TOPICS IN BLOOD BANKING

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Preface

Within the past few years, many important developments have occurred in blood banking. Far-reaching social questions have been raised about paid versus voluntary blood donation and the gift relationship. Broader federal controls have been instituted, and more may be on the way.

New methods for extending the shelf life and improving the oxygen-delivering capacity of liquid stored blood have been devised. Cryopreservation, once confined to the specialty blood bank, is now a practical reality. Autologous transfusion, both elective and intraoperative, is being used more widely.

Searching questions have been asked about bovine albumin and other diagnostic reagents. An International Working Party is considering criteria for the standardization of antiglobulin sera. The importance of the hepatitis B antigen has been recognized, and numerous methods of detection have been proposed and evaluated. New knowledge about the red cell membrane and its relation to blood grouping has accumulated.

Blood component therapy has come into its own. It is a reasonable expectation that in the future packed red blood cells will be used in at least 80 percent of transfusions. Platelet transfusions are commonplace. Even granulocyte transfusions are feasible. The use of cryoprecipitate and other factor VIII concentrates has revolutionized the management of hemophilia. The efficacy of Rh immune globulin has been established, and its use has been extended to Rh incompatible transfusions.

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Recognition of the importance of the HL-A antigens has stimulated the demand for leukocyte-poor blood.

Attitudes toward exchange transfusions have changed, and in modified form they are being used more frequently than heretofore in adults.

It is the purpose of this book to summarize and review for technologists the developments in these areas, as well as to cover some subjects, such as blood bank inspection programs, safety regulations, and communication, that have not been fully considered elsewhere. Most of the chapters should be of interest to medical students and physicians as well as to technologists.

Although some methodology is presented, technical detail easily found in other publications has been omitted.

One of the great pleasures encountered in writing this book was the generous response of those whom I consulted for advice: Doctors Lewellys Barker, Gary Becker, Ernest Beutler, Thomas Boggs, Joseph Bove, C. P. Engelfriet, Frank Gardner, Robert Graw, Eleanor Griffith, Charles Huggins, Angelyn Konugres, Harold Meryman, Lyndall Molthan, Frank Oski, William Pollack, Fred Rothstein, Paul Schmidt, Fred Stratton, Harold Wurzel, and Chester Zmijewski. I am also indebted to Miss Mary Eichman, Mr. Walter Haesler, Mrs. Delia Plegge, Mr. Robert Scheno, and Miss Jean Thomas for help and encouragement. However, any shortcomings or inaccuracies in this book are my responsibility.

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Washington, D.C.

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Blood Bank Organization

In the past, blood banking has not been recognized as an independent medical specialty, and most hospital blood banks have existed as an arm of another department, usually medicine or surgery.

Recently, blood banks have acquired more stature and greater autonomy. At the same time, they are being subjected to increased external controls, especially at state and national levels. These controls call for improved blood bank organization and practice.

One guide to blood bank organization is a review of the standards imposed by inspection programs.

INSPECTION PROGRAMS

There are currently in the United States two nationwide blood bank inspection programs. One is conducted by the American Association of Blood Banks (AABB) and the other by the Food and Drug Administration (FDA), Public Health Service, Department of Health, Education, and Welfare. Although there undoubtedly will be cooperation between the two agencies, their programs are independent.

The American Association of Blood Banks Program

The program of the AABB is a voluntary activity among institutional members of the Association. The inspectors are primarily interested in blood banking, and they are experts in the field. In the past, it has been customary for their visits to be

formally scheduled and for the blood bank undergoing inspection to receive an advance copy of the inspection report form. This form currently is being revised. The proposed new version consists of fourteen sections, of which eleven deal directly with technical matters. These sections are worth a brief review, because they indicate not only the scope and thoroughness of the inspection, but also what is expected of a good blood bank.

I. PERSONNEL, QUARTERS, AND EQUIPMENT. Questions in this section deal with:

1. Availability in the blood bank of an up-to-date copy of *Standards for Blood Banks and Transfusion Services* issued by the AABB, an acceptable technical manual, and a general manual of operating procedures.
2. Number and proficiency of personnel, who are expected to be thoroughly trained in blood group serology and the principles of blood banking.
3. Cleanliness, equipment, and extent of the assigned space, including the reception area, examining room, phlebotomy area, laboratory facilities, and storage space for blood and blood components, supplies and equipment, and records.

