Guidelines for quality assurance programmes for BLOOD TRANSFUSION SERVICES

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Chapter 1
Introduction

Quality assurance is concerned with every aspect of transfusion practice and applies to all activities of a blood transfusion service, from identification of potential donors, collection of blood, and preparation of blood products, to ensuring the best, safest, and most appropriate use of blood and blood products.

A system of quality assurance should be implemented in all transfusion services and blood banks. The minimum requirement for such a system is a manual of standard operating procedures and internal quality controls for all tests. More elaborate quality assurance procedures should be developed wherever possible, in accordance with local and national policy.

People are the most valuable and important resource of any blood transfusion service. This is especially true of the voluntary, non-remunerated donors, but also of the staff of the service, on whom effective quality assurance depends. Achievement and maintenance of quality within a transfusion service demand that staff working at all levels of the service show commitment to the common goal of quality. This, in turn, may require a significant change in attitude for many people. All personnel should be conscious of the implications of the work they are involved in, and aware of the importance of applied quality assurance. Only then will it be possible to guarantee the maximum safety of all procedures—for donors, for recipients, and for the staff themselves.

It is the responsibility of management to ensure that all available human resources are used in the most efficient, cost-effective, and ethical manner. Personnel must understand the relevance of their particular duties to the work of the transfusion service, and appreciate the contribution they can

make to quality by their attitudes to those duties. Failure to maintain quality is usually the result of human error, carelessness, or lack of understanding, rather than technological problems.

It is essential that the application of quality assurance principles has a demonstrable impact on an institution's operations and practices. Collection of information, as an integral part of quality assurance, must be purposeful and relevant to policy, and its influence on procedures must be apparent to the staff members involved. Without these elements, the time and effort expended on quality assurance are wasted and staff morale will decline; conversely, appreciable improvements in performance will enhance morale.

Ultimate responsibility for implementing and maintaining quality assurance procedures rests with the designated quality assurance officer. This officer should be accountable directly to the director of the transfusion service (see Chapter 9), rather than reporting through an intermediary. He or she will submit reports at regular intervals, offering interpretations where appropriate, and recommending remedial measures when necessary. Sound management practice dictates that any remedial action be implemented only after discussion with the head of the department concerned. The quality assurance officer should be advised of any new or revised procedures, so that their effectiveness may be monitored and evaluated.

Unless the fundamental importance of quality assurance is fully appreciated, the costs of its application may be a cause for concern. It is therefore important that a quality assurance programme can demonstrate its cost-effectiveness in terms of savings and benefits that offset the original expense of implementation. From the outset, however, it is essential that all procedures are carefully costed.

This manual provides essential information for the establishment of both basic and more complex quality assurance measures. It is directed to those who work in blood transfusion services and hospital blood banks. In blood centres, the principal concerns will be donor recruitment and selection, collection and laboratory screening of blood, and production, storage, and distribution of blood products. Some centres may be committed to large-scale production of components, using methods such as freeze-drying. In hospital blood banks, the emphasis is more likely to be on compatibility testing and monitoring of the clinical efficacy of blood and blood products.

These two kinds of establishment represent two parts of a continuous process that begins with donor recruitment and concludes with the beneficial effects of blood or its components for a recipient. Some establishments combine the functions of both blood transfusion centre and hospital blood bank. Certain parts of this manual may be of less interest to those with no direct involvement in one area or the other, but it is important that a total view of quality assurance be taken.

Chapter 2
Documentation

INTRODUCTION

Documentation is an integral part of a quality assurance programme. It constitutes the **history** and **evidence** relating to all elements that contribute to the quality of products and services. Standard operating procedures (SOPs) are the most significant initial element of documentation.

The purpose of documentation is:

- to provide evidence that specified standards have been applied—to donor selection, to the collection, processing, and issue of blood, and to the clinical utilization of blood and its products—by making available a durable record that allows the history of each donation to be traced and the participation of all personnel involved to be demonstrated;
- to define the quality policy;
- to minimize the potential for error that is inherent in oral communication;
- to instruct personnel in the details of all methods and procedures;
- to ensure that consistency and reliability procedures are applied—to donor selection, to the collection, processing, and
- to provide an audit trail (see page 38) and facilitate the investigation and resolution of alleged product defects, adverse reactions, or complaints (whether made by donors, staff, or transfusion recipients).

It is important that documents are designed to be simple and easy to follow. It is also essential for potential users to be involved in their design.

RECORDS AND DOCUMENTS

Blood collection and transfusion services should develop and maintain records and documents that demonstrate the achievement of specified quality standards and the effective operation of the quality system. These records and documents are used in connection with a wide variety of procedures and aspects of preparation. The use of such a system in the daily work helps to ensure that each staff member is consistent in performing the various tasks laid down in SOPs. Records and documents help to identify possible sources of error or of unwanted variability in performance.

A typical record form is shown in Fig. 1, and may be adapted for local use. The following are further examples of useful records and documents:

Receipts for material delivered, combined with set procedures for completing them, which ensure conformity to specified requirements. These receipts will help in the selection of sources of supply. The nature and extent of control exercised depend on the type of material and the demonstrated reliability of suppliers, as illustrated by supporting documents.

Fig. 1. Example of a typical record form

Title:	Preparation of a platelet concentrate
Number:	123, revision b
Reason for revision:	Modification of centrifugation time to improve yield with a new plastic bag

Date for completion/implementation:

30 December 1991

Approval: . . . . . .

Director of Component Preparation *Date*

Authorization: . . . . . .

Director of Blood Centre *Date*

Information on receipts, installation, commissioning, validations, and schedules of preventive maintenance and repair of equipment used in collection, processing, production, control, and issue of blood and blood products.

Product recall records. Every blood transfusion service should establish a procedure for the recall of a product known or suspected to be defective or hazardous, in accordance with specific requirements determined by national policy and good manufacturing practices.

Documents for notification of adverse reactions. All adverse effects following transfusion of blood or blood products should be recorded and regularly evaluated. This forms an essential basis for retrospective evaluation of quality assurance of blood collection and transfusion services. Prompt recording and reporting of delayed adverse effects, such as the transmission of infectious agents, should be emphasized.

Processing and testing records. Labelling of blood and blood products requires uniformity in the performance of various work procedures. This will reinforce other measures taken to ensure that products reach the required standards and, therefore, have reproducible clinical effects. Documents and records specific for each production step are used for recording activities as they are carried out. This helps to improve consistency and to identify unwanted variability of products or errors in procedures.

Shipment documents. The transfer of blood and blood products should always be recorded. Identification of errors should be followed by investigation and evaluation of transfer procedures, and remedial action to prevent recurrence.

Compatibility-testing records. Careful compatibility testing of donor and recipient blood is essential before blood or specific blood products are issued and requires completion of a detailed set of records and documents. Compatibility testing should be performed only on written request. Proper identification of the recipient is essential.

Internal and external audit documents (see Chapter 8). Performing an audit requires access to records and documents within the institution concerned. It is useful to monitor quality assurance periodically, but at unpredictable intervals, by examining selected sets of parameters or indicators of

performance of products and/or services. Documents provide information on the performance being evaluated.

Computer records. The increasing use of computers to register, store, and update records and documents makes it essential to consider certain technical aspects of the technology, particularly the stability of recorded material. National policy regarding restricted and recorded access to, and use of, computer registers of critical data should be established and followed. Before computer programmes are used for the recording and documenting of actions within blood transfusion services, there should be validation of performance of services and products in accordance with national regulations.

