

| X-Interval / Y-Interval | | | | | | |
|---|---|---|---|---|---|---|
| Formula for P(R) | Impossible | (7a) | (7b) | (7c) | (7d) | (7e) |

For convenience six cases will be distinguished, depending on the relative positions of the four quantities $X_{min}$, $X_{max}$, $Y_{min}$, $Y_{max}$. (See Figure D1.) One possibility is that $Y_{max} \leq X_{min}$, i.e., that the interval of possible Y-values lies (on the real-number axis) entirely to the left of the interval of possible X-values. This possibility can be ruled out, as inconsistent with (1). A second possibility is that $X_{max} \leq Y_{min}$, i.e., that the X-interval lies entirely to the left of the Y-interval. Then (4) cannot occur, i.e., reversal is impossible, so that

$$P(R) = 0 \qquad \text{if } X_{max} \leq Y_{min}. \tag{7a}$$

In all remaining cases, characterized by

$$X_{min} < Y_{max}, \qquad Y_{min} < X_{max},$$

the two intervals overlap. These cases may be divided into two classes, according as

$$X_{min} \leq Y_{min} \quad \text{or} \quad Y_{min} < X_{min}.$$

For the first class, $X_{min} < Y$ holds, so that (6) becomes

$$P(R) = \int_{Y_{min}}^{\min(Y_{max},X_{max})} g(Y) \int_{Y}^{X_{max}} f(X)\, dX\, dY,$$

or more explicitly

$$P(R) = \int_{Y_{min}}^{X_{max}} g(Y) \int_{Y}^{X_{max}} f(X)\, dX\, dY \tag{7b}$$

$$\text{if } X_{min} \leq Y_{min} < X_{max} \leq Y_{max},$$

$$P(R) = \int_{Y_{min}}^{Y_{max}} g(Y) \int_{Y}^{X_{max}} f(X)\, dX\, dY \tag{7c}$$

$$\text{if } X_{min} \leq Y_{min} < Y_{max} < X_{max}.$$

For the second class, both $X_{min} < Y$ and $X_{min} > Y$ are possible, so that (6) becomes

$$P(R) = \int_{Y_{min}}^{X_{min}} g(Y) \int_{X_{min}}^{X_{max}} f(X)\, dX\, dY + \int_{X_{min}}^{\min(Y_{max},X_{max})} g(Y) \int_{Y}^{X_{max}} f(X)\, dX\, dY.$$

The inner integral of the first summand represents the probability that X falls anywhere within its interval of possible values, and so is equal to 1. Thus, distinguishing the two cases within the second class, we have

$$P(R) = \int_{Y_{min}}^{X_{min}} g(Y)\, dY + \int_{X_{min}}^{Y_{max}} g(Y) \int_{Y}^{X_{max}} f(X)\, dX\, dY \qquad (7d)$$

$$\text{if } Y_{min} < X_{min} < Y_{max} < X_{max},$$

$$P(R) = \int_{Y_{min}}^{X_{min}} g(Y)\, dY + \int_{X_{min}}^{X_{max}} g(Y) \int_{Y}^{X_{max}} f(X)\, dX\, dY \qquad (7e)$$

$$\text{if } Y_{min} < X_{min} < X_{max} < Y_{max}.$$

Once the functions f(X) and g(Y) are specified, the desired probability P(R) can be calculated from (5) or (6) or (7), either exactly if the functions are simple enough to permit this, or approximately by use of an appropriate numerical-integration technique. The remainder of our theoretical analysis is therefore composed of two tasks. First, a rationale is needed for specifying the pair (f,g) of functions. Two such pairs will be formulated, one to provide an upper bound on P(R) and the other to provide an approximate lower bound (and estimate). Second, for each pair the theoretical calculations directed by (6) must be carried out. After the theoretical analysis is complete (i.e., both tasks accomplished), its results must still be given numerical application to the specific situation under study in this report.

Specification of Distributions. Suppose initially that f(X) and g(Y) were such as to "concentrate" X and Y very tightly about $\bar{X}$ and $\bar{Y}$ respectively, i.e., all values of $X - \bar{X}$ or $Y - \bar{Y}$ which differ substantially from 0 had very low probability. Then clearly the ranking (1), based on mean costs, is very unlikely to need reversing. In other words, P(R) will be near zero. Intuitively speaking, the more X and Y are concentrated about their respective means, the less P(R) will be. And conversely, the less X and Y are concentrated about their means, the greater P(R) will be.

