Quality Management

Training for

Blood

Transfusion

Services

Modules 9–12
PART 2: APPLYING QUALITY MANAGEMENT IN THE BTS

MODULE 9
Quality Management in the BTS

QMT 9.1: Presentation
Applying quality management in the BTS

QMT 9.2: Activity
Identifying critical control points and preparing flowcharts for BTS activities

QMT 9.3: Presentation
Steps in developing a quality system in the BTS

QMT 9.4: Presentation
Costing activities in a blood transfusion service

QMT 9.5: Presentation
Principles of stock control

QMT 9.6: Presentation
Quality aspects of contingency planning

QMT 9.7: Activity
Quality status analysis

QMT 9.8: Presentation
Preparing an action plan

QMT 9.9: Activity
Preparing a draft action plan

MODULE 10
Hygiene and Safety in the BTS

QMT 10.1: Presentation
Introduction to hygiene and safety in the BTS

QMT 10.2: Presentation
Hygiene in the BTS

QMT 10.3: Presentation
Biological and chemical safety in the BTS

QMT 10.4: Activity
Safety issues and minimizing risks
MODULE 11
Quality Systems in Blood Donor Management

QMT 11.1: Presentation
Introduction to quality systems in blood donor management

QMT 11.2: Presentation
Donor recruitment and selection

QMT 11.3: Activity
Donor recruitment and selection

QMT 11.4: Presentation
Blood collection

QMT 11.5: Activity
Blood collection

QMT 11.6: Presentation
Developing a documentation system for blood donor management

QMT 11.7: Presentation
Donor care, satisfaction and retention

QMT 11.8: Activity
Donor satisfaction

QMT 11.9: Activity
Identifying and monitoring critical control points in blood donor management

MODULE 12
Quality Systems in Laboratory Testing

QMT 12.1: Presentation
Introduction to quality systems in laboratory testing

QMT 12.2: Presentation
Evaluation and use of immuno-haematology reagents

QMT 12.3: Presentation
Evaluation and use of test kits for transfusion-transmissible infections

QMT 12.4: Activity
Selecting reagents and test kits

QMT 12.5: Presentation
Developing a documentation system for the laboratory

QMT 12.6: Presentation
External Quality Assessment (EQA) schemes

QMT 12.7: Activity
Identifying and monitoring critical control points in laboratory testing
PART 2

APPLYING QUALITY MANAGEMENT IN THE BTS

Modules 9–12
Module 9
Quality Management in the BTS
<table>
<thead>
<tr>
<th>QMT 9.1</th>
<th>Applying Quality Management in the BTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce how quality systems are applied to blood transfusion processes</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ WHO strategy for blood safety  
♦ Quality systems for blood safety  
♦ Introduction to Part 2 of the course |
| **Key points** | ♦ Modules 9–14 will demonstrate how to apply quality systems to the BTS  
  – Quality management in the BTS  
  – Hygiene and safety  
  – Donor management and blood collection  
  – Laboratory testing  
  – Blood component production and management  
  – The clinical interface |
| **Teaching focus** | ♦ Ensure the participants understand that Part 2 of the course will assist them in applying what they have learned to the various areas of the BTS  
♦ Emphasize that the modules are designed to guide participants in what to do, but not necessarily how to do it |
| **Learning outcomes** | Participants should be able to:  
♦ Explain the WHO strategy for blood safety  
♦ Define the key elements of the WHO Aide-Mémoire: Quality Systems for Blood Safety |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Quality Systems and the BTS  
5 WHO Strategy for Blood Safety  
6 Organization  
7 Blood Donors  
8 Testing and Processing of Blood  
9 Appropriate Clinical Use of Blood  
10 WHO Aide-Mémoire: Quality Systems for Blood Safety (1)  
11 WHO Aide-Mémoire: Quality Systems for Blood Safety (2)  
12 WHO Aide-Mémoire: Quality Systems for Blood Safety (3)  
13 WHO Aide-Mémoire: Quality Systems for Blood Safety (4)  
14 WHO Aide-Mémoire: Quality Systems for Blood Safety (5)  
15 Key Points  
16 Learning Outcomes |
| **Materials** | ♦ WHO Aide-Mémoire: Blood Safety  
♦ WHO Aide-Mémoire: Quality Systems for Blood Safety |
<p>| <strong>Related activity</strong> | QMT 9.2 Identifying Critical Control Points and Preparing Flowcharts for BTS Activities |</p>
<table>
<thead>
<tr>
<th>Time span</th>
<th>½ hour</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Presentation notes and handling the session</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Slide 4</strong></td>
<td></td>
</tr>
<tr>
<td>Quality Systems and the BTS</td>
<td>The slide compares the need in the food industry to ensure safe products and the need to satisfy customers of the BTS, where similar issues are of concern</td>
</tr>
<tr>
<td><strong>Slides 5 – 9</strong></td>
<td></td>
</tr>
<tr>
<td>WHO Strategy for Blood Safety: Organization, Blood Donors Testing and Processing of Blood, Appropriate Clinical Use of Blood</td>
<td>Slide 5 and the following four slides are a reminder of the information presented in QMT 1.1 Discuss each element of the integrated strategy for blood safety and relate them to the knowledge participants have gained during Part 1 of the course Emphasize that a quality management system does not supersede the BTS system, but is a documented and controlled layer that ensures that every element in the BTS system functions well and assists in continuous improvement</td>
</tr>
<tr>
<td><strong>Slides 10 – 15</strong></td>
<td></td>
</tr>
<tr>
<td>WHO Aide-Mémoire: Quality Systems for Blood Safety (1) – (5)</td>
<td>The first slide again shows the WHO Aide-Mémoire: Quality Systems for Blood Safety Discuss with the participants how they can use the checklist in the Aide-Mémoire to guide them during the planning and implementation of a quality system and afterwards to ensure all elements remain in place</td>
</tr>
</tbody>
</table>
Applying Quality Management in the BTS

WHO/QMT 9.1

Teaching Aim

- To introduce how quality systems are applied to blood transfusion processes

Core Topics

- WHO strategy for blood safety
- Quality systems for blood safety
- Introduction to Part 2 of the course
Quality Systems and the BTS

- Much of total quality management began in the food industry where the "safety" and "satisfaction" of customers is essential.
- The BTS has similar basic concerns:
  - Is blood safe?
  - Are the "users" of blood satisfied?
  - Are blood donors safe and satisfied?

WHO Strategy for Blood Safety

- WHO Aide-Mémoire: Blood Safety
- Four main areas:
  - Organization (nationally coordinated), with quality systems in all areas
  - Blood donors
  - Testing and processing of blood
  - Appropriate clinical use of blood

Organization

National coordination is essential to ensure:
- Management commitment and support at all levels
- National blood policy and plan
- Organizational structure (organigram)
- Job descriptions
- Well-defined responsibilities
- Quality system
Blood Donors

- Regular, voluntary non-remunerated blood donors recruited from low-risk populations
- Quality system for blood donor recruitment, donor selection and blood collection:
  - Documentation
  - Training
  - Principles of good manufacturing practice
  - Customer satisfaction
  - Checks on the "raw material": i.e. donor selection based on predefined criteria

Testing and Processing of Blood

- Testing of all donated blood for transfusion-transmissible infections and blood groups
  - Documentation
  - SOPs
  - Maintenance and calibration of equipment
  - Validation
  - Monitoring and evaluation
- Processing and storage of blood
  - Principles of good manufacturing practice

Appropriate Clinical Use of Blood

- Reduction in unnecessary transfusions
- Safe blood transfusions
  - Patient, clinician and hospital as customers
  - Customer satisfaction
  - Customer complaints
  - Documentation
  - Training
Developing a quality system
- Management commitment and support
- National quality plan/policy
- National quality manager

Organizational management
- Quality manager and quality section in blood centres and hospital blood banks
- Commitment and support of all staff
- Culture of quality

Quality standards
- Regulatory or legislative framework
- Appropriate national or international quality standards (e.g. ISO, GMP)

Documentation
- Standard operating procedures (SOPs)
- Comprehensive records
- Traceability
- Document control
WHO Aide-Mémoire: Quality Systems for Blood Safety (4)

- Training
  - National training policy and plan
  - Training of all BTS staff and other health care professionals involved in blood transfusion
  - Evaluation of the effectiveness of training

WHO Aide-Mémoire: Quality Systems for Blood Safety (5)

- Assessment
  - Identification of processes and procedures
  - Validation
  - Identification of indicators for monitoring
  - Ongoing data collection and analysis
  - Regular review of activities, including audits
  - Corrective and preventive action
  - External quality assessment

Key Points

- Modules 9-14 will demonstrate how to apply quality systems to the BTS
  - Quality management in the BTS
  - Hygiene and safety
  - Donor management and blood collection
  - Laboratory testing
  - Blood component production and management
  - The clinical interface
Learning Outcomes

You should now be able to:
- Explain the WHO strategy for blood safety
- Define the key elements of the WHO Aide-Mémoire: Quality Systems for Blood Safety
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 9.2</th>
<th><strong>Identifying Critical Control Points and Preparing Flowcharts for BTS activities</strong></th>
</tr>
</thead>
</table>
| **Teaching aim** | ♦ To analyse some activities within the transfusion process and identify critical control points  
♦ To draw a flowchart of the selected activities |
| **Core topics** | ♦ Analysing processes and procedures in the transfusion process  
♦ Identifying critical control points in BTS activities  
♦ Using flowcharts to analyse BTS processes and procedures |
| **Key points** | ♦ An understanding of processes and procedures is vital to ensure quality  
♦ Critical control points can be identified for all BTS activities  
♦ Flowcharts assist in analysing activities |
| **Teaching focus** | ♦ Use common BTS processes  
♦ Focus only on the critical control points  
♦ Ensure that all the critical control points have been identified  
♦ Focus on problems arising from the incorrect identification of critical control points |
| **Learning outcomes** | Participants should be able to:  
♦ Review processes in BTS activities  
♦ Identify critical control points  
♦ Produce accurate and consistent flowcharts of BTS processes and procedures |
| **Type of activity** | Group work |
| **Materials** | ♦ Instructions on processes and flowcharting (QMT 3.2 and QMT 3.3)  
♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 Allocate one of the activities below to each group:  
♦ Donor selection  
♦ Blood donation  
♦ Testing of donated blood  
♦ Processing of blood.  
2 Instruct the participants to:  
♦ Prepare a flow chart of the process  
♦ Identify the critical control points in the process  
♦ Justify the critical control points identified  
♦ Suggest indicators for measuring the degree of control of the process at the critical control points |
| **Review of the activity** | ♦ Ensure that the flowcharts are understandable  
♦ Ensure the critical control points are justifiable  
♦ Encourage open discussion on the critical control points and the indicators suggested |
<p>| <strong>Time span</strong> | 1½ hours |</p>
<table>
<thead>
<tr>
<th>QMT 9.3</th>
<th>Steps in Developing a Quality System in the BTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To highlight the steps in developing and implementing a quality system</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Commitment and support  
♦ Quality working group  
♦ Quality policy:  
  – National  
  – Local  
♦ Standards  
♦ Documentation  
♦ Activity plan  
♦ Training  
♦ Assessment |
| **Key points** | ♦ Commitment from all concerned is essential for success  
♦ Finalize a quality policy  
♦ Develop a quality plan ensuring:  
  – All processes and their appropriate quality needs are identified  
  – Monitoring and evaluation are built into the plan  
♦ The plan must be documented, followed and monitored |
| **Teaching focus** | ♦ Focus on achievable steps in developing and implementing a quality system in the BTS  
♦ Be sensitive to the varying situations of the participants |
| **Learning outcomes** | Participants should be able to:  
♦ List the steps in developing and implementing a quality system in the BTS |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Planning for Success  
5 Steps to be Taken (1)  
6 Steps to be Taken (2)  
7 Commitment and Support (1)  
8 Commitment and Support (2)  
9 Quality Working Group (1)  
10 Quality Working Group (2)  
11 Quality Policy  
12 Standards (1)  
13 Standards (2)  
14 Documentation  
15 Quality Plan  
16 Practical Aspects |
| Slide 4  | Planning for Success | ♦ The slide states the most important aspect of implementing a quality system |
| Slides 5 - 6 | Steps to be Taken (1) & (2) | ♦ These slides list the major steps that should be taken  
♦ Each point is dealt with in detail on the slides that follow |
| Slides 7 - 8 | Commitment and Support (1) & (2) | ♦ The two slides list the important activities that must be undertaken to ensure commitment from senior management  
♦ Discuss the problems that some participants may have with regard to access to senior management  
♦ Involve participants by asking them to suggest some solutions to the problems  
♦ Be sensitive to some of the issues that will be raised and try to identify workable solutions that can still result in an improved BTS, even at an institutional level |
| Slides 9 - 10 | Quality Working Group | ♦ The slide lists the people who should be included in the design and implementation of a quality system  
♦ Discuss how each point can be applied to the participants’ individual situations  
♦ Recognize that forming a quality group in a small institution may be difficult for some participants  
♦ Encourage participants to recognize the need to involve at least one other person, explaining that they cannot expect to do everything themselves |
| Slide 11 | Quality Policy | ♦ The slide states some simple steps in formulating a quality policy  
♦ Remind participants to use the knowledge they gained from the presentations in Part 1  
♦ Discuss how participants should proceed if senior management are not fully committed to the establishment of a quality system |
| Slides 12 – 13 Standards (1) & (2) | - The slide lists the basic steps in establishing standards for the BTS  
- Discuss how the quality system will depend on the standards used and how to use the various examples of standards that were distributed earlier to formulate standards for the BTS  
- Discuss how even simple standards can be effective  
- Emphasize the need to review standards on a regular basis |
| Slide 14 Documentation | - The slide lists steps in designing a documentation system  
- Emphasize the fact that documentation systems can be very difficult to handle if they are too complex  
- Remind participants of the dangers of too much documentation, as discussed in QMT 6.1 |
| Slide 15 Quality Plan | - The slide lists the elements of a quality plan  
- Emphasize that a quality plan is no different from other planning mechanisms, but will focus on quality issues only  
- Stress the need for the quality plan to reflect other BTS policies/regulations that may be in place |
| Slide 16 Practical Aspects | - This slide lists some practical steps in developing and implementing a quality system  
- Remind participants that implementation will not be a rapid process and that constant adjustment and review will be required |
| Slides 17 – 19 Elements of the Quality Plan (1), (2) & (3) | - The two slides outline the process of creating the quality plan and associated activities  
- Discuss how the key elements are identified by flowcharting processes/procedures in the BTS and identifying critical control points |
| Slide 20 Action Planning | - The slide lists the headings that should be included in the action plan  
- Remind participants how the action plan should be monitored and revised to ensure continuous improvement |
| Slide 21 Example of an Activity Plan | - The slide gives an example of an activity plan for the quality plan  
- Involve participants by asking them to suggest some other actions that could be included and what the other columns in the table (Responsible, Deadline, etc.) might contain |
| Slide 22 Training | - The slide reminds participants that, no matter how secure and achievable the plan is, training needs must be identified and met |
| Slides 23 – 25 Monitoring and Evaluation (1), (2) & (3) | - The two slides discuss how to monitor the implementation of the quality plan and its related activities to ensure that it results in improvements in the quality of outcomes  
- Remind participants of the knowledge they gained from Module 8: Assessment |
Steps in Developing a Quality System in the BTS

Teaching Aim

To highlight the steps in developing and implementing a quality system in the BTS

Core Topics

- Commitment and support
- Quality working group
- Quality policy
  - National
  - Local
- Standards
- Documentation
- Activity plan
- Training
- Assessment
Planning for Success

Build quality in at the beginning, not as an afterthought
Be realistic

Steps to Be Taken (1)

- Obtain commitment and support from senior BTS management
- Establish a quality working group
- Write a quality policy
- Write standards for each major element of a quality system and for BTS activities

Steps to Be Taken (2)

- Design a documentation system
- Create a plan with activities
- Ensure training needs are met
- Assess
Commitment and Support (1)

- Hold meetings and presentations for senior management in the BTS to explain:
  - The need for quality in the BTS: e.g. safe blood, accurate results, traceability
  - Value and benefits of quality in the BTS: e.g. reduced costs, fewer test failures, retained blood donors, improved public confidence
  - Need for a designated staff member to manage the quality system

Commitment and Support (2)

- Presentations/reports to national/local health authorities
  - Usually the task of senior management
- Obtain written commitment from all concerned before drafting the quality policy
- Obtain support and commitment from all staff
  - Commence quality awareness training

Quality Working Group (1)

- Quality coordinator/manager/officer designated by senior management
- Representatives of key BTS departments: e.g.
  - Blood donor division
  - Blood processing and testing laboratories
  - Blood group serology laboratory
  - Distribution/dispatch division
Quality Working Group (2)

- May include representatives of users of blood and national regulatory authorities
- Identify each member’s role
- Plan to meet regularly

Quality Policy

- Prepare draft
- Submit for review and approval
- Finalize
- Obtain approval, endorsement and support
  - All senior management should sign

Standards (1)

- Establish the standards that will be used to guide the quality system
  - National regulatory standards should always be incorporated into any standards document
  - Others: e.g. ISO, GMP, etc.
Standards (2)

- Decide on the format for the standards: e.g.
  - Book or file
  - Numbering system
  - Main sections e.g. will you include standards for specific BTS activities?

- Appoint writers and set deadlines for first drafts

Documentation

- Decide on the various levels of documents that the BTS will have: e.g.
  - Quality manual/standards document
  - Quality procedures
  - Operational procedures/instructions
  - Labels, records, forms

- Decide on "names" for each level of documentation

- Devise a numbering system

Quality Plan

- Written document
- Statement of the operation(s) to be carried out
- Statement of how quality will be assured, identifying:
  - Quality system and procedures
  - Customer needs and expectations
  - Standards and specifications
  - Responsibility and authority for activities in the plan
  - Timescale for activities
  - System of review and audit
**Practical Aspects**

- Identify key elements: e.g.
  - SOPs
  - Critical equipment list/maintenance and calibration
  - Quality awareness training for all staff concerned
- Identify a person responsible for each element
  - May be several people as long as there is a "team" leader
- Discuss and agree on deadlines
- Hold regular "progress" meetings

**Elements of the Quality Plan (1)**

- Identify process, sub-processes and procedures
  - Create a main process flowchart
  - Make a priority list of the sub-processes: e.g. donor selection, TTI testing
  - Keep in mind the set standards and specifications for the sub-process and its product/s
  - Identify critical control points in the sub-process
  - Select indicators and frequency of monitoring

**Elements of the Quality Plan (2)**

For each sub-process identified

- Documentation needed: e.g. SOPs, forms, records, labels
  - Example: TTI testing
  - SOPs: receipt and recording of donor samples; HIV tests; daily quality control; equipment maintenance, recording and storage of results
- Training needs
### Elements of the Quality Plan (3)

- Quality control (critical control points and indicators)
- Equipment needs
- Reagent needs, if any
- Monitoring and evaluation

### Action Planning

Use at least the following categories

- **ACTION** — what needs to be done?
- **RESPONSIBLE** — who will do it?
- **DEADLINE** — by when should it be completed?
- **INPUTS** — what needs to be done before this activity can take place?
- **INDICATORS** — what will show that it has been done?