Memoranda and communications, for example from supervisors and directors to staff, doctors, and hospitals, and between agencies, form a special group of documents and records. They should be archived appropriately, since they constitute important historical evidence of actions undertaken, and should be accessible and available to the staff concerned. Document review should be recorded and initialled.

Clinical records. The patient's clinical record is the final document in the quality chain, in which are recorded the identity and volume of the product administered, the date, time, and duration of administration, and the patient's vital signs, including temperature, pulse, respiration, and blood pressure.

PROCESS OF DOCUMENTATION

The process of documentation is at least as important as the documents themselves. The ability to trace, prospectively and retrospectively, all steps in all procedures, dating from the collection of the blood, is necessary for monitoring the production of components.

The important aspects of the process are described below.

1. Staff performing the following important production steps must be identifiable: collection of blood or components, preparation, testing, determination of suitability for use, delivery, transfusion, and follow-up. Identification is by an accessible list of signatures or of initials of the personnel who actually performed the important steps. If the identity

of personnel responsible for critical steps is unknown, assignment of responsibility and improvement in practice are virtually impossible.

2. Recording of what has been carried out is the next most important aspect of the documentation process. SOPs must be followed, and there must be evidence of this. At specific points in each procedure, staff must record the satisfactory completion of critical steps. There must be mechanisms to identify deletions, omissions, or modifications, and the person responsible for such changes (see item 5 below).
3. For most procedures in blood banking and transfusion medicine, timing is important for good results. Thus, the dates and times of arrival of samples, products, or reagents, and of critical preparative stages should be carefully noted. Documentation of timing will assist in identifying whether procedures have been adequately followed. To ensure optimum performance and to minimize risks, all samples, reagents, and blood components should be used before their expiry dates. Inappropriate timing or incorrect dating can adversely affect the usefulness of components and thus increase the risks to recipients.
4. In general, strict adherence to SOPs will result in reliable, reproducible performance and therefore in optimal quality of the service or product. Nevertheless, problems may still occur; all such problems, and steps taken to resolve them, must be recorded. The influence of these problems on the quality of the service or product can then be assessed for immediate and future action.
5. Changes or exceptions to, and deviations from, defined procedures are occasionally warranted. To minimize any adverse effects on the quality, efficacy, or safety of the service or product, including wastage of material and effort, any such modifications must be noted and be traceable to particular personnel; reasons for non-conformance to the SOP must also be noted. Approval for the modification is required from the responsible person, whose identity should be noted. No errors, changes, or deviations should be erased or obliterated from the record: rather, any changes should be identifiable, e.g. endorsed in ink with the initials or name of the responsible person, who can be traced.
6. Each member of staff is responsible to some higher authority, and there should be clear evidence of the chain of command. The record must indicate the person in charge of

the section in which a particular procedure is carried out. The individual responsible for the quality of all steps of each procedure should be named.

STANDARD OPERATING PROCEDURES

Every process that affects the quality of the products and services of the blood transfusion service should be the subject of a written SOP (see also Chapter 3). The SOP is the primary document that describes and validates the particular process or task, and is therefore an essential element of quality assurance. Each SOP should be current, dated, and periodically reviewed; it should be modified when necessary, formally authorized, and placed in the working manual. Superseded SOPs should be archived for a specified period of time before being discarded.

Important elements of documentation relating to compliance with SOPs are:

- selection of appropriate, qualified personnel, and recording of their training and fitness for specific tasks;
- records of validation of reagents and material, and calibration, maintenance, and cleaning of equipment;
- records of planned monitoring of work, which should include consideration of staff safety and environmental aspects;
- records of the transport and storage of reagents, samples, blood, and blood products.

DOCUMENTATION OF QUALITY CONTROL

All procedures should be performed in accordance with SOPs, and then documented for quality control purposes. Documentation should include records of sampling (test frequency, number of samples tested), review of results, control measurements, specifications, limits testing, and trend analysis. Problems regarding non-conformance with expectations, and subsequent actions taken must be recorded. All records and documents should comply with national regulations, as well as with medical requirements, and should be maintained in archives for a specified number of years (according to national policy). The qualifications, authority, and lines of responsibility

of the person responsible for the quality assurance programme must be defined.

SPECIFICATION OF DOCUMENTS

Records and documents released for use should conform to a standardized format, modified for local use. A typical example is shown in Fig. 1. The following specific items should normally be included:

— title
— reference and revision number
— reason for revision
— date for completion and approval
— authorization signature(s) and dates
— titles of approved signatures
— unique codes and approved terminology.

All changes to a document in use must be made in writing, dated, and signed by a designated person. Documents are reissued after the necessary alterations have been made. This must be followed by prompt removal of obsolete copies from all points of issue or use.

Chapter 3
Standard operating procedures manual

INTRODUCTION

The manual of standard operating procedures (SOPs) is a document covering all procedures undertaken in the blood transfusion service, including record-keeping, validation, and documentation. Such a document is essential for the following reasons:

- To facilitate management. The deviations and errors that are likely if procedures are described and explained orally to staff are avoided. More objective evaluation of performance of staff and the service as a whole, and of the blood products is possible, and measures of quality can be implemented more readily.
- To establish standards and references for procedures that permit critical review, and to provide the basis for generating documents and records.
- To help to reduce adverse effects on performance in the event of staff changes or absences.
- To simplify and standardize the training of new personnel.
- To assist in resolving contentious issues in cases of litigation.

Written SOPs should be available at the work-station where each task is performed. They will vary in format and content according to need. Specific examples of SOPs will cover such areas as:

— donor selection and phlebotomy
— testing and processing of blood and blood components
— training of staff

— health and safety
— use and maintenance of equipment.

Administrative instructions are also desirable (e.g. clear indication of the person to whom any anomalies or errors should be reported).

PREPARATION OF STANDARD OPERATING PROCEDURES

Responsibility for the final preparation and approval of each SOP rests with the head of the relevant section of the transfusion service, but all staff affected by a particular SOP should contribute to its development. Staff should also be encouraged to propose any necessary modifications and updating. The SOP must be authorized by the medical director.

CONTENT

All SOPs should be cross-referenced for ease of use; that is, each SOP should refer to appropriate sections of every other one to which it is related. Each must include the following elements:

- A clear, brief title and a unique document identity number.
- A brief description of the purpose of the procedure and the scientific principles involved.
- Specifications for staff allowed to perform the procedure, including their qualifications, experience, and training.
- Details of equipment and reagents required to perform the procedure and their location in the laboratory; formulae of the reagents and, when necessary, methods of reagent preparation should be included.
- Operating instructions and methods of use recommended by manufacturers of equipment and diagnostic reagents.
- Copies of any forms or labels to be completed or used during the procedure.
- Health and safety notes describing any hazards involved in the performance of the procedure, with appropriate reference to other SOPs, such as those concerned with the handling of pathological specimens or waste disposal.

- Precise details of the procedure, clearly described in numbered steps that logically follow the working sequence and that include any quality control procedures involved.
- The procedure for the interpretation and reporting of results, and the action to be taken if problems occur.

IMPLEMENTATION

The mere existence of SOPs does not ensure quality. All SOPs must be available to, familiar to, and understood by the relevant staff, and used as specified. All staff members involved in each procedure should sign the SOP to indicate that they have read and understood it.

Any alterations to the SOP should be authorized by the medical director. Staff involved in the particular procedure must sign the revised SOP to indicate that they have noted and understood the alterations. All SOPs should be periodically reviewed. Rigorous validation of modified SOPs must be undertaken before alterations are implemented.

Master copies of all SOPs should be retained in the office of the director of the transfusion service. All copies should be signed in ink. Unauthorized copies should be discarded.

