

**Safe
Blood
and
Blood
Products**

Introductory Module

**Guidelines and
Principles for
Safe Blood
Transfusion
Practice**



World Health
Organization

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Conversion of electronic files for the website edition was supported by Cooperative Agreement Number PS001426 from the Centers for Disease Control and Prevention (CDC), Atlanta, United States of America. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

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Acknowledgements

The World Health Organization would like to thank many blood transfusion medicine specialists for their part in the development of these materials.

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Preface

The human immunodeficiency virus (HIV) has focused attention worldwide on the need for safe blood and blood products. While the major route for the spread of HIV is heterosexual transmission, blood transfusion is the most efficient mechanism. It is estimated that the transmission of HIV through blood transfusion is more than 90% efficient. Preventing the spread of HIV through blood and blood products is, however, a goal that can be attained by every national blood programme.

In developing countries, blood transfusion services have traditionally been a low priority in health service development. The Blood Transfusion Safety Team in the World Health Organization recognizes the need to train staff involved in blood transfusion systems at national level. It would be impossible, however, to train and update all staff within the short and medium term, using conventional approaches. Suitable training facilities are limited and there is a serious shortage of trainers. Many laboratory technical staff and others involved in the collection and processing of blood work in small hospital blood banks which are distant from training facilities. Participation in conventional short- or long-term courses necessitates technicians leaving their workplace, which is costly and places additional demands on other staff or requires the appointment of replacement staff.

These learning materials, *Safe Blood and Blood Products*, are designed to provide an alternative means of rapidly improving the knowledge and technical skills of staff in blood transfusion services in developing countries. They have been designed for use in distance learning programmes in blood safety, although they can also be used for independent study or as resource materials in conventional training courses and in-service training programmes. They will enable blood transfusion services to update and upgrade staff in a practical and cost-effective way and to make effective use of limited training resources.

The materials have been produced for staff with responsibility for donor recruitment and retention, and for the collection, testing and issue of blood for transfusion. They comprise the following modules:

- Introductory Module: *Guidelines and Principles for Safe Blood Transfusion Practice*
 - Module 1: *Safe Blood Donation*
 - Module 2: *Screening for HIV and Other Infectious Agents*
 - Module 3: *Blood Group Serology.*
-

The modules have been written by blood transfusion specialists with knowledge and experience of developing countries and the modules have been under continuing review by many blood transfusion medicine experts throughout the world. Open Learning Associates, UK was responsible for the distance learning format, editing and production.

The English edition was first published in 1993. French, Spanish, Russian, Chinese and Portuguese editions have since been produced and the materials have also been translated into a number of national languages.

This second, updated edition of the materials has been developed to reflect changes in transfusion medicine and laboratory technology since the publication of the first edition.

Distance learning in blood safety

Since the publication of *Safe Blood and Blood Products*, WHO has held a series of regional and sub-regional workshops for senior blood transfusion service personnel from over 100 countries on establishing national distance learning programmes in blood safety. Programmes have since been established in every region of the world, using the WHO learning materials.

Part of the follow-up to the workshops has been the production of *Establishing a Distance Learning Programme in Blood Safety: A Guide for Programme Coordinators*. This provides a practical guide to the planning, implementation and evaluation of a distance learning programme in blood safety.

Other WHO learning materials

The Clinical Use of Blood consists of an open learning module and pocket handbook which provide comprehensive guidance on transfusion and alternatives to transfusion in the areas of general medicine, obstetrics, paediatrics and neonatology, surgery and anaesthesia, trauma and acute surgery, and burns. They are designed to promote a reduction in unnecessary transfusions through the wider use of plasma substitutes and more effective prevention and treatment of the conditions that may make transfusion necessary.

WHO has also published recommendations on *Developing a National Policy and Guidelines on the Clinical Use of Blood* which encourage the use of the learning materials in education and training programmes to promote effective clinical decisions on transfusion.

Additional learning materials in the *Safe Blood and Blood Products* series that are available or in development by the WHO Department of Blood Safety and Clinical Technology (WHO/BCT) include:

- *Costing Blood Transfusion Services*
 - *The Blood Cold Chain*
 - *Blood Collection*
 - *Blood Components Production*.
-

More detailed information on these materials and other documents and publications related to blood transfusion is available from WHO/BCT, which also issues regular reports on evaluations of the operational characteristics of many commercially available screening assays for transfusion-transmissible infections.

Information can be obtained from the BCT section of the WHO website at <http://www.who.int/bct> or by contacting WHO/BCT at WHO Headquarters or WHO Regional Offices.

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1

Introduction to the Module

The purpose of this section is to introduce you to the distance learning materials *Safe Blood and Blood Products* and, in particular, to *Guidelines and Principles for Safe Blood Transfusion Practice* which is the Introductory Module in the series.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 Explain the components of a distance learning programme in blood safety.
 - 2 Identify a personal “supporter” who can assist you throughout your work on this module.
 - 3 Assess your current knowledge, skills and experience in relation to the objectives of this module.
 - 4 Make a realistic Study Plan for your work on this module.
-

1.1 DISTANCE LEARNING IN BLOOD SAFETY

The World Health Organization (WHO) has set the goal that every country in the world should have supplies of blood and blood products that are as safe as possible, accessible at reasonable cost and adequate to meet national needs. Its strategy for achieving this goal emphasizes the importance of:

- collecting safer donations from low-risk blood donors
- testing all blood for the human immunodeficiency virus (HIV) and other transfusion-transmissible infections before transfusion
- minimizing unnecessary blood transfusions.

The successful implementation of this strategy will largely depend on the knowledge, skills and commitment of the people working in every blood transfusion service and hospital blood bank. Training will obviously play an important part in this process of improving the quality and safety of the blood supply.

In many countries, however, refresher courses and opportunities for further training are often limited, particularly for staff in small hospital blood banks who do not have easy access to training institutions. Few countries have adequate facilities or sufficient numbers of trainers to be able to meet the training needs of large numbers of staff who are scattered over wide geographical areas. During the foreseeable future, therefore, it will be very difficult to provide appropriate training for everyone who needs it, using conventional training approaches.

It is for this reason that the team responsible for Blood Transfusion Safety in the WHO Department of Blood Safety and Clinical Technology has developed *Safe Blood and Blood Products*, with the aim of assisting national blood programmes to overcome some of the logistic problems involved in providing training, particularly for staff who have several years of experience but who need to update their knowledge or learn new skills. The learning materials have been specifically designed for use in distance learning programmes in blood safety, although they can also be used as resources in conventional training courses and in-service training and for independent study.

Distance learning programmes in blood safety are a practical, cost-effective means of making the best possible use of limited training resources and enabling large numbers of people to participate at the same time. They are already operating in many countries throughout the world, although the way that they are organized depends on the needs and circumstances in each country.

What is distance learning?

Distance learning means that learners do not need to be in the same place as their trainer because, in many ways, the learning materials (such as this module) replace the trainer. Although laboratory practice is an essential part of a technical training course, this does not necessarily need to be undertaken in a training centre. Much of it can be completed in the learner's own workplace, as long as a suitably qualified and experienced senior member of staff is available to supervise it.

The combined use of learning materials and local expertise thus makes it possible to provide a comprehensive and in-depth training programme that would normally only be available in a specialized training institution. An additional advantage is that the training does not have to take place on fixed dates. Instead, it can be spread out over a period of time and can be planned to suit the needs of each individual learner, as well as the service in which he or she works.

Who are the materials for?

Safe Blood and Blood Products has been developed primarily for laboratory technical staff working in blood transfusion services, hospital blood banks and public health laboratories who are involved in the collection or processing of blood. It is not designed for basic or advanced training, and will be most useful for staff who have completed an initial training programme and already have some experience.

Module 1: *Safe Blood Donation* will also be useful for nurse-phlebotomists and anyone working in an organization such as a national Red Cross or Red Crescent Society who is responsible for blood donor recruitment and blood collection.

The materials will also be of interest to senior laboratory technical staff with responsibility for training and supervising other staff and to medical personnel, such as medical superintendents. The modules offer basic refresher and updating material as well as a comprehensive resource that they can integrate into local training programmes.

Using the materials

Whatever your particular area of work and training needs, you are almost certainly wondering how a distance learning programme will actually work in practice and what you will have to do. It is therefore important to read the rest of Section 1 carefully and make sure that you understand it before you move on to Section 2.

The learning materials have been specially written for this programme by international subject specialists. They are very different from textbooks because they are not simply concerned with providing information and increasing your theoretical knowledge, although this is a fundamental aim of the programme. Even more importantly, they are designed to help you to apply your knowledge more effectively in your everyday work so that, ultimately, you will be able to do your job better. They do this by asking you to carry out a series of practical activities. These are specifically designed to help you strengthen your existing skills or develop new ones and plan ways of introducing improved approaches and procedures in your work. When you have completed the programme, you can use the materials for reference and share them with other colleagues. Section 1.2 explains the structure of the modules and how to use them.

In addition to *Guidelines and Principles for Safe Blood Transfusion Practice*, there are three other modules in the learning programme which are each designed to extend your knowledge and skills in specific areas of blood transfusion practice.

Module 1: *Safe Blood Donation* focuses on the recruitment and selection of low-risk blood donors as the first step in ensuring the safety of the blood supply. In particular, it stresses the importance of building up a panel of regular, voluntary non-remunerated blood donors.

Module 2: *Screening for HIV and Other Infectious Agents* deals in detail with screening for the human immunodeficiency virus (HIV) and applies the same principles to screening for other infectious diseases.

Module 3: *Blood Group Serology* is designed to help you ensure that your basic serological knowledge and skills are fully up-to-date and includes details of techniques for blood grouping and compatibility testing.

As its title suggests, this Introductory Module provides a foundation for the programme as a whole, so it is important to work through it before moving on to the other modules. You can then use the modules in any sequence, depending on your own priorities and your particular training needs. For example, you may be a laboratory technician in a small hospital where you spend most of your time on serological work and on screening blood for transfusion-transmissible infections, and only occasionally come into direct contact with blood donors. You may decide to start with Module 3 to revise your basic serological skills, then to work through Module 2 which focuses on HIV and other infectious agents before coming to Module 1, which deals with the recruitment of low-risk donors. If your work is very specialized, you may even decide that one or more of the modules is not directly relevant to you at present. Whatever your job, however, talk to your trainer and your supervisor about the most appropriate order in which to study the modules.

The modules are the central part of the learning programme, but you are not expected to study them in isolation. Although the programme will operate in slightly different ways in each country, you should be contacted by a trainer before you start working through this Introductory Module. This person will help you throughout your studies and may organize group meetings with other learners and short courses or workshops for benchwork and other practical activities. You will also be asked to find a personal “supporter” – someone in your own workplace who can provide you with help and encouragement as you work through the modules. Sections 1.3 and 1.4 explain in more detail about the kind of support you should receive while you are studying.

If you are unfamiliar with this approach to learning, it may seem a little strange at first. However, once you have become used to it, you should find it enjoyable because it will help you to increase your knowledge and skills in the specific context of your own work. Distance learning is used widely throughout the world and there may be an open university or correspondence college in your country which provides courses that operate in a similar kind of way. If there is, you may know someone who has undertaken one of these courses and can give you advice on studying “at a distance”. You will find that many people prefer the flexibility that it offers, enabling them to study without having to leave their jobs and their families to travel to a distant training institution.

1.2 THE MODULES

The modules are all written in the same way as in this Introductory Module. Once you become familiar with its structure and approach, you should find it easy to move on to the next module.

Module objectives

In Section 1 of each module, there is a list of objectives which explain what you should be able to do by the time you have completed the module. You will be asked to complete an activity in which you assess your current knowledge, skills and experience in relation to each objective. You will find the objectives for this module, together with the activity, on pages 12–13. When you reach the end of the module, you will be asked to look at these objectives again to assess how much you have learned and whether you need to do further work on any of the sections.

Sections

Each objective is covered by a separate section of the module which provides the basic information needed to understand the subject. Take as much time as you need to read through it and to complete the activities and answer the self-assessment questions. Mark anything that you find difficult, then go back to those parts when you have finished the section and reread them until you are able to understand them. If you still find them complicated, seek help from your supporter, supervisor or another senior colleague. Don't be afraid to ask for assistance since what you are learning is extremely important and will directly benefit the centre in which you work.

If you are already familiar with some of the material, read it through carefully as a means of revision. Answer the self-assessment questions and carry out the activities because they are designed to help you to check your knowledge and identify any improvements that could be made in your own area of work.

Some parts of the modules may be more relevant to your work than others. This will depend on where you work and what your job is. In this module, for example, you will see that some parts are concerned with blood collection, although most of it focuses on work in the laboratory. Work through the parts that are relevant to you, completing the activities and answering the self-assessment questions. Then simply read the rest. Your trainer should highlight these areas when you first meet.

Learning objectives

At the beginning of each section, there is a list of learning objectives which explain what you should be able to do when you have completed that section. Like the broader module objectives, they are a guide for your learning and will help you to assess your own progress. You may even want to set additional objectives for yourself to help you apply what you are learning.

Activities

As you work through each section, you will be asked to complete a number of activities. The three activities in Section 1 of each module are designed to help you prepare for your studies, by asking you to:

- identify a personal “supporter” for your work on that module
- assess your current knowledge, skills and experience in relation to each module objective
- prepare a Study Plan.

Many of the activities throughout the modules ask you to review current approaches and procedures in your workplace, try out new ideas or methods, and identify ways of improving specific aspects of your work. They may suggest that you consult with colleagues, look at records or search for information, as well as plan and carry out particular tasks. These activities may take some time to complete, but it is important to do them thoroughly since their purpose is to help you to do your job more effectively and to identify any improvements that you think could be made in your workplace.

These kinds of activity are not designed to test your knowledge and so there are no right or wrong answers. Since they focus directly on your own work, your answers will generally depend entirely on local conditions and circumstances. You will find checklists for these work-based activities in the section **Activity Checklists and Answers** which you will find at the end of each module. Keep a special file or notebook for your notes and answers and use the checklists to help you decide whether you have completed these activities adequately. If you are not satisfied with your answers, or have faced any problems in carrying out any of the activities, you will find it helpful to discuss them with your supporter, supervisor or trainer. In fact, many of these activities specifically suggest that you should discuss your ideas with your colleagues.

The remaining activities are designed to help you test your ability to apply your knowledge. You will find most of these kinds of activity in Modules 2 and 3. Once you have completed an activity of this kind, check your response with the correct answer in the Activity Checklists and Answers. If your answer is incorrect, go back to the relevant part of the section and read it again until you are sure that you have understood it. If necessary, ask a senior colleague to explain it to you.

Action List and Action Plan

In some activities, you are asked to note down your ideas or recommendations for improving specific procedures or other aspects of your work. Summarize them on the Action List, which you will find in the last section of each module. In this module, the Action List is in Section 8 on page 95. When you complete the activity, write down the number of the activity in Column 1 and your ideas for improvement in Column 2. You will probably need to continue your Action List on a separate sheet of paper.

You may be able to put some of these ideas into practice before you reach the end of the module, but others will take more time. When you reach

the final section, therefore, you will be asked to review all the ideas that you have listed and draw up an Action Plan to put them into practice. You will need to discuss this with your supporter, supervisor and, perhaps, other senior members of staff so that, together, you can plan how to improve the efficiency and effectiveness of your programme. You will also need to discuss your Action Plan with your trainer. The Action Plans provide you with an important opportunity to apply what you have learned by identifying ways of making practical improvements in your workplace. They are therefore the most important part of your work on this learning programme.

You may find that it is not possible to introduce all the changes that you feel are appropriate, perhaps because you are not responsible for that particular area of work or because there are not enough staff or financial resources available. In such cases, it is particularly important to discuss your ideas with your supporter and supervisor so that you can set some objectives that you all agree are realistic, given the circumstances in which you work.

Summary

The summary at the end of each section lists the main points covered in the section. You may wish to add your own notes to this.

Self-assessment

Self-assessment questions are included at the end of most sections of the modules. These will help you to assess for yourself whether you have understood important points in the section. They are not like an examination. Once you have decided on your answers, look at the section **Answers to Self-assessment Questions** at the end of the module to check whether they are right. If you have chosen the correct answers, you should be ready to start work on the next section. If any of your answers are incorrect, go back to the relevant parts of the section and read them again. If you still find it difficult to understand something, ask your supporter or another senior colleague to explain it to you.

Progress Check

The Progress Check at the very end of each section asks you to look back at the learning objectives for that section and to check whether you have achieved them. Remember that the objectives are simply intended as a guide for your own learning and be as honest as possible in evaluating your own progress. If you feel that you have not achieved any of the objectives, go back over the relevant parts of the section and, if necessary, discuss any problems with your supporter, supervisor or trainer.

Glossary

In Modules 1, 2 and 3, you will find a Glossary, which contains definitions of technical terms. You will notice that the first time that any word in the Glossary is used, it is marked in **bold** (heavy type) in the text and the definition is given in the margin.

Appendices

Each module includes one or more appendices, which contain supplementary material such as examples of standard operating procedures, and more detailed information on selected topics.

Offprints

Accompanying the modules are four laminated copies of items that appear in the Introductory Module and Module 3 that you can display in your laboratory or photocopy for your own use:

- guidelines on safety in the laboratory
- checklist for signs of deterioration in blood or plasma
- checklist for issuing blood or plasma
- checklist for giving blood or plasma to a patient.

1.3 THE ROLE OF YOUR TRAINER

Before you start working through this module, you should be contacted by a trainer who will keep in touch with you throughout your work on the learning programme. Ideally, the trainer will visit you, but in some cases this may not be possible and you may be contacted by telephone, e-mail or post instead. Whichever means of communication is used, the purpose of this first contact is to answer any questions you have about how the programme works, discuss what you want to achieve from your study and help you to make a Study Plan.

You will find a blank Study Plan for your work on this module on page 15 and you will be asked to fill this in before you complete this section. In order to make your Study Plan, you will need to:

- complete Activities 1 and 2 in this section and discuss your responses with your trainer
- agree a timetable for working through the Introductory Module, including the dates by which you plan to complete each section
- set dates for meetings or other contact with your trainer and your supporter.

During the first meeting, your trainer may also ask you to complete Activities 1 and 2 in the other modules and to make a Study Plan for the next module that you will be studying.

Where you are learning new technical skills, particularly in your work on Modules 2 and 3, your practical work will need to be supervised. This should be undertaken by your normal supervisor or another suitably qualified senior member of the technical staff. This person should be present during the preliminary discussion with your trainer. If this is not possible, the trainer should contact them separately. It is also important for the trainer to explain to your supervisor that your work on this learning programme is likely to result in you making suggestions for improvements in the approaches or procedures used in your workplace. Since you will need the support and assistance of senior colleagues, particularly when

you prepare your Action Plan and begin to implement it, it is essential that they understand the purpose of the programme and the kind of work that you will be undertaking.

Meetings and workshops

When you discuss your Study Plan for this module with your trainer, you should plan the dates for further contact since your trainer's role is to support you throughout your work on the programme and to assist in making the learning process as smooth and enjoyable as possible. This contact will probably have to take place mostly by telephone, e-mail or letter, but you may be able to have face-to-face meetings and to take part in occasional workshops or short courses. The arrangements will depend on how the programme is organized in your country.

Individual meetings

If you and your trainer both work in the same part of the country, it may be possible to have periodic meetings on an individual basis. These will give you an opportunity to discuss your progress, obtain help with any problems you may have in using the materials or in carrying out the activities, and agree any necessary changes to your Study Plan.

Group meetings

If there are several people in your region taking part in the learning programme, the trainer may hold occasional group meetings to cover some subjects in more depth, deal with common problems and perhaps undertake some practical work. You will find that group meetings will provide valuable opportunities for sharing your knowledge, experience and ideas with other people who are also working through the materials.

You may have to travel to other hospitals or centres for group meetings organized by your trainer, but if there are other people in your hospital or centre who are also undertaking this learning programme, you could make your own arrangements to meet them for informal discussions. Even if you are working on a different module, you will still find this helpful.

Workshops and short courses

It may be possible for you to attend a workshop or short course in which you focus on practical work, particularly in relation to Modules 2 and 3. This would probably be held at national or regional level, although it may not be feasible in some countries. Your trainer will tell you about arrangements for meetings of this kind.

1.4 THE ROLE OF YOUR SUPPORTER

Even though there should be regular contact between you and the trainer, you will also need advice and support from people within your own workplace, particularly when you are doing some of the more challenging activities and want to discuss improvements that you think could be made to established approaches or procedures. You may need occasional assistance in finding information about national or local policies, or

about particular procedures or systems in your transfusion centre or hospital. There may also be times when you find it difficult to understand points in the materials and want to discuss them with other people working in the same area. It is therefore important to talk about your work on the learning programme with your colleagues and to share what you learn with them.

In order to ensure that you have continuing support throughout your work on this learning programme, you will need to identify a personal “supporter”. Your supporter should be a senior colleague from your own workplace who specifically agrees to provide encouragement and assistance to you as you work through the programme and to discuss your progress with you on a regular basis.

You may be able to identify several different people in your blood transfusion centre or hospital who could act as your supporter. Ideally, the person you select should be your supervisor, but if this is not possible or you do not have a supervisor, choose a senior member of staff who is willing to help you, such as the medical superintendent. It is not essential that your supporter should be a technical expert, but they should have a good knowledge and understanding of your particular area of work. You may decide to choose a different supporter for your work on each module.

ACTIVITY 1

Spend a few minutes thinking about the people with whom you work, particularly your supervisor and other senior colleagues, who could support you while you are working through this learning programme. Try to identify one person whom you think would be willing to spend some time talking to you periodically about your work on this module and helping you with any problems that you might face. It is important to choose someone who is prepared to discuss your ideas about ways of improving the service and to assist you in planning and implementing any changes that you identify as being necessary as a result of your work on this module.

Check that the person you have chosen is prepared to help you. Explain how the learning programme operates and what the role of the supporter involves. For example, you may wish to arrange a regular meeting every two or three weeks to discuss what you have learned and, in particular, your work on the activities and how you can use this to improve specific aspects of practice in your centre. Alternatively, you may prefer to arrange a meeting each time you complete one or two sections in the module. Try to arrange regular meetings from the start. Show the modules to your supporter so that they become familiar with the approach used in the materials.

If you have any difficulty in finding a supporter in your workplace, talk to your trainer who will help to find a suitable person to support you.

Your trainer will also need to speak to your supporter and explain more fully what this role involves.

Other sources of support are the Programme Manager for the national AIDS control programme in your country and the office of the World Health Representative, from which you should be able to obtain some of the publications referred to in the modules. Your Ministry of Health will also play an important role in supporting the programme and should be able to assist you if you need information about statistics or national policies.

1.5 ASSESSMENT

There are no examinations or other kinds of formal assessment in these learning materials because the most important test of your learning will be the quality of your own work and of the service provided by your blood transfusion centre or blood bank. This is why it is so important to put your Action Plans into practice. However, there are three ways in which your work will be evaluated.

Firstly, *you* will assess your own learning, using the Answers to Self-assessment Questions, Activity Checklists and Answers, Progress Checks and the outcomes of your Action Plans. As a professional, working in a service that is designed to save lives, you have a responsibility to be honest in evaluating your learning and deciding whether you have achieved the learning objectives. If you haven't, you will need to decide what to do in order to reach an acceptable standard and you should discuss this with your supporter and supervisor.

Secondly, your supporter and supervisor will monitor your progress and will need to approve any changes you want to make in implementing your Action Plans. They may also be asked to provide a report for your trainer on what you have achieved.

Thirdly, your trainer will want to check whether your work has met a specified standard. The way in which your learning is assessed will be decided in each country in which the programme operates, but it is important to keep your notes on your work on the activities and Action Plans so that your trainer can evaluate your progress. If you participate in any workshops or short courses as part of the programme, your trainer will be able to assess your ability to apply your knowledge by talking to you and observing your practical work.

Some countries may decide to introduce formal assessment procedures through an academic institution, recognized training centre or professional organization, but the policy on this will be determined on a national basis.