This observation leads immediately to our choice of a pair (f,g) of probability distributions to use in obtaining an upper bound for P(R). We choose f and g so as to concentrate X and Y "as little as possible" about their means, namely to be the uniform distributions over the respective intervals $(X_{min},X_{max})$ and $(Y_{min},Y_{max})$ over which the possible values of X and Y range.

It remains to describe how these two intervals are selected in this case. The cost (X or Y) of an alternative arises as a sum of products. Each product has many factors, each of which is an uncertain quantity, treatable as a random variable (denoted $X_{hi}$ or $Y_{jk}$). The products, then, can also be regarded as random variables (denoted $X_i$ or $Y_j$), so that

$$X = \sum_i X_i, \qquad Y = \sum_j Y_j \tag{8}$$

(the numbers of summands for X and Y need not be the same). The mean values of X and Y can be calculated from those of the $X_i$ and $Y_j$, as

$$\bar{X} = \sum_i \bar{X}_i, \qquad \bar{Y} = \sum_j \bar{Y}_j \tag{9}$$

Now each $X_i$ has a range $((X_i)_{min},(X_i)_{max})$ of possible values, calculable from Table 6 in Section 5.11, and so one might attribute a value to $X_{max}$ by the formula

$$X_{max} = \sum_i (X_i)_{max}, \tag{10}$$

with similar treatments for $X_{min}$, $Y_{min}$, and $Y_{max}$. This approach, however, is felt to lead to unrealistically wide intervals, and hence to an upper bound so conservative as to be unnecessarily uninformative. Instead, the following approach is adopted.

It is well known (and easy to derive) that a uniformly distributed random variable can differ from its mean by at most $\sqrt{3}$ times its standard deviation. Since each $X_{hi}$ is regarded as uniformly distributed, we see that its standard deviation is given by

$$(s_x)_{hi} = \frac{1}{2}\,[(X_{hi})_{max} - (X_{hi})_{min}]/\sqrt{3}. \tag{11}$$

If the $X_{hi}$'s are assumed independent, as is reasonable in the present context, then it follows that the variance of X is given by

$$s_x^2 = \sum_h \sum_i \left(\frac{\partial X}{\partial X_{hi}}\right)^2 S_{X_{hi}}^2, \tag{12}$$

where the derivatives are evaluated at the mean value of the $X_{hi}$. From equation (12), $s_x$ can be calculated. We now utilize the relation cited at the beginning of this paragraph to write

$$X_{min} = \bar{X} - s_x\sqrt{3}, \qquad X_{max} = \bar{X} + s_x\sqrt{3}; \tag{13}$$

values for $Y_{min}$ and $Y_{max}$ are found analogously. This completes the specification of the pair (f,g) to be used in finding an upper bound for P(R).

To obtain the estimate (and approximate lower bound), we continue to make use of the (generally valid) formula (9) for the mean value $\bar{X}$ of X, and formula (12) for its standard deviation $s_x$, and similarly obtain the values of the mean $\bar{Y}$ of Y and the associated standard deviation $s_y$. Now, however, we take f(X) and g(Y) to be the normal distributions with these respective means and variances. Here $X_{min} = Y_{min} = -\infty$, and $X_{max} = Y_{max} = \infty$.

The basis for regarding this pair (f,g) as an approximation to the proper distributions of X and Y, and hence the P(R)-value they yield as an "estimate" of the proper value, is provided by the Central Limit Theorem of probability theory, which asserts that under appropriate mathematical hypotheses, the distribution of a sum of random variables like X or Y in (8) is "asymptotically normal." The justification for believing this estimate to be on the "lower bound" side is hazier and more intuitive; some of the $(s_x)_{hi}$ or $(s_y)_{jk}$ are much larger than the others, and when this situation is examined in the light of the above-mentioned "mathematical hypotheses,"[143] it appears to the writer that the normal-distribution approximation yields more concentration about the mean (hence, a lower P(R)-value) than is actually the case.

Theoretical Calculations. For these calculations, it is convenient to introduce the quantity

$$D = \bar{Y} - \bar{X}, \tag{14}$$

which is non-negative by (1).

We turn first to the upper bound for P(R), involving uniform distributions. Here it is useful to introduce symbols for the half ranges of X and Y, i.e.,

$$a = \frac{1}{2}(X_{max} - X_{min}) = \bar{X} - X_{min} = X_{max} - \bar{X}, \tag{15a}$$

$$b = \frac{1}{2}(Y_{max} - Y_{min}) = \bar{Y} - Y_{min} = Y_{max} - \bar{Y}. \tag{15b}$$

[143] See pp. 491-492 of W. Feller, An Introduction to Probability Theory and Its Applications, Vol. 2, J. Wiley and Sons, 1966.