A flow-diagram representing the work of each section facilitates implementation of SOPs.

Chapter 4
Donor selection

INTRODUCTION

Despite the availability of sensitive and specific tests for the microbial screening of blood, meticulous attention to the selection of healthy, voluntary donors continues to be the most crucial element in ensuring the safety of blood products. The establishment of well coordinated programmes for the recruitment of voluntary, unpaid blood donors is therefore fundamental to the success of any blood transfusion service. Moreover, the retention of established donors should provide safer—and less costly—blood and blood products and therefore an assurance of quality.

Guidelines for the selection of suitable donors are intended to fulfil two major purposes:

- to protect potential transfusion *recipients* from the dangers of disease transmission;
- to minimize risks to the health of blood *donors.*

Thus, donor selection becomes an important aspect of quality assurance.

CRITERIA FOR DONOR ACCEPTANCE

Detailed criteria for the selection of voluntary blood donors must be determined as part of national policy, and will depend upon factors such as:

- the availability of voluntary donors;

- epidemiological data regarding the local prevalence of, or immunity to, various transmissible infections;
- demographic data such as age distribution, indicators of average weight, haemoglobin concentration;
- the general quality of the typical local diet.

Information of this type assists in the development of criteria such as the following:

- permissible frequency of donation and maximum annual number of donations;
- volume of blood collected;
- lower and upper age limits for donors;
- medical and, where applicable, donation history;
- the extent of medical assessment necessary (i.e. physical examination and other investigations, in addition to temperature, pulse, blood pressure, and weight);
- reasons for exclusion from donation.

These criteria should form the basis of a detailed donor manual, which is available to all staff members involved in blood collection, and which serves as a policy, procedural, and training document.

The quality of donor selection may be improved by the introduction of effective programmes for self-exclusion by potential donors who may have been at risk for infections transmissible through blood transfusion. Questions regarding eligibility for donation should be easily understandable, and privacy and confidentiality must be ensured at blood collection sessions to elicit truthful responses from potential donors.

STAFF TRAINING

Successful application of donor selection criteria depends largely upon the quality of the blood collection staff. Training and continuing education must be provided for staff specifically selected for their alertness, motivation, welcoming attitude, and proficiency—attributes that will have a direct bearing upon the recruitment, selection, and retention of safe donors.

Management should provide blood collection staff with recognition, attractive career prospects, and clear lines of responsibility. This will help to maintain morale and foster a

sense of fulfilment among staff, and contribute to operational quality and success.

DONOR RETENTION

While recruitment of new, low-risk donors is of the utmost importance in achieving national self-sufficiency in blood and blood products, the retention of known and established donors is safer and ultimately more cost-effective.

Retention of donors will be more successful in programmes where donors are warmly welcomed and receive ready responses to their queries, reliable advice, prompt post-donation information (e.g. blood-grouping and test results), expressions of thanks, and suitable small awards or tokens of appreciation.

INDICATORS OF EFFECTIVE DONOR SELECTION AND RETENTION

Calculation of the ratio of new to established donors is a useful indicator of the success of donor retention. Any adverse trend in the ratio that cannot be attributed merely to increased recruitment of new donors should prompt investigation and remedial action. Increased collections from repeat donors, with new donors recruited to replace those who are no longer available, can be monitored as part of a quality assurance programme, and the number of donations by each donor should be recorded.

It is also valuable to monitor the success of self-exclusion and donor selection by observing the incidence of abnormal results of microbiological screening tests. The value of these observations may be enhanced by correlating significant trends with geographical location, population groups, or sex of the donors.

The frequency of collection of blood units that subsequently have to be discarded, e.g. because of lack of information regarding infections or other hazards, should be monitored. This is an indicator of effective donor selection and rejection, which can reduce costs and waste.

Adverse events following transfusion, e.g. viral hepatitis or HIV infection, should be reported and recorded. Although these provide a gross assessment of the success of donor

selection, it must be remembered that only clinically recognized cases may be reported. Investigation in a "look-back" programme of cases with *suspected* transfusion-transmitted disease, including implicated donors, will therefore improve the selection of safe donors.

Calculation of the number of excess units collected (and thus wasted) and monitoring instances of insufficient collections (resulting in unfilled orders and cancelled surgical procedures) can also indicate the quality of donor recruitment and collection.

Donor cancellations, lost or lapsed donors, numbers of recruited donors compared with those actually bled, and the proportion of acceptable donors actually providing blood and components should also be monitored to help in assessing the quality of donor selection and blood collection.

Chapter 5
Blood collection

QUALITY OF COLLECTION

While many aspects of blood collection that are pertinent to quality assurance are subjective and difficult to measure, they are nevertheless important, and any means of measurement should be evaluated. Donor satisfaction can be actively surveyed, but complaints and spontaneous positive feedback should also be recorded, as a basis for improving the programme and for taking corrective action when necessary.

Several means exist for objectively measuring and recording the quality of blood collection. The absolute number, or frequency, of untoward occurrences should be noted. Objective quality measurement should include observation of

- adverse donor reactions (e.g. haematomas, vasovagal attacks);
- unsuccessful bleeds (insufficient collection for use);
- observation of free haemoglobin content of the units (e.g. pink or red plasma);
- microbial contamination of the units;
- over- and under-collection of blood units (resulting in the anticoagulant:blood ratio being too small or too large);
- units for which the collection time is prolonged (e.g. more than 9 minutes).

BLOOD COLLECTION ENVIRONMENT

Collection premises

Collection premises should be well lit and provide sufficient space. They should be clean, and waste disposal should be

properly organized. The arrangement of donor beds and all essential equipment should allow safe and efficient operation, and should provide donors with a measure of privacy.

Personnel

Besides having the required basic training and necessary qualifications, staff should have a pleasant and welcoming attitude, and should receive adequate practical training in the specific tasks associated with blood collection. It is especially important that blood collection staff be made aware of their vital role in obtaining sufficient blood and in maintaining quality for the benefit of the eventual transfusion recipients.

The number of staff should be sufficient to provide for management of adverse reactions of blood donors. A ratio of 4–6 donors to one staff member is often used, but there is considerable variation according to circumstances. Overwork of inadequately staffed teams may lead to fatigue, poor morale, errors, and an inappropriate and unacceptable attitude to donors.

Equipment

The selection, calibration, and cleaning of equipment such as scales and sphygmomanometers must be undertaken according to standard operating procedures. Needles and tubing should be reused only if the manufacturers indicate that this is allowable, and must then be properly decontaminated and sterilized after each use. Where financial resources are sufficient, disposable material (used only once) is preferable. Plastic bags are preferable to glass bottles for blood collection. Temperatures of blood units must be monitored and recorded during storage and transport.

Staff attitude

The blood donation process should take place in an atmosphere of personal warmth and professional efficiency. Allowing adequate time for each phase of the blood collection process and ensuring that donors are comfortable and properly cared for throughout will enhance the experience and increase the chances of retaining acceptable donors.

COMPONENT COLLECTION BY APHERESIS

Almost all aspects of quality assurance that apply to donors of whole blood apply equally to donors from whom blood components are collected by apheresis, either manually or by machine. In general, the criteria for selecting apheresis donors are the same as those for selecting donors of whole blood. However, there are certain additional and unique aspects of apheresis that can affect the safety of the process and the quality of the resulting components. Accurate donor identification is even more important for apheresis procedures than for whole blood donation, because part of the blood collected by apheresis is returned to the donor after removal of a specific component, e.g. platelets or plasma. Equipment must be thoroughly cleaned between donations. Software that comes in contact with donor blood must be sterile and preferably disposable; any non-disposable items must be thoroughly decontaminated and sterilized after each use.