1.6 INTRODUCTORY MODULE: GUIDELINES AND PRINCIPLES FOR SAFE BLOOD TRANSFUSION PRACTICE

Now that you have read about the learning programme and how to use the modules, you are almost ready to begin work on this Introductory Module. It covers a number of basic but important aspects of working in a blood transfusion service or hospital blood bank and is divided into eight sections.

Section 1: *Introduction to the Module* outlines the contents of the module and contains activities that are designed to help you to prepare for your work on it.

Section 2: *Professionalism* looks at the issue of professionalism within the transfusion service and hospital blood bank and considers the importance of confidentiality, standards of behaviour and dress and the role of professional organizations.

Section 3: *Safety Procedures* concentrates on health and safety in the workplace, particularly in the laboratory. It covers common hazards, the use of safety guidelines, protective clothing, the safe disposal of waste and disinfection procedures. It also considers the hazards associated with the handling of blood and the dispatch of samples.

Section 4: *Quality and Quality Assurance* introduces the principles of quality assurance, which is vital to a safe and efficient transfusion service. It also includes simple guidelines on preparing and using standard operating procedures, record-keeping and monitoring.

Section 5: *Safe Storage and Transportation of Blood and Plasma* focuses on developing an effective cold chain, temperature monitoring and the transportation of blood and plasma within the hospital or blood bank.

Section 6: *Preparing Basic Solutions* deals with the preparation of four basic solutions commonly used in blood transfusion practice: copper sulfate, antiseptic, saline and disinfectant solutions.

Section 7: *Stock Control* focuses on making the best use of consumable resources by developing and maintaining an efficient and cost-effective system of stock control.

Section 8: *Action Plan* is the final section in which you are asked to review all the ideas you have included in your Action List and to prepare an Action Plan as a basis for improving working practices in your transfusion centre or blood bank.

1.7 MODULE OBJECTIVES

There are six overall objectives for this module which specify what you should be able to do as a result of reading the text, answering the self-assessment questions, completing the activities and preparing your individual Action Plan.

When you have finished working through *Guidelines and Principles for Safe Blood Transfusion Practice*, you should be able to achieve the following objectives:

Section 2

Demonstrate a professional approach to your work.

Section 3

Identify specific hazards in your workplace and contribute to the design and implementation of safe working procedures.

Section 4

Contribute to the maintenance of a quality system in your workplace.

Section 5

Develop and maintain a system for the safe storage and transportation of blood and blood components.

Section 6

Prepare four basic solutions commonly used in blood transfusion practice.

Section 7

Efficiently manage stocks of consumables.

ACTIVITY 2

Before you begin work on Section 2, you will find it helpful to assess your current level of knowledge, skill and experience in relation to the module objectives and decide what you want to achieve by working through the module. Look carefully at the objectives and, for each one, decide whether you have:

- 1 A high level of knowledge, skill and experience.
- 2 A reasonably good level of knowledge, skill and experience.
- 3 Some knowledge, skill and experience.
- 4 Little or no knowledge, skill or experience.

The module objectives are repeated in the table below. Note down your rating (1, 2, 3 or 4) for each objective and add any comments you wish to make. Note any objectives that relate to areas of work that you do not undertake.

<i>Module objective</i>	<i>Rating (1–4)</i>	<i>Comments</i>
<p><i>Section 2</i> Demonstrate a professional approach to your work.</p> <p><i>Section 3</i> Identify specific hazards in your workplace and contribute to the design and implementation of safe working procedures.</p> <p><i>Section 4</i> Contribute to the maintenance of a quality system in your workplace.</p> <p><i>Section 5</i> Develop and maintain a system for the safe storage and transportation of blood and blood components.</p> <p><i>Section 6</i> Prepare four basic solutions commonly used in blood transfusion practice.</p> <p><i>Section 7</i> Efficiently manage stocks of consumables.</p>		

You have now identified the areas which will be mostly revision for you and the areas to which you need to pay particular attention. However, you may find that you only see the relevance of some of the objectives once you start to work through the module.

The module objectives are designed to help you to assess your own progress. When you reach the end of the module, you will be asked whether you feel that you have achieved them. The most important question to ask yourself then is whether you feel that you can do your job better as a result of your work on this module. If you feel that you would like to improve your knowledge, understanding and skills further, think carefully about the topics you would like to learn more about. Then talk to your supporter, supervisor or trainer about how you can achieve this.

1.8 PLANNING YOUR STUDY

You can take as little or as much time as you need to work through each module. The speed at which you complete it will partly depend on how much time you have available for study. It is important to discuss the programme with your supervisor so that you can agree the amount of time that can be allocated for your study, without disrupting your regular work or putting pressure on other members of staff. You might suggest, for instance, that you spend half a day or a day each week working through the modules, although you should be able to complete most of the activities during the course of your normal work. You may also wish to spend some of your own time studying the modules. Where the material is mainly revision for you, you will probably complete it quite quickly. If most of it is new to you, however, you may need more time than you originally planned.

To help you prepare your Study Plan, we suggest that your work on this module could perhaps be spread over a period of two months, although the amount of time you need will depend on your own circumstances. Once you have completed it, you will have a clearer idea about how long it might take you to work through the other modules.

ACTIVITY 3

Look quickly at the other sections in this module to get an idea of the content, level and approach and to assess how much of the material is likely to be new to you. Also look at some of the activities so that you understand the kind of work that you will be asked to do.

Try to estimate how much time you will need to study each section, including answering the self-assessment questions and completing the activities. Remember that you will also need to allocate time to meet with your supporter and trainer and to prepare your Action Plan. Then talk to your supervisor about the amount of time you could be allocated each week, or each month, for your work on this programme.

Now fill in the Study Plan on page 15. Copy the ratings of your knowledge, skills and experience from Activity 2 as they are an

STUDY PLAN

Section	Rating (1-4)	Planned completion date	Meeting dates	
			with trainer	with supporter
Section 2 Professionalism				
Section 3 Safety Procedures				
Section 4 Quality and Quality Assurance				
Section 5 Safe Storage and Transportation of Blood and Blood Components				
Section 6 Preparing Basic Solutions				
Section 7 Stock Control				
Section 8 Action Plan				

Notes

indication of how much time you will need to spend on each section. Then add the dates by which you plan to complete each section, taking into account your current knowledge, skills and experience in relation to each module objective and the time you are likely to have available for study. When you have arranged dates for meetings or other contact with your trainer and supporter, add these to your Study Plan.

Developing a realistic Study Plan will help you to organize your work on this module. It is important to try to keep to the schedule that you agree with your trainer, but tell them if you need to make any major changes to it because the work is taking more – or less – time than you expected.

SUMMARY

- 1 *Safe Blood and Blood Products* is a series of distance learning materials developed primarily for laboratory technical staff working in blood transfusion services, hospital blood banks and public health laboratories.
- 2 In addition to this Introductory Module, there are three other modules:
 - Module 1: *Safe Blood Donation*
 - Module 2: *Screening for HIV and Other Infectious Agents*
 - Module 3: *Blood Group Serology*.
- 3 The preparation and implementation of your Action Plans will be the most important part of your work on this programme.
- 4 A trainer will provide assistance to you throughout your studies.
- 5 You should identify a personal supporter in your workplace, preferably your supervisor, to provide ongoing support while you work through the modules.
- 6 Before starting work on this module, you should review your knowledge, skills and experience in relation to the module objectives.
- 7 A realistic Study Plan will help you to organize your work on this module.

PROGRESS CHECK

Before moving on to Section 2, spend a few minutes thinking about whether you have achieved the learning objectives for Section 1. These were to:

- 1 Explain the components of a distance learning programme in blood safety.

- 2 Identify a personal “supporter” who can assist you throughout your work on this module.
- 3 Assess your current knowledge, skills and experience in relation to the objectives of this module.
- 4 Make a realistic Study Plan for your work on this module.

If you feel confident that you have understood everything, turn to Section 2. If you feel that you need more information about the Introductory Module or about the learning programme as a whole, contact your trainer to discuss anything you are unsure about or talk to your supporter.

2

Professionalism

The purpose of this section is to examine the importance of professionalism in blood banking practice, both when collecting blood and also in dealing with colleagues, patients, relatives and other members of the public. In this section, you will look at your role as a professional and at some of the issues that you have to consider every day.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 Identify ways of ensuring that confidentiality is maintained in your donor clinic and laboratory.
 - 2 Maintain appropriate standards of behaviour and dress in your workplace.
 - 3 Describe the role of the professional organizations for nursing or laboratory technical staff in your country.
-

2.1 THE ROLE OF NURSING STAFF AT BLOOD DONOR SESSIONS

The role of nursing staff at blood donor sessions is to collect blood safely in a proper and recognized manner from suitable, healthy, low-risk donors. Their individual duties vary according to the number of donors bled at a session and the number of staff present, and depend on their experience and seniority. In some countries, blood is collected by laboratory technical staff or by organizations such as the Red Cross or Red Crescent Society. Regardless of who collects blood, however, you share the responsibility to ensure that:

- donors are appropriately screened to make sure that they are suitable as blood donors and that donation will not harm either the donors themselves or the recipients of their blood
- appropriate counselling and care is provided for donors before, during and after they donate blood
- each donor is bled into an appropriate blood collection bag
- blood bags and sample tubes are correctly labelled
- accurate and complete records are maintained
- work is performed to a high standard.

Module 1: *Safe Blood Donation* will help you to ensure that blood donor sessions are conducted in a professional and efficient way.

2.2 THE ROLE OF TECHNICAL STAFF IN PATHOLOGY LABORATORIES

The role of technical staff in pathology laboratories is to perform a range of diagnostic and screening tests that will assist qualified medical staff to diagnose, treat and monitor their patients.

The duties of staff vary according to the size of the laboratory and the services it offers. They can range from the reception of samples, the preparation of basic reagents and record-keeping to the performance of manual or automated tests and the training of other staff. These duties depend upon the experience and seniority of staff. Whatever your role, however, it is the responsibility of all technical staff to ensure that:

- the results issued are accurate
- the correct result is matched with the correct sample
- accurate and complete records are maintained
- work is performed to a high standard.

Module 2: *Screening for HIV and Other Infectious Agents* and Module 3: *Blood Group Serology* will help you to perform your work in a safe and professional manner.

Technical staff should not become involved in areas of work for which they are not trained or qualified, but should simply perform the required tests and provide information on the results that have been obtained. It

is appropriate for technical staff to comment on the accuracy of the results or on any factors which may interfere with them or affect them in any other way. You must *not* attempt to make a diagnosis, however, even though it is sometimes hard to decide where justified comment on laboratory test results stops and diagnosis begins. Diagnosis is the role of qualified medical staff.

There are times, however, when as a technical member of staff you may become involved in diagnosis if medical personnel are unsure about the meaning of some results and what they imply for the patient, such as in the case of protozoan infections where individual parasites can be found and clearly identified. In these situations, you should only give information about the purpose of the test, the results obtained, interfering factors, normal ranges and, possibly, the range of conditions which may give abnormal results. If doctors are unsure about their ability to diagnose, they should seek help from other medical staff – not from you.

The doctor–technician relationship

Blood is a potentially dangerous substance and so it should be prescribed only by a medically qualified person or someone nominated by a doctor. It should always be issued in accordance with the procedures established to ensure the safety of the recipient of the blood.

Friction sometimes arises between doctors and laboratory staff, particularly if doctors order blood without completing a blood request form or do not allow sufficient time for the technician to prepare the blood safely for transfusion. On the other hand, technicians do not always recognize the problems faced by medical staff when an emergency has arisen and blood or test results are required urgently. In situations like this, it is important to be as helpful and polite as possible.

If a doctor orders blood without filling in a blood request form, you should contact him or her immediately and state that you must receive a properly completed request form before you can issue the blood. An example of a request form is included in Section 6 of Module 3: *Blood Group Serology*. Remind the doctor that this procedure is essential to avoid any errors in compatibility testing that might be dangerous for the patient's health. If blood is requested at short notice, contact the doctor to find out the reason for this.

Sometimes doctors do not really understand the procedure and why it is important. If this is the case, you may find it helpful to prepare a simple information sheet giving details of the services offered by the laboratory, the times it is open, and the samples and request forms required before blood can be issued.

If there is no justifiable reason for a failure to complete request forms, however, and a doctor continually abuses the system, talk to the doctor in charge of blood transfusion since it will probably be easier for him or her to deal with the problem than for you to do so. Where there is no doctor with overall responsibility for blood transfusion, talk to your hospital medical superintendent instead and suggest that it may be worth considering appointing a hospital transfusion officer.

2.3 CONFIDENTIALITY

Whatever your role in blood transfusion practice, you have a responsibility to ensure that confidentiality is maintained at all times. As part of your normal work, you will be given and will produce a great deal of personal information about blood donors, patients, their family or their friends. This information is provided solely to assist you in your work and you must not disclose it to anyone else. All results are confidential, regardless of whom they apply to or what the actual result is.

Under normal circumstances, only medical staff should inform donors or patients of the results of laboratory tests. In some cases, however, it may be appropriate for another senior member of staff to give the results directly to the individual concerned, as long as they have received appropriate training in counselling. Postdonation counselling is discussed in more detail in Section 7 of Module 1: *Safe Blood Donation*.

All clinic and laboratory records should always be kept confidential by:

- allowing only essential staff to enter clinics, laboratories or laboratory offices where confidential information is kept
- ensuring that only the minimum information is accessible at any one time
- keeping records in a secure place to prevent unauthorized staff from having access to them
- securing records when the clinic, laboratory or office is unattended.

ACTIVITY 4

Note down the various ways in which confidentiality is maintained in your donor clinic or laboratory: for example, by allowing only authorized members of staff to have access to records.

Are there any ways in which you think confidentiality could be improved in your workplace? If so, note down your recommendations on your Action List and discuss them with your supporter.

2.4 STANDARDS OF BEHAVIOUR AND DRESS

Nursing and technical staff play a very important role in providing a service for the care and safety of patients. All staff involved in collecting, processing and testing blood are professional, highly dedicated people who have a very responsible position. They are therefore expected to act in a way that is consistent with this status.

The behaviour of all staff must be of the highest possible standard at all times. As part of your normal duties you will probably come into close contact with many different people: the general public, blood donors, patients and their relatives, as well as other professional groups, such

as medical, nursing, ancillary and administrative staff. It is very easy to respond badly to people who are upset, angry, impatient or simply rude, but it is important to remain calm and polite, even in the most difficult situations. Your behaviour will reflect not only on you as an individual, but also on your profession as a whole.

Standards of dress are an important means of maintaining the professional image of both nursing and technical staff. People will usually respond better to you if your appearance is clean and tidy. Nursing staff always wear easily recognizable uniforms and these must be kept clean and worn correctly at all times since blood donors expect to see properly-dressed staff acting in a professional manner at all times. There is generally no specific uniform for technical staff, apart from the normal protective clothing, but a neat and clean appearance is essential if you regularly deal with members of the public. You should always encourage people who give blood to become regular donors, but they are unlikely to return unless they have confidence in the person taking their blood.

In other words, you must show your professionalism in your behaviour, dress and relationships with all groups of people with whom you come into contact.

ACTIVITY 5

List any standards of behaviour and dress that are required in your workplace. Do you and your colleagues always follow them?

If you think there are any ways in which standards of behaviour and dress could be improved, note down your recommendations on your Action List and discuss them with your supporter.

2.5 PROFESSIONAL ORGANIZATIONS

In almost all countries, nursing staff are governed by a national professional organization which registers them as qualified personnel and provides guidelines for their professional practice.

Many countries also have a national professional organization for technical staff in pathology laboratories, such as an Institute of Medical Laboratory Sciences, which has its own code of professional conduct. Although entry to professional organizations of this kind may be restricted to staff with certain minimum qualifications, these organizations are concerned with the overall role of all technical staff in laboratories.

A code of conduct outlines the professional approach expected from staff in all aspects of their chosen profession. Look at the Code of Professional Conduct of the UK Institute of Medical Laboratory Sciences on page 23, which is an example of a code for technical staff. It covers all the main areas of behaviour that members of the Institute are expected to follow, although all laboratory staff would be expected to behave in the same professional manner. As you will see, it summarizes the issues we have considered in this section of the module.

Code of Professional Conduct of the UK Institute of Medical Laboratory Sciences

All members of the Institute shall always:

- 1 Exercise their professional judgement, skill and care to the best of their ability.
- 2 Fulfil their professional role with integrity, refraining from its misuse to the detriment of patients, employers or professional colleagues.
- 3 Seek to safeguard patients and others, particularly in relation to health and safety.
- 4 Treat with discretion all confidential and other information requiring protection, and avoid disclosing to any unauthorized person the result of any investigation or other information of a personal or confidential nature gained in the practice of their profession.
- 5 Act in good faith towards those with whom they stand in professional relationship and conduct themselves so as to uphold the reputation of their profession.
- 6 Strive to maintain, improve and update their professional knowledge and skill.
- 7 Promote the study and development of medical laboratory sciences and the education and training of medical laboratory scientists.

Figure 1: Example of a code of professional conduct

ACTIVITY 6

Is there a professional organization for your profession in your country? If there is and you are not already a member, find any information you can about it, including its objectives and functions. What qualifications do you need in order to join? Does it have a code of professional conduct? If it does, try to obtain a copy of the code and discuss it with your colleagues.

In many countries, trained technical staff need official recognition in order to be able to work in a pathology laboratory. They may have to be registered with the government or Ministry of Health although, in some countries, official registration is the responsibility of the professional organization.

ACTIVITY 7

If you are a member of the laboratory technical staff, do you need to be officially recognized as a technical person by your government or Ministry of Health when you have completed your training? If you do,

find out how you obtain this recognition. Do you need it to work in certain laboratories or to gain a more senior position in the laboratory in which you currently work?

SUMMARY

- 1 Technical staff should not attempt to diagnose. Their role is to perform a range of diagnostic and screening tests that will assist medical staff to diagnose, treat and monitor their patients.
- 2 Confidentiality must be maintained at all times.
- 3 High standards of behaviour and dress are required of all staff.
- 4 In many countries, codes of professional conduct are established by a professional organization. These should be followed by all staff.

SELF-ASSESSMENT

- 1 *List six responsibilities of nursing staff.*
 - 2 *List four responsibilities of technical staff.*
-

PROGRESS CHECK

Before moving on to Section 3, spend a few minutes thinking about whether you have achieved the learning objectives for Section 2. These were to:

- 1 Identify ways of ensuring that confidentiality is maintained in your donor clinic and laboratory.
- 2 Maintain appropriate standards of behaviour and dress in your workplace.
- 3 Describe the role of the professional organizations for nursing or laboratory technical staff in your country.

If you feel confident that you have understood everything, turn to Section 3.

If you feel that you still need to spend more time on this section, go back to the parts that are most unfamiliar or that you find difficult. You may find it helpful to talk to other people, such as your supporter or other senior colleagues, if there is anything that you are still not sure about.

3

Safety Procedures

The purpose of this section is to help you to identify the general risks you may meet when working in laboratories and the specific risks that may arise during blood donor sessions and in blood bank laboratories.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 Identify the specific hazards encountered in your workplace.
 - 2 Follow safety guidelines to maintain safety at blood donor sessions and in the laboratory.
 - 3 Ensure the correct use of protective clothing in your workplace.
 - 4 Apply safe procedures for the return of units of donated blood from mobile donor clinic sessions to the blood bank.
 - 5 Review your procedures for the dispatch of blood and serum samples.
 - 6 Review your procedures for the safe disposal of laboratory waste.
 - 7 Apply appropriate disinfection procedures in blood donor sessions and in the laboratory.
-

3.1 RESPONSIBILITY FOR SAFETY

The responsibility for safety at blood donor sessions and in the laboratory rests with everyone who works there – even if a particular person has been allocated overall responsibility for ensuring safety. It is the duty of every member of staff to behave in a responsible way in order to avoid endangering the safety of themselves or anyone else.

It is, however, the responsibility of the supervisor, or head of department, to ensure that all staff are fully trained in the tasks that they perform and know about all potential safety hazards. Even when staff are careful about how they perform their work, accidents are often caused because the correct safety procedures have not been explained to them.

3.2 RECOGNIZING POTENTIAL SAFETY HAZARDS

All staff involved in collecting blood have an obvious duty to ensure that members of the public are not exposed to unnecessary hazards. At a blood donor session in a fixed donor clinic or at mobile sessions held in such places as a community or school hall, donors are unlikely to be exposed to any additional environmental hazards than those that they meet in their normal daily lives. However, if donors are bled in the laboratory they could be exposed to many biological and chemical hazards. For this reason, donors should *not* be bled in laboratories.

The main risk to staff who collect blood is accidental infection through needlestick injury by “sharps”, such as:

- the lancet used to perform the predonation fingerprick
- the needle used to give a local anaesthetic before the venepuncture
- the collection needle.

All contaminated sharps must be handled carefully and disposed of in a suitable labelled container immediately after use.

ACTIVITY 8

How do you and your colleagues dispose of needles and other sharps when they have been used for collecting blood or in the laboratory?

Find a copy of any safety guidelines used in your donor clinic or laboratory and check that sharps are being disposed of in accordance with these guidelines. Identify any ways in which you could improve the safe disposal of sharps and note them down on your Action List.

Is there any policy about what to do if a needlestick injury occurs, either when collecting donated blood or in the laboratory? If there is, what advice is given to members of staff who suffer a needlestick injury and what action is taken to monitor them? What improvements could you make to your procedures for dealing with needlestick injuries? Note down your recommendations on your Action List and discuss them with your supporter.

All laboratories are potentially dangerous workplaces because they usually contain many different chemicals, including poisons and flammable solvents, as well as electrical equipment and often naked flames.

In pathology laboratories, there is a further danger of staff being exposed to the many infectious agents present in the pathological samples that need to be investigated. In many ways, this is a greater risk than the potential physical hazards. With some infectious agents, infection can occur very easily even when there is no specific incident involving a visible spillage of material. For example, infection can be transmitted by aerosols created by pipetting or as a result of centrifugation. It can also be transmitted through a small splash of material onto an open wound. As in blood donor sessions, needlestick injury is also a common route of infection with some infectious agents. In some laboratories, more than 50% of the samples that are examined may be potentially infectious.

ACTIVITY 9

Think carefully about the laboratory in which you work, the equipment you use and the work you do. List all the potential hazards that you think exist in your laboratory, using the following categories:

- *chemical, electrical and fire risks*
- *the risk of infection*
- *the risk of mechanical injury from such objects as broken glass, syringe needles or sharp blades.*

Safety guidelines

The potential hazards that technical staff encounter in laboratories are widely recognized and many manuals and sets of guidelines have been written to ensure safety in pathology laboratories. These guidelines can be divided into:

- international guidelines
- national guidelines
- local guidelines.

An example of international guidelines is the publication *Biosafety Guidelines for Diagnostic and Research Laboratories Working with HIV* (WHO AIDS Series, No. 9, 1991). Another useful document is *Laboratory Biosafety Manual* (WHO, 1997).

Your laboratory may follow national guidelines on safety or you may have guidelines that have been developed locally. How do the safety guidelines followed in your laboratory compare with the guidelines in Figure 2 on page 28? This is not an exhaustive list, but it covers some of the most important areas and should help you to avoid the potential hazards you identified in Activity 9.

SAFETY IN THE LABORATORY

- 1 Eating, drinking, smoking and applying cosmetics are prohibited in the laboratory.
- 2 Mouth pipetting is prohibited.
- 3 Staff must behave in a safe and responsible manner at all times.
- 4 Appropriate protective clothing must be worn at all times when in the laboratory and, whenever possible, gloves should be worn.
- 5 The laboratory must be kept clean and tidy and should only contain items necessary for the work carried out.
- 6 All work surfaces must be appropriately decontaminated at the end of each working day and after any spillages.
- 7 All staff must wash their hands when leaving the laboratory.
- 8 Care must be taken to avoid the formation of aerosols or the splashing of materials.
- 9 All contaminated waste or reusable materials must be appropriately decontaminated before disposal or reuse.
- 10 Access to the laboratory must be restricted to authorized personnel only.
- 11 All incidents or accidents must be reported immediately and appropriate action taken to prevent further occurrences.
- 12 All staff working in laboratories must be adequately trained, both in the duties they perform and in all safety aspects of laboratory work.

