K9

NBTS
recom. selec & Care of donors
AABB - recommended standards.

H E A L T H

QUALITY CONTROL IN BLOOD TRANSFUSION SERVICES

Strasbourg
1986

FOREWORD

Co-operation in the Blood Transfusion field under the auspices of the Council of Europe began in 1958 with the drawing up of European Agreement No. 26 on the Exchange of Therapeutic Substances of Human Origin. The guiding principles which have inspired all activities are : use of blood on a non-commercial basis (implying voluntary blood donation), mutual assistance, optimal use of blood and blood products, protection of the donor and the recipient and technical co-operation.

To complement other work completed under its auspices *), the Committee of experts on blood transfusion and immunohaematology (SP-HM) requested a Select committee of experts to study quality control procedures in blood transfusion services. Recognising that this practice varies in different countries; the SP-HM considered that it would be useful to set out proposals in a publication for consideration by appropriate professional and scientific bodies of individual countries, as a first step towards the development of common procedures.

Accordingly, the SP-HM envisages a periodic revision of this publication in the light of the experience of Blood Transfusion Services.

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*) A complete list of Agreements, Recommendations, and other reports in the blood transfusion and histocompatibility field appears in Appendix 1.

The Select committee on automation and quality control (SP-R-GS) was requested by the Committee of experts on blood transfusion and immunohaematology to prepare the report hereafter on the basis of experience and practice of the laboratories and blood transfusion services represented in the Committee. The work extended from 1982 to 1985. Although this publication results from the work of the Select committee, special tribute should be paid to the important contribution made by four members, particularly at the initial drafting stage :

Dr. E FREIESLEBEN (Denmark), Chairman

Prof. R BUTLER (Switzerland)

Dr. C HOGMAN (Sweden)

DR. W WAGSTAFF (United Kingdom)

The Select committee of experts was made up as follows :

(will be completed)

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PART A - GENERAL PRINCIPLES

These guidelines are intended as recommendations for the use of blood transfusion services concerned with the bleeding of donors and the preparation and issue of blood components to hospitals which they serve. They are also intended to be of use to those blood transfusion services which are concerned only with the selection of components for specific patients since the guidelines cover, as well as the production of components, the control of laboratory reagents and proficiency testing of staff carrying out the procedures necessary for the safe selection and transfusion of blood and its components.

Part B of these guidelines covers all of the normal components of blood which will be prepared at a routine Blood Transfusion Centre. They do not cover components of plasma produced by fractionation, since this aspect of blood transfusion work is covered by another expert group already in existence under the aegis of the Council of Europe.

Throughout the text it has been assumed that the principles of Good Manufacturing Practice (GMP) (1) will already have been followed so far as the basic materials are concerned. For example, no attempt has been made to cover the quality control of the production of plastic packs used for the bleeding of donors and for the transfer of components. It is accepted that the materials from which these packs are assembled and the sterilisation processes to which they have been subjected will already be covered by the most stringent regulations and an attempt at a repeat of these precautions and of quality control at blood transfusion service level would be both time-wasting and unnecessary (2). This same principle has been applied as regards the quality control of equipment used in blood transfusion laboratories. It is assumed that the equipment concerned has been manufactured and assembled with the highest regard to the needs of safety, and will meet the necessary standards set by the country of origin of the equipment and of that of the purchaser and user. In many instances, individual countries will already have established standards for various equipment used in blood transfusion work, and it has been assumed throughtout this document that these standards will be met, and accepted by users. The design of blood packs used for blood donation is a particular case in point, and no attempt has been made in this document to control, at blood transfusion service level, the physical characteristics of blood packs supplied by manufacturers who are governed by the competent authorities of the country concerned.

In considering the aims of quality control, in particular as applied to blood transfusion services, it is necessary to take into account the following distinct but closely interrelated facets.

i. quality requirements

ii. quality assurance
   a. quality control
   b. proficiency testing

i. Quality requirements

Quality requirement forms the basis of all quality control programmes. For each component, reagent or technique being checked, a set of parameters will be measured by specified techniques and the sum of these results will, to all intents and purposes, form a specification of the material under test. The standard to be met (quality requirement) for each parameter will be determined in different ways. In some cases, the requirement is self-evident, for instance in the testing of all components intended for transfusion by a recognised test for HBsAg. In other cases, where a variation in the requirement is possible through the means of the laboratory procedures being carried out, the requirements stated are those which have been found to be most effective and acceptable in clinical practice (for example a minimum volume of 50 ml has been suggested for the production of platelet concentrates).

ii. Quality assurance

a. Quality control

Quality control of any component, reagent or technique encompasses not only the quality requirement for each parameter to be checked, but the frequency with which tests should be carried out and the specification of the personnel who will carry out these tests.

Assurance of correct quality of any of the materials under investigation is achieved by the correct choice of a specific range of tests covering the component etc under investigation. The aim of any particular range of tests should be the monitoring which may occur in the material under test, so that the product which is eventually released for use should be not only safe but therapeutically active.

b. Proficiency testing

The line between quality control and proficiency testing is, in some cases, a delicate one. To a great extent, the performance of quality control procedures on components and reagents will be in itself a measure of the proficiency of the staff preparing these components. However, it is accepted that certain procedures are themselves more subject to operative variability, and the institution of proficiency testing exercises in these particular instances is recognised as being necessary. This is particularly the case when the test concerned deals with one or more unknowns, as in the case of grouping and crossmatching of blood for hospital patients. Chapter VI.1 of these guidelines deals specifically with the design and execution of proficiency testing exercises in blood group serology.

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A major question in any quality control organisation is that of the delineation of responsibility, both for the performance of the tests and for the supervision of the staff concerned. As a general principle, the tests should be carried out by staff not employed in the laboratory primarily responsible for the product and process being controlled. The

establishment in any Blood Transfusion Centre of a quality control laboratory bearing no allegiance to other departments within the centre, should be regarded as having the highest priority. However, it will be readily seen that some of the parameters to be checked are necessarily subjected to close scrutiny on each and every occasion. It would, for example, be completely impractical to ask a quality control laboratory to check the ABO and Rhesus typing performed by the grouping laboratory on each donation coming into the Centre. Under such circumstances, the control may be executed by the main laboratory carrying out the routine donation units, this can only be carried out by the specific laboratory concerned, for example, the disease screening laboratory or the plasma processing laboratory. Where a parameter is to be checked on a regular rather than a total basis, particularly where the introduction of a new technique is concerned, then these tests should be carried out by an independent quality control laboratory, irrespective of the type of test concerned. Where such an independent quality control laboratory can be established, it should be under the direct supervision of a competent senior member of staff whose own independence from the other production laboratories is guaranteed.

In addition to internal quality control, a full programme should also include external quality control. If a Blood Transfusion Service is integrated in a regional or national transfusion system, a reference laboratory should be charged with the execution of external quality control.

The consequences of instituting a full quality control programme should also be borne in mind. It is inevitable, even in the best of laboratories, that some materials will fail some of the tests, and a strict protocol should be drawn up showing action to be taken in such an eventuality. It is essential that all staff in a Blood Transfusion Centre be trained to accept quality control as a welcome and necessary part of everyday work. Under no circumstances should the quality control laboratory come to be regarded with suspicion by the other workers in the Centre, and the work of the quality control staff should not be allowed to be viewed by others as being counter-productive to the overall success of the Centre. It is of course possible that the other, equally counter-productive, extreme may come about whereby complacency is bred in the minds of the routine staff by the assurance that any errors they commit will be picked up further down the line by the quality control staff. A sensible scheme of rotation of junior staff between routine departments and the quality control department may help to overcome these particular difficulties.

Acceptability of any quality control scheme, and its proper application, will depend greatly on the drawing up and strict following of the protocol to be applied in the event of any test producing an unsatisfactory result. The drawing up of this protocol is in most cases a matter for local decision, but three features are felt to be sufficiently important to warrant stressing at this point.

i. Where any test produces an unsatisfactory result, the first step should be the repeat of this particular test on the material in question. This principle will of course be overriden if gross departures from the norm are immediately evident.

ii. Failures must be reported to the supervisors of the quality control department rather than the leaving of resolution of the problem to the routine staff responsible for the production of the component or reagent concerned.

iii. The supervisor of the quality control laboratory should be responsible for the decision as to whether a batch of components should be discarded, subject to the concurrence of the head of the institution. His decision must be respected and accepted by the supervisor and staff of the routine laboratory responsible for the production of the components, irrespective of the current state of supply and demand.

With these general principles in mind, Part B of these guidelines sets out suggested minima to be achieved in the overall quality control of blood transfusion services, these minima for consideration by appropriate professional and scientific bodies of individual countries.

References

(1) Guide to Good Manufacturing Practice, 1977
Her Majesty's Stationery Office, London.

(2) European Pharmacopoeia, 2nd Edition, Part II-2,
VI.2.2.2: Containers for Blood and Blood Components:
Publisher : Maisonneuve SA, France, 1983.

(3) The Collection, Fractionation, Quality Control, and Uses of Blood and Blood Products, WHO, Geneva, 1981.

PROCEDURES

PART B: QUALITY CONTROL ~~GUIDELINES~~

Chapter I: SELECTION OF DONORS

I.1 WHOLE BLOOD DONORS

In selecting individuals for blood donation the main purpose is to determine whether the person is in good health, in order to protect the donor against damage to his/her own health, and to protect the recipient against transmission of diseases or drugs ~~that~~ which could be detrimental to the patient.

Only persons in normal health with a good medical history should be accepted as donors of blood for therapeutic use.

The donor's medical history shall be evaluated, and the donor accepted, by a suitably qualified person trained to utilise ~~the local or official~~ guidelines for selection of blood donors. This person should work under the supervision of a physician. Abnormal conditions should preferably be referred to the physician in charge who should have the final decision on whether blood shall be collected from a donor. If the physician is in doubt the donor should be deferred.