Apheresis procedures are more complex than those of whole blood collection. Staff must receive specialized training, must demonstrate proficiency in the procedure before being certified as apheresis specialists, and must be more closely supervised than those who collect whole blood. The familiarity of apheresis staff with all aspects of the SOPs must be documented to minimize risks to both donors and recipients. The specific apheresis SOP should include details such as the following:

- extracorporeal volume in relation to donor's blood volume;
- additional laboratory tests required;
- allowable frequency of donations;
- special risks inherent in apheresis, and remedial actions that may be necessary;
- access to medical care.

Quality assurance of apheresis also involves the periodic collection and evaluation of information on subjective aspects of donors' experiences. Monitoring should aim to maximize donor satisfaction and to minimize complaints.

The quality of apheresis should be regularly and objectively evaluated. For example, the number and frequency of haematomas, citrate toxicity, unsuccessful procedures, and unwanted apheresis components should periodically be counted

and compared. After a member of the apheresis staff has been trained, the numbers of adverse events in which he or she is involved should be noted; subsequent performance should show improvement, which can be quantified by comparison with the initial findings. Goals for the proportion of successful procedures (or the lowest attainable proportion of unsuccessful procedures) can be established on the basis of the collective experience of all apheresis operators. Individual and departmental success rates can then be compared with expectations.

Special collections of apheresis components may occasionally be required from people who would not normally qualify as acceptable donors, e.g. people with hepatitis B surface antigen whose plasma is needed for reagent use or vaccine development. In such cases, additional criteria for apheresis should be established to minimize risks to staff, to other donors, and to the individuals undergoing the procedure.

Failures in apheresis equipment or materials should always be recorded. If there is evidence of repeated malfunctioning, the supplier should be notified and is then responsible for warning other users of potential risks relating to use of the particular product(s). In addition, it is essential that hazardous or defective equipment and materials are reported to the proper authorities.

AUTOLOGOUS COLLECTIONS: SPECIAL CONSIDERATIONS

Patients may occasionally serve as their own donors of blood or blood components (autologous collections). Autologous units of blood and components are collected, for example, before elective surgery, or in the immediate perioperative period. Procedures established for the collection, storage, and transfusion of such material must be even more stringent than those for homologous donations and must be followed meticulously. The indications and parameters for preoperative autologous collection may differ for blood centres compared with hospital services: the criteria for donation may be more stringent in the former than in the latter.

The two principal situations in which autologous collections are practical and appropriate, and should be encouraged, are described below.

- For patients who have clinically significant antibodies against cellular blood elements and who may be their own most available source of compatible blood and components.
- Alloimmunization through prior transfusions or pregnancy may result in multiple antibodies or an antibody to a high-frequency antigen in the blood of most homologous donors. In such cases, the availability of compatible blood or components from other sources may be extremely limited.
- In elective surgery with the probability of significant blood loss. If blood is to be set aside for such elective surgery patients, it is appropriate to collect autologous donations preoperatively.

Autologous transfusion does not carry any risk of alloimmunization or transmission of infectious diseases. Nevertheless, the indications for transfusion of autologous units should be the same as those for homologous units because other complications are not eliminated. For example, they may cause congestive heart failure if transfused in excess of the amount of surgical blood loss. In additon, autologous units may be given to the wrong patient, particularly if the correct procedures are not followed meticulously.

Some of the criteria for selection of autologous donors may be more liberal than those established for selection of homologous donors, unless the unused autologous units are to be made available for other patients, in which case *all* homologous donor selection criteria should be met. For example, lower haemoglobin levels for autologous donations, such as 100 g/litre, or 0.30 for erythrocyte volume fraction, are usually permitted, as are more frequent collections, e.g. up to five units over a 5-week period. The increased frequency of donation, however, makes iron therapy essential for the autologous donor.

The major contraindications to autologous donations are:

- bacteraemia (or the strong possibility of bacteraemia), which could result in the proliferation of organisms in blood units despite refrigeration;
- severe cardiovascular disease, e.g. marked aortic stenosis or left mainstem coronary artery disease, which could result in undue risk during the phlebotomy.

Additional local or national requirements may be established for the acceptability of potential donors of autologous collections.

The testing of autologous donations should comply with the requirements of national blood policy. Additionally, special, easily differentiated labelling must be applied to autologous units of blood, so that inadvertent transfusion to a patient other than the intended recipient is prevented. This is particularly critical if testing has not been performed, or if there are abnormal test results that prevent the use of the unit for other patients.

Many of the same measures of quality assurance that are applicable to homologous donation can be used to evaluate autologous collections. Patients' satisfaction or dissatisfaction with the phlebotomy experiences can be recorded and evaluated. Adverse reactions such as haematomas and vasovagal attacks, unsuccessful bleeds, and microbial contamination of units are quantifiable parameters that provide measures of quality for autologous collections.

Immediate, preoperative, isovolaemic haemodilution and perioperative blood salvage are additional means of autologous blood collection for transfusions. Mechanisms should be established to maximize the safety and efficacy of such methods and of reinfusion of the blood. For example, proper patient identification is imperative, storage times should be restricted, and blood potentially contaminated with bacteria or tumour cells should not be infused except in extraordinary circumstances or in an emergency.

Chapter 6
Laboratory aspects

INTRODUCTION

The purpose of laboratory testing is to ensure that blood and blood components meet specified standards of safety and efficacy. Two types of laboratory test are carried out within a quality assurance programme: **quality control** and **quality monitoring**.

Quality control refers to the sampling, specifications, and testing of blood components. Results of tests determine whether or not components are released. Quality monitoring is the regular analysis of randomly selected components and ensures that certain specifications are being met to an acceptable degree; it should also identify any problems that develop within the quality programme.

GENERAL CONSIDERATIONS

Accommodation and staffing in the laboratory should be such as to facilitate work of a high quality. Each laboratory section should be responsible for the quality of its own testing, documentation, and reporting of results. Comprehensive laboratory work records and reports should be stored safely and be easily available for reference for a defined period.

Before blood or blood components are released from quarantine, all mandatory laboratory tests must be completed. The results must be documented to show that individual donations have been tested and conform to the standards laid down by national or local policy, and the additional labelling indicating this must be affixed to the donations. All tests

should be conducted in accordance with national policy or, otherwise, according to well validated and documented techniques.

Only those reagents that meet nationally agreed specifications should be used, and only in techniques for which they are specifically recommended, validated, and quality controlled.

Specimens of blood and blood components received in the laboratory for testing should be:

- clearly labelled and documented;
- collected at the same time as the donations and in such a way as to prevent errors of identity;
- collected in such a way that the sterility of the donation system is not compromised;
- collected, transported, and stored in a manner that does not interfere with their suitability for testing.

SPECIFIC REQUIREMENTS

ABO blood grouping

The ABO blood group of each donation of blood should be determined, and the blood and blood components labelled

Table 1. Quality control of ABO grouping

Control test	Criteria of acceptability	Frequency
ABO reagent red cells (A_1 and B)		
Appearance	No visible haemolysis or turbidity in supernatant	Each series of tests
Specificity and sensitivity	Clear-cut appropriate reactions with anti-A, anti-B (and anti-A,B if used)	
ABO blood-grouping antibodies (anti-A, anti-B and anti-A,B if used)		
Appearance	No visible haemolysis, precipitate, particles, or gel formation	Each series of tests
Specificity and sensitivity	Clear-cut appropriate reactions with positive and negative control red cells	

appropriately. It should be determined by examination of both red cells and serum or plasma of the donor (Table 1).