Figure 2: Safety guidelines

It is vital that all staff always follow the guidelines that are used in your laboratory. If you and your colleagues think that they are not strict enough, it is quite acceptable to add to them to improve their effectiveness.

ACTIVITY 10

Try to obtain a copy of the national guidelines on laboratory safety for your country. Compare them with the safety guidelines used in your laboratory.

Look back at the list of potential hazards that you made in Activity 9. Can you identify additions or changes that are needed to the safety guidelines used in your laboratory? If so, note them down on your Action List and discuss them with your supporter.

Are safety guidelines clearly displayed in your laboratory? If not, put copies in a prominent place and make sure that all your colleagues read and understand them.

If there are no written safety guidelines in your laboratory, you may wish to use the guidelines on page 28. A separate copy is included as an Offprint with this module so that you can put it on the wall of your laboratory.

Laboratory layout

One factor that has a direct influence on safety is the actual design of the laboratory. Think, for example, about the position of furniture and equipment, the electricity supply and the available bench space in your laboratory.

ACTIVITY 11

Draw a simple plan of your laboratory and mark on it fixed items such as windows, doors, benches, gas taps, water taps, power points and safety hoods. Then add movable items which are not in cupboards or drawers, such as chairs and stools, flasks on benches and electrical equipment. When you have done this, note the position of stores of equipment and consumables, such as test-tubes, flasks, reagents and cloths.

Using different coloured pens, mark the position of safety equipment, such as fire extinguishers and fire cloths. Finally, mark facilities for the disposal of waste.

Look carefully at your plan, taking into consideration the safety guidelines or code of practice in your laboratory. Do you think that any changes are needed? If so, note down your recommendations on your Action List and discuss them with your supporter.

You may be able to make simple improvements, such as moving some equipment or consumables to a safer position. However, if you feel that there are more serious problems, it is essential to discuss them with your colleagues and supervisor and ensure that any action required is taken as soon as possible.

3.3 PROTECTIVE CLOTHING AND EQUIPMENT

Staff working in donor clinics should always be provided with suitable protective clothing. The type of clothing provided varies and is often worn as a uniform since it is very important that staff who come into contact with donors have a smart appearance. They should never wear soiled clothing.

All staff working in a laboratory or entering a laboratory should also be provided with – and should always wear – suitable clothing that provides additional protection. Laboratory coats are usually made from fairly thick and absorbent white cotton and provide an extra layer of material to protect the body in case of accidental spillages, although you should not

rely on them to provide complete protection. It is essential to ensure that your laboratory coat is correctly fastened and in good condition, which means that it should not have holes or missing fastenings. All protective clothing should be washed regularly and any damage should be promptly repaired. Each member of staff should have at least one set (and, ideally, two sets) of spare protective clothing available at any time, in case of soiling.

In addition to protective coats, other protective equipment may be needed in the laboratory when dealing with certain hazardous substances or equipment. Gloves should be worn whenever possible and safety glasses, full face shields or other protective devices may be necessary to prevent splashes onto your face and to protect your eyes. For your own safety, you should make full and correct use of all protective clothing and equipment at all times.

ACTIVITY 12

Is suitable protective clothing provided for donor clinic staff and technical staff in your workplace? If it is, do staff have sufficient sets of clothing? How often are they washed and are they in good enough condition to maintain a smart appearance and give adequate protection?

Do you think that any improvements could be made in the provision and use of protective clothing in your workplace? If so, note down your recommendations on your Action List and discuss them with your supporter.

3.4 RETURNING DONATED BLOOD FROM MOBILE DONOR CLINIC SESSIONS TO THE BLOOD BANK

Donated blood collected in mobile donor clinic sessions must be returned to the blood bank in a safe and secure way to ensure that it does not present a risk to members of the public or to laboratory staff. It should be placed in cold boxes to maintain the temperature between +2°C and +6°C. These should be securely fastened to ensure that any leakage will be contained and to prevent them from being opened before they reach the blood bank. The boxes should be clearly labelled to reduce the risk of loss in transit.

Always use suitably strong cold boxes for transporting units of donated blood in order to contain any spillages and minimize the risk of infection. This will also help laboratory staff to prevent the transmission of infection when they deal with the spillages. Any blood bags that have leaked should be disposed of appropriately and the remaining bags should be disinfected. The box and any other contents, such as ice packs, should also be disinfected and cleaned with detergent before re-use.

The transportation of donated blood to the blood bank is covered in more detail in Section 5.

ACTIVITY 13

What precautions are taken to ensure the safety of units of donated blood when they are returned to your blood bank from mobile blood donor sessions? Is the blood transported safely or do you think that the system could be improved? Note down any recommendations on your Action List and discuss them with your supporter.

3.5 DISPATCHING SAMPLES

You may sometimes need to send blood or serum samples or other pathological specimens to a laboratory in another hospital or to a national reference laboratory for further investigation. You may be able to use hospital or special transport for this, but sometimes it may be necessary to use public transport or postal services. Whatever means are used, samples must always be packaged safely and correctly.

The following procedure should be used for sending specimens safely.

- 1 Use a sample container that is strong and watertight and has a leak-proof screw lid. Plastic containers are preferable.
- 2 Clearly label the container.
- 3 Wrap the container in sufficient absorbent material to soak up the sample in case of spillage.
- 4 Pack this in a second watertight container or seal it in a leak-proof plastic bag. Heat-sealing is the best method, although the necessary equipment may not be available. Snap-tight bags or well-taped bags are alternatives.
- 5 Seal the accompanying documentation in a protective pouch and attach it to the outside of the second container or plastic bag.
- 6 Put this in an outer package that is capable of protecting the contents from physical damage while they are in transit.
- 7 Label the outer packaging to indicate that it contains pathological material. On the outside, write the name and address of your own laboratory as well as the name and address of the reference laboratory to which you are sending the sample.

Packages containing pathological specimens should be opened only by authorized personnel within the laboratory. Samples sometimes leak during transit, but if safety guidelines have been followed, the spillage will be limited and it will be contained in the packaging material. If a leakage occurs and contaminates the outside surfaces of other samples, the remaining containers should be disinfected so that testing can be performed safely. Dispose of the leaking sample appropriately and then disinfect the sample carrier and clean it with detergent before using it again.

Guidelines for the Safe Transportation of Infectious Substances and Diagnostic Specimens (WHO 1997) provides detailed guidance on packaging specimens. Other guidelines have been developed by international air transport and postal organizations.

ACTIVITY 14

How does your laboratory package specimens that have to be sent to other laboratories? Do you think that the procedure is safe or could it be improved? Note down any recommendations on your Action List and discuss them with your supporter.

3.6 THE SAFE DISPOSAL OF LABORATORY WASTE

One of the most important aspects of laboratory practice is the safe disposal of waste. If hazardous waste is not disposed of correctly, laboratory staff, other hospital staff or members of the public could be exposed to infectious material and become infected. It is therefore in everybody's interest to ensure that there are strict procedures for the disposal of waste and that these are followed at all times.

Some laboratory waste is not infectious. Manufacturers' packaging material and waste paper, for example, can be kept separate from infected waste and disposed of with the general waste. This reduces the volume of waste needing specialized disposal and is particularly useful if the facilities for the disposal of infected waste are limited.

All infected waste should be autoclaved before disposal. The material should be placed in appropriate secure containers and autoclaved under minimum conditions of 121°C for 30 minutes. The waste should then be disposed of by incineration. Incinerators must be operated in accordance with local regulations and the approval of the public health department.

Autoclaving and incineration are the ideal method for the final disposal of waste, but if this is not possible other suitable methods must be used, such as decontamination with bleach or 10% sodium hypochlorite. These methods should also be regulated and approved by the public health department.

Burying waste is the only option available in some areas. If this is the case, do as much as possible before burying it to minimize the risks of infection. Small amounts of infected waste should be soaked in a hypochlorite solution for at least 12 hours, put into a pit and then covered. Larger quantities should be put into a pit with a final concentration of 10% sodium hypochlorite, before being covered immediately.

Many countries face the problem of how to dispose safely of infected units of donated blood. Ideally, they should be autoclaved on a "fluids" cycle for an appropriate period and then incinerated. If incineration is not possible, the autoclaved packs can be buried reasonably safely as any infectious agents would be inactivated by the autoclaving.

If no autoclave is available, infected blood bags should be incinerated, but you must take care to ensure that the bags do not explode inside the incinerator since this would present a risk to the operators. The incinerator used to dispose of other infectious material, usually in the hospital boiler room, may be appropriate for this purpose.

If incineration is not possible, the safe disposal of infected blood bags is potentially quite dangerous. There are three further methods of disposal that you can use in this situation:

- 1 Securely package the waste and transport it to suitable facilities nearby for disposal.
- 2 Securely package the waste and bury it. If this is the only option, you should take extreme care to ensure that the bags are buried deeply and securely so that they cannot be dug up by animals. Infectivity may persist for a long time in sealed blood bags in some cases, such as with the hepatitis B virus.
- 3 Open the blood bags and pour the infected blood into a suitable deep pit with strong disinfectant, such as sodium hypochlorite in concentrated form. Cover it and then burn the bags immediately. You should take very great care when opening and disposing of the blood bags and ensure that the pit is not close to a water supply which could become contaminated.

You should never incinerate or autoclave chemicals unless you have been given specific instructions to do so by a senior member of staff. Waste chemicals should never be mixed, unless it is known that no chemical reaction will take place. This is essential to prevent any unwanted or even dangerous reactions occurring between the chemicals, which could endanger laboratory staff. Always follow local guidelines on the disposal of waste chemicals to ensure that chemical contamination of the surrounding land or water supply does not occur.

For further guidance, see *Safe Management of Wastes from Health-Care Activities* (WHO, 1999).

ACTIVITY 15

How is infectious waste disposed of in your laboratory? Do you think that proper precautions are always taken to ensure safe disposal? Can you suggest any additional precautions that could be taken? If so, discuss your ideas with your colleagues and note them down on your Action List. Discuss them with your supporter.

3.7 DISINFECTION PROCEDURES

At the end of each blood donor session, the clinic or any other premises used must be left clean and tidy and all equipment should be disinfected after use. A mobile team usually uses only its own equipment, which should be disinfected afterwards. Where items belonging to the premises are used, such as tables and chairs, these should also be cleaned with disinfectant at the end of the session.

At the end of each working day in the laboratory, or after a spillage, the appropriate disinfection procedures must be followed to ensure that any contaminated surfaces are effectively made safe. Non-autoclavable laboratory equipment or non-disposable items should be disinfected ready for reuse. Where blood bags or samples leak during transit, the remaining bags or samples and the cold box or sample carrier should be disinfected.

In all cases, disinfection must be performed before cleaning with detergent. There are many different disinfectants available and these act in different ways, so it is important to use the appropriate one in order to ensure effective disinfection. All disinfectants have what is known as a “contact time”, which means that they must be left in contact with an infectious agent for a certain period of time to ensure that it is completely inactivated. However, some disinfectants are themselves inactivated by the presence of organic material and so higher concentrations of disinfectant and longer contact times must be used in certain situations, such as a large spillage of infected blood. The preparation of disinfectant solutions is covered in Section 6.

After disinfection, you can clean with normal detergent and water to remove the inactivated material and the used disinfectant. Even if disinfection is performed correctly, all the waste material generated should be disposed of safely, preferably following autoclaving.

Always take great care when using any disinfectants containing chlorine. In the presence of some chemicals, it is very easy to liberate poisonous chlorine gas from some chlorine-containing solutions (when bleach and acid are mixed, for example). If you have any doubts about the exact composition of a spilt mixture containing infectious agents, you can neutralize any acid present by adding a small amount of saturated sodium bicarbonate solution before adding bleach or hypochlorite solution.

We shall return to the use of disinfectants in Section 6 and a standard operating procedure for the preparation of hypochlorite disinfectant solution is included in the Appendix. You may also find it helpful to obtain two publications from the WHO AIDS Series:

- *Guidelines on Sterilization and High-Level Disinfection Methods Effective Against Human Immunodeficiency Virus (HIV)* (WHO AIDS Series, No. 2, 1989)
- *Biosafety Guidelines for Diagnostic and Research Laboratories Working with HIV* (WHO AIDS Series, No. 9, 1991).

ACTIVITY 16

What disinfectants are available for use by donor clinic staff, mobile teams and in your laboratory? How are they used? Can you suggest any improvements to the disinfection procedures used in your workplace? If you can, note down your recommendations on your Action List and discuss them with your supporter.

SUMMARY

- 1 The responsibility for safety rests with every person who works in blood donor clinics or in the laboratory, even though there may be a particular person with designated responsibility for safety.
- 2 All laboratories are potentially dangerous workplaces so safety guidelines should always be followed carefully.
- 3 Suitable protective clothing should be issued and worn at all times when staff are on duty.
- 4 Units of donated blood should be securely packaged in a strong cold box for return from mobile donor clinic sessions to the blood bank.
- 5 International guidelines on packaging should be followed to ensure that blood or serum samples or other pathological specimens are transported safely.
- 6 All infectious waste should be disposed of safely. Where possible, it should be autoclaved and incinerated. Particular care should be taken with the disposal of infected units of donated blood.
- 7 Appropriate disinfection procedures should always be followed at the end of each working day and after spillages.

SELF-ASSESSMENT

- 3 *Why should protective clothing be worn in the laboratory?*
 - 4 *When blood or serum samples are transported, how many protective containers or packages should they be placed in?*
 - 5 *What are the minimum conditions under which infected waste should be autoclaved?*
 - 6 *Why is it important to take particular care when using any disinfectants containing chlorine?*
-

PROGRESS CHECK

Before moving on to Section 4, spend a few minutes thinking about whether you have achieved the learning objectives for Section 3. These were to:

- 1 Identify the specific hazards encountered in your workplace.
- 2 Follow safety guidelines to maintain safety at blood donor sessions and in the laboratory.
- 3 Ensure the correct use of protective clothing in your workplace.
- 4 Apply safe procedures for the return of units of donated blood from mobile donor clinic sessions to the blood bank.
- 5 Review your procedures for the dispatch of blood and serum samples.
- 6 Review your procedures for the safe disposal of laboratory waste.
- 7 Apply appropriate disinfection procedures in blood donor sessions and in the laboratory.

If you feel confident that you have understood everything, turn to Section 4.

If you feel that you need to spend more time on this section, go back to the parts that are most unfamiliar or that you find difficult. You may find it helpful to talk to other people, such as your supporter or other senior colleagues, if there is anything you are still not sure about.

4

Quality and Quality Assurance

The purpose of this section is to consider the subject of quality in relation to all aspects of blood transfusion practice, including:

- the need for quality
- the meaning and use of standard quality terms
- standard operating procedures (SOPs)
- record-keeping
- quality monitoring
- the responsibility for quality.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 Define “quality”, “quality systems”, “processes and procedures”, “quality assurance” and “quality control”.
 - 2 Identify the main areas of blood transfusion practice where failures of quality can occur.
 - 3 Review your documentation and identify areas where there are documents lacking and where the issue and use of documents is not controlled correctly.
 - 4 Contribute to the development of standard operating procedures and use them correctly.
 - 5 Review your record-keeping system and identify any areas where additional records should be kept.
 - 6 Review your monitoring procedures for the maintenance and calibration of all equipment used by your BTS.
 - 7 Accept responsibility for maintaining quality in all aspects of your own work.
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4.1 QUALITY

What do you understand by the word “quality”? Many people are confused about its meaning, particularly because so many terms are used in relation to quality, such as “quality system”, “quality assurance” and “quality control”.

ACTIVITY 17

Find a dictionary and look up the definition of quality. Write down this definition and then write down your own definition of quality as applied to blood transfusion practice. You may like to ask your colleagues what they understand quality to mean in the context of their work and then to compare your answers.

There are many definitions of quality. One of the simplest and most appropriate is “fitness for a purpose”, the purpose in this case being “safe transfusion”. The definition used by the World Health Organization in *Guidelines for Quality Assurance Programmes for Blood Transfusion Services* (1993) is:

The consistent and reliable performance of services or products in conformity with specified standards.

In this context, the “products” are blood and blood products that are both safe and effective for transfusion or other specified uses. A quality-based approach in all procedures ensures maximum safety, for recipients, donors and staff, and maximum clinical effectiveness of the products.

4.2 THE NEED FOR QUALITY

Why do you think that so much emphasis is put on quality in blood transfusion systems? You should always remember that a failure in quality in the system for collecting, transporting, testing, storing and issuing donated blood can have very serious, even fatal, consequences for a patient. Consider, for example, the following situations where failure in the quality system might be potentially dangerous for a patient:

- a mix-up is made during the session and the sample tubes and filled blood bags from two donors are inadvertently mislabelled
- incorrect test results are reported for a donor’s sample
- an infectious donation is not detected by the screening procedure
- a weak, but clinically important, red cell antibody is not detected when a compatibility test is performed
- a reagent is incorrectly prepared or labelled, leading to apparently correct, but actually false, test results
- a patient’s laboratory results are reported for a different patient.

The issue of an unsuitable unit of blood is avoidable, however, if the appropriate quality systems are designed, implemented and monitored.

ACTIVITY 18

Think about the various stages involved in blood transfusion practice, from the collection of a unit of blood to its issue for use.

Make a list of the key areas where failures in quality must be prevented in order to ensure that a unit of donated blood is safe for issue and use. Then compare your ideas with the list given in the Activity Checklists and Answers on pages 105–106.

As you can see, there are many areas in the collection and processing of donated blood that must be continually monitored to ensure quality in all aspects of a blood transfusion service. It is therefore essential to adopt a quality-oriented approach to all aspects of your work.

4.3 QUALITY SYSTEMS

The foundation for a quality-based approach is the development of a quality system. An effective quality system can help to prevent the occurrence of situations such as those listed above and thus help to ensure the safety of the blood supply. The definition of a quality system used by the WHO in its global Quality Management Project is:

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

A properly structured quality system is essential in the successful operation of every blood transfusion centre and hospital blood bank, not only in large and more structured services. No matter how many or how few units of blood are collected, or what testing is performed, every service should establish and maintain an appropriate quality system to ensure that the “final product” meets the basic requirements (specifications) for blood and blood products: that is, that they are both safe and efficacious.

Importantly, the development of a quality system can also help all staff to understand the importance of quality and how they, as individuals, can contribute to the overall quality of the products.

Introducing a quality system essentially involves four key stages:

- 1 Assessing what is required in order consistently to meet the requirements for the production of safe and effective blood and blood products.
- 2 Planning the action that needs to be taken and identifying the best way to do it.
- 3 Implementing the changes required, including establishing systems for monitoring and control.
- 4 Continuous monitoring of all aspects of the quality system to assess how well it is operating and to identify any changes needed in order to ensure that quality is maintained.

As you can see, the fourth stage then leads back to the first in a continuous cycle of quality improvement. This process of continuing improvement is at the centre of all quality systems.

Ways of developing a quality system that is appropriate for your blood transfusion system are covered more fully in Modules 1, 2 and 3. You may also find it helpful to obtain a copy of *Guidelines for Quality Assurance Programmes for Blood Transfusion Services* (WHO, 1993) from the World Health Representative in your country and to show it to your supervisor.

4.4 PROCESSES AND PROCEDURES

BTS activities broadly consist of processes and procedures. In general, these are the individual activities performed by a BTS in the provision of safe and effective blood and blood products. For example, the process of ensuring that blood is free from transfusion-transmissible infections (TTIs) involves a number of procedures:

- donor selection to identify and defer any “high risk” donors
- use of disposable blood bags to collect blood
- performance of reliable screening to identify any donations with evidence of the presence of an infectious agent
- retrieval and disposal of all unsuitable donations before any blood is released for use.

Together these procedures form the overall process of ensuring that the blood released for transfusion is as free as possible from any TTI. Most activities in a blood transfusion service can be described in terms of processes and procedures and the quality system is designed around these.

A process is defined as: “A series of steps or actions that lead to a desired result or output.”

A procedure is defined as: “A specific activity that forms the basic unit of a process.”

4.5 QUALITY ASSURANCE AND QUALITY CONTROL

Having defined quality and considered why it is so important, and then looked at the importance of developing a quality system, we now need to define “quality assurance” (QA) and “quality control” (QC) since these are terms that you will encounter frequently. They sound similar, but have very different meanings and cannot be interchanged. Look carefully at the following definitions that are used by WHO in *Guidelines for Quality Assurance Programmes for Blood Transfusion Services* (1993).

Quality assurance

The creation and operation of standards, programmes and effective management systems to ensure quality.

The overall range of activities and systems that provide confidence within the organisation and authorities that all quality requirements are met.

Quality assurance is therefore the result of maintenance of the quality system. It ensures that all work is of the required quality: in other words, that the work performed is consistently reliable, accurate and correct, and meets the defined standards (specifications). More specifically, in a blood transfusion context, it means that patients receive blood that meets the required specifications, and that any errors are identified and corrected as quickly as possible.

Quality control

That part of a quality assurance programme that consists of retrospective tests or other measures that must be completed with satisfactory results before proceeding further in a given process, and that demonstrates compliance with certain defined limits and specifications.

Checks put in place to ensure that processes, procedures and products meet the quality requirements.

Quality control is therefore an inspection or monitoring system used to ensure that specifications are met and that mistakes have not occurred. It consists of the specific procedures undertaken to monitor the work performed and the overall effectiveness of the quality system.

It is important to understand these definitions because they are important to your daily work, but if you are still unsure about their meaning, discuss them with your supporter or another senior colleague.

4.6 STANDARD OPERATING PROCEDURES

Standard operating procedures (SOPs) are a very important part of a quality system. An SOP is a document that specifies the way that a particular task should be undertaken within a particular work area. Each transfusion service should have SOPs covering all the procedures that are associated with the collection, testing, processing, storage and issue of blood and blood products. These will include specific activities such as donor selection, performing venepuncture, TTI testing, blood grouping, storage and transportation as well as all supporting activities such as maintenance of equipment, calibration, training, error management and cleaning.

SOPs are not simply guidelines to help staff to perform particular tasks. They are a set of written instructions that should be followed by all staff to ensure that specified standards are met *at all times*. Why is this standardization needed, and in this way?

- 1 It assists in the management of the work area because, if an SOP is followed correctly, all members of staff should perform a particular procedure in exactly the same way. This will reduce the likelihood of deviations and errors that might occur if instructions are simply given orally to staff, or if staff think that they know what to do and act without checking first.

- 2 It enables the performance of the task to be monitored in a more objective way because the SOP specifies the standards that should be achieved on every occasion.
- 3 It provides the basis for developing a full documentation system, including record keeping.
- 4 It simplifies and standardizes the training of staff.
- 5 It helps to reduce adverse effects on performance when there are staff changes or absences.
- 6 It can be used to assist in resolving disputed issues if there is legal action following a failure in quality in the service.

This may seem rather complicated if you are not familiar with SOPs, but remember that they are used to help all members of staff to do their jobs more efficiently and effectively. Even if SOPs have not yet been introduced in your work area, it is important to understand why they are being adopted in many blood transfusion services and hospital blood banks, and how they are used.

Examples of SOPs for the preparation of four basic solutions commonly used in blood transfusion practice are included in the Appendix. Look at them now before continuing with the remainder of this section. You will also find examples of SOPs in the Appendices of Modules 1 and 2.

Preparing an SOP

The preparation of an SOP should be a team effort. The first draft should be written by the people performing that particular procedure. The final draft should then be completed by the head of the particular work area, but should then be rechecked by a staff member who performs that procedure, before the SOP is formally issued. In order to ensure that an SOP is written in the correct way, a set of general guidelines should be provided so that all staff understand exactly what should be included in the draft, and in what order.

The contents of an SOP obviously depend on national and local policy and on the specific procedure it covers. In general, however, an SOP includes:

- a clear, brief title and a unique SOP identity number
- the date when the SOP was written or revised
- the name of the person who prepared or revised the SOP
- a brief description of the purpose of the procedure
- the responsibilities of staff using the SOP
- restrictions on the use of the SOP
- details of the equipment, reagents and other associated documentation required to perform the procedure
- health and safety guidelines describing any hazards involved in the performance of the procedure
- precise details of the procedure, clearly described in numbered steps that logically follow the working sequence, including any quality control procedures involved.

