Quality Management

Training for

Blood

Transfusion

Services

Modules 13–15
PART 2: APPLYING QUALITY MANAGEMENT IN THE BTS

MODULE 13
Quality Systems in Component Production and Management
QMT 13.1: Presentation
Introduction to quality systems in blood component production and management
QMT 13.2: Presentation
Quality monitoring of blood component production
QMT 13.3: Activity
Evaluation and monitoring of blood component production activities
QMT 13.4: Presentation
Quarantine and release
QMT 13.5: Presentation
Storage and transportation of blood components
QMT 13.6: Activity
Storage and transportation of blood components
QMT 13.7: Presentation
Blood stock management
QMT 13.8: Presentation
Developing a documentation system for blood component production
QMT 13.9: Activity
Identifying and monitoring critical control points in blood component production

MODULE 14
Quality Systems and the Clinical Interface
QMT 14.1: Presentation
Introduction to quality systems at the clinical interface
QMT 14.2: Presentation
Policy and guidelines on the clinical use of blood
QMT 14.3: Activity
The role of the BTS at the clinical interface
QMT 14.4: Presentation
Documentation in the hospital transfusion process
QMT 14.5: Activity
Designing a blood request form
Quality in the hospital transfusion process

Monitoring and evaluation of the hospital transfusion process

Haemovigilance

Identifying and monitoring critical control points for the clinical interface and the administration of blood

MODULE 15
Finalization of Participants' Action Plans and Completion of the Course

Review of the course

Laboratory/clinic visits in BTS

Completing individual action plans

Discussion of individual action plans

Review of quality systems

Post-course assessment

Course evaluation

Final discussions
PART 2

APPLYING QUALITY MANAGEMENT IN THE BTS

Modules 13–15
Module 13
Quality Systems in Component Production and Management
### Teaching aim
To review the elements of a quality system in relation to blood component production and management

### Core topics
- Elements of a quality system as applied to blood component production and management
- Quality issues in blood component production and management
  - Equipment
  - Selection of methodology
  - Labelling
  - Quarantine and release
  - Blood stock management
  - Storage and transportation
  - Issue of blood components
  - Documents
  - Quality monitoring

### Key points
- All the activities associated with the processing of blood components must be well-controlled and fully documented
- Quality systems must be in place to ensure that:
  - Untested or unsuitable blood components are segregated from those that are suitable for use
  - Blood components are stored and transported in a way that prevents deterioration
  - Blood stocks are adequately managed

### Teaching focus
- Remember that some BTSs do not prepare blood components
- Provide examples of product specifications
- Reinforce the use of flowcharts in analysing processes

### Learning outcomes
Participants should be able to:
- Identify the actions required to ensure quality in blood component production and management
- Identify the role of the quality manager in ensuring quality in blood component production and management

### Slides
1. Title
2. Teaching Aim
3. Core Topics (1)
4. Core Topics (2)
5. Elements of a Quality System (1)
6. Elements of a Quality System (2)
7. Elements of a Quality System (3)
8. Blood Components
9. Facilities and Equipment
<table>
<thead>
<tr>
<th>Slide</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Slides 5 - 7</strong>  Elements of a Quality System (1), (2) &amp; (3)  ♦ These three slides remind participants of the elements of a quality system  ♦ Slides 6 and 7 list each element and give examples in the component production area  ♦ Discuss these examples with participants  ♦ Some of the elements are dealt with in more detail in later presentations</td>
<td></td>
</tr>
<tr>
<td><strong>Slide 8</strong>  Blood Components  ♦ The slide lists three important points that must be kept in mind when designing a quality system for the blood component area  ♦ Stress that participants from centres which do not yet prepare blood components should apply the principles outlined in this session to whole blood</td>
<td></td>
</tr>
<tr>
<td><strong>Slide 9</strong>  Facilities and Equipment  ♦ The slide lists important issues relating to the equipment used in the blood component area  ♦ Remind participants that all the principles they learned about in QMT 8.4 apply to the equipment used in component preparation</td>
<td></td>
</tr>
<tr>
<td><strong>Slide 10</strong>  Selection of Methodology  ♦ The slide lists the main considerations regarding methodology  ♦ Emphasize the need to evaluate and validate all methods that will be used in this area  ♦ Discuss some of the quality implications and alternatives if a closed bag system is unavailable</td>
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</tbody>
</table>

**Materials**  None  
**Related activity**  None  
**Time span**  ¾ hour  

**Presentation notes and handling the session**
<table>
<thead>
<tr>
<th>Slides 11 – 13</th>
<th>Labelling (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ These three slides list important information and quality requirements regarding labelling in blood component production</td>
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<tr>
<td></td>
<td>♦ Emphasize the need for product status to be clearly identifiable</td>
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<td></td>
<td>♦ Discuss methods of validating labels</td>
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<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Blood Stock Management</th>
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<tbody>
<tr>
<td></td>
<td>♦ The slide lists the basic considerations for blood stock management</td>
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<tr>
<td></td>
<td>♦ The subject is dealt with in more detail in QMT 13.7</td>
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</table>

<table>
<thead>
<tr>
<th>Slide 15</th>
<th>Quarantine and Release</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide gives the main reasons for developing a quarantine/release procedure</td>
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<td></td>
<td>♦ More detail is given in QMT 13.4</td>
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<table>
<thead>
<tr>
<th>Slide 16</th>
<th>Storage and Transportation</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists the main reason why quality systems must be applied to the storage and transportation of blood and blood products</td>
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<td></td>
<td>♦ More detail is given in QMT 13.5</td>
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<table>
<thead>
<tr>
<th>Slide 17</th>
<th>Issue of Blood Components</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide introduces the quality requirements for the issue of blood and blood products</td>
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<table>
<thead>
<tr>
<th>Slides 18 – 19</th>
<th>Documents (1) &amp; (2)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide introduces the documentation requirements for the production of blood components</td>
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<td></td>
<td>♦ More detail is given in QMT 13.8</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 20 – 21</th>
<th>Quality Monitoring (1) &amp; (2)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists the important points regarding assessment of the quality system with regards to blood component production</td>
</tr>
<tr>
<td></td>
<td>♦ More detail is given in QMT 13.2</td>
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</table>

<table>
<thead>
<tr>
<th>Slide 22</th>
<th>Role of the Quality Manager</th>
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<tbody>
<tr>
<td></td>
<td>♦ The slide lists the main functions of the quality manager in this area</td>
</tr>
<tr>
<td></td>
<td>♦ Emphasize the role as being one of advocacy and not actual activity</td>
</tr>
</tbody>
</table>
Introduction to Quality Systems in Blood Component Production and Management

Teaching Aim

- To review the elements of a quality system in relation to blood component production and management

Core Topics (1)

- Elements of a quality system as applied to blood component production and management
- Quality issues in blood component production and management
  - Equipment
  - Selection of methodology
  - Labelling
  - Quarantine and release
Core Topics (2)

- Quality issues in blood component production and management
  - Blood stock management
  - Storage and transportation
  - Issue of blood components
  - Documents
  - Quality monitoring

Elements of a Quality System (1)

- Organizational management – policy, staff
- Quality standards - product specifications
- Documentation in blood component production and management
Elements of a Quality System (3)

- Training of staff
- Assessment
  - Validation of procedures
  - Monitoring and evaluation of the activities in blood component production and management
  - Quality control of products
  - Validation, maintenance and calibration of equipment

Blood Components

- Must be:
  - Prepared using good manufacturing practices
  - Prepared by well-trained staff
  - Safe and effective

Facilities and Equipment

- Maintain a clean environment for processing and storage
- Maintain and calibrate equipment to ensure that the equipment used for processing and storage operates reliably and consistently
  - Speed
  - Temperature
### Selection of Methodology

- Procedures involved in components preparation
  - Centrifugation
  - Component transfer
- Normally performed using closed, multiple blood bag systems
- Methods used for the preparation of blood components must be validated

### Labelling (1)

- Labelling of products is a critical activity
- Potential for mistakes to occur must be minimized
  - Label one product at a time
  - Staff training and awareness
  - Checking system

### Labelling (2)

- Labels must be clear, concise and adhere under all processing and storage conditions
- Labels
  - Identify the type of product, donation number, expiry date
  - Status of the product
Labelling (3)

- Processed products may require re-labelling: e.g.
  - Additional donation numbers to 'new' packs
  - New identification label with a new product specific expiry date and storage conditions

Blood Stock Management

- Blood stocks must be available to meet the users' demand
- Manage blood stock:
  - First in First out (FIFO)
  - Identify the minimum stock levels and take immediate action to replenish stock
  - Increase supply, as demand increases

Quarantine and Release

- Develop a system to prevent the issue of untested or unsuitable blood products
- Untested or unsuitable blood products must be segregated from blood products that are suitable for use
Storage and Transportation

- Blood and blood products must be stored and transported under the correct conditions to ensure they remain viable, safe and clinically effective
  - Suitably packaged
  - Blood cold chain maintained

Issue of Blood Components

- Issue only those blood components that meet release criteria
- Perform quality checks on blood components before issue
- Record:
  - Who issued the blood component
  - To whom the blood component was issued
  - When the blood component was issued

Documents (1)

- Documented procedures for:
  - Processing
  - Labelling
  - Packaging
  - Storage
  - Issue
  - Distribution
  - Transportation
Documents (2)

- Processing information:
  - Raw materials used (blood packs and donation)
  - Traceability of who, what and when the process took place
  - Environmental conditions/cleaning records
  - Maintenance and calibration records
  - Staff training records
- Quality monitoring information
  - Quality control results

Quality Monitoring (1)

- Develop product specifications
  - The basic requirements that each product has to meet to be considered suitable for use
  - Specifications cover parameters such as volume, level of bioactive substances
  - Specifications may be local, national or international

Quality Monitoring (2)

- Monitor and evaluate the blood component manufacturing process
  - Quality control
  - Analyse the QC data (statistical process control charts)
  - Use SPC as a tool for improving the quality of blood components
Role of the Quality Manager

- To develop a quality system that ensures:
  - Blood components are processed according to the principles of good manufacturing practice
  - Blood components are monitored and appropriate action is taken if products do not meet specifications
  - Formal release procedures
  - Storage and transportation conditions are defined and met

Key Points

- All activities associated with the processing of blood components must be well-controlled and fully documented
- Quality systems must be in place to ensure that:
  - Untested or unsuitable blood components are segregated from those that are suitable for use
  - Blood components are stored and transported in a way that prevents deterioration
  - Blood stocks are adequately managed

Learning Outcomes

You should now be able to:
- Identify the actions required to ensure quality in blood component production and management
- Identify the role of the quality manager in ensuring quality in blood component production and management
### QMT 13.2 Quality Monitoring of Blood Component Production

#### Teaching aim
To demonstrate how to apply quality monitoring in blood component production and management

#### Core topics
- Specifications
- Incoming blood units
- Product monitoring
- Monitoring plans
- Analysis and use of results

#### Key points
- The purpose of monitoring is to answer the basic question – are we producing what we are meant to be producing?
- The parameters to be monitored need to be matched to the product and its intended use
- Monitoring is a tool to generate data – whether positive or negative – to feed back into the process
- Monitoring is an integral part of any production process

#### Teaching focus
Keep the emphasis on GMP

#### Learning outcomes
Participants should be able to:
- Identify what needs to be monitored to ensure quality in blood component production and management
- Identify the role of the quality manager in quality monitoring

#### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Questions to Be Answered
5. Quality Monitoring (1)
6. Quality Monitoring (2)
7. Quality Monitoring (3)
8. Specifications
9. Specification Parameters (1)
10. Specification Parameters (2)
11. Specification Parameters (3)
12. Specification Parameters (4)
13. Incoming blood units
14. Monitoring Plans
15. What to Monitor (1)
16. What to Monitor (2)
17. When to Monitor
18. Who Monitors?
19. How Many to Monitor?
20. Analysis and Use of Results (1)
### Materials
None

### Related activity
QMT 13.3 Evaluation and Monitoring of Blood Component Production Activities

### Time span
¾ hour

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Questions to be Answered</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists key questions that must be asked and answered regarding blood component production</td>
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</table>