A blood sample from a donor whose ABO group is unknown, e.g. a first-time donor, should be tested twice and the ABO blood group accepted only when the results are in agreement. When possible, the second test should be performed by a different worker and by a different test method. For a donor whose ABO blood group is known, a single set of tests will suffice, provided that results of these tests agree with the ABO blood group previously recorded for that donor.

If manufacturers of reagents recommend additional controls, these should be used.

Rh(D) grouping

Where national policy requires it, the Rh(D) group of each donation of blood should be determined, and the blood and blood components labelled appropriately. The red cells of the donor should be tested against an Rh(D) grouping reagent by the manufacturer's recommended method (Table 2). The donation should be regarded as Rh(D)-positive if a positive reaction is obtained.

A negative reaction should be confirmed by testing with a further example of anti-D reagent. Donations giving clearly negative reactions with both anti-D reagents should be labelled Rh(D)-negative.

If reactions with the anti-D grouping reagents are different, the tests should be repeated; if the results are still ambiguous, the donation should be regarded as Rh(D)-positive.

Table 2. Quality control of Rh(D) blood group reagents

Control test	Criteria of acceptability	Frequency
Appearance	No visible haemolysis, precipitate, particles, or gel formation	Each series of tests
Specificity and sensitivity	Clear-cut appropriate reactions with known positive and negative control red cells	

Red cell antibody screen

Where national policy requires it, screening for the presence of clinically significant red cell antibodies should be carried out by examination of the serum or plasma of the donor, using recognized techniques. The testing method should be validated and quality controlled using a selection of weak red cell antibodies. Positive screening test results must be confirmed and antibodies must be identified.

Transmissible diseases

Hepatitis B virus

Each unit of blood or plasma collected should be tested for hepatitis B surface antigen (HBsAg) by a sensitive method, such as radioimmunoassay, enzyme-linked immunosorbent assay, or reverse passive haemagglutination. Only validated methods should be used: unvalidated modifications of commercial assays must not be used.

No material from a donation should be released from quarantine unless the donation has been tested and found to be HBsAg-negative. In addition to the test kit manufacturer's validation controls, acceptable specificity and sensitivity of the testing method should be demonstrated by other quality control measures, where appropriate or available (Table 3). No set of results should be considered acceptable unless the manufacturer's, and the national or local, quality control tests have satisfactorily met the defined criteria.

Table 3. Quality control of HBsAg testing

Control test	Criteria of acceptability	Frequency
Specificity	Clear-cut appropriate reactions with a panel of known HBsAg-negative and weakly positive sera	Each batch of test kits
Sensitivity	If appropriate, clear-cut positive reaction with at least one sample of a serum whose HBsAg concentration is equal to that specified for the national or local minimum level of sensitivity	Each series of tests

Human immunodeficiency virus

Where the national or local policy requires screening for human immunodeficiency virus (HIV) antibodies, their presence should be determined by examination of the serum or plasma from the donation, using an appropriate technique. Only validated methods should be used: unvalidated modifications of commercial assays must not be used.

Screening of pooled serum samples may be considered in areas where low prevalence of HIV is adequately documented, provided that the following requirements are met:

- before use, the test system should be validated locally by the laboratory;[1]
- the test system must be one in which the dilution of serum does not compromise sensitivity;
- stringent measures must be taken to ensure reliable sample identification;
- the pool should not include more than five individual serum samples;
- changes in HIV prevalence rates should be closely monitored.

No material from a donation should be released from quarantine unless the donation has been tested and found to be negative for HIV antibody.

In addition to the test kit manufacturer's validation controls, acceptable specificity and sensitivity of the testing method should be demonstrated by other quality control measures, where appropriate or available (Table 4). No set of results should be considered acceptable unless the manufacturer's, and the national or local, quality control tests have satisfactorily met the defined criteria.

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[1] *Operational characteristics of commercially available assays to detect antibodies to HIV-1 and/or HIV-2 in human sera. Report 4.* Geneva, World Health Organization, 1991 (unpublished WHO document GPA/RES/DIA/91.6, available on request from Global Programme on AIDS, World Health Organization, 1211 Geneva 27, Switzerland).
Global Programme on AIDS and Global Blood Safety Initiative: recommendations for testing HIV antibody on serum pools. *Weekly epidemiological record*, 1991, **44**: 326–327.

Table 4. Quality control of anti-HIV testing

Control test	Criteria of acceptability	Frequency
Specificity	Clear-cut appropriate reactions with a panel of known anti-HIV negative and weakly positive sera	Each batch of test kits
Sensitivity	If appropriate, clear-cut positive reaction with at least one sample of a serum whose anti-HIV concentration is equal to that specified for the national or local minimum level of sensitivity	Each series of tests

Syphilis

Where national or local policy requires it, each unit of blood or plasma collected should be screened for syphilis by a reliable method such as *Treponema pallidum* haemagglutination or the Venereal Disease Research Laboratory test. Only validated methods should be used: unvalidated modifications of commercial assays must not be used.

Depending on national or local policy, seropositive blood should be either discarded or kept for at least 72 hours at 2°C to 8°C before use. If the blood is used for the preparation of platelet concentrate, cryoprecipitate, or fresh plasma, the recipient should receive prophylactic therapy.

In addition to the test kit manufacturer's validation controls, acceptable specificity and sensitivity of the testing method should be demonstrated by other quality control measures taken in the laboratory (Table 5). No set of results should be

Table 5. Quality control of syphilis testing

Control test	Criteria of acceptability	Frequency
Specificity	Clear-cut positive reactions with a panel of known negative, and weakly and strongly positive, sera	Each batch of test kits
Sensitivity	If appropriate, clear-cut and positive reaction with at least one sample of a serum whose antibody concentration is equal to that specified for the national or local minimum level of sensitivity	Each series of tests

considered acceptable unless the manufacturer's, and the national or local, quality control tests have satisfactorily met the defined criteria.

Other infectious agents

Where national or local policy requires screening for other transfusion-transmissible infectious agents (e.g. cytomegalovirus, human T lymphotropic virus, hepatitis C virus, *Plasmodium*, trypanosomes), quality control measures should include tests to determine specificity and sensitivity using nationally or locally accepted criteria. Only validated methods should be used: unvalidated modifications of commercial assays must not be used.

EQUIPMENT

Monitoring the performance of laboratory equipment is an essential part of the quality assurance programme. Equipment specifications should meet technical, electrical, and health and safety standards.

Each piece of equipment should be assessed when it is first installed, and after any repairs or adjustments that may alter the way in which it functions. In addition, the performance of laboratory equipment must be monitored at predetermined intervals; the results should be recorded and analysed. Adjustments should be made if necessary. A programme of preventive maintenance, including cleaning, replacement of parts, and recalibration is mandatory, and should be documented. Where necessary, this programme should be planned in conjunction with maintenance engineers or with outside contract specialists, in order to minimize disruption of services.

CONSUMABLES

Consumable supplies should be selected and evaluated for their suitability, reliability, and cost-effectiveness compared with agreed specifications. Tests should be introduced to monitor their performance. Restricted choice or availability should not compromise quality.

STORAGE AND TRANSPORT OF BLOOD AND BLOOD COMPONENTS

Quality control of storage and transport begins with the collection of the unit of blood (or blood components) and ends with its transfusion (or disposal if unused). Storage and transport conditions must meet national or local specifications and should be such that the quality and integrity of components are maintained. Quality monitoring, especially of temperatures, should be defined in SOPs, and records must be maintained to document the history of the blood or blood component.

