External Quality Assessment of Transfusion Laboratory Practice

Guidelines on Establishing an EQA Scheme in Blood Group Serology

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Preface

Blood transfusion is an essential and life-saving support within the health care system, yet the safety of transfusion is not assured globally, particularly in countries with less developed health care systems. Threats associated with transfusion include:

- Inadequate supplies of blood and blood products to meet the needs of all patients requiring transfusion
- Risk of transfusion-transmitted infections
- Technical and clerical errors in the processing and testing of blood
- Inappropriate prescribing of blood and unnecessary transfusions
- Errors in the administration of blood and blood products.

The World Health Organization (WHO) advocates the following integrated strategy to national health authorities to promote the safety and accessibility of blood and reduce the risks associated with transfusion.

1. Establishment of a well-organized, nationally-coordinated blood transfusion service (BTS) that can provide adequate and timely supplies of safe blood for all patients when needed.
2. Collection of blood only from voluntary non-remunerated blood donors belonging to low-risk populations and selected using stringent criteria.
3. Quality-assured testing of all donated blood for transfusion-transmissible infections, including HIV, hepatitis viruses, syphilis and other infectious agents, blood groups and compatibility.
4. Reduction in unnecessary transfusions through the appropriate clinical use of blood and the safe administration of blood and blood products.
5. Implementation of effective quality systems, covering all aspects of BTS activities, including quality management, development and implementation of quality standards, effective documentation systems, training of all staff and regular quality assessment.

Through advocacy, training, materials development and technical support, WHO supports its Member States in implementing each element of this strategy for blood safety.

WHO QUALITY MANAGEMENT PROGRAMME

Recognizing that effective quality systems are required to ensure consistent quality and the safety of blood transfusion, WHO has established the Quality Management Programme (QMP) for blood transfusion services. The QMP is a major global initiative to support Member States in ensuring the overall safety of the transfusion process, from the recruitment of blood donors to the transfusion of blood and blood products and follow-up of the recipients. It was developed to support national capacity-building in the quality management of blood transfusion services and the implementation of quality systems. An Aide-Mémoire: *Quality Systems for Blood Safety* outlines the requirements for quality systems and Recommendations on *Establishing Quality Systems for Blood Transfusion Services* provide practical guidance in the establishment of quality systems.

Since the launch of the QMP in 2000, BTS directors and quality managers from over 100 countries have been trained in the basic principles of quality management for blood transfusion services. Initially conducted at regional and inter-regional levels, Quality Management Training (QMT) has cascaded to national and local levels, with follow-up and support from WHO, WHO Collaborating Centres and other centres of excellence designated as Regional Quality Training Centres. A QMT *Facilitator's Toolkit* provides a standardized curriculum and training materials to ensure consistency in teaching in all regions of the world.

EXTERNAL QUALITY ASSESSMENT

The QMP also addresses quality assessment, an integral component of a quality system. External quality assessment (EQA) is an important, but very specific and specialized, part of the monitoring process. Formal EQA schemes provide regular, independent assessment of performance to identify problems and weaknesses with the objective of improving performance and ensuring blood safety. EQA schemes for blood transfusion safety focus primarily on blood group serology and testing for transfusion-transmissible infections.

WHO has established regional EQA schemes in blood group serology and virology to increase access by BTSs to reliable external quality assessment. As the number of participating laboratories increases, it is expected that more countries will wish to establish national EQA schemes. These guidelines have been developed to assist institutions in designing, planning and implementing EQA schemes in blood group serology. Guidelines on the establishment of national EQA schemes for HIV serological testing are also available from WHO.

For further information on the Quality Management Programme and WHO EQA schemes, please contact Blood Transfusion Safety, Department of Essential Health Technologies at bloodsafety@who.int.

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Introduction

external quality assessment: The external assessment of a laboratory's performance using samples of known, but undisclosed, content and comparison with the performance of other laboratories.

quality: The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

Ability of a set of inherent characteristics of a product, system or process to fulfil the requirements of customers and other interested parties – ISO 9000 (2000).

quality system: The organizational structure, processes, procedures and resources needed to implement quality requirements.

external quality assessment scheme (EQAS): A recognized scheme for organizing EQA. This can be a local scheme or may be organized at national, regional or international level.

External quality assessment (EQA) in blood transfusion laboratory practice is an important component of a quality system for blood transfusion services. EQA is an external assessment of a laboratory's performance in testing samples of known, but undisclosed, content and comparison with the performance of other laboratories. It is designed to raise standards of performance in blood transfusion services, reference centres, hospital blood banks and other laboratories undertaking blood group serology testing for diagnostic purposes. It also helps to ensure the provision of appropriate, compatible blood and blood products for transfusion. Information generated by EQA provides an opportunity for continuous quality improvement through the identification of laboratory errors and the implementation of measures to prevent their recurrence. Thus EQA plays a vital role in making blood safer.

WHO plays an active role in advocacy to promote the establishment of EQA schemes and also encourages participation by blood transfusion laboratories in these schemes. National health authorities are urged to recognize the importance of EQA and support the implementation of schemes at national, state, provincial and district levels. Professional bodies are encouraged to endorse and support the establishment of EQA schemes.

External Quality Assessment of Transfusion Laboratory Practice has been produced to support WHO Member States in establishing and operating EQA schemes in blood group serology. It has been designed for use by national health authorities and EQA organizing institutions in the development of EQA schemes at national, state, provincial and district levels. It will also give participating laboratories an insight into the organization of EQA schemes in blood group serology and an understanding of the benefits of participation.

These guidelines are designed to support the establishment of EQA schemes for blood transfusion services at different stages of development. A phased approach should be considered if it is not possible initially to implement all the elements described here. The establishment of even a simple, small scheme can have a significant impact in raising standards. When establishing an EQA scheme in blood group serology, the most clinically important tests should be included first; the range of tests can then be expanded as the scheme is further developed.

The guidelines describe the principles for establishing and operating an EQA scheme in blood group serology. EQA schemes should be organized in accordance with these principles, although due consideration should also be given to any existing quality systems and regulatory mechanisms for BTSs and other laboratories.

1

External quality assessment

process: A series of steps or actions that lead to a desired result or output.

System of activities which uses resources to transform inputs into outputs – ISO 9000 (2000).

procedure: Specific activity that forms the basic unit of a process.

Specified way to carry out an activity or a process – ISO 9000 (2000).

haemovigilance: The monitoring, reporting and investigation of adverse incidents related to all blood transfusion activities.

test: Technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure – ISO 9000 (2000).

THE NEED FOR QUALITY IN BLOOD TRANSFUSION SERVICES

The provision of safe, appropriate and compatible blood and blood products for transfusion involves a number of processes. There is a risk of error in each process from the selection of blood donors and the collection, processing and testing of donated blood to the testing of patient samples, the issue of compatible blood and its administration to the patient. The blood transfusion laboratory plays a key role in this "transfusion chain" and quality failures in testing or other laboratory procedures can have serious implications for the recipients of blood and blood products.

Haemovigilance schemes, such as the Serious Hazards of Transfusion (SHOT) scheme in the United Kingdom, have shown that laboratory errors can lead to major morbidity or mortality in patients through the transfusion of incompatible or inappropriate blood.

Errors in the laboratory may be due to:

- Inadequate procedures for identification, leading to the mis-identification of patient or donor blood samples or units of blood
- Incorrect storage or inappropriate use of reagents
- Equipment failure
- Technical failure in serological testing
- Inaccuracies in recording or transcription
- Misinterpretation of results.

Errors often result from a combination of factors, with the original error being compounded by inadequate checking procedures in the laboratory or at the patient's bedside.

The aim of a blood transfusion laboratory in testing blood samples from patients and donors is to provide safe blood for transfusion. Transfusion laboratory practice relates to all processes and procedures put in place to achieve this aim. The implementation of a quality system in the laboratory minimizes errors and ensures that:

- Appropriate tests are performed on the correct samples
- Accurate results are obtained
- Correct blood product is provided for the correct patient at the correct time.

Accurate results are essential for blood group serology tests, such as ABO and RhD typing of the donor and patient, and compatibility testing. It is equally important that the results are transcribed, collated and interpreted correctly so that appropriate and compatible blood products are issued for transfusion.

EQA AS PART OF A QUALITY SYSTEM IN THE BLOOD TRANSFUSION LABORATORY

External quality assessment forms an integral part of the assessment of the overall quality system in a laboratory in which blood group serology is performed.

documentation: Written policies, instructions and records involved in providing a product or service.

Information and its support medium – ISO 9000 (2000).

standard operating procedure: Written instructions for the performance of a specific procedure.

internal quality control: Procedures that monitor the day-to-day reproducibility of test results and detect major errors in the analytical process.

audit: Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled – ISO 9000 (2000).

effectiveness: Measure of the extent to which planned activities are realized and planned results achieved – ISO 9000 (2000).

validation: Confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled – ISO 9000 (2000).

The key elements of a quality system are:

- Organizational management, including:
  - Quality policy and plan
  - Clear organizational structure
  - Designated individual(s) with responsibility for establishing and managing the quality system
  - Job descriptions for all staff
- National or international standards
- Documentation, including standard operating procedures (SOPs), and document control
- Training of all staff
- Assessment, including:
  - Evaluation, validation, calibration and maintenance
  - Internal quality control
  - Audit
  - External quality assessment.

Of particular importance to the blood transfusion laboratory are:

- Use of standard operating procedures
- Staff training
- Accurate and complete documentation
- Validation of equipment, reagents, techniques and, where applicable, software.

Assessment

Continuous quality improvement requires ongoing assessment and review of the effectiveness of all elements of the quality system, using both internal and external mechanisms, to ensure that the defined quality standards are being met consistently.

Internal assessment of the quality system in the laboratory includes:

- Full validation of all activities, processes, procedures, equipment, reagents and software prior to their introduction and use
- Regular monitoring of all critical activities where continuous measurement of the outcomes is both possible and appropriate

competency assessment: Process to assess an individual's skill and ability in performing a single procedure or set of related procedures.

- Use of specific control measures, such as quality control samples, to monitor the performance of critical activities
- Staff competency assessment
- Development of an internal audit system, using relevant standards or other regulatory/licensing requirements
- Development of a system for the reporting, investigation and analysis of errors, with effective corrective and preventive action.

External assessment of the quality system in the laboratory includes:

- Participation in an external quality assessment scheme
- External audit by a recognized, independent body.

EXTERNAL QUALITY ASSESSMENT

EQA is an effective way of identifying process problems within the laboratory and provides the laboratory with an objective view of its performance relative to other laboratories.

Participation in EQA involves testing sets of samples of known, but undisclosed, content that are sent to participating centres by the EQA scheme. Each participating laboratory receives an identical set of samples which should be processed in the same way as routine clinical samples to ensure that its performance in EQA accurately reflects its usual performance. Following the collation and analysis of results, each centre receives its own results, together with the anonymized results for all other participating centres, which enables it to compare its performance with other centres.

The measurement of performance through EQA enables the identification of any problems and deficiencies. As a result, the required corrective and preventive measures can be implemented. Thus, information generated by the scheme helps to improve the overall quality of the blood transfusion laboratory and the safety of the blood and blood products it issues for transfusion.

Even if a formal quality system is not in place, EQA can still be introduced into laboratory practice as part of a process of continuous quality improvement. However, EQA should not be used for assessing individual staff competency; this should be assessed against the performance of each standard operating procedure carried out by the staff member.

OBJECTIVES AND BENEFITS OF EQA

The overall objective of EQA is to improve standards of performance in blood transfusion laboratories. This can be achieved by raising awareness of the need for improvement, demonstrating the benefits of best practice and providing information, education and support for improvement.

Benefits to participating laboratories

The benefits of EQA to participating laboratories include:

- Comparison of their own performance with the performance of other participating laboratories

- Identification of problems relating to laboratory processes, techniques and reagents
- Provision of information and education to improve performance
- Encouragement of best practice
- Opportunities to enhance the credibility of the laboratory and increase public confidence
- Access to a network of laboratories for the exchange of information.

Benefits to health and regulatory authorities

The benefits of EQA to health and regulatory authorities include:

- Establishment of a network of blood transfusion laboratories with a known standard of performance
- Provision of useful information to assist in:
  - Setting standards
  - Reviewing testing strategies and technologies
  - Using resources effectively
  - Improving public confidence in the blood transfusion service
  - Supporting systems of accreditation.

accreditation: Process by which an independent and authorized agency certifies the quality and competence of an organization on the basis of certain predefined standards.

EQA is most effective in raising standards where the need for quality is recognized, especially when there is commitment from senior management to support the changes needed to improve performance. Participation in EQA can be an effective means of driving quality forward in situations where quality systems are not in place. EQA results can reveal poor performance and assist in identifying the need for standards, guidelines, education and training, and the resources required to support them.

