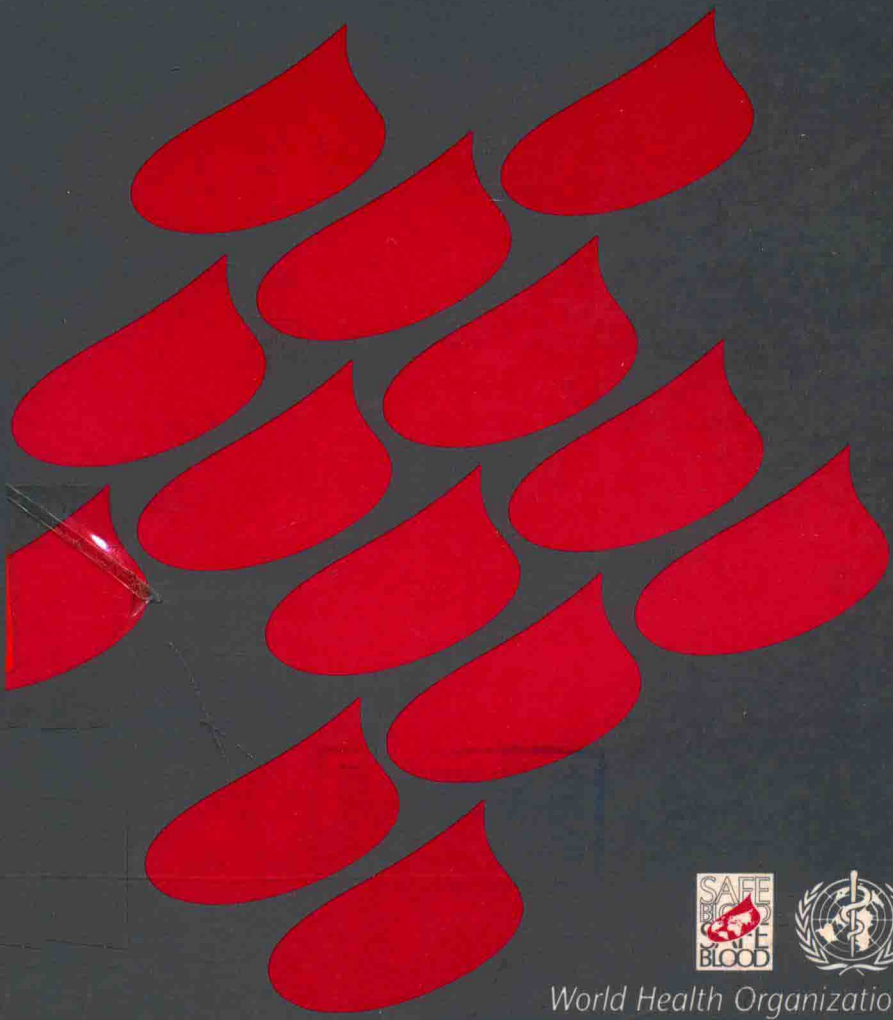
Guidelines for quality assurance programmes for BLOOD TRANSFUSION SERVICES



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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.