<table>
<thead>
<tr>
<th>Slides 5 - 7</th>
<th>Quality Monitoring (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The three slides list important points regarding the monitoring of blood components and the processes used to produce them</td>
<td></td>
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<tr>
<td>♦ Emphasize the similarity in the principles applied, although different approaches have to be taken, depending on the product being produced</td>
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</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Specifications</th>
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</thead>
<tbody>
<tr>
<td>♦ The slide lists the important points related to setting specifications for each blood component produced</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to cross-refer to international standards to establish national standards</td>
<td></td>
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<tr>
<td>♦ Stress the need to establish realistic and achievable specifications given the differences in normal values for the donor populations</td>
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</table>

<table>
<thead>
<tr>
<th>Slides 9 - 12</th>
<th>Specification Parameters (1) – (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list some examples of the different parameters that can be applied to different blood products</td>
<td></td>
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<tr>
<td>♦ Discuss each example given, emphasizing the reasons for using a particular parameter for a particular product</td>
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</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Incoming blood units</th>
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</thead>
<tbody>
<tr>
<td>♦ The slide lists some important points regarding the inspection of incoming blood units</td>
<td></td>
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<tr>
<td>♦ Link this concept with the earlier discussion on processes when inputs and outputs were introduced in QMT 3.2</td>
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<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Monitoring Plans</th>
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</thead>
<tbody>
<tr>
<td>♦ The slide lists the important information that should be documented in the monitoring plan for each blood component</td>
<td></td>
</tr>
<tr>
<td>♦ The next two slides deal with the details of each aspect</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 17</th>
<th>When to Monitor</th>
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<tbody>
<tr>
<td>♦ The slide shows the main points to consider when deciding on when to monitor</td>
<td></td>
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<tr>
<td>♦ Discuss the meaning of &quot;release testing&quot;, stressing the importance and significance of this as applied to blood components</td>
<td></td>
</tr>
<tr>
<td>♦ Re-emphasize the need to monitor incoming blood units</td>
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</tr>
<tr>
<td>Slide 18</td>
<td>Who Monitors?</td>
</tr>
<tr>
<td>----------------</td>
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<tr>
<td>✦ Discuss the advantages and disadvantages of selecting the two categories of staff mentioned on the slide to carry out the sampling</td>
<td></td>
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<tr>
<td>✦ Stress the need to ensure that staff are correctly trained</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 19</th>
<th>How Many to Monitor</th>
</tr>
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<tbody>
<tr>
<td>✦ The slide lists the factors that must be considered during the process of deciding how many to monitor</td>
<td></td>
</tr>
<tr>
<td>✦ Give some examples of international standards that can be used to guide the decisions, such as those published by the Council of Europe</td>
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</table>

<table>
<thead>
<tr>
<th>Slides 20 – 21</th>
<th>Analysis and Use of Results (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>✦ The slides list important points regarding the analysis and use of results</td>
<td></td>
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<tr>
<td>✦ Emphasize the need to use the tools discussed in QMT 8.6</td>
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</table>
Quality Monitoring of Blood Component Production

Teaching Aim

- To demonstrate how to apply quality monitoring in blood component production and management

Core Topics

- Quality monitoring
- Specifications
- Incoming blood units
- Product monitoring
- Monitoring plans
- Analysis and use of results
Questions to Be Answered

- Do you know about the quality of the products that you are producing?
- Is it sufficient simply to produce products without monitoring their quality?
- Are you producing products that meet the required standards?

Quality Monitoring (1)

- GMP requires a monitoring system to look at the quality of the final products
- Demonstrates the quality and consistency of procedures
- Assists in detecting donor selection problems

Quality Monitoring (2)

- Identifies whether products meet specifications
- Helps to correct the procedure through standardization
Quality Monitoring (3)

- Determined by the products and their specifications
- Focus on appropriate parameters
- Depends on numbers processed
- Depends on resources available

Specifications

- Each type of product needs its own specifications
- National or international specifications may be used
- Must be appropriate to the clinical use of the product
- Must be achievable
- Must be comprehensive

Specification Parameters (1)

Examples of parameters of different products
- Whole blood
  - Volume
  - Haemoglobin concentration
- Packed red cells/plasma reduced red cells
  - Volume
  - Haematocrit
### Specification Parameters (2)

- **Fresh frozen plasma**
  - Volume
  - Levels of coagulation factors

- **Cryoprecipitate**
  - Volume
  - Factor VIII level
  - Fibrinogen level

### Specification Parameters (3)

- **Platelet concentrates**
  - Volume
  - Platelet count
  - Platelet function
  - pH
  - Red cells, leucocyte count
  - Sterility

### Specification Parameters (4)

- **Other products: e.g. irradiated blood products, leucocyte depleted, washed**
  - Parameters as appropriate
Incoming Blood Units

- Incoming blood units are the inputs to the blood component process.
- Inputs must be checked prior to processing: e.g.
  - Haemolysis
  - Volume
  - Leaking packs
  - Accurate information on the pack label
- Incoming blood units that do not meet specifications should not be further processed.

Monitoring Plans

- What to monitor
- When to monitor
- Who performs the monitoring
- How many to monitor (sample size)
- Reporting of results
- Action to be taken

What to Monitor (1)

- Depends on the product
- The level of the bio-active component
  - e.g. haemoglobin level
- The specific activity of the bio-active component
  - e.g. platelet function
What to Monitor (2)

- Labelling / other critical information
- Contamination of the product
- Volume of the product

When to Monitor

- Depends on the product
- During production
  - At critical steps
- After production
  - Release testing not monitoring
- After release for clinical use
  - Random product testing
  - Clinical response

Who Monitors?

- Sampling by components production staff
  - Easier for in-process monitoring
- Sampling by independent personnel
  - e.g. Quality Department
  - Ensures impartiality
- Whoever monitors must be appropriately trained
How Many to Monitor?

- Agreed local (national) policy
  - Percentage
  - Fixed number per day/week/month
  - Should be stated in the specifications

- Depends on numbers processed
  - Release testing rather than monitoring

- Depends on parameters measured

Analysis and Use of Results (1)

- Reporting of results
  - Results need to be communicated
  - Results need to be used (positive and negative)
  - Quality monitoring tools may be used (graphs)
  - Action may be needed

Analysis and Use of Results (2)

- Corrective action identified and implemented

- Withdrawal/recall of implicated products
Key Points (1)

- The purpose of monitoring is to answer the basic question — are we producing what we are meant to be producing?
- The parameters to be monitored need to be matched to the product and its intended use.

Key Points (2)

- Monitoring is a tool to generate data — whether positive or negative — to feed back into the process.
- Monitoring is an integral part of any production process.

Learning Outcomes

You should now be able to:

- Identify what needs to be monitored to ensure quality in blood component production and management.
- Identify the role of the quality manager in quality monitoring.
### QMT 13.3 Evaluation and Monitoring of Blood Component Production Activities

**Teaching aims**
To provide practice in analysing component production activities and identifying appropriate validation and monitoring methods.

**Core topics**
- Identifying the validation of methodology used in the production of blood components
- Identifying monitoring strategies and SPC methods

**Key points**
- Critical control points in the process need to be identified

**Learning outcomes**
Participants should be able to:
- Outline the principles of evaluation and validation for component production
- Prepare a plan for monitoring and evaluation of components

**Teaching focus**
- Ensure that the terms "evaluation" and "validation" are clearly understood
- Ensure the monitoring plans are feasible
- Ensure the monitoring plans do not interfere with the workflow

**Type of activity**
Group work

**Materials**
- Case studies
- Flipcharts
- Pens

**Instructions**
1. Instruct the participants to read the scenarios and follow the instructions given.
2. Ensure they discuss the questions that follow the case studies.

**Review of the activity**

#### Scenario 1
- Ensure evaluation and validation plans include all the necessary steps taught in QMT 8.2
- Ensure GMP principles have been applied to ensure consistency in the production of the product
- Discuss the various documents that have been suggested by the participants, emphasizing their use
- Ensure the proposed records do not interfere with the process flow or overburden the worker
- Discuss the various suggestions put forward with regard to reducing the risk of bacterial contamination

#### Scenario 2
- Ensure the participants include all the steps of error management discussed in QMT 8.8
- Keep the discussion fairly general regarding quality control measures
- Ensure participants include all the steps in implementing a maintenance and calibration plan as outlined in QMT 8.4

**Time span**
1½ hours
Scenario 1

Due to a lack of resources, the blood bank normally issues only whole blood. On occasions, a specific request is received for packed red cells. The blood bank is investigating the possibility of producing partially packed cells which are separated by allowing the red cells to settle by gravity and aseptically removing the plasma.

Instructions
1. Design an evaluation and validation plan for approving the method that has been proposed.
2. What are the key GMP elements that should be introduced in the laboratory to ensure the processing of a quality product using this methodology?
3. What documentation should be included in the evaluation and validation plan?
4. If the method is approved, what documents should be maintained to ensure the process is carried out correctly?
5. List any special considerations to reduce the risk of bacterial contamination.

Scenario 2

The BTS processes whole blood into red cell concentrates, fresh frozen plasma and random platelet concentrates. These products are issued to hospitals for administration to patients.

A formal complaint from a doctor reaches you, the quality manager, about 6 units of platelet concentrates that were given to a patient with pancytopenia. Clinical and laboratory response to the transfusion were poor.

Instructions
Discuss the following questions.
1. As quality manager, what actions would you take to resolve this complaint?
2. What quality control (QC) programme (quality monitoring) should be in place to ensure that products consistently meet specifications?
3. How would you implement a maintenance and calibration plan for equipment in the components laboratory?
Scenario 1

Question 2

The following GMP elements should be introduced in the laboratory to ensure the processing of a quality product.

1. Raw material meets specifications: e.g. the donor meets selection criteria; the blood–anticoagulant ratio should be within predetermined limits.
2. Suitable environment for the processing of blood: e.g. clean laboratory areas.
3. Suitable processing equipment: e.g. centrifuges.
4. Approved procedures.
5. Training of staff to these procedures.
6. Quality monitoring and appropriate action if the monitoring reveals poor quality output.
7. Adequate records of the process kept for traceability purposes.
8. Accurate labelling of whole blood units as well as secondary packs.
9. The use of a closed system or, alternatively, aseptic techniques during the plasma separation procedure.

Question 3

The following documentation should be included in the evaluation and validation plan.

1. Validation plan.
2. Written and approved procedure.
3. Collected data (recorded in an appropriate format).
4. Validation form.

Question 4

The following documents should be introduced to ensure that the process is carried out correctly.

1. Standard operating procedures on how to perform the work.
2. Traceability of the main activities in the process: e.g.
   - Blood collected (by whom, date of collection)
   - Blood labelled
   - Date, time and by whom unit processed
   - Blood tested (by whom, date, results).
3. Evidence that the equipment (environmental records) and facilities (maintenance and calibration records) are appropriate and maintained.
4 Evidence that staff have been trained and are competent (training records).
5 Appropriate labels (identity and status labels).
6 Quality control data to demonstrate that the process is "in control".
7 Document of approved specification.

Question 5
The following steps should be taken to ensure that blood components are processed in a way that will minimize the risks of bacterial contamination.

1 Ensure an appropriate room temperature during processing.
2 Maintain the blood cold chain.
3 Set up and maintain disinfection/cleaning programmes for:
   ♦ Equipment: e.g. centrifuges
   ♦ Work areas: e.g. work surfaces.
4 Use a closed system for the transfer of plasma, rather than an open system.
5 Enforce strict aseptic techniques during processing where the use of an open system is unavoidable.

Scenario 2

Question 1
As quality manager, you should ensure the following actions are taken to resolve this complaint.

1 Log the complaint in the complaints register.
2 Discuss the complaint with the operational manager.
3 Audit batch-manufacturing records for evidence of production problems.
4 Look at quality control results at the time of batch processing.
5 Identify whether there is a poor quality product.
6 Identify possible system deficiencies: e.g. inadequate quality control or poor GMP practices.
7 Take action required to prevent any recurrence of the problem.
8 Document this action (corrective action request).
9 Provide feedback to the complainant, ensure that the low platelet count is not due to patient causes and inform the product manager.

Question 2
The quality control programme (quality monitoring) should include the following activities to ensure that products consistently meet specifications.
1 Pre-determined sampling plan with random sampling by an independent individual e.g. Quality Department.

2 Testing of the pre-defined parameters.

3 Pre-issue checks.

4 Use of statistical process control.

5 Timely corrective action.

**Question 3**

A maintenance and calibration plan for equipment in the components laboratory should include the following.