EQA SCHEMES

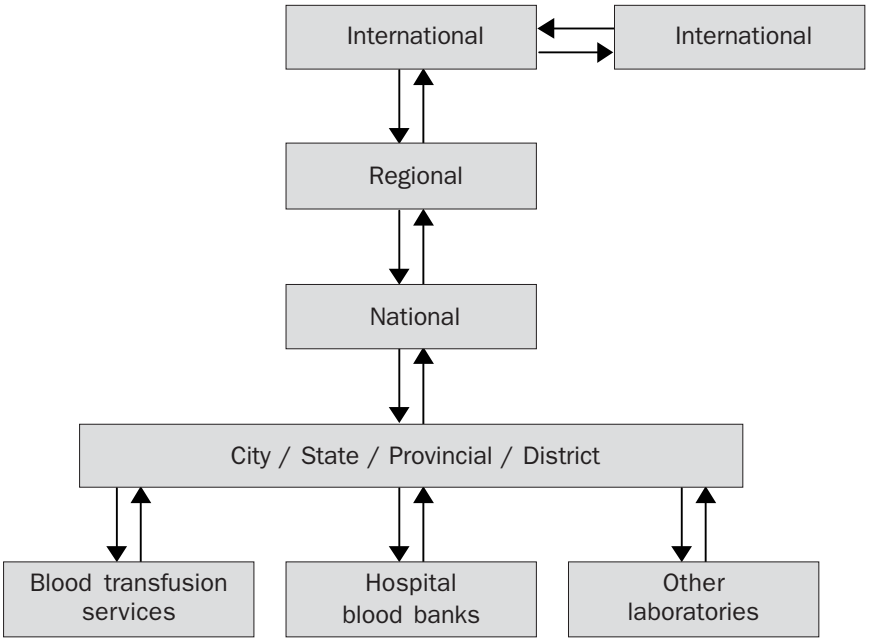
EQA should be organized as a formal and structured scheme in order to ensure effective planning and organization. This will ensure the uniform provision of samples for testing and a standardized approach to both the analysis and reporting of results and the monitoring of the performance of participating laboratories.

EQA should be made available to all laboratories in which blood group serology is performed, regardless of their size, workload or the complexity of the tests performed. Depending on the policy and regulatory systems currently in place, laboratories could participate in EQA on either a voluntary or a mandatory basis. Where participation is voluntary, laboratories should be actively encouraged to register for EQA of all tests that they routinely perform.

Figure 1 shows how a network of EQA schemes can be developed at international, regional and national levels. At each level, the scheme provides EQA, advice and support to its participating laboratories and, in turn, has its own performance monitored through participation in another EQA scheme.

WHO organizes EQA schemes in blood group serology at international and regional levels and supports the establishment of national EQA schemes based on country needs. At national level, schemes can be organized at

Figure 1: Network of EQA schemes



state/provincial/district/city level with participation by blood transfusion services, hospital blood banks and other laboratories or clinics undertaking blood group serology testing. Maximum benefit will be derived from an EQA scheme in which most participating laboratories are at a similar level of development.

When establishing a new EQA scheme in blood group serology, it can be helpful to seek information and support from WHO or other well-organized EQA schemes. At national level, it is advisable to investigate existing EQA schemes in other areas of pathology and the possibility of sharing organizational infrastructure, facilities and resources.

2

Establishing an EQA scheme in blood group serology

The establishment of an EQA scheme could be initiated by the national health authority, blood transfusion service, professional body or interested individuals. An organizing institution and a scheme organizer should be identified and an advisory committee should be constituted to oversee the establishment of the scheme and provide guidance on planning and organization.

An effective EQA scheme requires the commitment and support of the national health authority, professional bodies, the organizing institution, the EQA scheme organizer, the supplier of material for EQA exercises and participating laboratories. The success of the scheme depends on the trust and cooperation of all involved. In particular, the involvement of participating laboratories is vital in the organization of the scheme.

The roles and responsibilities of all involved should be clearly defined in order to ensure the effective operation of the scheme.

ORGANIZING INSTITUTION

The establishment of an EQA scheme for transfusion laboratory practice, at whatever level, requires the designation of an organizing institution to set up and operate the scheme. The organizing institution could be identified by government, the national regulatory authority, WHO or national professional bodies. It should be a reputed institution with suitable facilities and expertise in blood transfusion laboratory practice. In order to avoid any conflict of interest, an organization with commercial interests in supplying laboratory equipment or reagents related to blood transfusion should not be designated as the organizing institution.

Establishing an EQA scheme provides an opportunity for the organizing institution to become part of a network of laboratories for the exchange of information; this may also bring recognition to the institution.

The organizing institution should participate in a recognized international or regional EQA scheme in blood group serology. It should be able to demonstrate a satisfactory performance and also show that an effective quality system is in place.

The facilities and resources required for an EQA scheme include:

- Space
- Equipment
- Staff
- Technical support
- Administrative support
- Reliable source of exercise material
- Information management system.

Ideally, all the required facilities and resources will be provided by the organizing institution. However, it is important to avoid compromising the quality of the scheme by attempting to obtain them all from within one institution, if this is not feasible. If facilities are sought from different centres for an EQA scheme, an effective system of coordination will be required.

EQA SCHEME ORGANIZER

The EQA scheme organizer should be a professional who is respected by peers and the professional community and who has extensive knowledge and experience in transfusion laboratory practice. He/she should be knowledgeable of best practice in blood group serology and aware of common practice in different types of laboratories. In-depth knowledge and understanding of blood group serology is crucial to ensure the planning of effective exercises. The organizer should have an insight into possible causes of error and be able to offer effective advice, when required. Good communication skills and an ability to encourage and motivate participants are also essential.

The scheme organizer should be fully committed to EQA. If he/she is also employed in a participating laboratory, a mechanism should be put in place to ensure that there is no conflict of interest.

Organizing and managing an EQA scheme in blood group serology requires a large commitment of time and must therefore be adequately recognized and resourced. The tasks undertaken by the organizer of an EQA scheme are diverse and challenging. However, he/she will have an opportunity to learn new aspects of transfusion laboratory practice through interaction with participating laboratories and other organizations involved in blood transfusion safety.

Responsibilities

The scheme organizer is responsible for the general management, operation and ongoing development of the scheme, including the following activities.

1 General management:
   - Identifying the number of staff required and their training needs
   - Selecting staff and allocating staff time

- Financial management of the scheme
- Convening advisory committee meetings
- Communicating with suppliers, participating laboratories, the advisory committee, regulatory authorities, the media and, where applicable, accreditation authorities
- Ensuring the provision and use of a suitable information management system (manual or computerized) for the scheme
- Implementing, maintaining and auditing the scheme's quality system
- Preparing annual reports
- Preparing annual financial statements
- Handling complaints and taking corrective action
- Attending and presenting data at meetings of participating laboratories
- Promoting the scheme.

2 Operation of the scheme:
- Maintaining an up-to-date information manual for participating laboratories
- Devising exercises and sourcing exercise material
- Verifying data entry, analysing results, assigning scores and preparing reports
- Reporting to participating laboratories on any identified problems and advising on ways of improving performance
- Monitoring trends in performance.

3 Ongoing development of the scheme:
- Keeping up to date with developments in transfusion laboratory practice in blood group serology
- Initiating and implementing changes, as required, to ensure the continued relevance of the scheme
- Developing the education and training function of the scheme.

ADVISORY COMMITTEE

An advisory committee will be invaluable in the design, planning and implementation of the scheme. The membership of the advisory committee should comprise:

- EQA scheme organizer
- Selected experts in blood group serology
- Representatives of:
  - Institutions supplying bulk material for exercises
  - Health authorities
  - Participating laboratories
  - Professional bodies.

Once the EQA scheme is established, the advisory committee should continue to give direction for its effective continuation.

To ensure effective decision-making and communication, the size of the committee should be limited and members who will participate actively should be selected. The number and timing of advisory committee meetings will depend on the size of the scheme and the frequency of the distribution of exercises, but at least two meetings per year will be required.

The committee should make annual plans for exercises to facilitate the procurement of exercise material. Specific details of forthcoming exercises should be discussed at each meeting. Members of the advisory committee should maintain confidentiality of scheme information, including the content of exercises, especially if their own laboratory participates in the scheme.

Functions and responsibilities

The functions and responsibilities of the advisory committee include:

1 Setting policy on:
   - Strategy and direction of the scheme
   - Rules of participation
   - Tests to be included for assessment
   - Methods by which the definitive "correct answers" will be established
   - Principles of scoring and defining poor or unsatisfactory performance
   - Action to be taken on unsatisfactory performance
   - Complaints procedure
   - Promotion of the scheme
   - Role of the scheme in education and training.

2 Providing professional, scientific and medical guidance on operational matters, including:
   - Planning the aims and content of each exercise
   - Agreeing on the content of reports
   - Dealing with specific questions
   - Reflecting the views of participating laboratories
   - Reviewing complaints
   - Promoting the educational and training role of the scheme.

TECHNICAL AND ADMINISTRATIVE SUPPORT

Technical and administrative support is required to ensure the smooth running of the EQA scheme. This may be obtained within the organizing institution by the redesignation of existing staff, the appointment of suitably qualified staff or by contracting to outside agencies.

Technical and administrative tasks include:

- Processing material: e.g. filtering serum, suspending red cells in preservative
- Testing exercise material to ensure its suitability and documenting the results

- Dispensing and labelling exercise material
- Packing and dispatching questionnaires, exercises and final reports
- Organizing couriers and postal services
- Entering and analysing results and other information
- Invoicing participating laboratories for registration fees, if applicable.

INFORMATION MANAGEMENT SYSTEM

The requirements for information processing will depend on the scale and scope of the individual scheme. It is possible to operate an EQA scheme without any information technology, but the use of a computerized system makes essential tasks such as producing results forms much easier and allows for a more complex analysis of results.

It is ***essential*** to be able to:

- Create a database (manual or electronic) of the details of participating laboratories, including contact names, addresses, confidential registration codes and tests to be assessed
- Prepare exercise documentation, including letters, instructions, results forms and address labels
- Record the results from participating laboratories, using confidential registration codes
- Perform basic analyses, including comparison of each individual participating laboratory's results with the expected results and the collation of the overall results
- Prepare reports with the expected results, the individual results of each participating laboratory and other overall analyses or comments.

It is ***desirable*** to be able to:

- Analyse results within defined groups, such as laboratories using a particular technique
- Report data in different formats, such as histograms and scatter charts
- Generate scores for performance monitoring and cumulative scoring
- Search the database for specified criteria.

Specialized computer software can be developed, but many of these functions can also be achieved by the use of standard commercial software packages.

SOURCES OF EXERCISE MATERIAL

Providing exercise material for blood group serology can pose problems since red cells are required in addition to serum or plasma. In order to maintain the stability of the red cells, the supplier must identify, test and process the exercise material for use within a short time-scale.

Exercise material should be obtained from blood transfusion services, where possible, since donor blood is ideal as exercise material. It is

readily available in large volumes and is tested for transfusion-transmissible infections (TTIs) in accordance with local regulations. However, the ethics surrounding its use should be clarified and informed consent must be obtained from the donors. Finding the required number of donations containing antibodies of clinical significance could prove to be difficult. When no suitable donor material is available and patient material has to be used, full testing for TTIs must be performed and informed consent obtained.

If exercise material is obtained from outside the organizing institution, such as from another BTS or a commercial company, the supplier should be selected according to its ability to make reliable provision of the quantity of material required and assure its quality. Quality should be examined in terms of:

- Reliability of testing for TTIs
- Sterility
- Correct identification of the antibodies and antigen profiles requested.

There should be a formal agreement between the EQA scheme and the supplier to ensure that the supply of exercise material is reliable and meets all the specifications set by the scheme. Regular liaison is also required to ensure the availability and timely provision of appropriate exercise material.

It is essential that both the EQA scheme organizer and the supplier are able to fully characterize the exercise material, even if participating laboratories are not required to undertake extensive testing. See Section 5 for the selection of exercise material.

FINANCES

The resources required to establish and operate an EQA scheme in blood group serology must be identified, the costs estimated and funding sought. Figures 2 and 3 on pp. 14–15 show the broad categories of capital and recurrent costs and examples of the facilities and resources required for the establishment and operation of an EQA scheme. Possible sources of funding include government, health authorities, professional bodies, nongovernmental organizations and organizations providing research funds.

A regular source of funds will be required for the ongoing and successful operation of the scheme. If participation is voluntary, an EQA scheme could recover all or part of the operational costs by charging a fee to participating laboratories. If the scheme is mandatory, health authorities should allocate adequate resources to ensure its sustainability.

Care should be exercised if commercial companies are involved as the scheme should be seen to be impartial.

QUALITY SYSTEM OF THE EQA SCHEME

It is essential that the EQA scheme itself has a good quality system. Some elements of the organizing institution's own quality system could be utilized for this purpose, depending on the arrangements between the EQA scheme and the organizing institution. It will, however, be necessary for the scheme organizer to implement a specific, effective quality system for

Figure 2: Initial capital costs

Category	Examples
Accommodation	Purchase or lease of premises and/or modifications to an existing building for: ■ Office ■ Laboratory ■ Cold storage ■ Packing and distribution facilities ■ Record storage
Staff	■ Recruitment ■ Initial training, if necessary
Capital equipment	■ Laboratory – Centrifuge – Incubator – Cell-washer – Refrigerator – Freezer ■ Processing and dispensing – Laminar flow cabinet – Clamp stands – Pump – Racks ■ Storage, packing and dispatch – Cold room or refrigerator – Heat sealer ■ Office – Photocopier – Telephone – Fax ■ Information technology – Computer – Licences for software – Printer
Pilot study	■ Raw material and staff time for: – Study design – Processing – Dispensing and dispatch – Analysis and reporting
IT consultancy (optional)	■ Design of software programmes for: – Registration – Invoicing – Analysis of results – Production of reports

the scheme, with a quality policy stating how it will provide EQA services to meet the needs of participating laboratories. This policy should be included in the scheme's quality manual, with references to all processes and procedures in the quality system, including those specific to the EQA scheme and those in common with the organizing institution.