A complete medical and physical examination of blood donors is generally not possible in practice. One has to rely upon the donor's answers to some simple questions concerning his/her medical history and general health, combined with a simple inspection of donor's appearance and a ~~few~~ laboratory examinations.

To obtain relevant information about the donor's medical history and general health, it is recommended that a preprinted questionnaire be completed. Examples of such questionnaires are given in the ISBT Guide No. 1 (Paris, 1976) and as an Appendix to this chapter.

i. A standard donation is 450 ml ± 10%; an optimum blood/anticoagulant ratio is 7 to 1.

ii. Weight

No more than 13% of the estimated blood volume should be taken during one blood donation. The blood volume may be estimated from height and weight of the donor. (See Mollison, P L Blood Transfusion in Clinical Medicine, 7th Ed, pp 85-87 and tables 3.1 and 3.1 (continued), also see table 3.2.)

iii. Interval between donations

It is acknowledged that current practices in some transfusion services in Europe allow up to five standard donations per year to be taken from males and up to four per year from females, with a minimum interval between standard donations of two months.

It is recommended that these donation rates never be exceeded under any circumstances, and only be accepted by any transfusion service after careful consideration of the dietary habits of the populations concerned, and in the knowledge that extra care may be necessary, beyond routine haemoglobin or EVF estimation, in the monitoring of donors for iron deficiency. It is further recommended that an active donor panel be maintained of sufficient size to allow donors to be bled less often than the maximum rates stated, thus affording the donors extra protection and giving the system flexibility to deal with large-scale emergency situations.

iv. Age

Minimum: 18 years. If this is below the legal minimum age of consent, written parental approval will be needed.

Maximum: 65 years. Continuation beyond this time should be at the discretion of the responsible physician, as should the recruitment of any first-time donor above the age of 60.

v. Inspection of donor's appearance

Special note should be taken of plethora, poor physique, debilitation, undernutrition, anaemia, jaundice, cyanosis, dyspnoea, mental instability, intoxication from alcohol or narcotic drugs.

vi. Pulse and blood pressure

It is recommended that pulse and blood pressure be tested routinely. The pulse should be regular and between 50 and 110 beats per minute. The systolic blood pressure should not exceed 180 mm of mercury and the diastolic pressure 100 mm Hg.

vii. Laboratory examinations

Haemoglobin: should be determined each time the donor presents him/herself, unless substituted by estimation of EVF.

Minimum values before donation: Female donors: 125 g per litre
Male donors: 135 g per litre

The following table may be useful as a guide:

Haemoglobin and EVF (before donation)

	Haemoglobin grams per litre		Haemoglobin (Fe) mmol per litre		EVF
	Min	Max	Min	Max	Min
Males	135	180	8.4	11.2	0.41
Females	125	165	7.8	10.2	0.38

viii. Hazardous occupations

Hazardous occupations or hobbies should normally entail an interval of not less than 24 hours between donation and returning to the occupation or hobby. For example, such hazardous occupations or hobbies include piloting, bus or train driving, crane operating, climbing of ladders or scaffolding, gliding, climbing and diving.

ix. Medical history

- Acquired Immune Deficiency Syndrome (AIDS) (French: SIDA = Syndrome d'Immunodéficience Acquise): all blood donors should be provided with information on AIDS so that those in risk groups will refrain from donating. Blood and blood products with a known confirmed positive marker for AIDS should not be used for therapeutic purposes.

- Allergy: Persons with chronic atopic diseases such as asthma should not be accepted as donors. Prospective donors with pollen allergy should be deferred during the season; those receiving desensitisation injections should be deferred until 72 hours after the last injection. Persons with drug allergy may be accepted if a negative result is found by examining the donor's blood for drug specific IgE by a RAST test.

Donors with local eczema at the venepuncture site should be deferred temporarily.

- Anaemia: see laboratory examinations.

- Autoimmune diseases are causes for rejection

- Bronchitis: persons with symptoms of severe Chronic Bronchitis should not be accepted as donors.

- Cancer: see malignant diseases

- Common cold: see infectious diseases

- Diabetes: normally permanent rejection. Mild cases without medication may be referred to the physician in charge for decision.

- Drugs and medication: taking of a drug might indicate an underlying disease which may disqualify the donor.

It is recommended that a list of commonly used drugs, with rules for acceptablity of donors, approved by the medical staff of the Transfusion Centre, be available to the donor personnel.

- Epilepsy: normally permanent rejection, whether treated or not.

- Heart and blood vessel disease: persons with a history of heart disease, especially coronary disease, angina pectoris, severe cardiac arrhythmia, a history of ~~cerebral vascular~~ cerebrovascular diseases, arterial thrombosis or recurrent venous thrombosis are excluded. (see also Hypertension).

- Hypertension: a hypertensive person whether under treatment or not should not be accepted as a blood donor. The same is true for persons who are being treated with hypotensive drugs and have normal blood pressure (see also Chapter I.6).

- Immunisations, inoculations, vaccinations:

Attenuated viruses	Quarantine period
Small pox	Three weeks
Yellow fever	
Rubella	
Measles	
Poliomyelitis (oral)	

	Quarantine period
- Vaccines with killed bacteria	
Cholera Typhoid (T.A.B.)	Five days
- Inactivated virus vaccine	
Poliomyelitis (injection) Influenza	Three days
- Toxoids	
Diptheria Tetanus	Three days
- B.C.G.	No delay
- Hepatitis B vaccine	

- Infectious diseases: generally a quarantine of at least two weeks following cessation of symptoms; one week in the case of a common cold.

Confirmed Brucellosis - rejection for at least two years following full recovery.
Contact with an infectious disease: quarantine period - incubation period, or if unknown, four weeks.

(See also Tropical diseases, Toxoplasmosis and Tuberculosis).

- Intoxication, alcohol and drugs: illicit drug taking if admitted or suspected should debar. Persons clearly under the influence of alcohol should be deferred until sober.

- Jaundice and hepatitis: individuals with a history of jaundice or hepatitis may, at the discretion of the appropriate competent authority, be accepted as blood donors provided an approved test for HBsAg is negative. Persons whose blood gives a positive reaction for the presence of HBsAg are excluded. Presence of anti-HBs does not debar. Persons who have been in house contact with a case of hepatitis or who have received a transfusion of blood or blood products should have a quarantine period of six months. The same is true for acupuncture (other than under strict medical supervision) tattooing and ear-piercing. Hospital staff coming into direct contact with patients with hepatitis are accepted at the discretion of the physician-in-charge of the blood collecting unit. Donors without demonstrable markers of hepatitis who have donated blood to two patients strongly suspected of having transfusion-transmitted hepatitis should be excluded. The only donor of blood to a recipient with transfusion-transmitted hepatitis should also be excluded.

- Kidney diseases: acute glomerulonephritis: five years' quarantine period following complete recovery. Chronic nephritis and pyelonephritis: rejection.

- Malignant diseases: individuals with a malignant disease, or a history of such, are usually permanently excluded. The physician in charge may make exceptions to this rule in selected cases.

- Osteomyelitis: five years of quarantine after cessation of symptoms.

- Polycythaemia rubra vera: rejection.

- Pregnancy: pregnant women should not be accepted, other than in exceptional circumstances and at the discretion of the physician in charge of her pregnancy. Following pregnancy, the quarantine period should last as many months as the duration of the pregnancy, or at least throughout the lactation period.

- Rheumatic fever: an individual with a history of rheumatic fever should be deferred for two years and then examined for chronic heart sequelae. The latter complication is a cause for rejection.

- Surgery: major surgery: generally a quarantine period of six months. Minor surgery (tooth extraction, etc): one week, if no complications. Persons with a history of resection of the stomach are usually permanently excluded.

- Toxoplasmosis: quarantine for one year following clinical recovery.

- Transfusion: donors transfused with blood or blood products should be deferred for six months.

- Tropical diseases:

Malaria:

i. Individuals born or brought up in endemic malarious areas can be accepted as blood donors three years after their last visit to an endemic malarious area if the results of an approved immunological test are negative after cessation of the quarantine period. Individuals with a history of malaria can be accepted three years after becoming asymptomatic and cessation of antimalarial therapy if the result of an approved immunological test is negative after the quarantine period.

ii. All other persons who have visited an area where malaria is endemic can be accepted as blood donors six months after returning, if they have had no febrile episodes during or after their stay in the malarious area. Individuals having had such febrile episodes can be accepted if the results of an approved immunological test is negative six months after becoming asympomatic and cessation of therapy.

iii. The quarantine periods and immunological tests mentioned above may be omitted for donors whose red cells are discarded and whose plasma is used exclusively for fractionation into blood products, thus rendering it safe from the transmission of malaria. It should be rememberd that liquid or frozen untreated plasma and frozen cryoprecipitates cannot be regarded as wholly devoid of the cellular elements of blood and, therefore, of viable malarial parasites.

iv. Since questioning of the donor as to the country(ies) in which he was born, brought up or has visited is essential for effective detection, every transfusion service should have a map of the endemic zones and an alphabetical list of the countries concerned.

∧ of donors at risk

originating in

- Persons ~~coming~~ or returning from tropical areas should not be accepted as donors until three months after return. This quarantine period will solve the problem concerning some of the diseases mentioned in the following paragraph:

Dengue Fever Rift Valley Fever Sandfly Fever Schistosomiasis West Nile Fever Yellow Fever	a history of any of these diseases does not debar (see preceding paragraph)

Amoebic Dysentery: accepted if adequately treated

Relapsing Fever: accepted two years after recovery

Trypanosomiasis and Chagas disease: the blood of persons who have resided in endemic areas should be used only for plasma fractionation products.

- Tuberculosis: may be accepted after having been declared cured by the treating physician for a period of five years.

II.2 APHERESIS DONORS

The supervision and medical care of apheresis donors should be the responsibility of a physician specially trained in these techniques.