1 Identification of key processing equipment that must be maintained in order to prevent loss of production time.

2 Identification of key process equipment that must be calibrated to ensure that correct product specifications are achieved.

3 Listing of this equipment in an equipment register.

4 Establishment of a maintenance and calibration schedule that specifies:
   ♦ Maintenance and calibration time intervals
   ♦ Maintenance and calibration performed internally (organization)
   ♦ Maintenance and calibration performed externally (equipment manufacturer)
   ♦ Reference of the maintenance and calibration technique to authorized SOPs, where appropriate.

5 Documentation of all maintenance and calibration performed. A history file of the listed equipment must be kept.
## QMT 13.4 Quarantine and Release

### Teaching aim
To demonstrate how to develop systems for quarantine and release

### Core topics
- Principles
- Quarantine
- Release
- Responsibility
- Concessions
- Documentation

### Key points
- All donated blood should be placed in quarantine on receipt from collection teams
- There should be clear physical segregation of tested and untested products
- Responsible persons need to be identified who can authorize release of products
- A concession system may be needed in defined circumstances

### Teaching focus
Explore the issue of responsibility for release

### Learning outcomes
Participants should be able to:
- Explain the importance of quarantine and release
- List the key elements of an effective quarantine and release system
- Identify the role of the quality manager in quarantine and release

### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Principles of Quarantine and Release
5. Quarantine of Products (1)
6. Quarantine of Products (2)
7. Quarantine of Products (3)
8. Release of Products (1)
9. Release of Products (2)
10. Responsibility
11. Concessions (1)
12. Concessions (2)
13. Documentation
14. Documentation of Unsuitable Donations
15. Key Points (1)
16. Key Points (2)
17. Learning Outcomes

### Materials
None
<table>
<thead>
<tr>
<th>Related activity</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
<tr>
<td><strong>Presentation notes and handling the session</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Slide 4**  
Principles of Quarantine and Release | ♦ The slide outlines the major reasons and principles for applying a formal controlled quarantine/release procedure |
| **Slides 5 – 7**  
Quarantine of Products (1), (2) & (3) | ♦ The slides list the major areas of concern regarding the quarantine of blood products  
♦ Emphasize the need to have a separate, secure area for quarantined products |
| **Slides 8 – 9**  
Release of Products (1) & (2) | ♦ The slides list the two main activities in the release procedure  
♦ Emphasize the importance of responsibility and authority for the release of blood products, both to discard and clinical use |
| **Slide 10**  
Responsibility | ♦ The slide lists the important points to consider when establishing authority and responsibility for the release of blood products  
♦ Explore the involvement of the quality staff in release procedures |
| **Slides 11 – 12**  
Concessions (1) & (2) | ♦ Discuss the concept of concession notices, emphasizing the need to ensure that quality is maintained even though deviations are present  
♦ Give some examples of when concessions can be used |
| **Slides 13 – 14**  
Documentation & Documentation of Unsuitable Donations | ♦ The slide lists the main elements of the documentation system with regard to quarantine/release procedures  
♦ Discuss the control and possible format of such documentation  
♦ Discuss how documentation can assist in the monitoring of the quality system |
Quarantine and Release

Teaching Aim

- To demonstrate how to develop systems for quarantine and release

Core Topics

- Principles
- Quarantine
- Release
- Responsibility
- Concessions
- Documentation
## Principles of Quarantine and Release

- Prevention of the inadvertent issue of unsuitable products for clinical use
- Formal, interim segregation of untested products from tested, suitable products
- Clearly defined traceability of the status of products
- Labelling of acceptable products prior to issue

## Quarantine of Products (1)

- Three broad categories
  - Untested
  - Tested and suitable for clinical use
  - Tested and unsuitable for clinical use

## Quarantine of Products (2)

- Mechanism must be in place to prevent the issue of untested or unsuitable material for clinical use
- Blood returned from the donor sessions is quarantined until testing, etc., has been performed
  - Physical segregation in secured area
  - Blood not labelled for clinical use until release
Quarantine of Products (3)

- Blood can be processed into components first, but all components must be accounted for and kept in quarantine until release.

Release of Products (1)

- Physical movement of unsuitable products from quarantine to discard
  - Any processed components retrieved
  - All products accounted for and securely disposed of
  - Completed before release of suitable products

Release of Products (2)

- Physical movement of suitable products from quarantine to clinical stock area
  - Any processed components identified
  - All products properly labelled for clinical use
  - All products placed in inventory
Responsibility

- The initial quarantine of donated blood must be standard practice
- The responsibility for release of products needs to be clearly defined
  - Responsibility for release must lie with staff of sufficient seniority
  - Quality staff should be involved in the release of quarantine stock

Concessions (1)

- Allowed, specific deviation from the quality system: e.g. issue of uncrossmatched group O negative blood
- Allow the release / use of products not cleared for clinical use: e.g. uncrossmatched blood
- Criteria set on when and where concessions are allowed: e.g. emergency requirement for blood

Concessions (2)

- Documented system that must be followed
- Full documentation of the actions taken and responsibility for the release
Documentation

- All actions taken need to be documented
- Each batch of blood / products released should be fully documented
  - All required testing completed
  - All components identified and accounted for
  - Authorizing signatures
  - Date and time of release
- Double-checks required and recorded for release

Documentation of Unsuitable Donations

- The fate of unsuitable blood / products needs accurate and clear documentation
  - All unsuitable products accounted for prior to release of the suitable products
  - Clear audit trail indicating the secure removal and segregation of unsuitable products prior to disposal
  - Clear records detailing the disposal of all unsuitable products

Key Points (1)

- All donated blood should be placed in quarantine on receipt from the collection teams
- There should be clear physical segregation of tested and untested products
Key Points (2)

- Responsible persons need to be identified who can authorize release of products
- A concession system may be needed in defined circumstances

Learning Outcomes

You should now be able to:

- Explain the importance of quarantine and release
- List the key elements of an effective quarantine and release system
- Identify the role of the quality manager in quarantine and release
## QMT 13.5 Storage and Transportation of Blood Components

### Teaching aim
To demonstrate how to apply quality in the storage and transportation of blood components

### Core topics
- Storage
- Packaging
- Transportation
- Maintenance of the blood cold chain
- Documentation

### Key points
- Storage and transportation need to be controlled to ensure the quality of products is maintained from donor to patient, from "vein to vein"
- The blood cold chain needs to be maintained
- Transportation conditions are especially important
- Monitoring is essential

### Teaching focus
- Focus on the need to protect the product from "vein to vein"
- Explore different methods of transporting products to maintain the blood cold chain

### Learning outcomes
Participants should be able to:
- Identify the actions required to ensure quality in storage and transportation
- Explain what is meant by the blood cold chain
- Describe the elements of an effective blood cold chain
- Identify the role of the quality manager in ensuring quality in storage and transportation

### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Storage and Transportation
5. Storage (1)
6. Storage (2)
7. Protecting the Product
8. Transportation (1)
9. Transportation (2)
10. Transportation (3)
11. Maintaining the Blood Cold Chain (1)
12. Maintaining the Blood Cold Chain (2)
13. Monitoring (1)
14. Monitoring (2)
15. Documentation
16. Key Points
17. Learning Outcomes

### Materials
None
<table>
<thead>
<tr>
<th>Related activities</th>
<th>QMT 13.6 Storage and Transportation of Blood Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time span</td>
<td>½ hour</td>
</tr>
<tr>
<td>Presentation notes and handling the session</td>
<td></td>
</tr>
<tr>
<td><strong>Slide 4</strong>&lt;br&gt;Storage and Transportation</td>
<td>✦ The slide introduces the content of the presentation and the main reasons why it is essential to ensure the correct storage and transportation of blood and blood products</td>
</tr>
<tr>
<td><strong>Slides 5 – 6</strong>&lt;br&gt;Storage (1) &amp; (2)</td>
<td>✦ The slides list the important aspects to be considered in ensuring the correct storage of blood and blood products  &lt;br&gt;✦ Discuss each point, emphasizing the role that the quality manager plays in ensuring correct storage</td>
</tr>
<tr>
<td><strong>Slide 7</strong>&lt;br&gt;Protecting the Product</td>
<td>✦ Emphasize the need to ensure that packaging protects the product  &lt;br&gt;✦ Discuss some examples of how poor packaging can have an impact on perceptions of the quality of the product</td>
</tr>
<tr>
<td><strong>Slides 8 – 10</strong>&lt;br&gt;Transportation (1), (2) &amp; (3)</td>
<td>✦ The slides list the main considerations during the transportation of blood products  &lt;br&gt;✦ Invite the participants to give some examples of constraints and discuss possible solutions</td>
</tr>
<tr>
<td><strong>Slides 11 – 12</strong>&lt;br&gt;Labelling (1) &amp; (2)</td>
<td>✦ The slides list important aspects of the blood cold chain  &lt;br&gt;✦ Discuss the definition of the blood cold chain, emphasizing the different requirements for different blood products</td>
</tr>
<tr>
<td><strong>Slides 13 – 14</strong>&lt;br&gt;Monitoring (1) &amp; (2)</td>
<td>✦ The slides list the main control points that must be monitored to ensure the blood cold chain is not broken  &lt;br&gt;✦ Discuss some of the examples given and some simple solutions where resources are scarce</td>
</tr>
<tr>
<td><strong>Slide 15</strong>&lt;br&gt;Documentation</td>
<td>✦ Discuss how the documentation system links with maintenance and monitoring of the blood cold chain  &lt;br&gt;✦ Emphasize the need for SOPs to cover all aspects of the process</td>
</tr>
</tbody>
</table>
Storage and Transportation of Blood Components

Teaching Aim

- To demonstrate how to apply quality in the storage and transportation of blood components

Core Topics

- Storage
- Packaging
- Transportation
- Maintenance of the blood cold chain
- Documentation
Storage and Transportation

- Blood and blood products need to be stored under the right conditions to ensure that they remain viable, safe and clinically effective
- Blood and blood products need to be distributed under the right conditions — blood cold chain

Storage (1)

- Storage conditions need to be appropriate and correct for each product
  - Temperature
  - Cleanliness
  - Agitation (platelets)
- Storage needs to be secure to prevent unauthorized access
  - People
  - Vermin/insects, etc.

Storage (2)

- Storage needs to be monitored to ensure that the correct conditions are maintained throughout
  - Continuous temperature monitoring
  - Alarm systems on all storage equipment
- Different requirements for different products
- Separate storage areas for quarantine products and released products
Protecting the Product

- Final product packaging
  - Protects the product from physical harm
  - Maintains the optimum temperature
  - Clean packaging to minimize the risks of microbial contamination

Transportation (1)

- Physical separation of cellular products from any ice packs used to maintain temperature
- Transportation conditions need to be appropriate for the product
  - Temperature
  - Time taken

Transportation (2)

- Packaging needs to be appropriate
  - Sturdy enough to protect the product
  - Able to maintain product at correct temperature
  - Addressed adequately (names of sender and recipient)
  - Labelled adequately (biohazard, contents, handling and storage conditions)
Transportation (3)

- Transportation requirements
  - BTS transport or external contract
  - The product arrives at its destination within the expected timeframe
  - The product has not been damaged in transport
  - The product has not been interfered with in any way

Maintaining the Blood Cold Chain (1)

- The blood cold chain is central to the storage and transportation of blood and products - the correct temperature must be maintained
- The blood cold chain runs from donor to patient

Maintaining the Blood Cold Chain (2)

- The maximum time that products are not at the correct storage temperature must be defined
- Procedures must be put in place detailing action to be taken in the case of 'out of specification' products
Monitoring (1)

- Monitoring of the blood cold chain
  - Temperature monitoring devices
  - At start, during transportation and at destination
  - Blood time temperature indicators
- Monitoring the transportation system
  - Time taken from A to B
  - Integrity of the packaging upon arrival
  - Temperature of product during transportation

Monitoring (2)

- Labelling
  - Accuracy
  - Clarity

Documentation

- Documentation is needed to record key parameters during storage and transportation
  - Temperature during storage and transportation
  - Stock levels of products for clinical use
  - Products despatched and actually received
  - Times of despatch and receipt
  - Destination of products
  - Personnel responsible
Key Points

- Storage and transportation need to be controlled to ensure the quality of products is maintained from donor to patient, from 'vein to vein'
- The blood cold chain needs to be maintained
- Transportation conditions are especially important
- Monitoring is essential