IDENTIFICATION OF PARTICIPATING LABORATORIES

When organizing an EQA scheme, the advisory committee should define the profile of laboratories that should be encouraged or required to participate. The scheme should be actively promoted to encourage full participation, but

Figure 3: Ongoing recurrent costs

Category	Examples
Accommodation	■ Rent ■ Maintenance ■ Overheads
Staff	■ Salaries and benefits ■ Training and education ■ Travel and related costs ■ Conference fees
Equipment	■ Maintenance contracts ■ Replacement and repairs
Exercise material	■ Raw material – Acquisition – Processing, including blood bags, filtration and connectors for pooling
Laboratory testing	■ Reagents ■ Consumables: e.g. tubes and pipettes
Office	■ Telephone ■ Stationery ■ Consumables for printing and photocopying
Information technology	■ Development of software ■ IT support ■ Internet connection
Dispensing, packing and dispatch	■ Bottles ■ Packaging ■ Postage/courier
Meetings	■ Advisory committee ■ Annual meeting of participants ■ Workshops
Consultancy fees	■ Statistician ■ IT development ■ Transfusion specialist

the most effective mechanisms for promotion will depend on whether it is a voluntary or mandatory scheme. It is important to be aware of the number and type of laboratories that intend to participate as this will have an impact on the organization of the EQA scheme.

Potential participating laboratories should be sent a preliminary questionnaire to identify:

- Staffing levels
- Overall workload
- Range of tests routinely undertaken
- Techniques and reagents used
- Quality system in place.

This information can be used to ensure a suitable design for the format of EQA exercises (Section 4) and may be also be useful for categorizing laboratories for performance monitoring (Section 6). An example of a preliminary questionnaire to obtain general information about participating laboratories is included as Annex 1.

ORGANIZING A PILOT STUDY

A pilot study should be undertaken to test the structure of the EQA scheme, proposed methods of operation and design of exercises. The purpose of a pilot study is to expose any unforeseen logistical problems and identify solutions before scaling up the operation of the scheme and offering formal participation.

The design of the format for EQA exercises should be based on the information collected from potential participating laboratories.

Systems will need to be developed for:

- Registration of participating laboratories
- Preparation and distribution of exercises
- Collation and analysis of results and other information from participating laboratories
- Performance monitoring.

At least two exercise distributions should be sent to a limited number of participating laboratories. These laboratories should be selected to represent different groups of participants in terms of their distance from the organizing centre, the size of their laboratories or the techniques they use.

The pilot study should include the following steps.

1 Establishment of an information management system to:
   - Hold details of participating laboratories
   - Collate and analyse data
   - Generate reports.

2 Serological testing of material for:
   - Initial suitability
   - Validation of sample stability throughout the duration of the exercise
   - Determination of the expected results on the closing date of the exercise.

3 Processing, dispensing and labelling of the exercise material and preparation of the required documentation.

4 Distribution of the exercise to selected laboratories and to a recognized, competent laboratory for the confirmation of expected results.

5 Analysis of the results and preparation of exercise reports.

6 Internal trial of the performance monitoring system (this does not need to be shared with participants at this stage).

7 Monitoring of problems in areas such as the preparation of exercise material, sample stability, clarity of instructions, return of results, use of results forms and suitability of the exercise format.

8 Analysis of feedback from participating laboratories.

9 Implementation of changes required to solve any problems that have been identified.

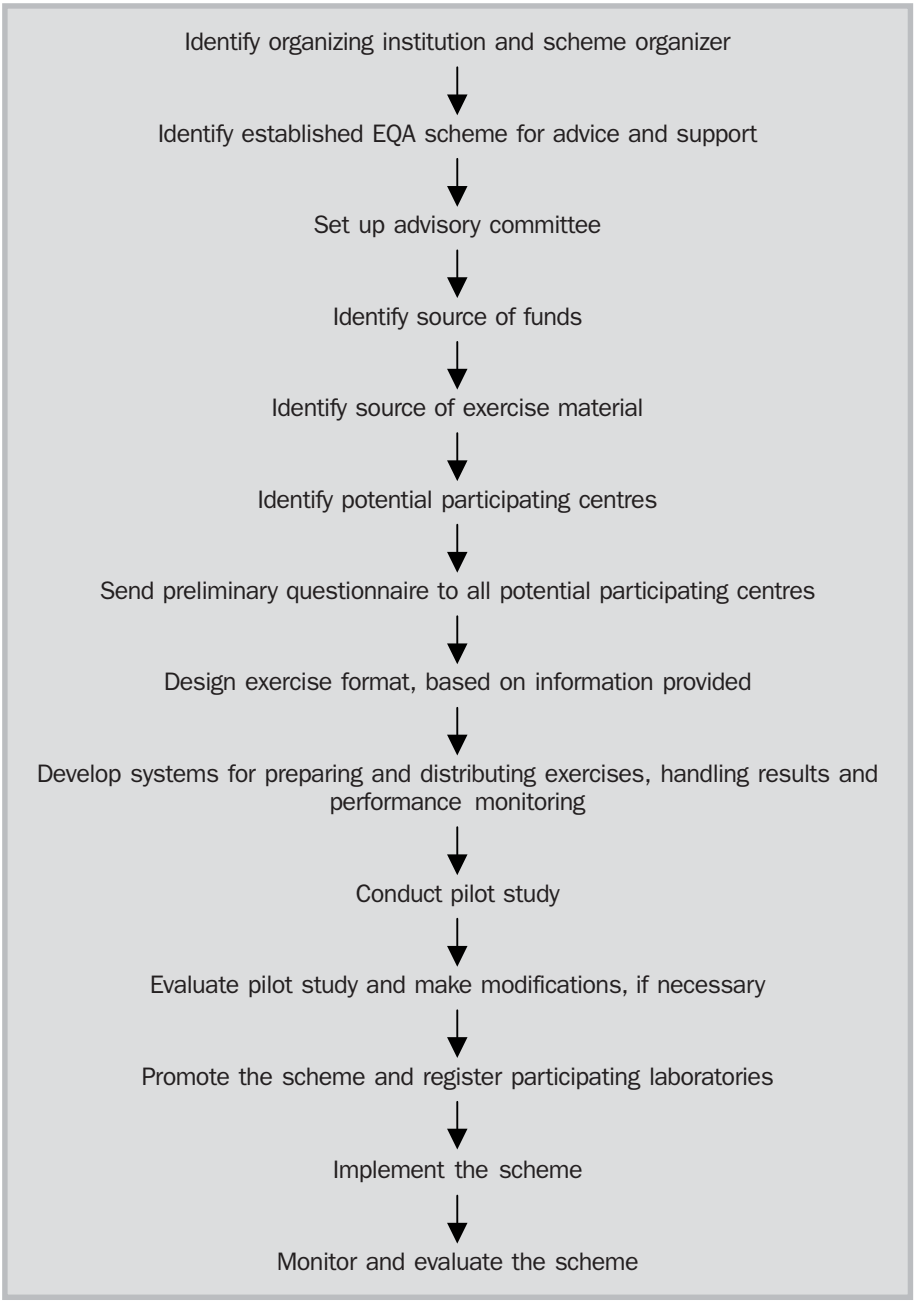
10 Review of recurrent operating costs.

Participating laboratories should be asked to comment on any problems they encountered and to make suggestions for improvement. At the completion of the pilot study, a review should be made of problems experienced in the operation of the scheme and comments from participants. Adjustments can then be made to the design of the scheme and to the estimate of operating costs, if necessary.

PRACTICAL STEPS IN ESTABLISHING AN EQA SCHEME

An outline of the practical steps to be taken in establishing an EQA scheme in blood group serology is shown in Figure 4.

Figure 4: Steps in establishing an EQA scheme in blood group serology



3

Participating laboratories

In order to participate effectively in an EQA scheme, participating laboratories should recognize the need for quality and the role of EQA within a quality system in the blood transfusion laboratory. Understanding the benefits of EQA and the way in which the scheme works will encourage compliance with the rules of participation. This will enhance the value of the scheme to the individual participating centres and the overall quality of the information generated.

All staff in participating laboratories should have access to the EQA results and the reports distributed by the scheme. Any problems identified should be discussed openly and dealt with as problems relating to laboratory procedures and practices rather than as criticism of individual members of staff. Analysis of the root causes of errors in EQA provides the opportunity for participating laboratories to implement changes to prevent similar errors being made in the clinical setting.

Once the scheme is established and open to participation, a formal registration process is required in order to gather contact details and other essential information from participating laboratories and also to provide them with the information they need for effective participation. This information should be provided in the form of an information manual. The scheme organizer may also consider organizing seminars for potential participants to explain the scheme.

INFORMATION MANUAL

An information manual should be developed to explain the management and operation of the scheme and give practical instructions for participation. The information manual should be distributed with a registration form.

The information manual should include:

- Aims of the EQA scheme
- Description of the organizing institution
- Contact details of the scheme organizer
- Details of the advisory committee
- Explanation of the commitment needed from participating laboratories and the benefits of participation
- Rules of participation
- Description of the exercises offered and instructions for their completion

- Explanation of the performance monitoring and scoring system
- Definition of unsatisfactory performance and action to be taken in the event of unsatisfactory performance.

Rules of participation

Clear rules of participation in the scheme should be determined by the advisory committee. These rules should set out:

- What is expected of participating laboratories
- The service to be provided by the scheme
- How the information collected, including performance data, will be used.

Participating laboratories should agree to these rules at the time of registration.

An example of rules of participation is shown in Figure 5.

Figure 5: Example of rules of participation in an EQA scheme

Examples of rules for participating laboratories

To maximize benefit to participating laboratories and ensure the validity of scheme data:

- Only those techniques and technologies that are used for routine testing of samples should be used for EQA samples
- Samples should not be tested only by the most senior or experienced staff
- Samples should be tested alongside routine samples; they should not be kept aside for testing separately
- Samples should not be tested more than once and the results compared unless all samples are also routinely tested in this way
- Excess exercise material may be used for other purposes such as staff training or internal quality control once the EQA results have been submitted
- Results must be returned by the closing date specified for the exercise
- There must be acceptance of agreed procedures for performance monitoring and follow-up of unsatisfactory performance
- Copyright of scheme data must be observed to ensure that they are not published or presented out of context; permission must be sought from the advisory committee before data are used.

Examples of rules for the scheme

To ensure the effective operation of the scheme:

- The confidentiality of performance data must be maintained between the scheme organizer and the participating laboratory, unless there is an obligation by legislation or prior agreement for them to be disclosed to a third party
- Exercises provided should have a reliable sample quality
- There must be a clear time-scale for the distribution of exercises and the return of reports.

REGISTRATION

At registration, all interested laboratories should be sent a registration form, together with the information manual. The registration form should request the following information.

1 Contact details for the delivery of samples and reports:
   - Name of the participating laboratory
   - Name of contact
   - Full postal address
   - Telephone number
   - Fax number
   - E-mail address, where available.

2 The name and address of an additional person may be given for correspondence regarding performance, if required.

3 The tests offered by the scheme on which the participating laboratory wishes to be assessed. This will enable the scheme to identify the tests for which exercise results can be expected from each laboratory. Ideally, participating laboratories should be assessed for all tests that they routinely perform.

The registration form should also include a section to be signed by the participating laboratory, indicating its agreement to abide by the rules of participation. An example of a registration form is included as Annex 2.

Each participating laboratory should be allocated a confidential registration code for use in correspondence with the scheme to ensure confidentiality of results and performance data. This code and the information on the registration form for each laboratory should be entered into the scheme's information management system. If a computer database is used, each component of these details (such as the registration code and each line of the address) should be entered as separate fields to facilitate searches on the data.

Information on participating laboratories should be kept up to date by annual re-registration; a new registration form should be distributed with a copy of the current registration details for confirmation. This will enable the scheme to obtain updated technical information and contact details. Similarly, the preliminary questionnaire for participating laboratories should also be distributed annually to enable the scheme to be aware of and respond to any changes in their practice.

4

Design of EQA exercise formats

Information obtained from the preliminary questionnaires completed by potential participating laboratories should be used in designing EQA exercises. This may include staffing levels, overall workload and the range of tests, techniques and reagents used. Whenever possible, each exercise should have an educational function, exploring areas with wide variations in practice or suspected or proven poor performance.

The following practical issues should be kept in mind when designing EQA exercises in blood group serology:

- Selection of tests
- Principles of the selection of exercise material and sample presentation
- Validation of sample stability
- Risk assessment of exercise material
- Number of samples per exercise
- Frequency of exercises
- Exercise instructions
- Results forms
- Return of results
- Variations in exercise formats.

SELECTION OF TESTS

An EQA scheme should meet the needs of each participating laboratory and assess all clinically important tests that it routinely performs. However, it is not always advisable to include a technology or test used by participating laboratories if it is of limited clinical value. The time required to complete the exercises should not adversely affect the routine work of the laboratory and should be kept to the minimum required for the adequate testing of laboratory procedures. Additional tests should be introduced with caution.

Minimum tests

It is suggested that, at a minimum, the following tests should be included:

- ABO grouping: cell and serum grouping
- RhD typing: where testing is mandatory
- Compatibility testing: e.g. crossmatching.

More advanced tests

More advanced tests that may be introduced according to local priorities and practices include:

- Antibody screening
- Antibody identification
- Haemolysin test, if appropriate
- Direct antiglobulin test
- Red cell phenotyping.

PRINCIPLES OF THE SELECTION OF EXERCISE MATERIAL

The following general principles apply to the provision of material for EQA exercises:

- All participating laboratories should test identical exercise material
- The material must remain stable throughout the duration of the exercise
- Whenever possible, the material should be presented in a format that resembles clinical samples received by participating laboratories, without compromising the stability of the material.

Crossmatching, antibody screening and identification

The ideal material for crossmatching and antibody screening is plasma that contains undiluted, weak clinically significant IgG antibodies. However, depending on the scale of the scheme, it may be necessary to pool plasma separated from whole blood and/or collected by apheresis and to dilute antibodies to provide sufficient volumes. Diluted strong antibodies do not always have the same performance characteristics as undiluted weak antibodies. Very high dilutions of potent antibody-containing sera should therefore be avoided, wherever possible. Whatever the limitations of the material available, it is essential to adhere to the principle of providing all participating laboratories with identical test material.