### Example of an Activity Plan

<table>
<thead>
<tr>
<th>Action</th>
<th>Responsible</th>
<th>Deadline</th>
<th>Inputs</th>
<th>Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create donor selection criteria</td>
<td>Clinic sister</td>
<td>May 2004</td>
<td>Standards Epidemiological data</td>
<td>First draft completed SOP written</td>
</tr>
<tr>
<td>Implement the quality system in HIV testing:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) SOP</td>
<td>Writer laboratory worker</td>
<td>Sept 2004</td>
<td>Standards Train writer on SOP generation</td>
<td>SOP in place Staff trained and certified as competent</td>
</tr>
<tr>
<td>b) Equipment maintenance protocol</td>
<td>Senior technician</td>
<td></td>
<td>Train senior technician on SPC</td>
<td>Regular maintenance done and recorded</td>
</tr>
<tr>
<td>c) Daily quality control</td>
<td>Senior technician</td>
<td></td>
<td>Equipment supplier to assist with maintenance protocols</td>
<td>SPC charts in place and reviewed</td>
</tr>
</tbody>
</table>
Training

- As the plan is developed, identify staff training needs and establish a plan for meeting them
- Consider:
  - Quality awareness training, including how to write SOPs
  - Job-specific training: e.g. competency training using SOPs
  - Skills-based training
  - Training the trainers

Monitoring and Evaluation (1)

- For each sub-process, identify the points that should be monitored
- Gather data and analyse
- Evaluate the impact of the activities on the quality outcome of the sub-process

Monitoring and Evaluation (2)

- Adjust where necessary: e.g. donor selection criteria introduced
  - Monitor prevalence of TTIs in blood donors and evaluate the impact
  - Is there a positive impact on the number of TTIs found in donated blood?
Monitoring and Evaluation (3)

- Monitor progress of each activity
- Assess individual members of the quality working group and their output
- Ensure the agreed quality procedure is applied to each activity: e.g. SOP writing
- Ensure the activities and outputs comply with the written standards

Key Points

- Commitment from all concerned is essential for success
- Finalize a quality policy
- Develop a quality plan ensuring:
  - All processes and their appropriate quality needs are identified
  - Monitoring and evaluation are built into the plan
- The plan must be documented, followed and monitored

Learning Outcomes

You should now be able to:

- List the steps in developing and implementing a quality system in the BTS
<table>
<thead>
<tr>
<th>QMT 9.4</th>
<th><strong>Costing Activities in a Blood Transfusion Service</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To highlight the importance of costing all BTS activities</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Definition of costing  
♦ Benefits of costing  
♦ WHO Manual ‘Costing Blood Transfusion Services’  
♦ Basic cost analysis of BTS activities |
| **Key points** | ♦ The quality manager needs to understand the principles of costing  
♦ Accurate costing of BTS activities enables accurate budget planning and resource mobilization  
♦ Sustainability of the BTS is not achievable without costing procedures  
♦ Costing BTS activities contributes to quality monitoring |
| **Teaching focus** | ♦ Focus on simplicity  
♦ Concentrate on basic principles and practice rather than trying to identify specific costs  
♦ Give a range of examples where the actual cost is higher than expected due to poor quality |
| **Learning outcomes** | Participants should be able to:  
♦ Explain the value of comprehensive costing of all BTS activities  
♦ Define key factors that need to be taken into account in costing the activities of a BTS |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Definition of Costing  
5 Benefits of Costing  
6 WHO Manual: Costing Blood Transfusion Services  
7 Allocation of Costs by Activity  
8 Costing  
9 Example of Classification  
10 Personnel Costs  
11 Capital Costs  
12 Recurrent Costs  
13 Methodology  
14 Calculation of Total Costs  
15 Other Factors Affecting BTS Costs  
16 Key Points  
17 Learning Outcomes |
<p>| <strong>Materials</strong> | WHO manual: <em>Costing Blood Transfusion Services</em> |</p>
<table>
<thead>
<tr>
<th>Related activity</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
</tbody>
</table>

**Presentation notes and handling the session**

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Definition of Costing</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide gives a definition of costing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Benefits of Costing</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide lists the benefits of costing</td>
</tr>
<tr>
<td>♦</td>
<td>Discuss each point with the participants, giving examples of each</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>WHO Manual: Costing Blood Transfusion Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>This slide shows the cover page of the manual and introduces the following slides that outline the various steps in the manual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Allocation of Costs by Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide shows how BTS activities are divided into four main categories for the purposes of costing</td>
</tr>
<tr>
<td>♦</td>
<td>Outline the various elements of the four main categories</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Costing</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide describes how each category has three main areas of cost: i.e. personnel, capital costs and recurrent costs</td>
</tr>
<tr>
<td>♦</td>
<td>Each is detailed further on the following slides</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Example of Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>This slide shows an example of part of one of the classification sheets</td>
</tr>
<tr>
<td>♦</td>
<td>Use this example to outline how each section is broken down further into individual costs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Personnel Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide lists the main categories of personnel that can be included in the costing; other categories can be added</td>
</tr>
<tr>
<td>♦</td>
<td>Emphasize the need to include volunteer workers in the costing and why this is necessary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 11</th>
<th>Capital Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide gives a definition of capital costs and some examples</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Recurrent Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide gives a definition of recurrent costs and some examples</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>This slide states the two types of worksheet provided in the manual</td>
</tr>
<tr>
<td>♦</td>
<td>If available and of help, show the participants some examples from the electronic version of the spreadsheet</td>
</tr>
<tr>
<td>♦</td>
<td>Explain how the electronic version simplifies all calculations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Calculation of Total Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide explains how total costs are calculated and how this leads to the calculation of the cost of a usable unit of blood</td>
</tr>
<tr>
<td>♦</td>
<td>Explain why the unit cost is based on number of units distributed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 15</th>
<th>Other Factors Affecting BTS Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide lists some of the data that have to be collected in order to calculate the total costs of the BTS</td>
</tr>
</tbody>
</table>
Costing Activities in a Blood Transfusion Service

WHO/QMT 9.4

Teaching Aim

- To highlight the importance of costing all BTS activities

Core Topics

- Definition of costing
- Benefits of costing
- WHO manual "Costing Blood Transfusion Services"
- Basic cost analysis of BTS activities
Definition of Costing

- Estimating the value of resources used to produce a desired product or service

Benefits of Costing

- Provides accurate costs for budget planning
- Enables realistic planning for sustainability, improvement and expansion
- Enables evaluation of productivity and cost-effectiveness
- Improves resource mobilization
- Assists in establishing a clear identity for the financial and administrative structure of the BTS

WHO Manual: Costing Blood Transfusion Services

A WHO manual to assist BTSs in:
- Planning
- Mobilizing resources

Ultimate goal - an adequate, sustainable supply of safe blood
Allocation of Costs by Activity

Costing

- Classify costs of personnel, capital and recurrent needs
- Sub-divide the costs into distinct activities
  - Recruitment
  - Collection
  - Processing
  - Storage and distribution

Example of Classification
**Personnel Costs**

- Medical director
- Administrative and general staff
- Donor recruitment staff
- Clinic staff
- Laboratory staff
- Quality staff
- Others: e.g. volunteers

**Capital Costs**

One-time investment costs generally incurred during Year 1 of operation or during expansion: e.g.

- Purchase, construction or renovation of BTS building
- Purchase of vehicles
- Purchase and installation of equipment
- Purchase of furniture
- Other fixed assets

**Recurrent Costs**

Operational costs that are incurred in the course of one year, usually on a regular basis: e.g.

- Personnel costs
- Vehicle running costs
- Utilities: e.g. electricity, water, telephone
- Office, clinic, laboratory and other supplies
- Equipment maintenance, repair and spare parts
- Training
Methodology

Calculate total BTS costs using:
- Computerized worksheets (Excel spreadsheet)
or
- Manual worksheets

Calculation of Total Costs

Costs can be calculated for:
- An activity: e.g. recruitment, collection, processing:
  Capital + recurrent costs = Total cost per activity
- Sum of all "costs per activity" = Total BTS costs
- A useable unit of blood
  Total BTS costs/Number of units distributed

Other Factors Affecting BTS Costs

Other factors that affect total BTS costs: e.g.
- Number of donors screened
- Number of donors accepted
- Number of donors bled
- Number of useful units collected
- Number of units processed, by product
- Number of discards, by product
- Number of units distributed by product
### Key Points

- The quality manager needs to understand the principles of costing
- Accurate costing of BTS activities enables accurate budget planning and resource mobilization
- Sustainability of the BTS is not achievable without costing procedures
- Costing BTS activities contributes to quality monitoring

### Learning Outcomes

You should now be able to:

- Explain the value of comprehensive costing of all BTS activities
- Define key factors that need to be taken into account in costing the activities of a BTS
# QMT 9.5 Principles of Stock Control

## Teaching aim
To highlight the importance of stock control and correct storage conditions

## Core topics
- Stock control and ordering
- Perishable and non-perishable materials
- Delivery checks
- Quarantine of materials
- Inspection of incoming materials
- Correct storage of perishable materials
- Monitoring correct storage conditions
- Documentation

## Key points
- All BTSs need a good stock management system
- Sufficient stocks of critical items must be maintained at all times
- All incoming materials must be appropriately checked before use
- Quarantine and release procedures must be in place for certain items
- Monitoring of usage can help ensure adequate stock levels are maintained

## Teaching focus
- Highlight the problems of stock control when delivery times cannot be guaranteed
- Stress the importance of correct storage conditions
- Emphasize the need for contingency plans for refrigerator/freezer failure
- Reinforce the importance of documenting the monitoring of storage conditions

## Learning outcomes
Participants should be able to:
- Describe methods of monitoring the stock control system
- Identify the factors that can influence storage conditions
- Explain the principles of quarantine/release procedures
- List essential documentation and records for stock control

## Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Stock Control (1)
5. Stock Control (2)
6. Stock Control (3)
7. Stock Control (4)
8. Stock Records
9. Ordering Supplies (1)
10. Ordering Supplies (2)
11. Delivery Checks
12. Quarantine of Materials (1)
<table>
<thead>
<tr>
<th>Materials</th>
<th>Examples of stock records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related activity</td>
<td>None</td>
</tr>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
</tbody>
</table>

**Presentation notes and handling the session**

**Slides 4 - 7**  
Stock Control (1), (2), (3) & (4)  
- The following four slides list the basic elements and reasons for stock control  
- Discuss each point with the participants  
- Be sensitive to the fact that some participants may have no control over stock management

**Slide 8**  
Stock Records  
- The slide lists the reasons for maintaining stock records

**Slides 9 - 10**  
Ordering Supplies (1) & (2)  
- The first slide raises the question of who has overall responsibility for ordering supplies  
- Discuss potential problems related to each ordering system and invite participants to suggest possible solutions  
- Introduce the WHO bulk procurement scheme for HIV test kits

**Slide 11**  
Delivery Checks  
- Emphasize the need to check every item against the order that was placed  
- Discuss the need to communicate with the supplier with regard to specifications  
- The next two slides discuss quarantine in more detail

**Slides 12 - 13**  
Quarantine of Materials (1) & (2)  
- These two slides list essential activities to ensure the effective quarantine of materials

**Slide 14**  
Inspection of Incoming Materials  
- The slide lists important points regarding the inspection of incoming materials  
- Remind participants of the control of a process where inputs are also controlled  
- Emphasize the need to identify critical items
<table>
<thead>
<tr>
<th>Slides 15 – 16</th>
<th>Perishable/Non-Perishable Materials (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides indicate the need for different procedures for the storage of perishable and non-perishable materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 17</th>
<th>Storage of Perishables</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists considerations regarding the storage of perishable materials</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to establish the correct storage conditions for all materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 18 – 19</th>
<th>Monitoring of Storage Conditions (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides list important indicators to monitor in order to ensure constant, correct storage conditions</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 20 – 22</th>
<th>Documentation (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The three slides list the documents and records that must be maintained to ensure a well-functioning system for stock management</td>
<td></td>
</tr>
</tbody>
</table>
Principles of Stock Control

Teaching Aim

- To highlight the importance of stock control and correct storage conditions

Core Topics

- Stock control and ordering
- Perishable and non-perishable materials
- Delivery checks
- Quarantine of materials
- Inspection of incoming materials
- Correct storage of perishable materials
- Monitoring correct storage conditions
- Documentation
Stock Control (1)

- Good stock control ensures that items are always available in the right quantity at the right time
- Critical stock items are all items that directly or indirectly affect the ability to collect, test, process and distribute blood and blood products
- Critical stock items must meet quality requirements

Stock Control (2)

- The use of poor quality items may result in a poor quality end product or service
- Designate an individual with responsibility and authority for:
  - Ordering stock from approved suppliers (with advice from users)
  - Inspecting incoming materials
  - Storing the stock at appropriate conditions
  - Monitoring stock levels (usage)
  - Re-ordering when necessary

Stock Control (3)

- Ensure sufficient quantities of stock by ordering in time
- Problems when delivery times cannot be guaranteed
- Reliable source of supply
- Plan ahead
- Ordering stock
Stock Control (4)

- Accurate records of deliveries, stock and usage
- Rotation of stock - perishable/non-perishable
- Contingency plans needed
  - Lack of stock
  - Loss of stock
  - Loss of appropriate storage conditions

Stock Records

- Monitor trends in usage
- Monitor delivery schedules and reliability of each supplier
- Identify items with little usage and help to rationalize items used and held in stock
- Ensure accountability for all items ordered
- Enable regular stock checks

Ordering Supplies (1)

- Who is responsible for ordering supplies?
  - External to BTS (e.g. central government)
  - BTS
    - Central purchasing department
    - Technical department
Ordering Supplies (2)

- Determine an appropriate stock level
  - User needs
  - Storage space
  - Cost
  - Specific ordering strategies: bulk, standing order, as required
    - WHO bulk procurement scheme: HIV test kits
  - Delivery time
  - Quarantine period

Delivery Checks

- All material should be checked on delivery
- The checks should ensure
  - Conformity with order
  - Quality specifications are met
- Follow quarantine/release procedure

Quarantine of Materials (1)

- Quarantine materials until incoming tests have been performed and the materials have passed
  - Depends on materials
  - Depends on type of checks performed
  - May involve quality department in performing checks and authorizing release
Quarantine of Materials (2)

- Physical labelling and segregation
  - Clear labels indicating that materials not yet checked
  - Locked storage areas
- Release of suitable materials to active stock
  - Clear labels indicating that materials have passed required checks

Inspection of Incoming Materials

- Inspection depends on the supplier
  - Regular supplier
  - Audited supplier
  - Goods of a nature that a supplier statement may be sufficient
- Inspection specifications needed for all items

Perishable/Non-Perishable Materials (1)

- Need to distinguish between materials that are perishable and those that are not
  - Perishables include reagents, blood bags
  - Non-perishables include plastics, collection tubes, equipment
Perishable/Non-Perishable Materials (2)

- Perishables have stricter storage conditions and expiry dates and require significant release testing
  - Controlled storage conditions
  - Stock rotation (first in first out “FIFO”)
  - Quarantine areas

Storage of Perishables

- Storage conditions
  - Correct temperature (and humidity)
  - Sufficient space
  - Security with appropriate accessibility
  - Protected from infestation
  - Protected from bacterial/fungal contamination

- Stock rotation
  - Expiry dates
  - Usage rates

Monitoring of Storage Conditions (1)

- Regular/continuous monitoring of storage conditions
  - Temperature
  - Signs of infestation
  - Signs of dampness

- Access to storage area
  - Staff allowed in the area
  - Unauthorized access
Monitoring of Storage Conditions (2)

- Quarantine integrity
  - Quarantine materials labelled and separated adequately
  - Formal release of materials from quarantine

Documentation (1)

- Records (manual or electronic)
  - Clear description of item
  - Supplier’s generic/trade name and product code
  - In-house product code
  - Expiry date
  - Delivery date and quantity
  - Unit quantity

Documentation (2)

- Records (manual or electronic)
  - Supplier’s name and contact person
  - Lead time for supply
  - Normal internal users of the item
  - Desirable stock figure
  - Re-order point and normal re-order quantity
**Documentation (3)**

- Documented procedures for stock control, including:
  - List of approved suppliers and their products
  - Ordering of goods
  - Receipt of goods
  - Quarantine and release procedures
  - Record keeping
  - Stock control
  - Stock checks
  - Training records

**Key Points (1)**

- All BTSs need a good stock management system
- Sufficient stocks of critical items must be maintained at all times
- All incoming materials must be appropriately checked before use

**Key Points (2)**

- Quarantine and release procedures must be in place for certain items
- Monitoring of usage can help ensure adequate stock levels are maintained
Learning Outcomes

You should now be able to:

- Describe methods of monitoring the stock control system
- Identify the factors that can influence storage conditions
- Explain the principles of quarantine/release procedures
- List essential documentation and records for stock control
### Teaching aim
To encourage the development of contingency plans to ensure an adequate supply of safe blood products at all times.

### Core topics
- Maintaining the safety and adequacy of the blood supply
- Plans and procedures
- Major disasters or incidents
- Responsibility: role of the quality manager
- Planning to minimize adverse outcomes
- Co-ordination with other agencies

### Key points
- Things do go wrong
- Disasters do happen
- The continuity of the blood supply is essential
- Contingency planning is essential
- Documented procedures need to be in place, available to all staff and reviewed at appropriate intervals
- Plans need to be incorporated into appropriate national and local contingency plans

### Teaching focus
Provide examples of different situations in which the safety and adequacy of the blood supply may be compromised.

### Learning outcomes
Participants will be able to:
- Identify situations that may threaten the safety and adequacy of the blood supply
- Develop a contingency plan for the BTS

### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Adequacy
5. Incidents and Disasters
6. Examples of Incidents (1)
7. Examples of Incidents (2)
8. Plan
9. Responsibility and Planning
10. Disaster Planning Team
11. Planning (1)
12. Planning (2)
13. Planning a Response (1)
14. Planning a Response (2)
15. Living with the Possibilities
16. Co-ordination with Other Agencies
17. Key Points (1)
18. Key Points (2)
19. Learning Outcomes
<table>
<thead>
<tr>
<th>Materials</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related activity</td>
<td>None</td>
</tr>
<tr>
<td>Time span</td>
<td>½ hour</td>
</tr>
</tbody>
</table>

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Adequacy</th>
<th>♦ The slide lists the reasons for contingency planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slide 5</td>
<td>Incidents and Disasters</td>
<td>♦ The slide defines an incident with regard to contingency planning in the BTS: i.e. any potential threat to the adequacy of the blood supply</td>
</tr>
<tr>
<td>Slides 6 - 7</td>
<td>Examples of Incidents (1) and (2)</td>
<td>♦ The two slides list some examples of incidents in the BTS ♦ Ask the participants to suggest some other examples of major incidents and equipment and supply failures ♦ Discuss possible solutions to the examples given ♦ Explain how part of contingency planning would be to document the discussions you are having</td>
</tr>
<tr>
<td>Slide 8</td>
<td>Plan</td>
<td>♦ The slide emphasizes the importance of planning</td>
</tr>
<tr>
<td>Slide 9</td>
<td>Responsibility and Planning</td>
<td>♦ Ensure that participants understand the role of the quality manager in contingency planning ♦ Emphasize the need to ensure that contingency planning takes account of any national and local disaster plans ♦ Give some examples of specific and generic plans</td>
</tr>
<tr>
<td>Slide 10</td>
<td>Disaster Planning Team</td>
<td>♦ The slide lists the various persons who should be in the disaster planning team</td>
</tr>
<tr>
<td>Slides 11 - 12</td>
<td>Planning (1) &amp; (2)</td>
<td>♦ The slides list the essential contents of a contingency plan</td>
</tr>
<tr>
<td>Slides 13 - 14</td>
<td>Planning a Response (1) &amp; (2)</td>
<td>♦ Slide 13 shows how to structure the possible solutions ♦ Discuss some examples of each level with the participants ♦ Slide 14 lists some possible actions that could be included in the planned response ♦ Discuss each point and the various incidents they relate to</td>
</tr>
<tr>
<td>Slide 15</td>
<td>Living with the Possibilities</td>
<td>♦ The slide emphasizes why contingency planning is important</td>
</tr>
<tr>
<td>Slide 16</td>
<td>Coordination with Other Agencies</td>
<td>♦ The slide emphasizes the need and reasons for coordination with other agencies</td>
</tr>
</tbody>
</table>
Quality Aspects of Contingency Planning

WHO/QMT 9.6

Teaching Aim

- To encourage the development of contingency plans to ensure an adequate supply of safe blood products at all times

Core Topics

- Maintaining the safety and adequacy of the blood supply
- Plans and procedures
- Major disasters or incidents
- Responsibility: role of the quality manager
- Planning to minimize adverse outcomes
- Coordination with other agencies
Adequacy

- Adequacy is an important quality element
- Adequate supplies of safe blood and blood products should be available to meet any situation
- Adequacy of the blood supply depends on many other elements: e.g.
  - Good planning
  - Adequate number of suitable blood donors
  - Availability of blood bags, reagents and test kits
  - Adequate number of trained staff

Incidents and Disasters

- Potential threats to adequacy of blood supply
- Major incidents and disasters
  - Man-made
  - Natural
- Localized incidents
  - Power failure
  - Equipment failure
  - Supply failure

Examples of Incidents (1)

- Loss of a donor session venue with no local alternative
- Session venue cannot be used when team arrives
- Temporary sudden loss of donors due to outbreaks of disease
- Sudden significant increased demand: e.g. major train crash involving many people
Examples of Incidents (2)

- Supply problems
  - No blood bags left in stock, nothing available in country for 1-2 weeks
  - Shortage of test kits or reagents due to delivery problems
- Breakdown of cold storage equipment
- Mobile team vehicle breaks down on way to session

Plan

Those who fail to plan, plan to fail

Responsibility and Planning

The quality manager is responsible for ensuring:
- Appropriate contingency plans at each local centre are prepared, available and reviewed
- Each local centre has a disaster planning team which is responsible for the development and management of the plans
  - Specific plans (clearly definable incidents)
  - Generic plans (to cover a wide range of similar issues)
Disaster Planning Team

- A team of senior staff from the different areas of the BTS
- Represent all the main BTS activities
- May be led by the quality manager
- Can look at all potential problems and how to respond to them
- Have the authority to put plans in place

Planning (1)

- Documented plans should be in place to deal with any incident that threatens the adequacy or safety of the blood supply
- Identify the possible incidents and resultant threats to product quality/patient safety

Planning (2)

Identify
- What needs to be done to prevent/minimize adverse outcomes
- How to do it
- Who is responsible for ensuring that it is done
- Who needs to be directly involved
- Who needs to know
Planning a Response (1)

- Define different levels of solutions
  - Resolvable internally/externally
  - Resolvable quickly/longer period
  - Resolvable by simple response/complex changes
  - No loss/minimal loss/acceptable loss/significant loss
- Plan what needs to be done until the situation is resolved

Planning a Response (2)

- Define different actions to minimize adverse outcomes
  - Obtain blood from another blood centre
  - Repair immediately
  - Borrow stock from another laboratory/hospital/BTS
  - Delay testing until stock arrives
  - Transfer workload to another site
- Plan how to handle the possibility of a sudden increase in donor numbers in response to a disaster

Living with the Possibilities

- An incident could happen at any time
- Policies and plans need to be in place
- These need to be available to all staff
- All staff need to know what to do and when
- Policies and plans need to be reviewed regularly
### Coordination with Other Agencies

- BTS disaster plans need to be included in appropriate national plans.
- Plans at the local blood centre should be included in plans of local emergency services.
- BTS needs to be actively involved in planning response to disasters/emergencies where
  - Blood or blood products may be needed
  - The public may THINK that blood may be needed

### Key Points (1)

- Things do go wrong
- Disasters do happen
- The continuity of a safe blood supply is essential
- Contingency planning is essential

### Key Points (2)

- Documented procedures need to be in place, available to all staff and reviewed at appropriate intervals.
- BTS plans need to be incorporated into appropriate national and local contingency plans.
# Learning Outcomes

You should now be able to:

- Identify situations that may threaten the safety and adequacy of the blood supply
- Develop a contingency plan for the BTS
<table>
<thead>
<tr>
<th><strong>QMT 9.7</strong></th>
<th><strong>Quality Status Analysis</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To assist participants to assess the level of the quality system in their own BTS</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>The use of the Quality Status Questionnaire as a tool for education and monitoring</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>The Quality Status Questionnaire will help participants to begin the process of preparing their action plans</td>
</tr>
</tbody>
</table>
| **Teaching focus** | ♦ If necessary, assist participants in answering the questions  
♦ Be sensitive to possible language problems  
♦ Be alert to indications of a participant being unable to answer due to lack of understanding – this could be an indicator for some reinforced learning for the individual participant |
| **Learning outcomes** | Participants should be able to:  
♦ Use the information in the questionnaire to monitor their own progress |
| **Type of activity** | Individual |
| **Materials** | ♦ Quality Status Questionnaire (QMT 9.7.xls)  
♦ Pens |
| **Preparation** | ♦ Prior to coming to the training course, the participants should have received the questionnaire and been asked to complete as much as possible in advance |
| **Instructions** | 1 Check that all participants received the questionnaire before attending the course.  
2 Instruct participants to finish completing the questionnaire and to ask any questions they may have.  
3 Assist any participants who have difficulties in completing the questionnaire. |
| **Review of the activity** | ♦ Review responses to the questions on an individual basis  
♦ Ensure any areas of uncertainty are clarified  
♦ Prior to the end of the course, review the responses and identify common problem areas; during QMT 15.4, discuss any common problems and possible solutions in a group activity  
♦ Ensure the major individual problems identified are addressed in the action plans. |
| **Time span** | 1 hour |
Quality Status Report for Individual BTSs

Background Information
1. Name of centre
2. Address of centre
3. Approximate number of units collected annually
4. Component preparation

<table>
<thead>
<tr>
<th>Component</th>
<th>Prepared (Yes/No)</th>
<th>By single whole blood donation</th>
<th>By apheresis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packed red cells</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fresh frozen plasma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelet concentrates</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. What percentage of donations are collected from voluntary, non-remunerated blood donors?