Learning Outcomes

You should now be able to:

- Identify the actions required to ensure quality in storage and transportation
- Explain what is meant by the blood cold chain
- Describe the elements of an effective blood cold chain
- Identify the role of the quality manager in ensuring quality in storage and transportation
**ACTIVITY**

<table>
<thead>
<tr>
<th>QMT 13.6</th>
<th><strong>Storage and Transportation of Blood Components</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To provide practice in developing standards and policies for the storage, transportation and distribution of blood components</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Quarantine and release procedures  
♦ Blood cold chain maintenance  
♦ Security during transportation |
| **Key points** | All staff should be made aware of the impact of poor quality during the storage, transportation and distribution of blood products |
| **Teaching focus** | Explore all possible scenarios, keeping in mind that many countries do not have the resources available to countries in the developed world |
| **Learning outcomes** | Participants should be able to:  
♦ Develop standards for storage, transportation and distribution  
♦ List the documents required to ensure a quality approach |
| **Type of activity** | Group work |
| **Materials** | ♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 **Scenario**  
The BTS is setting up a quality system and needs to ensure a quality approach to the storage, transportation and distribution of blood and blood products.  
2 Instruct the participants to identify the following:  
♦ The standards that need to be identified  
♦ The procedures that need to be put in place to ensure the standards are met  
♦ The records that should be maintained to ensure that procedures are followed  
♦ The resources that will be needed to meet the standards. |
| **Review of the activity** | Ensure that:  
♦ Participants correctly identify the procedures, records and resources needed  
♦ Participants identify a procedure for quarantine and release  
♦ Participants consider cold chain procedures  
♦ Procedures include distribution protocols  
♦ Participants identify critical control points |
<p>| <strong>Time span</strong> | 1 hour |</p>
<table>
<thead>
<tr>
<th>QMT 13.7</th>
<th>Blood Stock Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To demonstrate how to apply quality to blood stock management</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Importance of blood stock management  
♦ Managing blood stocks  
♦ Managing fluctuations in supply and demand  
♦ Minimum blood stock levels  
♦ Documentation |
| **Key points** | ♦ Proper management of stock is essential for the BTS to be able consistently to provide clinical users with sufficient products  
♦ Stock management also includes the management of other factors that can affect stocks of blood  
♦ Minimum stock levels and actions to be taken to replenish stocks need to be defined |
| **Teaching focus** | ♦ Stress the importance of managing stocks to ensure the availability of desired components of particular blood groups at all times  
♦ Explore the issue of returning blood for re-use  
♦ Highlight the importance of minimizing the number of blood units that expire |
| **Learning outcomes** | Participants should be able to:  
♦ Explain the importance of managing blood stocks  
♦ Identify the actions required to ensure that blood stocks are managed effectively  
♦ Identify the role of the quality manager in ensuring effective blood stock management |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Importance of Blood Stock Management  
5 Managing Blood Stocks (1)  
6 Managing Blood Stocks (2)  
7 Returned Blood  
8 Managing Fluctuations in Supply and Demand  
9 Donor Management  
10 Variable Clinical Demands  
11 Management of Clinical Use  
12 Donations/Products (1)  
13 Donations/Products (2)  
14 Donations/Products (3)  
15 Minimum Blood Stock Levels  
16 Key Points  
17 Learning Outcomes |
### Materials
None

### Related activity
None

### Time span
¾ hour

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Importance of Blood Stock Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The presentation is designed to give the participants sufficient background information to establish a system of blood stock control</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for participants to consult with personnel trained in stock management</td>
<td></td>
</tr>
<tr>
<td>♦ The slide lists important reasons why blood stocks must be managed efficiently</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 5 - 6</th>
<th>Managing Blood Stocks (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list important considerations when managing blood stocks</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Returned Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Link these points to the previous presentation on blood cold chain maintenance</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Managing Fluctuations in Supply and Demand</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Invite participants to suggest some ideas on how to deal with fluctuations</td>
<td></td>
</tr>
<tr>
<td>♦ Donor and clinical use management are discussed in more detail on slides 9 and 10</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Donor Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some potential threats to the donor management programme</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss these points, keeping in mind the issues raised in Module 11 on donor management and QMT 9.6 on contingency planning</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Variable Clinical Demands</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the major reasons for variations in clinical demand</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize how the BTS may not have control over some of these factors</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 11</th>
<th>Management of Clinical Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Discuss how the points listed can assist in managing the clinical use of blood</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to control the re-issue of returned, unused stock and refer back to the maintenance of the blood cold chain</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 12 - 14</th>
<th>Donations/Products (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The three slides list the basic requirements and considerations for managing blood stocks</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for constant monitoring to ensure true requirements are known and met</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 15</th>
<th>Minimum Blood Stock Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the basis for setting minimum levels of stock</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss some of the practicalities, such as determining the maximum time span for the minimum stock: e.g. stock available for seven days of average use</td>
<td></td>
</tr>
</tbody>
</table>
Blood Stock Management

Teaching Aim

- To demonstrate how to apply quality to blood stock management

Core Topics

- Importance of blood stock management
- Managing blood stocks
- Managing fluctuations in supply and demand
- Minimum blood stock levels
- Documentation
Importance of Blood Stock Management

- Blood must be available for use at all times
- Minimize outdating as blood is perishable and has a limited shelf-life
- The BTS must ensure that it has sufficient blood stocks for routine and emergency requirements
- The BTS needs to identify the required type and number of blood products, by blood group

Managing Blood Stocks (1)

- First-in-First-out (FIFO)
- Maximal Surgical Blood Ordering Schedule (MSBOS)
- Group wise cut-off level, depending on blood requirements
- Components in preparation

Managing Blood Stocks (2)

- Regular updating of stock
- Use of alternative blood groups
- Frequency of donations
- Turn-around time for processing
- Information on blood donors
Returned Blood

- Policy on returned blood
- Strict criteria needed for re-use
- Clear documentation needed to ensure traceability

Managing Fluctuations in Supply and Demand

- Supply and demand are variable — influenced by many different external factors
- Both need to be managed as best as possible to minimize any threats to availability of sufficient stocks of blood
- Donor management
- Management of clinical use

Donor Management

- Threats from
  - Gradual loss of donors due to dissatisfaction / lack of motivation
  - Temporary shortages due to holiday / religious periods
  - Management by
    - Continuous recruitment and retention programme
    - Planning a consistent, predictable supply
Variable Clinical Demands

- Regular periods of increased use
- Specific planned increase in use: e.g. transplants
- Unexpected sudden demand: e.g. large perioperative bleeding, major disasters
- Demand for specific blood products: e.g.
  - Chemotherapy in leukaemia
  - Other non-surgical requirements

Management of Clinical Use

- Appropriate clinical use of blood
- Use of crystalloids/colloids/blood substitutes
- Building up of stocks in advance of planned increases in use
- Re-issue of returned unused stock

Donations/Products (1)

- Need for sufficient capacity to be able to respond to sudden and unexpected demands for blood (incidents/disasters/mass public events)
- General usage data needs to be collected to enable planning of normal stock levels
  - Hospital usage rates
  - Requirements for special blood products
Donations/Products (2)

- The balance of major blood groups is important and needs to complement the patient population
  - ABO is the major issue
  - Rh may be significant in parts of the world
  - Issues where the donor and recipient populations are from different ethnic groups

Donations/Products (3)

- The balance of products available needs to reflect normal demand for the individual products
  - Monitoring demand and usage provides this information

Minimum Blood Stock Levels

- Setting minimum levels is an important element of stock management
  - Depends on supply and demand
- Procedures need to be in place for:
  - Setting critical minimum levels
  - Action to be taken to build the stock
  - Action to be taken to conserve the stock
  - Contingency planning
Key Points

- Proper management of stock is essential for the BTS to be able to provide clinical users with sufficient products
- Stock management includes the management of the other factors that can affect stocks of blood
- Minimum stock levels and actions to be taken to replenish stocks need to be defined

Learning Outcomes

You should now be able to:

- Explain the importance of managing blood stocks
- Identify the actions required to ensure that blood stocks are managed effectively
- Identify the role of the quality manager in ensuring effective blood stock management
### QMT 13.8 Developing a Documentation System for Blood Component Production

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To demonstrate how to develop an effective documentation system for blood component production</th>
</tr>
</thead>
</table>
| **Core topics**  | ♦ What to document  
                     ♦ Types of documentation  
                     ♦ Labelling  
                     ♦ Traceability |
| **Key points**   | ♦ Documentation is an essential requisite  
                     ♦ GMP guidelines should be followed  
                     ♦ All processing and associated activities need to be documented  
                     ♦ The labelling of products is a critical area with the potential for major errors if not effectively controlled |
| **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 information that needs to be documented  
                     ♦ Identify the basic labelling required on blood products |
| **Slides**       | 1 Title  
                     2 Teaching Aim  
                     3 Core Topics  
                     4 Basic Documentation (1)  
                     5 Basic Documentation (2)  
                     6 Document Types  
                     7 Traceability  
                     8 Labelling (1)  
                     9 Labelling (2)  
                     10 Key Points  
                     11 Learning Outcomes |
| **Materials**    | None |
| **Related activity** | None |
| **Time span**   | ½ hour |
| **Presentation notes and handling the session** | ♦ The slides list the important elements of a documentation system in blood component preparation  
                     ♦ Stress the importance of applying GMP principles and the basic rules of quality system regarding documentation |
<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Document Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide lists the types of documents that must be considered in blood component preparation</td>
</tr>
<tr>
<td>♦</td>
<td>Invite the participants to give some examples of each type of document</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide re-emphasizes the need to ensure traceability of all blood and blood products</td>
</tr>
<tr>
<td>♦</td>
<td>Stress the importance of simplicity and clarity in the documentation system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 8 – 9</th>
<th>Labelling (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The two slides re-emphasize the need for a comprehensive labelling system to ensure traceability and minimize risks</td>
</tr>
</tbody>
</table>
## Developing a Documentation System for Blood Component Production

WHO/QMT 13.8

---

### Teaching Aim

- To demonstrate how to develop an effective documentation system for blood component production

---

### Core Topics

- What to document
- Types of documentation
- Labelling
- Traceability

---

WHO/QMT 13.8 3 of 12
## Basic Documentation (1)

- GMP requires documentation of everything directly related to the raw material and its processing
- Documentation may be electronic or manual
- Documentation includes
  - Processing information (including pack lot numbers)
  - QC/QM data
  - Environmental conditions/cleaning records
  - Maintenance/servicing/calibration records
  - Staff training records

## Basic Documentation (2)

It should demonstrate that:

- The work has been done using controlled and laid-down procedures
- The equipment and facilities are appropriate and maintained
- The staff performing the work are adequately trained

## Document Types (1)

- SOPs
  - Instructions on how to perform the work
- Forms
  - Record information in a standardized way
Document Types (2)

- Datasheets
  - Easy to see information needed to do the work
- Labels
  - Information that indicates the type of product, expiry date, and lot / batch
  - Status of the product

Traceability

- The need to ensure that all products can be traced back to their original donations and to their original donors
- A complete documentation system for donations and all processing / testing performed on them
  - Including any reagent / consumable lot numbers
- Enables look-back to be performed

Labelling (1)

- Labelling of products is a critical activity
- Labelling may include
  - Donation number
  - Product type
  - Volume or other individual product-specific information
  - Production and expiry dates
  - Lot/batch number
Labelling (2)

- The potential for mistakes to occur must be minimized
  - Way of working
  - Staff training and awareness
- Simple checking systems need to be in place
  - Monitoring of all or % of products

Key Points

- Documentation is essential
- GMP guidelines should be followed
- All processing and associated activities need to be documented
- The labelling of products is a critical area, with the potential for major errors if not effectively controlled

Learning Outcomes

You should now be able to:

- Identify the information that needs to be documented
- Identify the basic labelling required on blood products
<table>
<thead>
<tr>
<th>QMT 13.9</th>
<th><strong>Identifying and Monitoring Critical Control Points in Component Production</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To identify critical control points in blood component production activities</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Identifying the monitoring points available&lt;br&gt;♦ Identifying monitoring strategies and evaluation methods</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>Critical control points in the process need to be identified</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Ensure that the terms &quot;monitoring&quot; and &quot;evaluation&quot; are clearly understood&lt;br&gt;♦ Ensure the plans are feasible&lt;br&gt;♦ Ensure the monitoring plans do not interfere with the workflow</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to:&lt;br&gt;♦ Identify the critical control points in the process at which monitoring should take place&lt;br&gt;♦ Identify the kind of monitoring that should take place</td>
</tr>
<tr>
<td><strong>Type of activity</strong></td>
<td>Group work</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>♦ Flipcharts&lt;br&gt;♦ Pens</td>
</tr>
<tr>
<td><strong>Instructions</strong></td>
<td>1 Allocate one component from the following list to each group:&lt;br&gt;♦ Packed red cells&lt;br&gt;♦ Platelet concentrates&lt;br&gt;♦ Fresh frozen plasma&lt;br&gt;♦ Cryoprecipitate.&lt;br&gt;2 Instruct the participants to carry out the following:&lt;br&gt;♦ Prepare a process flow chart&lt;br&gt;♦ Establish the critical control points&lt;br&gt;♦ Design a plan for monitoring and evaluation of the process.</td>
</tr>
<tr>
<td><strong>Review of the activity</strong></td>
<td>Ensure that:&lt;br&gt;♦ The participants produce appropriate flowcharts&lt;br&gt;♦ The process mapping includes labelling&lt;br&gt;♦ Critical control points are correctly identified&lt;br&gt;♦ The plan to monitor and evaluate the process is realistic&lt;br&gt;♦ The plan includes some use of SPC</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>1½ hours</td>
</tr>
</tbody>
</table>
Module 14
Quality Systems and the Clinical Interface
### QMT 14.1 Introduction to Quality Systems at the Clinical Interface

#### Teaching aim
To review the elements of a quality system in relation to the clinical interface

#### Core topics
- Definition of the clinical interface
- Elements of a quality system as applied to the clinical interface
- Quality issues at the clinical interface
  - Importance of an effective clinical interface
  - Role of the BTS/hospital blood bank
  - Hospital transfusion process
  - Good transfusion practice

#### Key points
- The need for quality continues after the blood leaves the BTS
- The BTS has an important role in ensuring the quality of the clinical transfusion process
- The needs of both the patient and the clinician must be considered in determining how to ensure customer satisfaction
- The quality system of documentation extends to the clinical interface
- All staff involved in the clinical interface require training
- Effective communication is required between the BTS and hospital

#### Teaching focus
- Acknowledge the different relationships between BTSs and hospitals in different countries
- Refer to WHO recommendations and learning materials on the clinical use of blood

#### Learning outcomes
Participants should be able to:
- Identify the actions required to ensure quality at the clinical interface
- Identify the role of the quality manager in ensuring quality at the clinical interface

#### 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. Responsibilities of the BTS
8. Good Clinical Transfusion Practice (1)
9. Good Clinical Transfusion Practice (2)
10. Customer Satisfaction
11. Needs of the Patient (1)
12. Needs of the Patient (2)
<table>
<thead>
<tr>
<th>13</th>
<th>Needs of the Clinician</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Training at the Clinical Interface</td>
</tr>
<tr>
<td>15</td>
<td>The BTS/Hospital Relationship (1)</td>
</tr>
<tr>
<td>16</td>
<td>The BTS/Hospital Relationship (2)</td>
</tr>
<tr>
<td>17</td>
<td>Key Points (1)</td>
</tr>
<tr>
<td>18</td>
<td>Key Points (2)</td>
</tr>
<tr>
<td>19</td>
<td>Learning Outcomes</td>
</tr>
</tbody>
</table>

**Materials**

None

**Related activities**

QMT 14.3 The Role of the BTS at the Clinical Interface

**Time span**

½ hour

**Presentation notes and handling the session**

<table>
<thead>
<tr>
<th>Slides 4 - 6</th>
<th>Elements of a Quality System (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The presentation is an introduction to the module</td>
</tr>
<tr>
<td></td>
<td>♦ Some of the elements are dealt with in more detail in later presentations</td>
</tr>
<tr>
<td></td>
<td>♦ The first slide reminds participants of the elements of a quality system</td>
</tr>
<tr>
<td></td>
<td>♦ Slides 5 and 6 show how these elements link with the clinical interface</td>
</tr>
<tr>
<td></td>
<td>♦ Give some examples of each element with regard to the clinical interface</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Responsibilities of the BTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide reminds participants of the main role of the BTS</td>
</tr>
<tr>
<td></td>
<td>♦ Stress the importance of the BTS giving assistance to prescribers of blood</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 8 - 9</th>
<th>Good Clinical Transfusion Practice (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list key points regarding good clinical transfusion practice</td>
</tr>
<tr>
<td></td>
<td>♦ Stress the importance of the role of the BTS in ensuring that transfusion takes place only when clinically necessary</td>
</tr>
<tr>
<td></td>
<td>♦ Give some examples of cases where this may occur</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Customer Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists the two important customers at the clinical interface</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss how the concept of customer satisfaction links in with this aspect of the BTS</td>
</tr>
<tr>
<td></td>
<td>♦ Stress the importance of acknowledging other customers on the clinical side, such as nurses</td>
</tr>
<tr>
<td></td>
<td>♦ The needs of each customer are described in the next few slides</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 - 12</th>
<th>Needs of the Patient (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list the basic needs of the patient</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss informed consent and how this can be obtained</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Needs of the Clinician</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ Discuss how the quality system that has been described during the whole course leads directly to satisfying the needs of the clinician and patient</td>
</tr>
<tr>
<td>Slide 14</td>
<td>Training at the Clinical Interface</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>✦ The slide list three questions related to training needs at the clinical interface</td>
<td></td>
</tr>
<tr>
<td>✦ Invite the participants to give answers to the questions and discuss the answers given</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 15 – 16</th>
<th>The BTS/Hospital Relationship (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>✦ The slide lists important points regarding the hospital(s) the BTS serves</td>
<td></td>
</tr>
<tr>
<td>✦ Discuss each point and explore how each aspect can be established</td>
<td></td>
</tr>
</tbody>
</table>
Introduction to Quality Systems at the Clinical Interface

Teaching Aim

- To review the elements of a quality system in relation to the clinical interface

Core Topics

- Definition of the clinical interface
- Elements of a quality system as applied to the clinical interface
- Quality issues at the clinical interface
  - Importance of an effective clinical interface
  - Role of the BTS/hospital blood bank
  - Hospital transfusion process
  - Appropriate clinical use of blood
Elements of a Quality System (1)

Organizational management — policy, staff

Quality standards — guidelines for clinical use of blood, blood ordering schedule (BOS)

Documentation on the transfusion process

Elements of a Quality System (2)

Organizational management — policy, staff

Quality standards — guidelines for clinical use of blood, blood ordering schedule (BOS)

Documentation on the transfusion process

Elements of a Quality System (3)

Training of staff according to SOPs

Assessment
  — Monitoring and evaluation
  — Haemovigilance
  — Complaints
Responsibilities of the BTS

Ensuring the product is fit for its intended use
- Stringent donor selection procedures
- Blood collection with the utmost care
- Product manufacture that assures appropriate standards and high quality
- Storage / transportation under correct conditions
- Guidance to prescribers in appropriate clinical use

Good Clinical Transfusion Practice (1)

The transfusion of safe blood products to treat a condition leading to significant morbidity or mortality that cannot be prevented or managed effectively by other means

Good Clinical Transfusion Practice (2)

- The clinician should prescribe transfusion only when:
  - Clinical and laboratory indications that transfusion is needed
  - No suitable alternative treatments are available
  - Benefits to the patient are likely to outweigh the risks
- The clinician should be aware of the risks of TTIs in the products supplied
Customer Satisfaction

Two customers at the clinical interface:

- The patient
  - Will the transfusion benefit the patient?
  - How can poor patient outcomes be prevented?
- The clinician

Needs of the Patient (1)

- Reduced risk of mortality
- Improved health and quality of life
- Confidence in the product
- Optimal ratio of benefit to risk
- Informed consent

Needs of the Patient (2)

- Informed consent: the patient needs to be informed about:
  - Advantages/disadvantages of transfusion
  - Alternatives to transfusion
  - Risk of TTIs versus risks of not transfusing
  - Need for safe donors / autologous donation
  - Consent
**Needs of the Clinician**

- Improved clinical outcome, with minimum risk
  - e.g. by raising haemoglobin level, platelet count, Factor VIII level
- Product
  - Availability of the right product at the right time
  - High quality and efficacy
  - Ease of use

**Training at the Clinical Interface**

- Who needs to be trained?
- What training do they require?
- Who should provide the training?

**The BTS/Hospital Relationship (1)**

- Depends on type of service
  - Centralized BTS
  - Hospital-based
- Two-way communications
- Hospital Transfusion Committees
  - Transfusion policy and guidelines
  - Charges / agreements
The BTS/Hospital Relationship (2)

The BTS is responsible for:

- Information and advice on:
  - Available products and their usage
  - Alternatives to transfusion
  - Correct storage conditions
- Blood request form
- Role of the quality manager

Key Points (1)

- The need for quality continues after the blood leaves the BTS
- The BTS has an important role in ensuring the quality of the clinical transfusion process
- The needs of both the patient and the clinician must be considered in determining how to ensure customer satisfaction

Key Points (2)

- The quality system of documentation extends to the clinical interface
- All staff involved in the clinical interface require training
- Effective communication is required between the BTS and hospital
Learning Outcomes

You should now be able to:

- Identify the actions required to ensure quality at the clinical interface
- Identify the role of the quality manager in ensuring quality at the clinical interface
<table>
<thead>
<tr>
<th>QMT 14.2</th>
<th><strong>Policy and Guidelines on the Clinical Use of Blood</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To demonstrate how a policy and guidelines on the clinical use of blood can improve the quality of clinical transfusion practice</td>
</tr>
</tbody>
</table>
| **Core topics**   | ♦ Policy on the clinical use of blood  
                     ♦ Guidelines on the appropriate clinical use of blood  
                     ♦ The role of the BTS in the development of a policy and guidelines on the appropriate clinical use of blood  
                     ♦ The role of a hospital transfusion committee |
| **Key points**    | ♦ The BTS should play a key role in the development of a national policy and guidelines on the clinical use of blood, in collaboration with national health authorities and clinical specialists  
                     ♦ Transfusion committees, both national and hospital-based, need to be formed to ensure policy making and monitoring |
| **Teaching focus**| ♦ Refer to WHO recommendations and other relevant material, including learning materials: *The Clinical Use of Blood*  
                     ♦ Provide examples of national policies |
| **Learning outcomes** | Participants should be able to:  
                      ♦ Explain the importance of the appropriate clinical use of blood for safe transfusion  
                      ♦ Identify the actions required to promote good transfusion practice  
                      ♦ Identify the role of the BTS in promoting good transfusion practice |
| **Slides**        | 1 Title  
                     2 Teaching Aim  
                     3 Core Topics  
                     4 Strategy for the Appropriate Clinical Use of Blood  
                     5 WHO Materials on the Clinical Use of Blood  
                     6 National Policy on the Clinical Use of Blood (1)  
                     7 National Policy on the Clinical Use of Blood (2)  
                     8 Developing a National Policy  
                     9 Key Elements of the Appropriate Clinical Use of Blood (1)  
                     10 Key Elements of the Appropriate Clinical Use of Blood (2)  
                     11 National Committee on the Clinical Use of Blood  
                     12 Education and Training (1)  
                     13 Education and Training (2)  
                     14 Education and Training (3)  
                     15 Key Points  
                     16 Learning Outcomes |
<table>
<thead>
<tr>
<th>Materials</th>
<th>WHO materials:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Aide-Mémoire: <em>The Clinical Use of Blood</em></td>
</tr>
<tr>
<td></td>
<td>- <em>Recommendations on Developing a National Policy and Guidelines on the Clinical Use of Blood</em></td>
</tr>
<tr>
<td></td>
<td>- <em>The Clinical Use of Blood</em></td>
</tr>
<tr>
<td></td>
<td>- Module</td>
</tr>
<tr>
<td></td>
<td>- Handbook</td>
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</tbody>
</table>

| Related activities         | QMT 14.3 The Role of the BTS at the Clinical Interface                                              |

| Time span                 | ¾ hour                                                                                            |