The frequency of red cell phenotypes and the specificity of antibodies most commonly encountered in the populations tested by participating laboratories should be taken into consideration. Exercises should be designed using commonly encountered antibodies so that screening and identification panels are likely to include red cells positive for the corresponding antigens. This is especially important when operating an EQA scheme across a large area. Allo-antibodies selected for EQA exercises should generally be clinically significant, unless there is a specific educational aim in including an IgM antibody that is non-reactive at 37 ºC.

Even if some participating laboratories do not use the indirect antiglobulin test (IAT), it is still valid to distribute sera containing antibodies reacting only by IAT, in order to encourage changes in practice.

ABO and RhD typing

Whole blood samples taken directly from standard blood donations may be used for ABO and RhD typing. The anticoagulants ACD, CPD or CPDA should be used since they preserve red cells better than EDTA. The advantage of using whole blood samples is that they are in the same format as clinical samples entering the laboratory and can be used for both manual and automated blood grouping systems. However, whole blood will not remain stable for extended periods outside appropriate storage conditions. If a whole blood sample is provided for ABO and RhD typing, separate serum samples must still be provided for crossmatching, antibody screening and identification.

Sample stability is of paramount importance. It may be necessary, depending on distribution conditions, to prepare separate (matching) serum and red cell samples, thus allowing for the preservation of red cells. Red cells can be suspended in a sterile preservative solution containing antibiotics, such as Alsever's solution. Matched plasma or serum samples with added sodium azide (1 g/L), can be supplied separately.

It is possible to convert plasma to serum, which offers the advantage of a "clearer" sample appearance; it is easier to sterilize filtered serum than plasma. However, the conversion of plasma to serum is time consuming and may introduce contamination.

Decisions on the sample format should be made on the basis of the requirements of participating laboratories and the validation of sample stability, including sterility testing. See Annex 3 for a method of converting plasma to serum and the preparation of Alsever's solution.

VALIDATION OF SAMPLE STABILITY

Whichever sample format is used, it will be necessary to validate sample stability before the scheme becomes fully operational in order to ensure that samples are fit for use when they arrive in participating laboratories. The stability of samples can be tested by:

- Sending material to one or more distant participating laboratories which then return it for re-testing
- Leaving samples unopened, at ambient temperature, for the length of time that specimens are expected to spend in the postal system, and then re-testing.

Results on re-testing should be comparable to the original results and the samples should remain sterile. See Section 5 for guidance on testing samples throughout the duration of each exercise.

RISK ASSESSMENT OF MATERIAL

Biological material can never be guaranteed to be free from infective agents, even when tested and found negative for markers of infection, such as HIV and hepatitis B. Exercise material should therefore be handled and disposed of in the same way as routine pathological samples. Details of the potential risks of the material should be included in the product insert with each set of exercise material and also sent with the initial registration information. See Annex 4 for an example of a product insert.

NUMBER OF SAMPLES PER EXERCISE

The exercise should be designed to assess participating laboratories on the maximum number of tests, using the minimum number of samples, with:

- An adequate number of samples (minimum two) for ABO and RhD typing, to give variation in blood groups and allow transcription or transposition errors to be identified
- At least one of the serum samples provided for crossmatching (and antibody screening and identification, if included) containing atypical antibodies of potential clinical significance.

FREQUENCY OF EXERCISES

At least three, preferably four, exercises should be distributed each year in order to permit an adequate assessment of laboratory procedures and practices and to gather sufficient data for cumulative performance monitoring.

EXERCISE INSTRUCTIONS

Clear instructions should be included with each exercise on:

- Requirements for testing by participating laboratories
- How the results should be reported
- Closing date for the return of results.

A reminder should be included that EQA samples must be tested in the same way as clinical samples: i.e. by the routine methods and procedures currently in use in each individual participating laboratory and not necessarily all those listed on the results form. An example of an exercise instruction sheet is included as Annex 5.

RESULTS FORMS

In order to maintain confidentiality, completed results forms should be identified only by the registration codes of individual participating laboratories.

The results forms should be designed so that they are simple and unambiguous and require only necessary information to be entered. Information can be collected by giving tick box options or the opportunity to enter free text. There are advantages to both approaches:

- Tick boxes make the data easy to collate and analyse as responses are standard and require no interpretation; this is important if there are a large number of participating laboratories
- Free text allows the entry of detailed information.

The most appropriate option should be chosen for each entry field on the results form.

The exercise code or number and the participating centre's registration code should be clearly displayed on the results form. The form should allow for the following information to be recorded:

- Date samples received
- Date samples tested

- Sample quality
- Interpretation of results: e.g. ABO group
- Reaction grades obtained for individual tests, such as patient cells vs. anti-A, anti-B, anti-A,B
- Information regarding the techniques, technologies and reagents used to obtain the results.

An example of a results form is included as Annex 6.

RETURN OF RESULTS

Participating laboratories should test the EQA samples and return the results to the scheme as soon as possible after receipt of the samples. A closing date should be specified, usually two weeks from the time of distribution, although this may vary according to local conditions for distribution and the stability of the exercise material. It is necessary to have a set closing date as a "cut off" for accepting results so that sample quality can be monitored up to the last available date for testing. Ensuring that results are received by a set date also allows the prompt analysis of results from as many laboratories as possible.

VARIATIONS IN EXERCISE FORMATS

Once an EQA scheme is operational, it can be further developed to include variations in the format of exercises to test specific laboratory procedures and case studies to test skills in the interpretation of results. Questionnaires may be distributed to obtain more detailed information on processes within the participating laboratories and to assist in determining the causes of problems identified in previous exercises.

Suggestions for variations in exercises

1 To investigate responses to requests for the urgent provision of blood, a time limit could be set on exercise testing and questions asked regarding the tests that have been set up and completed in that time.

2 To look at transcription and transposition errors in more depth, samples could be labelled with details such as the "patient's" name, date of birth and hospital number that should be recorded on the results form.

3 To explore variations in the sensitivity of testing, the same material could be used for several donor samples and the reaction strength compared when tested against a weak antibody in the crossmatch.

4 To assess trends in performance in antibody detection and crossmatching, samples from the same pool of antibody-containing material could be distributed periodically.

5 Where serum is provided for antibody identification without the corresponding red cells, the "patient's" red cell phenotypes could be provided, as in the example in Annex 5. These fictional phenotypes could be used to adjust the difficulty of the

identification of an antibody or mixture of antibodies by increasing or reducing the number of negative phenotypes given. This will alter the number of corresponding antibodies that might possibly be present. Realistic phenotypes should be provided and should not contraindicate the antibody specificity(s) present in the serum.

6 Antibody identification results could be given for fictional patients and questions asked regarding:
   — The antibodies that could be positively identified
   — The antibodies that could not be excluded
   — The phenotyped blood that would be requested for these patients.

7 "Clinical" scenarios could be given and questions posed such as "Would you transfuse this blood?"

5

Operating an EQA scheme in blood group serology

Once the final exercise design has been agreed and at least two successful pilot exercises have been completed, the steps outlined below will need to be followed for each exercise dispatched:

- Planning the exercise
- Selection of exercise material
- Processing and serological testing of exercise material for suitability and stability
- Dispensing of exercise material
- Preparation of exercise documentation
- Packing and dispatch of exercise material
- Defining "correct" results
- Recording and analysis of results
- Initial follow-up of incorrect results
- Reporting the results
- Performance monitoring (optional – see Section 6)
- Documentation of the exercise for internal audit.

It is useful to work with a checklist throughout the exercise; this forms an audit trail and should be kept as part of the exercise documentation. An example of an exercise checklist is attached as Annex 7.

PLANNING THE EXERCISE

Each exercise should be planned well in advance in order to allow sufficient time to obtain the material required. The advisory committee should agree the aim and content of the exercise. Whenever possible, exercises should explore areas where there are wide variations in practice or suspected poor performance. They should also demonstrate the benefits of good practice.

At this stage, it is important to give careful consideration to:

- What the exercise is intended to demonstrate
- Potential problems
- How to distinguish between clinically and non-clinically significant antibodies in performance monitoring of antibody screening.

SELECTION OF EXERCISE MATERIAL

In EQA exercises, serum and cells from different sources are used to simulate a "patient" sample. They are often obtained and tested at different times so checks must be made to ensure consistency in ABO groups between the serum and cells (or whole blood) provided as the patient sample. Other red cell phenotypes should also be feasible, considering the antibodies present in the serum sample. Since the same material will be used for many different tests, the impact of the choice of blood groups and antibodies on all elements of the exercise should be carefully considered.

Poor planning at this stage can lead to problems such as the exercise failing to assess what was originally intended and elements having to be withdrawn from performance monitoring. This checking process should take place prior to the selection of exercise material. Further checks should also be made once the material has been selected for use to ensure that the whole exercise works in practice.

PROCESSING AND SEROLOGICAL TESTING FOR SAMPLE SUITABILITY AND STABILITY

Once the exercise material has been received by the EQAS organizer, it is important that it is fully characterized, even if extensive testing by participating laboratories is not required.

All serum/plasma samples, including those intended to contain no antibodies to red cell antigens other than ABO (inert), should be tested by:

- All IAT technologies commonly used by participating laboratories
- An enzyme technique at 37°C
- Direct agglutination at 4°C.

Atypical antibodies which need to be determined in the EQA exercise should be positively identified. The presence of other antibodies to common red cell antigens should be excluded by obtaining a negative reaction with cells having homozygous expression of the required antigen.

Donor red cells should be phenotyped for antigens corresponding to those antibodies in the patient samples.

The presence of antibodies of which the scheme is unaware may cause problems if unexpected (but not necessarily incorrect) results are submitted by participating laboratories. If the problem is not recognized, participants will be penalized unfairly; even if it is recognized, some or all of the exercise will have to be withdrawn from performance monitoring. Such problems will prevent the aims of EQA being achieved and may cause the EQA scheme to lose credibility with participating laboratories.

Once specificity has been established, it may be necessary to dilute antibodies to achieve the reaction strength required to achieve the aims of the exercise. Inert plasma should be used for diluting antibody-containing sera; however, care must be taken to match for ABO group and to consider the effects of dilution on all aspects of the exercise. It is advisable to make and test small volumes of trial dilutions before diluting the bulk of the material.

When the specificity and reactivity of the material have been established, the bulk material should be pooled and processed according to the sample presentation required; for example:

- Whole blood
- Red cells suspended in Alsever's solution and separate serum samples.

Confirmation of results by the EQA scheme

In order to ensure that the material continues to react as intended, it is important to re-test it after processing and prior to dispensing it into vials, using all technologies in common use by participating laboratories. A brief serological check is required after dispensing to confirm that the vials have been labelled correctly.

The stability of exercise material must be monitored throughout the duration of the exercise. Three exercises should be sent by the EQA scheme to itself at the same time and by the same means as the main distribution of exercise material. This material should be tested:

- On arrival back at the organizing institution
- After a defined period at ambient temperature
- On the closing date of the exercise.

A suggested sequence of testing is shown below:

When	Check
Pre-processing	Samples meet specifications
Post-processing	No change in samples
Post-dispensing	Samples in correct vials
After posting	Stability of samples
7 days on bench	Stability of samples if receipt is delayed
Closing date of exercise	Stability of samples and determination of expected results

DISPENSING OF MATERIAL

Adhesive vial labels should be prepared for each vial of each sample, showing:

- Exercise number or code
- Sample number
- Storage conditions
- Any other relevant information.

To obtain the optimal shelf life, all samples should be dispensed into clean, sterilized glass bottles or new plastic vials, in an aseptic manner. Sample containers should be strong and watertight with a leak-proof screw lid; plastic containers are preferable. Aliquots should be sent for sterility testing prior to dispatch.

Before dispensing samples for each “patient” or “donor”, checks must be made that the correct pool of material is being used and that the corresponding labels contain the correct information. Each pool of “patient” or “donor” material should be dispensed, labelled and stored before moving on to the next sample to ensure that there is no error in labelling.

A sufficient number of vials should be prepared both to meet the requirements of participating laboratories and to allow the scheme to keep some spare vials in storage at 4°C. Spare vials are required in case participating laboratories require replacement samples because of loss or breakage or for repeat testing following an error. Additional vials will also be required by the scheme for in-house testing throughout the duration of the exercise.

PREPARATION OF EXERCISE DOCUMENTATION

The following documentation should be prepared well before the exercise is to be dispatched:

- Exercise instruction sheets
- Results forms specifically coded for each participating laboratory
- Any additional documentation required, such as questionnaires.

It is advisable, however, not to print any part of the documentation that is dependent on the specificity of the material until this has been tested and confirmed. It is then important to collate and proof-read all documents that are to be distributed together. This will allow for the checking of each type of document to ensure that there are no contradictions, ambiguities or omissions in the information.

PACKING AND DISPATCH

Health and safety issues should be considered for all groups of workers who may be exposed to exercise material, including postal workers. Exercises should be packed and labelled in conformity with local or international postal regulations, such as IATA (International Air Transport Authority) regulations, as applicable.

Each vial should be clearly labelled, wrapped in sufficient absorbent material to soak up the sample in case of breakage or leakage and then sealed in a watertight secondary package. Accompanying documents should be sealed within a protective pouch and attached to the outside of the package. The secondary package should be placed in further packaging that is capable of protecting the contents from physical damage while they are in transit.

The external packaging should be labelled to indicate that it contains pathological material. The name and address of the EQA scheme should be written on the outside as well as the name and address of the participating laboratory to which the exercise is being sent.