II. DONOR SELECTION. This section includes numerous detailed questions concerning the medical history and the physical examination. Attention also is paid to the retention of proper records, including the review of records to detect donors previously found to be positive for hepatitis B antigen (HBAg) or associated with a reported case of hepatitis. Donor identification is stressed. The questionnaire is designed to determine whether an adequately trained supervisor is in charge, whether interviewers are qualified, and whether a licensed physician is present or available for consultation during donor selection. Inquiry is also made as to the availability of a manual outlining donor requirements, together with a map or list of areas considered endemic for malaria.

III. COLLECTION OF BLOOD. Questions are aimed at establishing that:

1. Blood donation is adequately supervised, with a licensed physician available for consultation.
2. A manual is available and the personnel are familiar with recommended procedures.
3. Materials are properly sterilized, labeled, stored, and handled.
4. The phlebotomy site is correctly prepared.
5. The technique of blood collection is acceptable.
6. The unit of blood and the pilot tubes are correctly identified and refrigerated.
7. Drugs and equipment for prevention and treatment of donor reactions are available, adequate, and in date.
8. Therapeutic bleedings (including therapeutic plasmapheresis) are under appropriate medical authorization, both as to their collection and their use for patient transfusion.

IV. IDENTIFICATION OF DONOR BLOOD. The inspector is required to report as to whether the ABO and Rh groups are correctly determined and whether diagnostic

reagents are in date and meet United States Public Health Service (USPHS) standards. He also reports on whether donor sera are tested for unexpected antibodies and, when indicated, for lytic anti-A and/or anti-B. Attention is paid to the method of testing for syphilis and of recording and reporting the results. Similar attention is given to tests for HBAg, together with safety precautions. There are also questions about the handling of donor samples, about laboratory records, and about labels.

V. Quality Control of Serologic Testing. This includes questions concerning:

1. Proficiency tests of personnel.
2. Selection and calibration of equipment.
3. Periodic testing of diagnostic reagents, including reagent red cells.
4. Recording the results of the above procedures.
5. Identification (by initials or signatures) of personnel who have performed or recorded serologic procedures.

VI. Storage and Transportation. The questions in this section are aimed at determining that:

1. Refrigerators are adequate in number and capacity.
2. Refrigerators are clean, contain no extraneous materials and are properly labeled.
3. The temperature is uniformly maintained, with appropriate sensors.
4. There is an alarm system that is activated when the temperature is either too high or too low, transmits a signal to personnel who will respond intelligently, and has a separate power supply.
5. Emergency power is provided for refrigerators.

There are questions concerning the retesting of blood received from other establishments and also about the inspection of stored blood daily, and immediately before issue, for color, appearance, and expiration date.

Attention is paid to the conditions under which blood is returned to the blood bank for reissue.

If the bank ships blood, the shipping containers must be inspected to be sure they are designed so that liquid blood or components will be kept between 1° C and 10° C, that frozen components will not thaw, and that platelet preparations will be maintained at temperatures that will preserve their function.

There are also questions concerning the safe disposal of unused donor bloods and blood components.

VII. The Recipient. Many of the questions in this section are similar to those in Section IV. In addition, there are questions about the conditions under which blood is dispensed in emergencies. There are also detailed questions about compatibility testing and cross-matching, about precautions taken if the blood is warmed before transfusion, and about filters for whole blood or blood components. The inspector also reports on whether the addition of medication to the blood before transfusion is prohibited.

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VIII. PREPARATION OF BLOOD COMPONENTS. The inspector is required to report on whether the personnel have been instructed in acceptable procedures, whether adequate and suitable equipment is available, and whether labels conform to standards. In addition, there are detailed questions concerning the preparation of the following components: red blood cells, frozen red blood cells, leukocyte-poor red blood cells, single donor plasma, single donor plasma fresh frozen, single donor cryoprecipitate, platelet concentrates, platelet-rich plasma, and modified whole blood; that is, blood reconstituted by returning the plasma to the red cells after removal of cryoprecipitate or platelets.

IX. PLASMAPHERESIS. There are many detailed questions in this section to insure that plasmapheresis is carried out safely and ethically, under medical supervision. If donors are immunized to stimulate antibody production, detailed information is requested, including questions concerning peer group review of the immunization and hyperimmunization programs and compliance with World Health Organization recommendations.