Other than in exceptional circumstances (to be decided by the supervisory physician), donors for apheresis procedures shall meet the usual criteria for ordinary whole blood donations.

In addition, the following criteria should be observed:

i. Age: Ordinarily, the donors shall be between 18 and 60 years of age.

ii. Medical history: special attention should be given to the following conditions:

- Abnormal bleeding episodes (women donors should not receive heparin during menses)
- A history suggestive of fluid retention (of special interest if steroids and/or plasma expanders are to be used)
- The taking of drugs containing acetylsalicylic acid within seven days prior to thrombocytapheresis
- Allergy to beef or pork if heparin is to be used
- A history of gastric trouble (if steroids are to be used)
- A history of weight loss
- Adverse reactions to prior apheresis donations

iii. Tests to be carried out

- before a first cytapheresis procedure and before enrolment in a long-term plasmapheresis programme

- Evaluation by a physician

- Pulse, blood pressure, temperature

- Urine: protein, sugar

- Blood: red cell, white cell and platelet counts

  serum protein analysis such as total protein analysis and/or electrophoresis and/or quantitation of single proteins, especially albumin and IgG

  ALT (+ LDH)

  ← If more than 40 years of age: ECG

  ← If steriods are to be given: recent chest X-ray

- at first donation by manual plasmapheresis and at all subsequent apheresis donations by whatever means:

- Pulse, blood pressure

- Haemoglobin or EVF (see ~~6~~ I.1.vii above)

- Serum protein analysis such as total protein analysis and/or electrophoresis and/or quantitation of single proteins, especially albumin and IgG (for documentation)

- For leukapheresis: white cell, differential and platelet counts (for documentation)

- For thrombocytapheresis: platelet count (for documentation)

- on donors undergoing serial apheresis - at least every four ~~m~~months

- Evaluation by a physician of the following laboratory investigations:

  . Serum protein analysis such as total protein analysis and/or electrophoresis and/or quantitation of single proteins, especially albumin and IgG.

  Special attention should be paid to any significant fall in these values even though they may still come within the accepted normal limits.

- ALT

iv. Frequency of donation and maximal amounts of removal:

- Not more than 15 litres of plasma should be removed from one donor per year.

- Not more than 1 litre of plasma should be removed from one donor per week.

- Not more than 650 ml of plasma should be removed from one donor per apheresis procedure.

- Erythrocyte loss should preferably be kept below 20 ml of packed red cells per week.

- The interval between one apheresis procedure and a whole blood donation should be at least 48 hours.

Selected references:

Standards for Blood Banks and Transfusion Services
10 ed. American Asssociation of Blood Banks, Washington 1981

Criteria for the Selection of Blood Donors
Guide No. 1 International Society of Blood Transfusion, Paris 1976

Memorandum of the Selection, Medical Examination and Care of Blood Donors
National Blood Transfusion Service, England and Wales, 1977

Richtlinien zur Blutgruppenbestimmung und Bluttransfusion
Deutscher Arzte-Verlag GmbH, Köln-Lövenich, 1980

Technical Manual
8 ed. American Association of Blood Banks, Washington 1981

WHO Technical Report Series, No. 626, Geneva 1978

NB Specific immunisation programmes are not considered in this document but donors enrolled for this purpose should at least fulfill the minimum criteria outlined above (see also "Collection, fractionation, quality control and use of blood and blood products", WHO Geneva, 1981).

Council of Europe Strasbourg 1986

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Addendum I

QC in Blood Transfusion services

Model of a Donor Selection Questionnaire

	Yes	No
Are you in good health?	☐	☐
Have you within the last twelve months:		
Been ill	☐	☐
Been pregnant	☐	☐
Been vaccinated or had any shots	☐	☐
Received a transfusion	☐	☐
Been tattooed, had your ears pierced, or experienced acupuncture	☐	☐
Been operated upon	☐	☐
Had unexpected weight loss, unexplained fever, or swollen glands	☐	☐
Have you within the last three years:		
Lived or travelled abroad	☐	☐
When and where	☐	☐
Have you within the last month:		
Taken any medication or drugs	☐	☐
Which	☐	
Been exposed to contagious disease in your family or at your job	☐	☐
Have you ever suffered from:		
Jaundice	☐	☐
Malaria	☐	☐
Tuberculosis	☐	☐
Rheumatic fever	☐	☐
Heart disease	☐	☐
Pain over the heart	☐	☐
High or low blood pressure	☐	☐
Convulsions as an adult	☐	☐
Fainting as an adult	☐	☐
Stomach diseases	☐	☐
Renal diseases	☐	☐

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Diabetes	☐	☐
Allergy	☐	☐
Anaemia	☐	☐
Malignant tumours (cancer)	☐	☐

Have you previously given blood? ☐ ☐

Chapter II: BLOOD COLLECTION PROCEDURES

1. Equipment used at blood donation sessions

Reference should be made to Chapter VIII for quality control procedures to be applied to equipment used at blood donation sessions.

2. Pre-donation investigation of containers

The blood containers should be inspected for defects before use as well as after the donation. Defects may be hidden behind the label pasted on the container. Glass bottles should be inspected before use for the prescribed content (and appearance) of the anticoagulant solution. For plastic bags, abnormal moisture on the surface of the bag after unpacking will cause suspicion of leakage through a defect. If one or more bags in any package is found to be abnormally damp all the bags in that package should be rejected.

3. Preparation of the phlebotomy site

Although it is impossible to guarantee 100% ~~sterile~~ skin surface for phlebotomy, a strict, standardised procedure for the preparation of the phlebotomy area should exist. Of particular importance is that the antiseptic solution used be allowed to dry completely before venepuncture, and that the prepared area not be touched with fingers before the needle has been inserted.

4. Need for successful venepuncture and proper mixing

When taking blood for the preparation of labile blood components, a successful and uncomplicated venepuncture is of ~~some~~ importance.

Measurement of blood volume taken into glass bottles is usually accomplished by simple inspection. With plastic bags the most efficient way of measuring the blood volume taken is by weighing the filled container, deducting the tare weight of container and anticoagulant solution, and converting the weight to ~~millimetres~~ by applying the specific gravity of blood (whole blood: 1.06). A variety of equipment has been developed to automate the procedure, with mechanical agitation during blood collection, vacuum bag agitators, automatic scales etc, some being supplied with a device which automatically shuts off the blood flow when a preset value is reached. Such equipment must be controlled for accuracy periodically, for example balances should be checked with known control weights, and automatic shut-off devices by weighing a number of filled containers on a balance checked for accuracy or by using known control weights. If mechanical agitation equipment is unavailable, proper manual mixing by slow inversion at intervals of $^{1}/_{2}$ - 1 minute has been shown to be an effective method of preventing the activation of labile coagulation factors.

Only donations which have been uneventful throughout and subjected to no undue prolongation should be allocated for the production of components and derivatives.

5. Handling of filled containers and samples

Both glass and plastic containers should be checked after donation for any defect which may be revealed by the extra contents. During ~~the~~ separation from the donor of the freshly filled plastic bag of blood, a completely efficient method of sealing the tube is obligatory. Immediately after sealing the donor tube, the contents of the part of the tube which still communicate with the bag should be completely discharged into the bag by stripping and the tube allowed to refill with mixed anticoagulated blood.

The organisation should be such as to minimise the possibility of errors in labelling of blood containers and blood samples, for example the taking of samples at the end of donation should be directly linked with the cessation of donation with the minimum possible time interval, and the blood bag and corresponding samples should not be removed from the donor's bedside until a satisfactory check on correct labelling has been carried out. In this respect, it is recommended that each bed should have its individual facilities for the handling of samples during donation and labelling.

Measures should be taken to ensure that the needle punctures in the rubber seal of a bottle are completely closed after withdrawal of the needles, as otherwise the vacuum created following cooling may draw in contaminated air. A simple, but not foolproof, method of checking the integrity of the seal is to clean the surface of the rubber stopper after withdrawal of the needles and turn the bottle upside-down several times, inspecting for blood stains at the perforation sites.

6. Maintenance of records

Full records must be maintained at blood donation sessions, to cover the following parameters:

i. the date, donation number and identity of the donor of each successful donation

ii. the date, donation number and identity of the donor for each unsuccessful donation, with reasons for the failure of the donation

iii. full details of rejected donors with the reasons for their rejection

iv. full details of any adverse reactions in a donor at any stage of the procedure

So far as possible the records of blood donation sessions should allow identification by blood transfusion staff of each important phase associated with the donation. These records should be used for the regular compilation of statistics which should be studied monthly by the individual with ultimate responsibility for the blood donation session, who will take such action on them as deemed necessary.

7. Return of red blood cells of donors undergoing manual plasmapheresis

Since confusion between two bags of concentrated red blood cells during their centrifugation and return to individual donors is the biggest inherent danger in manual plasmapheresis, a proper identification system to avoid this is an absolute necessity. For instance the donor may be asked to sign the label of the bag and to confirm his signature before the return of the red cells, and each donor should be made aware of his own blood group and asked to check this on the label of the cells returned to him.

In addition, use can be made of the integral numbering system on the pilot tube of plastic bags, perhaps by transferring this number to the wrist of the donor.

Chapter III: BLOOD AND BLOOD COMPONENTS

General comments

It should be recognised that some of the components covered in this section are prepared from others also detailed, for instance whole blood acts as a source material for most other components, while fresh frozen plasma acts as a source material for cryoprecipitate. General quality control measures carried out on a source material need not necessarily be repeated on components prepared from them, unless the parameters being checked may be changed by the processes.

Where volumes are stated in these quality control requirements, it is assumed that these will be measured not by destructive tests of the component concerned but by the application of a formula involving the density of the component and the measured weight.

It is suggested that any new development in component preparation involving an open system should be subjected to intensive testing for maintenance of sterility during the developmental phase. Other than this, routine sterility testing as an ongoing quality control measure is thought to be of limited value. Blood components prepared by an open system should be used as quickly as possible, and, in any event, within four hours of preparation if stored or transported unrefrigerated, and within 24 hours if stored or transported at recommended temperatures (1 to 10 °C). If sterility controls are performed the relevant unit(s) should not be used for transfusion.