<table>
<thead>
<tr>
<th>Presentation notes and handling the session</th>
</tr>
</thead>
</table>

| Slide 4 | Strategy for the Appropriate Clinical Use of Blood | ♦ The slide lists the important activities that will assist in ensuring the appropriate clinical use of blood |
|         |                                                    | ♦ Discuss what each element contributes |

| Slide 5 | WHO Materials on The Clinical Use of Blood | ♦ The slide shows the covers of the WHO advocacy and training materials available |

| Slides 6 - 7 | National Policy on the Clinical Use of Blood (1) & (2) | ♦ The slides list the essential elements of a national policy on the clinical use of blood |
|              |                                                        | ♦ Discuss each point with the participants referring them to the WHO document *Developing a National Policy and Guidelines on the Clinical Use of Blood* |

| Slide 8 | Developing a National Policy | ♦ The slide lists the first steps in developing a national policy on the clinical use of blood |
|         |                              | ♦ Discuss how these could be implemented |

| Slides 9 - 10 | Key Elements of the Appropriate Clinical Use of Blood | ♦ The slides list the key elements that must be in place to ensure the appropriate clinical use of blood |
|               |                                                        | ♦ Discuss each point, outlining the responsibilities of the BTS and quality manager for each of these elements |

| Slide 11 | National Committee on the Clinical Use of Blood | ♦ The slide lists the recommended membership of a national committee on the clinical use of blood |
|          |                                                    | ♦ Refer the participants to the appropriate section in the WHO document *Developing a National Policy and Guidelines on the Clinical Use of Blood* |
|          |                                                    | ♦ Invite the participants to discuss why each type of member should be on the committee |

| Slides 12 - 14 | Education and Training (1), (2) & (3) | ♦ The slides identify the need for formal education programmes, in-service training and continuing medical education for staff involved in the clinical transfusion process |
Blood transfusion is an essential part of patient care. When used correctly, it saves lives and improves health. However, blood transfusion carries a potential risk of acute or delayed complications and transfusion-transmitted infections and should be prescribed only to treat conditions associated with significant morbidity or mortality that cannot be prevented or managed effectively by other means.

Blood is a scarce human resource and ensuring its safety and clinical effectiveness requires investment – both human and financial.

The national blood transfusion service (BTS) is responsible for ensuring the provision of an adequate supply of safe blood for all patients requiring transfusion. The national health programme should develop policies and strategies to reduce the need for transfusion, minimize unnecessary transfusions and ensure the safe and appropriate use of blood and blood products. These strategies should include:

- Prevention, early diagnosis and effective treatment of conditions that could result in the need for transfusion
- Use of good surgical and anaesthetic techniques, pharmaceuticals and medical devices to reduce blood loss
- Availability and use of simple alternatives for volume replacement, including intravenous replacement fluids (crystalloids and colloids)
- Appropriate prescribing of blood and blood products in accordance with national guidelines
- Safe pre-transfusion procedures
- Safe administration of blood and blood products.

The national blood programme and clinical users of blood and blood products should work together to implement these policies and strategies.

Words of advice

- Secure government commitment and support for the development and implementation of a policy to promote the safe, appropriate use of blood
- Ensure a safe and adequate supply of blood and blood products
- Ensure the availability and use of simple alternatives to transfusion
- Establish a national committee on the clinical use of blood
- Develop national guidelines on the clinical use of blood
- Involve professional bodies and patient associations in the establishment of systems to ensure the safe and appropriate use of blood
- Provide training for all clinicians, nurses, BTS/hospital blood bank staff and other personnel involved in the transfusion process
- Establish transfusion committees in each hospital in which transfusion takes place
- Establish a system to monitor and evaluate blood usage
- Establish a national haemovigilance system to monitor, report and investigate adverse events associated with transfusion

The national blood programme has the responsibility to ensure that blood and blood products provided for clinical use are safe, adequate to meet demand, clinically effective and produced consistently to appropriate standards. While responsibility for the decision to transfuse ultimately rests with individual clinicians, consistently effective clinical transfusion practice cannot be achieved unless the following are in place:

- A well organized, nationally coordinated blood transfusion service to ensure the availability of, and access to, safe blood and blood products
- National blood policy and plan incorporating the clinical use of blood, with appropriate supportive regulations
- National committee on the clinical use of blood within the national blood programme
- Availability of intravenous replacement fluids, and medical devices and pharmaceuticals to reduce blood loss

Quality system for the BTS, hospital blood banks and all clinical departments involved in transfusion, including:

- Standard operating procedures
- Documentation of requests for blood, blood sampling, the administration of blood and monitoring the transfused patient
- Systems to monitor adverse events and errors related to transfusion
- Clinical audit.

National clinical guidelines

Transfusion guidelines should represent a consensus by clinical specialists, the BTS, pharmacists and professional bodies on the most effective treatments for specific conditions. They should be practical, comprehensive and relevant to local conditions. They should include:

- Clinical and laboratory indications for the use of blood, blood products and alternatives to transfusion
- Information on available blood products and alternatives to transfusion: dosage, storage conditions, risk of transfusion-transmissible infection, means of administration, contraindications and precautions
- Standard blood request form to provide full information about the patient and the need for transfusion
- Blood ordering schedule, as a guide to the number of units of blood and blood products that should normally be requested for each type of operation, with guidance on its adaptation by each hospital
- Instructions for the development of standard operating procedures at hospital level.

The national committee on the clinical use of blood should work to ensure the effective implementation of the guidelines.

Hospital transfusion committees

A transfusion committee should be established in each hospital to implement the national policy and guidelines and monitor the use of blood and blood products at the local level. The committee should have authority within the hospital structure to determine hospital policy in relation to transfusion and resolve any identified problems.

The main functions of a hospital transfusion committee include:

- Developing systems for the implementation of the national guidelines within the hospital
- Liaison with the BTS to ensure the availability of required blood and blood products at all times
- Liaison with the relevant department to ensure a reliable supply of intravenous replacement fluids and other alternatives to transfusion at all times
- Developing a hospital blood ordering schedule

Education and training

The effective implementation of the national policy and guidelines requires education and training in clinical blood use and safe clinical transfusion procedures for clinicians, nurses, BTS/blood bank staff and other personnel involved in transfusion, including:

- Undergraduate and postgraduate programmes in:
  - Medical schools and teaching hospitals
  - Medical laboratory technology training institutions
  - Schools of nursing
  - Paramedical schools
- In-service training for:
  - Clinicians
  - Nurses
  - Blood transfusion service and hospital blood bank staff
- Continuing medical education:
  - Hospital clinical meetings
  - Seminars and conferences
  - Medical publications.

Monitoring and evaluation

At national level, responsibility for monitoring and evaluation should be shared by the BTS, the national committee on the clinical use of blood and the department responsible for the supply of intravenous replacement fluids and other alternatives to transfusion.

The monitoring system should cover:

- The safety, adequacy and reliability of the supply of blood, blood products and alternatives to transfusion
- The traceability of all blood and blood products, from blood collection to transfusion
- Compliance with the national guidelines on transfusion and the impact on prescribing practice
- Differences in blood usage within hospitals and between similar hospitals at regional, provincial and district level
- Haemovigilance – the monitoring, reporting and investigation of all adverse events related to transfusion.
Policy and Guidelines on the Clinical Use of Blood

WHO/QMT 14.2

Teaching Aim

- To demonstrate how a policy and guidelines on the clinical use of blood can improve the quality of clinical transfusion practice

Core Topics

- Policy on the clinical use of blood
- Guidelines on the appropriate clinical use of blood
- The role of the BTS in the development of a policy and guidelines on the appropriate clinical use of blood
- The role of a hospital transfusion committee
Strategy for the Appropriate Clinical Use of Blood

- National policy and guidelines
- Prevention, early diagnosis and treatment
- Availability of alternatives to transfusion — e.g. crystalloids and colloids
- Training of clinicians and BTS staff
- Effective clinical transfusion practice
- Monitoring and evaluation

WHO Materials on The Clinical Use of Blood

National Policy on the Clinical Use of Blood (1)

Key elements
- Commitment by health authorities to strengthen public and primary health care to reduce the need for transfusion
- A BTS capable of providing safe and adequate supplies of blood
- Promotion and availability of intravenous replacement fluids
National Policy on the Clinical Use of Blood (2)

- National guidelines on the clinical use of blood
- National Committee on the Clinical Use of Blood
- Hospital transfusion committees
- Education and training for prescribers of blood
- Monitoring and evaluation of clinical blood usage

Developing a National Policy

- Sensitize Ministry of Health
- Establish Working Group to draft national policy
  - Clinical specialists
  - Senior BTS personnel: Medical Director/Quality Manager
  - Senior pharmacists
- Submit policy for approval and support

Key Elements of the Appropriate Clinical Use of Blood (1)

- Adequate supplies of safe blood
- Adequate supplies of alternatives to transfusion
  - Crystalloids and colloids
  - Pharmaceuticals and medical devices to reduce the need for transfusion
- Sterile, disposable equipment for blood samples and blood administration
Key Elements of the Appropriate Clinical Use of Blood (2)

- Guidelines on the appropriate clinical use of blood
- Standard blood request form
- Blood ordering schedule
- Standard operating procedures for all stages of the clinical transfusion process

National Committee on the Clinical Use of Blood

Members
- Representatives of Ministry of Health
- Senior clinical specialists
- Blood Transfusion Service
- Pharmacy
- Other relevant organizations: e.g. patient associations

Education and Training (1)

Undergraduate and postgraduate programmes
- Medical schools and teaching hospitals
- Medical laboratory technology training institutions
- Schools of nursing
- Paramedical schools
### Education and Training (2)

<table>
<thead>
<tr>
<th>In-service training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinicians</td>
</tr>
<tr>
<td>Nurses</td>
</tr>
<tr>
<td>BTS/hospital blood bank technical staff</td>
</tr>
</tbody>
</table>

### Education and Training (3)

<table>
<thead>
<tr>
<th>Continuing medical education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital clinical meetings</td>
</tr>
<tr>
<td>Seminars and conferences</td>
</tr>
<tr>
<td>Medical publications</td>
</tr>
<tr>
<td>Journal clubs</td>
</tr>
</tbody>
</table>

### Key Points

- The BTS should play a key role in the development of a national policy and guidelines on the clinical use of blood, in collaboration with national health authorities and clinical specialists.
- Transfusion committees, both national and hospital-based, need to be formed to ensure effective policy making and monitoring.
Learning Outcomes

You should now be able to:

- Explain the importance of the appropriate clinical use of blood for safe transfusion
- Identify the actions required to promote the appropriate clinical use of blood
- Identify the role of the BTS in promoting the appropriate clinical use of blood
### QMT 14.3: The Role of the BTS at the Clinical Interface

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To explore the role of the BTS at the clinical interface</th>
</tr>
</thead>
</table>

**Core topics**
- The BTS has an important role to play in good transfusion practice
- Ensuring good transfusion practice requires effective collaboration between the BTS and prescribers of blood

**Key points**
- The BTS/hospital communication link is a two-way process
- Continuous quality improvement requires quality data from hospitals supplied by the BTS

**Teaching focus**
Discuss different approaches to ensure the "quality" use of blood products

**Learning outcomes**
- Participants should be able to:
  - Describe the role of the BTS at the clinical interface
  - List the players in establishing quality at the clinical interface

**Type of activity**
Group work

**Materials**
- QMT 14.3: Case Study
- Flipcharts
- Pens

**Instructions**
1. Instruct the participants to read the scenario and follow the instructions.

**Review of the activity**
- Ensure the participants include the formation of a hospital transfusion committee in the strategy and list suggestions for the membership of the committee
- Ensure the roles of the BTS and the quality manager are clearly defined and include information exchange with the hospital, such as about the products available from the BTS
- Ensure the strategy devised by the participants includes a training element for all staff at the clinical interface
- Ensure the monitoring data suggested include adverse transfusion reactions and customer complaints

**Time span**
1 hour
The Role of the BTS at the Clinical Interface

Scenario

A blood bank has spent three years in setting up the following systems.

1 Procuring safe blood through suitable procedures for donor motivation, donor recruitment, donor selection, blood collection and donor retention.

2 Following GMP principles in the processing and testing of blood and blood components.

3 Ensuring the quality management system applies to compatibility testing and issue of blood to patients.

The quality manager of the blood bank has made the following observations:

♦ The blood bank has been proactive in establishing quality management systems to ensure that blood is safe
♦ The hospitals that are serviced by the blood bank lack quality management systems for ensuring the appropriate clinical use of blood
♦ There is little communication between the blood bank and clinicians and other hospital staff
♦ Adverse reactions to transfusion are not reported to the blood bank.