Quality Systems
1. Is the organizational structure defined and documented? Yes No
2. Is the document authorized (signed) by the head of the centre? Yes No
3. Is there a chart (organigam) that shows the organizational structure with authority, responsibility and accountability? (If yes, please attach a copy)
4. Do all staff have a job description that specifies tasks, authority and responsibilities and accountability? All departments? Yes No If no, in some departments? State which
5. When are job descriptions reviewed? Regularly When tasks change Rarely
6. Is there a specific person appointed as the quality manager/officer? Yes No
If yes, please give the name of this person
7. What proportion of time does the person devote to this function?

<table>
<thead>
<tr>
<th></th>
<th>100%</th>
<th>50-100%</th>
<th>&lt;50%</th>
</tr>
</thead>
</table>
8. Does the centre have a documented quality policy? Yes No
9. Is there a quality manual available? Yes No
If yes, is this a current edition?
10. Are there written procedures (SOPs)? All departments? Yes No If no, in some departments? State which
11. Is there a plan for regular review of documents? Yes No
If yes, when was the last review and how many documents were reviewed?
12. Are quality system documents controlled? Yes No
Training

13. Is there a training policy or strategy? | Yes | No |
---|---|---|
14. Is there a system for assessing the training needs of all staff? | | |
15. Staff training (please tick the appropriate box if applicable)

<table>
<thead>
<tr>
<th>Type of staff</th>
<th>Training programmes</th>
<th>Curriculum developed</th>
<th>Training material</th>
<th>Technical training</th>
<th>Management training</th>
<th>On-going education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood donor motivators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood donor counsellors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor clinic staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab technicians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescribers of blood</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others (specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. Is there a system for assessing the outcomes of the training programmes? | | |
17. Are staff trained to standard operating procedures (SOPs) to ensure competency? | | |
18. When were staff last trained to ensure competency?

<table>
<thead>
<tr>
<th>Type of staff</th>
<th>Last trained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical personnel</td>
<td></td>
</tr>
<tr>
<td>Blood donor recruiters</td>
<td></td>
</tr>
<tr>
<td>Blood donor counsellors</td>
<td></td>
</tr>
<tr>
<td>Donor clinic staff</td>
<td></td>
</tr>
<tr>
<td>Laboratory technicians</td>
<td></td>
</tr>
<tr>
<td>Prescribers of blood</td>
<td></td>
</tr>
<tr>
<td>Others (specify)</td>
<td></td>
</tr>
</tbody>
</table>

19. Are records maintained of all training in the centre? | | |

Stock Control (Consumables)

20. Does the centre have direct control over ordering? | | |
21. Is there a system of stock control? | | |
22. Has a minimum stock level been determined for each critical item? | | |
23. Are there documented procedures for the inspection of all critical supplies which are received? | | |
   If yes, give a few examples
24. Is stock maintained under the correct conditions? e.g. refrigerators | | |
25. Are those conditions monitored? e.g. temperature monitoring | | |
26. On approximately how many occasions in the last 12 months has your BTS run out of a critical item? | | |
27. Are there procedures in place for such occasions? | | |
28. Approximately how many kits or reagents were discarded in the last 12 months due to expiry? | | |

Quality Audits

29. Is there a general policy on quality audits? | | |
30. Is there a documented audit schedule? | | |
31. Does the centre have trained auditors? | | |
32. Does the centre have authorized auditors? | | |
33. Last quality audits done

<table>
<thead>
<tr>
<th>Date of last audit</th>
<th>By whom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>External</td>
<td></td>
</tr>
</tbody>
</table>

34. Non-conformances identified during the last audit

<table>
<thead>
<tr>
<th>No. identified</th>
<th>No. not closed by due date</th>
</tr>
</thead>
</table>
### Equipment

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>35. Has all critical equipment been identified and documented?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, please provide a copy of the list</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36. Is there a documented policy for validating new critical equipment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37. Is there a documented policy for calibration of all critical equipment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38. Are the methods for calibration documented?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no, some equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State which</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39. Do the methods include the frequency of calibration?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40. Is there a maintenance schedule for all critical equipment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no, some equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State which</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41. Are records kept of calibrations?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do these include the following?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>When the calibration was done</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who performed the calibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The result of the calibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>42. Are records kept of maintenance and repair?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>43. Is there a system to ensure that equipment is calibrated and maintained within the specified time period?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>44. How many pieces of equipment are currently not in use due to breakdown?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45. Are refrigerators and freezers:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarmed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connected to an emergency generator?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitored?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>46. How often are the temperatures of refrigerators and freezers checked?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>47. How is the information from the check recorded?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Safety

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>48. Is there a documented policy on safety procedures at your centre?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>49. Is there a person responsible for ensuring safe work practices?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50. Are there standard operating procedures (SOPs) covering the following safety issues?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work-related injuries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste disposal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>51. Is there a specific area in training that ensures staff are aware of their responsibility regarding cleanliness and tidiness?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Errors

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>52. Is there a documented policy or strategy for error reporting and handling?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>53. If yes, does the policy include the following?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporting errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigating errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resolving errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>54. In the last 12 months:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Errors reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Errors solved</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table

<table>
<thead>
<tr>
<th>Errors reported</th>
<th>&gt;20</th>
<th>20</th>
<th>10</th>
<th>&lt;10</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Errors solved</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Blood Donor Clinic

55. Is there an identified separate department responsible for blood donor management? [ ] Yes [ ] No

56. Are the following documents available?

<table>
<thead>
<tr>
<th>SOPs</th>
<th>Information material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor education</td>
<td>Yes</td>
</tr>
<tr>
<td>Donor motivation</td>
<td>No</td>
</tr>
<tr>
<td>Donor recruitment</td>
<td>Yes</td>
</tr>
<tr>
<td>Donor retention</td>
<td>No</td>
</tr>
<tr>
<td>Donor counselling</td>
<td>Yes</td>
</tr>
</tbody>
</table>

57. Is a questionnaire used for donor selection? [ ] Yes [ ] No

58. Are epidemiological data used to target low-risk groups for blood donation? [ ] Yes [ ] No

59. Is there a blood donor register? [ ] Yes [ ] No

60. Does the register clearly differentiate between active and deferred blood donors? [ ] Yes [ ] No

61. Are data from donor selection activities monitored, analyzed and acted on? [ ] Yes [ ] No

62. Are data received from the laboratory regarding positive results monitored, analyzed and used? [ ] Yes [ ] No

### Laboratory Testing

63. Is there a documented policy or strategy for tests performed on donated blood? [ ] Yes [ ] No

64. Are there standard operating procedures (SOPs) for the following?
   - HIV testing
   - HBsAg testing
   - HCV testing
   - Syphilis screening
   - ABO grouping
   - Rh grouping
   - Antibody screening

65. Control used on testing for transfusion-transmissible infections (TTIs):
   - Internal quality controls (IQC)? [ ] Yes [ ] No
   - Controls graphed? [ ] Yes [ ] No
   - Validation of test runs based on kit controls? [ ] Yes [ ] No
   - Validation of test runs based on IQC? [ ] Yes [ ] No

66. Are records maintained of invalid test runs? [ ] Yes [ ] No

67. Is there a documented system for ensuring the accuracy of data entry/transcription? [ ] Yes [ ] No

68. What control are used in blood group serology? [ ]

69. How frequently are the blood group serology controls used? [ ]

70. Which of the following are recorded about tests performed?
   - Date of test [ ]
   - Person performing test [ ]
   - Name, batch no. and expiry date of reagents/kit used [ ]
   - Results of calculations [ ]
   - Whether the test run was valid [ ]
   - Other [ ]

71. Are there any circumstances under which you would accept results from invalid runs? [ ] Yes [ ] No
   Briefly describe the circumstances and how you would control this. [ ]
### Laboratory Testing (continued)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>72. Are there any circumstances under which you would use expired reagents or test kits?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Briefly describe the circumstances and how you would control this.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>73. Does the testing laboratory participate in an external quality assessment scheme (EQAS) for:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TTI testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood group serology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please state the names of the schemes and the tests covered:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Processing of Blood Products

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>74. Are there documented specifications for each product made?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75. Are there standard operating procedures (SOPs) for the production of each product?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>76. Are there records of quality monitoring of production?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>77. Is the data from quality monitoring analyzed on a continuing basis?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>78. Are there formal written quarantine/release procedures?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>79. Is there a system of blood stock control?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>80. Percentage of expired products:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blood group</th>
<th>Whole blood</th>
<th>Packed cells</th>
<th>FFP</th>
<th>Platelet concentrates</th>
</tr>
</thead>
<tbody>
<tr>
<td>O RhD pos</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A RhD pos</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B RhD pos</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB RhD pos</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O RhD neg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A RhD neg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B RhD neg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB RhD neg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Clinical Interface

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>81. Are there standard operating procedures (SOPs) for the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cross-matching</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Issue of blood and blood products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managing adverse transfusion reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigating post-transfusion infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>82. Is there a system for monitoring turn-around time?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>83. Are there guidelines for the clinical use of blood?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>84. Is there a system for auditing the guidelines?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>85. Is there a standard blood request form?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, please provide a copy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>86. How many of the hospitals to whom you provide blood have hospital transfusion committees?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>87. Is there a documented blood order schedule for surgical cases?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>88. Are there established criteria for monitoring the activities of the cross-match laboratory?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>89. What is the cross-matched to transfused ratio?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90. Has the laboratory ever had to carry out a formal look-back?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, how successful was it in tracing all the applicable records?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>91. Are alternatives to human blood available? If yes, please list the products used</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## QMT 9.8 Preparing an Action Plan

### Teaching aim
To introduce participants to the preparation of their individual action plans

### Core topics
- Introduction to preparing an action plan
- Steps in the action plan
- Identifying priority areas

### Key points
- The action plan should include all the main elements of a quality management system
- Identify priority areas from the quality status questionnaire
- Action plans developed during the course will form the foundation for planning participants’ quality systems

### Teaching focus
- Emphasize that the suggested steps are only examples and that participants’ plans will vary considerably, depending on their own situations
- Emphasize the need to base the action plans on identified needs
- Encourage simplicity

### Learning outcomes
Participants should be able to:
- List the main areas to consider when preparing the first draft of a basic plan of action

### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Remember!
5. Suggested Steps – Organizational Management (1)
6. Suggested Steps – Organizational Management (2)
7. Suggested Steps – Processes and Procedures
8. Suggested Steps – Documentation (1)
9. Suggested Steps – Documentation (2)
10. Suggested Steps – Documentation (3)
11. Suggested Steps – Maintenance and Calibration
12. Suggested Steps – Assessment
13. Key Points
14. Learning Outcomes

### Materials
None

### Related activity
- QMT 9.9 Preparing a Draft Action Plan

### Time span
½ hour

### Presentation notes and handling the session

#### Slide 4
Remember!
- The slide suggests that participants must keep in mind when preparing their action plans
| Slides 5 - 12  |
| Suggested Steps |
| ♦ These slides suggest some activities that participants might include in their action plans |
| ♦ The slides include all the main areas covered in Modules 2–9 |
| ♦ Emphasize the need for participants to focus on their own needs and identified gaps and priorities |
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 9.9</th>
<th>Preparing a Draft Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To assist participants in drafting their individual action plans</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ The first draft of the action plans will be refined at the end of the course  
♦ Participants will have an opportunity for individual discussion with facilitators  
♦ Other help will be available, as required |
| **Key points** | ♦ Participants’ plans should initially focus on the next 6–12 months  
♦ Plans should be realistic and achievable  
♦ Plan to succeed |
| **Teaching focus** | ♦ Encourage participants to be honest and realistic about what is achievable  
♦ Try to identify specific problems in participants’ individual BTSs  
♦ Look for gaps in the participants’ plans  
♦ Suggest alternatives, where appropriate |
| **Learning outcomes** | Participants should be able to:  
♦ Identify priority areas from the quality status questionnaire  
♦ Apply the knowledge gained in the course to prepare an action plan |
| **Type of activity** | Individual work |
| **Materials** | ♦ QMT 9.9: Action Plan forms  
♦ Completed Quality Status Questionnaires (QMT 9.7) |
| **Instructions** | 1 Instruct participants to develop an action plan for their BTS for the next 6 – 12 months.  
2 Instruct them that their action plans should focus on meeting quality requirements in their own BTS, as reported or identified by the answers to the Quality Status Questionnaire.  
3 Permit them to work with another participant from the same centre or country, if they wish.  
4 Inform them that the action plans will be finalized and reviewed at the end of the course – see QMT 15.3 and QMT 15.4. |
| **Review of the activity** | ♦ Review each participant’s action plan and ensure that their plans address identified deficiencies and needs  
♦ Ensure their plans are realistic and not over-ambitious  
♦ Ensure that, where participants plan action at the national level, they do not omit their own individual centre from the plan  
♦ Keep in mind that some participants will not be able to develop action plans for national or even regional level activity, but will have to focus on their own centre only |
<p>| <strong>Time span</strong> | 3 hours |</p>
<table>
<thead>
<tr>
<th>Action</th>
<th>Responsible</th>
<th>Required resources</th>
<th>By when</th>
<th>Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
Module 10
Hygiene and Safety in the BTS
# Introduction to Hygiene and Safety in the BTS

## Teaching aim
To review the elements of a quality system in relation to hygiene and safety in the BTS

## Core topics
- Hygiene and safety as quality issues
- Safety policy and procedures
- Biosafety
- Other safety issues: mechanical/electrical/chemical/fire/radiation safety
- Disposal of waste
- Responsibilities for safety

## Key points
- A safety policy is an essential component of each of the elements of the quality system
- The safety policy should reflect the commitment by the organization to hygiene and safety issues
- Responsibilities for hygiene and safety should be defined

## Teaching focus
- Emphasize that the quality manager is responsible for ensuring a hygiene and safety policy is in place
- Provide examples of safety policies

## Learning outcomes
Participants should be able to:
- Identify quality issues in relation to hygiene and safety in the BTS
- Define key elements of a safety policy for a BTS
- Identify the responsibilities of the organization and staff for hygiene and safety
- Identify the role of the quality manager in ensuring hygiene and safety in the BTS

## Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Quality Aspects of Hygiene and Safety
5. Staff Requirements
6. Key Elements of a Safety Policy (1)
7. Key Elements of a Safety Policy (2)
8. Identifying Risks
9. Biosafety
10. Other Safety Issues (1)
11. Other Safety Issues (2)
12. Disposal of Waste
13. Responsibilities for Safety
14. Key Points
15. Learning Outcomes
<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Quality Aspects of Hygiene and Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide introduces general aspects of the involvement of the quality manager/quality department in hygiene and safety</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Staff Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists staff requirements with regard to hygiene and safety</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to train all staff to appreciate their individual roles in the hygiene and safety aspects of their work</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 6 - 7</th>
<th>Key Elements of a Safety Policy (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These two slides list the essential areas that should be addressed in the safety policy</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to link procedures for reporting and dealing with incidents and accidents with the error reporting system</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Identifying Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The points on the slide give advice on the process of identifying risks</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that flowcharting processes and procedures not only assists in quality improvement, but also assists in identifying hygiene and safety risks</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Biosafety</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Discuss each point on the slide</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for all staff to be familiar with universal safety precautions</td>
<td></td>
</tr>
<tr>
<td>♦ Universal precautions and biosafety are dealt with in more detail in QMT 10.3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 10 - 11</th>
<th>Other Safety Issues (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These two slides list the important areas to consider with regard to mechanical, electrical, chemical, fire and radiation safety</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants, giving and asking for examples of risks and possible safety precautions to reduce those risks</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Disposal of Waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives some basic information regarding the disposal of waste</td>
<td></td>
</tr>
<tr>
<td>♦ Refer the participants to the Aide-Mémoire: Safe Health-Care Waste Management</td>
<td></td>
</tr>
<tr>
<td>♦ Handling biological hazardous waste is dealt with in more detail in QMT 10.3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Responsibilities for Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide emphasizes the responsibilities of all staff in ensuring safety</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the role of the quality manager</td>
<td></td>
</tr>
</tbody>
</table>
Health-care waste is a by-product of health care that includes sharps, non-sharps, blood, body parts, chemicals, pharmaceuticals, medical devices and radioactive materials. Poor management of health-care waste exposes health-care workers, waste handlers and the community to infections, toxic effects and injuries. It may also damage the environment. In addition, it creates opportunities for the collection of disposable medical equipment (particularly syringes), its re-sale and potential re-use without sterilisation, which causes an important burden of disease worldwide.

The most important principles underlying effective programmes for the management of health-care waste include, firstly, the assignment of legal and financial responsibility for safe management to the waste producer; and, secondly, the responsibility of duty of care. Precaution should be applied whenever risks are uncertain.

It is essential that everyone concerned by health-care waste should understand that health-care waste management is an integral part of health care, and that creating harm through inadequate waste management reduces the overall benefits of health care.

Policies and plans for the safe management of health-care waste should address the following three elements:

1. The establishment of a comprehensive system of health-care waste management, from the generation of waste to its disposal – to be implemented gradually.
2. The training of all those involved and increasing awareness.
3. The selection of safe and environment-friendly options for the management of health-care waste.

Words of advice

- Secure government commitment and support for safe health-care waste management
- Conduct an initial assessment of the situation of potential harms from health-care waste
- Manage waste comprehensively, addressing responsibilities, resources, waste minimization, handling and disposal
- Raise awareness among those responsible for regulating, generating and handling waste and provide training in safe practices
- Select safe, environment-friendly and sustainable waste management options
- Monitor and evaluate waste management activities and their impact

Checklist

for action at national and local level

National policy for safe health-care waste management
- Designation of responsible authority
- Regulatory framework and guidelines
- Initial assessment
- Integration into overall waste management plan
- Monitoring and evaluation

Comprehensive system of health-care waste management
- Assignment of waste management responsibilities to personnel
- Allocation of resources
- Minimization of waste
- Segregation of waste
- Safe collection, handling and storage
- Safe treatment and disposal

Awareness and training
- Inclusion of waste management in the curricula of health-care personnel
- National training package
- Train the trainers programme
- Education on health risks
- Education on safe practices

Selection of options for the management of health-care waste
- Review of available options
- Checks of safety and environment-friendliness
- Ensure workers’ safety
- Evaluation of sustainability
- Assessment of acceptability
- Monitoring of safety and efficiency
**Key elements**

### National policy for safe health-care waste management

It is the responsibility of governments to create a framework for the safe management of health-care waste and to ensure that health-care facility managers take their share of responsibility to manage wastes safely. This requires a national coordinating mechanism involving the Ministry of Health and other stakeholders. It is important that a designated authority coordinates these efforts and receives sufficient political support, funding and trained staff.

Important activities for a national strategy to achieve safe health-care waste management include:

- Identification of key partners, including but not necessarily limited to: Ministry of Health, Environment Agency, non-governmental organizations, waste producers and waste disposal companies or services
- Designation of the responsible authority for policy formulation, implementation and evaluation
- Initial assessment and analysis of problems leading to unsafe handling or disposal
- Development of a national policy framework stating that the management of waste is part of the health-care system, and that health-care services should be assigned legal and financial responsibility for safe waste management and should manage their waste with duty of care
- Development of a regulatory framework and national guidelines, based on a comprehensive approach, including training, occupational health and safety issues and sound choices of waste management options, according to local circumstances
- Development of an enforcement mechanism
- Setting of practical targets or objectives over a specified time period
- Establishment of a national and regional infrastructure for health-care waste disposal
- Support of regional and municipal authorities in implementation
- Integration of waste minimization into national purchasing policies
- Routine monitoring of impact through process indicators (number of health-care establishments with safe waste management systems) and outcome indicators (e.g. number of accidents involving health-care waste).

### Comprehensive system

Facilities that generate health-care waste should set up a comprehensive waste management system based on the most appropriate means of achieving the safe, environment-friendly management of waste. The system should start with basic measures and then gradually be improved. First steps should include the segregation and safe handling, treatment and disposal of sharps.