It is also suggested that when new methods of preparation are adopted, a sufficient number of units be studied to demonstrate that the method is valid and to establish the reference values of the preparation

It is assumed throughout that, at the various stages in the handling and transfusion of blood and its components, visual examination will lead to the detection of gross changes such as haemolysis, unusual turbidity, clotting and discolouration, which will result in rejection of the unit concerned and the institution of the appropriate investigations. These changes will not be seen in all cases of contamination.

1. Quality control of whole blood

Although there is a diminishing use of whole blood as a transfusion fluid, it acts as a source material for many other components. Much of the quality control necessary to ensure the safety and effectiveness of this material takes place at the time of blood collection and reference should be made to Chapter II. In addition to the measures carried out at the time of collection, the parameters listed below must also be checked.

Where there is an agreed indication for the transfusion of red blood cells together with multiple haemostatic factors, and these latter factors are not readily available in component form, a case can be made for the transfusion of whole blood within 12 hours of donation.

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PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
HBsAg	neg. by approved screening test	all units	screening lab
Syphilis (when required)	neg. screening test	all units	screening lab
volume, excluding anticoagulant	450ml ± 10%	all units weighing of 1% of all units	processing lab

2. Quality control of red cell concentrate

This product is defined as being the result of removal of part of the plasma from whole blood, without further processing.

Except during the introductory phase of new materials or techniques, tests other than those shown are not thought to be a routine necessity.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
Volume	280 ± 60 ml	1% of all units	processing lab
EVF	0.70 ± 0.05	6 units per month	QC lab

If other types of red cell concentrates are used, the degree of concentration must be indicated on the label.

3. Quality control of washed red cell suspension (plasma protein poor and plasma protein free)

It is recognised that there is a differential need for red cells from which plasma protein has either been mainly or totally removed. In practice, it has been found that red cell suspensions which meet the requirements shown for protein poor red cells are clinically acceptable as protein free red cells after a further two washes. It should be noted that preparation of these components is particularly susceptible to potential contamination, which will have an influence on the expiry period. Extra caution should be ~~used~~ displayed if the wash solution contains no glucose.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
residual plasma protein in protein poor red cells	<0.5 g/unit	4 units per month	QC lab

4. Quality control of leucocyte-poor blood

By removal of the buffy-coat layer a blood unit can be depleted of white cells and platelets thus diminishing the formation of microaggregates and causing fewer febrile reactions. However, in this leucocyte-poor red cell concentrate a considerable number of white cells may still remain.

In certain cases the red cells must be purified further into leucocyte-free red cell concentrate which can be obtained, for example, by passing the blood through special leucocyte filters or by certain freezing/washing procedures. It is advisable to use leucocyte-poor red cell concentrate to produce such a leucocyte-free preparation.

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NAME OF THE PRODUCT	PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
Leucocyte-poor red cell concentrate	residual white cells in red cell preparation	$< 1.2\ 10^9$ per unit	4 units per month or 5% of units, whichever is higher	sampling: processing lab
	loss of red cells	less than 10% of original red cell mass		determination QC lab
Leucocyte-free red cell concentrate (1)	residual white cells in red cell preparation	$< 0.1\ 10^9$ per unit	4 units per month	sampling: processing lab
	haemolysis in supernantant	not red on inspection		determination QC lab
	loss of red cells	less than 15% of original red cell mass		

(1) These requirements shall be deemed to have been met if 20% of the units sampled fall within the values indicated.

5. Quality control of platelet rich plasma and platelet concentrate

Though most platelet transfusions are in the form of a concentrate some workers use a platelet rich plasma and so the protocol caters for both these products. The quality requirements for volume and pH are based on the assumption that storage will be at a controlled temperature of 22 °C + 2° C, a prerequisite for platelet viability.

The eliciting of the swirling phenomenon, based on light scattering by platelets of normal morphology in movement, may be carried out either as a separate quality control procedure or as a routine part of the issue and transfusion of these products.

To avoid problems with aggregated platelets during performance of counts, it is recommended that the units selected for quality control be taken on a random basis after routine storage for 24 hours.

Although the quality requirement for residual leucocytes is expressed here as a total count, the major immunogenetic hazard in these preparations is likely to come from contaminating lymphocytes.

A reasonably accurate measure of red cell contamination of platelet concentrates may be obtained by visual inspection. A unit which does not have a pink or red discolouration may be assumed to contain insufficient red cells to pose practical problems of ABO or Rh incompatibility, except in the case of Rh negative female recipients of child bearing age or younger.

PARAMETER TO BE CHECKED	QUALITY REQUIRMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
volume	$\geqslant$50 ml	all units	processing lab
thrombocyte count*	$\geqslant 60 \times 10^9$ /unit	1% of all units with a minimum of 4 units/month	QC lab
residual leucocytes*	$\leqslant 0.2 \times 10^9$/unit	1% of all units with a minimum of 4 units/month	QC lab
pH* measured at the end of the recommended shelf life	$\geqslant$6.0	1% of all units with a minimum of 4 units/month	QC lab

* These requirements shall be deemed to have been met if 75% of the units sampled fall within the values indicated.

6. Quality control of frozen fresh plasma

Donations with irregular antibodies deemed to be of clinical significance should not be used for the preparation of Fresh Frozen Plasma.

Titration of Anti-A and Anti-B agglutinins or haemolysins may not be routinely necessary where the supply of this component always avoids the possibility of incompatibility between donor plasma and recipient's red cells. Whenever possible blood group compatible plasma should be given. If group O plasma is given to patients other than of group O, reference should be made to the relevant recommendations of the European Pharmacopoeia.

Pooling of the units selected for quality control of Factor VIIIc content is recommended as a simple and effective means of discounting inevitable variation in levels of this Factor in individual donors. Duplicated testing for Factor VIIIc in the manner indicated is intended to control both preparation and storage of the product. If plasma from Rh-positive donors is to be given to female Rh-negative recipients, the risk of Rh-immunisation should be considered.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
ABO + Rh*	typing	all units	grouping lab
HBsAg*	neg. by an approved screening test	all units	screening lab
syphilis* (when required)	neg. screening test	all units	screening lab
volume	stated volume ± 10%	all units	processing lab
Factor VIIIc	> 0.7 I.U./ml	Every two months: a. pool of 6 units of plasma during first month of storage b. pool of 6 units of plasma during last month of storage	QC lab

* Unless performed on whole blood used as the source.

7. Quality control of single donor frozen cryoprecipitate

The comments on the protocol for fresh frozen plasma apply equally in the case of single donor frozen cryoprecipitate.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
estimated volume	10 - 20 ml	all units	processing lab
Factor VIIIc	>70 I.U./unit	Every two months: a. pool of 6 units during first month of storage b. pool of 6 units during last month of storage	QC lab

8. Quality control of cryoprecipitate-depleted plasma

Quality requirements are the same as those of frozen fresh plasma except for Factor VIIIc which should be omitted.

9. Quality control of granulocyte preparations

The recommended tests are those which are within the capabilities of all establishments preparing this product. Sophisticated tests for granulocyte functions are time-consuming and not generally available, and in any case are probably unnecessary if the storage period of the product is limited to 24 hours. However, such function tests should be used in the establishment of new materials or techniques for the separation and harvesting of granulocytes.

Routine cross matching of the recipient against the red cells of individual donors may not be necessary if postive steps are taken to remove red cells from the preparation, for example by the in vitro use of sedimenting agents.

Where sedimenting agents are used, either in the in vitro treatment of buffy coats or in the performance of leucapheresis, their presence should be indicated on the label of the final product.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED
ABO + Rh*	typing	all units	grouping lab
HBsAg*	neg. by an approved screening test	all units	screening lab
syphilis* (when required)	neg. by an approved screening test	all units	screening lab
EVF[1] (when prepared by cell separators)	<0.01	all units	QC lab
volume	leucapheresis 500 ml	each unit	processing lab
Granulocytes [1]	$\geq 15 \times 10^9$ (total dose)	each ~~unit~~ final preparation.	QC lab
RBC compatibility	compatibility test: negative	each unit	grouping lab

* Unless performed on whole blood used as the source

1 These estimations may be carried out retrospectively

CHAPTER IV: STORAGE OF BLOOD AND BLOOD COMPONENTS

1. Aspects of red cell preservation

The anti-coagulant solutions used ~~so far~~ to date have been developed to preserve red cells for a certain period of time. They were originally designed for storage of whole blood but have been used also in blood component preparation. Platelets, leucocytes and coagulation factors can be successfully harvested. All of the solutions contain sodium citrate, citric acid and glucose, some of them in addition adenine, guanosine and phosphate.

Citrate binds calcium and prevents clotting of the blood. Glucose is used by the red cell during storage and each glucose molecule gives two molecules of adenosine tri-phosphate (ATP) which is formed by phosphorylation of adenosine di-phosphate (ADP). ATP is an energy rich molecule which is used to support the energy demanding functions of the erythrocyte, such as membrane flexibility and certain membrane transport functions. During its action in energy consuming operations ATP is transformed back to ADP. Citric acid is added to the anticoagulant in order to obtain a hydrogen ion concentration which is suitably high at the beginning of storage at + 4 °C. Without this addition the blood would be too alkaline at storage temperature. During storage an increasing acidity occurs which reduces the glycolysis. The content of adenosine nucleotides (ATP, ADP, AMP) decreases during storage. By addition of adenine which is a main component in the adenosine nucleotides, the erythrocytes can synthesise new AMP, ADP and ATP and compensate for the losses.