Within the ranges of integration in (7),

$$f(X) = 1/2a, \qquad g(Y) = 1/2b.$$

Thus for example (7b) becomes

$$P(R) = \int_{\bar{Y} - b}^{\bar{X} + a} (1/2b) \int_{Y}^{\bar{X} + a} (1/2a)\, dX\, dY,$$

yielding

$$P(R) = (a + b - D)^2/8ab. \tag{16b}$$

Similarly, (7c) and (7e) lead respectively to

$$P(R) = (a - D)/2a, \tag{16c}$$

$$P(R) = (b - D)/2b. \tag{16e}$$

The conditions for (7d) to apply are inconsistent with (1).

Now we consider the lower bound for P(R), involving the normal distribution. Here it is convenient to write

$$X = \bar{X} + us_x, \qquad Y = \bar{Y} + vs_y,$$

where u and v are normal random variables with zero mean and unit standard deviation. The probability of reversal is given by

$$\begin{aligned} P(R) &= \text{Prob}(Y < X) \\ &= \text{Prob}(\bar{Y} + vs_y < \bar{X} + us_x) \\ &= \text{Prob}(us_x - vs_y > D). \end{aligned}$$

Since X and Y are assumed independent, the same is true of u and v, and so $z = us_x - vs_y$ is a normal random variable with mean zero and standard deviation $s_z$ given by

$$s_z^2 = s_x^2 + s_y^2. \tag{17}$$

Continuing,

$$\begin{aligned} P(R) &= \text{Prob}(z > D) \\ &= \text{Prob}(z/s_z > D/s_z) \\ &= 1 - F(D/s_z) \end{aligned} \tag{18}$$

where F is the "standardized" normal distribution. Thus P(R) for the lower bound can readily be evaluated using standard tables.

Numerical Application. The methodology necessary to determine bounds on the reversal probabilities P(R) is now complete. The task which remains is to perform, for each pair of alternatives to be prepared, the calculations necessary: to obtain the means $\bar{X}$ and $\bar{Y}$, to obtain standard

deviations by (12) plus its analog for $\bar{Y}$; to obtain the upper bound on P(R) by use of (13), (14), (15), and (16) or (7a); to obtain the estimate and approximate lower bound for P(R) by use of (14), (17) and (18). The required values will be parameterized in terms of HAA test ineffectiveness, which is represented as H. We will not burden the reader with the calculations.

In computing the standard deviations, it would be incorrect to include deviation which is present in both alternatives (i.e., joint deviation) since joint deviation will not affect the ranking of the cost of the alternatives. Let $S_{A \text{ vs. } B}$ be the standard deviation of alternative A excluding the joint deviation of alternatives A and B, and let $m_A$ be the mean cost of alternative A. The means and standard deviations of frozen blood (FB) and Milwaukee programs with transfusion review (TR) and 28-day life (28) are:

$$m_{FB} = \$24.20; \quad S_{FB \text{ vs. TR or } 28} = \$8.51;$$

$$m_{28} = \$6.98 + \$24.08\ H\ (+ \$1.00 \text{ if } H < .7);$$

$$S_{28 \text{ vs. } FB} = (\$7.833 + \$44.289\ H + \$155.758\ H^2)^{1/2};$$

$$S_{28 \text{ vs. } TR} = (\$1.367 + \$6.734\ H + \$26.474\ H^2)^{1/2};$$

$$m_{TR} = \$8.14 + \$22.07\ H\ (+ \$1.00 \text{ if } H < .7);$$

$$S_{TR \text{ vs. } FB} = (\$7.356 + \$41.568\ H + \$141.889\ H^2)^{1/2};$$

$$S_{TR \text{ vs. } 28} = (\$.89 + \$4.013\ H + \$12.605\ H^2)^{1/2}.$$

Table D1 shows the means and standard deviations for values of H starting at 0.0 and increasing to 1.0 in increments of 0.1. Table D2 shows the bounding probabilities. Figures D and E were prepared using these values.

## D2. Analysis for Figure F

Preparation of this figure requires derivation of equations for the mean cost of the alternatives as a function of cost associated with death and hepatitis test effectiveness. Since the transfusion fee, cytomegolovirus cost and liquid processing costs are the same for all alternatives, they can be omitted as cost factors in this analysis. As an aid in deriving the mean cost equations, the following definitions are used:

H: % hepatitis test ineffectiveness;
CD: cost associated with death;
anu: average number of units per transfusion.