Important activities include:

- Assignment of responsibilities for waste management
- Allocation of sufficient human and financial resources
- Waste minimization, including purchasing policies and stock management practices
- Segregation of waste into harmful and non-harmful categories
- Implementation of safe handling, storage, transportation, treatment and disposal options
- Monitoring of waste production and waste destination.

### Awareness and training

Awareness of the risks related to health-care waste and training in safe practices is essential in obtaining both commitment and behaviour change by all involved in the management of health-care waste.

Important activities include:

- Advocacy targeting policy makers and health-care facility managers regarding the risks and responsibilities related to health-care waste
- Inclusion of health-care waste management into the training curricula of nurses, doctors and health-care managers
- Development of a national training package, adapted to various professional categories
- Development of a ‘train-the-trainers’ programme
- Education of health-care and waste workers and the community on the risks associated with health-care waste and safe management practices.

### Selection of options

Waste management options should be efficient, safe and environment-friendly to protect people from voluntary and accidental exposure to waste when collecting, handling, storing, transporting, treating or disposing of waste.

Important activities include:

- Identification of available centralized waste management and disposal resources
- Choice of sustainable management and disposal options, according to:
  - Affordability
  - Environment-friendliness
  - Efficiency
  - Workers’ safety
  - Prevention of the re-use of disposable medical equipment (e.g. syringes)
  - Social acceptability
- Identification of appropriate options for all levels of health-care facilities
- Monitoring and evaluation of safety and efficiency.

Related documents and additional information on health-care waste management can be obtained on the World-Wide Web at www.healthcarewaste.org

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**Department of Protection of the Human Environment**  
**World Health Organization**  
**20 Avenue Appia, CH-1211 Geneva 27, Switzerland**  
**Fax: +41 22 791 4159. E-mail: hcwaste@who.int**
Introduction to
Hygiene and Safety in the BTS

Teaching Aim

- To review the elements of a quality system in relation to hygiene and safety in the BTS

Core Topics

- Hygiene and safety as quality issues
- Safety policy and procedures
- Biosafety
- Other safety issues: mechanical/electrical/chemical/fire/radiation safety
- Disposal of waste
- Responsibilities for safety
Quality Aspects of Hygiene and Safety

- General hygiene and safety should be a component of the quality system
- Quality manager is responsible for ensuring that a separate hygiene and safety policy is in place and is implemented
- Documented protocols (Safety Manual)

Staff Requirements

- Designation of safety officer who is responsible to senior management
- Safety training for all staff
  - Induction
  - Ongoing
- Staff are responsible for safety in their work areas

Key Elements of a Safety Policy (1)

- Statement of commitment to hygiene and safety
- Responsibility of the organization and the staff
- Policies and procedures to ensure a safe workplace
- System of identifying risks
Key Elements of a Safety Policy (2)

- Vaccination and exposure policy
- Provision for personal protective equipment: e.g. gloves, masks, goggles, clothing
- Procedures to deal with incidents and accidents

Identifying Risks

- Effective and systematic way of dealing with hygiene and safety issues
- Analysis of processes and procedures
  - Associated risks
  - Safeguards to be put in place
  - Assessment of overall risk to individuals and products
- Training of appropriate staff to identify risks and minimize the effects

Biosafety

- Universal safety precautions
- Transportation
- Decontamination and containment of spills
- Biohazardous waste - disinfection and disposal
Other Safety Issues (1)

- BTS contains hazardous areas:
  - Laboratories
  - Donor clinics (public area)
- BTS has a duty to staff and public to ensure safety
- BTS risks deterring donors through poor safety standards

Other Safety Issues (2)

- Specific hazards should be identified and assessed
  - Mechanical hazards: e.g. moving equipment, physical obstacles
  - Electrical hazards: e.g. poor wiring systems, overloading of individual power points
  - Chemical hazards: e.g. corrosives and poisons
  - Fire hazards
  - Radiation hazards

Disposal of Waste

- Types of waste
  - Non-hazardous: e.g. paper
  - Biohazardous: e.g. containing human material
  - Hazardous: e.g. chemicals, sharp metal or glass, radioactive material
- Procedures must be in place for the safe and effective disposal of waste
Responsibilities for Safety

- The organization is responsible for ensuring the work environment is a safe place to work in.
- Each individual is responsible for his/her own safety and that of everyone else working with them.

Key Points

- A safety policy is an essential component of each of the elements of the quality system.
- The safety policy should reflect the commitment by the organization to hygiene and safety issues.
- Responsibilities for hygiene and safety should be defined.

Learning Outcomes

You should now be able to:
- Identify quality issues in relation to hygiene and safety in the BTS.
- Define key elements of a safety policy for a BTS.
- Identify the responsibilities of the organization and staff for hygiene and safety.
- Identify the role of the quality manager in ensuring hygiene and safety in the BTS.
**QMT 10.2  Hygiene in the BTS**

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To demonstrate the importance of hygiene and cleanliness in the BTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Hygiene in work areas as a quality requirement &lt;br&gt;♦ Personal hygiene</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>♦ Good hygiene requires cleanliness and tidiness &lt;br&gt;♦ Cleanliness and tidiness of work area is a quality requirement to protect donors, staff and products &lt;br&gt;♦ Personal hygiene is essential</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to: &lt;br&gt;♦ Explain why hygiene is a quality requirement &lt;br&gt;♦ Identify the actions required to ensure hygiene in the BTS</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Emphasize the importance of hygiene for the quality of the product and the protection of staff and donors &lt;br&gt;♦ Emphasize the need for the continual cleaning of surfaces, equipment, etc. &lt;br&gt;♦ Ensure participants understand that cleaning is the responsibility of all staff</td>
</tr>
<tr>
<td><strong>Slides</strong></td>
<td>1 Title &lt;br&gt;2 Teaching Aim &lt;br&gt;3 Core Topics &lt;br&gt;4 Hygiene (1) &lt;br&gt;5 Hygiene (2) &lt;br&gt;6 Cleanliness (1) &lt;br&gt;7 Cleanliness (2) &lt;br&gt;8 Tidiness &lt;br&gt;9 Donor Clinic (1) &lt;br&gt;10 Donor Clinic (2) &lt;br&gt;11 Laboratory and Production Areas (1) &lt;br&gt;12 Laboratory and Production Areas (2) &lt;br&gt;13 Storage and Transportation of Blood Products &lt;br&gt;14 Personal Hygiene &lt;br&gt;15 Key Points &lt;br&gt;16 Learning Outcomes</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Related activity</strong></td>
<td>QMT 10.4  Safety Issues and Minimizing Risks</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>¾ hour</td>
</tr>
<tr>
<td>Presentation notes and handling the session</td>
<td></td>
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<tr>
<td>--------------------------------------------</td>
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<tr>
<td><strong>Slides 4 - 5</strong></td>
<td></td>
</tr>
<tr>
<td>Hygiene (1) &amp; (2)</td>
<td></td>
</tr>
<tr>
<td>♦ These two slides list important points related to hygiene</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for a hygienic work area in order to protect the entire blood transfusion process</td>
<td></td>
</tr>
<tr>
<td><strong>Slides 6 - 7</strong></td>
<td></td>
</tr>
<tr>
<td>Cleanliness (1) &amp; (2)</td>
<td></td>
</tr>
<tr>
<td>♦ These slides list relevant points regarding cleanliness</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to ensure all staff are involved in maintaining a clean working environment</td>
<td></td>
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<tr>
<td><strong>Slide 8</strong></td>
<td></td>
</tr>
<tr>
<td>Tidiness</td>
<td></td>
</tr>
<tr>
<td>♦ The slide lists reasons for maintaining a tidy work area</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants, giving some examples</td>
<td></td>
</tr>
<tr>
<td><strong>Slides 9 - 10</strong></td>
<td></td>
</tr>
<tr>
<td>Donor Clinic</td>
<td></td>
</tr>
<tr>
<td>♦ The slide lists reasons for maintaining a clean and tidy donor area</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants, emphasizing that good hygiene and safety will result in improved donor retention and safety for donors and patients</td>
<td></td>
</tr>
<tr>
<td>♦ This aspect is discussed further in Module 11</td>
<td></td>
</tr>
<tr>
<td><strong>Slides 11 - 12</strong></td>
<td></td>
</tr>
<tr>
<td>Laboratory &amp; Production Areas (1) &amp; (2)</td>
<td></td>
</tr>
<tr>
<td>♦ The slides deal with important aspects of hygiene and safety in the production and laboratory areas</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with participants</td>
<td></td>
</tr>
<tr>
<td><strong>Slide 13</strong></td>
<td></td>
</tr>
<tr>
<td>Transportation of Blood Products</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss the reasons for regular disinfection and cleaning of the items listed on the slide</td>
<td></td>
</tr>
<tr>
<td><strong>Slide 14</strong></td>
<td></td>
</tr>
<tr>
<td>Personal Hygiene</td>
<td></td>
</tr>
<tr>
<td>♦ The slide lists the various elements of personal hygiene and safety</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point on the slide</td>
<td></td>
</tr>
</tbody>
</table>
Hygiene in the BTS

WHO/QMT 10.2

Teaching Aim

- To demonstrate the importance of hygiene and cleanliness in BTS

Core Topics

- Hygiene in work areas as a quality requirement
- Personal hygiene
Hygiene (1)
- Includes both cleanliness and tidiness
- Is a quality requirement
- Applies to all BTS activities
  - Donor clinic
  - Laboratory areas
  - Production and storage areas
  - During transportation of blood products

Hygiene (2)
- Lack of hygiene may lead to
  - Contaminated end product
  - Unsafe conditions for employees to work in
  - Placing donors at risk

Cleanliness (1)
- Cleanliness is essential in all BTS activities
- Product safety is critical
- Dirty working conditions can lead to microbial contamination of the product
- Reliability of test results can be compromised by dirty working conditions
Cleanliness (2)

- Cleaning
  - Regular
  - In response to an incident: e.g. spillage

- Appropriate cleaning procedures
  - Frequency
  - Materials and cleaning agents
  - Methods

- Documentation

- Regular monitoring and evaluation of cleaning

Tidiness

- Untidy work areas
  - Are dangerous
  - Give a bad impression
  - Lead to poor hygiene: e.g. infestations
  - Indicate that cleaning is performed poorly

- All staff are responsible for ensuring that work areas are tidy

Donor Clinic (1)

- The first direct contact between donor and the BTS

- Impressions are important - donor retention
**Donor Clinic (2)**

- Blood collection must be performed in a way that is safe for the donor and the patient
  - Donor arm cleansing
  - Cleanliness of equipment
  - Cleanliness of environment
- Special considerations for mobile sessions

---

**Laboratory and Production Areas (1)**

Dirty conditions can lead to:

- Incorrect test results due to contaminated reagents
- Wastage of reagents because of contamination
- Contamination of samples

---

**Laboratory and Production Areas (2)**

- Contamination of equipment: e.g.
  - Centrifuges
  - Plasma extractors
  - Tube sealers
  - Benches
  - Water bath
- Contamination of blood products
- Risks to staff
Storage and Transportation of Blood Products

- Regular disinfection and cleaning of blood storage areas
- Regular disinfection and cleaning:
  - Transport containers: keep dry
  - Ice packs
  - Packing area

Personal Hygiene

- Poor personal hygiene can contaminate products and lead to cross-infection in staff
- Protective clothing
  - Regular change
  - Appropriate usage
- No eating, drinking or smoking in work areas
- Handwashing before and after visiting toilets and eating/smoking breaks and after laboratory work

Key Points

- Good hygiene requires cleanliness and tidiness
- Cleanliness and tidiness of work area is a quality requirement to protect donors, staff and products
- Personal hygiene is essential
<table>
<thead>
<tr>
<th>Learning Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>You should now be able to:</td>
</tr>
<tr>
<td>- Explain why hygiene is a quality requirement</td>
</tr>
<tr>
<td>- Identify the actions required to ensure hygiene in the BTS</td>
</tr>
</tbody>
</table>
# QMT 10.3 Biological and Chemical Safety in the BTS

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To demonstrate the importance of biological and chemical safety in the BTS</th>
</tr>
</thead>
</table>
| **Core topics**  | ♦ Types of hazardous material  
|                  | ♦ Universal safety precautions  
|                  | ♦ Safe handling of hazardous material  
|                  | ♦ Safe disposal of hazardous waste |
| **Key points**   | ♦ Universal safety precautions must be followed for the protection of staff, the environment and the general public  
|                  | ♦ Potentially hazardous material must be handled safely and disposed of in the correct manner  
|                  | ♦ Hazardous material must be appropriately labelled and transported in appropriate containers  
|                  | ♦ All hazardous spills must be contained and decontaminated |
| **Teaching focus** | ♦ Ensure that participants are familiar with universal safety precautions  
|                  | ♦ Discuss the role of the quality manager in ensuring there is a system for the correct handling and disposal of hazardous waste |
| **Learning outcomes** | Participants should be able to:  
|                  | ♦ Identify the actions required to ensure biological and chemical safety in the BTS |
| **Slides**       | 1 Title  
|                  | 2 Teaching Aim  
|                  | 3 Core Topics  
|                  | 4 Types of Hazardous Material  
|                  | 5 Universal Safety Precautions (1)  
|                  | 6 Universal Safety Precautions (2)  
|                  | 7 Safe Handling of Hazardous Material  
|                  | 8 Hygienic Practices  
|                  | 9 Safe Disposal of Hazardous Waste (1)  
|                  | 10 Safe Disposal of Hazardous Waste (2)  
|                  | 11 Containing Hazardous Spills  
|                  | 12 Safe Transport of Hazardous Material  
|                  | 13 Key Points (1)  
|                  | 14 Key Points (2)  
<p>|                  | 15 Learning Outcomes |
| <strong>Materials</strong>    | None |
| <strong>Related activity</strong> | QMT 10.4 Safety Issues and Minimizing Risks |
| <strong>Time span</strong>    | ¾ hour |</p>
<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Types of Hazardous Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide introduces the types of hazardous material encountered in the BTS</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Slides 5 - 6</th>
<th>Universal Safety Precautions (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list the basic rules of universal safety precautions</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Safe Handling of Hazardous Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide outlines general advice on the safe handling of hazardous materials</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants, giving examples of how each can be implemented</td>
<td></td>
</tr>
<tr>
<td>♦ Safe disposal of hazardous materials is dealt with in detail on slides 9 and 10</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Hygienic Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some basic rules of hygienic practices to be followed in a blood transfusion service</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 9 - 10</th>
<th>Safe Disposal of Hazardous Waste (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Discuss each point regarding the safe disposal of hazardous waste</td>
<td></td>
</tr>
<tr>
<td>♦ Remind participants of the information contained in the Aide-Mémoire: <em>Safe Health-Care Waste Management</em></td>
<td></td>
</tr>
<tr>
<td>♦ Discuss with participants how hazardous waste is dealt with in their centres and any problems they have encountered</td>
<td></td>
</tr>
<tr>
<td>♦ Involve all participants in suggesting possible solutions</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 11</th>
<th>Containing Hazardous Spills</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Discuss each point on the slide, using examples of materials that can be used to contain spills</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Safe Transport of Hazardous Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Discuss the need to transport all hazardous materials in a safe manner</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the possible risks to the general public during the transportation of hazardous material</td>
<td></td>
</tr>
</tbody>
</table>
Biological and Chemical Safety in the BTS

Teaching Aim

- To demonstrate the importance of biological and chemical safety in the BTS

Core Topics

- Types of hazardous material
- Universal safety precautions
- Safe handling of hazardous material
- Safe disposal of hazardous waste
### Types of Hazardous Material

- Blood transfusion services handle a range of hazardous materials
  - Biologicals: e.g. infectious agents
  - Chemical: e.g. copper sulfate
- Some of these materials are purchased for use in specific BTS activities
- Some of these materials are generated as a result of specific BTS activities

### Universal Safety Precautions (1)

- Training of all staff in universal safety precautions
- Fully documented procedures
- The treatment of all biological and chemical materials as potentially hazardous
- Appropriate personal protection equipment provided and used

### Universal Safety Precautions (2)

- Correct handling and disposal of sharps
  - Needles
  - Other "sharp" items
- Hepatitis B vaccination of staff
Safe Handling of Hazardous Material

- Safe practice at all times
  - Personal protection
  - Only handle hazardous material when necessary
- Hygienic practices
- Appropriate packaging and transport of specimens
- Decontamination and containment of spills
- Safe disposal of hazardous waste

Hygienic Practices

- Cover cuts and abrasions
- Wash hands before and after handling donations, specimens, components
- Do not eat, drink, smoke or apply cosmetics in areas where donations, specimens or components are handled

Safe Disposal of Hazardous Waste (1)

- Proper separation of waste
  - Hazardous/non-hazardous
  - Sharps/non-sharps
  - Liquid/solid
Safe Disposal of Hazardous Waste (2)

- Appropriate disposal
  - Pre-treatment: e.g. autoclaving, disinfection, inactivation, neutralization
  - Incineration
  - Landfill

Containing Hazardous Spills

- Contain the spill
  - Absorbent material
  - Specialized inert containment material
- Mop up the substance
  - Absorbent material
- Disinfect/neutralize/decontaminate as appropriate
  - Biological/chemical
- Disposal of contaminated material

Safe Transport of Hazardous Material

- Transport only where necessary
- Identify risks: i.e. biological or chemical
- Package appropriately
  - Correct containers and labelling
- Transportation by appropriate, authorized, trained carriers
- Full documentation
Key Points (1)

- Universal safety precautions must be followed for the protection of staff, the environment and the general public.
- Potentially hazardous material must be handled safely and disposed of in the correct manner.

Key Points (2)

- Hazardous material must be appropriately labelled and transported in appropriate containers.
- All hazardous spills must be contained and decontaminated.

Learning Outcomes

You should now be able to:

- Identify the actions required to ensure biological and chemical safety in the BTS.
# QMT 10.4 Safety Issues and Minimizing Risks

<table>
<thead>
<tr>
<th>Teaching aims</th>
<th>To provide participants with practice in identifying safety issues and how to resolve them</th>
</tr>
</thead>
</table>
| Core topics   | ♦ Identification of key safety issues  
♦ Creating awareness of safety issues  
♦ Actions needed to minimize risks |
| Key points    | An analysis of the safety aspects of all processes and procedures is essential |
| Teaching focus| ♦ Give examples of the types of potential risk to staff, donors and the public  
♦ Ensure that safety plans are feasible and cover key areas |
| Learning outcomes | Participants should be able to:  
♦ Identify key BTS safety issues  
♦ List the key elements of maintaining a safe workplace  
♦ Design a plan for safety checks in the BTS |
| Type of activity | Group work |
| Materials     | ♦ Flipcharts  
♦ Pens |
| Instructions  | 1 Allocate one of the following areas to each group:  
♦ Disposal of biohazard waste  
♦ Chemical store  
♦ Injuries to staff  
♦ Injuries to donors.  
2 Instruct them to:  
♦ Identify the key safety issues  
♦ Design a plan for minimizing the risks and monitoring the safety issues identified. |
| Review of the activity | ♦ Ensure that the following have been covered:  
– Biohazard issues  
– Staff safety  
– Public safety  
– Good housekeeping  
♦ Ensure the plan is realistic |
| Time span     | 1½ hours |
Module 11
Quality Systems in Blood Donor Management
<table>
<thead>
<tr>
<th>QMT 11.1</th>
<th><strong>Introduction to Quality Systems in Blood Donor Management</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To review the elements of a quality system in relation to blood donor management</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Elements of a quality system as applied to blood donor management  
♦ Quality issues in donor management  
  - Recruitment  
  - Selection  
  - Blood Collection  
  - Documentation  
  - Donor care, satisfaction and retention  
♦ Role of the quality manager |
| **Key points** | ♦ The quality system in blood donor management should focus on the activities of:  
  - Recruitment  
  - Selection  
  - Collection  
  - Documentation  
  - Donor care, satisfaction, retention |
| **Teaching focus** | ♦ Acknowledge and expand on the differences in approach by different BTSs  
♦ Regular low-risk blood donors are the foundation of a safe and adequate blood supply  
♦ Discuss the role of the quality manager in ensuring quality in blood collection |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the actions required to ensure quality in blood donor management  
♦ Identify the role of the quality manager in ensuring quality in blood donor management |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Elements of a Quality System (1)  
5 Elements of a Quality System (2)  
6 Elements of a Quality System (3)  
7 Donor Recruitment (1)  
8 Donor Recruitment (2)  
9 Donor Selection  
10 Blood Collection  
11 Documents (1)  
12 Documents (2) |
|   | 13 Donor Care, Satisfaction and Retention (1)  
|   | 14 Donor Care, Satisfaction and Retention (1)  
|   | 15 Role of the Quality Manager (1)  
|   | 16 Role of the Quality Manager (2)  
|   | 17 Key Points  
|   | 18 Learning Outcomes  

**Materials**

None

**Related activity**

None

**Time span**

½ hour

**Presentation notes and handling the session**

**Slides 4 - 6**

Elements of a Quality System (1), (2) & (3)

- The presentation is an introduction to the module; do not go into too much detail as each aspect is dealt with in detail in the presentations that follow
- The first slide reminds the participants of the elements of a quality system
- Slides 5–6 show the participants how these elements can be applied broadly to blood donor management

**Slides 7 - 8**

Donor Recruitment (1) & (2)

- The two slides list the main areas in blood donor recruitment that should be addressed by the quality system
- Donor recruitment is dealt with in detail in QMT 11.2

**Slide 9**

Donor Selection

- The slide lists key reasons for establishing donor selection criteria and the main areas that should be considered when developing these criteria
- Donor selection is dealt with in detail in QMT 11.2

**Slide 10**

Blood Collection

- The points listed on the slide show how the quality system influences practices in blood collection through the establishment of controlled processes and procedures
- Blood collection is dealt with in detail in QMT 11.4

**Slides 11 - 12**

Documents (1) & (2)