A list of participating laboratories’ registration codes is helpful when packing exercises and reports to ensure that no laboratory is missed. It is also important to have a protocol for packing, including checking that the correct combinations of specimens and documents have been packed for each participating laboratory. Annex 8 contains an example of a record of exercise distributions and returned results that can be used as a packing

checklist. If exercises are all distributed on a single day, it is sufficient to note the date and place a tick in the columns "Documentation packed", "Samples packed" and "Exercise distributed" against each participating laboratory. The date of packing and distribution should be recorded for any participating laboratory to which exercises are sent on other dates.

DEFINING "CORRECT" RESULTS

Each result submitted by a participating laboratory must be compared with the "correct" result defined by the EQA organizing centre. This definitive result can be obtained by testing in-house, preferably by more than one worker, or by taking a consensus of results from designated reference centres. If any exercise material has deteriorated significantly and the expected results are not obtained by all commonly used IAT technologies on the closing date, a decision should be taken on whether to withdraw that sample from performance monitoring.

The organizing centre and any designated reference centres should take part in another recognized EQA scheme to monitor their own performance in determining the correct results for exercise material. The EQAS organizer may wish to make the organizing centre's EQA results available to participating laboratories, perhaps in the annual report, to promote confidence in the scheme.

RECORDING AND ANALYSIS OF RESULTS

It is essential to ensure that all results received from participating laboratories are recorded, either by transcribing them in a manual system or by data entry to a computerized system. To ensure that they have been recorded accurately, the results should be entered twice, preferably by two different individuals, using a system in which the initial results cannot be seen at the second entry. Where this is not possible, extensive checking is required, especially if any laboratories appear to have made errors. Irrespective of the information recording system used, all incorrect results should be checked with the original results form and verified.

When results forms are returned to the scheme, they should be date-stamped and the date of their receipt recorded in the record of distributions and returned results. A check is required at this point to ensure that all returned results have been entered for analysis.

Analysis should begin as soon as all results have been entered and verified. In some exceptional circumstances, the scheme organizer may decide to accept results that have been returned after the closing date. However, results received after the initial report has been posted to participating laboratories should not be accepted as the correct results will be known at this stage.

The analyses performed will depend on the scale and aims of the scheme and the information technology available. As a minimum, the organizer should be able to identify:

- Participating laboratories that have returned results forms
- Participating laboratories that have made errors
- Tests in which errors were made.

In addition, a simple calculation of the number of correct and incorrect results found could be reported to give an overall summary of performance.

In a more complex analysis, results can be examined for trends and comparisons can be made between groups of participants, such as those using different techniques. When undertaking this type of analysis, it is important to ensure that all variables influencing the results have been considered before reporting the findings.

Care should also be taken when small numbers are involved as apparent correlations may have no genuine statistical significance and there is also a risk of breach of confidentiality. In cases of doubt, help should be sought from a professional statistician.

INITIAL FOLLOW-UP OF INCORRECT RESULTS

The EQAS organizer should contact participating laboratories that have made any errors to discuss the incorrect results, find out the root causes of problems and offer advice. If it is not possible to contact all laboratories directly, priority should be given to those laboratories that have made errors with the most significant potential impact on patient care. The information gathered in this way may give an insight into possible common sources of error and can be of use in deciding how to approach further analysis.

If required, additional samples for repeat testing should be sent to assist participating laboratories in identifying the sources of error. The results obtained with these repeat samples should not be included in the overall analysis.

Following receipt of their initial report, participating laboratories should be encouraged to contact the scheme organizer for advice if their results indicate any problems. All communication with participating laboratories regarding their performance should be logged and the main points documented.

In all contact with participants, and especially regarding errors, scheme personnel should be non-judgemental, constructive and consistent in their approach. Any advice offered should be evidence-based rather than an expression of personal opinion and should take into account national standards or guidelines, where these exist.

REPORTING

EQA provides a “snapshot” of laboratories’ performance and, inevitably, the information reported back to them can give only a retrospective view of performance at the time the exercise was completed. Each participating laboratory should receive an individual confidential report stating the expected results of the exercise, together with its own results. A simple analysis of the number of laboratories that obtained, or failed to obtain, the expected results may also be included in this initial report. If a scoring system is used, the scores obtained by a participating laboratory should appear in the individual report for that laboratory.

If the results cannot be analysed quickly, a copy of the expected results should be sent to all participating laboratories immediately after the

closing date. The EQAS organizer should then aim to issue reports with individual and overall results within four weeks of the closing date.

A supplementary report with more detailed analysis may be issued subsequently. If analysis reveals any common factors affecting results, this information can be presented as learning points. Any further analysis reported should be relevant and statistically sound. It should also be presented in a format that is visually attractive, easy to understand and unambiguous. Comments and recommendations should be objective and supported by the data presented. Personal comments and criticism or the inclusion of any information or comments that risk breaching confidentiality must be avoided.

An example of an exercise analysis and report is included as Annex 9.

DOCUMENTING THE EXERCISE FOR INTERNAL AUDIT

A separate file should be kept for each exercise, containing records that can be used for internal audit, including:

- All documentation relating to the exercise, including a copy of the instructions sheet, results form, exercise analysis and all reports
- Completed exercise checklist (see Annex 7)
- Record of the source(s) of all material used in the exercise
- Records of related testing, both serological and bacteriological; documentation for each exercise should show how, when and by whom the samples were prepared, tested and dispatched
- Completed record of distributions and returned results, including the dates on which reports were dispatched (see Annex 8)
- Laboratories to which exercises were distributed
- Laboratories that returned results
- When and by whom the data were entered
- When and to whom reports were dispatched
- Laboratories that made errors and details of communication with these laboratories.

6

Performance monitoring

Performance monitoring involves setting standards of acceptable performance and identifying participating laboratories that fail to reach these standards. The EQA scheme's objective in identifying unsatisfactory performance is to offer advice and support to assist these laboratories in improving their performance.

The need for monitoring of the performance of individual laboratories – and the initiation of appropriate corrective and preventive action in cases of persistent unsatisfactory performance – will be determined by the place of EQA within the existing national quality system. If there is no formal system of accreditation or prescribed action on unsatisfactory performance by an external agency such as a national regulatory authority, the advisory committee should decide the form of performance monitoring and follow-up action to be taken by the EQA scheme.

SETTING STANDARDS OF ACCEPTABLE PERFORMANCE

The first step in performance monitoring is to define standards of satisfactory, unsatisfactory and, possibly, "borderline" performance. The potential clinical significance of errors must be considered when defining standards of acceptable performance. When establishing an EQA scheme, it is therefore advisable to operate the scheme for a defined period, such as one year, with initial follow-up of errors as described in Section 5, but no formal performance monitoring or scoring. During this time, information can be gathered on current levels of performance within each category of testing, such as ABO grouping and crossmatching. This process will allow realistically achievable standards of acceptable performance to be set whilst ensuring that major errors, such as an incorrect ABO group, are defined as unsatisfactory. For the purpose of performance monitoring, it may be appropriate to categorize participating laboratories by criteria such as the size of the laboratory or the type of technology used.

Unsatisfactory performance should be defined for incorrect results and also for the non-return or late return of results. For performance monitoring, there should be no differentiation between incorrect results due to technical errors or procedural errors, such as the incorrect transcription of results or the transposition of samples, although they may be analysed and reported separately. An incorrect result in the blood transfusion laboratory or hospital blood bank can have the same serious consequences, regardless of the reason for the error. For this reason, it is advisable to base performance monitoring – and numerical scoring, if used – on interpretations made (such as ABO group) rather than on serological reactions recorded for each test.

Performance standards should be agreed by an external agency that is independent of the organizer, such as the advisory committee or accreditation agency, with input from participating laboratories and recognized experts. The same agency should also be responsible for regularly reviewing the definitions of unsatisfactory performance and making changes, where necessary, to reflect improvements in overall performance.

NUMERICAL SCORING SYSTEMS FOR PERFORMANCE MONITORING

The numerical scoring of results enables the EQA scheme to monitor individual performance objectively. Scoring can be "weighted" to reflect the potential clinical significance of errors made. Scores can also be adjusted according to the degree of consensus on results.

Cumulative scores can be used to identify persistent unsatisfactory performance as well as laboratories with "borderline" performance. Once the system is established, the cumulative scores for each area of testing, such as ABO grouping or crossmatching, should be given with each exercise report. If this is not possible, cumulative scores can be provided for each laboratory in an annual summary to show trends in individual performance.

A scoring system that is positive and rewards achievement is generally better received by participants than one that penalizes unsatisfactory performance. However, when using reward points alone, it is difficult to design a system where scores are adjusted for clinical significance as points should be awarded for partially correct results and some minor incorrect results. It is possible to overcome this problem by designing a system with both reward and penalty points, but this is still more difficult to use for cumulative scoring than a penalty scoring system. A system using penalty points is easiest to weight for clinical significance and to use for the identification of unsatisfactory performance on a cumulative basis.

Examples of numerical scoring systems for performance monitoring are included as Annex 9. One is based on a system of penalty points and the second uses both positive and negative scores.

FOLLOW-UP OF UNSATISFACTORY PERFORMANCE

Any follow-up actions by the EQA scheme should comply with the procedures laid down by the advisory committee. For example, as described in Section 5, the initial contact could be made by the EQAS organizer to determine possible causes of error and offer advice.

If there is no subsequent improvement in performance, a letter should be sent to the head of the laboratory to report on the situation, formalize the advice offered previously and suggest possible solutions. Procedures should be put in place to ensure that, once a laboratory becomes an unsatisfactory performer, its progress is then monitored until consistent satisfactory performance is achieved. Scheme personnel should be non-judgemental and constructive regarding unsatisfactory performance. Any advice offered should be evidence-based and in line with national standards or guidelines, where these exist.

SELF-ASSESSMENT

In the absence of any performance monitoring or follow-up by the EQA scheme, a comparison of an individual laboratory's results with those obtained by other laboratories is a useful means of highlighting the need for improvement. This process can often raise standards with no intervention from an external source.

It can be helpful for the scheme organizer to issue an individual "action sheet" to each laboratory that has made errors. The action sheet should outline the nature of the problem and require the laboratory to record details of:

- Probable cause
- Any corrective or preventive action taken.

This action sheet could form an internal mechanism for improving laboratory performance and need not be returned to the scheme organizer. Even if performance monitoring is already established, the use of action sheets will be a useful introduction to quality systems for participating laboratories, whether or not they are already in place.

The issue of an annual certificate of participation, detailing the number of exercises undertaken, can be a positive means of encouraging continued participation.

7

Role of the EQA scheme in education and training

EDUCATION

The main purpose of an EQA scheme is to identify areas of poor performance and to provide assistance to address any problems detected. Education should therefore be inherent in all activities of an EQA scheme. It can be provided to laboratories on an individual basis as well as to all participating laboratories and other transfusion professionals.

The scheme has a particularly important educational role regarding errors made in EQA exercises by individual participating laboratories. EQA scheme personnel can help laboratories to identify the root causes of errors and make suggestions for changes in practice and procedures to prevent their recurrence. Errors in EQA exercises may be due to specific technical issues, such as the incorrect or inappropriate use of techniques and/or reagents. However, apparently simple errors, such as transcription errors resulting in the recording of an incorrect ABO group, can be indicative of wider problems and deficiencies in a laboratory's quality system. For example, there may be no SOP for documenting and checking ABO grouping results or, if an SOP is in place, staff may not be following it because of inadequate training. Similarly, non-detection of a weak antibody could be due to poor technique or to failures in the quality system such as inadequate maintenance of equipment (e.g. cell-washer) or the lack of validation of reagents.

Education can be provided more widely in the form of reports on the overall performance of different techniques and technologies which provide specific learning points on best practice. Once a scheme is well established it may also be possible, with the help of the advisory committee, to organize an annual scientific meeting or a workshop for participating laboratories to address issues highlighted by the EQA exercises.

The scheme organizer should, where possible, communicate information generated by the scheme not only to participants but also to a wider audience, by making presentations at local, national and international meetings and through publications. EQA data can also be used as a basis for the writing and review of guidelines, making education accessible to all those working in the field of blood transfusion.

TRAINING

Where possible, the EQA scheme should provide training for staff from participating laboratories with unsatisfactory performance in EQA. A recognized procedure for offering training to laboratories with persistent unsatisfactory performance should be agreed by the advisory committee or regulatory authority. This is necessary to avoid any breach of confidentiality by singling out individual laboratories that have performed poorly. Details of the procedure should be included in the information manual for participating laboratories and should be agreed at the time of registration. If the EQA scheme does not have adequate time or facilities to offer training, arrangements could be made for training to be provided by another institution, such as the national blood transfusion service or a reference laboratory.

The EQA scheme may also become involved with the distribution of training materials to participating laboratories or with the organization of training workshops that are also open to other laboratories. In addition, the EQA network can be used for the distribution of education and training materials from other recognized sources, such as relevant professional bodies.

8

Monitoring and evaluating an EQA scheme

For an EQA scheme to progress, it is important to monitor its development and evaluate its impact on a regular basis. Evaluation should be undertaken at least once a year and an annual report produced.

INDICATORS

Process and outcome indicators that could be used to assess the success of a scheme are listed below. It should be recognized, however, that an improvement in relation to outcome indicators could be influenced by factors not directly related to participation in an EQA scheme, such as the introduction of improved reagents or technology.

Process indicators

Examples of process indicators include:

- Frequency of advisory committee meetings and attendance
- Number of participating laboratories
- Number of laboratories returning results for each exercise
- Number of laboratories registering for additional tests
- Increasing complexity of exercises
- Number of problems recorded in relation to the operation of the scheme
- Number of complaints received regarding the operation of the scheme
- Number of times exercise material fails to meet stability or sterility testing standards
- Number of complaints received regarding poor sample quality
- Feedback from participants
- Educational meetings held and number of attendees
- Publications by the scheme.