When red cell concentrates are prepared a considerable part of the glucose and adenine are removed with the plasma. If not compensated for in other ways (eg larger amount than normal of adenine and glucose in the anticoagulant or addition via a separate suspension/preservative medium), sufficient viability of the red cells can only be maintained if the cells are not concentrated too much. Normal CPD-adenine red cell concentrate, therefore, should not have an EVF above 0.70. This also keeps the viscosity sufficiently low so that the concentrate can be transfused without necessarily being diluted before administration.

Platelets and leucocytes rapidly lose their viability at + 4 °C. They form microaggregates which are present in considerable amounts already after 3-4 days storage of whole blood and even more rapidly in red cell concentrate. The microaggregates are not removed by filtering through the ordinary transfusion sets. They are considered to be able to cause decreased lung function by clogging the lung capillaries at massive transfusions. If the main part of the platelets is removed during blood component preparation the formation of microaggregates is considerably decreased. Removal of 50-70% of the leucocytes reduces the frequency of febrile reactions by about 50%.

Red cells from which 90% or more of the plasma has been removed can be stored with well maintained viability if the suspension medium contains sodium chloride, adenine, and glucose. In order to prevent increased spontaneous storage hemolysis which, under these circumstances, will occur particularly towards the end of the storage period, the suspension medium should, in addition, contain either mannitol or sucrose. Quality control parameters for these red cell suspensions, when defined, should follow the same format as those laid down for red cell concentrates (Chapter III, para 2).

2. Erythrocyte preparations

Red cells may be stored at refrigerator temperature (4 °C ± 2° C) either in the total content of its own plasma (whole blood) or in a reduced volume of its plasma (red cell concentrate), or in a synthetic storage medium (red cell suspension). Alternatively, red cells may be frozen under certain thoroughly-specified conditions and stored at -80 °C or below that temperature.

The quality of the preparations is influenced by storage. Some of the changes that occur have no clinical importance in the majority of instances but must be taken into consideration in certain cases. For practical reasons the expiry date has to be noted onthe unit. This, however, does not mean that a unit close to out-dating is useful in all clinical situations.

The most important quality requirement of red cell preparations is the survival of red cells in the circulation of a normal, human recipient. The mean 24h post-transfusion survival or red cells shall be no less than 75%. This has to be assured for each procedure under the conditions of routine use.

4 3. Plasma products

Recommended storage conditions for frozen fresh plasma and cryoprecipitate and for cryoprecipitate-depleted plasma are given below:

PRODUCT	TEMPERATURE AND LENGTH OF STORAGE
Frozen fresh plasma and cryoprecipitate	12 months at - 30 °C or below 6 months at - 25 °C to - 30 °C 3 months at - 18°C to - 25°C
Cryoprecipitate depleted plasma	2 years at - 18 °C or below

CHAPTER V: ISSUE AND TRANSPORTATION

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
Leakage	No leakage at any part of containers, eg by visual inspection after pressure in a plasma extractor.	All units	Processing and receiving laboratory
Visual changes	No abnormal colour (purple red cell mass, haemolysis in plasma). No visible clots. Plasma not murky.	All units	"
Time of issue	Marked on transit document.	All units	"
Identification	See Chapter 7	All units	"

Blood and blood products should be transported at a temperature as near to recommended storage temperature as possible, and, on receipt, unless intended for immediate therapeutic use, should be transferred to storage under recommended conditions.

During transportation of blood, the temperature of red cell containing products must be kept between +2 ° and +10 °C; platelet products: between 22 °C and +24 °C; frozen plasma: transport in the frozen state, as close as possible to recommended storage temperature. Plasma after thawing: at 0-4 °C. ~~It is recommended to use some form of temperature indicator or monitoring of the shipping containers used.~~ * below Containers for transporting red cell products should be pre-cooled to 4 °C and those for the transport of platelets should be kept open at room temperature for 30 minutes before use. If temperatures of containers for red cell products are just below 10 °C on receipt, the shelf life of the preparations should be reduced.

Returned blood or blood products ~~shall~~ should not be reissued for transfusion if ~~container closure~~ the bag or bottle has been penetrated or entered, the blood or product has not been maintained continuously within the approved temperature range, or if the requirements of issue mentioned ~~above~~ below have not been met.

* It is recommended that some form of temperature indicator be used to monitor shipping containers

For continuity of format these paragraphs should come before the table, under the heading "General Comments".

CHAPTER VI: LABORATORY PROCEDURES

VI.1 Blood group serology

General comments

The purpose of quality control in transfusion related blood group serology is to minimize the number of errors and to provide a feeling of security ~~to~~ for the laboratory personnel. Errors may be classified in two major categories:

a. errors of organisation due to incorrect identification of samples or mistakes in transcription or in filing of results;

b. technical errors, due to poor quality of equipment, reagents or performance of the tests.

Quality control intended to avoid errors of organisation (a) is achieved by checking periodically the respective procedures. A more rigid quality control can be applied to the technical procedures (b) and corresponding recommendations are given in this chapter.

A general approach in quality control of donor or patient blood group serology is to compare ABO- and Rh-typing results with previous data. This will disclose errors of both categories. # Classification of ~~the~~ errors ~~if~~ any should be ~~tried~~ stumpled in order to obtain more detailed information about ~~their~~ its sources.

Quality control of serological techniques should be based upon internal and external quality controls. The internal controls are ordinarily executed by the serology laboratory itself. Results of the controls must be recorded systematically and be regularly reviewed by the supervisor of the laboratory.

1. Internal quality control

The quality control procedures in blood group serology are sub-divided into controls for equipment, reagents and techniques. This classification is considered to provide clarity, in spite of partial overlapping, especially between controls for reagents and techniques.

1.1 Quality control of equipment

Equipment used in transfusion serology, in particular centrifuges, automatic cell washers, waterbaths, incubators, refrigerators, freezers, microscopes and Rh-viewboxes, should undergo regular quality controls (Chapter VIII). ~~reference is made to chapter VIII for this purpose~~. Equipment for automated blood grouping should also be controlled systematically, according to the manufacturer's instructions.

1.2 Quality control of reagents

The quality control of reagents should detect deviations from the established minimal quality requirements (specifications). Such requirements have been issued by the Council of Europe for blood grouping antisera and antiglobulin sera (1). Summarised requirements are included in the tables of this section.

It is ~~presumed~~ assumed that an evaluation of ~~the~~ quality is performed on samples before purchasing larger batches of commercial reagents. The following control procedures serve as routine checking before use.

The quality control procedures recommended in this section may basically be applied to reagents used for manual and automated techniques. However, reagents for blood grouping machines may ~~need~~ have special quality requirements and more detailed controls; these are usually supplied by the manufacturers of the equipment.

QUALITY CONTROL OF REAGENT BLOOD CELLS

parameter to be checked	quality requirements	frequency of control
appearance	no haemolysis or turbidity in the supernatant by visual inspection	each day
reactivity and specificity	clearcut reactions with selected antisera against declared RBC antigens;	each lot on first and last day of declared shelf life.

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QUALITY CONTROL OF ABO-ANTISERA		
PARAMETER TO BE CHECKED	QUALITY REQUIREMENTS	FREQUENCY OF CONTROL
appearance	no haemolysis, precipitate, particles or gel-formation by visual inspection	each day
reactivity and specificity	no immune haemolysis, rouleaux formation or prozone phenomenon. Clearcut reactions with RBC bearing the corresponding antigen(s); no false reactions. (See also Quality Control of ABO and Rh typing)	each new lot
potency	Undiluted serum should give a 3 to 4 plus reaction in saline tube test using a 3% RBC suspension at room temperature. Titres should be of 128 for anti-A, anti-B and anti-AB with A_1 - and B-cells; 64 with A2 and A_2B cells.	each new lot
avidity	Macroscopic agglutination appearing with a 50% RBC suspension in homologous serum, using the slide test; 5 sec for anti-A, anti-B and anti-AB with A_1 - and/or B-cells, 20 sec with A2 and A2B cells	each new lot

QUALITY CONTROL OF Rh-ANTISERA		
PARAMETER TO BE CHECKED	QUALITY REQUIREMENTS	FREQUENCY OF CONTROL
Appearance	as for ABO-antisera	
reactivity and specificity	as for ABO-antisera	
potency	Undiluted serum to give a 3 to 4 plus reaction in the designated test for each serum and a titre of 32 for anti-D anti-C, anti-E, anti-CD, anti-DE and anti-CDE using R_1r-, R_2r-, R'r- or R"r-RBC	each new lot
avidity (for rapid slide anti-D testing)	Visible agglution appearing with 40% RBC suspension in homologous serum using the slide test at 40°: 30 sec using RBC with Rh-phenotypes mentioned above	each new lot

QUALITY CONTROL OF ANTIGLOBULIN SERUM (BROAD SPECTRUM) USED FOR THE INDIRECT ANTIGLOBULIN TEST		
PARAMETER TO BE CHECKED	QUALITY REQUIREMENTS	FREQUENCY OF CONTROL
appearance	no precipitate, particles or gel formation by visual inspection	each day
reactivity and specificty	a) no haemolytic activity; no agglutination of unsensitized RBC of any ABO group	each day
	b) agglutination of RBC sensitised with anti-D serum containing not more than 2 nanograms/ml antibody activity	each day
	c) agglutination of RBC sensitized with a complement-binding allo-antibody (e.g. anti-Le^a) to a higher titer in the presence than in the absence of complement	each new lot
	d) agglutination of RBC coated with C3b and C3d and no or weak agglutination with C4 coated REC.	each new lot

QUALITY CONTROL OF BOVINE SERUM ALBUMIN (BSA)		
PARAMETER TO BE CHECKED	QUALITY REQUIREMENTS	FREQUENCY OF CONTROL
Appearance	no precipitate, particles or gel-formation by visual inspection	each day
purity	> 98 % albumin as determined by electrophoresis	each new lot
reactivity	no agglutination of unsensitized RBC; no haemolytic activity; no prozone or "tailing" phenomena	each month

QUALITY CONTROL OF PROTEASES		
PARAMETER TO BE CHECKED	QUALITY REQUIREMENTS	FREQUENCY OF CONTROL
reactivity	no agglutination or haemolysis using inert AB-serum. Agglutination of cells sensitised with a weak IgG anti-D	each day
potency	an IgG antibody, preferably anti-D, standardised to give a titre about 64-128 by the protease technique, should show the same titre on repeated testing with different batches	each day

QUALITY CONTROL OF SALINE		
PARAMETER TO BE CHECKED	QUALITY REQUIREMENTS	FREQUENCY OF CONTROL
appearance	no turbidity or particles by visual inspection	each day
NaCl content	0.154 mol/l (= 9 g/l) as measured by conductivity or quantitation of Na^+ or Cl^-	each new lot
pH	pH 6.0 - 8.0	a. each new lot for buffered saline b. daily for non-buffered saline

QUALITY CONTROL OF LOW IONIC STRENGTH SALT SOLUTIONS (LISS)		
PARAMETERS TO BE CHECKED	QUALITY REQUIREMENTS	FREQUENCY OF CONTROL
appearance	No turbidity or particles by visual inspection	each day
pH	6.7 (range 6.5-7)	each new lot
conductivity	3.7 m.mol/cm at 23°C (Range 3.44-3.75)	each new lot

1.3 Quality control of techniques

Provided that the quality of equipment and reagents fulfil the requirements, false results are due to the technique itself, either because of inadequacy of the method or - more often - because of "operational errors" as a consequence of inaccurate performance or incorrect interpretation.