- The first slide gives the rationale for ensuring that the documentation system encompasses blood donor management
- The second slide lists some of the documents that should be generated
- Documentation in blood donor management is dealt with in detail in QMT 11.6

**Slides 13 - 14**

Donor Care, Satisfaction and Retention (1) & (2)

- The two slides introduce the concepts of donor care and "customer" satisfaction
- Link the concepts on the slide to total quality management through examples of customer care during the donation process
- QMT 11.7 deals in detail with this aspect of blood donor management

**Slides 15 - 16**

Role of the Quality Manager (1) & (2)

- These two slides list the major reasons for ensuring that the quality management system encompasses blood donor management and the role of the quality manager in ensuring quality systems are put in place in this particular area
Introduction to Quality Systems in Blood Donor Management

Teaching Aim

- To review the elements of a quality system in relation to blood donor management

Core Topics

- Elements of a quality system as applied to blood donor management
- Quality issues in donor management
  - Recruitment
  - Selection
  - Blood collection
  - Documentation
  - Donor care, satisfaction and retention
- Role of the quality manager
Elements of a Quality System (1)

- Organizational management
- Training
- Outputs
- Customer
- Supplier
- Inputs
- Standards
- Documentation
- Assessment

Elements of a Quality System (2)

- Organizational management
  - Policies on blood donor management
  - Identification of specific staff requirements
- Quality standards
  - Guidelines on blood donor recruitment
  - Donor selection criteria
  - Blood collection

Elements of a Quality System (3)

- Training of staff in blood donor management
- Documentation in donor management
- Assessments
  - Validation of equipment, materials, procedures and software
  - Monitoring and evaluation of donor management activities
Donor Recruitment (1)

- The recruitment of blood donors is key to ensuring a safe and adequate blood supply
- Identify and train dedicated recruitment staff

Donor Recruitment (2)

- Development of guidelines for the recruitment of low risk blood donors
  - Identify target population groups
  - Develop recruitment strategies
  - Education of potential donors
  - Identify high quality donors (safe, reliable, retained)

Donor Selection

- The selection of blood donors is key to ensuring a safe blood supply
  - Protect the patient
  - Protect the donor
- Predonation information and counselling
- Development of donor selection criteria
  - Specific risk groups
  - General medical assessment
Blood Collection

- The collection of blood must be performed in a controlled way
- The safety of both the donor and the donated blood are critical
  - Donors must be treated in a way that encourages them to donate again
  - The quality of the blood must be guaranteed
- All procedures must be properly developed, validated and monitored

Documents (1)

- Documents are a key part of any quality system
- Blood collection activities must be documented fully to enable monitoring and ensure full traceability from donor to donation

Documents (2)

- Complete and accurate donor records
- Labelling of donations
- Materials used (batch numbers, etc.)
- Identity of staff directly involved in the process
- Number of donors attending and donations actually collected
Donor Care, Satisfaction and Retention (1)

- Blood donors should be cared for throughout the whole process of donation
- Retention of blood donors is essential to ensure the safety and adequacy of the blood supply
  - Recruitment is expensive
  - Resources must not be wasted
- Retention is influenced by donor satisfaction

Donor Care, Satisfaction and Retention (2)

- Donor satisfaction reflects the quality of the care taken of them when they donate
  - Before
  - During
  - After

Role of the Quality Manager (1)

- The quality of the donors directly affects the quality of the donated blood
- The quality of the donated blood affects the quality of care of the patient
Role of the Quality Manager (2)

- The quality manager is responsible for ensuring the appropriate policies and procedures are in place to:
  - Ensure the highest quality donors are recruited
  - Ensure collection activities are of a high quality
  - Ensure the overall quality of the blood collected

Key Points

- The quality system in blood donor management should focus on the activities of:
  - Recruitment
  - Selection
  - Collection
  - Documentation
  - Donor care, satisfaction, retention

Learning Outcomes

You should now be able to:
- Identify the actions required to ensure quality in blood donor management
- Identify the role of the quality manager in ensuring quality in blood donor management
### QMT 11.2 Donor Recruitment and Selection

<table>
<thead>
<tr>
<th>Teaching aim</th>
<th>To demonstrate how to apply quality to donor recruitment and selection</th>
</tr>
</thead>
</table>
| Core topics  | ♦ Donor recruitment  
♦ Donor selection  
♦ Assessment |
| Key points   | ♦ Applying quality to donor recruitment and selection ensures that:  
   − The lowest risk blood donor populations are identified  
   − The safest blood donors are recruited and retained |
| Teaching focus | ♦ Explain the importance of an analysis of populations to identify groups to target or avoid  
♦ Emphasize that quality means meeting and exceeding the customer’s expectations  
♦ Ensure that all relevant WHO recommendations and guidelines are included in the presentation |
| Learning outcomes | Participants should be able to:  
♦ Identify the quality issues related to the processes of donor recruitment and selection  
♦ Identify the actions required to ensure quality in donor recruitment and selection  
♦ Identify the role of the quality manager in donor recruitment and selection |
| Slides | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Policies and Guidelines  
5 Donor Recruitment Programme  
6 Identifying Lowest Risk Donor Groups (1)  
7 Identifying Lowest Risk Donor Groups (2)  
8 Donor Education and Motivation (1)  
9 Donor Education and Motivation (2)  
10 Donor Education and Motivation (3)  
11 Donor Selection (1)  
12 Donor Selection (2)  
13 Donor Selection (3)  
14 Donor Retention (1)  
15 Donor Retention (2)  
16 Assessment (1)  
17 Assessment (2)  
18 Monitoring and Evaluation  
19 Documentation |
<table>
<thead>
<tr>
<th>Key Points</th>
<th>Learning Outcomes</th>
</tr>
</thead>
</table>

### Materials
- WHO Aide-Mémoire: *Blood Safety* (already distributed)
- WHO Distance Learning Materials: Safe Blood and Blood Products. Module 1: *Safe Blood Donation* (to be distributed at the end of the course)
- WHO Recruiting, Educating and Retaining Safe Blood Donors (to be distributed at the end of the course)

### Related activity
- QMT 11.3  Donor Recruitment and Selection

### Time span
- 1 hour

### Presentation notes and handling the session

#### Slide 4
**Policies and Guidelines**
- The slide discusses the need for implementing documented policies and guidelines in donor recruitment and donor selection

#### Slide 5
**Donor Recruitment Programme**
- The slide lists the important areas that should be addressed in order to ensure a comprehensive donor recruitment programme
- Further details are given in the following slides

#### Slides 6 – 7
**Identifying Lowest Risk Donor Groups (1) & (2)**
- The first slide emphasizes the fact that voluntary, non-remunerated blood donors are safer than other donor groups
- Discuss each different group with the participants
- Emphasize the differences between family/replacement, paid and coerced blood donors
- Involve participants in the discussion by asking them to suggest reasons why regular, voluntary, non-remunerated blood donors are safer than other types of donor
- Stress the importance of the role of the quality manager and the quality system in identifying low risk donor groups

#### Slides 8 – 10
**Donor Education and Motivation (1) & (2)**
- These three slides stress the importance of donor education and motivation, the reasons for an education programme for donors and some suggested education methods
- Discuss each point with the participants, emphasizing the role of the quality system in the programme

#### Slides 11 – 13
**Donor Selection (1), (2) & (3)**
- The slides list important reasons for ensuring that donor selection is based on national documented policies and some of the mechanisms for ensuring a comprehensive donor selection process
- Focus on the role of the quality system rather than the technicalities of donor selection
- Emphasize the different identified needs and approaches of different countries

#### Slides 14 – 15
**Donor Retention (1) & (2)**
- The two slides provide information on donor retention and the rationale for a donor retention programme
- Donor retention is introduced at this point to ensure that participants understand that donor recruitment programmes must incorporate an element that will promote donor retention
- More details are given in QMT 11.7
<table>
<thead>
<tr>
<th>Slides 16 – 17 Assessment (1) &amp; (2)</th>
<th>♦ The two slides list the major activities of the quality department that will ensure controlled procedures in the donor recruitment and selection processes</th>
</tr>
</thead>
</table>
| Slide 18 Monitoring and Evaluation | ♦ The slide lists the major activities that will ensure that the processes are monitored and evaluated  
♦ Stress the link between the general principles of assessment and the donor recruitment and selection processes |
| Slide 19 Documentation            | ♦ The slide introduces the concept of extending the documentation system to donor recruitment and selection  
♦ Further details are given in QMT 11.6 |
Donor Recruitment and Selection

Teaching Aim

- To demonstrate how to apply quality to blood donor recruitment and selection

Core Topics

- Donor recruitment
- Donor selection
- Assessment
Policies and Guidelines

- Safe blood starts with the recruitment, selection and retention of safe donors
- Policies must be developed to ensure the recruitment, selection and retention of the safest blood donors available to the BTS
  - Recruitment policy and strategy
  - Selection criteria
  - Retention policy and strategy
  - National policies, where possible

Donor Recruitment Programme

An adequate supply of low risk donors requires

- A donor recruitment programme
- A dedicated recruitment section with trained staff
- Appropriate funding to support donor recruitment activities

Identifying Lowest Risk Donor Groups (1)

- Regular voluntary non-remunerated blood donors are safer than
  - Family replacement donors
  - Paid donors
  - Compulsory/coerced donors
Identifying Lowest Risk Donor Groups (2)

- Recruitment targeted at lowest risk population groups
  - Use of epidemiological data
- Recruitment strategies used to
  - Encourage regular voluntary non-remunerated donation
  - Discourage unsuitable donors

Donor Education and Motivation (1)

- Education and motivation of target donor groups is essential for success

Donor Education and Motivation (2)

- Education programmes need to focus on:
  - The understanding that blood donation is a life-saving service to the community
  - Promoting voluntary non-remunerated donation
  - The importance of self-deferral
  - The importance of donor selection and the donation of safe blood
  - The importance of regular donation
Donor Education and Motivation (3)

- Methods used must reflect the media available and that are most likely to be effective
  - Voluntary blood donor and other associations
  - Media (newspapers, radio and television)
  - Local and national advertising campaigns
  - Educational talks
  - Street recruitment campaigns
  - Pre-donation information

Donor Selection (1)

- Donor selection criteria are essential
  - Based on national/local conditions and disease levels
  - Based on accepted regional/international practice

- Protect the donor
  - Ensure that it is safe for the donor to donate

- Protect the recipient
  - Ensure that any risk of transfusion-transmitted infection or other adverse effect is minimized

Donor Selection (2)

- Pre-donation information (before the session)
- Pre-donation evaluation and counselling
  - Confidentiality
  - What to look for and why: e.g. venous access
  - What to ask and why: e.g. medical history
  - What to do and why: e.g. check of haemoglobin level

- Informed consent
Donor Selection (3)

- Well-trained staff
- Full documentation of the outcomes of the donor selection process

Donor Retention (1)

- Donor retention is key to a sustainable blood supply
- Policy and strategies are needed to ensure donor retention

Donor Retention (2)

- Donor retention versus donor recruitment
  - Less expensive to retain than recruit donors
  - Increased safety associated with regular blood donors
  - Overall sustainability of the BTS if donors are retained and donate regularly
  - Better overall planning and ability to maintain minimum stock levels
Assessment (1)

- Identify the critical control points in
  - Recruitment
  - Selection
  - Retention

Assessment (2)

- Identify indicators for success of donor recruitment, selection and retention policies and strategies: e.g.
  - Increase in overall donor numbers
  - Increase in number of voluntary non-remunerated donors
  - Increase in number of times donors return to donate
  - Decrease in seroprevalence of TTIs in the donor base

Monitoring and Evaluation

- Analyse the data
- Feed back the information
  - Review of policies and procedures
  - Amendment of strategies
  - Update of donor education and motivation programmes
  - Regular training and updating of staff
Documentation

- Applying quality systems to donor recruitment and selection requires documentation of all activities
  - See QMT 11.6

Key Points

- Applying quality to donor recruitment and selection ensures that:
  - The lowest risk blood donor populations are identified
  - The safest donors are recruited and retained

Learning Outcomes

You should now be able to:
- Identify the quality issues related to the processes of donor recruitment and selection
- Identify the actions required to ensure quality in donor recruitment and selection
- Identify the role of the quality manager in donor recruitment and selection
<table>
<thead>
<tr>
<th>QMT 11.3</th>
<th>Donor Recruitment and Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching aims</td>
<td>To enable participants to examine the benefits of introducing a quality system in blood donor recruitment and selection activities</td>
</tr>
<tr>
<td>Core topics</td>
<td>Quality awareness training of staff in donor recruitment and selection</td>
</tr>
<tr>
<td>Key points</td>
<td>Donor recruitment staff should understand the impact of quality on the BTS</td>
</tr>
<tr>
<td>Teaching focus</td>
<td>Discuss the adverse effects of poor donor recruitment strategies and attitudes</td>
</tr>
<tr>
<td>Learning outcomes</td>
<td>Participants should be able to:</td>
</tr>
<tr>
<td></td>
<td>♦ Explain the importance of quality in blood donor recruitment and selection</td>
</tr>
<tr>
<td>Type of activity</td>
<td>Group work</td>
</tr>
<tr>
<td>Materials</td>
<td>♦ QMT 11.3: Case study</td>
</tr>
<tr>
<td></td>
<td>♦ Flipcharts</td>
</tr>
<tr>
<td></td>
<td>♦ Pens</td>
</tr>
<tr>
<td>Instructions</td>
<td>1 Instruct participants to read and analyse the case study and to discuss the questions that are given.</td>
</tr>
<tr>
<td>Review of the activity</td>
<td>♦ Ensure that the following have been covered:</td>
</tr>
<tr>
<td></td>
<td>− Management commitment, including establishment of a donor recruitment department</td>
</tr>
<tr>
<td></td>
<td>− Policies and guidelines</td>
</tr>
<tr>
<td></td>
<td>− Methods of identifying the lowest risk population groups</td>
</tr>
<tr>
<td></td>
<td>− Strategies for the recruitment of voluntary, non-remunerated blood donors from the lowest risk population groups</td>
</tr>
<tr>
<td></td>
<td>− Strategies for donor retention</td>
</tr>
<tr>
<td></td>
<td>− Documentation, with an emphasis on traceability</td>
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<td></td>
<td>− Training</td>
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<td></td>
<td>− Assessment</td>
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<tr>
<td></td>
<td>− Effective selection/screening strategies and documented criteria</td>
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<td></td>
<td>− Clean environment</td>
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<td></td>
<td>− Public relations</td>
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<tr>
<td></td>
<td>♦ Emphasize the differences in each country/region in donor recruitment and selection strategies, ensuring that participants understand that data must be used to create and monitor their strategies</td>
</tr>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
</tbody>
</table>
Blood Donor Recruitment and Selection

A blood transfusion service, which has been operating for several years, procures approximately 50 000 units of blood annually. A nursing sister has recently been employed by the service to head the blood donor section. During the first few weeks on the job, the sister makes the following observations.

♦ The BTS obtains 70% of its blood from family/replacement donors.
♦ All the donor staff are involved in donor recruitment and selection.
♦ No staff have training or experience in public relations or marketing.
♦ None of the staff have training records related to donor selection.
♦ Although all staff have a job description, the activities related to donor recruitment are not stated on any of their job descriptions.
♦ The testing laboratory does not report back to the donor staff regarding seroprevalence rates for HIV and HBsAg, the two markers that are tested for at the centre. The sister has specifically requested the figures and, to date, has been informed that the seroprevalence rate for all blood donations is 5% for HIV antibodies.
♦ Although the staff carry out a donor selection exercise, there is no documented guide to the questions that should be asked during the selection process.
♦ Records of donor selection and the outcomes for each donor are either missing or incomplete.
♦ The sister has also observed a donor assistant being impolite to a donor who has come to donate for the first time. When approached, the donor assistant has given the excuse of a personal crisis the day before and explained that this had affected her behaviour.
♦ When questioned about certain ways of carrying out a task, many of the staff respond by saying "We have been doing things this way for years."
♦ Although there is a quality officer, this member of staff is only concerned with matters in the laboratory.

Instructions

Discuss the following questions.

1 Does the BTS have a comprehensive quality system? Justify your answer by identifying all the areas in the quality system that have not been addressed in the donor recruitment and selection areas.

2 List the quality management activities that could result in improved donor recruitment.

3 What quality activities would assist in reducing the seroprevalence rate that has been observed in blood donations?

4 Design a simple quality plan to improve quality in donor recruitment, the main target being to reduce reliance on family/replacement blood donors.
# QMT 11.4 Blood Collection

## Teaching aim
To demonstrate how to apply quality to blood collection

## Core topics
- Pre-donation checks of equipment and materials
- Donor identification
- Donor arm cleansing
- Venepuncture and blood collection
- Care of the donor
- Handling of donations and samples
- Quality issues at mobile sessions

## Key points
- Quality in blood collection protects the donor and the recipient
- Quality in blood collection ensures the quality of the product

## Teaching focus
- Introduce the topic in a very broad way
- Be aware of significant differences between countries in the way in which blood is collected
- Keep the focus on quality aspects of blood collection
- Discuss the additional problems in applying quality in mobile donor sessions

## Learning outcomes
Participants should be able to:
- Identify the quality issues related to the process of blood collection
- Identify specific quality issues related to blood collection at mobile donor sessions
- Identify the actions required to ensure quality in blood collection
- Identify the role of the quality manager in ensuring quality in blood collection

## Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Pre-Donation Checks of Equipment and Materials
5. Donor Identification
6. Donor Arm Cleansing
7. Venepuncture
8. Blood Collection
9. Care of the Donor
10. Handling of Donations and Samples (1)
11. Handling of Donations and Samples (2)
12. Quality Issues at Mobile Sessions (1)
13. Quality Issues at Mobile Sessions (2)
14. Key Points
15. Learning Outcomes (1)
16. Learning Outcomes (2)

## Materials
None
<table>
<thead>
<tr>
<th>Related activity</th>
<th>QMT 11.5  Blood Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
<tr>
<td>Presentation notes and handling the session</td>
<td></td>
</tr>
<tr>
<td><strong>Slide 4</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Pre-Donation Checks of Equipment and Materials | ♦ The slide lists some of the important quality issues related to the validation of equipment and materials prior to carrying out a venepuncture for blood donation  
♦ Give some examples to illustrate these points |
| **Slide 5**              |                            |
| Donor Identification     | ♦ The slide lists some important checks that should be performed to verify the identity of the donor  
♦ Discuss how keeping accurate donor records assists in traceability and donor identification  
♦ Ask the participants to give some examples to illustrate why donor identification is essential  
♦ Discuss the labelling of donated units with particular reference to when units should be labelled, stressing the applicability of quarantine/release procedures and other quality issues |
| **Slide 6**              |                            |
| Donor Arm Cleansing      | ♦ The slide lists key quality issues in donor arm cleansing and both why and how it is necessary to control the procedure  
♦ Emphasize the role of the quality manager, stressing the need for the manager to establish best practice |
| **Slide 7**              |                            |
| Venepuncture              | ♦ The slide lists the areas that must be covered by the quality system  
♦ Emphasize the need to establish best practice by accessing reference material and/or expertise in the field |
| **Slide 8**              |                            |
| Blood Collection         | ♦ The slide lists some examples of critical control points in blood collection  
♦ Discuss some of the mechanisms for the quality control of the critical points  
♦ Discuss the labelling of specimens in the context of the quality system with particular reference to traceability |
| **Slide 9**              |                            |
| Care of the Donor        | ♦ The slide lists important aspects of donor care  
♦ Discuss each point emphasizing the importance of customer satisfaction in the donor clinic |
| **Slides 10 – 11**       |                            |
| Handling of Donations and Samples (1) & (2) | ♦ The slides list the areas that must be considered when handling donated blood and the associated specimens  
♦ Discuss these points in relation to a quality management system |
| **Slides 12 – 13**       |                            |
| Quality Issues at Mobile Sessions (1) & (2) | ♦ These two slides list the special considerations that must be taken into account during mobile donation sessions  
♦ Emphasize the need for the quality system to establish protocols to minimize the risks associated with mobile sessions |
Blood Collection

WHO/QMT 11.4

Teaching Aim

- To demonstrate how to apply quality to blood collection

Core Topics

- Pre-donation checks of equipment and materials
- Donor identification
- Donor arm cleansing
- Venepuncture and blood collection
- Care of the donor
- Handling of donations and samples
- Quality issues at mobile sessions
Pre-Donation Checks of Equipment and Materials

- Safety of both donor and donation is a priority
- All equipment and materials must be
  - Correct
  - Safe to use
  - Ready for use
- Records of all materials used for each donor/donation – traceability
  - Identity
  - Batch numbers
  - Labelling of donated units

Donor Identification

- Correct identification of the donor is essential
  - At reception
  - Immediately before venepuncture
- Cross-check the donor with available records
  - Name, address, date of birth
- Re-check the donor’s identity

Donor Arm Cleansing

- Cleansing of the arm prior to venepuncture to minimize risk of bacterial contamination
- SOP
  - Methodology
  - Selection of cleansing agent
- Training of staff
- Assessment of
  - Compliance
  - Effectiveness
Venepuncture

- SOP
- Methodology
  - Selection of vein
  - Arm cleansing
  - Donor identity checks
  - Pack checks: e.g. contamination, in date, correct pack type
  - Venepuncture

Blood Collection

- Constant monitoring during donation
  - Blood flow
  - Agitation of pack
  - Collection time
  - Volume collected
- Sample collection
  - Identity checks
  - Correct handling
  - Labelling

Care of the Donor

- The donor as a customer
- Donor care - before, during and after donation
  - Donating blood should be a pleasant experience
  - The venue must be a safe place for the donor
  - The venue must be comfortable - temperature, surroundings
  - Staff must be trained in interpersonal skills
- Adverse reactions
  - Facilities to deal with any reactions during or after donation
Handling of Donations and Samples (1)

- Donated blood and samples must be handled appropriately before processing/testing and storage.
- Appropriate temperature
  - Storage
  - Transportation

Handling of Donations and Samples (2)

- Clean and secure environment
  - Prevention of contamination
  - Prevention of interference
  - Prevention of unauthorized removal
  - Prevention of inadvertent clinical use

Quality Issues at Mobile Sessions (1)

- Quality system applies equally to both static and mobile sessions.
- Logistics are more complex for mobile sessions: e.g.
  - Transportation of staff and equipment
  - Packing and unpacking of all session equipment, documents, consumables and disposables
  - Suitability of venue
  - Confidentiality
  - Support may be far away
Quality Issues at Mobile Sessions (2)

- Venue environment is not so easy to control
  - Cleanliness
  - Security
  - Space
  - Services
- Storage and transportation
  - Temperature control

Key Points

- Quality in blood collection protects the donor and the recipient
- Quality in blood collection ensures the quality of the product

Learning Outcomes (1)

You should now be able to:
- Identify the quality issues related to the process of blood collection
- Identify specific quality issues related to blood collection at mobile donor sessions
<table>
<thead>
<tr>
<th>Learning Outcomes (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Identify the actions required to ensure quality in blood collection</td>
</tr>
<tr>
<td>- Identify the role of the quality manager in ensuring quality in blood collection</td>
</tr>
</tbody>
</table>
**QMT 11.5 Blood Collection**

### Teaching aims
To enable participants to examine the benefits of introducing a quality system to blood collection activities.