Outcome indicators

Examples of outcome indicators include:

- Number of satisfactory and unsatisfactory performers
- Change in overall scores

- Trends in performance with the same antibody used for cross-matching or antibody screening over several exercises
- Change in techniques used by participating laboratories: e.g. from slide to tube
- Number of participating laboratories receiving accreditation.

Where a haemovigilance scheme is in place, it is possible to monitor the number of incidents of reported adverse effects of transfusion, especially those where the originating error was made in the laboratory.

ANNUAL REPORT

An annual report on the scheme should be compiled and distributed to participating laboratories and other interested parties. Its contents may include:

- Summary of the exercises distributed
- Summary of overall performance, highlighting any trends
- Learning points from the exercises
- Details of developments within the scheme
- Overall assessment of the impact of the scheme
- Accounts, if appropriate.

Glossary

Accreditation

Process by which an independent and authorized agency certifies the quality and competence of an organization on the basis of certain predefined standards.

Audit

Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled – ISO 9000 (2000).

Competency assessment

Process to assess an individual's skill and ability in performing a single procedure or set of related procedures.

Documentation

Written policies, instructions and records involved in providing a product or service.

Information and its support medium – ISO 9000 (2000).

Effectiveness

Measure of the extent to which planned activities are realized and planned results achieved – ISO 9000 (2000).

External quality assessment (EQA)

The external assessment of a laboratory's performance using samples of known, but undisclosed, content and comparison with the performance of other laboratories.

External quality assessment scheme (EQAS)

A recognized scheme for organizing EQA. This can be a local scheme or organized at national, regional or international level.

Haemovigilance

The monitoring, reporting and investigating of adverse incidents related to all blood transfusion activities.

Internal quality control (IQC)

Procedures that monitor the day-to-day reproducibility of test results and will detect major errors in the analytical process

Procedure

Specific activity that forms the basic unit of a process.

Specified way to carry out an activity or a process – ISO 9000 (2000).

Process

A series of steps or actions that lead to a desired result or output.

System of activities that uses resources to transform inputs into outputs – ISO 9000 (2000).

Quality

The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

Ability of a set of inherent characteristics of a product, system or process to fulfil requirements of customers and other interested parties – ISO 9000 (2000).

Quality management

Coordinated activities to direct and control an organization with regard to quality – ISO 9000 (2000).

Quality management system

System to establish a quality policy and quality objectives and to achieve those objectives – ISO 9000 (2000).

Quality system

Organizational structure, processes, procedures and resources needed to implement quality requirements.

Standard operating procedure (SOP)

Written instructions for the performance of a specific procedure.

Test

Technical operation that consists of the determination of one or more characteristics of a given product, process or service according to a specified procedure – ISO 9000 (2000).

Validation

Confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

Annexes

The following annexes are provided for information and as examples on which prospective EQA scheme organizers may wish to base their documentation and other aspects of the design of their scheme, with appropriate local modifications.

1 Preliminary questionnaire for potential participating laboratories

2 Registration form

3 Techniques for the conversion of plasma to serum and preparation of Alsever's solution

4 Product insert

5 Exercise instructions

6 Results form

7 Exercise checklist

8 Record of exercise distributions and returned results

9 Exercise analysis and report

10 Numerical scoring systems

Annexes

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10 Numerical scoring systems

Annex 1

EXAMPLE

Preliminary questionnaire for participating laboratories

Please complete this questionnaire regarding blood transfusion laboratory practice and general quality measures in your laboratory to enable the EQA scheme to plan appropriate exercises and developments to the scheme.

Part 1: Contact details

Name of laboratory: _____

Name of contact: _____

Address: _____

_____

Telephone number: _____

Fax number: _____

E-mail address: _____

Part 2: Blood transfusion laboratory

1 Number of staff:

☐ Full-time

☐ Part-time

2 ☐ Number of these staff qualified in laboratory technology

3 Number of samples processed per year from:

☐ Patients potentially requiring transfusion

☐ Antenatal patients

☐ Blood donors

☐ Others (please specify)

4 Which of the following blood group serology tests are included in your routine pre-transfusion testing?

❑ ABO grouping

❑ RhD typing

❑ Antibody screening

❑ Crossmatching by direct agglutination

❑ Crossmatching by indirect antiglobulin test

❑ Other (please specify)

5 Is an out of routine hours (on-call) service provided?

❑ Yes ❑ No

If yes, are the same procedures/techniques used for pre-transfusion testing?

❑ Yes ❑ No

6 If the test is indicated, is your laboratory able to undertake the following?

❑ Antibody identification
❑ Antibody titration
❑ Red cell phenotyping (other than ABO and RhD)
❑ Elution studies

7 Does your laboratory have any automation for ABO and RhD typing or antibody screening?

❑ Yes ❑ No

8 Please indicate when serological controls are set up:

	ABO grouping	RhD typing	Antibody screening	Cross-matching
With each batch of tests	❑	❑	❑	❑
With each individual test (if not working in batches)	❑	❑	❑	❑
Daily	❑	❑	❑	❑
Other	❑	❑	❑	❑
Not used	❑	❑	❑	❑

9 **ABO technique used**

❑ Tube
❑ Slide
❑ Column agglutination
❑ Other

RhD typing technique used

❑ Tube
❑ Slide
❑ Column agglutination
❑ Other

10 **ABO and RhD typing reagents used**

	Polyclonal	Monoclonal	Reagent manufacturer
Anti-A	❑	❑	_____
Anti-B	❑	❑	_____
Anti-A,B	❑	❑	_____
Anti-D (1)	❑	❑	_____
Anti-D (2)	❑	❑	_____

11 **IAT techniques**

Indicate which of the following are used to perform **IAT** testing for crossmatching, antibody screening and identification (select all that apply).

Tube LISS suspension	Tube LISS addition	Tube NISS	Microplate Liquid phase	Microplate Solid phase*	Column agglutination*	Other**
❑	❑	❑	❑	❑	❑	❑

* State manufacturer: _____

** Specify: _____

12 **AHG reagent used for IAT testing**

	Manufacturer/supplier
❑ Polyspecific	_____
❑ Anti-IgG	_____

13 Indicate for which of the following an enzyme technique is used:

- ❑ Crossmatching
- ❑ Antibody screening
- ❑ Antibody identification
- ❑ If yes, which technique? _____

Part 3: Quality system

1 Is the organizational structure within your institution defined and documented?

❑ Yes ❑ No

2 Are job descriptions written for:

- ❑ All members of staff
- ❑ For some members of staff
- ❑ No

3 Is there a system for assessing the training needs of the staff: e.g. at appraisal?

❑ Yes ❑ No

4 Is there a staff training policy?

❑ Yes ❑ No

5 Is competency assessment undertaken for all laboratory staff?

❑ Yes ❑ No

6 Are written standard operating procedures in place?

- ❑ For all tests and procedures
- ❑ For some tests and procedures
- ❑ No

7 Is there a system for equipment validation and calibration?

❑ Yes ❑ No

8 Is there a record of equipment maintenance and repair?

❑ Yes ❑ No

9 Is there a system for the evaluation of test kits and reagents?

❑ Yes ❑ No

10 Are all reagents used according to the manufacturers' instructions?

❑ Yes ❑ No

11 Are all reagents validated in-house?

❑ Yes ❑ No

12 Are all reagents used within their expiry date?

❑ Yes ❑ No

13 Is there a maximum blood ordering schedule in operation for surgical cases?

❑ Yes ❑ No

14 Is there a mechanism for reporting and investigating errors?

❑ Yes ❑ No

Thank you for completing this questionnaire. If you wish to expand on your answers or make any comments, please enclose a separate sheet.

Annex 2

EXAMPLE

Registration form for participating laboratories

External Quality Assessment Scheme for Transfusion Laboratory Practice

CONFIDENTIAL REGISTRATION DETAILS

For EQAS use only

Laboratory registration code:

PLEASE COMPLETE USING BLOCK CAPITALS

1 Name and address of the person to whom test material is to be dispatched. A survey report and any queries will also be sent to this address.

Name of laboratory: _____

Name of contact: _____

Position: _____

Department: _____

Hospital (if applicable): _____

Street: _____

District: _____

Town: _____ Post code: _____

Country: _____

Telephone number: _____

Fax number: _____

E-mail: _____

2 Name and address of the person responsible for the performance of the registering laboratory. An additional survey report will be sent to this address (this section is optional).

Name of laboratory: _____

Name of contact: _____

Position: _____

Department: _____

Hospital (if applicable): _____

Street: _____

District: _____

Town: _____ Post code: _____

Country: _____

Telephone number: _____

Fax number: _____

E-mail: _____

3 Tests for which the laboratory wishes to register (please tick as appropriate):

- ❑ ABO grouping
- ❑ RhD typing
- ❑ Compatibility testing (e.g. crossmatching)
- ❑ Antibody screening
- ❑ Antibody identification
- ❑ Red cell phenotyping

This laboratory agrees to abide by the rules of participation of the External Quality Assessment Scheme

Authorized by:

Signature: _____

Name: _____

Position: _____

Date: _____

Annex 3

Techniques for the conversion of plasma to serum and preparation of Alsever's solution

CONVERSION OF CITRATED PLASMA TO "SERUM" USING CALCIUM CHLORIDE AND KAOLIN

Preparation of kaolin solution

1 Dissolve 10 g $CaCl_2.2H_20$ and 1 g $MgCl_2.6H_20$ in 400 ml of deionized or freshly distilled water.

2 Add 5 g kaolin (colloidal hydrated aluminium silicate) and make the volume up to 100 ml with more water.

3 Store at 4°C until used.

Conversion to "serum"

1 Measure the volume of the plasma and place into a clean glass beaker.

2 Place the beaker into a 37°C water bath for the plasma to warm up.

3 Stirring the plasma (with a motorized stirrer, if possible), add 1 ml of well-mixed kaolin solution per 100 ml plasma, plus 0.1 g sodium azide per 100 ml plasma.

4 Once the clot has formed, continue to stir for about one hour.

5 Remove the stirrer, cover the beaker and store at 4°C overnight.

6 Cover the top of a clean beaker with muslin cloth, secured with a rubber band, and strain the serum into the clean beaker. The clot can be squeezed to obtain the maximum volume of serum.

7 Filter the serum into a clean sterilized container, using a 0.45 µ filter and, if possible, through a 0.2 µ filter.

This serum can be stored for up to one year at 4°C.

PREPARATION OF MODIFIED ALSEVER'S SOLUTION

For storage of red cells for in vitro use only.

Materials

- Citric acid: monohydrate 0.5 g
- Dextrose 19.0 g
- Sodium chloride 4.2 g
- Trisodium citrate-di-hydrate 8.0 g
- Neomycin sulphate 0.5 g
- Chloramphenicol 0.33 g

Method

1 Dissolve the citric acid, dextrose, sodium chloride and trisodium citrate in 600 ml of deionized or freshly distilled water.

2 Add the chloramphenicol and neomycin sulphate. Mix well.

3 Dilute to 1000 ml with more deionized or distilled water.

4 Place into clean, sterilized vials and store at 4°C.

Washed red blood cells can be suspended in the Alsever's solution as a 1–10% suspension and stored at 4°C. These cells should be suitable for in vitro use for up to four weeks, but appropriate controls must be used to ensure that the antigens are still viable.

Annex 4

EXAMPLE

Product insert

USE OF PACKAGED MATERIAL

This material is intended to represent clinical samples for the assessment of the performance of clinical laboratories undertaking routine blood group serology.

EXERCISE PACKAGE

The exercise package comprises a plastic transport bag containing documents and a sealed, clear plastic bag which contains:

- A polystyrene box within which vials of sera and/or red cell and whole blood samples are held
- A pad that will absorb up to 50 ml of liquid: i.e. the entire contents of the package in the event of a breakage or leakage of all the vials.

CONTENTS OF THIS PACKAGE

This polystyrene box contains one vial each of:

- Up to 4 serum samples
- Up to 8 red cell/whole blood samples.

Information required to control hazardous substances

1 Red cell samples are prepared from material from a single donation that has been tested and found negative for:
   - HIV 1 and 2 antibodies
   - HCV antibodies
   - HBsAg.

   The samples are suspended in a modified Alsever's solution containing the antibiotics chloramphenicol and neomycin.

2 Whole blood samples are prepared from pooled donations that have been tested and found negative for:
   - HIV 1 and 2 antibodies
   - HCV antibodies
   - HBsAg.

   The antibiotics chloramphenicol and neomycin have been added to the samples.

3 Serum samples comprise several donations, all of which have been tested and found negative for:
   - HIV 1 and 2 antibodies
   - HCV antibodies
   - HBsAg.

EQA "serum" samples contain 0.08 to 0.12% weight/volume of sodium azide:

- Sodium azide is toxic on ingestion or inhalation. Its primary hazard at this concentration is that, on disposal via the waste system, compounds can form with lead, copper or other heavy metals. When dry, such compounds can explode on mechanical shock or on heating
- The explosive risk can be minimized by flushing any material discarded via the waste system with a large volume of water.

Opening of vials

Remove the plastic seal and gently unscrew the cap from the vial.

It is recommended that serum samples are centrifuged prior to testing.

Complement activity in serum samples

"Serum" samples are prepared from defibrinated plasma. These samples contain no complement activity or greatly reduced levels. However, serum samples do not contain antibodies that are dependent on complement activation for their detection.