Appendices may be attached that include any additional relevant documentation, such as copies of standard forms or labels to be completed or used during the procedure, and operating instructions and methods of use recommended by manufacturers of equipment and diagnostic reagents.

Simply preparing SOPs will not ensure quality; they must be followed by all staff at all times. SOPs must be comprehensive and concise and produced in a simple and clear style that can easily be understood by all staff who use the SOP. They need to be available to relevant staff in the place where each task is performed and these staff should, of course, be familiar with them, understand them and use them as specified. All staff members involved in each procedure should sign the relevant SOP record to indicate that they have read and understood it.

Each SOP should be reviewed regularly, ideally once a year. It should be updated where necessary, since modifications may be needed as a result of:

- direct changes in the procedure: for example, amendments in the manufacturer's instructions for performing an assay, or changes in local or national policy
- indirect changes in the procedure: for example, alterations in an associated procedure that might affect certain parts of the SOP.

Any alteration to an SOP should be undertaken in a controlled way with a new version number. It should be authorized by the head of the work area involved, with additional review by the quality manager, where such a position exists. Staff involved in performing the particular procedure should sign the new SOP record to indicate that they have been trained against the new version of the SOP.

ACTIVITY 19

Are SOPs used in your work area? If they are, do they contain all or most of the components in the list above? Do all relevant staff follow them carefully at all times?

Think about any improvements that you think could be made to them or the way in which they are used. Add your ideas to your Action List and discuss them with your supporter.

If SOPs are not used in your work area, talk to your supervisor about the possibility of introducing them. It may be possible to obtain copies of SOPs from other blood transfusion services or blood banks. However, it would be essential to review them very carefully and make any adaptations needed to ensure that they conform with national and local policy and are appropriate for your own work place. Note down your recommendations on your Action List and discuss them with your supporter.

4.7 DOCUMENT CONTROL

SOPs are only one of a number of formal documents that form a key part of any quality system. Other key documents include forms, datasheets, policies and specifications; you may be able to think of other types of documents. These documents either contain important information or are a means of recording important information – which then itself forms an important part of the quality system.

Since these documents are such a central part of the quality system, it is essential that their production, distribution and use are strictly controlled. As BTS activities develop, associated documentation needs to develop with them. This means that documents need to be updated and new versions produced. If different versions of any document are in circulation, however, it may not be clear to staff which version is the correct one. It is therefore essential to have a system that controls the documents that are in use at any time; document control is a critical part of any quality system. To be able to achieve this, the first requirement is to be able to uniquely identify each document. All formal documents therefore need to have certain levels of identification.

All documents should have, as a minimum, the following information:

- A unique document number, including a version number and ideally a code to indicate the type of document: e.g. SOP/LAB/SCR/001/01 where:
 - SOP/ indicates the document is an SOP
 - LAB/ indicates it is a laboratory document
 - SCR/ indicates it is a screening laboratory document
 - 001/ is the document number
 - 01/ is the version number
- the date prepared
- the author
- the name of the datafile, if prepared electronically.

The introduction and management of an effective document control system is the responsibility of the quality department of the BTS. Where there is no quality department, individual work areas can manage their own systems, but it is important that all departments of the BTS follow a common approach. The management of an effective document control system requires considerable effort, both by the staff of the quality department (if one exists) and by clinic and laboratory staff. Once a system has been introduced, however, the quality benefits of the consistent use of the correct documents soon become obvious and the whole system becomes easier to manage and maintain.

We have already discussed the need for the regular review of SOPs in Section 4.6. This review process applies to all controlled documents. As part of the document control system, a regular formal review process needs to be put in place; ideally, documents should be reviewed at least once a year. This process need not be complicated – the documents in use simply need to be checked to make sure that they are still correct and still in use. Documents that are no longer in use should be withdrawn from circulation as there is no value in them remaining in the system.

ACTIVITY 20

Apart from any SOPs, what other formal documents are used in your work area? How are these documents controlled so that only the correct version is in use? Do all relevant staff use the documentation in the correct way?

Think about any improvements that you think could be made in the way in which documents are produced and distributed in your workplace. Add your ideas to your Action List and discuss them with your supporter.

If formal documents are either not used in your workplace or their production and distribution is not controlled, talk to your supervisor about the possibility of introducing them. It may be possible to obtain copies of documents from other blood transfusion services or blood banks. However, it would be essential to review them very carefully and make any adaptations needed to ensure that they conform with national and local policy and are appropriate for your own workplace. Note down your recommendations on your Action List and discuss them with your supporter.

4.8 RECORDS AND RECORD-KEEPING

Records are working documents that are completed or generated during a work activity. They include completed forms, automated printouts and reports and any other documents that contain information generated during the processes of the collection, testing, storage and use of the blood and blood products provided by the blood transfusion service or blood bank.

Records are one of the most important parts of a quality system because they provide evidence that specified standards have been applied. They should cover the whole process from the collection of donated blood to its use: donor selection, the collection of blood, testing, disposal of unsuitable donations, storage, issue and transfusion. Complete and accurate records enable the history of each unit of donated blood to be traced back from the patient to the donor, from “vein-to-vein”, which enables any transfusion-related incidents to be investigated.

Records should be as clear as possible and filed in a logical way so that they can be easily retrieved and easily referred to and understood, even a number of years later when there may have been many changes in working practices. All documents should be completed fully and in a clear and concise way and, ideally, should then be checked by a senior person to ensure that they have been completed properly and no mistakes have been made.

Blood collection records

Once a donor has arrived at the donor clinic, the first step is to complete the donor’s record card or complete a new one for a new donor. All the actions subsequently taken should then be recorded, even if no blood is collected, since the donor may:

- self-defer: that is, decide not to give blood
- be deferred because of a potential risk to their own health, either temporarily because of an existing condition which is expected to improve, or permanently
- be deferred, either temporarily or permanently, because of a potential risk to the recipient
- be accepted and bled in the normal way.

There are a number of records that should be kept of each donor and their donations and these are described in detail, with examples, in Module 1: *Safe Blood Donation*. Remember that records should be kept for all donors, not only those who give blood but also those who are deferred, for whatever reason, so that their suitability to donate blood can be checked if they return at a later date. Strict confidentiality must be maintained about the identity of donors and the reasons for any deferrals. This information must be accurately recorded, but should not be accessible to anyone except authorized members of staff.

Other collection records that should be kept include:

- the donation number of the unit of blood
- the type of blood collection bag used
- the batch number of the blood bag used
- the batch number of the local anaesthetic (if used)
- the weight of the pack/volume of blood collected
- the name of the person performing the venepuncture.

It is important, for example, to be able to trace back the blood collection bags used if it is found that a batch of bags is faulty.

Other records that need to be maintained, even though they are not linked to individual donors or donations, include the calibration of scales or balances used to measure the volume of blood donated, checks on the working of sphygmomanometers used and the cleaning of reusable equipment.

Laboratory records

Once the unit of blood has been collected, it must be tested before release for clinical use. The nature and extent of this testing vary, but all testing normally includes:

- screening for the presence of transfusion-transmissible infections
- blood grouping.

Although these two areas of testing are very different, the type of information that they generate is similar. Complete and accurate records are essential for most aspects of the actual testing performed, including:

- the individual tests performed
- the sources and batch numbers of the reagents and assays used

- the results obtained
- the results of any quality control and quality control samples tested
- the fate of the tested unit of blood: that is, whether it is suitable for release or has to be disposed of
- calibration and maintenance of the equipment used.

As with individual donor records, strict confidentiality must be maintained at all times. Donors' names should not appear on blood collection bags or samples, or in laboratory testing records. Instead, only numbers, alphanumeric codes or other identification codes should be used.

Relevant information about the results of screening should be recorded on individual donor records and checked by a senior member of staff. This is particularly important where donated blood has to be disposed of because the presence of an infectious agent, such as HIV, has been detected. In such a case the donor's record, whether it is written or electronic, should be marked clearly that the donor is "Permanently excluded", in order to prevent the donor from making further donations. However, the specific reason for deferral should not be recorded on this record; instead, a separate, confidential and restricted file should be started for each infected donor.

You will look in more detail at the kinds of record that need to be kept in Module 2: *Screening for HIV and Other Infectious Agents* and Module 3: *Blood Group Serology*.

Blood issue and usage records

Once the donated blood has been tested and released as being suitable for clinical use, records are needed of the fate of each donation and any products made from it. As previously mentioned, full traceability from donor to patient, from "vein-to-vein", is an essential part of the quality system. Some blood banks normally issue units of blood to hospitals only as they require them; others perform routine cross-matching and then issue the blood for those specific patients. In either case, clear and accurate records are required of the fate of the donations.

In many blood banks, units of blood are cross-matched for a number of different patients. If this is the case, it is only necessary to keep a record of the patient who actually receives the blood, but it is essential that the patient who actually received the blood is clearly identified.

Units of blood may be discarded, either because they are not suitable for use or because they have expired. In such cases, records are needed to show the reason for discarding them and to provide evidence that they were disposed of safely.

There are many points in the process of collecting, testing and use of blood where records are required. You will look at examples of records in more detail when you work through Modules 1, 2 and 3, but Activity 21 should help you to begin reviewing the record-keeping system in your workplace.

ACTIVITY 21

List the information that you generate and the records that you keep in your work area.

Are there any actions you take during your work where you obtain information, but do not record it? If you think that this information needs to be put into a formal record, note down your recommendations on your Action List and discuss them with your supporter.

Storage of records

Once any individual activity has concluded and the required documentation has been completed, the documentation then forms part of the record of that activity. Records should initially be kept in the work area, but should then be moved to long-term storage for archiving when they are no longer needed in the work area.

Records should always be stored carefully and securely, and for an appropriate period of time. From your own experience, you know that it is essential to be able to find the relevant records quickly and easily, for example, if the accuracy of any result is questioned or the original report from the laboratory has been lost. Records also contain information that may be useful in the future in the analysis of the effectiveness of current procedures or in the planning and development of new procedures.

The length of time for which records must be kept varies in different countries, depending upon the requirements of the Ministry of Health, regulatory body or other official agency. Do you know how long records should be kept in your country?

To ensure that records are complete and accessible, a monitoring system should be used to list all the records stored, their location and, if appropriate, the date of their disposal.

Since BTS records contain personal information, they must be kept secure and confidential at all times. They should always be stored in a way that ensures security but allows access to authorized staff. They must be protected from physical damage by moisture, heat, fire, sunlight, vermin and chemicals. In addition, they must be secure against theft, deliberate alteration and any other tampering. However, they must also be accessible to authorized staff if they need to refer to them. A full log should be kept of record usage to ensure that, if records are retrieved for reference or research purposes, there is a record of who has them. This log, which can be used to ensure that they are returned when finished with, should record :

- who took the records
- why they were used
- when they were taken
- when they were returned.

Ideally, there should be a second check to confirm that they have been returned.

Disposal of records

If records are finally removed for disposal, they should be disposed of in a way that ensures that no unauthorized person has access to the confidential information that they contain. Records should be destroyed immediately, ideally by incineration or, alternatively, by shredding. They should never be left lying around before disposal when there is a chance that anyone could read or even remove them. Again, a disposal log should be set up, recording the date of disposal and giving details of the records disposed of and the method of disposal. Where possible, a second check should be made by another person to confirm that they have all been destroyed.

ACTIVITY 22

What procedures are used in your workplace for the long-term storage of records and their subsequent disposal, if this is done, of records? Can you identify any ways in which they could be improved? If so, note down your recommendations on your Action List and discuss them with your supporter.

4.9 QUALITY MONITORING

Good training, the use of SOPs and other controlled documents, and comprehensive record-keeping are important elements of a quality system, but there are many aspects of blood transfusion practice that also require regular monitoring to ensure that a full and effective quality system is in place.

Quality monitoring is used to identify and analyse deviations from standards or specifications. Two important areas are:

- monitoring the outcomes of processes and procedures
- monitoring the operation of any equipment used.

Whatever monitoring is performed, it is essential that it is undertaken on an ongoing and regular basis, and that the data generated are analysed, any problems are identified and the appropriate action is taken to solve the problem.

Monitoring processes and procedures

Monitoring the outcomes of testing in the laboratory may be easier than monitoring outcomes in other areas of the blood transfusion service, such as blood donor sessions. Virtually all laboratory tests involve the use of control material or samples and the results obtained from them are used to ensure that the test is performing consistently.

The monitoring of tests in this way can demonstrate whether there has been any decline in the performance of a test or any variation between different batches of reagents. Outcomes of other activities can be similarly monitored; suitable parameters simply need to be identified. At

a donor session, for example, the number of venepuncture failures and the weight/volume of donations may be monitored. The number of outdated donations could be monitored in the blood issue department. Monitoring of outcomes is important in all main work areas to ensure that there is consistency and that quality is maintained.

Monitoring of equipment

There is considerable variation in the level and complexity of equipment used in blood transfusion services. People often think that more sophisticated equipment requires less attention, but unfortunately this is not always the case, the opposite is often true. There are two important areas in which monitoring is necessary:

- routine maintenance
- calibration.

All equipment needs regular maintenance, even if only once a year for certain items, to ensure that it is working as efficiently and reliably as possible. Many items of equipment also need regular calibration to ensure accuracy and precision. It is important that incubators and water-baths are regularly calibrated, as well as the more obvious items such as scales used to measure the volume of blood collected, pipettes, balances and any automated sampling or dispensing equipment.

Additionally, temperature-critical items such as incubators, water-baths, refrigerators and freezers should be monitored on a daily basis and acceptable operating ranges should be established around the required temperature.

All maintenance and calibration should be recorded, together with any necessary follow-up action taken.

WHO has produced the following documents on maintenance and calibration which you will find helpful if you work in a laboratory:

- *Specifications for Production/Assembly of Basic Laboratory Equipment* (WHO/LAB/84.2)
- *Self-instruction Sheets for Users of Primary Health Care Laboratory Equipment* (WHO, LAB/85.7)
- *Calibration and Maintenance of Semi-Automated Haematology Equipment* (WHO/LBS/92.8)
- *Maintenance and Repair of Laboratory, Diagnostic Imaging and Hospital Equipment* (WHO, 1994)
- *Calibration and Control of Basic Blood Cell Counters* (WHO/LAB/97.2).

ACTIVITY 23

Make a list of all the equipment in your work area. Find out when the last service was performed on each item and whether there is a maintenance contract for it.

Mark the items that require regular calibration. Then note down the last time that each item was calibrated and the results of the calibration.

Note down on your Action List any improvements that could be made in the monitoring of equipment and discuss them with your supporter.

4.10 AUDITS

We have considered a number of components of quality systems, but one of the most important issues is how effectively the quality system operates. An audit is a tool for inspecting the operation of the quality system. It is a formal review of those factors involved in assuring quality which is undertaken to identify areas where the system has either not been adhered to or where it has not been adequate. A well planned and comprehensive audit programme will cover each area of the service and should also assess the way in which its different components relate to each other. An audit can, however, focus on very specific areas. For example, as well as checking individual test results, the validity of the testing itself would be examined through the review of the actual and expected results of control samples, quality control samples and other test monitoring systems.

Audits may be internal, when they are usually performed by experienced senior staff. They may also be external, when they are conducted by trained auditors, by or on behalf of the regulatory authority for the service. It is important not to be worried about an audit because, no matter how good a system appears to be, there are always areas where improvements can be made. A great deal can be learned from a well performed audit, but if you are aware of any problems, you should obviously take action to correct them before an audit takes place.

If any problems are identified, they must be resolved as soon as possible. Specific action must be decided on and a reasonable time agreed within which to implement the required changes. A follow-up audit is then usually carried out to ensure that the changes have actually been made and that the situation has improved accordingly.

An audit trail is sometimes followed as part of an audit. An audit trail performed on a particular donation for example, would attempt to trace that donation through all the processes that it has undergone from its collection at a donor session to its issue to a patient. It would check that all necessary testing has been performed correctly and accurately and that all the necessary records are available, accurate and complete. This would demonstrate that the unit has been correctly designated as being fit for issue. In larger blood transfusion services, audit trails do not necessarily involve all the work areas at the same time as they are designed to follow a specific route through a process involving many tasks in the collection, screening and issue of donated blood.

4.11 RESPONSIBILITY FOR QUALITY

Who is responsible for quality? The answer is that *you* – and all other members of staff involved in blood transfusion – are responsible for

ensuring quality, even though you may not be the person who is responsible for setting up the quality system and monitoring it. A failure to maintain quality is usually the result of human error, carelessness or a lack of understanding rather than of technological problems. The need for quality and ways of maintaining it should therefore be included in the training of all staff at an early stage. Everyone should be encouraged to understand its importance in relation to their particular area of work. No matter what their individual jobs, donor clinic staff and laboratory technical staff have to work together as a team to build and maintain an appropriate quality system.

Larger blood transfusion services should have an individual specifically responsible for quality, the quality manager, together with a separate quality department, who together are responsible for coordinating the quality system within the BTS. Smaller BTSs and hospital blood banks should have a designated individual with responsibility for quality.

Senior staff have a responsibility to ensure that quality is being maintained at all times. When any changes to working patterns are proposed, their possible adverse effects on quality should be considered. All failures of quality should be reported immediately to the appropriate senior staff. They should take immediate action to deal with the situation and always review the particular part of the system where the quality failure has occurred and identify whether any changes are required.

SUMMARY

- 1 Quality is the consistent and reliable performance of services or products in conformity with specified standards.
- 2 Quality is essential in all aspects of blood transfusion work to ensure the safety of donors, recipients and staff.
- 3 The quality system comprises the organizational structure, processes, procedures and resources needed to implement the quality requirements.
- 4 Quality assurance is the overall range of activities and systems that provide confidence within the organization and authorities that all quality requirements are met. Quality control is an inspection system to monitor the effectiveness of the quality assurance system.
- 5 Standard operating procedures are written instructions on how a particular task should be undertaken. They should be followed by all staff at all times.
- 6 Document control is a key part of the quality system. The production and distribution of all documents should be controlled in such a way that all documents in use are current and their location is recorded.
- 7 Accurate and complete records are an essential part of a quality system.
- 8 Regular monitoring is required of the outcomes of all BTS activities and the operation of all equipment.

- 9 Audits are formal reviews of the quality system undertaken to identify failings of the system and ways of resolving them.
- 10 Each member of staff has a moral and professional responsibility for maintaining quality in all aspects of their work.

SELF-ASSESSMENT

- 7 *Why is quality so important in blood transfusion work?*
 - 8 *Why should standard operating procedures be regularly reviewed and updated, where necessary?*
 - 9 *Why are audits valuable?*
-

PROGRESS CHECK

Before moving on to Section 5, spend a few minutes thinking about whether you have achieved the learning objectives for Section 4. These were to:

- 1 Define “quality”, “quality systems”, “processes and procedures”, “quality assurance” and “quality control”.
- 2 Identify the main areas of blood transfusion practice where failures of quality can occur.
- 3 Review your documentation and identify areas where there are documents lacking and where the issue and use of documents is not controlled correctly.
- 4 Contribute to the development of standard operating procedures and use them correctly.
- 5 Review your record-keeping system and identify any areas where additional records should be kept.
- 6 Review your monitoring procedures for the maintenance and calibration of all equipment used by your BTS.
- 7 Accept responsibility for maintaining quality in all aspects of your own work.

If you feel confident that you have understood everything, turn to Section 5.

If you feel that you need to spend more time on this section, go back to the parts that are most unfamiliar or that you find difficult. You may find it helpful to talk to other people, such as your supporter or other senior colleagues, if there is anything you are still not sure about.

5

Safe Storage and Transportation of Blood and Blood Components

The purpose of this section is to describe the simple procedures for the safe storage and transportation of blood and blood components that should be followed in every blood bank or transfusion service, whatever its size and the equipment and materials available. It focuses on the storage and transportation of blood and blood components that have been collected or prepared in plastic blood collection bags containing an anticoagulant–preservative solution.

A more in-depth module, *The Blood Cold Chain*, has been developed by WHO. It contains WHO specifications for refrigeration equipment for blood storage and guidance on its installation, use, monitoring and maintenance.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 State the correct temperature ranges for the storage of blood and blood components.
- 2 Review the procedures for the storage of blood and blood components in your blood bank and take any appropriate action required to ensure their safety.
- 3 Review the procedures for the transportation of blood and blood components in your blood bank and take any appropriate action required to ensure their safety.

The storage and transportation of apheresis products, such as granulocytes, are not covered in this module. If you would like further information on this, try to obtain a copy of the American Association of Blood Bank's *Technical Manual*, which is updated annually.

5.1 THE BLOOD COLD CHAIN

The “blood cold chain” is a systematic process for the safe storage and transportation of blood – from its collection from the donor to its administration to a patient who requires transfusion. It is referred to as a “cold chain” because blood and blood products must be kept cold as they are moved from one storage facility to another until they are required for transfusion.

The blood cold chain is fragile – one weak link and the chain may break. Always remember that a failure in quality in any part of the chain can have very serious, even fatal, consequences for the recipient.

The blood cold chain is often thought to be simply a collection of refrigerators and freezers, but the importance of people – people like *you* – cannot be stressed enough. Even if the finest and most modern equipment and vehicles are available, the blood cold chain will not be effective if people do not handle blood properly.

The essential parts of the blood cold chain are:

- trained staff
- standard operating procedures
- suitable equipment for the safe storage and transportation of blood and blood products
- controlled environment
- monitoring of processes, equipment and the quality of the products.

When blood is collected, tested and issued in one place, the blood cold chain may simply consist of one refrigerator and one Very Important Person (VIP) who is responsible for blood storage, as you can see in Figure 3.

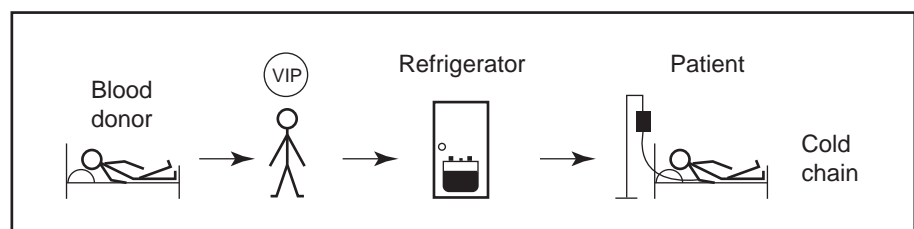


Figure 3: A simple cold chain

Figure 4 on page 56 shows another, more complex, kind of cold chain where the blood is collected both in the blood transfusion centre or hospital and outside it, using mobile collection vehicles. The blood is stored in the centre until it has been tested and is then transported to other hospitals in various ways.

Everyone involved in the blood transfusion process, from the collection of blood to its administration to the patient, is involved in the blood cold chain.