### Core topics
- The role of the quality manager in blood collection
- Monitoring of blood collection activities

### Key points
- Applying standard procedures to collection activities
- Training of blood collection staff

### Teaching focus
Ensure the participants clearly understand the role of the quality manager in blood collection.

### Learning outcomes
Participants should be able to:
- Explain the importance of good quality in blood collection
- Explain the role of the quality manager in blood collection

### Type of activity
Group work

### Materials
- Flipcharts
- Pens

### Instructions
1. Instruct participants to read the scenario.
2. Instruct the groups to form an audit team and select a team leader who will make the presentation at the end of the activity.
3. Instruct them to draft an audit checklist keeping the following questions in mind:
   - What quality system elements should be examined?
   - What quality control records should be examined during the course of the audit?
   - What hygiene and safety aspects could you investigate to prove or disprove the suspected cause of the donor’s septicaemia?
   - What role is expected of the quality manager?

### Review of the activity
- Ensure that the following have been covered in the checklist:
  - Documentation related to technique, training, records and inspection/control/monitoring of equipment used
  - Documentation of the validation of techniques and equipment: e.g. best practice for cleansing of the venepuncture site
  - General hygiene in the clinic and the blood collection process
  - Error or quality incident management system
  - Skills training for the aseptic technique and monitoring (QC) of both the technique and the cleansing solution used
- Discuss the quality manager’s role. Ensure that the participants understand that the role is one of guidance and coordination—not doing

### Time span
1 hour
A blood transfusion service has been operating for some years with no serious adverse donor reactions. The management has always seen their BTS as following safe, effective methods of blood collection.

A complaint has been lodged with the BTS that a blood donor had been taken into hospital with septicaemia. This donor donated 48 hours prior to admission and the suspected cause is poor aseptic technique during the phlebotomy.

The BTS has requested an external audit of the quality management system in the blood donor clinic as there are no trained auditors within the organization.
### QMT 11.6 Developing a Documentation System for Blood Donor Management

#### Teaching aim
To demonstrate how to develop an effective documentation system for blood donor management

#### Core topics
- Types and levels of documents required
- Traceability — donor to donation
- Confidentiality
- Monitoring and evaluation

#### Key points
- Each activity in the donor clinic, and the outcome of each activity, should be documented
- A documentation system enables the BTS to manage the blood donor programme: e.g.
  - Assists in donor recall and retention
  - Ensures traceability
  - Records and analyzes successes and failures
  - Assists in error analysis

#### Learning outcomes
Participants should be able to:
- Apply the principles of documentation in quality systems to blood donor management
- Explain the need for traceability

#### Teaching focus
- Keep the focus on simplicity of all records
- Discuss why traceability is essential
- Emphasize the importance for confidentiality

#### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Types and Levels of Documents Required (1)
5. Types and Levels of Documents Required (2)
6. Documentation for Donors (1)
7. Documentation for Donors (2)
8. Documentation about Donors (1)
9. Documentation about Donors (2)
10. Documentation at Donor Sessions
11. Documentation of Incidents (1)
12. Documentation of Incidents (2)
13. Traceability
14. Confidentiality
15. Monitoring and Evaluation
16. Key Points
17. Learning Outcomes

#### Materials
WHO Distance Learning Materials: Safe Blood and Blood Products. Module 1: Safe Blood Donation
<table>
<thead>
<tr>
<th>Related activity</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time span</td>
<td>½ hour</td>
</tr>
</tbody>
</table>

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slides 4 - 5</th>
<th>Types and Levels of Documents Required (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list the levels of documentation that should be included in the documentation system of the blood donor clinic</td>
<td></td>
</tr>
<tr>
<td>♦ Remind the participants of the levels of documentation required, as discussed in QMT 6.1</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss the examples given for each level and involve the participants by asking them to give further examples</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 6 - 7</th>
<th>Documentation for Donors (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides list the main documents that should be included in the information given to donors</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss the need and reasons for controlling some of the examples given</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 8 - 9</th>
<th>Documentation about Donors (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list the main types of documents and records that contain information about blood donors</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss some examples of the use of this information</td>
<td></td>
</tr>
<tr>
<td>♦ Involve participants by asking them for some examples of usage</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Documentation at Donor Sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some broad categories of information about blood donor sessions that should be collected and analysed</td>
<td></td>
</tr>
<tr>
<td>♦ Give some examples of the information that should be recorded about each category (e.g. venue unsuitable for a mobile clinic) and the reasons for the conclusion</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 - 12</th>
<th>Documentation of Incidents (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list the main categories of quality incidents that should be documented</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for all incidents to be recorded and investigated according to an SOP and as discussed in the presentation on error management (QMT 8.8)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the main reasons for ensuring traceability and a few broad areas that must be recorded in the donor clinic</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to begin the documentation trail from the point of donation to ensure complete traceability of all blood and blood products</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Confidentiality</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists important facts regarding confidentiality in the donor clinic</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss some of the reasons and mechanisms for ensuring confidentiality</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 15</th>
<th>Monitoring and Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the main reasons for assessing all activities in the donor clinic</td>
<td></td>
</tr>
<tr>
<td>♦ Give some examples for each category listed</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for analysis of the findings in order to achieve continual improvement</td>
<td></td>
</tr>
</tbody>
</table>
Developing a Documentation System for Blood Donor Management

WHO/QMT 11.6

Teaching Aim

- To demonstrate how to develop an effective documentation system for blood donor management

Core Topics

- Types and levels of documents required
- Traceability – donor to donation
- Confidentiality
- Monitoring and evaluation
Types and Levels of Documents Required (1)

- Blood donor management is dependent on an effective documentation system
  - Documents must be carefully designed
  - Documents must be kept up-to-date
- Level 1 and 2 documents define the overall donor management system
  - Policies and plans

Types and Levels of Documents Required (2)

- Level 3 documents define criteria and procedures to be followed
  - Procedures define how to perform activities
  - Criteria define precise requirements
  - Guidelines provide a framework to work within
- Level 4 documents record data and provide information
  - Forms and registers are used to record data
  - Leaflets, posters, etc. provide basic information to donors

Documentation for Donors (1)

Documents to give information to donors

- General advice
  - Pre- and post-donation
  - Information about giving blood
- Deferral information
  - Self-deferral on the basis of medical condition
  - Self-deferral on the basis of risk behaviour
Documentation for Donors (2)

- Donor recruitment information
  - General recruitment information to increase awareness
  - Donor retention information for all donors
  - To encourage donors to recruit other donors

Documentation about Donors (1)

Documents used to record information about donors

- Identity
  - Name, address, date of birth, etc.

- Medical information
  - All relevant history
  - Deferral information

Documentation about Donors (2)

- Donation history
  - Number of donations
  - Donation dates
  - Any incidents during donation e.g. reactions, fall
Documentation at Donor Sessions

Documents used to record information about donor sessions
- Venue assessment
- Staff
- Equipment
- Material
  - Lot numbers
  - Expiry dates

Documentation of Incidents (1)

- Documentation system to record incidents at sessions and specific donor issues
  - Errors
  - Accidents
  - Donor complaints
  - Donor feedback

Documentation of Incidents (2)

- Full record of the event/issue and any action taken
  - Investigation
  - Findings
  - Outcomes
  - Changes to practice
Traceability

- Traceability is one of the driving forces for ensuring complete documentation in the transfusion process, both in the BTS and the hospital.
- Traceability is one of the key elements of any quality system:
  - Full traceability from 'vein to vein' is required
  - Full records of donor identity and donation number
  - Full records of all events associated with the donation process

Confidentiality

- Confidentiality is critical in the management of blood donors.
- All donor information is privileged and must be kept confidential:
  - Records must be kept secure at all times
  - Only designated staff should have access to records

Monitoring and Evaluation

- Analysis of data collected to determine effectiveness of strategies and activities:
  - Recruitment campaigns
  - Donor session analysis
  - Complaints
  - Errors
- Audits of donor management activities:
  - Findings
  - Corrective action required
Key Points

- Each activity in the donor clinic, and the outcome of each activity, should be documented
- A documentation system enables the BTS to manage the blood donor programme: e.g.
  - Assists in donor recall and retention
  - Ensures traceability
  - Records and analyzes successes and failures
  - Assists in error analysis

Learning Outcomes

You should now be able to:

- Apply the principles of documentation in quality systems to blood donor management
- Explain the need for traceability
**QMT 11.7 Donor Care, Satisfaction and Retention**

**Teaching aim**
To emphasize the importance of high quality donor care in ensuring donor satisfaction and retention

**Core topics**
- Donor care
- Donor satisfaction
- Donor retention
- Donor complaints

**Key points**
- The quality system should ensure that the donor is treated as an important customer
- Donor satisfaction and retention are directly influenced by the quality of donor care
- Complaints must be formally investigated both to satisfy the donor and to critically examine BTS practice

**Teaching focus**
- Introduce the concept of the donor as a customer
- Emphasize the importance of recognizing and understanding donors’ needs

**Learning outcomes**
Participants should be able to:
- Explain how high quality donor care promotes donor satisfaction which leads to retention
- Identify the actions required to ensure high quality donor care
- Explain the role of the quality manager in ensuring donor satisfaction

**Slides**
1. Title
2. Teaching Aim
3. Core Topics
4. Donor Care
5. Donor Recruitment and Selection (1)
6. Donor Recruitment and Selection (2)
7. Donor Counselling
8. The Donation Process (1)
9. The Donation Process (2)
10. Donor Satisfaction (1)
11. Donor Satisfaction (2)
12. Donor Feedback and Complaints
13. Investigating Donor Complaints
14. Outcomes of Donor Complaints
15. Donor Retention (1)
16. Donor Retention (2)
17. Key Points
18. Learning Outcomes

**Materials**
None

**Related activity**
QMT 11.8 Donor Satisfaction
<table>
<thead>
<tr>
<th>Time span</th>
<th>½ hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation notes and handling the session</td>
<td></td>
</tr>
</tbody>
</table>
| **Slide 4** Donor Care | ♦ The slide lists important points related to donor care and why it is important  
♦ Discuss each point with the participants |
| **Slides 5 – 6** Donor Recruitment and Selection (1) & (2) | ♦ The two slides list the main activities that ensure donor care at the start of the donor management process: i.e. donor recruitment and selection  
♦ Stress the importance of sensitivity and confidentiality, using some examples from scenarios of donor deferrals |
| **Slide 7** Donor Counselling | ♦ The slide lists the main activities required to ensure a quality approach to donor counselling  
♦ Discuss some examples of monitoring the counselling system |
| **Slides 8 – 9** Donation Process | ♦ The two slides list some important aspects that must be considered to ensure donor satisfaction during the donation process |
| **Slides 10 – 11** Donor Satisfaction (1) & (2) | ♦ The two slides list the important social aspects of donor satisfaction  
♦ Emphasize the role of the quality manager in ensuring social skills are developed and monitored |
| **Slide 12** Donor Feedback and Complaints | ♦ The slide deals with some important aspects of donor feedback and complaints  
♦ Emphasize the need to monitor both positive and negative feedback from donors and how both lead to continuous improvement |
| **Slide 13** Investigating Donor Complaints | ♦ The slide lists the major activities in ensuring that donor complaints are recorded and investigated and that both corrective and preventive action are taken  
♦ Emphasize the need to incorporate donor complaints into the error management system |
| **Slide 14** Outcomes of Donor Complaints | ♦ The slide provides advice on why and how donor complaints should be dealt with |
| **Slides 15 – 16** Donor Retention (1) & (2) | ♦ The first slide list important points on donor retention  
♦ The second slide emphasizes the reasons why donor retention is important  
♦ Discuss each point with the participants |
Donor Care, Satisfaction and Retention

Teaching Aim

- To emphasize the importance of high quality donor care in ensuring donor satisfaction and retention

Core Topics

- Donor care
- Donor satisfaction
- Donor retention
- Donor complaints
Donor Care

- Donors are the BTS’s “raw material”, but they are also customers
  - Donors are customers of the recruitment process
  - Donors are the BTS’s most important resource
  - Without donors, a BTS cannot function
  - All activities involving donors must include an element which acknowledges their importance
  - Donor care/safety/satisfaction is critical
- Customers must be respected and valued

Donor Recruitment and Selection (1)

- Donor care should be demonstrated at many different stages of the process of donation
- Recruitment information
  - Make clear the value of the blood donor
  - Make clear the BTS’s respect for donors

Donor Recruitment and Selection (2)

- Donor reception
- Donor selection process
  - Performed professionally and with care
  - Clarity and openness in discussing issues
  - Sensitivity and confidentiality at all times
Donor Counselling

- Pre- and post-donation information and counselling are important aspects of donor care.
- The quality system should ensure that:
  - Procedures are in place for pre- and post-donation counselling.
  - Procedures are in place for informing donors of any test results.
  - Staff are trained.
  - The system is monitored and evaluated.

Donation Process (1)

- Session venue:
  - Accessible.
  - Clean and comfortable.
  - Privacy when required (counselling).
- Staff:
  - Clean and tidy.
  - Professional and competent.

Donation Process (2)

- Process:
  - Safe.
  - Professional and efficient.
  - Not an unpleasant experience.
Donor Satisfaction (1)

- The outcome of donor care focus and activities
- Donors are happy to give blood and support the BTS
  - They understand the importance of donating
  - They feel valued
  - They are respected
  - They are acknowledged
- Donors are then willing to help "educate" others

Donor Satisfaction (2)

- Staff
  - Clearly understand the importance of the donor
  - Provide a congenial atmosphere
  - Are courteous and well trained
- Confidentiality
  - Donors feel that confidentiality has been maintained
  - Donors feel safe

Donor Feedback and Complaints

- Feedback
  - Is welcomed and acknowledged
  - Positive and negative feedback is dealt with evenly
  - Response is made to donors, where appropriate
- Complaints
  - Are taken seriously
  - May be about any area of contact with the BTS
  - May range from serious to trivial
  - Are recorded and acknowledged
Investigating Donor Complaints

- Standard procedures for handling complaints
  - Trained staff for dealing with complaints
  - Always quickly and effectively dealt with
  - Outcomes of investigations are always fed back to donors, whatever the findings
  - Measures to ensure that identified errors/problems are corrected and prevented from recurring

Outcomes of Donor Complaints

- Donor complaints may be useful in identifying areas of poor practice - poor quality
- Donors themselves are the best people to assess how they are actually treated at a donor clinic
- The BTS must always be open to criticism and be willing to learn from it
- Positive response to a complaint may make it easier to retain the donor

Donor Retention (1)

- The outcome of donor satisfaction
- Donors continue to donate regularly and become committed to the work of the BTS
- Retention is key to the sustainability of the BTS
- BTS donor activities must focus on retention
Donor Retention (2)

- Donor retention is more cost-effective than donor recruitment
- Planning collections is simpler and more effective with a base of mainly regular donors
- Regular donors are "safer" than "new" donors
  - Lower prevalence of TTI markers
  - Less likely to be at risk of TTIs

Key Points

- The quality system should ensure that the donor is treated as an important customer
- Donor satisfaction and retention are directly influenced by the quality of donor care
- Complaints must be formally investigated to both satisfy the donor and to critically examine BTS practice

Learning Outcomes

You should now be able to:

- Explain how high quality donor care promotes donor satisfaction, which leads to retention
- Identify the actions required to ensure high quality donor care
- Explain the role of the quality manager in ensuring donor satisfaction
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 11.8</th>
<th>Donor Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>♦ To encourage participants to examine any aspects of the donor selection and blood collection process that may lead to donor dissatisfaction  &lt;br&gt; ♦ To assist participants to examine those aspects of a quality system that would promote donor satisfaction</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ The importance of donor satisfaction  &lt;br&gt; ♦ Communication between the donor and the BTS</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>♦ Donor satisfaction is essential to achieve retention of voluntary donors  &lt;br&gt; ♦ All staff need to be aware of the importance of donor satisfaction</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Emphasize that donor satisfaction can be very dependent upon staff attitude and responsiveness  &lt;br&gt; ♦ Acknowledge the need for specialized communication skills in the blood donor clinic</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to:  &lt;br&gt; ♦ Explain how a quality focused approach can play a major part in ensuring blood donor satisfaction</td>
</tr>
<tr>
<td><strong>Type of activity</strong></td>
<td>Group work</td>
</tr>
<tr>
<td><strong>Materials required</strong></td>
<td>♦ Case studies  &lt;br&gt; ♦ Flipcharts  &lt;br&gt; ♦ Pens</td>
</tr>
<tr>
<td><strong>Instructions</strong></td>
<td>1 Instruct the groups to read each case study.  2 Instruct them to carry out the following for each case study:  &lt;br&gt; ♦ List the failures in the quality system that have resulted in the donors being dissatisfied  &lt;br&gt; ♦ Identify any measures that could be taken to improve donor satisfaction.</td>
</tr>
<tr>
<td><strong>Review of the activity</strong></td>
<td>Ensure that the following have been covered:  &lt;br&gt; ♦ Training of all staff in public relations  &lt;br&gt; ♦ Training of staff on how to handle customer complaints  &lt;br&gt; ♦ Training of staff in counselling (not only for counselling in relation to TTIs)  &lt;br&gt; ♦ SOPs for donor selection, donor deferral, donor counselling, customer complaints  &lt;br&gt; ♦ General hygiene and safety policy and SOPs covering those aspects</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>½ hour</td>
</tr>
</tbody>
</table>
Case Study 1

A young healthy man has presented himself for donation for the first time. He has completed all relevant forms and has so far passed through the donor selection process. However, he has recently had a sports injury and has been on a drug that requires him to be temporarily deferred for two weeks. The clinic staff member doing the screening informs him that he is deferred and to return, if he wishes, in two weeks time.

When the donor leaves the BTS, he is feeling slightly apprehensive. He thinks of telling his friends that the BTS were not very nice to him, but does not because he is worried that they will assume that he was deferred for HIV risk. He never tells anyone about his attempt to donate blood and never returns to the BTS.

Case Study 2

A blood donor who has donated 20 times has just completed his donation and is seated in the donor lounge with a drink and a few biscuits. He is reading the daily newspaper, but is distracted by two things.

Firstly, a staff member from another part of the BTS is having a private conversation with a visitor and the conversation is loud enough for the donor to follow.

Secondly, the donor sees a dirty piece of cotton wool under the table in the corner of the room. The cotton wool looks as if it has old blood stains on it. The donor points out the problem to the donor attendant who simply picks up the cotton wool, throws it in the nearest dustbin and returns to the donor kitchen to make a cup of tea for the next donor who has just finished his donation.

The donor who pointed out the problem leaves the BTS rapidly without finishing his drink and biscuits and never returns.

Case Study 3

A blood donor who has recently given blood telephones the BTS out of normal working hours. He has done this because, two days after donating, he suddenly became very ill and is concerned that his blood should not be used for transfusion.

The following conversation takes place between the laboratory technician on duty:

Technician  Hello.
Donor  Is that the blood transfusion service?
Technician  Yes.
Donor  I wonder if you could help me? I donated blood three days ago and the sister who bled me was Sister Anne. Could I speak to her?
Technician  She is not here and the clinic isn’t open today.
Donor: Oh! Well, maybe you could help me. Yesterday I became very ill and I don’t think you should use my blood.

Technician: I don’t know what to do and besides I am too busy. Please phone on Monday.

Donor: Well, I really am quite worried about my blood. Are you sure there is nothing you can do?

Technician: Look. I told you I’m too busy! And there is no one here to help you. Phone on Monday.