The quality control procedures recommended in this section are focussed on the techniques but they will of course disclose also poor quality of equipment and/or reagents.

QUALITY CONTROL OF ABO- AND Rh-TYPING			
	MINIMAL REQUIREMENTS FOR TESTING (1)	CONTROL SAMPLES	FREQUENCY
ABO-typing	use of anti-A and anti-B.AB-serum as a negative control if reverse typing cannot be performed	one blood sample of each of the following types: 0, A_1, A_2, B, A_1B and A_2B	each test series or at least once a day, provided the same reagents are used throughout
ABO-reverse-typing	use of A and B cells		
Rh(D)-typing (incl. D^u)	typing in duplicate using two different anti-D sera; use of the indirect anti-globulin test for D^u-confirmation in donors	one Rh(D) pos, one Rh(D) neg sample	
Rh-pheno-typing	typing in duplicate using two different antisera for each Rh-factor	for complete Rh-phenotyping: one sample of each of the following Rh-types: R_1r, R_2r, R'r, R"r and rr	

(1) These are to be regarded as absolute minimal requirements, made possible by the introduction of monoclonal reagents

QUALITY CONTROL OF RBC ALLOANTIBODY TESTING			
KIND OF TESTING	MINIMAL REQUIREMENTS FOR TESTING	CONTROL SAMPLES	FREQUENCY
(a) testing for immune anti-A and anti-B (in blood donors)	use of A_1- and B-RBC	serum samples with an amount of immune anti-A and immune anti-B respectively above and below the accepted antibody levels	each test series
(b) Testing for irregular alloantibodies (in donors)	use of tests which will detect strongly reacting antibodies of clinical significance	serum samples with known RBC-alloantibodies	occasional input by the supervisor of the laboratory
(c) testing for irregular alloantibodies (in patients)	use of at least - a saline test at 37°C - an enzyme test - the indirect antiglobulin test - or manual or automated testing with equivalent sensitivity	as for (b),	as for (b)
(d) cross-matching	use of at least - a saline test at 37°C - the indirect antiglobulin test - or manual or automated testing with equivalent sensitivity	as for (b).	as for (b)

1.4 Quality Control of Quantitation

For practical purposes, RBC antibody quantitation is confined to the quantitation of anti-D. It is recommended that this be carried out by automated techniques rather than by manual titration, the test serum being assigned an anti-D value expressed in International Units per millilitre after comparison with a curve derived from standard sera. All sera should be tested in duplicate as a minimum, and all national and in-house standards calibrated against the International Standard for anti-D. Records should be kept of the data derived from processing the standard sera, these figures should show no more variance than 2 standard deviations.

2. External quality control

The internal quality controls described above should be ~~completed~~ complemented by regular external quality control, ie participation in a proficiency testing programme.

In proficiency tests, coded "normal" and "problem" blood samples are distributed from a national or regional reference laboratory to the participants, usually twice to four times a year. The exercise can be limited to compatibility testing, since ABO-grouping, Rh-typing and -phenotyping as well as alloantibody detection will be automatically included. The proficiency test panel may consist of four to six blood samples, ~~whereby~~ the participants ~~are~~ asked to test each RBC against each serum (or plasma) for compatibility. The panel should be composed in such a way that compatible as well as incompatible combinations occur. The proficiency test may be completed by asking for titration of one or two of the detected antibodies.

In the reference centre the results are collated and accuracy scores determined. The ~~total of the~~ results should be communicated to all participating laboratories (in coded or uncoded form, according to ~~the~~ local agreement) in order to enable each laboratory to compare ~~the~~ own quality standard with that of a large number of other laboratories, including the reference centre.

If no proficiency programme is available in a particular geographical area, the laboratory should arrange mutual proficiency testing with another laboratory. Although such an external quality control will not be as informative as ~~the~~ participation in a comprehensive proficiency test programme, it will be a valuable ~~completion of~~ addition to the internal quality control procedure.

Selected references

1. European agreement on the exchanges of blood-grouping reagents, European Treaty Series No. 39. (1978)

2. Quality assurance in the blood transfusion laboratory, Guide No. 3, International Society of Blood Transfusion, Paris 1978.

3. Technical Manual, 8 ed. American Association of Blood Banks, Washington 1981.

4. Quality control in blood banking, B A Myhre and E I Goldstein, ed. by John Wiley and sons, New York/London/Sidney/Toronto, 1974.

5. Serological and Immunological Methods of the Canadian Board of Blood Transfusion Services, Eighth Edition, 1980.

Chapter VI.2: DISEASE SCREENING

General comments

The quality control of disease screening tests is unique in importance since it represents the testing of validity of quality control tests carried out on blood and blood products intended for transfusion. With one exception, the tests concerned involve those for the presence of direct body response to invasion by microbiological agents, and so collaboration with the appropriate reference microbiological laboratories is absolutely essential.

All testing of screening procedures should be divided into four sections.

a. Internal, day to day quality assurance covering both reagents and techniques.

b. External quality checks, in particular confirmation of postive findings and in addition confirmation of negative results where this is thought to be necessary in the setting up of a new technique or the testing of new reagents. Such confirmation should be carried out by the appropriate reference laboratory concerned with microbiological agents.

c. Occasional internal quality control exercises, using a panel of sera which have been built up by comparison with standards available.

d. Occasional external quality control exercises, involving the testing of a panel of sera circulated to laboratories by an approved reference institution.

1. Quality control of HBsAg testing

It is accepted that, though all blood and blood products will be tested by an approved third generation test for Hepatitis B surface Antigen, rapid testing to enable the urgent release of products for immediate transfusion may necessitate the use of a less sensitive technique, the results of this screening test to be confirmed later by the approved third generation test. Both methods, where used, must be controlled. National or international standards should be used in the assessment of new tests and in the selection of working standards for everyday use.

It is essential that positive control sera are inserted randomly into the routine of testing, so that the operator does not become accustomed to looking for a positive result at a particular place in any one batch of tests.

Positive results on donations should be checked by repetition, where possible by a different technique.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
3rd generation HBsAg test	pos. with 2 ng/ml standard	2 tests/run	screening lab.
rapid screening test for HBsAG	pos. with 10 ng/ml	2 tests/series	screening lab.

2. Quality control of syphilis testing

There is a continuing discussion over the need for a test for syphilis on blood donors, but most countries still require its performance. The nature of the test is invariably left to the transfusion centre carrying it out, but most centres use either a cardiolipin test employing a lecithin based antigen or a test employing a variant of the Treponemal pallidum haemagglutinin test (T.P.H.A.). Variants of the cardiolipin test may be employed either manually or on blood grouping machines, both techniques should be controlled where both are used. As with tests for Hepatitis B surface Antigen , it may be that a rapid manual test is carried out for the clearance of blood and blood products for immediate and urgent issue. Where the test is repeated on this donation in a more routine fahsion on an automated piece of apparatus, both tests should be controlled in the normal way.

The relatively complex nature of syphilitic serology means that a wide panel of sera from different types of case must be used in occasional external quality control and in the assessment of any new batch of reagent or of a new technique. This assessment panel of sera must contain at least one sample from an early untreated case of syphilis, and one from a treated case. Each type of serum in the panel must be tested at differing dilutions, and the new reagent adjusted to afford the maximum chance of detecting a positive reaction.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
lecithin-based reagent, and TPHA reagents	detection of weak pos. serum	minimum - start and end of run	grouping lab or screening lab.
new reagent batch	detection of panel of pos. sera.	each batch	screening lab.

3. Quality control of malarial antibody testing

The only test presently available which is suitable for routine use in a transfusion centre is the indirect fluorescent antibody technique (I.F.A.T.), employing slides coated with malarial antigen. At the moment, it is possible to employ slides coated only with either Plasmodium falciparum or Plasmodium fieldii. An I.F.A.T. test should be carried out against sera from all donors with a significant history (see Chapter I). Postivitity at a titre of 1 in 20 or more may be considered significant.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENT (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
malarial IFAT test - each antigen	detection of weak pos. serum (titre 1/20)	each run	screening lab

4. Quality control of cytomegalovirus (C.M.V.) testing

Testing for CMV IgG antibody is theoretically possible by techniques employing radioimmunoassay, enzyme linked immunosorbent assay (E.L.S.A.), complement fixation, anti-complementary immunofluorescence, and passive haemagglutination. In the screening laboratory of a transfusion centre, choice will inevitably be aimed at a simple reliable test with a relatively high sensitivity, and current evidence is that ELISA may come to replace complement fixation as the test of choice.