- 1 Managers of the blood cold chain are responsible for:
 - the selection and purchase of blood cold chain equipment

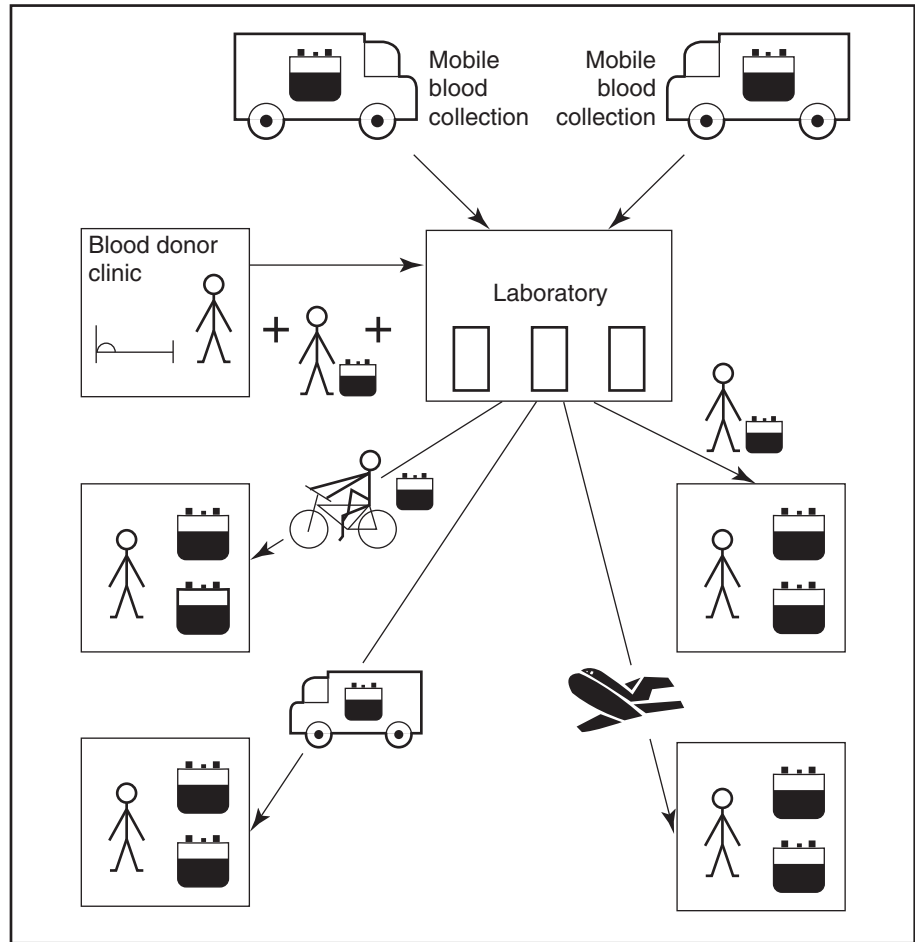


Figure 4: A more complex cold chain

- establishing a quality system for the correct installation, usage, monitoring, maintenance, servicing and repair of the equipment
 - developing a training programme for all users of blood cold chain equipment.
- 2 Donor session staff are responsible for:
- safe storage of donated blood during blood collection sessions
 - packing donated blood for transport to the blood bank
 - safe transportation of donated blood
 - monitoring the temperature during transportation, particularly on long distances
 - delivering blood to the laboratory at the required temperatures and within the specified timescale.
- 3 Laboratory technical staff are responsible for:
- installation of blood cold chain equipment
 - verifying the operation of new or repaired blood cold chain equipment
 - maintenance of blood cold chain equipment
 - receipt and inspection of incoming units of blood

- storage of blood and blood products in accordance with SOPs
 - monitoring the temperature of stored products
 - packing blood and blood products appropriately for transportation, according to the mode and duration of travel
 - quality control of blood cold chain equipment and products.
- 4 Hospital clinical staff are responsible for:
- reception of blood and blood products from the blood bank
 - correct storage of blood and blood products in wards, operating rooms and other clinical areas
 - monitoring the temperature of stored blood products in clinical areas
 - operation of blood warmers
 - safe transfusion of blood and blood products.

It is essential that all users of blood cold chain equipment understand the importance of the blood cold chain and are trained in its correct maintenance and use. However simple or complex the cold chain is, the most important part of it is that very important person who looks after the blood – *you*.

The blood cold chain involves three main processes:

- storage of blood and blood products
- packing and transportation of blood and blood products
- maintenance of blood cold chain equipment.

A quality failure in one or more of these processes will compromise the safety and effectiveness of the cold chain, resulting in a poor quality blood product that may endanger the life of the patient.

5.2 STORAGE OF BLOOD AND BLOOD PRODUCTS

Whole blood and red cells

The most important points to remember about the storage of whole blood and red cells are:

- whole blood and red cells must be stored at a temperature of +2°C to +6°C
- whole blood and red cells must never be allowed to freeze.

The main reasons for giving a red cell transfusion are to restore or help to maintain the body's oxygen-carrying capacity and to maintain the volume of blood circulating around the body. If blood is not stored between +2°C and +6°C, its oxygen-carrying ability is greatly reduced.

The anticoagulant–preservative solution in the blood bag stops the blood from clotting; it also contains nutrients for the blood during storage. The red cells can carry and deliver oxygen only if they remain viable: that is, if they retain the same constituents as they have during their normal circulation in the body.

The most important substances in maintaining the viability of the red cells are glucose and adenosine triphosphate (ATP), and it is essential to keep a balance between ATP, glucose and pH. One of the anticoagulants most commonly used is citrate phosphate dextrose with adenine (CPDA-1). Dextrose and adenine help the red cells to maintain ATP during storage and citrate stops the blood from clotting. Storing blood or red cells between +2°C and +6°C in a refrigerator is essential to make sure that the dextrose is not used too quickly. The maximum storage time is 35 days.

Another important reason for storing blood within this temperature range is to keep the growth of any bacterial contamination in the unit of blood to a minimum. If blood is stored above +6°C, any bacteria that may inadvertently have been allowed to enter the unit during collection may increase to such an extent that transfusion of the blood could be fatal.

The lower limit of +2°C is also very important. This is because red cells are very sensitive to freezing. If they are allowed to freeze, the red cell membranes burst and haemoglobin is released: that is, the cell is haemolysed. If they are transfused, this can be fatal.

Table 1 summarizes the essential storage and transportation conditions for whole blood and red cells.

Table 1: Storage and transportation conditions for whole blood and red cells

<i>Conditions</i>	<i>Storage temperature</i>	<i>Maximum storage/ transportation time</i>
Storage	+2°C to +6°C	Average 35 days
Transportation of unprocessed whole blood	+2°C to +10°C	Within 6 hours
Transportation of unprocessed whole blood destined for component production (e.g. fresh frozen plasma, platelet concentrates)	+20°C to +24°C	Within 6 hours
Transportation of processed blood	+2°C to +10°C	Within 24 hours

Fresh frozen plasma

Fresh frozen plasma (FFP) is plasma that has been separated from a unit of whole blood within 6–8 hours of donation and has been rapidly frozen to, and maintained at, a temperature of –20°C or colder. FFP is given to a patient to restore, or help to maintain, coagulation factors. Crystalloids and colloids are recommended for plasma volume replacement and plasma should be used only when these are unavailable and as a life-saving procedure.

Plasma contains water, electrolytes, coagulation factors and proteins (mostly albumin). Most of the coagulation factors are stable at refrigerator temperature, except for Factor VIII and Factor V, which are essential in

the clotting mechanism. If plasma is not stored frozen at -20°C or colder, the coagulation factors such as Factor VIII and Factor V in the plasma will deteriorate and their amount will be greatly reduced. There is no point in giving fresh frozen plasma to a patient to improve the coagulation factors if the plasma contains little or no Factor VIII or Factor V.

Plasma must be frozen solid at all times until it is thawed before use. It should be discarded if it is not frozen solid and feels soft. If possible, it should be stored in a cardboard container to protect the “pigtail” tubing which breaks very easily when it is frozen. The period of storage and therefore the viability of the plasma proteins will vary according to the storage temperature.

Cryoprecipitate

Cryoprecipitate is the cold-insoluble portion of plasma remaining after FFP has been thawed. It contains approximately 50% of the Factor VIII and von Willebrand Factor, 20–40% of the fibrinogen and some of the Factor XIII originally present in the fresh plasma.

In preparing cryoprecipitate, plasma is separated from red cells within 6 to 8 hours of blood collection and is frozen solid rapidly, within a maximum of 30 minutes. The plasma is then thawed slowly at below $+4^{\circ}\text{C}$. In order to obtain the maximum yield of cryoprecipitate from a blood donation, it is essential that standard procedures for the collection, storage and processing of the component are strictly adhered to. Its stability during storage is dependent on the temperature at which it is stored. The optimal storage temperature is -40°C .

Table 2 shows the permitted storage times and temperature for both fresh frozen plasma and cryoprecipitate.

Table 2: Storage conditions for fresh plasma and cryoprecipitate

<i>Product/Condition</i>	<i>Storage temperature</i>	<i>Maximum storage time</i>
FFP	-65° or colder	7 years
FFP/cryoprecipitate	-40°C to -64°C	24 months
FFP/cryoprecipitate	-30°C to -39°C	12 months
FFP/cryoprecipitate	-25°C to -29°C	6 months
FFP/cryoprecipitate	-20°C to -24°C	3 months
Thawed plasma/ cryoprecipitate	$+2^{\circ}\text{C}$ to $+6^{\circ}\text{C}$	24 hours

Plasma derivatives

Plasma derivatives are produced from large pools of donor plasma which have been fractionated by chromatography or cold ethanol precipitation into more purified protein products. Table 3 on page 60 shows the storage conditions for commonly used plasma derivatives. It is essential to store all plasma derivatives in accordance with the manufacturer’s instructions.

Table 3: Storage conditions for plasma derivatives

<i>Product/Presentation</i>	<i>Storage temperature</i>	<i>Maximum storage time</i>	<i>Other considerations</i>
Albumin (liquid)	Room temperature (not higher than 37°C)	3 years	Do not freeze
Plasma protein fractions (powder)	+2°C to +8°C	5 years	Use within 4 hours of opening
Immune serum globulin (liquid)	+2°C to +8°C	3 years	Do not freeze Use promptly
Factor VIII	+2°C to +8°C	1 year	Do not freeze
	Room temperature	3 months	Use within 3 hours of reconstitution
Factor IX	+2°C to +8°C	1 year	Do not freeze
	Room temperature	1 month	Use within 3 hours of reconstitution

Platelet concentrates

Platelet transfusions are used to prevent spontaneous bleeding or to stop bleeding in those patients with established hypoplastic anaemia or bone marrow failure, due to replacement with malignant cells or to chemotherapy.

Both manual and automated methods can be used in the preparation of platelet concentrates. Lower temperatures affect platelet function and separation. For this reason, whole blood that will be used for the preparation of platelet concentrates and other blood components should be kept at a temperature between +20°C and +24°C until it is processed.

Platelet-rich plasma must be separated from whole blood by centrifugation within 8 hours of blood collection. Additional centrifugation and removal of most of the supernatant plasma may then concentrate the platelets.

In order to maintain platelet function, platelet concentrates should be stored at a temperature of +20°C to +24°C with continuous agitation on a special platelet agitator. They should *never* be placed in a refrigerator or freezer. The shelf-life and storage conditions differ according to the type of blood bag used. They can be stored for up to 72 hours, unless stored in specialized platelet packs validated for a longer storage period of five days.

If no platelet agitator is available, platelet concentrates must be transfused within 30 minutes of completion of testing (provided that the results of testing for transfusion-transmissible infections are negative), unless the blood bank is equipped with:

- air conditioning with a temperature monitoring system that will maintain an ambient temperature of between +20°C and +24°C
- a platelet incubator that will keep the platelet concentrates at a temperature of +20°C to +24°C.

Since platelet concentrates are stored at room temperature, there is a risk of bacterial contamination. Storage conditions and expiry dates should be strictly adhered to in order to prevent this potentially fatal complication. If the hermetic seal of any blood bag is broken, platelet concentrates should be used as soon as possible, but must be transfused within 6 hours if stored at +20°C to +24°C.

The temperature in the immediate vicinity of the platelet storage area should be monitored and recorded to ensure that the storage temperature is within the correct range (+20°C to +24°C). An air conditioning unit may be needed to maintain the ambient temperature below +24°C.

Platelet concentrates should be issued from the blood bank in a blood transport box or insulated carrier that will maintain the temperature at room temperature and infused within 30 minutes, unless a special coolant pouch that can maintain the temperature at +20°C to +24°C is available.

Table 4 shows the correct conditions for the storage and transportation for platelet concentrates.

Table 4: Storage and transportation conditions for platelet concentrates

<i>Conditions</i>	<i>Storage temperature</i>	<i>Maximum storage time</i>
Storage	+20°C to +24°C	72 hours to 5 days, depending on the blood bag used
Transportation	+20°C to +24°C	Not to exceed 24 hours
After issue, before transfusion	+20°C to +24°C	15–30 minutes
Open system, pooled	+20°C to +24°C	4 hours

ACTIVITY 24

How are platelet concentrates stored in your blood bank? Is there a platelet rotator or agitator?

At what temperature are they stored? If they are kept at room temperature, attach a sheet of paper and a thermometer as close to the rotator/agitator as possible. Record the temperature at least four times a day and check whether it is maintained within the acceptable range. Assess whether an air conditioning unit is needed to maintain the ambient temperature below +24°C.

If platelet concentrates are not stored correctly, note down on your Action List any changes that are needed and discuss them with your supervisor.

5.3 THE BLOOD STORAGE REFRIGERATOR

Whole blood and red cells should be stored in a blood bank refrigerator: that is, one that is specifically designed for the storage of blood. Blood bank refrigerators have inbuilt temperature monitoring and alarm devices and a cooling fan to ensure the even distribution of cold air throughout the equipment.

Domestic refrigerators are *not* suitable for the storage of blood because their construction is less robust and there is poor air circulation. Every effort should be made to obtain a blood bank refrigerator if one is not currently available.

All staff should be trained to comply with the following procedure.

- 1 Open the door only when it is necessary to take out or put in blood.
- 2 Arrange the blood so there is room for cold air to move around inside the refrigerator. The units of blood should be kept in baskets in an upright position or laid flat on the shelf. They should never be packed so tightly that the cold air cannot circulate.
- 3 If only one refrigerator is available, store tested and untested blood, and cross-matched and uncross-matched blood in separate marked areas.
- 4 Never keep anything except whole blood, red cells or thawed fresh frozen plasma in the blood refrigerator.
- 5 Never store platelet concentrates in a refrigerator as they lose their viability at low temperatures.
- 6 If a domestic refrigerator is used, never store blood in the door where the temperature is normally higher than inside.
- 7 Never store whole blood or red cells near the freezer compartment of a domestic refrigerator.

Figure 5 on page 63 illustrates these simple ways of using a domestic refrigerator efficiently.

ACTIVITY 25

Check all the refrigerators in your blood bank and in any clinical areas in the hospital where blood is stored, including wards, operating rooms and out-patient clinics. Is blood being stored correctly, as shown in Figure 5? If not, note down on your Action List any changes needed in the way that blood is stored and discuss them with your colleagues.

Any blood that is stored away from the main blood bank, such as in hospital wards and operating rooms, must be stored under similar conditions. If you find any refrigerators where blood is not being stored

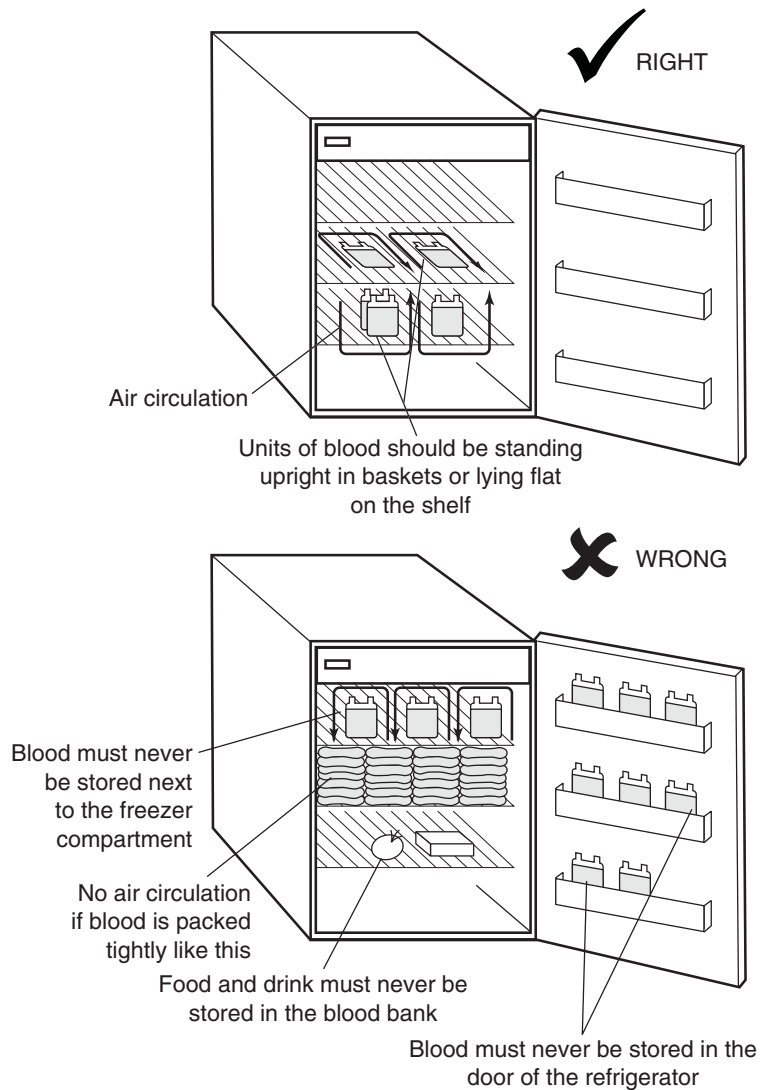


Figure 5: Using a domestic refrigerator for blood storage

correctly, talk to all the staff who use them about how they can keep them working efficiently in order to keep blood safe.

Monitoring the temperature

It is essential to have some means of monitoring and recording the temperature inside refrigerators and freezers during storage and also to have an alarm system. The temperature inside any blood storage equipment must be checked and recorded at least twice a day.

Special blood bank refrigerators have automatic monitoring systems that record the temperature continuously on a chart. However, even if there are automatic monitoring devices on the refrigerators in your blood bank, the temperature should still be monitored manually.

The safest and easiest way to check the temperature of a refrigerator is to use a thermometer. The ideal thermometer is a maximum/minimum thermometer that can show how high and how low the temperature has been, but any thermometer that covers the temperature range for blood storage can be used. The thermometer should be left on a high shelf one day, and on a low shelf the next day, to measure any variation in temperature inside the refrigerator.

The temperature should be checked at least twice a day, including early in the morning and at the end of each working day. Even if the equipment is working efficiently, the first temperature may be a little low if the outside temperature has been low overnight.

At the end of a working day, the temperature is often higher, particularly if the door has been opened more than is necessary. If the door is opened too many times or is left open, it not only affects the temperature but also causes ice to build up on the evaporator. This means that the refrigerator will not work efficiently and will need defrosting more often.

The temperature must be written down, preferably on a chart or in a record book, along with the date and time it was taken and the position of the thermometer. If the temperature is not between +2°C and +6°C, the possible cause and any action taken should also be recorded.

It is a good idea to stick a temperature chart on the front of the refrigerator to remind you that the temperature must be taken regularly. Figure 6 shows an example of a chart or a page in a record book.

Figure 6: Example of a temperature record

TEMPERATURE RECORD				
Date	Time	Shelf	Temperature	Action
6.11.01	9.00 am	High	4°C	None
6.11.01	4.00 pm	Low	10°C	To be checked in 30 minutes
6.11.01	5.00 pm	Low	8°C	None

In refrigerators without an internal cooling mechanism, such as domestic refrigerators, some areas may be warmer or colder than others. For example, the lower shelves are often colder than shelves higher up and it is often colder near the back of the refrigerator. You can find out whether your refrigerator has “hot spots” and “cold spots” by checking the temperature on different shelves at different times. If these temperatures are still within the range +2°C to +6°C, the blood should be safe. If one area is continually outside this range, you should move the blood on to another shelf that is within the range.

ACTIVITY 25

Measure the temperature in different parts of each refrigerator used in your blood bank: for example, on the top shelf, middle shelf and bottom shelf. Take the temperature on at least five different days so that you can calculate the average temperature for each part. Always take the temperature at the same time of the day.

What would you do if you got the following results?

Shelf	Average temperature
Top	+2°C
Middle	+3°C
Bottom	+1°C

Check your answer with the one given in the Activity Checklists and Answers.

The temperatures in refrigerators used for storing blood in hospital wards and operating rooms should be checked in the same way. If they are not being checked at least twice a day, try to find someone who works in the clinical area to take responsibility for monitoring and recording the temperature. Explain the procedure carefully and check periodically whether it is being carried out correctly. Alternatively, make yourself responsible for checking those refrigerators because they contain blood that has been issued by your blood bank which must be kept safe for patients.

Even if blood storage equipment works efficiently, however, the temperature may often be higher than +6°C if the door is opened very frequently.

ACTIVITY 27

Find out how often the doors of the refrigerators and freezers in your blood bank are opened. You can do this by attaching a sheet of paper to the door of each one with instructions asking people to make a mark every time they open the door. You will probably find that this alone will make you all think more carefully before opening the door.

At the end of every working day, record the number of times that each door has been opened. Do this for at least a week.

Whatever the number of times that each door is opened during the period of a day, it is likely to be too often.

It is usually possible to reduce the number of times that a refrigerator or freezer door is opened. Try to think of some ways of persuading people in your blood bank not to open the door of the refrigerator too often. Explain to them why it is so important that the door should not be opened unnecessarily and put a notice or handwritten sign on the door reminding them not to open it unless it is essential.

STOP!
DO YOU NEED
TO OPEN THIS DOOR?

ACTIVITY 28

Put a notice or sign on the doors of all the refrigerators and freezers in your blood bank reminding staff not to open them unnecessarily. After a few weeks, again check the number of times the doors are opened each day by asking each member of staff to make a mark on a sheet of paper each time they open the door.

Has there been a reduction in the number of times that the doors are opened? If not, ask your colleagues why they open the doors so frequently and try to agree on ways of reducing this in the future. Note down your recommendations on your Action List and discuss them with your supporter.

Plasma freezer

The temperature of the plasma freezer must be checked at least twice a day in the morning and the late afternoon. The temperature and the time it was measured must be recorded, together with any action taken if the temperature has risen above the expected temperature (see Table 2 on page 59). Fresh frozen plasma that has thawed and has been refrozen should be discarded.

5.4 TRANSPORTATION OF BLOOD AND BLOOD COMPONENTS

An efficient system must be in use to ensure that all blood and blood components are maintained in the correct storage conditions whenever they are moved from one location to another, including:

- from mobile collection sites to the processing laboratory
- from the blood bank to a different facility (to a hospital, blood bank or clinic)
- from the hospital blood bank to wards and operating rooms.

The maximum transit time for blood and blood components is 24 hours.

Inspecting the blood packs

Before transportation from the blood bank to a hospital or within the hospital, blood packs should always be inspected for deterioration or damage. Discoloration or signs of leakage may be the only warning that the blood has been bacterially contaminated and that it could cause a severe or fatal reaction when transfused. Each pack should be checked for the following signs.

- 1 Any sign of haemolysis in the plasma indicating that the blood has been contaminated, allowed to freeze or become too warm.
- 2 Any sign of haemolysis on the line between the red cells and plasma. If you suspect this, gently mix the unit and allow it to “settle out” before being issued.
- 3 Any sign of contamination, such as a change of colour in the red cells, which often look darker or purple/black when contaminated.

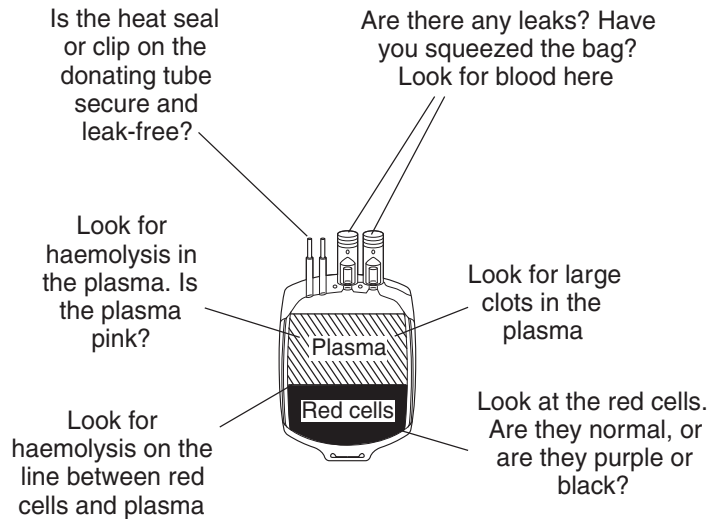


Figure 7: Checking for signs of deterioration

- 4 Any clots, which may mean that the blood was not mixed properly with the anticoagulant when it was collected.
- 5 Any signs that there is a leak in the bag or that it has already been opened.