There should be a designated storage area for quarantine of blood and blood components which are still being tested, so that the material cannot be released for issue until it has met all the quality standards and this has been documented.

Chapter 7
Blood components

INTRODUCTION

Quality monitoring is the testing of randomly selected components to ensure that they reliably achieve certain specific standards. Analysis of the pattern of test results and detection of irregularities allow the quality monitoring programme to identify any deficiencies in the production of components. Quality monitoring is acceptable only after a process has been fully validated and introduced into routine use. It is important to note that validation will normally require data from more extensive tests than are listed in these specifications.

Where possible, 1% of components should be committed for testing. If scarcity of a particular component makes this impossible, a representative aliquot may be obtained aseptically from the main unit. Owing to the biological variability of blood components, quality is acceptable if at least 75% of test results fall within the specification limits.

The staff who perform the tests should not be involved in the production process; people responsible for analysis of results should have been trained specially for this purpose, and should maintain skills for accurate assessment of the results.

The results of quality monitoring should be reported to the processing staff to make them aware of their responsibility for producing components of acceptable quality.

QUALITY MONITORING TESTS

Volume

The volume of blood drawn should be measured to protect the donor and to control the proportion of blood to anticoagulant

Table 6. Scheme for quality monitoring of blood and blood components

Blood component	Test	Specification
Whole blood	Volume	Stated volume ±10%
Red cell concentrate	Packed cell volume (PCV)	0.60±0.1
Red cell concentrate, supplemented (e g. SAGM[a])	PCV	0.6±0.1
Red cell concentrate, leukocyte-depleted, filtered	Residual leukocytes Erythrocyte loss	$<1.2\times10^9$ per unit <15%
Red cell concentrate, washed	Erythrocyte loss	<20%
Platelet concentrate	pH Volume Platelet count Leukocyte count Erythrocyte count	6.0–7.4 50–60 ml $>55\times10^9$ per unit $<0.12\times10^9$ per unit $<1.2\times10^9$ per unit
Fresh frozen plasma (fresh and at expiry)	Volume Factor VIII coagulation activity (if applicable)	Stated volume ±10% >0.5 IU/ml
Single donor plasma	Volume	Stated volume±10%
Cryoprecipitate (fresh and at expiry)	Volume Factor VIII coagulation activity	10–25 ml >70 IU/unit
Plasma for fractionation	Specifications will be set by fractionation centres	

[a] Sodium chloride, adenine, glucose, mannitol.

in whole blood. This may be done by application of a formula involving weight and relative density:

$$\text{volume (ml)} = \frac{\text{weight of component} - \text{weight of pack(s) including anticoagulant (g)}}{\text{relative density of component}}$$

Accepted relative densities are:

whole blood 1.06
concentrated red cells 1.09
plasma or platelets 1.03.

pH

The pH of components should be measured at the expiry date, using a pH meter according to the manufacturer's instructions. Temperature affects pH, and all readings should therefore be taken with buffers and components at the storage temperature.

Packed cell volume

Packed cell volume may be determined using a micro-haematocrit centrifuge. Care should be taken to mix the sample thoroughly. The measuring equipment used should be standardized, and appropriate controls of time and speed of centrifugation should be carried out.

Factor VIII coagulation activity

If assays of factor VIII coagulation activity are required, they should be carried out by a laboratory that employs a recommended method on a regular basis. The method should be standardized using both national and local standards prepared from blood components likely to be tested.[1]

Total leukocytes, red cells, and platelet counts

The values for total leukocytes, red cells, and platelet counts should be determined using recognized methods. Counts are normally expressed as total cells per unit.

Sterility

An aseptic technique must be used for collection of blood, and asepsis must be maintained in the processing laboratory. Routine sterility testing on a limited number of components may be carried out to monitor asepsis and must form part of

[1] Reference material can be obtained from the National Institute for Biological Standards and Control, Potters Bar, Herts EN6 3QG, England. See *Biological substances: international standards and reference reagents 1990*. Geneva, World Health Organization, 1991.

any investigation of adverse transfusion reactions. Any new or modified method used in component preparation, particularly where an "open" system is involved, should be validated. When sterility testing is performed, it should be on samples from components in the final container and by methods that meet national or local specifications.

Defects in blood packs

At all stages in the handling of plastic blood packs, special attention should be paid to any defects that may occur, e.g. pinhole leaks. Such defects are more likely to be noticed in the processing laboratory when the packs are subjected to stress during centrifugation. All defects should be recorded and their causes identified; remedial steps should be taken to prevent recurrence. Defects that are not the result of maltreatment or mishandling should be immediately reported to the manufacturer. If any defect appears to be batch-related, all packs and components from the batch should be placed in quarantine for further investigation.

Macroscopic inspection

All blood and blood components should be inspected for abnormal appearance, e.g. haemolysis, before processing, before issue, and immediately before administration. An abnormal unit must be quarantined and the abnormality investigated by the transfusion centre. The result of the investigation must be documented and reported to the director of the centre and other relevant individuals in order to prevent repetition of a technical error, or to initiate medical investigation of the donor, if appropriate.

Adverse effects

All adverse effects of transfusion must be documented and notified to the transfusion centre. The likely causes of any adverse reaction must be thoroughly investigated, and findings should be communicated to the clinician who reported the incident. Other relevant individuals (as defined in local policy) should be informed, and where appropriate, immediate action

taken to prevent recurrences. All action taken must be documented.

Feedback

To ensure optimal efficacy of blood and blood components, it is important to encourage regular and frequent communication with clinicians who prescribe the products. Such dialogue is a valuable tool for monitoring quality and assessing the correlation of *in vivo* function with *in vitro* testing.

Chapter 8
Transfusion committees and audits

INTRODUCTION

The audit is a management tool for monitoring the quality assurance system. It constitutes a formal review of all factors involved in assuring quality of products or service. The audit may be either a quality audit or a medical audit.

QUALITY AUDIT

A well planned, comprehensive quality audit will cover each activity of a blood transfusion service and should also assess the manner in which the various components of the service relate to each other. It can also, however, be selective and specific, focusing on particular areas. The procedures may be internal or external.

Internal audit

Description

Internal audits may be carried out as:

- regular departmental or unit self-assessment procedures, using the mechanisms of peer review circles, whenever possible, in each activity area;
- periodic inspections by director, manager, or supervisor in charge.

All transfusion services should maintain relevant and cost-effective internal auditing system(s). Regular audits should be

carried out by senior staff members, and periodic spot-check audits should be carried out by the director.

Internal audit activity areas

An internal audit may comprise a review of several factors that can be dealt with singly or together, in one or several activity area(s). Selective aspects that may be considered suitable for internal audit in the different activity areas are the following:

- donor aspects, e.g. planning, deferrals, SOPs, interviews, screening, adverse reactions;
- production of blood components, e.g. process, control, documentation, efficiency of the system for tracing the blood or blood product from the donor to the patient;
- shortage of blood or components;
- inventory control;
- issue and shipping of blood and/or components;
- labelling;
- quality control testing, documentation, quarantine, and release mechanisms;
- preventive maintenance of equipment;
- personnel training;
- documentation of all processes.

External audit

Description

Document trails and product audits are often used for external audits.

The **document trail** looks at standard operating procedures, documentation systems, batch records, complaints files, reports and actions of transfusion committees and ad hoc committees, and remedial action files.