Instructions

1 Outline a strategy to address the poor relationship between the blood bank and the clinicians and other hospital staff with the ultimate goal of ensuring the appropriate clinical use of blood.

2 Broadly describe what data should be obtained and how the BTS and the quality manager should obtain and use it to ensure the appropriate clinical use of blood.
<table>
<thead>
<tr>
<th>QMT 14.4</th>
<th>Documentation in the Hospital Transfusion Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To demonstrate how an effective documentation system can be used to improve the hospital transfusion process</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Information to be recorded  
♦ Importance of documentation in the hospital transfusion process  
♦ Using documentation in the hospital transfusion process for improvement in all aspects of blood transfusion |
| **Key points** | ♦ All stages of the transfusion must be documented from the time the patient is identified and the sample taken to the time the transfusion is completed  
♦ Noting all staff involved helps to identify training needs and clarify errors |
| **Teaching focus** | ♦ Emphasize the importance of full traceability of donations  
♦ Focus on the lack of traceability if records are incomplete or inaccurate |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the information that needs to be documented in relation to the hospital transfusion process  
♦ Identify the actions required to establish an effective system for documenting the hospital transfusion process  
♦ Identify the role of the BTS in developing an effective system for documenting the hospital transfusion process |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 What Needs to be Documented? (1)  
5 What Needs to be Documented? (2)  
6 What Needs to be Documented? (3)  
7 Why Do They Need to be Documented?  
8 Basic Requirements (1)  
9 Basic Requirements (2)  
10 SOPs Required (1)  
11 SOPs Required (2)  
12 Patient Identification  
13 Product Identification  
14 Recording the Transfusion  
15 Records of Monitoring the Patient  
16 Recording Adverse Events  
17 Key Points  
18 Learning Outcomes (1)  
19 Learning Outcomes (2) |
<table>
<thead>
<tr>
<th>Materials</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related activity</td>
<td>QMT 14.5 Designing a Blood Request Form</td>
</tr>
<tr>
<td>Time span</td>
<td>½ hour</td>
</tr>
</tbody>
</table>

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slides 4 - 6</th>
<th>What Needs to be Documented? (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The presentation is an introduction to applying a documentation system to the hospital transfusion process</td>
<td></td>
</tr>
<tr>
<td>♦ The slides list all the information that should be documented</td>
<td></td>
</tr>
<tr>
<td>♦ More details on what should be documented are given in QMT 14.6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Why Do They Need to be Documented?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the major reasons for documenting all steps in the hospital transfusion process</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point in depth with the participants</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 8 - 9</th>
<th>Basic Requirements (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list the main components of the documentation system</td>
<td></td>
</tr>
<tr>
<td>♦ Identification information is dealt with in detail in QMT 14.6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 10 - 11</th>
<th>SOPs Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists examples of the SOPs required</td>
<td></td>
</tr>
<tr>
<td>♦ Invite the participants to give more examples</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for the SOPs to be part of the BTS documentation system, even if not created by them</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Patient Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the SOPs that must be generated to ensure positive patient identification</td>
<td></td>
</tr>
<tr>
<td>♦ The subject is explored in more detail in QMT 14.6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Product Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the important elements of product identification related to the hospital transfusion process</td>
<td></td>
</tr>
<tr>
<td>♦ Remind participants about the labelling requirements taught in QMT 13.4 and QMT 13.8</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Recording the Transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists important information that should be recorded and maintained regarding the transfusion itself</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point, emphasizing the reasons for recording the information</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 15</th>
<th>Records of Monitoring the Patient (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the information that should be recorded about the monitoring of the patient before, during and after transfusion</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each of the points listed on the slide, again emphasizing the reasons for the records that are kept</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 16</th>
<th>Recording Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some examples of the details that should be recorded if a transfusion reaction occurs</td>
<td></td>
</tr>
<tr>
<td>♦ Stress the importance of the records in investigating transfusion reactions</td>
<td></td>
</tr>
</tbody>
</table>
Documentation in the Hospital Transfusion Process

WHO/QMT 14.4

Teaching Aim

- To demonstrate how an effective documentation system can be used to improve the hospital transfusion process

Core Topics

- Information to be recorded
- Importance of documentation in the hospital transfusion process
- Using documentation in the hospital transfusion process for improvement in all aspects of blood transfusion
### What Needs to be Documented? (1)
- Patient's records
- Blood request form
- Pre-transfusion blood sample
- Crossmatching and test results

### What Needs to be Documented? (2)
- Number of each unit of blood
  - Crossmatched
  - Issued
  - Transfused
- All other details related to the transfusion process

### What Needs to be Documented? (3)
- Informed consent
- Administration of the unit
  - Set-up of each transfusion
  - Time of transfusion
- Monitoring of the transfused patient
- Transfusion reactions
Why Do They Need to be Documented?

- To provide full record of patient's care
- Traceability
  - Which donations actually transfused
  - Transfusion events
- Blood stock management
  - Numbers of units originally requested
  - Numbers crossmatched and not used
- Medico-legal implications

Basic Requirements (1)

- SOPs
  - Clear instructions
  - Including what records to keep
- Patient identification
  - Record of identification of the correct patient

Basic Requirements (2)

- Sample identification
  - Correct sample from correct patient
  - Crossmatch using correct sample
- Product identification
  - Donation number
  - Right product
SOPs Required (1)

- Ordering blood — standard and emergency
- Using the blood request form, including retention of the record
- Taking blood sample and associated records
- Compatibility testing
- Storage, transportation, issue and all associated records

SOPs Required (2)

Clinical SOPs are the responsibility of the hospital
- Administering the blood, including final patient identity check at the bedside
- Recording the transfusion
- Records of the monitoring of the patient, including adverse reactions
- Management, reporting and investigation of adverse reactions

Patient Identification

- SOP on checking patient identification
  - Identification at the bedside
  - Staff performing identification
  - Identifiers used
  - Identification of all samples collected
Product Identification

- Identification of each product
  - Cross-check with patient details
  - Product details: e.g. type, number, integrity
  - Staff checking the product identification

Recording the Transfusion

- Transfusion details: record in patient's case notes / file
  - Type and volume of product
  - Donation number of each product / unit
  - Blood group
  - Time at which transfusion started and stopped
  - Signature of person responsible for transfusion

Records of Monitoring the Patient

- All monitoring activities performed
  - Record details in patient's case notes / file
  - Baseline patient information
    - Temperature
    - Pulse
    - Respiratory rate
  - Change of administration sets
  - Evidence of improved clinical status
Recording Adverse Events

- Record symptoms / signs of reactions
  - Immediate or delayed
  - Action taken and outcome of action
  - Transfusion reaction report form completed

Key Points

- All stages of the transfusion must be documented from the time the patient is identified and the blood sample is taken to the time the transfusion is completed
- Noting all staff involved helps to identify errors and training needs

Learning Outcomes (1)

You should now be able to:
- Identify the information that needs to be documented in relation to the hospital transfusion process
- Identify the actions required to establish an effective system for documenting the hospital transfusion process
<table>
<thead>
<tr>
<th>Learning Outcomes (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>You should now be able to:</td>
</tr>
<tr>
<td>- Identify the role of the BTS in developing an effective system for documenting the hospital transfusion process</td>
</tr>
</tbody>
</table>
## ACTIVITY

### QMT 14.5 Designing a Blood Request Form

**Teaching aim**  
To determine the key information required to identify a patient and his/her blood needs

**Core topics**  
- Relevant clinical information
- Simplifying documentation to focus only on that which is needed
- Identifying who should design a blood request form

**Key points**  
- Transfusion should occur only when clinically indicated
- Patient details must be completed accurately to ensure correct identification

**Teaching focus**  
- Remind participants of the importance of the basic information required
- Emphasize the importance of legibility
- Discuss relevant and irrelevant information

**Learning outcomes**  
Participants should be able to:
- List the essential information required on a blood request form
- Explain why this information is required
- Produce an appropriate and effective blood request form

**Type of activity**  
Group work

**Materials required**  
- Flipcharts
- Pens

**Instructions**  
1. Instruct participants to identify the critical information on a blood request form that is needed by:
   - The BTS/blood bank
   - The hospital.
2. Ask them to justify each item: i.e. why it should be included.
3. Instruct them to identify the role of the BTS in ensuring that the blood request form is always completed fully and accurately by prescribing clinicians.
4. If there is sufficient time, ask them to design a simple layout for a blood request form.

**Review of the activity**  
- Discuss each item proposed, including the justification for it to be included on the form
- Ensure that participants understand that the BTS and the hospital have an equal need for traceability

**Time span**  
1 hour
<table>
<thead>
<tr>
<th>QMT 14.6</th>
<th>Quality in the Hospital Transfusion Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To identify the role of the BTS in ensuring quality in the hospital transfusion process</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Hospital transfusion process</td>
</tr>
<tr>
<td></td>
<td>♦ Positive identification</td>
</tr>
<tr>
<td></td>
<td>♦ Storage of blood components</td>
</tr>
<tr>
<td></td>
<td>♦ Requests for blood</td>
</tr>
<tr>
<td></td>
<td>♦ Responsibilities of the compatibility testing laboratory</td>
</tr>
<tr>
<td></td>
<td>♦ Administration of blood</td>
</tr>
<tr>
<td></td>
<td>♦ Role of the BTS/blood bank</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>♦ The BTS has a responsibility to ensure that hospitals using its products meet quality standards in transfusion practice</td>
</tr>
<tr>
<td></td>
<td>♦ The BTS should assist hospitals to develop policies and SOPs for each stage of the clinical transfusion process</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to:</td>
</tr>
<tr>
<td></td>
<td>♦ Identify the actions required to ensure quality in the hospital transfusion process</td>
</tr>
<tr>
<td></td>
<td>♦ Identify the role of the BTS/blood bank in ensuring quality in the hospital transfusion process</td>
</tr>
<tr>
<td></td>
<td>♦ Identify the role of the quality manager in ensuring quality in the hospital transfusion process</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Stress the importance of the role of the BTS in the transfusion process</td>
</tr>
<tr>
<td></td>
<td>♦ Emphasize the role of a documentation system in ensuring patient, specimen and product identification</td>
</tr>
<tr>
<td><strong>Slides</strong></td>
<td>1 Title</td>
</tr>
<tr>
<td></td>
<td>2 Teaching Aim</td>
</tr>
<tr>
<td></td>
<td>3 Core Topics (1)</td>
</tr>
<tr>
<td></td>
<td>4 Core Topics (2)</td>
</tr>
<tr>
<td></td>
<td>5 Risks of Poor Quality at the Bedside (1)</td>
</tr>
<tr>
<td></td>
<td>6 Risks of Poor Quality at the Bedside (2)</td>
</tr>
<tr>
<td></td>
<td>7 Patient Identification (1)</td>
</tr>
<tr>
<td></td>
<td>8 Patient Identification (2)</td>
</tr>
<tr>
<td></td>
<td>9 Blood Request Form (1)</td>
</tr>
<tr>
<td></td>
<td>10 Blood Request Form (2)</td>
</tr>
<tr>
<td></td>
<td>11 Sample Identification (1)</td>
</tr>
<tr>
<td></td>
<td>12 Sample Identification (2)</td>
</tr>
<tr>
<td></td>
<td>13 Rejection of Samples (1)</td>
</tr>
<tr>
<td></td>
<td>14 Rejection of Samples (2)</td>
</tr>
<tr>
<td></td>
<td>15 Product Identification (1)</td>
</tr>
<tr>
<td></td>
<td>16 Product Identification (2)</td>
</tr>
<tr>
<td></td>
<td>17 Storage of Blood in Clinical Areas</td>
</tr>
<tr>
<td>Slides 5 - 6</td>
<td>Risks of Poor Quality at the Bedside (1) &amp; (2)</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>♦ The slides list the main risks associated with transfusion and the quality elements that minimize these risks</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss the potential impact of a quality management system on minimizing the risks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 7 - 8</th>
<th>Patient Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The first slide lists the important points regarding patient identification and the questions that must be asked and answered to ensure positive patient identification</td>
</tr>
<tr>
<td></td>
<td>♦ Invite the participants to suggest some answers to the questions</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss the suggestions given</td>
</tr>
<tr>
<td></td>
<td>♦ Slide 8 gives some examples of the details needed to ensure positive patient identification</td>
</tr>
<tr>
<td></td>
<td>♦ Invite the participants to suggest any other details that should be included, particularly those relevant to their own situations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 9 - 10</th>
<th>Blood Request Form (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list the details that should be on a blood request form</td>
</tr>
<tr>
<td></td>
<td>♦ Invite the participants to suggest any other details that should be included, particularly those relevant to their own situations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 - 12</th>
<th>Sample Identification (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list required information regarding sample integrity and identification</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss each point with the participants</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 13 - 14</th>
<th>Rejection of Samples (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides list some important points regarding the rejection of samples</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss some examples for the bullets on slide 14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 15 - 16</th>
<th>Product Identification (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides outline the checks that should be carried out at each point in the chain of product selection to transfusion</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss each point, emphasizing the need for accurate records of the checks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 17</th>
<th>Storage of Blood in Clinical Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide reminds participants of the points discussed during QMT 13.5</td>
</tr>
<tr>
<td></td>
<td>♦ Stress the importance of maintaining the blood cold chain at all times</td>
</tr>
<tr>
<td>Slides 18 - 19</td>
<td>The BTS/Hospital Relationship (1) &amp; (2)</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td></td>
<td>♦ The slides list important points regarding practice at the patient's bedside</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss each point and explore how each one can be established</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 20 - 21</th>
<th>The Role of the BTS in Clinical Transfusion Practice (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides summarize the role of the BTS at the clinical interface</td>
</tr>
</tbody>
</table>
Quality in the Hospital Transfusion Process