Figure 7 gives a simple checklist for signs of deterioration in whole blood and red cell components. You could stick this checklist on a wall near the refrigerator to remind everyone to check the blood before it is issued.

Blood transport boxes

Specially designed blood transport boxes should be used, wherever possible. If these are not available, sturdy, well-insulated cardboard or styrofoam containers can maintain the correct temperature if they contain adequate cooling material.

The refrigerant recommended for most shipments is wet ice in leak-proof containers, such as plastic bags. Wet ice from commercial ice-making machines is satisfactory. Super-cooled cubed ice, canned ice or dry ice should not be used for the storage or transportation of whole blood or red cells, because they can create very low local temperatures which may cause the haemolysis of red cells in their immediate vicinity. Blood shipped by air may freeze if transported in an unpressurized storage compartment.

Blood Time Temperature Indicator (BTTI)

A donated unit of blood is exposed to varying temperatures during processing and transportation. Quality monitoring of equipment and standard operating procedures for the handling of blood reduce the risk of exposure to unsafe temperatures. However, there still remains an undefined risk of a unit being returned to available stock in a refrigerator when it has been exposed cumulatively, or on a single occasion, to a temperature outside the correct range for an unknown period of time.

The Blood Time Temperature Indicator (BTTI) has been developed by WHO, in consultation with manufacturers, to provide a reliable device for

monitoring the temperature of a consignment of blood during transportation. This is the first step in the development of an indicator that will effectively show whether a blood component has been stored at an adverse storage temperature at any one time or cumulatively.

The BTTI is based on the migration of a chemical through a paper wick. It is a card that, on activation, shows colour changes when the cumulative temperature of exposure exceeds +10°C. The BTTI has four windows, labelled 1 to 4, that will turn blue on undue thermal exposure. As soon as a temperature of +10°C is exceeded, the first window will turn blue. The second and third windows will turn blue if the temperature remains above +10°C or at every successive exposure to this temperature. The higher the temperature, the faster the blue colour spreads through windows 1 to 3. Window 4 will turn blue immediately if the temperature in the container exceeds +17°C at any time. The coloration in the windows is easy to observe and although coloration may stop, it is irreversible.

The BTTI is not intended to replace existing quality assurance measures for the safe transportation of blood components. It is a simple tool to assist personnel handling blood components to decide whether to use or discard a particular consignment of blood.

The BTTI is useful in monitoring the temperature of whole blood and red cells in the following situations:

- storage in cold boxes in the case of a power failure
- transportation in blood transport boxes from one blood bank to another
- movement of blood from the blood bank to the patient's bedside
- return of unused blood from the point of potential use to the hospital blood bank.

Further information on the Blood Time Temperature Indicator is available from:

World Health Organization
Blood Safety and Clinical Technology
CH-1211, Geneva 27, Switzerland
Fax: +41 22 791 4836. E-mail: bloodsafety@who.int

Transportation from the collection site to the processing laboratory

Whole blood that will not be used for component preparation should be placed in a blood transport box at a temperature of +2°C to +10°C and should be transported from the collection site to the laboratory as quickly as possible; the time between collection and processing must *not* exceed 8 hours.

The blood should be packed into the cold box, surrounded by ice packs which have been stored frozen in the plasma freezer ready for use. Cool air moves downwards so ice should be placed above the blood, not around or underneath it. *Never* allow blood to touch the ice packs. If cold boxes with separate compartments are not available, ice packs should

be wrapped in several layers of paper. When blood is to be transported long distances in hot weather, there should always be as much ice as there is blood.

If the storage temperature is not maintained between +2°C and +10°C during transportation, the most likely reasons are that:

- the box is not properly insulated and may need to be replaced
- there were not enough ice packs
- the ice packs were not completely frozen and the freezer may need to be checked.

A maximum/minimum thermometer should always be reset and put inside the box, without touching the ice packs, so that the maximum and minimum temperatures reached inside the box can be recorded. The temperature should always be measured as soon as the container arrives. It is important to remember that temperatures in buses, trains and delivery vans may be very much higher than the surrounding temperature. On arrival at the blood bank, the temperature will probably be above +6°C, so the blood must be put into the refrigerator as soon as possible.

If blood collected at mobile donor sessions is destined for component preparation, the blood packs should be allowed to cool after venepuncture to a temperature of +20°C to +24°C. They should then be transported from the collection site to the component preparation laboratory in a well-insulated box with no ice.

It is essential to record the temperature of each unit of blood when it arrives in the laboratory from mobile sessions.

ACTIVITY 29

Review the procedures in your blood bank for the transportation of whole blood from the collection site back to the processing laboratory.

- *What type of container is used to transport whole blood from the collection site to the processing laboratory?*
- *Is whole blood received in the processing laboratory at a temperature outside the range of +2 °C and +10 °C?*
- *Is a form kept to record the temperature of whole blood on arrival?*
- *How long does it take to process the components and store them at the correct temperatures?*

Identify any problems and possible solutions. Note down your recommendations on your Action List and discuss them with your supporter.

Transportation from the blood bank to other branches or hospital blood banks***Whole blood and red cells***

Whole blood and red cells should be transported in a box that can maintain a temperature range of +2°C to +10°C.

Cubed wet ice is more suitable than chipped or broken ice for the long-distance shipment of blood because it melts slowly.

In boxes shipped a long distance or at high environmental temperatures, the volume of ice should at least equal that of the blood. The temperature in an insulated container can be considered to be in the range of +2°C to +10°C as long as unmelted ice remains in the box.

Fresh frozen plasma and cryoprecipitate

All frozen components should be transported in a manner that will maintain their frozen state. The temperature should therefore be maintained at -20°C or colder. This can be achieved with a suitable quantity of dry ice in well-insulated containers or standard shipping cartons lined with insulating material such as plastic air bubble packaging or dry packaging fragments.

There should be at least as much wet ice in the cold box as there is plasma. It is important to protect the frozen plasma units during transportation. If possible, they should be placed in plastic bags and then packed in cardboard boxes in case of thawing as a result of small cracks that may not be visible.

A simple method to determine whether a plasma unit has thawed and refrozen during transportation is to place a rubber band around the unit at the time of preparation. Once the unit freezes, it leaves an indentation at the sides. If the unit has thawed after it has been frozen and the rubber band has been removed, the indentation will have disappeared.

Platelet concentrates

Every effort must be made to ensure that platelet concentrates are maintained at a temperature between +20°C and +24°C during transportation. A well-insulated container without added ice is often sufficient.

Containers for transporting platelet concentrates should be equilibrated at room temperature before use.

If outdoor temperatures are extremely high, special gel pouches or containers with a power source can be used to maintain a temperature of +20°C to +24°C for up to 12 hours.

Platelet concentrates should reach their destination within a 24-hour period, which is the maximum time allowed without agitation.

Reception in the hospital blood bank

When blood or blood components arrive in the hospital blood bank, three actions should always be taken immediately.

- 1 Record the time of arrival.
- 2 Measure and record the temperature in the container.
- 3 Inspect the unit carefully for any of the signs of haemolysis or contamination shown in Figure 7 on page 67.

The temperature of whole blood and red cell units should always be measured on arrival.

If the ice packs have not melted when the blood packs are delivered, it is usually a good sign that they have remained at the correct temperature.

If you find that whole blood or red cells have reached a temperature above +10°C by the time they arrive in the blood bank, a decision must be made about whether to discard them or not. This will depend on the temperature reached and the length of time the units have been out of the refrigerator. They can be used if they have been out of the refrigerator for less than two hours, provided that there is no sign of any haemolysis. If a whole blood or red cell unit shows any signs of haemolysis or contamination, it must be discarded.

The decision to discard a unit of blood should be taken only after consulting with senior colleagues at your hospital or blood bank.

When it is necessary to discard whole blood or red cells because they show signs of haemolysis or contamination, it is important to find out why this has happened. If the blood was sent to you from a blood transfusion centre or another hospital, you must inform them as soon as possible so that they can improve their system for transporting blood. Always remember to let them know the time the blood arrived and the temperature inside the container on arrival.

If the blood has been collected and stored in your own blood bank, you must try to trace the unit back to the point when it was collected to see whether all procedures have been followed correctly and where the problem lies.

If you find that blood or red cells are not being kept at the correct temperatures when they are being transported, there are three main things that you could do to prevent this from happening in the future.

- 1 Use more suitable cold boxes.
- 2 Check that ice packs are always completely frozen when boxes are packed.
- 3 Use more ice packs, particularly if the weather is very hot or the units will be transported over a long distance.

ACTIVITY 30

The next time that blood is due to be delivered to your hospital or to leave your blood bank, ask if you can accompany it.

Measure the temperature of the blood by placing a thermometer between two units that have been rubberbanded together:

- *before leaving*
- *on arrival.*

If your measurements show that blood or blood components are not being kept at the correct temperatures, what action could you take? Note down your recommendations on your Action List and discuss them with your supporter.

Whenever you identify a problem of this kind, always talk to your colleagues in the blood bank to ensure that they also know how to pack a cold box correctly.

Issue of blood and blood components

When blood is issued from the blood bank, the time of issue must always be recorded. If the ambient temperature (the temperature inside the blood bank) is greater than +25°C, or if there is a possibility that the blood will not be transfused immediately, the blood should be issued in a cold box or insulated carrier that will keep the temperature under +10°C.

Once issued by the blood bank, the transfusion of whole blood, red cells and thawed fresh frozen plasma should be commenced within 30 minutes of their removal from refrigeration. If the transfusion cannot be started within this period, the units must be stored in a refrigerator at a temperature of +2°C to +6°C. The temperature inside every refrigerator used for blood storage in wards, operating rooms and other clinical areas should be monitored and recorded every four hours to ensure that the temperature remains within this range.

If the ward or operating room does not have a refrigerator that is appropriate for storing blood, the blood should not be released from the blood bank until immediately before transfusion.

Warming blood

Nurses and doctors may tell you that the blood must be allowed to “warm up” before transfusion, and that this will take time. On average, it takes only 30 minutes for a unit of blood to reach +10°C. Cold blood administered at a slow rate does not have ill-effects and blood warming is unnecessary unless the patient is receiving large volumes of blood in a very short space of time. In cases where rapid transfusion is required, complications such as cardiac arrhythmia can be avoided if blood is warmed to +37°C.

The final decision about whether blood needs to be warmed must be taken by a medical doctor. If it is considered necessary, blood is normally warmed in the clinical area and it is essential that it is warmed safely.

Blood should be warmed with a special blood warmer specifically designed for this purpose. This apparatus should be equipped with a visible temperature monitoring device and an audible alarm.

If an automatic blood warmer is not available, the blood bag should be gently warmed in a sink or bowl of water that is between +30°C and

+37°C. It should be kept upright to keep the “pigtail” tubing and entry and exit ports free from water. The temperature of the water must be measured, using a thermometer. Blood must never be in contact with water that is hotter than +37°C as this causes extensive haemolysis of the red cells. *If haemolysed blood is transfused, it can be fatal.*

Thawing fresh frozen plasma

Before use, fresh frozen plasma should be thawed in the blood bank in a water-bath at a temperature between +30°C and +37°C. The temperature of the water must be measured as temperatures above +37°C will destroy any clotting factors and proteins. The plasma unit should be kept upright and, if possible, put inside another plastic bag to prevent water from coming into contact with the entry port since this might contaminate the unit when the “giving-set” needle is pushed into the bag.

As with whole blood or red cells, bacteria can proliferate in plasma that is held at ambient (room) temperature. It is therefore important to avoid thawing plasma unless you know it is certain to be used. Fresh frozen plasma should never be thawed “just in case”.

After thawing, the plasma unit should be issued in a blood transport box in which the temperature is maintained between +2°C and +6°C.

Fresh frozen plasma should be infused within 30 minutes of thawing. If not required for immediate use, it should be stored in a refrigerator at a temperature of +2°C to +6°C and transfused within 24 hours. Plasma stored at this temperature for up to 24 hours can be used for volume expansion, but not for the correction of coagulation defects.

Returned and reissued blood

If a unit of blood is returned to the blood bank, use the following checklist to decide whether it should be put back into stock or discarded.

- 1 Even if the person returning the unit reports that it has not been opened, check this by squeezing the bag gently and looking for blood at the entry port.
- 2 Check the temperature by hand by folding the unit around a thermometer.
- 3 Check the time that the unit was issued.
- 4 After mixing the unit gently, let it “settle-out” in the refrigerator and look for signs of haemolysis or other signs of deterioration in the plasma and red cells.

The next time you have any units of whole blood or red cells that have reached their expiry date and are going to be discarded, complete the following activity.

ACTIVITY 31

Using “out-of-date” units of whole blood or red cells, measure how long it takes in your blood bank for the units to reach +10 °C, +15 °C,

+20 °C, +25 °C or higher, once they have been removed from the refrigerator by placing a thermometer between two units that have been rubberbanded together.

If you got the following results, what should you do when blood is issued from your blood bank?

Time to reach	+10°C	+15°C	+20°C	+25°C
	10 min	20 min	30 min	40 min

Check your answer with the one given in the Activity Checklists and Answers.

THE UNIT MUST BE DISCARDED IF:

It has been out of the refrigerator for longer than 30 minutes

or

There is any sign that the bag has been opened

or

There is any sign of haemolysis

The decision to discard a unit of blood should be taken only after consulting with senior colleagues at your hospital or blood bank. If the unit is discarded, the date and the cause must be recorded, and the unit disposed of safely.

Blood is donated in order to save lives. It is extremely precious and it is *your* responsibility to make sure that blood and blood products are kept in such a way that those life-saving properties are preserved.

SUMMARY

- 1 Everyone involved in the blood transfusion process, from collection to transfusion, is responsible for maintaining a safe and effective blood cold chain.
- 2 Whole blood and red cells must always be stored at +2°C to +6°C.
- 3 Whole blood and red cells must never be allowed to freeze.
- 4 The optimal storage temperature for fresh frozen plasma and cryoprecipitate is –40°C or colder. They must always be frozen solid.
- 5 Platelet concentrates must be stored at +20°C to +24°C with constant agitation. They must never be stored in a refrigerator or freezer.

- 6 Blood and blood products should never be stored in unmonitored refrigerators or freezers.
- 7 The doors of blood storage refrigerators and freezers should be opened only when absolutely necessary.
- 8 Whole blood and red cells must be kept within the temperature range of +2°C to +10°C during transportation, with the exception of unprocessed blood that will be used for the production of blood components: this should be transported at a temperature of +20°C to +24°C.
- 9 During transportation, frozen components must be maintained at a temperature that ensures they will remain frozen.
- 10 Platelet concentrates should be transported at a temperature range between +20°C and +24°C.
- 11 Blood should always be checked for haemolysis, contamination or other signs of deterioration before being transported, on arrival in the blood bank and before being issued. If any signs of deterioration are present, the unit must be discarded.
- 12 It is rarely necessary to warm blood. If warming is required, a blood warmer should be used.
- 13 Fresh frozen plasma should never be thawed in water that is hotter than +37°C. Once thawed, it must be stored in a refrigerator between +2°C and +6°C and transfused within 24 hours.

SELF-ASSESSMENT

- 9 *Why must there be a higher limit in the correct temperature range for the storage of blood?*
 - 10 *Why must there be a lower limit in the correct temperature range for the storage of blood?*
 - 11 *Why is it so important to store fresh frozen plasma at -20°C or colder?*
 - 12 *Why should blood not be stored in the door of a refrigerator?*
 - 13 *Why should blood never be heated to more than +37°C?*
-

PROGRESS CHECK

Before moving on to Section 6, spend a few minutes thinking about whether you have achieved the learning objectives for Section 5. These were to:

- 1 State the correct temperature ranges for the storage of blood and blood components.
- 2 Review the procedures for the storage of blood and blood components in your blood bank and take any appropriate action required to ensure their safety.
- 3 Review the procedures for the transportation of blood and blood components in your blood bank and take any appropriate action required to ensure their safety.

If you feel confident that you have understood everything in this section, turn to Section 6.

If you feel that you need to spend more time on this section, go back to the parts that are most unfamiliar or that you have found difficult. You may find it helpful to talk to other people, such as your supporter or other senior colleagues, if there is anything you are still not sure about.

6

Preparing Basic Solutions

This section covers the preparation of basic solutions widely used in blood transfusion practice. Examples of standard operating procedures are given in the Appendix for the preparation of the following four solutions or types of solution:

- copper sulfate solutions
- antiseptic solutions
- saline solutions
- disinfectant solutions.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 Review the procedures used in your laboratory for the preparation of four basic solutions.
 - 2 Systematically and accurately prepare four basic solutions, using standard operating procedures.
-

Preparing basic solutions is relatively simple if you have adequate supplies of raw materials. Using pure materials is essential. Most solutions are based on water containing different dissolved chemicals and it is vital to use good quality distilled or deionized water. If you have problems obtaining pure water in your laboratory, you could use “water for injection” or “water for irrigation” which you should be able to get from the pharmacy.

ACTIVITY 32

What is the source of the pure water used in your laboratory? Is it distilled or deionized? If supplies are sometimes limited in your laboratory, find out whether you can get any from the pharmacy or any other sources.

It is important to make an accurate measurement of the volumes of liquids and the weights of dry chemicals used. Calibrated glassware should be used to measure the volumes of liquids and should be chemically clean and free of grease. Ideally, all glassware should be regularly soaked in 2 mol/litre hydrochloric acid for at least 12 hours. All balances used to weigh dry reagents must be calibrated regularly, preferably using standard weights. If possible, use disposable weighing boats, although you can use reusable glass containers if they are thoroughly cleaned after each use.

If you are unable to obtain the necessary raw materials or equipment locally, you should be able to get them from a specialized laboratory or the national reference laboratory.

Appropriate documentation must always be completed to ensure the quality of the prepared solutions. All prepared solutions should be clearly labelled with:

- the name of the solution
- the concentration (if appropriate)
- the batch number
- the date of preparation
- the date of expiry.

6.1 COPPER SULFATE SOLUTIONS

Copper sulfate solutions are used to check that a donor has a sufficiently high haemoglobin level to be eligible to give blood. Two strengths of copper sulfate solution are normally used, each of which has a different specific gravity (relative density): one for male donors and one for female donors. The specific gravity of the solution used for male donors is higher than that used for female donors; this reflects the minimum acceptable haemoglobin concentrations for male and female donors. The minimum haemoglobin levels may vary

in different countries, depending on the normal haemoglobin ranges in the population, the volume of blood taken at each donation and the frequency of donation.

It is important to ensure that copper sulfate solutions are prepared as accurately as possible, using good quality reagents, and that the specific gravity is checked before use. In many countries, it is possible to obtain bulk volumes of copper sulfate solutions which can then simply be divided into smaller amounts (aliquots) for use.

A standard operating procedure for preparing copper sulfate solutions is given in the Appendix. Module 1 also contains an example of a standard operating procedure for haemoglobin screening using the copper sulfate method.

6.2 ANTISEPTIC SOLUTIONS

Antiseptic solutions are used to cleanse the arm of the donor before venepuncture. There are several solutions that are suitable, particularly alcohols which are effective and evaporate quickly, leaving no residue, although they are not always easily available. Pharmaceutical grade 70% (v/v) isopropanol is the most effective and this can usually be obtained in the form of prepacked impregnated swabs. Alternatively, 70% (v/v) pharmaceutical grade ethanol in distilled water can be used. When using bulk volumes of antiseptic solutions, always take care to ensure that the solutions themselves do not become infected and test them regularly for bacterial contamination. Many commercially prepared solutions are available and these are often more practical to use, although the best approach is to use individual impregnated swabs.

Some blood transfusion services use a two-stage procedure to clean the donor's arm, using a proprietary antiseptic solution to clean the venepuncture site and then an alcohol swab to remove any remaining antiseptic solution and give the site a second cleansing.

A standard operating procedure for preparing antiseptic solutions is given in the Appendix.

6.3 SALINE SOLUTIONS

A good supply of saline is vital for performing red cell serology work. Saline solutions are used to dilute or wash red cells in order to avoid haemolysis. The basic 0.85% saline solution is very easy to prepare, although many laboratories now use a buffered saline solution to ensure the correct pH (this is generally agreed to be pH 6.8).

Buffered saline can be prepared in the laboratory if the chemicals required are easily available and accurate weighing and pH measurement are possible. However, many laboratories find it simpler to obtain buffered saline tablets and dissolve them in water to prepare the appropriate saline solution. If this is not possible, normal saline (0.9% sodium chloride) can usually be obtained from the pharmacy.

A standard operating procedure for preparing saline solutions is given in the Appendix.

6.4 DISINFECTANT SOLUTIONS

Disinfectant solutions are used to inactivate any infectious agents that may be present in blood or other body fluids. They must always be available for cleaning working surfaces, equipment that cannot be autoclaved and non-disposable items and for dealing with any spillages involving pathological specimens or other known infectious material.

There are many disinfectant solutions, with varying levels of effectiveness. In most countries, the most widely available disinfectant is sodium hypochlorite solution (more commonly known as *bleach* or *chlorox*), which is a particularly effective antiviral disinfectant solution.

To ensure effective disinfection, follow the manufacturer's instructions or any other specific guidelines that have been given and dilute the concentrated solution to the correct working strength. It is important to use all disinfectant solutions within their expiry date as some solutions, such as hypochlorite, lose their activity very quickly.

If you have not already done so, you may find it helpful to obtain the two publications from the WHO AIDS Series that were referred to earlier, in Section 3:

- *Guidelines on Sterilization and High-Level Disinfection Methods Effective Against Human Immunodeficiency Virus (HIV)* (WHO AIDS Series, No. 2, 1989)
- *Biosafety Guidelines for Diagnostic and Research Laboratories Working with HIV* (WHO AIDS Series, No. 9, 1991).

A standard operating procedure for preparing hypochlorite disinfectant solutions is given in the Appendix.

ACTIVITY 33

Find out where ready-prepared basic solutions can be obtained from in your country and whether it is more cost-effective to buy them or to prepare them in the laboratory.

Read the standard operating procedures in the Appendix and compare them with your procedures for preparing basic solutions. Are there any improvements you could make to your own procedures for preparing basic solutions? If so, note them down on your Action List and discuss them with your supporter.

SUMMARY

- 1 Good quality raw materials are essential for the preparation of basic solutions.

- 2 Distilled or deionized water is the basis for most solutions.
- 3 Appropriate documentation should be completed when preparing solutions and the solutions should be clearly labelled.
- 4 The volumes of liquids and the weights of dry chemicals should be measured accurately, using clean, calibrated glassware and balances.

SELF-ASSESSMENT

- 15 *Which copper sulfate solution has a higher specific gravity – the solution used for male donors or the solution used for female donors?*
 - 16 *Why should disinfectant solutions always be used within their expiry date?*
-

PROGRESS CHECK

Before moving on to Section 7, spend a few minutes thinking about whether you have achieved the learning objectives for Section 6. These were to:

- 1 Review the procedures used in your laboratory for the preparation of four basic solutions.
- 2 Systematically and accurately prepare four basic solutions, using standard operating procedures.

If you feel confident that you have understood everything in this section, turn to Section 7.

If you feel that you need to spend more time on this section, go back to the parts that are most unfamiliar or that you find difficult. You may find it helpful to talk to other people, such as your supporter or other senior colleagues, if there is anything you are still not sure about.

7

Stock Control

The purpose of this section is to help you to make the best use of consumable resources by developing and maintaining an efficient and cost-effective system of stock control.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 Explain the importance of an efficient system of stock control.
 - 2 Develop a simple stock card.
 - 3 Order supplies in an efficient and cost-effective way.
 - 4 Carry out a stock check.
-

7.1 CONSUMABLES

Whether you work in a large blood transfusion service with modern sophisticated equipment or a small hospital blood bank with simple equipment, you cannot do your job properly without adequate supplies of consumables.

ACTIVITY 34

Over a period of one day, make a list of all the consumable items that you use. Divide them into categories, such as blood collection bags, reagents, anti-HIV test kits, glassware, stationery and so on.

Can you remember any occasions when there were insufficient supplies of any of these items? If so, which ones? What happens when any of these items are out of stock? Can you do your work efficiently?