X. STORAGE AND ISSUE OF BLOOD COMPONENTS. This section is concerned with single donor plasma, single donor plasma fresh frozen, single donor cryoprecipitate, and platelet concentrates. The inspector is asked to report on blood bank practices concerning maintenance of correct storage temperatures, compatibility testing, the use of appropriate recipient sets, and the observance of safe expiration dates.

XI. TRANSFUSION REACTIONS AND COMPLICATIONS. A checklist is provided for a report on whether transfusion reactions are reported promptly and investigated adequately.

For a number of years, I actively participated in the AABB's inspection program and found that although blood banks vary considerably, there are certain areas in which deficiencies are most likely to occur. Many blood banks are forced to operate without adequate space and particularly without an adequate storage area. Technologists usually are highly motivated and adequately trained, but it is hard to have a licensed physician available for consultations. Many blood banks are completely ignorant of how to ship blood and blood components, and therefore, they may find it difficult to evaluate the shipments they receive. Above all, the record keeping tends to be poor. Records may be incomplete and unsigned, and labels—especially of blood components—may be inadequate.

The Federal Program

Until recently, federal inspection was limited to licensed establishments shipping blood in interstate commerce. However, effective 3 April 1973, it became mandatory for all "owners or operators of establishments that engage in the collection, manufacturing, preparation, propagation, compounding, or processing of human blood or blood products" to register with the Food and Drug Administration. The regulation affects a wide variety of establishments. For example, a laboratory that merely cross-matches blood in conjunction with transfusion, even though it does not collect or process blood, must register. Or, to illustrate further, registration is also required

of establishments that manufacture plasma by plasmapheresis, even though the plasma so obtained may be used only for unlicensed laboratory control reagents.

Legally, the above action is based on the definition of "drug" in the Federal Food, Drug, and Cosmetic Act, which states that "The term 'drug' means (A) articles recognized in the official United States Pharmacopeia . . .; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. . . ." It is the purpose of the action to encourage uniform practices in blood banks throughout the Nation, and to raise the level of such practices so that American consumers will have "sufficient quantities of high quality, safe human blood and blood products." It is also hoped that the program will provide "accurate and up-to-date information concerning the amount of blood collected in this country, the number and location of collection facilities . . . the volume of blood components that is transfused annually." Registration involves the annual submission of a form,* and it is expected that following an initial inspection, biennial inspections will be carried out.

A distinction should be made between registration and licensure. Registration is not a prelude to licensing, and registration does not permit the shipping of blood or blood products in interstate commerce. Licensed blood banks commonly undergo annual, rather than biennial, inspections.

A technical guide for registered blood banks is currently in preparation, but has not been completed. In the meantime, the best written, comprehensive guides to good blood bank practice are the following:

Code of Federal Regulations, Title 21, Part 273.
Manual of Tests for Syphilis, Public Health Service Publication No. 411 (Revised January, 1969), U. S. Government Printing Office, Washington, D. C. 20402.
Technical Methods and Procedures.
Standards for Blood Banks and Transfusion Services.

Publications 3 and 4 are obtainable from the American Association of Blood Banks, 1828 L Street, NW, Washington, D. C. 20034.† There is a charge for these manuals. The *Standards* is now in its sixth edition.

Inspectors for the FDA program are specially trained, having completed the Advanced Course for Drug Inspectors: Intrastate Blood Banks. Inspectors' guidelines for the evaluation of intrastate blood banks include the following general subjects:

I. DONOR SUITABILITY.
II. BLOOD COLLECTION.
III. TESTING THE BLOOD.
IV. GENERAL REQUIREMENTS. These include manufacturing responsibility, periodic check on sterile technique for open systems, the final container, reissue of blood, and issue prior to determination of test results.

* Obtained from the Bureau of Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

† Also from 30 North Michigan Avenue, Chicago, Illinois 60602.

V. LABELING.
VI. SHIPPING CONTAINERS.
VII. RECORDS.
VIII. OTHER BLOOD PRODUCTS. These include red blood cells, heparinized whole blood, single donor plasma, cryoprecipitated anti-hemophilic factor (AHF), and modified whole blood.
IX. TRANSFUSION SERVICES. Questions concerning emergency transfusions, compatibility tests, the handling of adverse reactions, and blood component therapy are included.