HANDLING AND DISPOSAL OF PACKAGED MATERIAL

The source material from which the samples were obtained has been tested and found negative for HIV 1 and 2 antibodies, HCV antibodies and HBsAg. However, as with all preparations of human origin, the material cannot be assumed to be free from infectious agents. It should therefore be handled and discarded as if potentially infectious, in accordance with local practices and regulations.

Annex 5

EXAMPLE

Exercise instructions

EXERCISE INSTRUCTIONS AND PATIENT RED CELL PHENOTYPES FOR EXERCISE 01/04

Material provided

- 3 "patient" red cell samples: P1, P2 and P3
- 3 matched "patient" serum samples: P1, P2 and P3
- 3 "donor" red cell samples, labelled with ABO and RhD types: DW, DY and DZ.

Instructions for testing and reporting results

Using your routine method, perform the tests for which you are registered on each "patient" sample:

- ABO grouping
- RhD typing
- Antibody screening
- Antibody identification
- Compatibility testing vs. "donor" samples*.

* Do **not** phenotype "patient" or "donor" samples. The red cell phenotypes of the "patient" samples are supplied with each exercise. **However, it is appreciated that in a clinical situation where antibodies are present in a patient's serum, phenotyping of the donors and the selection of antigen negative blood may be part of the pre-transfusion protocol.**

Patient sample	Rh				MNSs				P_1	Lu	Kell	Lewis		Duffy		Kidd	
	C	c	E	e	M	N	S	s	P_1	Lu^a	K	Le^a	Le^b	Fy^a	Fy^b	Jk^a	Jk^b
1	+	0	0	+	+	0	+	0	+	0	0	+	0	+	0	0	+
2	0	+	+	0	+	0	+	0	+	0	+	0	0	+	0	+	0
3	0	+	+	0	+	+	0	+	+	0	+	0	+	0	+	+	0

THE CLOSING DATE FOR EXERCISE 01/04 is 02/02/2004

If you have any problems or queries regarding Exercise 01/04, please contact the EQA scheme organizer:

- Name of organizer
- Title of organizer
- Address
- Telephone number
- Fax number
- E-mail address

Annex 6

EXAMPLE

Exercise results form

EXERCISE 01/04 **LABORATORY REGISTRATION CODE:**

1 Date samples received _____

2 Date samples tested _____

3 Date form completed _____

4 Sample quality

	Serum			Patient cells			Donor cells		
	P1	P2	P3	P1	P2	P3	DW	DY	DZ
Satisfactory	❑	❑	❑	❑	❑	❑	❑	❑	❑
Unsatisfactory	❑	❑	❑	❑	❑	❑	❑	❑	❑

If unsatisfactory, state reason.

5 Abbreviations used on the form

Alb	Albumin
DAT	Direct antiglobulin test
Enz	Enzyme
IAT	Indirect antiglobulin test
ID	Identification
LISS	Low ionic strength saline
NISS	Normal ionic strength saline
Neg	Negative
Pos	Positive
RT	Room temperature
UI	Unable to interpret

6 Reaction strength

- Strong positive = 3+ or 4+
- Weak positive = 1+ or 2+ by tube, or equivalent by other technologies

THE CLOSING DATE FOR EXERCISE 01/04 is 02/02/04

EXERCISE 01/04 **LABORATORY REGISTRATION CODE:**

7 ABO and RhD grouping results

	Reaction strength									Interpretation					
Patient 1	α	β	αβ	A	B	O	D1*	D2*	Cont**	A	B	O	AB	UI	Other
Negative	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Weak positive	❑	❑	❑	❑	❑	❑	❑	❑	❑	Pos	Neg	UI	Other		
Strong positive	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		
Mixed field	❑	❑	❑	❑	❑	❑	❑	❑	❑						

Patient 2	α	β	αβ	A	B	O	D1*	D2*	Cont**	A	B	O	AB	UI	Other
Negative	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Weak positive	❑	❑	❑	❑	❑	❑	❑	❑	❑	Pos	Neg	UI	Other		
Strong positive	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		
Mixed field	❑	❑	❑	❑	❑	❑	❑	❑	❑						

Patient 3	α	β	αβ	A	B	O	D1*	D2*	Cont**	A	B	O	AB	UI	Other
Negative	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Weak positive	❑	❑	❑	❑	❑	❑	❑	❑	❑	Pos	Neg	UI	Other		
Strong positive	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑		
Mixed field	❑	❑	❑	❑	❑	❑	❑	❑	❑						

α anti-A
β anti-B
αβ anti-A,B
D1* Routine anti-D reagent
D2* Second anti-D, if used
Cont ** Negative reagent/diluent control/AB serum, if used

8 ABO technique used

- ❑ Tube
- ❑ Microplate
- ❑ Slide
- ❑ Column agglutination
- ❑ Other

RhD typing technique used

- ❑ Tube
- ❑ Microplate
- ❑ Slide
- ❑ Column agglutination
- ❑ Other

9 ABO and RhD typing reagents used

	Polyclonal	Monoclonal	Reagent manufacturer
Anti-A	❑	❑	_____
Anti-B	❑	❑	_____
Anti-A,B	❑	❑	_____
Anti-D (1)	❑	❑	_____
Anti-D (2)	❑	❑	_____

EXERCISE 01/04 **LABORATORY REGISTRATION CODE:**

10 Crossmatching results

Patient 1	Donor W					Donor Y					Donor Z				
	IAT	DRT	Alb	Enz	Other	IAT	DRT	Alb	Enz	Other	IAT	DRT	Alb	Enz	Other
Negative	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Weak pos	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Strong pos	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Compatible			❑					❑					❑		
Incompatible			❑					❑					❑		

Patient 2	Donor W					Donor Y					Donor Z				
	IAT	DRT	Alb	Enz	Other	IAT	DRT	Alb	Enz	Other	IAT	DRT	Alb	Enz	Other
Negative	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Weak pos	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Strong pos	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Compatible			❑					❑					❑		
Incompatible			❑					❑					❑		

Patient 3	Donor W					Donor Y					Donor Z				
	IAT	DRT	Alb	Enz	Other	IAT	DRT	Alb	Enz	Other	IAT	DRT	Alb	Enz	Other
Negative	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Weak pos	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Strong pos	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Compatible			❑					❑					❑		
Incompatible			❑					❑					❑		

11 IAT techniques used for crossmatching

Indicate which of the following were used to perform **IAT** testing for crossmatching, antibody screening and identification (select all that apply).

	Tube LISS suspension	Tube LISS addition	Tube NISS	Microplate Liquid phase	Microplate Solid phase*	Column agglutination*	Other**
Screen	❑	❑	❑	❑	❑	❑	❑
Patient 1	❑	❑	❑	❑	❑	❑	❑
Patient 2	❑	❑	❑	❑	❑	❑	❑
Patient 3	❑	❑	❑	❑	❑	❑	❑

* State manufacturer: _____

** Specify: _____

EXERCISE 01/04 **LABORATORY REGISTRATION CODE:**

12 AHG reagent used for IAT testing

Manufacturer/supplier

- ❑ Polyspecific _____
- ❑ Anti-IgG _____

13 Antibody screening results

	Reaction grades			Interpretation
Patient 1	IAT	Enz	Other*	
Negative	❑	❑	❑	❑ None detected
Weak positive	❑	❑	❑	❑ Antibody present
Strong positive	❑	❑	❑	
Patient 2	IAT	Enz	Other*	
Negative	❑	❑	❑	❑ None detected
Weak positive	❑	❑	❑	❑ Antibody present
Strong positive	❑	❑	❑	
Patient 3	IAT	Enz	Other*	
Negative	❑	❑	❑	❑ None detected
Weak positive	❑	❑	❑	❑ Antibody present
Strong positive	❑	❑	❑	

***** An alternative to the IAT: e.g. PEG or manual polybrene

14 IAT techniques used for antibody screening

	Tube LISS suspension	Tube LISS addition	Tube NISS	Microplate Liquid phase	Microplate Solid phase*	Column agglutination*	Other**
Screen	❑	❑	❑	❑	❑	❑	❑
Patient 1	❑	❑	❑	❑	❑	❑	❑
Patient 2	❑	❑	❑	❑	❑	❑	❑
Patient 3	❑	❑	❑	❑	❑	❑	❑

* State manufacturer: _____

** Specify: _____

Complete sections 15, 16 and 17 only for "patients" on whom antibody ID was undertaken

15 Number of reagent red cells

Indicate the number of reagent red cells used for ID by IAT (include screening cells):
e.g. 3 cell screen + 10 cell identification panel = 13

	≤1–4	15–25	>25
Patient 1	❑	❑	❑
Patient 2	❑	❑	❑
Patient 3	❑	❑	❑

EXERCISE 01/04 **LABORATORY REGISTRATION CODE:**

16 Enzyme panel

Indicate whether an enzyme ID panel was included.

	Yes	No
Patient 1	❑	❑
Patient 2	❑	❑
Patient 3	❑	❑

17 Antibody identification results

(No more than two specificities from list are present in a "patient" sample)

	D	C	c±E	E	e±C	M	N	S	s	P1	Lu^a	K	k	Le^a	Le^b	Fy^a	Fy^b	Jk^a	Jk^b	UI
Patient 1	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Patient 2	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑
Patient 3	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑	❑

Note

Anti-c±E = anti-c with or without anti-E

Anti-e±C = anti-e with or without anti-C. These count as a single specificity.

It is necessary to exclude only clinically significant antibodies

18 Referral

Please indicate whether the sample would be referred for confirmation or elucidation prior to a non-emergency transfusion being given.

	Yes	No
Patient 1	❑	❑
Patient 2	❑	❑
Patient 3	❑	❑

Annex 7

EXAMPLE

Exercise checklist

Procedure	Signature	Date
Request exercise material		
Check that exercise material meets specifications		
Perform pre-acceptance testing serology		
Review pre-acceptance results		
Process material		
Print labels for exercise material vials		
Dispense into vials		
Perform post-dispensing serology		
Complete any registration amendments		
List participants for specific exercise		
Make labels for posting exercise material		
Print list used for packing and dispatch		
Print exercise instructions		
Print product insert		
Print results forms		
Collate and proof-read appropriate documentation		
Pack exercise material and documentation		
Distribute exercise to participants		
Distribute three self-addressed sets of material to EQA scheme for post-distribution serology		
Perform post-distribution serology: ■ Day 1 ■ Day 7 (stored at room temperature) ■ Final day		
Decide on correct results		

Procedure	Signature	Date
If necessary, review penalty scoring		
Transcribe results or enter into computer system		
Cross-check for transcription or data entry errors		
Edit results and re-check		
Double-check errors against results forms		
Check the number of errors		
Contact all participating laboratories with errors		
Analyse results		
Write preliminary report and comments		
Complete final proof-reading, revision and printing of reports		
Perform further analysis, if necessary		
Write report supplement, if necessary		
Write up log of errors and non-returns		
Check exercise file is complete		

Annex 8

EXAMPLE

Record of exercise distribution and returned results

Laboratory code	Documentation packed	Samples packed	Exercise distributed	Results received	Report to laboratory	Report to second contact	Supplementary report sent
0001							
0002							
0003							
0004							
0005							
0006							
0007							
0008							
0009							
0010							
0011							
0012							
0013							
0014							
0015							
0016							
0017							
0018							
0019							
0020							
0021							
0022							
0023							
0024							

Annex 9

EXAMPLE

Exercise analysis and report

BLOOD GROUP SEROLOGY	**Laboratory registration code:**
EXERCISE 01/04 **Date: 20 February 2004**	
Summary of exercise material and your performance	Page 1 of 6

SUMMARY OF EXERCISE MATERIAL

"Patient" 1	A RhD positive, inert	"Donor" W	O RhD positive, Fy(a+b-)
"Patient" 2	O RhD positive, anti-Fy^a titre 4 vs Fy(a+b+) cells	"Donor" Y	A RhD positive, Fy(a-b+)
"Patient" 3	A RhD positive, inert	"Donor" Z	O RhD positive, Fy(a-b+)

Titre obtained by tube LISS suspension in the EQAS laboratory on the closing date

Index

Definition of penalty scores	
0 to 79	Satisfactory
80 to 99	Borderline
100 to 150	Unsatisfactory

Your performance summary		Penalty score this exercise	Cumulative performance
Non-return penalty		0	Satisfactory
ABO	No errors	0	Satisfactory
RhD	No errors	0	Satisfactory
Antibody screen	No errors	0	Satisfactory
Antibody identification	No errors	0	Satisfactory
Crossmatch	No errors	0	Satisfactory

Aims of the exercise: To assess performance in detecting an incompatibility due to: a) major ABO mismatch (A to O) and b) weak anti-Fy^a against Fy(a+b-) red cells.

Return rate: Results were returned by 455/466 (97.6%) participants by the closing date.

Transcription/transposition errors: Eight participants were responsible for ten transcription errors, as follows: both screening errors, the one antibody identification error, two missed incompatibilities and five missed compatibilities. One further participant transposed "Donor" cells W and Z, resulting in one missed incompatibility and one missed compatibility.

Crossmatching: Excluding transcription and transposition errors, five participants missed the incompatibility between the anti-Fy^a and the Fy(a+b-) unit. There was no correlation with IAT technology.

BLOOD GROUP SEROLOGY	Laboratory registration code:
EXERCISE 01/04 Date: 20 February 2004	
Summary of exercise material and your performance	Page 2 of 6

Discussion: Transposition of donor samples is a major source of error in crossmatching since many critical steps are involved, such as removing cells from the donor bags and transferring them to correctly-labelled tubes before washing. Five participants detected the anti-Fy^a in the screen but not the crossmatch, even with a cell homozygous for the Fy^a antigen. Making consistently accurate cell suspensions is a challenge in crossmatching, since segments removed from the pigtail (and aliquots from the EQA samples) vary in concentration and always require resuspension. This may explain some of the errors seen only in crossmatching, even with cells homozygous for the relevant antigen.