There are two avenues of approach in testing for IgG antibody to CMV.

a. The screening of all donations for CMV negativity, to enable the building up of a panel of CMV negative donations for use in highly susceptible cases.

b. The screening for donations with a high titre of CMV antibody which would be suitable for making therapeutic immunoglobulin.

Control of the screening procedure employed will obviously depend upon the desired end product, but is achieved by logical choice of titre in the positive control sample.

PARAMETER TO BE CHECKED	QUALITY REQUIREMENTS (SPECIFICATION)	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
CMV-negativity test	neg. with control serum titre 1/30	each tray in ELISA test	screening lab.
High titre CMV donor screening test	pos. with control serum titre 1/128	each tray in ELISA test	screening lab.

Chapter VII: TRANSFUSION PRACTICES

1. Pretransfusion measures

1.1 Identification of patient at blood sampling

Samples for blood typing and compatibility testing must have a clear-cut identification. The following rules are recommended.

The patient identification shall be indicated on the tube label before the sample is drawn. Normally, name and birth date will serve as sufficient identification. In newborn infants, the sex and the number on the identification wrist band is noted in addition. ~~Concerning~~ In patients with unknown identity, a unique series of numbers may be used on wrist bands and attached to the patient according to specified rules.

In immediate relation to sampling the data on the tube label must be checked either by asking the patient to tell his/her name and birth date, or by reading these ~~data~~ or other ~~above specified~~ data, on a wrist band ~~securely~~ attached to the patient, ~~under safe precautions~~. This identity control shall be done even if the patient is known to the investigator, who with his/her signature on the order form shall certify that it has been performed.

1.2 Blood group serological investigations

These include blood typing, antibody screening and compatibility testing before transfusion of red cell products.

1.2.1 ~~2.~~ Blood typing

The ABO and Rh_o(D) blood type and, when needed. other blood types, shall be performed before transusions except in emergencies when a delay may be life-threatening. It is further recommended ~~to make an~~ antibody screening (that) for the detection of irregular erythrocyte antibodies in ~~connection~~ with (conjunction) patient blood typing. be carried out

The normal procedure shall be to make the investigation in due time before expected transfusions, eg in elective surgery. ~~Acute investigations may be done in emergencies~~.

The laboratory must have a safe procedure of ~~blood typing~~. It shall double-check the data at issuing a ~~certificate~~ containing patient identification, blood group and other ~~serological~~ findings which may be important in transfusions. It is ~~recommended~~ that the certificate is enclosed in the respective patient's ~~record~~.

1.2.2 ~~3.~~ Compatibility testing

The compatibility between donor and recipient ~~has to~~ must be assured in transfusions of products containing ~~considerable~~ amounts of red cells visible to the naked eye.

The laboratory must have a secure procedure for blood typing which will include double-checking of data at the time of issuing a report on the blood group, and other serological findings, for inclusion in the patient's clinical record

The basis for compatibility is a correctly determined ABO and Rh (D) blood type in donor and recipient. When irregular erythrocyte antibodies are present in the patient's circulation, ~~the transfused red cells have to be compatible with respect to the corresponding blood group specifities.~~ only red cells which lack the corresponding antigens should be selected for transfusion.

~~Selection of compatible units shall be done on the basis of blood type and other serological findings.~~

Cross match between donor red cells and recipient's serum shall be done in all cases with irregular erythrocyte antibodies. It is recommended as a routine procedure even when no antibodies have been found but may be omitted if other measures (eg, type and screen, see below) are taken to guarantee safety. The cross-match shall include a sufficiently safe technique to detect irregular erythrocyte antibodies, such as the indirect antiglobulin technique.

A type and screen procedure, where used as a replacement for cross-match, must include:

1. a safe checking procedure when the blood units are delivered
2. test cells which cover all antigens, preferably homozygous, corresponding to the vast majority of clinically important antibodies, and
3. sufficiently sensitive techniques for the detection of erythrocyte antibodies.

2 Transfusion

2.1 Security measures

The medical person who gives the transfusion to a patient is responsible for the control of identity and other security measures.

Control of identity shall be done either by asking the patient to tell his/her name and birth date or by reading these or other ~~types of~~ details identification on a wrist-band which has been attached to the patient according to ~~certain~~ well specified rules.

Control of compatibility between patient and blood unit shall be done by

1. comparing the identity information received from the patient with data on the laboratory's certificate of compatibility testing (if appropriate),

2. checking the certificate of the patient's blood group against the blood group notation on the blood unit label, and

3. checking that the expiry date of the blood unit has not been passed.

The identification number and nature of the used units shall be noted in the patient's record so that the donors can be traced if necessary.

2.2 5. The risk of air embolism is possible under some circumstances

At blood transfusion air embolism ~~can occur~~ if the operator is not sufficiently careful and skilful. When rigid containers (glass bottles) are used the speed of the transfusion shall not be increased by raising the pressure in the container.

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An air vent shall not be ~~entered~~ into a flexible container (plastic bag).

If the transfusion set incorporates a filter situated in the lower part of the drip chamber, the blood level should be above the filter. It is important that the transfusion sets are of ~~sufficient~~ quality, without leaks, so that no air can be sucked into the system by the blood flow. | good |

Infusion sets with two inlet ports combined with a y-connector may cause danger by suction of air into the system when only one of the ports is used and the other is not sufficiently well closed. Care shall be taken, therefore, to keep the unused port safely closed during transfusion. If both ports are used simultaneously, both of the two connected units ~~have to~~ must be collapsable and shall be non-vented.

2.3 ~~8.~~ Handling of frozen units

Frozen units have to be handled with great care since ~~they~~ the containers may be brittle and may easily crack at low temperatures.

After thawing of frozen plasma the content shall be inspected to ensure that all cryoprecipitate has been dissolved and that the container is not damaged. Containers which leak ~~have to~~ must be discarded. Thawed preparations should be transfused as soon as possible.

2.4 ~~7.~~ Warming of blood

Rapid transfusion of cold blood through a central venous catheter may in itself be dangerous. ~~Therefore, warming devices are often used for this purpose. The equipments have to be controlled that over-heating does not occur since heat-denatured blood is a deadly threat to the patients.~~ Any warming device used must be controlled and monitored to ensure that over-heating of the blood does not occur.

2.5 ~~8.~~ Addition of drugs to blood

Because of the risk of damage to the blood constitutents no drugs or infusion solutions may be added to blood units unless it has been clearly shown that the addition is not dangerous either to the blood or to the integrity of the system.

3 ~~9.~~ Transfusion complications

Complications may occur either in direct relation to the transfusion or with a delay of hours or days. All serious complications shall be investigated, mild reactions according to the judgement of the responsible physician.

3.1 When a serious complication after transfusion of red cell preparations has occured and the patient shows chills, fever, breathing difficulties, shock, back pain (which cannot be related to the patient's underlying disease) the following shall be observed.

3.1.1 Check that the ABO and Rh blood group of the blood unit label is compatible with the patient's blood group certificate. If irregular antibodies outside the ABO and Rh$_o$(D) systems are present, check if blood of compatible blood type has been used.

~~In the case of repeated febrile transfusion reactions, it is recommended to use leucocyte poor blood for subsequent transfusions.~~

3.12 A blood sample taken before the transfusion (may be available at the compatibility testing laboratory), a blood sample taken after the transfusion, the blood unit with the transfusion set maintained in site, and the pilot tube shall be sent for investigation. It is recommended that this includes a direct smear and a bacterial culture test of the content of the blood unit, a serological investigation for blood group incompatibility, and inspection of the blood unit for any damage.

3.2 In the case of repeated, febrile non-haemolytic transfusion reactions, the use of leucocyte-poor blood for subsequent transfusions is recommended, preferably after investigation for the presence of antibodies to leucocyte antigens.

Chapter VIII: CONTROL OF EQUIPMENT

1. Environmental control

a. Premises for donor sessions

When sessions are performed by mobile teams, a realistic attitude towards environmental standards is necessary. The premises should satisfy common sense requirements for the health and safety of both the mobile teams and the donors concerned, with due regard to relevant legislation or regulations. Points to check should include adequate heating, lighting and ventilation, general cleanliness, provision of a secure supply of water and electricity, adequate sanitation, compliance with fire regulations, satisfactory access for unloading and loading of equipment by the mobile team, adequate space to allow free access to the bleed and rest beds.

Where the sessional venue is permanent and under the control of the transfusion centre, provision should additionally be made for proper cleaning by, for example, the use of non-slip, washable floor material installed without inaccessible corners, avoidance of internal window ledges, etc. Where possible, ventilation should be by an air-conditioning unit to avoid the need for open windows. Air changes, together with temperature and humidity control, should be adequate to cope with the maximum number of people likely to be in the room, and with the heat output from any equipment used. A maximum/minimum thermometer should be installed and checked daily by the quality control division.

b. Routine laboratories

The same general principles apply as those suggested for permanent sessional venues. The aim must be to provide a comfortable working environment for the laboratory staff. Bench design, as well as flooring, should eliminate corners which would be difficult to clean. In addition to the control of temperature and humidity, excess noise must be avoided by the removal to a separate site of all excessively noisy pieces of equipment. Volatile and toxic materials must be handled in appropriate exhaust cabinets to avoid atmospheric pollution. A maximum/minimum thermometer should be installed and checked daily by the quality control division.

c. Computers and electro-mechanical devices

These items of equipment may have special requirements such as a more precise atmospheric control or the provision of a non-standard or stabilized electrial supply. Such requirements should be checked with the manufacturers and secured before installation. Where special environmental control is necessary, maximum/minimum and wet-bulb thermometers should be installed and checked daily by the quality control division.

d. Blood processing laboratories

At transfusion centre level, blood component production may be either a closed process, as in the case of the separation of cells and plasma in a multiple bag system, or open, as in the case of washed red cells. A closed process may safely be carried out in the normal type of environment described for routine laboratories.