For some blood bank workers, the mandatory, unscheduled inspections of representatives of the FDA are likely to be stressful. The following suggestions may help:

1. Take a positive, constructive attitude toward the inspection. Deficiencies must be found and corrected, but the basic philosophy of the inspection program is to find out what is being done in the blood bank and why. A constructive attitude can lead to a useful exchange of information between the inspector and the blood bank worker.
2. Be sure that communication is open and accurate. Inspectors visit many establishments in diverse sections of the United States. The terminology used in one sector may be quite different from that used in another. One must be sure that a common language is spoken.
3. Be sure that copies of federal regulations are at hand and that the personnel are familiar with these regulations, together with any other procedural manuals used by the blood bank.
4. Keep accurate, clear, concurrent records. The inspector should be able to follow each step in the operation, and the records should speak for themselves. These records should be indelible, and they should be signed. Perfect records are not expected; in fact, perfect records raise the suspicion that either someone is cheating or data are being transferred. For the most part, transferred records are not fully informative, and they carry the danger of clerical error.

   Federal inspectors are often criticized for their emphasis on records. This attitude on their part can be defended. The inspection necessarily must take only a short time and is conducted only once every two years. In the meantime, blood bank personnel and practices are likely to change. Records must be used as the best reflection as to what has gone on in the period since the previous inspection.
5. Do not allow the inspection to interfere with necessary patient care. The inspectors realize that usually the blood bank is busy and that they must accomplish the inspection without imposing any threat to the patient. They try to be flexible and to observe much without question. They should not be criticized for just standing and watching the blood bank operation.
6. Do not allow the inspection program to interfere with legitimate research. It is not the intent of the program to stifle ethical, well-conceived investigation.

7. Remember that advisory opinions are a part of the mission. There is no formal advisory program, but inspectors and other members of the agency can be helpful when questions arise.
8. Do not conduct any last-minute operations that hopefully will put the blood bank in a good light. Such efforts ignore the purpose of the program and are embarrassingly apparent to any inspector with a modicum of experience.

Federal inspectors whom I have interviewed are unanimous in stating that the chief deficiencies they find in blood banks involve record keeping.

SAFETY MEASURES

The finding of a high incidence of hepatitis among nurses in dialysis units and sporadic outbreaks of hepatitis among laboratory personnel have prompted stricter blood bank safety precautions. These precautions are for the protection of the staff; the hazard of infecting the stored blood is trivial. Crucial requirements in assuring blood bank safety are supervision, planning, and the establishment of practical routines.

Supervision

Safety regulations are most likely to be observed when specific persons are directly charged with the responsibility and authority to interpret and enforce them. Safety officers should not assume a punitive attitude; their function is to educate and protect their fellow workers and to serve as liaison persons between the laboratory and the housekeeping and medical staffs. In addition to surveillance of the laboratory and indoctrination of new personnel, they should record and report all laboratory accidents.

Planning

In planning blood banks, a flow chart of the operations should be drawn up and kept clearly in mind, and provisions should be made for the following:

A Reception Area. Casual visitors have no place in laboratories. Messengers with blood specimens should not be exposed to the working area, and technologists should not be interrupted to receive specimens.

A Phlebotomy Area. Some transfusion centers no longer bleed donors, but if they do, a special area should be set aside for this purpose, together with an examining room and a separate canteen. Eating, smoking, and drinking should not be allowed in the phlebotomy area. Extraneous items of equipment should be excluded. The presence of centrifuges, refrigerators, and fans is undesirable, because they tend to create aerosols. If the donor room looks out upon an area where there is a great deal of activity and dust, windows should be kept closed. If windows are ever opened, they should be screened. There should be no dust catchers, such as exposed pipes, over the donor beds or chairs. The walls should be easily cleaned; peeling or flaking paint or plaster should not be tolerated.

A SHIPPING AREA. Blood shipments and blood collected on mobile units should be received, packed, or unpacked in a separate area. Portable refrigerators, cartons, and other packing materials should not be allowed in the laboratory working area.

A LABORATORY AREA. As already indicated, the laboratory should be a separate unit.

A UTILITY AREA. Pipette washers and dryers, pumps, ovens, autoclaves, utility sinks, and other utility equipment should be located outside the laboratory proper.

STORAGE AREAS. A blood bank that does double duty as a storeroom simply cannot be kept clean. Storage facilities should be ample and readily accessible. There should be separate accommodations for blood or blood components, for supplies and equipment, and for records.

SPECIAL HOUSING FOR CENTRIFUGES AND REFRIGERATORS. It already has been mentioned that this equipment can create potentially dangerous aerosols. This is particularly likely with centrifuges, especially if containers are overfilled or if breakage occurs. Technologists need small instruments in the laboratory, but large centrifuges can be placed in an area with an exhaust fan; some laboratories use fume hoods for this purpose.