BLOOD GROUP SEROLOGY	**Laboratory registration code:**
EXERCISE 01/04 **Date: 20 February 2004**	
ABO and RhD grouping	Page 3 of 6

SUMMARY OF EXERCISE MATERIAL

"Patient" 1 A RhD positive
"Patient" 2 O RhD positive
"Patient" 3 A RhD positive

Your results in bold
Correct results are shaded
UI = Unable to interpret

Patient 1

Your result:	**A RhD positive**		**Your score = 0**
Overall results:	A RhD positive	100.0% (n = 455)	

Patient 2

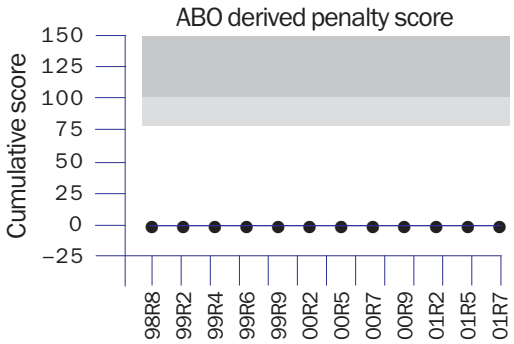
Your result:	**O RhD positive**		**Your score = 0**
Overall results:	O RhD positive	100.0% (n = 455)	

Patient 3

Your result:	**A RhD positive**		**Your score = 0**
Overall results:	A RhD positive	99.6% (n =453)	
	A RhD variant	0.4% (n = 2)	

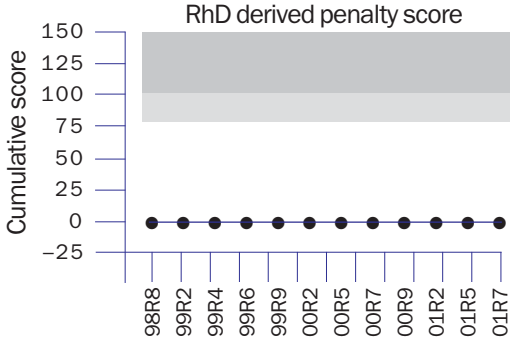
Your overall score for this exercise:	**ABO**	**0 (satisfactory)**
	RhD	**0 (satisfactory)**

Your last three returns contribute to the cumulative scores



Current performance: Satisfactory
Cumulative score: 0

Unsatisfactory
Borderline
Satisfactory



Current performance: Satisfactory
Cumulative score: 0

Unsatisfactory
Borderline
Satisfactory

BLOOD GROUP SEROLOGY	**Laboratory registration code:**
EXERCISE 01/04 **Date: 20 February 2004**	
Antibody screening and identification	Page 4 of 6

SUMMARY OF EXERCISE MATERIAL

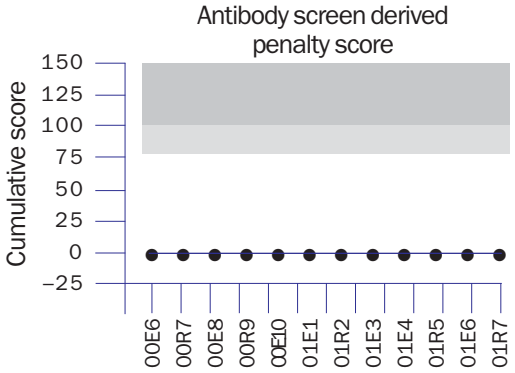
"Patient" 1 Inert
"Patient" 2 Anti-Fy[a]
"Patient" 3 Inert

Your results in bold
Correct results are shaded
UI = Unable to interpret

	Antibody screen		Antibody identification	
Patient 1				
Your result:	**No antibody detected**	**Your score = 0**		
Overall results:	No antibody detected	100.0% (n = 452)		
Patient 2				
Your result:	**Antibody detected**	**Your score = 0**	**Fya**	**Your score = 0**
Overall results:	Antibody detected	99.8% (n = 451)	Fy[a]	99.7% (n = 381)
	No antibody detected	0.2% (n = 1)	Fy[b]	
Patient 3				
Your result:	**No antibody detected**	**Your score = 0**		
Overall results:	No antibody detected	99.8% (n = 451)		
	Antibody detected	0.2% (n = 1)		

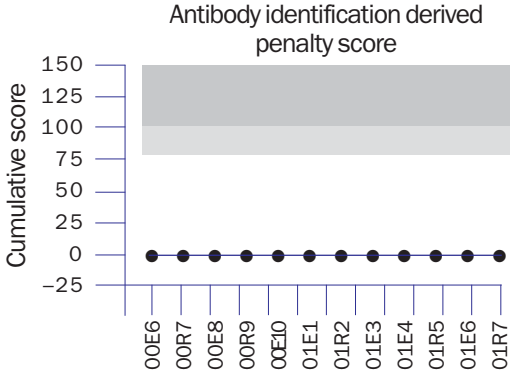
Your overall score for this exercise:	**Antibody screen**	**0 (satisfactory)**
	Antibody identification	**0 (satisfactory)**

Your last three returns contribute to the cumulative scores



Current performance: Satisfactory
Cumulative score: 0

Unsatisfactory
Borderline
Satisfactory



Current performance: Satisfactory
Cumulative score: 0

Unsatisfactory
Borderline
Satisfactory

BLOOD GROUP SEROLOGY	**Laboratory registration code:**
EXERCISE 01/04 **Date: 20 February 2004**	
Crossmatching summary	Page 5 of 6

SUMMARY OF EXERCISE MATERIAL

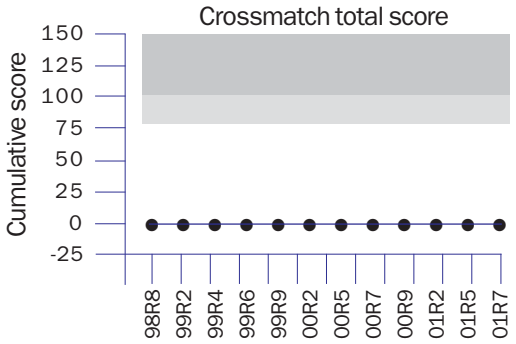
"Patient" 1 A RhD positive, inert	"Donor" W O RhD positive, Fy(a+b-)
"Patient" 2 O RhD positive,anti-Fy^a	"Donor" Y A RhD positive, Fy(a-b+)
"Patient" 3 A RhD positive, inert	"Donor" Z O RhD positive, Fy(a-b+)

Your results in bold
Correct results are shaded
UI = Unable to interpret

	Donor W	Donor Y	Donor Z	
Patient 1				
Your result:	**C**	**C**	**C**	**Your score = 0**
Overall results:	C 99.8% (n = 445) I 0.2% (n = 1)	C 100% (n = 446)	C 100.0% (n = 446)	
Patient 2				
Your result:	**I**	**I**	**C**	**Your score = 0**
Overall results:	I 98.2% (n = 438) C 1.8% (n = 8)	I 100% (n = 446)	C 98.7% (n = 440) I 1.3% (n = 6)	
Patient 3				
Your result:	**C**	**C**	**C**	**Your score = 0**
Overall results:	C 99.6% (n = 444) I 0.4% (n = 2)	C 99.8% (n = 445) I 0.2% (n = 1)	C 99.8% (n = 445) I 0.2% (n = 1)	

Your overall score for this exercise: **Crossmatch total score** **0**

Your last three returns contribute to the cumulative scores



Current performance: Satisfactory
Cumulative score: 0

Unsatisfactory
Borderline
Satisfactory

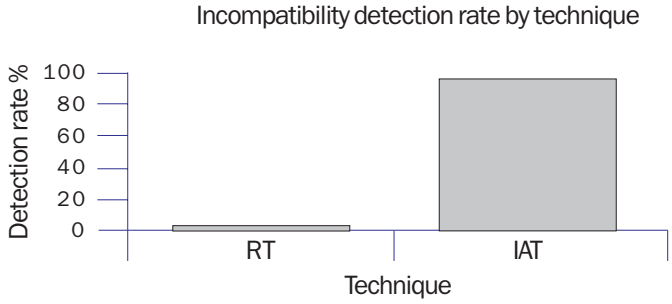
BLOOD GROUP SEROLOGY	**Laboratory registration code:**
EXERCISE 01/04 **Date: 20 February 2004**	
Crossmatching details	Page 6 of 6

SUMMARY OF EXERCISE MATERIAL

"Patient" 2 O RhD positive, anti-Fy[a]
"Donor" W O RhD positive, Fy(a+b-)
"Donor" Y A RhD positive, Fy(a-b+)

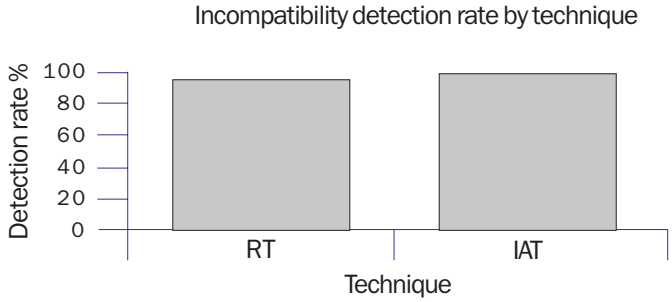
Your results in bold
Correct results are shaded
UI = Unable to interpret

"Patient" 2 against "Donor" W



Technique	No. labs.	% detection
RT	131	3.8
IAT	386	97.2

"Patient" 2 against "Donor" Y



Technique	No. labs.	% detection
RT	107	97.2
IAT	305	100

Annex 10

EXAMPLE

Numerical scoring systems

EXAMPLE 1: PENALTY POINTS

This scoring system is based on allocating penalty points for errors made, and is weighted according to consensus results.

Assessment

There are six areas of assessment:

- ABO grouping
- RhD typing
- Antibody screening
- Antibody identification
- Crossmatching
- Non-return of results.

Participants are scored on their interpretations in each of the tests for which they are registered, and for non-return of results.

Scoring is weighted according to the potential clinical significance of the type of error, as follows:

- 100 points for incorrect ABO group
- 40 points for a false positive crossmatching result.

Scoring reduces, as stated below, with decreasing consensus of results.

The score for each area is added over three exercises into a running score for that area of assessment. The running score for each area of assessment ranges from 0 to 150. For each component of the exercise, any total of greater than 150 is set to 150.

ABO and RhD typing

For each incorrect ABO grouping (excluding subgroups of blood group A) where at least 20% participants obtain the expected result	**100**
Note: A result of UI (unable to interpret) will incur a penalty (50 points) unless the cell is DAT positive.	
For each incorrect RhD grouping where at least 20% participants obtain the expected result	**100**
Note: a result of UI (unable to interpret) will incur a penalty (50 points) unless the cell is DAT positive.	

Antibody screening

For each false-negative antibody screen

- Where 20%–49% of participants obtain the expected result 20
- Where 50%–79% of participants obtain the expected result 40
- Where 80%–100% of participants obtain the expected result **80**

For each false-positive antibody screen

- Where 20%–49% of participants obtain the expected result 10
- Where 50%–79% of participants obtain the expected result 20
- Where 80%–100% of participants obtain the expected result **40**

Antibody identification

For each incorrect antibody identification

Example 1: 1 anti-E (correct result anti-D)

Example 2: 2 anti-E (correct result anti-E+Fy^a)

- Where 20%–49% of participants obtain the expected result 20
- Where 50%–79% of participants obtain the expected result 40
- Where 80%–100% of participants obtain the expected result **80**

For each partially correct identification

Example 1: 1 anti-E+K or anti-E+UI (correct result anti-E)

Example 2: 2 anti-E+UI (correct result anti-E+Fy^a)

- Where 20%–49% of participants obtain the expected result 10
- Where 50%–79% of participants obtain the expected result 20
- Where 80%–100% of participants obtain the expected result **40**

For being unable to identify any specific antibody **50**
e.g. UI (correct result anti-E or anti-E+Fy^a)

Note: Participants registered for antibody identification with an antibody screen error do not incur an additional identification error for that sample.

Crossmatching

For each missed serological incompatibility

- Where 20%–49% of participants obtain the expected result 20
- Where 50% –79% of participants obtain the expected result 40
- Where 80%–100% of participants obtain the expected result **80**

For each missed serological compatibility

- Where 20%–49% of participants obtain the expected result 10
- Where 50%–79% of participants obtain the expected result 20
- Where 80%–100% of participants obtain the expected result **40**

Non-return (or late return) of results

For each non-return or late return of results for an exercise **50**

EXAMPLE 2: REWARD AND PENALTY POINTS

This scoring system allocates reward points for what has been achieved and deducts penalty points for errors.

The participating laboratory's score is given for each test together with the maximum achievable points; this can also be expressed as a percentage. Additional points can be awarded in each category for following national guidelines for testing, where these are in place.

ABO	
Correct interpretation of group	40
Incorrect interpretation of group	–40
RhD	
Correct interpretation of RhD type	20
Incorrect interpretation of RhD type	–20
Antibody screening	
Correct interpretation	20
False positive screen	0
False negative screen	–20
Antibody identification	
Correct identification	20
Correct identification of antibodies present, but additional specificities not excluded	0
Partially incorrect (only one of two antibodies identified)	–10
Incorrect identification	–20
Crossmatching	
Correct compatibility	20
Correct incompatibility	20
False incompatibility	0
False compatibility	–20
Tests performed in accordance with national guidelines (e.g. reagents or techniques selected)	10
Non-return of results	0