A **product audit** consists of selecting and tracking specific blood units or blood components that have been released for transfusion, and identifying unsuitable units or components used for transfusion. It includes tracing the pathway from donor to recipient (or from recipient back to donor).

Rationale

The AIDS pandemic has encouraged many countries to use external consultants to review their blood transfusion services

and systems. Although the review process is usually broad-based, involving among other things the organization of training workshops to address specific issues, this mechanism can be further developed, refined, and exploited to advantage.

Data derived from an external audit facilitate decision-making by management. Outside evaluation can correct any preconceived ideas about the status of the quality assurance systems, procedures, methods, communications, and training requirements. It can often identify discrepancies between what actually happens and what management thinks is happening, for instance by determining whether established policies have been implemented and are being followed.

External audits are especially useful in providing objective and unbiased assessment of the status (efficiency, safety) of the system and in identifying the need for appropriate corrective procedures, including training and retraining. The results of an external audit may be helpful in obtaining the resources needed to meet the requirements of the quality assurance policy or guidelines of the institution. An external audit also helps to encourage communication and dialogue within and between different departments or services.

Respect and mutual confidence between the auditor and those in the service being audited are highly desirable, if the audit is to be a rewarding and educational experience.

Essential elements

An external audit should be carried out by qualified and trained individuals, with the skills and tact essential for the task.

Professional standards and guidelines should be used for purposes of comparison—with established norms, with other systems, or within the same system over a period of time—and to assess improvements and deficiencies.

Appropriate indicators should be used which can be quantitatively appraised on checklists (see, for example, the Global Blood Safety Initiative questionnaire[1]).

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[1] WHO/Global Blood Safety Initiative. *Questionnaire to update data on blood transfusion services.* Geneva, World Health Organizationl 1991 (unpublished WHO document WHO/LBS/90.1, available on request from Health Laboratory Technology and Blood Safety, World Health Organization, 1211 Geneva 27, Switzerland).

Proper planning and preparation are essential to ensure the successful outcome of the audit.

MEDICAL AUDIT

Medical audit, carried out through a working group—which may be part of the transfusion committee—evaluates the actual use of blood transfusion for compliance with established local or national guidelines in order to promote optimal transfusion practice.

Transfusion committees are established primarily to review, define, and evaluate the use of blood and blood components, with the main aim of improving the quality of patient care. They may be constituted either as formal standing committees or as ad hoc committees for specific purposes. National or regional blood transfusion committees formulate the policy pertaining to a quality assurance programme and influence its proper implementation, including the rules and practices for all aspects of the transfusion service at the national or regional level. A hospital transfusion committee operates at the functional level of the transfusion service. It influences all areas of hospital services, the training of staff, and undergraduate and graduate teaching programmes related to the appropriate use of blood and sound transfusion practices. The committee also evaluates any adverse effects of the transfusion of blood or blood components.

Medical audit by the hospital transfusion committee

Composition

The hospital transfusion committee should include representatives from:

- major users of blood, e.g. obstetricians, paediatricians, surgeons, anaesthetists, internal medicine specialists, intensive care specialists, haematologists;
- the nursing staff;
- the medical administration;
- the provider group:
  - the medical director of the transfusion service (or representative), who should not be the chairman of the committee;

— the quality assurance manager or equivalent;
— a representative of the hospital blood bank.

Terms of reference

The hospital transfusion committee should:

- make recommendations for the collection of data and for the statistical reports of the transfusion service; review and analyse the data;
- establish and monitor appropriate recording procedures for all aspects of blood transfusion practice within the hospital;
- monitor the provision and use of blood and blood products and resolve any problems of supply and demand;
- audit blood usage in different disciplines and circumstances; the audit may be carried out routinely or as spot-checks.

  From the above, it would be possible to establish and maintain blood ordering schedules.

- investigate reports of adverse transfusion reactions, evaluate the circumstances and causes, and decide upon appropriate remedial actions and their implementation; this may involve several departments, as well as the hospital administration;
- review current practices with a view to their possible upgrading, and make recommendations if necessary;
- establish policies for transfusion practice that relate specifically to the hospital;
- assess the impact on staff attitudes, documentation requirements, and funding of activities arising from the deliberations of the committee;
- identify priority issues, e.g. number of units transfused in "emergencies" without testing for markers for transfusion-transmissible infectious agents and without validation procedures;
- promote the advantages of the logical, scientific approach of external scrutiny in the analysis of issues and problems.

Functions

The frequency of the committee's meetings must be decided and adhered to; all committee activities must be documented and reports disseminated.

The functions of the committee chairman should be identified. He or she should be responsible for implementation of policies within the hospital. However, enforcement is never easy among professional peers. Consensus based upon discussion and the consideration of sound evidence is more likely to be successful. When agreement is then documented, it acquires some force, because implementation of the policies will be monitored.

The Committee should define its approach to problems and deficiencies. A punitive or derogatory approach, for example, can generate resentment among staff, impede cooperation, and result in failure to bring about improvements.

Guidelines for the medical audit of patients' charts for data capture

The committee should:

- determine priority indicators that are considered useful for the assessment of quality;
- design forms specifically for indicators that capture data effectively; the forms should define the sources of the data, e.g. specific activity area(s) of the blood transfusion service, anaesthetists' notes, physicians' notes;
- ensure that two particular elements are included in every review, namely, the reason for transfusion and the effects of the transfusion.

Possible indicators

Ideally, all transfusion services should have the following information available for continuous monitoring of basic operational quality:

- the total number of units of blood or components transfused during a defined period;
- the number of patients transfused within that period compared with the total number of inpatients (it is preferable that each component be dealt with separately);
- the number of units of each component transfused per transfused patient;
- the ratio of whole blood used to red cell concentrate;
- the ratio of number of units transfused to number of units requested;

- the number of date-expired units or components;
- products used for no clearly indicated purpose;
- the number and type of transfusion reactions;
- workload and output for the various sections within the blood transfusion service;
- the number of units issued that were not cross-matched;
- the number of urgent requests compared with the number of routine requests;
- the number of unused units returned;
- the number of surgical operations cancelled because of a lack of blood;
- the number of late pre-operative requests, indicating ward or clinic, and identifying the surgeon who made the requests.

Database

Each activity area in each hospital and linked transfusion service should develop a database. The transfusion committee should decide which variables should be measured and how frequently the data should be collected and reviewed. Trends evaluated by periodic review of the database can help in quality assessment exercises.

The database can also be used by management to monitor and evaluate quality, not only within the hospital, but in all the services in the region. Some data may be considered critical and should therefore be continuously monitored. Once accurate statistics can be generated from the database, it will become possible to evaluate progress as well as to determine the effects of new policies or procedures.

Medical audit by national and regional committees

Committees at the national and regional level can analyse information from quality audits, medical audits, and databases from the operational levels, in order to make decisions and to formulate or change guidelines and policies pertaining to specific issues.

Securing political commitment at the national level can be effective in bringing about rapid changes of attitude concerning the need to establish well organized quality assurance programmes within a national blood transfusion service.

Chapter 9

Role of management in quality assurance

INTRODUCTION

Consistently high quality in a blood transfusion service must be seen as a collective objective, the attainment of which depends upon leadership. It is very much a team effort: commitment to quality is an empty gesture unless it is clearly impressed at *every* level of the service.

The broad nature of quality assurance demands an interaction between professional staff and all other personnel at a centre, and this is achieved only through careful planning, systematic implementation, and regular assessment. Management has a major role in confirming the completeness, relevance, and effectiveness of quality assurance, and can do this through monitoring and evaluation, participation in external quality assessment schemes, staff training, identifying errors and taking remedial actions to prevent recurrences, and appointment of a quality assurance officer.