Laboratory technician hangs up the phone.
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 11.9</th>
<th>Identifying and Monitoring Critical Control Points in Blood Donor Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To identify the critical control points for assessing the processes in blood donor management</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Using flowcharts to identify critical control points in the process of blood donor management  
♦ Indicators and tools for monitoring and controlling the blood donor management process |
| **Key points** | ♦ The selection of donors is the first step in ensuring the safety of the blood supply  
♦ The quality of the blood collection process may directly affect the quality of the raw material |
| **Teaching focus** | ♦ Emphasize the reasons for monitoring  
♦ Ensure that appropriate monitoring tools are identified  
♦ Focus on the key indicators |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the critical control points in the process of blood donor management  
♦ Identify indicators and appropriate tools for monitoring the critical control points in the process of blood donor management |
| **Type of activity** | Group work |
| **Materials** | ♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 Instruct the participants to:  
♦ Prepare a flowchart of the blood donor management system  
♦ Identify the critical control points and justify why they have chosen each particular control point  
♦ Identify indicators at each control point and suggest some tools for monitoring the indicators. |
| **Review of the activity** | ♦ Ensure the flowcharts are understandable  
♦ Ensure the critical control points are justifiable  
♦ Encourage open discussion on the critical control points and the indicators and monitoring tools suggested |
| **Time span** | 1½ hours |
Module 12
Quality Systems in Laboratory Testing
### QMT 12.1 Introduction to Quality Systems in Laboratory Testing

**Teaching aim**
To review the elements of a quality system in relation to laboratory testing

**Core topics**
- Elements of a quality system as applied to laboratory testing
- Quality issues in laboratory testing
  - Equipment
  - Samples
  - Selection and use of reagents/test kits
  - Quality control
  - Laboratory documents
  - Handling of test results

**Key points**
- A quality system is essential in the laboratory to ensure the correct results for the correct donation/donor and patient
- The quality system in the laboratory should cover:
  - Organization and staff
  - Facilities and equipment
  - Reagents/test kits
  - Documentation
  - Samples
  - Handling of test results
  - Quality control
  - Assessment

**Teaching focus**
Emphasize that all laboratories have similar quality needs

**Learning outcomes**
Participants should be able to:
- Identify the actions required to ensure quality in laboratory testing
- Identify the role of the quality manager in ensuring quality in laboratory testing

**Slides**
1. Title
2. Teaching Aim
3. Core Topics
4. Need for Quality Systems (1)
5. Need for Quality Systems (2)
6. Elements of a Quality System (1)
7. Elements of a Quality System (2)
8. Elements of a Quality System (3)
9. Elements of the Quality System (4)
10. Equipment
11. Samples (1)
12. Samples (2)
13. Selection and Use of Reagents/Test Kits
14. Laboratory Quality Control
<table>
<thead>
<tr>
<th>Slide</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 - 5</td>
<td>The presentation is an introduction to the module. Do not go into too much detail as each aspect is dealt with in detail in the presentations that follow. They two slides list the major reasons for introducing quality systems in the laboratory. Discuss some of the consequences of the possible errors listed on slide 5.</td>
</tr>
<tr>
<td>6 - 9</td>
<td>The slides remind the participants of the main elements of the quality system and give some examples in the laboratory.</td>
</tr>
<tr>
<td>10</td>
<td>The slide reminds participants of essential activities related to equipment. Remind participants of the knowledge they gained in QMT 8.4.</td>
</tr>
<tr>
<td>11 - 12</td>
<td>The two slides give the rationale for including samples in the quality system and some examples of checks that should be carried out. Invite participants to give any other examples of checks that should be carried out on samples received in the testing laboratory.</td>
</tr>
<tr>
<td>13</td>
<td>The slide lists the major elements in the selection and use of laboratory reagents and test kits. The subject is dealt with in detail in QMT 12.2 and QMT 12.3.</td>
</tr>
<tr>
<td>14</td>
<td>The slide introduces the main elements of laboratory quality control. The subject is dealt with in more detail in QMT 12.2 and QMT 12.3.</td>
</tr>
<tr>
<td>15 - 17</td>
<td>The two slides list the main areas to consider when applying the documentation system to the laboratory. More detail is given in QMT 12.5.</td>
</tr>
<tr>
<td>Slide 18</td>
<td>Handling of Test Results</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>• The slide lists important aspects of handling laboratory results</td>
<td></td>
</tr>
<tr>
<td>• Explain the term ‘turn-around time’ and emphasize the need to monitor and control this aspect</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 19</th>
<th>Monitoring and Using the Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The slide lists the activities that will assist in assessing the quality system in the laboratory</td>
<td></td>
</tr>
<tr>
<td>• Remind participants of SPC and the use of simple tools to monitor the data collected</td>
<td></td>
</tr>
</tbody>
</table>
Introduction to Quality Systems in Laboratories

Teaching Aim

To review the elements of a quality system in relation to laboratory testing

Core Topics

- Elements of a quality system as applied to laboratory testing
- Quality issues in laboratory testing
  - Equipment
  - Samples
  - Selection and use of reagents/test kits
  - Quality control
  - Laboratory documents
  - Handling of test results
Need for Quality Systems (1)

- Quality systems are required in the laboratory to ensure consistent and accurate results
- Absence of quality systems in the laboratory leads to inaccurate results

Need for Quality Systems (2)

- Consequences of inaccurate results include
  - Wrong result
  - Wrong unit identified as seropositive
  - Wrong unit discarded
  - Seropositive unit issued
  - Wrong patient informed about sero-status

Elements of a Quality System (1)

- Organizational management
- Training
- Documentation
- Assessment
- Inputs
- Outputs
- Standards
### Elements of a Quality System (2)

- Organizational management
  - Quality policy
  - Staff
  - Responsibilities
  - Safety policy
  - Hygiene
- Quality standards
  - Testing strategies

### Elements of a Quality System (3)

- Documentation in laboratories
  - SOPs
  - Maintenance and calibration records
  - Test results
  - Quality control results

### Elements of a Quality System (4)

- Training of staff
  - According to SOPs
  - Certified as competent
- Assessment
  - Validation of equipment and procedures
  - Monitoring and evaluation of test results
  - External quality assessment
Equipment

- Evaluated
- Validated
  - Does it do what you want it to do?
- Calibrated
- Maintained

Samples (1)

Samples are the ‘inputs’ to the testing process – a poor quality sample leads to poor quality results

- Clear identification
  - Importance for all types of samples
- Confidentiality
  - Coded identification for donations

Samples (2)

- Quality
  - Correct type of sample: e.g. clotted
  - Sufficient volume
  - Not damaged: e.g. haemolysis
### Selection and Use of Reagents/Test Kits

- Evaluated
- Methodology validated
- Controlled during routine use

### Laboratory Quality Control

- **Controls**
  - Reagent/test kit controls (manufacturer’s)
  - Internal
  - External
- **Proficiency testing (competency assessment)**

### Laboratory Documents (1)

- **Testing strategies**
  - Confirmatory tests
  - Methodology
- **Protocols**
  - Specimen identification
  - Confidentiality
Laboratory Documents (2)

- SOPs: e.g.
  - Inspection of incoming materials
  - Equipment maintenance and calibration
  - Validation
  - Regular kit or reagent control
  - Sample processing
  - Result interpretation
  - Safety

Laboratory Documents (3)

- Records: e.g.
  - Equipment maintenance and calibration
  - Validation
  - Control charts
  - Test results
  - Training

Handling of Test Results

- Turn-around time
- Authorization
- Archiving and storage
- Confidentiality
Monitoring and Using the Data

- Control of processes and procedures
- Improved quality outcomes
- Validation and re-validation of methodology and test kits/reagents
- Early detection of problems

Key Points (1)

- A quality system is essential in the laboratory to ensure the correct results for the correct donation/donor and patient

Key Points (2)

- The quality system in the laboratory should cover:
  - Organization and staff
  - Facilities and equipment
  - Reagents/test kits
  - Documentation
  - Samples
  - Handling of test results
  - Quality control
  - Assessment
## Learning Outcomes

You should now be able to:

- Identify the actions required to ensure quality in laboratory testing
- Identify the role of the quality manager in ensuring quality in laboratory testing
PRESENTATION

<table>
<thead>
<tr>
<th>QMT 12.2</th>
<th>Evaluation and Use of Immunohaematology Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To demonstrate how to apply quality to the evaluation and use of immunohaematology (IH) reagents</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Definitions  
♦ Selection and evaluation  
♦ Validation  
♦ Control during routine use |
| **Key points** | ♦ Selection of immunohaematology reagents is a process that needs to be planned carefully  
♦ The characteristics that should be examined include specificity, sensitivity, potency and avidity  
♦ Overall performance depends on a number of factors, including methodology and staff  
♦ Testing needs and the resources available to meet those needs must be taken into account in the selection of reagents |
| **Teaching focus** | ♦ Be aware of the limitations on procurement in different countries  
♦ Promote the ideal, with an acceptance of the reality |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the actions required to ensure quality in the evaluation and use of immunohaematology reagents  
♦ Identify the role of the quality manager in the evaluation and use of immunohaematology reagents |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Definitions (1)  
5 Definitions (2)  
6 Need for Selection of IH Reagents  
7 Principles of Selection of IH Reagents (1)  
8 Principles of Selection of IH Reagents (2)  
9 Range of Reagents (1)  
10 Range of Reagents (2)  
11 Selection of Reagents (1)  
12 Selection of Reagents (2)  
13 What Determines Overall Performance?  
14 Evaluation and Final Selection (1)  
15 Evaluation and Final Selection (2)  
16 Validation of Anti-Sera  
17 Validation of Red Cell Reagents  
18 Control During Routine Use (1) |
### Materials
None

### Related activity
QMT 12.4 Selecting Reagents and Test Kits

### Time span
¾ hour

#### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slides 4 - 5</th>
<th>Definitions (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list the definitions of the characteristics that must be validated for all immunohaematology reagents</td>
</tr>
<tr>
<td></td>
<td>♦ Ensure participants are clear about the definitions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Need for Selection of Immunohaematology Reagents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists the main reasons for ensuring that a selection process is in place for all immunohaematology reagents</td>
</tr>
<tr>
<td></td>
<td>♦ Give some examples of each point</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 7 - 8</th>
<th>Principles of Selection of IH Reagents (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list the main principles to be applied when evaluating and selecting reagents</td>
</tr>
<tr>
<td></td>
<td>♦ Remind participants of the information given in QMT 8.2 and the experience they gained in the activity QMT 8.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 9 - 10</th>
<th>Range of Reagents (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The two slides reminds the participants of the various reagents used in immunohaematological tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 - 12</th>
<th>Selection of Reagents (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list the important questions that must be asked and answered in the evaluation and validation process</td>
</tr>
<tr>
<td></td>
<td>♦ Involve participants in the presentation by asking them to give some justification for the questions that are asked</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>What Determines Overall Performance?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists some further influences on the selection of immunohaematology reagents</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 14 - 15</th>
<th>Evaluation and Final Selection (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ These two slides list the major activities in selecting immunohaematology reagents</td>
</tr>
<tr>
<td></td>
<td>♦ Review the steps for evaluation and validation that were covered in QMT 8.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 16</th>
<th>Validation of Anti-sera</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists the main characteristics that are examined during the validation process</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss each characteristic and use some examples to illustrate the points</td>
</tr>
<tr>
<td>Slide 17</td>
<td>Validation of Red Cell Reagents</td>
</tr>
<tr>
<td>----------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>♦ The slide lists the main characteristics that are examined during the validation process</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each characteristic, again using examples to illustrate the point</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the importance of using international reference documents or standards for establishing national or local specifications for all immunohaematology reagents: e.g. Council of Europe, American Association of Blood Banks</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 18 – 20</th>
<th>Control During Routine Use (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These three slides list the important characteristics that should be monitored for control during routine use</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for correct storage and discuss some simple mechanisms for ensuring correct storage during routine use, with particular reference to the crossmatch laboratory</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 21</th>
<th>Role of the Quality Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Emphasize the role of the quality manager with particular reference to the need to ensure effective systems are in place</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss the active role the quality manager can play in monitoring control during routine use</td>
<td></td>
</tr>
</tbody>
</table>
Evaluation and Use of Immunohaematology Reagents

Teaching Aim

To demonstrate how to apply quality to the evaluation and use of immunohaematology reagents

Core Topics

- Definitions
- Selection and evaluation
- Validation
- Control during routine use
Definitions (1)

- **Avidity**
  - Speed with which a particular antibody combines with the corresponding antigenic determinant

- **Specificity**
  - The ability of an antibody to recognize its specific antigen only

Definitions (2)

- **Sensitivity**
  - Measure of the ability to detect the weakest possible expression of an antigen

- **Potency**
  - Measure of the strength of an antibody
  - **Titre of the antibody, the reciprocal of the greatest dilution, which gives agglutination of red cells of the appropriate group**

Need for Selection of IH Reagents

- Directly contributes to the safety of the blood supply
- Avoids the possibility of unethical business practices: e.g. counterfeit or diluted reagents
- Ensures reliable results
Principles of Selection of IH Reagents (1)

- Must be of high quality BUT also cost-effective
- Done on the basis of laboratory and quality requirements, not cost alone
  - Cheap reagents often actually cost more because of poor specificity and failed tests

Principles of Selection of IH Reagents (2)

- Must do what is required of them
- Ensure continuous and reliable supply
- Ensure suitability for methodology and available resources

Range of Reagents (1)

- Anti-sera and cells used for ABO blood grouping
- Anti-sera used for Rh typing
- Anti human globulin
- Other reagents: e.g. Low Ionic Strength Saline (LISS)
Range of Reagents (2)

- Anti-sera used for red cell phenotyping
- Red cells used for detection and identification of red cell antibodies

Selection of Reagents (1)

- What will the reagent be used for?
  - Donation/donor testing
  - Patient testing
- How is it to be used?
  - Manual/automated, large numbers/small numbers
  - Methodology: e.g. tube, slide, micro-titre plate
- Who is going to use it?

Selection of Reagents (2)

- What constraints are there?
  - Resources available
  - Reagents available
  - Time scale for results
  - Existing systems to interface with and any future plans: e.g. automated equipment
What Determines Overall Performance?

- Specificity, sensitivity, potency and avidity are key factors - but other factors also need to be considered: e.g.
  - Ease of use
  - Sample quality
  - Equipment performance
  - Clear instructions
  - Competence of staff

Evaluation and Final Selection (1)

- Define specific requirements for the IH reagent
- Collect all available relevant data
- Assess on paper against specific requirements and list the most suitable
- Prepare a validation protocol for laboratory assessment

Evaluation and Final Selection (2)

- Validate the most suitable IH reagent/s
- Review the results
- Select the IH reagent
Validation of Anti-Sera

- Appearance
- Specificity
  - False reactions
- Potency (titre)
- Sensitivity
  - Heterozygous or weak expressions of red cell antigens: e.g. Anti-A versus A\(_2\)B cells
- Avidity

Validation of Red Cell Reagents

- Appearance
- Antigens present
- Specificity
  - False reactions
- Polyagglutination
- Haematocrit

Control During Routine Use (1)

- Is the reagent performing correctly?
  - According to manufacturer’s specifications
  - As expected following laboratory evaluation
  - Consistently
  - Reliably
Control During Routine Use (2)

- Is the reagent being used correctly?
  - Many problems are due to the user — NOT the manufacturer
  - SOPs must be validated
  - Staff must follow SOPs

Control During Routine Use (3)

- Validation protocol on receipt in the laboratory
  - Checks on receipt
  - Specifications for release into routine use
- Quality control in routine use
  - For every batch of tests
  - Regularly: e.g. daily
- Storage conditions
  - During use
  - Stock

Role of the Quality Manager

- Ensuring systems are in place for:
  - Evaluation
  - Validation
  - Quality control
- SOPs are in place and used
- Results of validation, re-validation and quality control are analysed and the analysis is used for improvement
Key Points (1)

- Selection of immunohaematology reagents is a process that needs to be planned carefully.
- The characteristics that should be examined include specificity, sensitivity, potency and avidity.

Key Points (2)

- Overall performance depends on a number of factors, including methodology and staff.
- Testing needs and the resources available to meet those needs must be taken into account in the selection of reagents.

Learning Outcomes

You should now be able to:
- Identify the actions required to ensure quality in the evaluation and use of immunohaematology reagents.
- Identify the role of the quality manager in the evaluation and use of immunohaematology reagents.
<table>
<thead>
<tr>
<th>QMT 12.3</th>
<th>Evaluation and Use of Test Kits for Transfusion-Transmissible Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To demonstrate how to apply quality to evaluation and use of test kits for transfusion-transmissible infections (TTIs)</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Definitions  
♦ Selection and evaluation  
♦ Validation  
♦ Control during routine use |
| **Key points** | ♦ The basic principles of selection and evaluation apply to all test kits used in the BTS  
♦ Batch testing is essential  
♦ Other factors influence choice  
  – Constraints  
  – Resources |
| **Teaching focus** | ♦ Be aware of the limitations on procurement in different countries  
♦ Promote the ideal, with an acceptance of the reality  
♦ Demonstrate the potential false economy of using cheap test kits |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the actions required to ensure quality in the evaluation and use of TTI test kits  
♦ Identify the role of the quality manager in the evaluation and use of TTI test kits |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Sensitivity  
5 Calculation of Sensitivity  
6 Specificity  
7 Calculation of Specificity  
8 Selection of Test Kits (1)  
9 Selection of Test Kits (2)  
10 Selection of Test Kits (3)  
11 Selection of Test Kits (4)  
12 Selection of Test Kits (5)  
13 What Determines Overall Performance?  
14 Evaluation and Final Selection (1)  
15 Evaluation and Final Selection (2)  
16 Validation  
17 Control During Routine Use (1)  
18 Control During Routine Use (2)  
19 Control During Routine Use (3)  
20 Role of the Quality Manager |
<table>
<thead>
<tr>
<th>Key Points</th>
<th>Learning Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>22</td>
</tr>
</tbody>
</table>

**Materials**
None

**Related activity**
QMT 12.4 Selecting Reagents and Test Kits

**Time span**
¾ hour

**Presentation notes and handling the session**

<table>
<thead>
<tr>
<th>Slides 4 - 5</th>
<th>Sensitivity &amp; Calculation of Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The first slide gives a definition and explanation of sensitivity</td>
<td></td>
</tr>
<tr>
<td>♦ Introduce the definition and use slide 5 to further define the meaning of sensitivity, demonstrating how this is calculated</td>
<td></td>
</tr>
<tr>
<td>♦ Explain that the term &quot;True positives&quot; refers to the number of true positives as detected by the test being analysed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 6 - 7</th>
<th>Specificity &amp; Calculation of Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Slide 6 gives a definition and explanation of specificity as applied to a analytical test</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss the differences between defining sensitivity and specificity for TTI testing and IH reagents</td>
<td></td>
</tr>
<tr>
<td>♦ Slide 7 shows how to calculate specificity</td>
<td></td>
</tr>
<tr>
<td>♦ Explain that the term &quot;True negatives&quot; refers to the number of true negatives as detected by the test being analysed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 8 - 12</th>
<th>Selection of test kits (1) – (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The five slides list the essential areas that should be examined during evaluation, selection and validation of test kits for TTls</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point emphasizing the similarities and differences between the selection of IH reagents and test kits for TTls</td>
<td></td>
</tr>
<tr>
<td>♦ Give some examples to demonstrate how test kits with poor specificity can increase costs</td>
<td></td>
</tr>
<tr>
<td>♦ Remind participants of the general principles of evaluation and validation as given in QMT 8.2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>What Determines Overall Performance?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some further influences on the selection of test kits for TTls</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss the similar and different considerations that need to be taken into account in the selection of IH reagents and TTI test kits</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 14 - 15</th>
<th>Evaluation and Final Selection (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides list the major activities in selecting test kits for TTls</td>
<td></td>
</tr>
<tr>
<td>♦ Demonstrate how the principles of evaluation, validation and selection should be applied equally to both IH reagents and TTI test kits</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 16</th>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide lists the main areas to cover during validation</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants, giving examples where possible</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 17 - 19</th>
<th>Control During Routine Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The three slides give some advice on the various aspects that should be controlled during routine use</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 20</th>
<th>Role of the Quality Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the main areas that should be ensured by the quality manager</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the role as a coordinating one</td>
<td></td>
</tr>
</tbody>
</table>
Evaluation and Use of Test Kits for Transfusion-Transmissible Infections

Teaching Aim

- To demonstrate how to apply quality to the evaluation and use of test kits for transfusion-transmissible infections (TTIs)

Core Topics

- Definitions
- Selection and evaluation
- Validation
- Control during routine use
Sensitivity

- The ability of an assay/reagent to detect very small amounts of analyte
- The ability of a test to detect positive cases (the absence of false negatives)
  - Probability of an assay detecting all infected individuals

Calculation of Sensitivity

- 100 sera are tested by a reference test
  - 5 sera are true positives
  - 95 sera are true negatives
- The test you use detects only 4 positives – one false negative
- Sensitivity = \( \frac{\text{True positives}}{\text{True positives} + \text{false negatives}} \times 100 \)
- In the above case = \( \frac{4}{4 + 1} \times 100 = 80\% \)

Specificity

- The degree of false reactivity associated with an assay/reagent
- The ability of the test to identify all negatives correctly: i.e. produces no false positives
Calculation of Specificity

- 100 sera are tested by a reference test
  - 5 sera are true positives
  - 95 sera are true negatives
- The test you use detects 6 positives - one false positive
- Specificity = \( \frac{\text{True negatives}}{\text{True negatives} + \text{false positives}} \times 100 \)
- In the above case = \( \frac{94}{94 + 1} \times 100 = 98.9\% \)

Selection of Test Kits (1)

- Directly contributes to the safety of the blood supply
- Must be of high quality, reliable and consistent
- Must do what is required of them

Selection of Test Kits (2)

- Should be selected on the basis of laboratory/quality requirements, not cost alone
  - Cheap tests kits often actually cost a lot more because of poor specificity and failed test runs
- Kit size
  - Number of tests per kit
  - Different sizes available
  - Other reagents in the kit: e.g. diluent
WHO/QMT 12.3

Selection of Test Kits (3)

- Shelf life
  - Overall shelf life of the kit and all reagents in the kit
  - Life of reagent when delivered
  - Time between ordering and delivery

- Robustness during transportation
  - Time to ship from storage centre to user (door to door)
  - Storage/handling requirements during transport
  - Actual conditions during transport

Selection of Test Kits (4)

- What is the assay used for?
  - Number of tests and frequency of testing

- How will it be used?
  - Manual or automated
  - Methodology

- Who will use it?