Keep your list for use in Activities 36–38.

You may have been surprised by the number of kinds of consumable that you listed in Activity 34. Remember that these were simply the items you used in one day and you may also use others on a regular basis. Although most of these consumables are basic requirements for good blood transfusion practice, your colleagues may use some additional consumables if they are working in different technical areas.

There should always be sufficient quantities of the consumable items that you use so that you can do your job properly. You can only ensure this if there is an efficient stock control system in operation and new stocks are ordered well before existing stocks run out.

There may be occasions, however, when there are insufficient stocks of some items because of circumstances beyond your control. For example, it may be very difficult to obtain supplies of certain consumables in your country. In this case, it is particularly important to try to find a reliable source of supply and to plan ahead so that you request new stocks some time before you are likely to need them.

Organizing the control of stocks of consumables can be a complex task and one person should be allocated responsibility for this. However, everyone working in the blood bank also has a responsibility to alert that person if supplies of a particular item are being used more quickly than usual. A stock control system depends on good organization, but everybody can play their part in ensuring that it works well.

7.2 STOCK CARD

A stock control system need not be complicated. The basic requirement is a stock card, which is a record of the order, delivery and use of each item. This is very important because it enables trends in the use of each consumable to be monitored and indicates when it is necessary to place

the next order and what quantity to order. It therefore assists in ensuring that adequate, but not excessive, stocks are always available.

Stock cards are normally maintained by the laboratory stores officer or by the person allocated this responsibility by the head of the blood bank or transfusion service. However, even if laboratory consumables are ordered by the medical stores, pharmacy or laboratory headquarters and are stored there, every department should have a simple record of its own consumables.

A separate stock card is required for each laboratory consumable. An example of a stock card is shown in Figure 8 on page 85.

The top part of the card contains certain basic information:

- 1 *Name of the item.* For example, anti-A blood group serum, 75 x 12 mm glass tubes.
- 2 *An individual code number.* This will make identification of the item more precise, and make record-keeping easier.
- 3 *Minimum stock level.* Orders should always be placed before the stock runs out and when there is still a sufficient quantity or volume to last during the period between order and delivery. It is essential to record the level below which the existing stock should not fall before an order is made, taking into account normal rates of use and the supplier's delivery schedule.
- 4 *Order unit.* Each item will be supplied in a minimum quantity, weight or volume. For example, the size of a single unit of one particular item may be 100 g, whereas another item may only be available by the kilogram. You need to know the size of a single unit so that you can calculate the total number of units that need to be ordered.
- 5 *Minimum order.* Some items will be supplied only if a minimum quantity or volume, such as 1 kg or 5 litres, is ordered. This information is necessary in calculating the quantities to order.
- 6 *Delivery time.* Information on the supplier's normal delivery schedule will enable you to order stock in good time before it runs out. For example, the supplier may need the order four weeks before delivery.
- 7 *Storage.* The location where the item should be stored and the required storage conditions should be specified: for example, at a certain room temperature, in a refrigerator or freezer, in darkness, or with adequate ventilation. When the stocks arrive, they can immediately be stored correctly and found easily when required.
- 8 *Other comments.* The usage rate of one item, such as anti-A, may be identical or very similar to that of another item, such as anti-B. They may also come from the same

STOCK CARD

Item _____ Code _____ Minimum stock level _____

Order unit _____ Minimum order _____ Delivery time _____

Storage _____

Other comments _____

Date	Stock level (carried forward)	STOCK ISSUED		Need to reorder? (Yes/No)	STOCK ORDERED		STOCK RECEIVED		Total in stock
		Quantity	Signature		Quantity	Signature	Quantity	Signature	

Figure 8: Example of a stock card

supplier. In this case, it makes sense to check the quantities in stock of both items so that an order can be placed for both of them at the same time. You could therefore use the “Other comments” section to add a note such as “Check item X before ordering”. Alternatively, it may be necessary to check with the director or another designated person before reordering, in case the item is not functioning as well as it should.

Even if two items are normally purchased or supplied in equal quantity or volume, they should still each have their own stock card. This is because you may have to obtain them from different suppliers or there may be a difference in the date when they are delivered or in the rate of usage.

The stock record part of the card should be kept completely up to date, with entries made at the time of every issue, order or delivery of stock. Each entry should show:

- the date
- the quantity/volume of the item issued, ordered or received
- the signature of the person issuing, ordering or taking delivery of the item.

It is important to make only *one* type of entry per line (*either* stock issued *or* stock ordered *or* stock received) and to enter the total quantity in stock on that date in the last column. The total quantity in stock should be carried forward to the “Stock level (carried forward)” column of the next line at the time of the next entry.

The “Need to reorder?” column acts as a reminder for you to check the stock situation against the minimum stock level so that further supplies can be ordered in good time.

The stock card system can be very useful in a number of ways. For example, the quantity/volume received can easily be checked against the quantity/volume ordered, before the items are placed in the store. If the period of time before delivery is longer than expected, it may be necessary to allow for longer delivery times in the future.

Stock cards also enable you to:

- monitor the rate of usage of each item of laboratory consumables
- monitor the delivery schedules and reliability of each supplier
- identify the items that are being used very little and that may be tying up funds that could be used for purchasing other items
- ensure accountability for the acquisition and use of every laboratory consumable.

Stock cards need to be filed in a logical sequence, either in alphabetical order or according to the code number, so that they can be located quickly and easily.

ACTIVITY 35

What system of stock control is used in your blood bank? How effective is it?

If stock cards or similar kinds of record are used, compare them with the example given in Figure 8. Do you think any additional information needs to be recorded in your system in order to keep efficient control of stocks of all consumables? If so, note your recommendations on your Action List.

If stock cards are not used in your blood bank, look carefully at Figure 8 and think about how it could be adapted to develop a simple stock card for your laboratory. Note down your ideas on your Action List and discuss them with the person responsible for managing the supplies of consumables, and with your supporter.

7.3 ORDERING SUPPLIES

A correctly-maintained stock card makes it easy to decide how much of any item to order, and when, because the necessary information is all together in one place. It should show how long it normally takes between ordering and delivery, how quickly each item is being used and whether there are any times when the usage rate is normally higher or lower than usual. It should then be a matter of simple arithmetic to decide how much to order and how often.

Consider the following example. The usage rate of a particular item, as shown by the record of issue, is 100 g per week. The item is supplied in units of 200 g and the size of the minimum order is one unit. Minimum stocks of 1 kg (enough for ten weeks) are maintained and an order is normally placed every four weeks. It is therefore necessary to place an order for 400 g (two units) per month, unless the usage rate changes significantly.

Some items can, of course, be ordered in larger quantities so that it becomes unnecessary to place an order so often. In our example above, for instance, it might be better to place an order for 1.2 kg every three months, rather than a smaller order every four weeks. However, this will depend on how quickly the item expires. If an item has a short expiry date, you should obviously not order larger quantities than it is possible to use within that period. For example, red cell suspension for use in grouping has a short expiry date which is usually about four weeks, whereas the expiry date for antisera is usually two years.

ACTIVITY 36

Look back at the list you made in Activity 34. Against each item, note the normal period of time before expiry, as specified by the supplier or manufacturer. Keep your list for further use in the next activity.

Methods of ordering supplies

There are three main methods of ordering laboratory consumables:

- bulk orders
- standing orders
- orders as required.

The choice of method will to some extent depend on the item to be ordered.

Bulk orders

It is appropriate to make a bulk order for a consumable if relatively large quantities will be used, there is adequate storage space and the item has a long expiry date. Items such as blood collection bags could be ordered annually, for example, depending on the availability of funds. It is important not to spend most of your budget on one consumable, but you may be able to purchase some items at a reduced price if you buy a large enough quantity.

Standing orders

With a standing order, an order is made for delivery of a fixed quantity of a particular item each week or month. It is normally used for items with short expiry dates or where the supply may otherwise be erratic. A regional transfusion service or blood bank, for example, may place a standing order with the central transfusion service for a weekly supply of a particular quantity of red cells for grouping. Since there is no need to place a separate order each week, this reduces the amount of time and paperwork involved. It may also be possible to obtain a reduced price if you make a standing order, because it also involves less administrative work for the supplier.

Orders as required

The most common way of ordering supplies is to order items as and when they are required. Stock cards are obviously very important here because they make it easy to monitor stock levels and show when it is necessary to re-order.

Figure 9 on page 89 compares the advantages and disadvantages of these three systems.

ACTIVITY 37

Look back at the list you made in Activities 34 and 36 of consumable items and their expiry dates. Decide which ordering method is most appropriate for each item:

- *bulk order: perhaps every six months or annually*
 - *standing order*
 - *order as and when required.*
-

	<i>Bulk</i>	<i>Standing order</i>	<i>When required</i>
Ties up large amount of funds in one item	Yes	No	No
Possible problems in storage space, wastage or item being spoilt	Yes	No	No
Cheaper per unit	Yes	Possibly	No
Risk of shortage	No	No	Yes
Greater use of stock card required	No	No	Yes

Figure 9: Advantages and disadvantages of ordering methods

7.4 STOCK CHECK

If a stock card system is used effectively, it should provide an accurate record of all the stock available, as well as providing vital information about when and how much to order. However, a stock check – a physical check of all the consumables in the stores of your laboratory – will still be needed periodically to ensure that all stock is accounted for.

A physical check may reveal that the quantity of stock recorded on the stock card does not correspond with what is actually there, perhaps because the issue of stock has not been recorded systematically. Alternatively, it may mean that the loss or theft of certain consumables has not been noticed or reported, or that items recorded as having been delivered did not actually arrive.

When you carry out a stock check, use the following procedure:

- 1 Arrange to do the stock check when no deliveries or issues are expected. Make sure that no stock enters or leaves the storeroom until the check has been completed.
- 2 Ensure that nothing is moved in the storeroom while the stock check is taking place.
- 3 Arrange for two people to carry out the stock check together, so that they can verify the quantity or volume of each item that is in stock.
- 4 Physically check and record the quantity or volume of each item and then compare it with the figure on the stock card.
- 5 Thoroughly investigate and report any difference between the actual stock and the figures recorded on the stock card. It may be necessary to contact the suppliers to check what has been delivered or to introduce a new system for the issue of consumables.

ACTIVITY 38

Using the list of consumables that you made in Activity 34, select five items.

Do a physical stock check on those items by checking the quantity/volume of each item in stock.

If your laboratory already uses stock cards or a similar kind of record, compare the findings of your stock check with what is recorded on the stock cards. Is there any difference? If there is, report this to the person in charge of the stores. Keep a record of your stock check in case you need it for future reference.

If stock cards or similar kinds of records are not used in your laboratory, record your stock check because it will provide important information that can be used as a basis for preparing a stock card for every item of laboratory consumables.

If there are no stock cards or other kinds of records, a physical stock check can tell you only what *is* in stock, not what *ought* to be in stock. This should underline the importance of using a suitable system of stock control.

ACTIVITY 39

Look back at your responses to the activities in Section 7. Make a note on your Action List of any ways in which you think the stock control system in your laboratory could be improved. Discuss them with the person in charge of managing supplies of consumables and with your supporter.

SUMMARY

- 1 An efficient system of stock control is essential for the efficient functioning of the donor clinic and laboratory.
- 2 A stock card for each consumable item is the basis for a stock control system.
- 3 The most appropriate method of ordering supplies depends on the nature of each individual consumable.
- 4 A physical stock check should be carried out periodically to compare the actual stock level of each item with the quantity/volume recorded on the stock card.

SELF-ASSESSMENT

- 17 *Why is it important to record minimum stock levels?*
 - 18 *What are the three basic methods for ordering stock?*
 - 19 *Why should physical stock checks be carried out by two people?*
-

PROGRESS CHECK

Before moving on to Section 8, spend a few minutes thinking about whether you have achieved the learning objectives for Section 8. These were to:

- 1 Explain the importance of an efficient system of stock control.
- 2 Develop a simple stock card.
- 3 Order supplies in an efficient and cost-effective way.
- 4 Carry out a stock check.

If you feel confident that you have understood everything in this section, turn to Section 9.

If you feel that you need to spend more time on this section, go back to the parts that are most unfamiliar or that you find difficult. You may find it helpful to talk to other people, such as your supporter or other senior colleagues, if there is anything you are still not sure about.

8

Action Plan

This final section focuses on the Action List you have been building up as you have worked through this module. You have probably identified a number of improvements that you think could be made in your transfusion service or blood bank and it is now time to identify priorities and begin putting your ideas into action.

LEARNING OBJECTIVES

When you have completed this section, you should be able to:

- 1 Reassess your knowledge and skills in relation to the module objectives now that you have completed the Introductory Module.
 - 2 Review your Action List, identifying improvements that you can implement and those that will require action by others.
 - 3 Prepare and implement a realistic Action Plan to introduce changes that will improve the quality of the service provided by your transfusion service or blood bank.
-

8.1 REVIEWING YOUR PROGRESS

Before you start making your Action Plan, think carefully about the module objectives and the progress you have made since you started working through this module.

ACTIVITY 40

Complete the table below. You will notice that it is the same as the one you filled in for Activity 2. Use it to review the knowledge you have gained and the skills you have developed as a result of your work on this module. Have you changed your rating in relation to each module objective?

You should have made some identifiable progress in each area covered by this module. If there is anything you still do not feel confident about, however, reread the appropriate section and then discuss any remaining problems with your supporter or trainer before continuing with your Action Plan.

8.2 MAKING YOUR ACTION PLAN

The Action Plan provides you with an opportunity to make practical improvements in your own workplace, within any financial, resource or staffing constraints that exist. As you worked through this module, you

<i>Module objective</i>	<i>Rating (1–4)</i>	<i>Comments</i>
<p><i>Section 2</i> Demonstrate a professional approach to your work.</p> <p><i>Section 3</i> Identify specific hazards in your workplace and contribute to the design and implementation of safe working procedures.</p> <p><i>Section 4</i> Contribute to the maintenance of a quality system in your workplace.</p> <p><i>Section 5</i> Develop and maintain a system for the safe storage and transportation of blood and plasma.</p> <p><i>Section 6</i> Efficiently maintain blood storage equipment and deal with unexpected problems.</p> <p><i>Section 7</i> Prepare four basic solutions commonly used in blood transfusion practice.</p>		

have been noting down your ideas on the Action List. You should have listed the number of the activity in Column 1 and noted your ideas for improvement in Column 2. You should also have discussed your ideas with your supporter.

You may have tried out some of your ideas already, but some may require more time and effort and so it is important to identify priorities. You may not be in a position to put all your ideas into action yourself and it may be necessary to convince other members of staff to take the actions that you have identified as being both necessary and feasible.

ACTIVITY 41

Look carefully at all the suggestions for improvements that you have written down on your Action List. Mark those where you have not yet been able to take any action. Then divide them into two categories:

- 1 **Actions that you can take.** *Choose the ones that you think are most important and put them in order of priority. Note them down in Column 1 of the Action Plan on page 95. In Column 2, briefly summarize the action that you plan to take. In Column 3, note down the results that you would expect after taking this action.*
- 2 **Actions that others could take.** *Note them down in Column 1 of the Action Plan. In Column 2, write down the name of the person who would be responsible for making the changes that you are recommending. In Column 3, summarize the results that you would expect.*

Then show your plan to your supervisor and supporter and discuss it with them. Your ideas for improvement may need to be modified as a result of these discussions. Other senior staff may also need to be consulted before your Action Plan can be agreed. You should also discuss it with your trainer at this stage.

When you have reached agreement about the actions you are going to take, set a date when you hope to complete them and note this in Column 4. Also use Column 4 to set a date by which you expect the completion of any actions that others have agreed to take.

Your Action Plan is now ready.

8.3 IMPLEMENTING YOUR ACTION PLAN

You should now begin to implement your Action Plan along the lines agreed with your supervisor and supporter. It will probably take you several weeks or months to put your all plans into action and you may need more time than you expected. In fact, you will probably start the next module in the programme before you are able to complete everything. You may also find that some of your ideas for improvement are more

ACTION LIST

<i>Activity number</i>	<i>Ideas for improvement</i>

ACTION PLAN

<i>Ideas for improvement</i>	<i>Planned action</i>	<i>Expected results</i>	<i>Planned completion date</i>	<i>Actual completion date</i>	<i>Actual results</i>

difficult to put into action than you expected and you may need to revise some of your plans if they are too ambitious or are not working as well as you hoped. However, if you have thought carefully about how you could apply what you have learned from this module and have discussed your ideas with the appropriate people, you should be able to put most of them into practice. You may even find that there are some unexpected benefits. If you have any problems during this time, talk to your supporter or supervisor and ask them for any assistance you need. You should also give them regular reports on your progress.

ACTIVITY 42

Once you have completed each action you included in your Action Plan, note down the date in Column 5 and the final results in Column 6. Then review the implementation of your Action Plan by comparing the actual results with the results that you expected. Also compare the planned completion dates with the actual completion dates. Discuss the outcomes with your supporter and supervisor.

Identify any further actions required to ensure the implementation of the improvements you have identified as being necessary.

Over the next few months, monitor the effectiveness of any changes you have been able to introduce and be prepared to make further changes or take any follow-up action needed to ensure that they continue to lead to improved quality in your transfusion service or blood bank.

As you work through the remainder of the programme, you will be asked to complete an Action List and Action Plan for each module. This approach can be applied to almost any situation and you may decide to use it in other areas of your work to improve the quality of the service that you provide.

PROGRESS CHECK

Now that you have completed this module, spend some time thinking about whether you have achieved the learning objectives for this section. These were to:

- 1 Reassess your knowledge and skills in relation to the module objectives now that you have completed the Introductory Module.
 - 2 Review your Action List, identifying improvements that you can implement and those that will require action by others.
 - 3 Prepare and implement a realistic Action Plan to introduce changes that will improve the quality of the service provided by your transfusion service or blood bank.
-

Activity Checklists and Answers

SECTION 1

Activity 1

Purpose

To identify a personal “supporter” for your work on this learning programme.

Checklist

You should have:

- Identified senior colleagues in your workplace who could provide assistance to you as you work through the learning programme
- Selected one particular person, ideally your supervisor, to be your supporter for the Introductory Module and checked that they are willing to assist you
- Explained how the learning programme operates and what the role of the supporter involves
- Agreed how frequently you will meet to discuss your work on this module
- Showed the modules to your supporter
- Informed your trainer about who your supporter is
- Asked your trainer for assistance if you have any difficulty in finding a supporter in your workplace.

Activity 2

Purpose

To assess your knowledge, skills and experience before you start work on this module.

Checklist

You should have:

- Looked carefully at the module objectives and, for each one, assessed your current knowledge, skills and experience using the rating 1, 2, 3 or 4
- Noted your ratings on the table on page 13
- Added any further comments you wish to make, such as any module objectives that are not relevant to your own work at present.

Activity 3**Purpose**

To make a realistic Study Plan for your work on this module.

Checklist

You should have:

- Quickly looked at the other sections of the module to get an idea of its content, level and approach and assess how much of the material is likely to be new to you
- Estimated the amount of time you think you will need to study each section, including completing the activities and answering the self-assessment questions
- Discussed with your supervisor how much time could be allocated for study on a regular basis
- Completed the Study Plan on page 15, adding the dates when you plan to complete each section and the dates of meetings with your trainer and supporter.

SECTION 2**Activity 4****Purpose**

To identify any ways in which the maintenance of confidentiality could be improved in your donor clinic and laboratory.

Checklist

You should have:

- Reviewed your current procedure for maintaining confidentiality about donors, the recipients of blood, their family and friends
- Identified any ways in which you think that confidentiality could be improved and noted your recommendations on your Action List.

Activity 5**Purpose**

To review the standards of behaviour and dress in your donor clinic and laboratory.

Checklist

You should have:

- Listed the standards of behaviour and dress required in your workplace and commented on whether they are actually followed by staff
- Identified any ways in which the standards of dress and behaviour could be improved and noted down your recommendations on your Action List.

Activity 6**Purpose**

To find out information about the appropriate professional organization in your country.

Checklist

You should have:

- Identified any professional organization relevant to your own work and gathered information about its objectives and functions
- Noted any qualifications needed to become a member
- Obtained a copy of its code of professional conduct, if it has one, and discussed it with your colleagues.

Activity 7**Purpose**

To find out any regulations for technical recognition in your country.

Checklist

You should have:

- Noted whether you need official recognition as a technical person on completion of your training
- Found out how to obtain this recognition
- Found out whether you need it to work in certain laboratories or to gain a more senior position in the laboratory in which you currently work.

SECTION 3**Activity 8****Purpose**

To reduce the risk of needlestick injury.

Checklist

You should have:

- Reviewed the procedure in your donor clinic or laboratory for disposing of sharps after use
- Read local guidelines on safety and checked whether sharps are being disposed of in accordance with these guidelines
- Identified any ways in which the disposal of sharps could be improved and noted your recommendations on your Action List
- Read any policy available on needlestick injuries and noted the advice given to staff who suffer a needlestick injury
- Reviewed the procedure for monitoring staff after a needlestick injury
- Identified any ways in which the procedures for dealing with needlestick injuries could be improved, and noted your recommendations on your Action List.

Activity 9**Purpose**

To identify potential hazards in your laboratory.

Checklist

You should have:

- Listed all the potential hazards in your laboratory, dividing them into the following categories:
 - chemical, electrical and fire risks
 - the risk of infection
 - the risk of mechanical injury.

Activity 10**Purpose**

To review the safety guidelines used in your laboratory.

Checklist

You should have:

- Obtained copies of any national guidelines on laboratory safety in your country and compared them with any safety guidelines used in your laboratory
- Identified any additions or changes needed to the safety guidelines used in your laboratory in order to avoid the potential hazards you listed in Activity 9, and noted your recommendations on your Action List
- Checked that safety notices are displayed in your laboratory and that all members of staff have read and understood them.

Activity 11**Purpose**

To identify ways in which your laboratory could be made safer.

Checklist

You should have:

- Drawn a simple plan of your laboratory, marking the position of:
 - fixed items
 - moveable items
 - stored items
 - safety equipment
 - facilities for the disposal of waste
- Identified any changes you think should be made, taking safety guidelines into account, and noted down your recommendations on your Action List.

Activity 12**Purpose**

To identify any improvements required in the provision and use of protective clothing in your workplace.

Checklist

You should have:

- Noted whether protective clothing is provided for staff and whether they have sufficient sets
- Noted how often protective clothing is washed and commented on its condition
- Identified any ways in which the provision and use of protective clothing could be improved, and noted your recommendations on your Action List.

Activity 13**Purpose**

To improve the safety precautions taken for the return of blood from mobile donor sessions to your blood bank.

Checklist

You should have:

- Reviewed the safety precautions taken for the transportation of donated blood to your blood bank
- Identified any improvements needed in the procedures for transporting blood to your blood bank and noted your recommendations on your Action List.

Activity 14**Purpose**

To ensure the safety of the procedure used in your laboratory for the dispatch of pathological material.

Checklist

You should have:

- Compared the procedure for packing blood or serum samples or other pathological specimens in your laboratory with the procedure described on page 31
- Identified any improvements needed in the procedure for the dispatch of pathological material and noted your recommendations on your Action List.

Activity 15**Purpose**

To ensure the safe disposal of infectious waste in your laboratory.

Checklist

You should have:

- Reviewed the procedures used in your laboratory for disposing of infectious waste
- Identified any additional precautions you think should be taken
- Discussed your ideas with your colleagues and noted your recommendations on your Action List.

Activity 16**Purpose**

To review the disinfection procedures used in your workplace.

Checklist

You should have:

- Identified the disinfectants used in the donor clinic, by mobile teams and in the laboratory
- Noted how they are used
- Identified any improvements needed to the disinfection procedures used in your workplace and noted your recommendations on your Action List.

SECTION 4**Activity 17****Purpose**

To understand the meaning of “quality” in the context of blood transfusion practice.

Checklist

You should have:

- Looked up the definition of “quality” in a dictionary
- Written down your own definition, as applied to blood transfusion practice
- Asked your colleagues to define quality in the context of their own work and compared your answers.