Open processes must be carried out under stricter environmental control either by the use of laminar flow cabinets or in the pressurised system of a suite of clean rooms provided with air passed into the inner cubicle through high efficiency particulate air (H.E.P.A.) filters.

2. Equipment control

Assessment of the performance of blood transfusion equipment is mandatory on three specific occasions:

i. On installation of the machinery.

ii. After any repairs or adjustments which may potentially alter the function of the equipment.

iii. If ever a doubt arises that the machine is not functioning properly.

In addition to this, a schedule of routine and regular checking of machine function may be drawn up, the interval of testing for each particular machine depending on two main factors. These two factors are the frequency of use of the piece of equipment, and its expected "life" in the laboratory.

Assessment of the efficiency of blood transfusion equipment may be either direct or indirect. A direct assessment comes from the carrying out of pre-determined checks at regular time intervals, aimed at the control of the proper function of the piece of equipment. Indirect information may be obtained by other quality control measures such as the proficiency testing of personnel. Satisfactory performance in this sort of exercise is an indication of not only adequate function of the laboratory personnel, but of the equipment they use.

Inevitably, different schedules may be designed for different types of equipment in use. Each piece of equipment should have an individual record where the type of control, the date at which the control was carried out and the initials of the performer are recorded. Each person using the machine and the supervisor of the laboratory concerned should be informed in writing of the control schedules, and the appropriate head of department should check regularly that the controls have been carried out and any remedial action taken.

In addition to the performance of a regular schedule of quality controls, it must be remembered that regular maintenance of equipment forms an essential part of quality assurance. Many of the larger and more expensive items of laboratory equipment are subject to maintenance contracts with the manufacturer, these maintenance contracts should be very carefully worked out between the supplier and a legal representative of the user, and adhered to strictly thereafter. Where no maintenance contract exists for a piece of apparatus, collaboration between the scientific and technical staff of the transfusion centre and the relevant engineering staff should ensure that a proper schedule of planned preventive maintenance is drawn up for each piece of apparatus, in addition to the schedule of quality control measures which will be carried out by the scientific and technical staff. The meticulous recording of maintenance and repairs is just as important as the recording of the results of specific quality control tests for any piece of equipment.

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Proper education of the personnel using blood transfusion laboratory equipment is essential. The staff must know not only how the tests are to be done, but why they must be done, and they should be fully instructed not only in the performance of quality control tests but in the rapid detection of departures from the norm. In almost every case, normal functioning of the machine is defined by the manufacturer and confirmed at assessment on installation. Meticulous charting of quality control measures will be the best method of quick recognition of deterioration in function.

The following list of equipment and suggested quality control checks does not include blood grouping machines. This omission is quite deliberate since in any blood transfusion service the incidence of regular donors varies up to approximately 90%. It follows that the amount of control material going through the blood grouping machine of a transfusion centre is without parallel in any other laboratory circumstance. Where such a machine is installed in a hospital laboratory which deals with patients almost exclusively of an unknown group, the user is recommended to contact the appropriate blood transfusion centre or reference laboratory for a supply of the weaker groups which may cause difficulty with blood grouping machines, for instance A_2B and Du. Under these circumstances, of course, a check on the machine function must be carried out daily by the passage through the system of an adequate number of known control cells, at the beginning and end of the run at the very least.

EQUIPMENT	METHOD OF CONTROL	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
Blood bag refrigerator Cold room Freezer containing transfusates	Graphic recorder plus independent audible alarm	Daily	Technician
Laboratory refrigerator Laboratory freezer Incubators Water baths	Thermometer Precision thermometer	Daily Semi-annually	Technician Technician
Blood bag centrifuge	Precision RPM meter plus stopwatch to control speed, acceleration & retardation	Bimonthly	Engineering
Table centrifuge	RPM meter plus stopwatch to control speed, acceleration and retardation.	Occasionally	Technician
Coombs' automatic washer	Anti-D sensitised cells	Every run	Technician
Haemoglobin photometer	Hb working standard Hb calibration standard Hb quality control sample	Every 10th sample Daily Monthly	Technician Technician Technician

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EQUIPMENT	METHOD OF CONTROL	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
Gamma and beta counter	Background count Working standard in each well ^{129}I standard	Daily Daily Semi-annually	Technician Technician Technician
Cell counters	Calibration: reference sample Drift: working standard	Daily Every 20th sample	Technician Technician
Automatic pipettes	Dye- or isotope-labelled protein (1% variation allowed)	Each batch of tips	Technician
Balance	Analytical-control weights 5mg - 100g Preparative-control weights 100mg - 100g	Semi-annually	Technician
pH meter	Control solutions pH 4 - 7, 7 - 10	Each time of use	Technician
Densitometer	Standard electrophoresis graph	Semi-annually	Technician/ Chemist
Spectrophotometer	Linearity: 340 nm $K_2 Cr_2O_7$ 405 nm p-nitrophenol 700 nm Cu SO_4 Light scattering: 240 nm 260 nm NaI Wavelength scale: holium filter Quality control sample	Semi-annually " " " " Anually	Technician/ Chemist " " " " "
Platelet agitator	Thermometer Frequency of agitation	Daily Monthly	Technician Technician
Laminar flow hood and HEPA filters	Air pressure meter ~~Particular~~ Particule counter	Daily Trimonthly	User Microbiologist

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EQUIPMENT	METHOD OF CONTROL	FREQUENCY OF CONTROL	CONTROL EXECUTED BY
Blood mixer (swing)	Control weighing	Bimonthly	Engineering
Spring balance for bags	Control weighing	monthly	Engineering
Blood bag tube sealer	Pressure on bag and tube	Every bag	Technician
Blood transport container	Thermometer	Every time of use (on receipt)	Technician

3. Reproducibility of results

A check of reproducibility is based on two principle concepts:

a. The determination of accuracy of the equipment by the testing of a reference standard.

b. The determination of the drift occurring during the routine day by the testing of working standard at intervals.

Since examination of reproducibility implies that the test concerned is quantitative in nature, it follows that numerical values can be obtained for each type of control applied. Graphic plotting of the results of tests for accuracy and drift should be carried out so that a gradual deterioration in performance can be quickly identified and corrected.

Where a numerical value cannot be ascribed to the result of quality control tests, reproducibility can best be assessed by the inclusion in the schedule of testing of appropriate strong and weak positive controls at regular intervals.

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Chapter IX - RECORD KEEPING

With records of results of quality control procedures a distinction should be made between records of results which may require prompt or almost immediate correction, and records of results which can only be evaluated statistically or by summing up over a certain period.

Examples of the former are given throughout the preceding chapters. Most typical examples are those where a quality control procedure is prescribed for each unit of a blood product or for each laboratory procedure.

Examples of the latter records (summary records) are given below. The director of the transfusion service or a specially designated person should evaluate statistical variations from the usual pattern or from given normal values. Evaluation may take place monthly or quarterly, and annually.

Rejection or deferral of blood donors (numbers, reasons).

Donor reactions (numbers, sex, age, reaction category).

Unsatisfactory ~~bleedings~~ donations (numbers, category).

Positive tests for hepatitis (numbers, specific, false).

Discarded units of blood and blood components (numbers, categories, reasons).

Outdating of units of blood and blood components (for each category, the outdating ~~in~~ as a percentage of the number of useable units) ~~in each category~~.

Transfusion complications (numbers, category) including transfusion-associated hepatitis.

External complaints (number, origin, category).

Clerical errors (numbers, category).

There are a number of other records which are important in transfusion centres but which do not deal directly with quality control. Examples are: routine working documents, blood group documents for patients and donors, the proportion of cross-matched units to used (transfused) units of blood products, statistics of issue and return of blood units etc. Many of these records are mainly used for administrative or organisational purposes.

It is essential that the recording system ensures a continuity of documentation of all procedures performed, from the blood donor to the recipient, ie each significant step should be recorded in a manner that permits tracing a product or procedure from the first step to final disposition.

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Records of quality control procedures must include identification of the person(s) performing the tests or procedures. Any corrective actions taken must also be recorded. If corrections in records are necessary, the original recording must not be obliterated, but must remain legible. Records of quality control procedures should be signed by the supervisor.

Records should be kept for a period according to local or national requirements. In many countries the minimum retention period is five years.

APPENDIX I

Resolutions and Recommendations adopted by the Committee of Ministers of the Council of Europe in the field of blood transfusion and histocompatibility

Resolution

(78) 29 Harmonisation of legislations of member States relating to removal, grafting and transplantation of human substances (11 May 1978)

Recommendations

R (80) 5 concerning blood products for the treatment of haemophiliacs (30 April 1980)

R (81) 5 concerning antenatal administration of anti-D immunoglobulin (17 March 1981)

R (81) 14 on preventing the transmission of infectious diseases in the international transfer of blood, its components and derivatives (11 September 1981)

R (83) 8 on preventing the possible transmission of acquired immune deficiency syndrome (AIDS) from affected blood donors to patients receiving blood or blood products (23 June 1983)

R (84) 6 on the prevention of the transmission of malaria by blood transfusion (28 February 1984)

R (85) 12 on the screening of blood donors for the presence of AIDS markers (13 September 1985)

Publications in the Blood Transfusion Field

The production and use of cellular blood components for transfusion (1976)

The indications for the use of albumin, plasma protein solution and plasma substitutes (1978)

Preparation and use of coagulation Factors VIII and IX for transfusion (1980)

Assessment of the risk of transmitting infectious diseases by international transfer of blood, its components and derivatives (1981)

European co-operation in the field of blood. Miscellany on the occasion of the 20th anniversary of the Committee of experts on blood transfusion and immunohaematology (1983)

Essential aspects of tissue typing. Preparation, use, storage of reagents and standardisation of complement (1983)

Study of the current position of the training programmes for future specialists in blood transfusion in member States of the Council of Europe and in Finland (1985)

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