The question of housing refrigerators is a difficult one. For some blood banks, a cold room is the answer. Refrigerator compressors are heat makers as well as a potential source of aerosols. Refrigerators must be accessible to the working area, but they are best housed outside of it.

QUARTERS FOR HBAg TESTING. This ideally is a separate, lockable room which is used only for this purpose. However, a simple cubicle screened from other laboratory activities is acceptable, provided it is clearly separate from the donor area. It may be equipped not only for HBAg testing but also for performing routine serologic tests on high-risk specimens. It should have a separate refrigerator for opened reagents and for specimens or units of blood positive for HBAg. Leakproof waste receptacles and easy access to hand-washing facilities also should be provided.

QUARTERS FOR AUTOMATED BLOOD GROUPING. With current automated equipment for blood grouping, dozens of specimens may be open at one time, and the readout consists of a long roll of filter paper stained with red cells, plasma, and blood grouping reagents. Personnel should be protected from the hazards inherent in the operation, and the equipment should be protected from the uninformed but curious passerby. This room also can be used for instruments for automated antibody detection.

STERILIZABLE OR ONE-USE DISPOSABLE EQUIPMENT. In purchasing equipment and supplies, the question of general cleanliness, sterilization, and disposability should be prominent. Equipment and supplies should be adequate in amount so that dangerous improvisations will be precluded.

TELEPHONES. It is doubtful that a telephone should be allowed in the laboratory area, but some experts believe that if one is permitted, it should be the type of instrument that is answered with a pushbutton and provided with a speaker.

HAND-WASHING FACILITIES. Utility sinks should not be used for this purpose. The wash basin should be equipped with an automatic soap dispenser and with taps that are operable with the elbows or with a foot treadle.

PROVISION FOR PERSONNEL COMFORT. Technologists are not allowed to smoke or eat in work areas or to place food in blood bank refrigerators. They also are required to wear protective clothing. It is unrealistic to expect strict compliance with these rules if their personal comfort and needs are disregarded. Suitable and readily accessible locker, lunchroom, and lounge facilities should be provided. Moreover, the psychologic needs of the personnel must be remembered. Subdivision of the work area may help to cut down cross infection. It also tends to give the technologist a sense of ownership, privacy, and increased responsibility. The introduction of extraneous decorative items such as house plants is to be discouraged, but working areas should be made attractive through the use of cheerful, washable paints and materials.

Routine Housekeeping Procedures

In formulating housekeeping procedures, it is helpful to know something about the hepatitis virus (HBV). HBAg, which may represent the outer coat of HBV, is rich in protein and also contains lipid. It is resistant to most chemicals. It is not destroyed by ether at 4° C overnight, by 1 percent sodium deoxycholate, or by 1 percent Tween 80-ether for one hour. It is resistant to freeze-thawing and to heating at 56° C for several hours or at 60° C for one hour. It is destroyed by autoclaving and by incineration. Therefore, the following routines are recommended:

LABORATORY SURFACES. Floors should be smooth; carpeting is not permissible. They should be dry mopped and wet mopped daily. Workbenches should be cleaned at least at the end of each work shift. Plastic-coated coverings for bench tops can be purchased and may be helpful. For routine cleaning, various chemicals have been recommended. A good one is hypochlorite solution in a concentration of 1000 ppm of free chlorine. (Practically, this means Clorox diluted 1:20). If blood or other body fluids are spilled on floors or workbenches, it is recommended that a concentration of 10,000 ppm free chlorine be used. An alternative is 10 percent aqueous formaldehyde. The chemical should be allowed time to react with the spilled material after it is applied.

Periodic cleaning of walls and shelving is necessary. The walls should be smooth and washable. They should not be plastered with notices, instructions, and charts hung up at random. If these must be posted, a special place can be provided, or they can be enclosed in washable transparent covers. In cleaning shelving, the under, as well as the upper, surfaces must be remembered. Objects above eye level may be overlooked, for example, lighting fixtures. They must be cleaned regularly, preferably when the laboratory work load is light.

METAL SURFACES. Provided they are movable and can withstand heat, metal surfaces may be sterilized by autoclaving. Otherwise, a chemical agent must be used. The choice of chemical agent is empirical and is based on experience with other viruses. Formalin, glutaraldehyde, or hypochlorite are possibilities.

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