Activity 18**Purpose**

To identify the key areas in blood transfusion practice, from the collection of a unit of blood to its issue for use, where failures in quality must be prevented in order to ensure the safety of the blood.

Answer

Your answer should have included the following points:

- 1 Self-exclusion or self-deferral of donors who are unsuitable, either because of a risk to their own health or to that of the recipient of their blood.
- 2 Correct recording of the donor’s identity.
- 3 Reliable blood donor screening procedures to identify unsuitable donors.
- 4 Correct venepuncture and collection of the donated blood.
- 5 Correct labelling of blood collection bags and sample tubes.
- 6 Correct packaging and transportation back to the blood bank.

- 7 Reliable screening of the donated blood in the blood bank.
- 8 Correct identification, removal and safe disposal of any unsuitable units of donated blood.
- 9 Correct storage of blood before issue and use.
- 10 Reliable matching of blood before issue and use.

Activity 19

Purpose

To review the use of standard operating procedures in your workplace.

Checklist

You should have:

- Looked at the examples of four SOPs given in the Appendix
- Compared any SOPs used in your workplace with the components listed on pages 42–43
- Assessed whether all staff follow SOPs appropriately and at all times as part of the quality system in your workplace
- Identified any improvements that you think could be made to your SOPs or the way they are used and noted your recommendations on your Action List
- Talked to your supervisor about introducing SOPs if they are not yet used in your workplace
- Noted your recommendations about introducing SOPs on your Action List.

Activity 20

Purpose

To review the use of formal documents, other than SOPs, in your workplace.

Checklist

You should have:

- Listed all the formal documents, apart from SOPs, used in your workplace
- Identified how these documents are controlled so that the correct version is in use
- Assessed whether the relevant staff use the documentation correctly
- Identified any improvements that could be made in the way documents are produced and distributed and noted your recommendations on your Action List
- Talked to your supervisor about introducing and controlling formal documents if they are not already used in your workplace
- Noted your recommendations on your Action List.

Activity 21**Purpose**

To review the record-keeping system in your workplace.

Checklist

You should have:

- Listed all the records kept in your workplace in the order in which they are used
- Identified any information which you obtain but do not record during the course of your work
- Identified any additional records that need to be kept and noted your recommendations on your Action List.

Activity 22**Purpose**

To review the procedures used in your workplace for the storage and disposal of records.

Checklist

You should have:

- Assessed the procedures used in your workplace for the storage and disposal of records
- Identified any improvements needed in these procedures and noted your recommendations on your Action List.

Activity 23**Purpose**

To review the monitoring procedures for the maintenance and calibration of donor clinic and laboratory equipment.

Checklist

You should have:

- Listed all the equipment in your workplace that needs to be maintained
- Noted down when the last service was performed on each item
- Noted whether there is a maintenance contract for each of these items
- Noted the items that require regular calibration
- Noted down the last time that each of these items was calibrated and the results of the calibration
- Identified any improvements needed in the procedures for monitoring equipment and noted your recommendations on your Action List.

SECTION 5**Activity 24****Purpose**

To assess whether platelet concentrates are being stored correctly in your blood bank.

Checklist

You should have:

- Noted whether there is a platelet rotator or agitator
- Recorded whether the temperature at which platelet concentrates are stored is maintained within the acceptable range throughout the day
- Assessed whether an air conditioning unit is needed
- Identified any improvements needed in the way platelet concentrates are stored and noted your recommendations on your Action List.

Activity 25**Purpose**

To assess whether blood is being stored correctly in your blood bank.

Checklist

You should have:

- Checked each refrigerator where blood is stored to assess whether it is being stored correctly, as shown in Figure 5 on page 63
- Identified any improvements needed in the way blood is stored, noted your recommendations on your Action List and discussed them with colleagues.

Activity 26**Purpose**

To monitor the temperature of refrigerators in your blood bank.

Checklist

You should have:

- Checked the temperature in different parts of each refrigerator at the same time each day for five days
- Recognized that, in the example, the temperature on the bottom shelf is too low
- Recognized that, if it is not possible to increase the temperature in any part of the refrigerator to the correct range, blood should not be stored on that shelf although reagents and samples can be stored there.

Activity 27**Purpose**

To monitor the number of times that refrigerator and freezer doors are opened in your blood bank.

Checklist

You should have:

- Attached a sheet of paper to the doors of all refrigerators and freezers in the blood bank, with instructions requesting staff to mark it each time they open the door
- Over the period of a week, recorded the number of times each door was opened each day.

Activity 28**Purpose**

To reduce the number of times that refrigerator and freezer doors are opened in your blood bank.

Checklist

You should have:

- Put a notice on the door of each refrigerator and freezer reminding staff not to open it unnecessarily
- After a few weeks, again asked staff to note each time they open the door of a refrigerator or freezer and checked whether there has been a reduction in the number of times each door has been opened
- Asked your colleagues why they open doors so frequently and discussed ways of reducing the number of times that refrigerator and freezer doors are opened
- Noted any recommendations on your Action List.

Activity 29**Purpose**

To ensure that your blood bank follows the correct procedures for the transportation of whole blood from the collection site back to the processing laboratory.

Checklist

You should have:

- Noted the type of container that is used to transport whole blood
- Checked whether the temperature of the whole blood remains within the correct range
- Checked whether the temperature of the whole blood is recorded upon arrival

- Noted the time taken to process the components and store them at the correct temperature
- Noted any action required on your Action List.

Activity 30**Purpose**

To ensure that blood and blood components are kept at the correct temperatures when being transported.

Checklist

You should have:

- Accompanied blood or blood components on their journey from or to your blood bank
- Measured and recorded the temperature before leaving and on arrival
- Checked whether the temperature of the blood or blood components remained within the correct range
- Noted any action required on your Action List.

Activity 31**Purpose**

To monitor the length of time it takes for units of blood to warm up after they are removed from the refrigerator in your blood bank.

Checklist

You should have:

- Measured how long it takes for “out-of-date” blood or red cells to reach the temperatures of +10°C, +15°C, +20°C and +25°C after removal from the refrigerator
- Noted that, in the example, the blood quickly reached a temperature outside the correct range and that it would be necessary to issue blood in a cold box or other insulated container to keep the temperature below +10°C.

SECTION 6**Activity 32****Purpose**

To ensure the availability of a supply of pure water for use in the preparation of basic solutions.

Checklist

You should have:

- Identified the source of the pure water used in your laboratory and what type it is
- Identified an alternative source if supplies are sometimes limited.

Activity 33**Purpose**

To ensure the correct preparation of basic solutions used in your laboratory.

Checklist

You should have:

- Found out whether it is possible and cost-effective to buy ready-prepared basic solutions
- Read the standard operating procedures in the Appendix and compared them with the procedures used in your laboratory
- Identified any improvements needed in the procedures for the preparation of basic solutions and noted your recommendations on your Action List.

SECTION 7**Activity 34****Purpose**

To identify the most commonly used consumable items in your work area.

Checklist

You should have:

- Listed the consumables that you used during the period of one day at work
- Noted any occasions when stocks ran out and the effects on your work
- Kept your list for use in Activities 36–38.

Activity 35**Purpose**

To review the stock card used in your blood bank or to contribute to the development of a stock card.

Checklist

You should have:

- Reviewed the stock control system in your blood bank
- Compared any stock card used in your blood bank with the example given in Figure 8 on page 85
- Identified any additional information you think should be added to the stock card you use and noted your recommendations on your Action List
- Suggested ways of adapting Figure 8 for use in your blood bank, if stock cards are not currently used, and noted your recommendations on your Action List
- Discussed your ideas with the person responsible for managing supplies of consumables.

Activity 36**Purpose**

To find out the expiry times for consumable items used in your laboratory.

Checklist

You should have:

- Used the information provided by manufacturers or suppliers to identify the normal period of time before expiry of the consumables that you listed in Activity 34
- Kept your list for use in Activity 37.

Activity 37**Purpose**

To identify the most appropriate ordering methods for various consumable items.

Checklist

You should have:

- Noted the most suitable method of ordering each consumable item on the list you made for Activities 34 and 36, taking into account their expiry dates.

Activity 38**Purpose**

To assess the efficiency of your stock control system.

Checklist

You should have:

- Selected five items from the list of consumables you made in Activity 34

- Checked the actual quantity/volume of each of these items in stock
- Compared this with the quantity/volume recorded on the stock cards, if you use them, and noted any differences
- Investigated these differences and reported them to the appropriate person
- Recorded the findings of your stock check for future use.

Activity 39

Purpose

To ensure that there is an efficient system of stock control in your laboratory.

Checklist

You should have:

- Looked back at your responses to Activities 34–38
- Identified any improvements needed to the system of stock control in your laboratory and noted your recommendations on your Action List
- Discussed your ideas for improvements with the person in charge of managing supplies.

SECTION 8

Activity 40

Purpose

To assess the progress you have made through your work on this module.

Checklist

You should have:

- Assessed your knowledge, skills and experience in relation to each of the module objectives now that you have reached the end of the module
- Completed the table on page 93
- Identified any areas where you still do not feel fully confident about your knowledge or skills
- Reread the appropriate sections of the module and discussed any remaining problems with your supporter or trainer before continuing with your Action Plan.

Activity 41

Purpose

To plan how to implement the improvements that you have identified as being necessary to ensure quality in your blood transfusion service or blood bank.

Checklist

You should have:

- Looked at all the suggestions for improvements that you have included on your Action List and marked those where you have not yet been able to take any action
- Divided them into two categories:
 - actions that you can take
 - actions that others could take
- Identified priorities for action
- Filled in your Action Plan, as follows:
 - Column 1: the improvements you have identified as being necessary
 - Column 2: the action you plan to take or the name of the person who would be responsible for taking action
 - Column 3: the results you would expect as a result of implementing your planned actions
- Discussed your plan with your supervisor, supporter, trainer and any other appropriate senior staff
- Modified your plan, where necessary
- Filled in Column 4 with the dates by which you hope each planned action will be completed.

Activity 42**Purpose**

To review the implementation of your Action Plan and identify any follow-up action required.

Checklist

You should have:

- Filled in Column 5 with the dates on which you completed each planned action and compared them with the planned completion dates
 - Summarized the results of your planned action in Column 6 and compared them with the results you had expected
 - Discussed the outcomes with your supporter
 - Discussed the outcomes with your supervisor
 - Identified any further actions required to ensure the implementation of the improvements you identified as being necessary
 - Monitored the effectiveness of the changes you have been able to introduce
 - Identified any further changes or follow-up action required.
-

Answers to Self-assessment Questions

SECTION 2

- 1 All nursing staff have a responsibility to ensure that:
 - donors are appropriately screened to make sure that they are suitable as blood donors and that donation would not harm either the donors themselves or the recipients of their blood
 - appropriate counselling and care are provided for donors before, during and after they donate blood
 - each donor is bled into an appropriate blood collection bag
 - blood bags and sample tubes are correctly labelled
 - accurate and complete records are maintained
 - work is performed to a high standard.
- 2 All technical staff have a responsibility to ensure that:
 - the results issued are accurate
 - the correct result is matched with the correct sample
 - accurate and complete records are maintained
 - work is performed to a high standard.

SECTION 3

- 3 Suitable laboratory clothing should always be worn correctly to protect the body from accidental spillages.
- 4 Blood and serum samples and other pathological specimens should be placed in three containers or packages when being transported:
 - samples should be placed in a strong, watertight container with a leak-proof screw lid; this should be

- clearly labelled and wrapped in sufficient absorbent material to soak up the sample in case of spillage
- this should then be placed in a second watertight container or leak-proof plastic bag, which has the accompanying documentation attached to the outside
 - this should be placed in an outer package that is capable of protecting the contents from physical damage during transit and which is labelled to indicate that it contains pathological material.
- 5 Infected waste should be placed in appropriate secure containers and autoclaved under minimum conditions of 121°C for 30 minutes. The waste should then be disposed of by incineration or by other approved means if incineration is not possible.
- 6 It is important to take particular care when using any disinfectants containing chlorine because, in the presence of some chemicals, it is very easy to liberate poisonous chlorine gas from some chlorine-containing solutions.

SECTION 4

- 7 Any failure in the quality of the system for the collection, transportation, testing, storage and issue of donated blood can have serious consequences for the patient receiving the blood, and may even be fatal.
- 8 Standard operating procedures should be reviewed regularly and updated, where necessary, in case there have been any direct or indirect changes in the procedure.
- 9 Audits are valuable because they provide a means of assessing both the implementation and the effectiveness of the quality system.

SECTION 5

- 10 There must be a higher limit to the correct temperature range for the storage of blood to prevent dextrose from being used too quickly and to slow down the growth of any bacteria which might be present.
- 11 There must be a lower limit to the correct temperature range for the storage of blood to prevent red cells from freezing because it is extremely dangerous to transfuse haemolysed red cells.
- 12 Fresh frozen plasma must be stored frozen at -20°C or lower to preserve the clotting factors, particularly Factor VIII and Factor V.
- 13 Blood should not be stored in the door of a refrigerator because the temperature is higher in the door than inside the refrigerator.

- 14 Blood should never be heated to more than +37°C because this causes haemolysis of the red cells, which can be fatal if transfused.

SECTION 6

- 15 The specific gravity of the copper sulfate solution used for male donors is higher than that used for female donors.
- 16 It is important to use disinfectant solutions within their expiry date because some solutions, such as sodium hypochlorite, lose their activity very quickly.

SECTION 7

- 17 Recording the minimum stock level reminds you to reorder when that level is reached so that the stock of a particular item never runs out.
- 18 The three basic methods of ordering stock are:
- bulk orders
 - standing orders
 - orders as required.
- 19 Two people should carry out the stock check together so that they can verify the quantity or volume of each item that is in stock.
-

Appendices

Examples of Standard Operating Procedures

A Preparation of 70% alcohol donor arm cleansing solution

STANDARD OPERATING PROCEDURE SOP/BTS/LAB/009/01		
Preparation of copper sulfate solutions		
This SOP replaces	Quality Manager	Date effective
New		Copy no
1 PURPOSE	To define the procedure for the preparation of copper sulfate solutions for use in assessing the suitability of donors.	
2 RESPONSIBILITIES	<p>All BTS Reagents Laboratory staff All trained and authorized BTS Reagents Laboratory staff can use this SOP.</p> <p>Head of Reagents Laboratory Head of the Reagents Laboratory must resolve any:</p> <ul style="list-style-type: none"> ■ Problems with the process ■ Difficulties using the SOP ■ Borderline interpretations. 	
3 RESTRICTIONS	This SOP must not be used by unauthorized Reagents Laboratory staff or by any non-Reagents Laboratory staff.	
4 DEFINITIONS	<p>Reagents Laboratory The BTS laboratory whose responsibility it is to prepare those reagents used by the BTS that are not purchased or supplied ready to use.</p>	
5 ITEMS REQUIRED	<p>Stock copper sulfate solutions Good quality deionised/distilled water Pre-printed self adhesive labels with the reagent, batch and expiry date Documentation:</p> <ul style="list-style-type: none"> ■ Copper sulfate preparation worksheet (FRM/BTS/RL/001) ■ Standard reagents preparation details (DAT/BTS/RL/003). 	
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STANDARD OPERATING PROCEDURE SOP/BTS/LAB/009/01**6 PROCEDURE**

- 6.1** Determine the volume of copper sulfate to be prepared and whether “male” or “female”.
- 6.2** Label the preparation vessel with the reagent, batch number and expiry date.
- 6.3** Carefully measure out the required volume of stock solution (see reagent preparation details DAT/BTS/RL/003).
- 6.4** Make up to the final volume with distilled/deionised water and mix well.
- 6.5** Check that the specific gravity of the solution is within the acceptable range (see reagent preparation details DAT/BTS/RL/003).
 - 6.5a** If it is not, recap the solution and mix again.
 - 6.5b** Recheck the specific gravity.
 - 6.5c** If the specific gravity is still not within the acceptable range, attach a “quarantine” label to the solution and inform a senior member of staff.
- 6.6** If the specific gravity is within the acceptable range, dispense into vials for use and complete the preparation record (FRM/BTS/RL/001).
 - 6.6a** Label sufficient vials with the reagent, batch number and expiry date.
 - 6.6b** Dispense 20 ml of solution into each vial and recap.
 - 6.6c** Check that all the vials have the correct volume of solution in them.
 - 6.6d** Complete the preparation record (FRM/BTS/RL/001) recording the number of vials prepared.
- 6.7** Quarantine the vials until the release checks/tests have been performed.

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B Preparation of 70% alcohol donor arm cleansing solution

STANDARD OPERATING PROCEDURE SOP/BTS/LAB/010/01

Preparation of 70% alcohol donor arm cleansing solution

This SOP replaces	Quality Manager	Date effective
New		Copy no

1 PURPOSE

To define the procedure for the preparation of the 70% alcohol solution used to cleanse donors' arms prior to venepuncture.

2 RESPONSIBILITIES

All BTS Reagents Laboratory staff

All trained and authorized BTS Reagents Laboratory staff can use this SOP.

Head of Reagents Laboratory

Head of the Reagents Laboratory must resolve any:

- Problems with the process
- Difficulties using the SOP
- Borderline interpretations.

3 RESTRICTIONS

This SOP must not be used by unauthorized Reagents Laboratory staff or by any non-Reagents Laboratory staff.

4 DEFINITIONS

Reagents Laboratory

The BTS laboratory whose responsibility it is to prepare those reagents used by the BTS that are not purchased or supplied ready to use.

5 ITEMS REQUIRED

Stock ethanol/industrial methylated spirit (ideally 96%, but from 90–99% can be used)

Good quality deionised/distilled water

Measuring cylinders

Pre-printed self-adhesive labels with the reagent, batch and expiry date

Documentation:

- Donor arm cleansing solution preparation record (FRM/BTS/RL/002)
- Reagent preparation details (DAT/BTS/RL/003).

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STANDARD OPERATING PROCEDURE SOP/BTS/LAB/010/01**6 PROCEDURE**

- 6.1** Determine the volume of cleansing solution to prepare.
- 6.2** Determine the dilution of the stock solution to give the volume required. Reagent preparation details (DAT/BTS/RL/003).
- 6.2a** Determine the stock concentration.
- 6.2b** Using the following formula, calculate the dilution factor:
- $$\frac{100}{\% \text{ concentration of stock}} \times 70 = \text{ml of stock per 100 ml working solution.}$$
- 6.3** Label the measuring cylinder to be used with the reagent, batch and expiry date.
- 6.4** Measure out the volume of stock solution in a measuring cylinder.
- 6.5** Make up to the final volume with distilled/deionised water and mix well.
- 6.6** Complete the preparation record (FRM/BTS/RL/002).
- 6.7** Dispense into vials for use.
- 6.7a** Label sufficient vials with the reagent, batch and expiry date.
- 6.7b** Dispense 20 ml of prepared solution into each vial and cap.
- 6.7c** Check that all the vials have the correct volume in them.
- 6.7d** Complete the preparation record (FRM/BTS/RL/002), indicating the number of vials prepared.
- 6.8** Quarantine the vials until the release checks/tests have been performed.

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C Preparation of normal 0.9% saline solutions

STANDARD OPERATING PROCEDURE SOP/BTS/LAB/011/01

Preparation of normal 0.9% saline solution

This SOP replaces

Quality Manager

Date effective

New

Copy no

1 PURPOSE

To define the procedure for the preparation of normal 0.9% saline solution.

2 RESPONSIBILITIES

All BTS Reagents Laboratory staff

All trained and authorized BTS Reagents Laboratory staff can use this SOP.

Head of Reagents Laboratory

Head of the Reagents Laboratory must resolve any:

- Problems with the process
- Difficulties using the SOP
- Borderline interpretations.

3 RESTRICTIONS

This SOP must not be used by unauthorized Reagents Laboratory staff or by any non-Reagents Laboratory staff.

4 DEFINITIONS

Reagents Laboratory

The BTS laboratory whose responsibility it is to prepare those reagents used by the BTS that are not purchased or supplied ready to use.

5 ITEMS REQUIRED

High-grade sodium chloride crystals

Good quality deionized/distilled water

Calibrated balance

Pre-printed self adhesive labels with the reagent, batch number and expiry date

Documentation:

- 0.9% saline preparation worksheet (FRM/BTS/RL/003)
- Use and maintenance of ABC electronic balance (SOP/BTS/RL/002/01)
- Reagent preparation details (DAT/BTS/RL/003).

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STANDARD OPERATING PROCEDURE SOP/BTS/LAB/011/01**6 PROCEDURE**

- 6.1** Determine the volume of 0.9% saline to be prepared.
- 6.2** Label the preparation vessel with the reagent, batch number and expiry date.
- 6.3** Carefully weigh out the required amount of sodium chloride crystals (see reagent preparation details DAT/BTS/RL/003).
- 6.4** Tip the sodium chloride crystals into the preparation vessel and add 80% of the total volume of water required.
 - 6.4a** Cap the vessel and mix well to ensure that the crystals have dissolved completely.
 - 6.4b** Add the remaining water to give the correct final volume.
 - 6.4c** Recap and mix well.
- 6.5** Complete the preparation record (FRM/BTS/RL/003) and dispense into vials for use.
 - 6.5a** Label sufficient vials with the reagent, batch number and expiry date.
 - 6.5b** Dispense 20 ml of solution into each vial and recap.
 - 6.5c** Check that all the vials have the correct volume of solution in them.
 - 6.5d** Complete the preparation record (FRM/BTS/RL/003) recording the number of vials prepared.
- 6.6** Quarantine the vials until the release checks/tests have been performed.

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D Preparation of hypochlorite solution

STANDARD OPERATING PROCEDURE SOP/BTS/LAB/012/01		
Preparation of hypochlorite solution		
This SOP replaces	Quality Manager	Date effective
New		Copy no
<p>1 PURPOSE</p> <p>To define the procedure for the preparation of sodium hypochlorite solution used for disinfection/ decontamination of hard surfaces.</p>		
<p>2 RESPONSIBILITIES</p> <p>All BTS Reagents Laboratory staff All trained and authorized BTS Reagents Laboratory staff can use this SOP.</p> <p>Head of Reagents Laboratory Head of the Reagents Laboratory must resolve any:</p> <ul style="list-style-type: none"> ■ Problems with the process ■ Difficulties using the SOP ■ Borderline interpretations. 		
<p>3 RESTRICTIONS</p> <p>This SOP must not be used by unauthorized Reagents Laboratory staff or by any non-Reagents Laboratory staff.</p>		
<p>4 DEFINITIONS</p> <p>Reagents Laboratory The BTS laboratory whose responsibility it is to prepare those reagents used by the BTS that are not purchased or supplied ready to use.</p>		
<p>5 ITEMS REQUIRED</p> <p>Stock copper sulfate solution Good quality deionized/distilled water Stock male and female dye solutions Calibrated balance Pre-printed self-adhesive labels with the reagent, batch and expiry date Documentation:</p> <ul style="list-style-type: none"> ■ Sodium hypochlorite solution preparation worksheet (FRM/BTS/RL/004) ■ Reagent preparation details (DAT/BTS/RL/003). 		
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STANDARD OPERATING PROCEDURE SOP/BTS/LAB/012/01**6 PROCEDURE**

- 6.1** Determine the volume of hypochlorite solution to be prepared.
- 6.2** Determine the free chlorine concentration of the stock solution and calculate the dilution required to give the required volume at the required final free chlorine concentration (see Reagent preparation details DAT/BTS/RL/003).
- 6.3** Label the preparation vessel with the reagent, batch number and expiry date.
- 6.4** Using a measuring cylinder, carefully measure out the required amount of stock solution required.
- 6.5** Make up to the final volume with distilled/deionised water.
- 6.6** Cap and mix well.
- 6.7** Complete the preparation record (FRM/BTS/RL/004) and dispense for use.
 - 6.7a** Label sufficient dispense bottles with the reagent, batch number and expiry date.
 - 6.7b** Dispense 200 ml of solution into each bottle.
 - 6.7c** Check that all the bottles have the correct volume of solution in them.
 - 6.7d** Complete the preparation record (FRM/BTS/RL/004), recording the number of bottles prepared.
- 6.8** Quarantine the bottles until the release checks/tests have been performed.

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