MONITORING AND EVALUATION

Monitoring and evaluation can take various forms, the most useful of which are:

- *Quality control procedures*, which generate documents or records that can be examined and evaluated. These in-house retrospective checks yield valuable information regarding failure; for example, whether failures occur regularly or erratically, and in which activity areas. Such information

may sometimes indicate staffing and/or workload problems. Quality control problems are rarely the result of poor procedures, as these should be validated before implementation. Poor adherence to procedures, or use of poorly written procedures, however, can sometimes be identified through use of quality control.

- *Audit*, which provides a valuable way of assessing quality assurance (see Chapter 8).

EXTERNAL QUALITY ASSESSMENT SCHEMES

External quality assessment schemes, also termed external proficiency testing, or quality assurance/control programmes, serve a useful purpose, even in disciplines such as immunohaematology or transfusion medicine, where results are often subjective and/or are expressed qualitatively. For a transfusion laboratory to benefit from involvement in such a scheme, both the organizers and the participating laboratory should note certain important points.

Careful preparation of external quality assessment schemes is essential, with a specific, achievable aim for each survey. It must be possible to assess and compare the information obtained from participants in order to evaluate the methods—and any variations—in use. An action sheet must be returned to each participating laboratory, which requires acknowledgment of receipt of the individual and collective results by the director or laboratory manager. A commentary should also be sent, which emphasizes the educational value of participation in the scheme.

For the involvement of the participating laboratory to be of value, it is essential that the tests be done as part of the laboratory's routine work, carried out by the members of staff who would ordinarily be responsible, and not necessarily by the most senior and experienced personnel. Prompt response to the action sheet increases the educational value of the programme. Participating laboratories should be encouraged (when necessary) to discuss their performance, and ways of improving it, with the organizing laboratory. Ideally, there should be a mechanism for helping poor performers to resolve their problems.

It is possible for a laboratory team to establish a small, initially simple, cost-effective external quality assessment scheme for a country or region. The scheme should include

specimens that group positively or negatively for clinically important antigens or antibodies in specified test systems, and may include material for disease screening. An informative and simple variant is to include two identical specimens in a group of three or four, or dilutions of an atypical antibody. Efficient collation, communication, and follow-up are important for achieving success in the scheme.

TRAINING

The vast majority of quality failures are caused by human error, ignorance, or carelessness, and not by defective technology. Procedures are usually well documented and validated elsewhere before they are adopted by a transfusion service or centre, but validation of staff is often ignored. Thus, human factors are the most important variables in any procedure. For this reason, training of staff and evaluation of training are of particular importance. Training should be planned, relevant, and continuous. The training protocol should be constantly assessed and updated as required. Even where local training is formalized, all new staff members should be oriented to the workplace and revalidated.

IDENTIFICATION OF ERRORS AND REMEDIAL ACTION

It is as important to analyse and categorize errors as it is to detect them: without some understanding of how, when, or where an error occurred, the appropriate remedial action cannot be taken. The two major categories of error that occur are consequential and inconsequential (discrepancies). The former usually have more serious repercussions and may lead to litigation. The latter are often detectable during or just after completion of routine procedures and should be dealt with and corrected immediately.

The major sources of error are:

- *Clerical.* Many clerical errors have serious consequences. Training, monitoring, and retraining are necessary to reduce their occurrence. It is important to remember that clerical errors are not always due to lack of knowledge or skill, or to problems of attitude. They are often the results of illegibility of transcribed numbers, and, occasionally, of excessively

complicated procedures and reports. The possibilities of staff illiteracy or dyslexia may also have to be considered.

- *Organizational.* Organizational problems can be internal, or influenced by external factors. Staff members' personal difficulties and/or workload problems can lead to errors.
- *Technical.* Technical errors may be caused by staff or by deficiencies in reagents and/or equipment. Full investigation of a technical error is important: it will often reveal a breakdown in quality assurance measures.

Remedial action requires:

- investigation of the error;
- reassessment of staff, procedures, quality control, reagents and consumables, and equipment, and documentation of each of these;
- conclusions and recommendations;
- reports and action.

Whatever the cause, an error must be corrected as soon as possible.

THE QUALITY ASSURANCE OFFICER

The staff member in charge of quality assurance is of primary importance; he or she must have credibility, organizational abilities, and good communication skills. The position should preferably be full-time and carries responsibility for the following tasks:

- organization of all documents, including standard operating procedures, relating to quality assurance;
- establishment of recognized and referenced standards, in cooperation with the director of the transfusion service and other senior personnel;
- ensuring that the standards comply with national specifications (if any);
- review of quality controls and monitoring;
- initiation of investigation and remedial action when errors occur, in cooperation with the head of the section in question and the director of the service;
- ensuring that all staff and all new methods, reagents, equipment, and components are validated;
- reporting directly to the director of the transfusion service.

Annex
Definitions of terms

The terms defined in this annex are frequently encountered in the context of quality assurance programmes; many have been used elsewhere in this publication.

audit	A formal review within the quality assurance programme to identify problems and approaches to their resolution.
good manufacturing practice	All the elements in *established* practice that will collectively lead to final products or services consistently meeting expected specifications.
guidelines	Recommendations, as part of a quality assurance programme, that are not binding or compulsory but that embody optimal approaches and considerations.
internal quality control	Routine checkpoints, defined by standard operating procedures, that confirm the validity of a procedure every time it is carried out.
materiel	All components, materials, or other supplies that are to be incorporated or used in the testing or processing of products or services.
policy	The stated aims, objectives, and standards adopted by a transfusion service. These may be determined institutionally, locally, professionally, nationally, or internationally.

proficiency testing	An external assessment of the ability of staff to undertake a series of prescribed tests.
quality	The consistent, reliable performance of services or products in conformity with specified standards.
quality assurance	The creation and operation of standards, programmes, and effective management systems to ensure quality. Quality assurance is achieved by the application of good manufacturing practice.
quality control	That part of a quality assurance programme which consists of retrospective tests or measures that must be completed with satisfactory results before proceeding further in a given process, and which demonstrates compliance with certain defined limits and specifications.
quality monitoring	That part of quality assurance, concerned with maintenance and improvement of quality, that deals with the identification and use of indicators to detect variations from standards or specifications.
quarantine	In transfusion terms, quarantine is the status of blood and blood components, segregated from others, that await a decision on their suitability for processing or issue.
sensitivity	The limit of detectable, specific reactions using certain reagents or test systems.
specificity	The ability of a reagent or test system to react selectively. Ideally, it represents the absence of false-positive reactions.

standards	Criteria against which processes and products can be measured qualitatively and/or quantitatively.
validation	That part of a quality assurance programme that evaluates *in advance* the steps involved in operational procedures or product preparation to ensure quality, effectiveness, and reliability.

The safety and efficacy of the various activities of blood transfusion services can be guaranteed only by the systematic application of quality assurance measures. This manual provides information on all the essential elements of quality assurance programmes, whether these are established in small hospital blood banks or in transfusion centres dedicated to the large-scale production of blood components. Topics covered include donor selection, the collection, testing, storage, and transport of blood, and monitoring and control of laboratory and clerical procedures.

Throughout the manual, it is stressed that the cornerstones of quality assurance are the comprehensive documentation and rigid observance of standard operating procedures, and the commitment of all personnel to the common goal of quality. The success of quality assurance thus depends additionally on staff training and attitudes, on effective management, and on the demonstrable cost-effectiveness of programmes; these areas, too, are clearly and thoughtfully addressed.

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