The unit cost of frozen blood is the sum of costs for outdating, special processing, and donor payment; and equals 1.75% (outdate rate) x

Table D1

| H | $m_{FB}$ | $S_{FB}$ | $m_{28}$ | $S_{28 \text{ vs. } FB}$ | $S_{28 \text{ vs. } TR}$ | $m_{TR}$ | $S_{TR \text{ vs. } FB}$ | $S_{TR \text{ vs. } 28}$ |
|---|---|---|---|---|---|---|---|---|
| 0 | $24.20 | $8.51 | $ 7.980 | $ 2.80 | $1.17 | $ 8.140 | $ 2.71 | $ .94 |
| .1 | 24.20 | 8.51 | 10.388 | 3.72 | 1.52 | 10.347 | 3.60 | 1.19 |
| .2 | 24.20 | 8.51 | 12.796 | 4.79 | 1.94 | 13.554 | 4.62 | 1.48 |
| .3 | 24.20 | 8.51 | 15.204 | 5.93 | 2.40 | 15.761 | 5.71 | 1.80 |
| .4 | 24.20 | 8.51 | 17.612 | 7.10 | 2.85 | 17.968 | 6.83 | 2.08 |
| .5 | 24.20 | 8.51 | 20.020 | 8.30 | 3.37 | 20.175 | 7.98 | 2.46 |
| .6 | 24.20 | 8.51 | 22.428 | 9.51 | 3.865 | 22.382 | 9.13 | 2.80 |
| .7 | 24.20 | 8.51 | 23.836 | 10.73 | 4.36 | 23.589 | 10.29 | 3.14 |
| .8 | 24.20 | 8.51 | 26.244 | 11.96 | 4.84 | 25.796 | 11.46 | 3.45 |
| .9 | 24.20 | 8.51 | 28.652 | 13.19 | 5.37 | 28.003 | 12.64 | 3.84 |
| 1.0 | 24.20 | 8.51 | 31.060 | 14.42 | 5.88 | 30.210 | 13.81 | 4.18 |

Table D2

| H | TR pref 28 | | FB pref TR or 28 | |
|---|---|---|---|---|
| | $P_{Normal}$ | $P_{Uniform}$ | $P_{Normal}$ | $P_{Uniform}$ |
| 0 | .220 | .236[J] | .005 | .020[J] |
| .1 | .310 | .321[J] | .068 | .071[J] |
| .2 | .378 | .387[L] | .116 | .138[J] |
| .3 | .427 | .433[L] | .188 | .212[J] |
| .4 | .461 | .464[L] | .273 | .288[J] |
| .5 | .485 | .487[L] | .359 | .367[J] |
| .6 | .504[M] | .503[K] | .441 | .443[J] |
| .7 | .518[M] | .516[K] | .482 | .483[L] |
| .8 | .530[M] | .527[K] | .544[M] | .540[K] |
| .9 | .539[M] | .535[K] | .599[M] | .587[K] |
| 1.0 | .547[M] | .542[K] | .644[M] | .626[K] |

J: Computed Using Equation (16b)
K: Computed as 1-P(R) Using Equation (16c)
L: Computed Using Equation (16e)
M: Computed as 1-P(R)

$37.60 (processing cost)/98.25% transfused + $22.50 increased processing cost for frozen blood + 12.8% of donors paid x $8 av donor payment/98.25% transfused or $24.20.

The unit cost of either Milwaukee control alternative (MCP) includes expectation of costs of hepatitis, hemolytic reaction, febrile reaction, and program operation. These amount to: (1/anu) [H x (.75% hep incidence rate) x (28 days of hosp for hep x $110 per day + 90% recover x $750 convalescence + 10% die x CD) + .04% hemolytic reaction x $3000 treatment + .04% hemolytic reaction x 25% die x CD + .01% febrile death x CD] + 2.5% of units cause febrile reaction x 10% serious x 1 day of hosp for serious febrile x $110 per day + $1.50 for program operation = (1/anu) [H (28.16 + .00075 CD) + 1.20 + .0002 CD] + 1.78.

When MCP is coupled with transfusion review, costs of outdating shortage and review total: 6% outdate x $16.60 processing fee/94% transfused + 1% shortage x 1.75 days of hosp x $110 per day x 1.35/anu + $35.00 per review x (5% of units/anu) reviewed. For this alternative, anu = 3.385 and the mean cost equation is 4.45 + 8.32 H + .000059 CD + .00022 CD x H. The cost increases by $1.00 above 30% HAA effectiveness.