Selection of Test Kits (5)

- What constraints are there?
  - Resources
  - Methodology
  - What sensitivity?
  - What specificity?
  - National regulations
  - Testing strategy
What Determines Overall Performance?

- Specificity and sensitivity are key factors - BUT other factors should be considered: e.g.
  - Ease of use
  - Sample type and quantity
  - Sample/reagent addition checks
  - Available technology and methodology
  - Clear instructions
  - Competence of staff

Evaluation and Final Selection (1)

- Define specific requirements for the test kit
- Collect all available relevant data
- Assess on paper against specific requirements and list the most suitable
- Prepare a validation protocol for laboratory assessment

Evaluation and Final Selection (2)

- Validate most suitable selected test kit
- Review results
- Select test kit
Validation

- Validate assay itself against known, fully characterized material
- Review available data
  - Evaluation by other laboratories
  - List of test kits evaluated by WHO
- Equipment to be used, if relevant

Control During Routine Use (1)

- Is the assay performing correctly?
  - According to manufacturer’s specifications
  - As expected following laboratory evaluation
  - Consistently
  - Reliably

Control During Routine Use (2)

- Is the assay being used correctly?
  - Many problems are due to the user, NOT the manufacturer
  - Staff must follow SOPs
  - SOPs must be validated
  - Equipment must be properly maintained and calibrated
Control During Routine Use (3)

- Validation on receipt in the laboratory
  - Shelf life
  - Batch testing
- Quality control in routine use
  - For every batch of test
- Storage conditions
  - During use
  - Stock

Role of the Quality Manager

- The quality manager should ensure that:
  - Evaluation is based on sound quality and scientific principles
  - SOPs are in place and are used
  - Staff are trained and certified as competent
  - Validation and re-validation are performed
  - Data are analysed and used to:
    - Improve quality
    - Identify problems

Key Points

- The basic principles of selection and evaluation apply to all test kits used in the BTS
- Batch testing is essential
- Other factors influence choice
  - Constraints
  - Resources
### Learning Outcomes

You should now be able to:

- Identify the actions required to ensure quality in the evaluation and use of TTI test kits
- Identify the role of the quality manager in the evaluation and use of TTI test kits
## ACTIVITY

<table>
<thead>
<tr>
<th>QMT 12.4</th>
<th>Selecting Reagents and Test Kits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To provide practice in selecting reagents and test kits for specified activities</td>
</tr>
</tbody>
</table>
| **Core topics**         | ♦ General criteria for selecting reagents and test kits  
♦ Identifying the correct reagents and test kits to use |
| **Key points**          | ♦ Importance of selecting high quality, cost-effective reagents and test kits  
♦ Constraints on the selection of ideal reagents/test kits  
♦ Selection is deciding ‘fitness for purpose’ |
| **Teaching focus**      | ♦ Emphasize the balance between what is needed and what is available  
♦ Encourage discussion on different ways to solve problems |
| **Learning outcomes**   | Participants should be able to:  
♦ Analyse requirements and list key criteria for selecting test kits and/or reagents |
| **Type of activity**    | Group work |
| **Materials**           | ♦ QMT 12.4: Case Studies  
♦ Flipcharts  
♦ Pens |
| **Instructions**        | 1 Instruct the participants to carry out the instructions in each scenario. |
| **Review of the activity** | ♦ Allow the groups to compare their decision-making process for each scenario  
♦ Ensure that the selections are based on the principles discussed in QMT 12.2 and QMT 12.3 |
| **Time span**           | 1½ hours |
Selecting Reagents and Test Kits

Scenario 1
A blood transfusion service, which collects 100,000 units a year is reviewing its test kits for HIV. The technology currently in use is a semi-automated micro-titre plate system. The prevalence in the donor population is 15%. Five micro-titre test kits are to be evaluated.

1. Describe how you would do the evaluation and which characteristics should be examined.

2. If you have obtained the data below, indicate which test kit you would select and why.

<table>
<thead>
<tr>
<th>Assay</th>
<th>Sensitivity %</th>
<th>Specificity %</th>
<th>Cost/test US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test kit A</td>
<td>96.1</td>
<td>100</td>
<td>0.8</td>
</tr>
<tr>
<td>Test kit B</td>
<td>100</td>
<td>98.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Test kit C</td>
<td>97.3</td>
<td>99.9</td>
<td>1.2</td>
</tr>
<tr>
<td>Test kit D</td>
<td>100</td>
<td>97.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Test kit E</td>
<td>99.0</td>
<td>100</td>
<td>1.4</td>
</tr>
</tbody>
</table>

Scenario 2
The BTS has a policy of "Group and Hold Serum" for patients scheduled for surgery. This involves grouping the patient for ABO and RhD and a red cell antibody screen.

1. List the characteristics that should be examined in relation to the ABO antisera.

2. List the criteria you would use for selecting the antibody-screening reagents.
## QMT 12.5 Developing a Documentation System for the Laboratory

### Teaching aim
To demonstrate how to develop an effective documentation system in the laboratory

### Core topics
- Essential documentation in the laboratory
- Laboratory records
- Recording and analysing laboratory data

### Key points
- Laboratory documentation is essential for traceability
- Laboratories produce large amounts of data
- Data should be analysed and used to improve laboratory performance

### Teaching focus
- Clarify the information that needs to be documented
- Give examples of different types of documentation

### Learning outcomes
Participants should be able to:
- Identify the types of documents that are required in the laboratory
- List the essential laboratory records that should be maintained
- Identify the data that should be analysed to ensure continuous improvement

### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Recording Laboratory Data
5. Documents in the Laboratory
6. SOPs in the Laboratory (1)
7. SOPs in the Laboratory (2)
8. Records (1)
9. Records (2)
10. Laboratory Donor Records
11. Laboratory Patient Records (1)
12. Laboratory Patient Records (2)
13. Laboratory Records - Testing (1)
14. Laboratory Records - Testing (2)
15. Laboratory Records – Equipment (1)
16. Laboratory Records – Equipment (2)
17. Common Sources of Errors in Records
18. Verification of Records
19. Analyzing and Using Laboratory Data
20. Key Points
21. Learning Outcomes

### Materials
Examples of laboratory documentation
<table>
<thead>
<tr>
<th>Related activity</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
</tbody>
</table>

**Presentation notes and handling the session**

**Slide 4**
Recording Laboratory Data
- The slide lists the major reasons for establishing and maintaining a documentation system in the laboratory
- Discuss each point, emphasizing the major reasons why traceability is so important

**Slide 5**
Documents in the Laboratory
- The slide lists the major types of documents that should be kept in the laboratory
- Discuss and give some examples of each

**Slides 6 - 7**
SOPs in the Laboratory
- The two slides list many different examples of SOPs
- Involve participants in the discussion by inviting them to give more examples

**Slides 8 - 9**
Records (1) & (2)
- The slides list examples of the records that are generated in the laboratory
- Discuss each one, asking participants to give reasons why the record should be maintained

**Slide 10**
Laboratory Donor Records
- The slide lists some important points regarding donor records in the laboratory
- Emphasize the need for confidentiality, but stress the importance of maintaining traceability
- Discuss some examples of how this can be done

**Slides 11 - 12**
Laboratory Patient Records
- The slides list important points regarding patient records in the laboratory and give some examples of the types of information that should be retained
- Discuss the need to apply any local regulations on general ethical issues in the laboratory

**Slides 13 - 14**
Laboratory Records – Testing (1) & (2)
- The slides list the various kinds of records that are generated in the laboratory
- Discuss the value of the records in strengthening and improving the quality system
- Outline some of the mechanisms of archiving records, such as registers, computer disks, CD

**Slides 15 - 16**
Laboratory Records – Equipment (1) & (2)
- The slides list the main records that should be kept regarding equipment in a laboratory
- Discuss how the use of these records can assist in improving the quality system
- Outline the use of equipment records during a quality audit

**Slide 17**
Common Sources of Errors in Records
- The slide lists some of the major causes of errors in records
- Discuss each one and suggest some mechanisms that could prevent these kinds of errors

**Slide 18**
Verification of Records
- Discuss the points on the slide with particular reference to cross-checking by an independent person
- Emphasize the need to keep the records system simple, but stringent in its requirements
<table>
<thead>
<tr>
<th>Slide 19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysing and Using Laboratory Data</td>
</tr>
<tr>
<td>- The slide lists the main use of laboratory data</td>
</tr>
<tr>
<td>- Remind participants of the information discussed in QMT 8.6 and QMT 8.7</td>
</tr>
</tbody>
</table>
Developing a Documentation System for the Laboratory

Teaching Aim

- To demonstrate how to develop an effective documentation system in the laboratory

Core Topics

- Essential documentation in the laboratory
- Laboratory records
- Recording and analysing laboratory data
Recording Laboratory Data

To ensure:
- Consistency
- Reproducibility
- Traceability
- Efficiency

Who did it
When they did it
Which test they used
What the results were
Who approved the results

Documents in the Laboratory

- Policies
- SOPs
- Forms
- Records
- Safety manual

SOPs in the Laboratory (1)

Many SOPs are required: e.g.
- Test methods
- Maintenance and calibration
- Use of equipment
- Safety precautions
SOPs in the Laboratory (2)

Many SOPs are required: e.g.
- How to validate test performance
- How to interpret the test results
- How to record test results and interpretations
- How to report the test results

Records (1)

Many records are generated: e.g.
- Donor/patient
- Testing
- Equipment maintenance & calibration
- Validation of equipment and test methods

Records (2)

Many records are generated: e.g.
- Completed forms: e.g.
  - Temperature monitoring charts
- Training records
- Monitoring outcomes: e.g. charts
### Laboratory Donor Records

- Keep donor's identity confidential
  - Secure storage of records
- Allow positive traceability of donor’s results
  - Donor's name must be confidential; however, the use of unique identifiers is essential

### Laboratory Patient Records (1)

- Keep patient’s identity confidential
  - Coded identifiers
  - Secure storage of records
- Allow positive identification and a link of the sample to the patient
  - Unique identifiers essential: e.g. hospital number
  - Linked to a laboratory number

### Laboratory Patient Records (2)

- Record the date and time of sample collection and reception
- Record the requesting Medical Officer and tests requested
Laboratory Records - Testing (1)

Many records are generated: e.g.
- Donor / patient identifiers
- Test worksheets
- Reader print-outs (if applicable)
- Test reports
- Control charts

Laboratory Records - Testing (2)

Test worksheets: e.g.
- Assay / reagent name and batch number; expiry date
- Date tests were performed
- Operator identity and signature
- Results of controls and specimens
- Calculations (if applicable)
- Interpretation of results

Laboratory Records - Equipment (1)

- Instructions for use
- Calibration status
- Calibration worksheet
  - Equipment identification (unique)
  - Date of calibration
  - Operator name
  - Calculations
  - Outcome
Laboratory Records - Equipment (2)

- Calibration certificate
- Routine maintenance and calibration records
- Records of repairs

Common Sources of Errors in Records

- Inaccurate transcription
- Misinterpretation
- Fatigue, monotony
- Stress

Verification of Records

- All recording tasks performed manually should be checked independently by a second person
  - Transcriptions
  - Calculations
  - Results interpretation (including visually read assays)
  - Manual data entry for electronic record keeping
- Checking confirmed by signature and date
Analyzing and Using Laboratory Data

- Monitor processes using SPC rules
  - Use simple visualization tools
  - Plot graphs
  - Apply simple statistical tools
- Monitor to detect:
  - Trends
  - Failures
- Use information for improvement

Key Points

- Laboratory documentation is essential for traceability
- Laboratories produce large amounts of data
- Data should be analysed and used to improve laboratory performance

Learning Outcomes

You should now be able to:
- Identify the types of documents that are required in the laboratory
- List the essential laboratory records that should be maintained
- Identify the data that should be analysed to ensure continuous improvement
<table>
<thead>
<tr>
<th>QMT 12.6</th>
<th>External Quality Assessment (EQA) Schemes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To promote participation of BTS laboratories in appropriate EQA schemes</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Principles of EQA  
♦ Objectives of EQA  
♦ Benefits of EQA  
♦ Organization and Process of EQA  
♦ WHO-EQA schemes |
| **Key points** | ♦ External quality assessment provides confidence in the overall performance in the laboratory  
♦ EQA is one of the tools used to monitor and improve quality |
| **Teaching focus** | ♦ Give examples of national and international schemes  
♦ Encourage participation in EQA |
| **Learning outcomes** | Participants should be able to:  
♦ List the objectives and benefits of EQA  
♦ Define the role of EQA in a quality system  
♦ Identify the role of the quality manager in EQA |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 External Quality Assessment (EQA)  
5 Structure of EQA Schemes  
6 Objectives of EQA (1)  
7 Objectives of EQA (2)  
8 Objectives of EQA (3)  
9 Process of EQA Schemes  
10 Organization of EQA Schemes  
11 Basis of Success of EQA Schemes  
12 Role of the Quality Manager  
13 What Can the Participating Laboratory Gain?  
14 EQA Process  
15 EQA Schemes as Part of QMP (1)  
16 EQA Schemes as Part of QMP (1)  
17 Role of WHO (1)  
18 Role of WHO (2)  
19 Role of IEQA Schemes (1)  
20 Role of IEQA Schemes (2)  
21 Role of REQA Centre  
22 Key Points  
23 Learning Outcomes |
<p>| <strong>Materials</strong> | None |
| <strong>Related activity</strong> | None |</p>
<table>
<thead>
<tr>
<th>Time span</th>
<th>¾ hour</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Slide 4</strong>&lt;br&gt;External Quality Assessment</td>
<td>♦ The slide gives a definition of EQA</td>
</tr>
<tr>
<td><strong>Slide 5</strong>&lt;br&gt;Structure of EQA Schemes</td>
<td>♦ The slide shows the overall global structure of EQA schemes with particular reference to WHO schemes</td>
</tr>
<tr>
<td><strong>Slides 6 - 8</strong>&lt;br&gt;Objectives of EQA (1), (2) &amp; (3)</td>
<td>♦ The three slides list the objectives of EQA&lt;br&gt;♦ Discuss each point with the participants, explaining the reasoning behind each</td>
</tr>
<tr>
<td><strong>Slide 9</strong>&lt;br&gt;Process of EQA Schemes</td>
<td>♦ The slides show a flowchart of the movement of information and samples in a typical EQA scheme</td>
</tr>
<tr>
<td><strong>Slide 10</strong>&lt;br&gt;Organization of EQA Schemes</td>
<td>♦ The slide lists some of the decisions that must be made regarding the organization of the scheme&lt;br&gt;♦ Emphasize the need for dedicated resources, including staff to carry out some of the activities</td>
</tr>
<tr>
<td><strong>Slide 11</strong>&lt;br&gt;Basis of Success of EQA Schemes</td>
<td>♦ The slide lists some important points in ensuring the success of EQA schemes&lt;br&gt;♦ Emphasize the fact that EQA schemes should be voluntary and should lead to quality improvement NOT punishment</td>
</tr>
<tr>
<td><strong>Slide 12</strong>&lt;br&gt;Role of the Quality Manager</td>
<td>♦ The slide lists the main activities in the role of the quality manager</td>
</tr>
<tr>
<td><strong>Slide 13</strong>&lt;br&gt;What Can the Participating Laboratory Gain?</td>
<td>♦ The slide lists the main benefits of participating in an EQA scheme&lt;br&gt;♦ Emphasize the need to provide awareness training for staff that will show them how the laboratory will benefit from participation</td>
</tr>
<tr>
<td><strong>Slide 14</strong>&lt;br&gt;EQA Process</td>
<td>♦ The slide reminds participants of the information given in slide 9&lt;br&gt;♦ Discuss the new concept, introduced here, of completing a questionnaire before participating to ensure the scheme caters as best as possible for all participants’ needs</td>
</tr>
<tr>
<td><strong>Slides 15 - 16</strong>&lt;br&gt;EQA Schemes as Part of QMP (1) &amp; (2)</td>
<td>♦ The two slides explain the role of EQA in the WHO QMP</td>
</tr>
<tr>
<td><strong>Slides 17 - 18</strong>&lt;br&gt;Role of WHO (1) &amp; (2)</td>
<td>♦ The two slides provide examples of how WHO is involved in EQA schemes and the role it plays in ensuring participation</td>
</tr>
<tr>
<td><strong>Slides 19 - 20</strong>&lt;br&gt;Role of IEQA Schemes (1) &amp; (2)</td>
<td>♦ The activities of IEQA schemes are listed on the two slides&lt;br&gt;♦ Emphasize the cascade effect of IEQA to REQA to NEQA</td>
</tr>
<tr>
<td><strong>Slide 21</strong>&lt;br&gt;Role of REQA Centre</td>
<td>♦ The slide lists what participants should be able to expect from regional EQA organizers</td>
</tr>
</tbody>
</table>
External Quality Assessment (EQA) Schemes

Teaching Aim

- To promote participation of BTS laboratories in appropriate EQA schemes

Core Topics

- Principles of EQA
- Objectives of EQA
- Benefits of EQA
- Organization and process of EQA
- WHO-EQA schemes
External Quality Assessment (EQA)

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

Structure of EQA Schemes

- National EQAS
- Regional EQAS
- Joint/Other EQAS

Objectives of EQA (1)

- Monitor laboratory performance and evaluate QC measures
- Establish inter-laboratory comparability
- Improve reliability of future testing
- Ensure credibility of laboratory
Objectives of EQA (2)

- Stimulate performance improvements and promote high standards of practice
- Encourage use of standard reagents/methodology and trained personnel
- Identify common errors

Objectives of EQA (3)

- Provide mechanisms to remedy deficiencies revealed
- Facilitate information exchange
- Support accreditation
- Education through exercises, reports and meetings

Process of EQA Schemes

<table>
<thead>
<tr>
<th>Organizing laboratory</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare QA specimen</td>
<td>Examine specimen</td>
</tr>
<tr>
<td>Analyze results</td>
<td>Report results</td>
</tr>
<tr>
<td>Prepare report</td>
<td>Evaluate</td>
</tr>
</tbody>
</table>
Organization of EQA Schemes

- Frequency of distribution
- Transport of specimens
- Testing by participating laboratories
- Turnaround time
- Documentation of results and feedback
- Improvement of performance

Basis of Success of EQA Schemes

- Voluntary participation
- Confidentiality of individual report
- Avoiding provocative statements
- Identify unsatisfactory performers in groups/individuals to identify trends
- Providing educational opportunities
- Organizer acts as adviser rather than enforcer

Role of the Quality Manager

- Ensure participation
- Review the analysis of results as a tool for improvement
- Coordinate resolution of identified problems
What Can the Participating Laboratory Gain?

- Comparison of performance and results
- Minimization of errors
- Self-appraisal
- Objective evidence of quality
- Identification of training needs

EQA Schemes as Part of QMP (1)

- EQA — a recognized component of quality system
- QMT course
  - Helps participants to understand how EQA fits into a quality system
  - Introduces participants to the Regional EQA schemes of WHO
EQA Schemes as Part of QMP (2)

- EQA schemes assists in monitoring the impact of QMT courses
- Helps to identify areas for improvement and act on them with QMT follow-up courses

Role of WHO (1)

- Identify Regional EQA centres for TTI and blood group serology
- Enrol REQA centres in IEQA schemes
- Organize QMT course in REQA centre, if also the Regional Quality Training Centre

Role of WHO (2)

- Identify participants for REQA scheme
- Advocacy and technical support for EQA schemes
  - Government and professional bodies
- Funding
Role of IEQA Schemes (1)

- Support establishment of REQA schemes
  - Material
  - Training for REQA staff
  - Training at follow-up workshops for REQA participants

Role of IEQA Schemes (2)

- Ongoing involvement
  - Monitor REQA centre — validate results
  - Troubleshooting
  - Advice and practical help with development

Role of REQA Centre

- Take part in International EQA schemes (IEQAS)
- Provide EQA to the region
- Register participants in REQA schemes
- Undertake performance monitoring and offer follow-up support to participants
- Support start-up of NEQA schemes
Key Points

- External quality assessment provides confidence in the overall performance in the laboratory
- EQA is one of the tools used to monitor and improve quality

Learning Outcomes

You should now be able to:
- List the objectives and benefits of EQA
- Define the role of EQA in a quality system
- Identify the role of the quality manager in EQA
<table>
<thead>
<tr>
<th>QMT 12.7</th>
<th>Identifying and Monitoring Critical Control Points in Laboratory Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To identify the critical control points for assessing and controlling the processes in the testing laboratory</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Using flowcharts to identify critical control points in the processes in the testing laboratory ♦ Indicators and tools for monitoring and controlling the processes in the laboratory</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>♦ Ensuring a well-defined flow of work in the laboratory leads to improved quality ♦ The laboratory environment provides much data for analysis and use as indicators ♦ Indicators in the laboratory should be monitored through the use of SPC</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Emphasize the need for well-defined flowcharts ♦ Emphasize the reasons for monitoring and analysing data in the laboratory ♦ Focus on the key indicators</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to: ♦ Identify the critical control points in the processes in the testing laboratory ♦ Identify indicators and appropriate tools for monitoring the critical control points</td>
</tr>
<tr>
<td><strong>Type of activity</strong></td>
<td>Group work</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>♦ Pens ♦ Flipcharts</td>
</tr>
<tr>
<td><strong>Instructions</strong></td>
<td>1 Instruct the participants to: ♦ Prepare flowcharts for the testing laboratory for both routine donor blood group serology and routine testing for transfusion-transmissible infections ♦ Identify the critical control points and justify why they have chosen each particular control point ♦ Identify indicators at each control point and suggest some tools for monitoring the indicators</td>
</tr>
<tr>
<td><strong>Review of the activity</strong></td>
<td>♦ Ensure the flowcharts are well-defined and include all major steps ♦ Ensure the critical control points are justifiable ♦ Encourage open discussion on the critical control points and the indicators and monitoring tools suggested</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>1½ hours</td>
</tr>
</tbody>
</table>