When MCP is coupled with 28-day life, costs of outdating and shortage total: 3% outdate x $16.60 processing fee/97% transfused + .3% shortage x 1.75 days of hosp x $110 per day x 1.35/anu. For this alternative, anu = 3.1 and the cost equation is 2.92 + 9.08 H + .000065 CD + .00024 CD x H. The cost increases by $1.00 above 30% HAA effectiveness.

Figure F is prepared by calculating which alternative has the lowest cost among these three. Thus MCP with transfusion review is preferred to frozen blood when 18.75 (+ 1.00 if H < .7) > 8.32 H + .000059 CD + .00022 CD x H, and is preferred to MCP with 28-day life when 1.53 < .76 H + .000006 CD + .00002 CD x H. Table D3 shows the values where equality obtains in these relations.

Table D3

| H | CD for FB Preferred to MCP with TR (Thousands of $) | CD for MCP with TR Preferred to MCP with 28 (Thousands of $) |
|---|---|---|
| 0 | 41 | 30 |
| .1 | 48 | 35 |
| .2 | 56 | 42 |
| .3 | 65 | 50 |
| .4 | 72 | 60 |
| .5 | 86 | 72 |
| .6 | 105 | 88 |
| .7 | 130 | 108 |
| .8 | 166 | 138 |
| .9 | 221 | 182 |
| 1.0 | 318 | 255 |

☆ U. S. GOVERNMENT PRINTING OFFICE : 1973--542-648/30

FORM NBS-114A (1-71)

| U.S. DEPT. OF COMM. BIBLIOGRAPHIC DATA SHEET | 1. PUBLICATION OR REPORT NO. NBS TN-777 | 2. Gov't Accession No. | 3. Recipient's Accession No. |
|---|---|---|---|

4. TITLE AND SUBTITLE

Cost Analysis of Blood Banking Alternatives

5. Publication Date: September 1973

6. Performing Organization Code

7. AUTHOR(S)

Ted Miller, Marge King, John Flannagan, Ernst Nilsson, Bob Lemieux

8. Performing Organization

9. PERFORMING ORGANIZATION NAME AND ADDRESS

NATIONAL BUREAU OF STANDARDS
DEPARTMENT OF COMMERCE
WASHINGTON, D.C. 20234

10. Project/Task/Work Unit No.: 4314473

11. Contract/Grant No.

12. Sponsoring Organization Name and Address

Office of the Assistant Secretary
for Planning and Evaluation
Department of Health, Education, and Welfare
Room 5526, HEW North Building, Washington, D.C. 20201

13. Type of Report & Period Covered: Final 3/72 - 8/72

14. Sponsoring Agency Code

15. SUPPLEMENTARY NOTES

16. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.)

This report provides a description of the current blood banking system and of the collection and derivation of quantitative information concerning system operation and blood cost. A reasonably accurate but somewhat incomplete profile of practices, attitudes, and likely costs of present and alternative systems has been developed. Among the topics presented are: 1) a discussion of the blood collection process including statistics on present use and future needs; 2) information relating to donor motivation, attitudes and incentives; 3) a brief summary of demonstration programs in the U.S. and national blood programs in other countries which provides some insight concerning means for improving blood quality and availability; 4) a description of blood processing, storage and distribution procedures; 5) narrative and statistical information relating to blood utilization practices; 6) discussions of post transfusion reactions and frozen blood programs; 7) a discussion of current governmental and professional standards, regulations and controls which influence many, but not all, concerns involved in blood collection and processing.

This information serves as the basis for the selection of alternatives analyzed in a cost effectiveness analysis of eight apparently viable alternatives to the current system. Because of the possible variation which might be ascribed to many of the parameters used as a basis for costing alternatives, the sensitivity analysis is crucial in the comparison of alternatives.

17. KEY WORDS (Alphabetical order, separated by semicolons)

Blood banks; blood utilization statistics; cost benefit analysis; donor profiles; peer review; regulatory activities; sensitivity analysis

18. AVAILABILITY STATEMENT

[X] UNLIMITED.

[ ] FOR OFFICIAL DISTRIBUTION. DO NOT RELEASE TO NTIS.

| 19. SECURITY CLASS (THIS REPORT) | 21. NO. OF PAGES |
|---|---|
| UNCLASSIFIED | 121 |
| 20. SECURITY CLASS (THIS PAGE) | 22. Price |
| UNCLASSIFIED | $1.35 |

USCOMM-DC 66244-P71

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