Teaching Aim

- To identify the role of the BTS in ensuring quality in the hospital transfusion process

Core Topics (1)

- Hospital transfusion process
- Positive identification
- Storage of blood components
- Requests for blood
Core Topics (2)

- Responsibilities of the compatibility testing laboratory
- Administration of blood
- Role of the BTS/blood bank

Risks of Poor Quality at the Bedside (1)

- ABO incompatibility: one of the major causes of transfusion-associated morbidity and mortality
- Safe transfusion depends on:
  - Accurate, unique identification of the patient
  - Correct labelling of the blood sample
  - Final check of the patient, product and documentation at the patient’s bedside

Risks of Poor Quality at the Bedside (2)

- Defective product:
  - Bacterial contamination
  - Haemolysis
  - Loss of function
- Safe transfusion depends on:
  - Correct storage conditions
  - Use within correct time limits
  - Inspection before infusion
Patient Identification (1)

- Positive patient identification is essential at:
  - Completion of blood request form
  - Collection and labelling of blood sample
  - Administration of blood product

- How is this achieved?
- Who is responsible?
- What records are required?

Patient Identification (2)

- Information needed for correct patient identification:
  - Patient's family name and given name
  - Patient's unique hospital number
  - Patient's date of birth
  - Patient's gender

Blood Request Form (1)

- The blood request form should contain:
  - Patient identification details
  - Diagnosis / indication for transfusion
  - Number and type of product required
  - Group, screen and hold of patient's serum
  - Date of the request
  - Urgency of the request
  - Time, date and place when product is required
  - Requesting clinician / hospital
Blood Request Form (2)

- Patient information on the blood request form must match patient information on the blood sample

Sample Identification (1)

- Clear policy by hospital transfusion committee on requirements for sample identification
- SOP for collection and labelling of blood samples
- Correct container
- Correct volume of sample

Sample Identification (2)

- Accurate labelling of blood sample:
  - Patient's given name and family name
  - Patient's date of birth
  - Patient's unique hospital number
  - Date / time of sample collection
  - Signature of person taking sample
Rejection of Samples (1)

- Need for clear policy and SOPs on rejection of blood samples
- Sample should be rejected if there is any doubt about:
  - Patient identity
  - Specimen integrity

Rejection of Samples (2)

- Reasons for rejection of samples:
  - Incomplete sample label
  - Sample without label
  - Specimen integrity
  - Any other concern over identity or quality

Product Identification (1)

- At selection of the product
  - Compatibility labelling at the BTS
  - Records
- At issue of the product
  - Quality checks
  - Documentation
Product Identification (2)

- On receipt at the hospital/clinical area
  - Product integrity, including storage
  - Correct product
  - Correct patient
- At the patient's bedside
  - Correct product
  - Labelled for correct patient
  - Correct patient
  - Product integrity

Storage of Blood in Clinical Areas

- Risk of bacterial contamination, haemolysis or loss of function in blood products when removed from correct storage conditions
- Blood products must be transported and stored in the correct conditions after issue
- Blood products must be administered within the correct time limits

Transfusion Practice at the Bedside (1)

Correct procedures
- Administration of blood products:
  e.g. filtration, pooling, warming blood
- Final patient identity check at the bedside
- Recording the transfusion
- Monitoring the transfused patient
- Investigating and managing transfusion reactions
**Transfusion Practice at the Bedside (2)**

Correct documentation
- SOPs for each stage of the transfusion process
- Record of transfusion in patient notes
- Monitoring of transfused patient
- Transfusion reactions
- Patient management

---

**The Role of the BTS in Clinical Transfusion Practice (1)**

To help ensure that
- The right blood
- Gets to the right patient
- At the right time

---

**The Role of the BTS in Clinical Transfusion Practice (2)**

- Record-keeping
- Training
- Monitoring clinical blood usage
- Advice and guidance
- Advocacy
- Adequacy
Key Points

- The BTS has a responsibility to ensure that hospitals using its products meet quality standards in transfusion practice.
- The BTS should assist hospitals to develop policies and SOPs for each stage of the clinical transfusion process.

Learning Outcomes

You should now be able to:

- Identify the actions required to ensure quality in the hospital transfusion process.
- Identify the role of the BTS / blood bank in ensuring quality in the hospital transfusion process.
- Identify the role of the quality manager in ensuring quality in the hospital transfusion process.
# QMT 14.7 Quality in the Hospital Transfusion Process

<table>
<thead>
<tr>
<th>Teaching aim</th>
<th>To identify key quality aspects of transfusion requests and the administration of blood products</th>
</tr>
</thead>
</table>
| Core topics  | ♦ Sample identification  
               ♦ Patient identification  
               ♦ Product identification |
| Key points   | ♦ The BTS has an active role in ensuring quality at the bedside  
               ♦ Correct sample from the correct patient  
               ♦ Correct product for the correct patient |
| Teaching focus | ♦ Discuss the different approaches to ensuring quality at the bedside |
| Learning outcomes | Participants should be able to:  
                      ♦ List the documents needed to ensure quality at the bedside |
| Type of activity | Group work |
| Materials required | ♦ QMT 14.7: Case Study  
                            ♦ Flipcharts  
                            ♦ Pens |
| Instructions | 1 Instruct the participants to read the scenario and follow the instructions on the activity sheet. |
| Review of the activity | ♦ Ensure that participants include the implementation of SOPs and training in their suggestions for corrective and preventive actions  
                           ♦ Ensure that the list of procedures includes the positive identification of patients and labelling of the blood sample  
                           ♦ Discuss the similarities and differences in the approaches taken by the different groups |
| Time span | 1 hour |
Quality in the Hospital Transfusion Process

Scenario

Two patients have been identified as requiring transfusion. The doctor in charge instructs the ward nurse to arrange two units of packed red cells for each patient.

The nurse obtains the necessary sample collection containers and fills in the patients' details on the loose labels and signs them. The nurse then becomes extremely busy with new admissions and forgets to draw the blood.

When off duty she remembers that she has not drawn the blood and phones the ward and asks her colleague to do it for her.

The drawn samples are sent for crossmatching and units are sent to the ward for transfusion.

Both patients have a reaction to the transfusion. The initial investigation of the incidents shows that they have both suffered an ABO-incompatible transfusion reaction.

After further investigation, it is found that there was a mistake in the identification of the two patients.

Instructions

1. Outline the appropriate corrective and preventive actions that should be taken.
2. List the procedures that should be in place to ensure an improved quality approach.
**QMT 14.8 Monitoring and Evaluation of the Hospital Transfusion Process**

**Teaching aim**
To demonstrate how monitoring and evaluation can be used to improve the quality of the hospital transfusion process

**Core topics**
- Monitoring and evaluation
- Indicators
- Analysing and using data for improvement in all aspects of blood transfusion

**Key points**
- All aspects of the process of transfusion should be monitored and the results analysed and acted on
- A hospital transfusion committee should be established in every hospital
- The BTS and hospital blood bank should be represented on the hospital transfusion committee
- The clinical use of blood should be monitored using defined indicators

**Teaching focus**
- Illustrate the importance of monitoring and feedback with reference to crossmatch:transfusion ratios
- Emphasize the importance of using monitoring data to reduce unnecessary transfusions
- Give examples of national monitoring and reporting systems

**Learning outcomes**
Participants should be able to:
- Explain how information from monitoring and evaluation can be used to improve hospital transfusion practice
- Identify the actions required to develop a system for the monitoring and evaluation of the hospital transfusion process
- Identify the role of the BTS in the monitoring and evaluation of the hospital transfusion process

**Slides**
1. Title
2. Teaching Aim
3. Core Topics
4. The Transfusion Process (1)
5. The Transfusion Process (2)
6. The Transfusion Process (3)
7. Monitoring and Evaluation (1)
8. Monitoring and Evaluation (2)
9. Hospital Indicators (1)
10. Hospital Indicators (2)
11. BTS Indicators
12. Adverse Outcomes of Transfusion
13. Analysis and Use of Data (1)
14. Analysis and Use of Data (2)
15. Analysis and Use of Data (3)
<table>
<thead>
<tr>
<th>Slide</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slides 4 - 6</td>
<td>The Transfusion Process (1), (2) &amp; (3)</td>
</tr>
<tr>
<td>Slide 7 - 8</td>
<td>Monitoring and Evaluation (1) &amp; (2)</td>
</tr>
<tr>
<td>Slide 9 - 10</td>
<td>Hospital Indicators</td>
</tr>
<tr>
<td>Slide 11</td>
<td>BTS Indicators</td>
</tr>
<tr>
<td>Slide 12</td>
<td>Adverse Outcomes of Transfusion</td>
</tr>
<tr>
<td>Slides 13 - 16</td>
<td>Analysis and Use of Data (1) – (4)</td>
</tr>
<tr>
<td>Slides 17 - 18</td>
<td>Hospital Transfusion Committee (1) &amp; (2)</td>
</tr>
</tbody>
</table>

- The three slides remind participants of the various sub-processes and activities within the transfusion process
- Emphasize that monitoring should occur at all points

- The first slide reminds participants of the use and characteristics of indicators in monitoring and evaluation
- Slide 8 examines the role of the various parties involved

- The slide lists some examples of indicators for monitoring the hospital process
- Invite the participants to give other possible indicators

- The indicators listed are examples of what the BTS can monitor
- Discuss each one, emphasizing the use of the data

- The slide explores the two main causes of adverse outcomes of transfusion

- The slides emphasize the principle of analysing and using data to improve quality
- Discuss the points with the participants, emphasizing the use of the data

- The slides emphasize the need for transfusion committees at hospital level
- Remind participants of the national committee, as discussed in QMT 14.2
- Discuss the reasons for including each type of member on the committee
<table>
<thead>
<tr>
<th>Slide 19</th>
<th>Role of the Hospital Transfusion Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the major activities and responsibilities of the hospital transfusion committee</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 20</th>
<th>Haemovigilance</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide introduces the concept of haemovigilance, which is dealt with in more detail in QMT 14.9</td>
<td></td>
</tr>
</tbody>
</table>
Monitoring and Evaluation of the Hospital Transfusion Process

Teaching Aim

- To demonstrate how monitoring and evaluation can be used to improve the quality of the hospital transfusion process

Core Topics

- Monitoring and evaluation
- Indicators
- Analysing and using data for improvement in all aspects of blood transfusion
The Transfusion Process (1)

The transfusion process in the hospital includes a broad range of events

- Ordering of blood
  - Clinical guidelines
  - Patient identification
  - Sufficient stocks available at BTS

The Transfusion Process (2)

- Patient’s blood sample
  - Sufficient and good quality
  - Sample identification
  - Documentation
  - Crossmatch / compatibility testing process

- Delivery and storage to clinical area
  - Temperature
  - Security

The Transfusion Process (3)

- Transfusion
  - Correct identification of patient and unit(s)
  - Monitoring of the transfusion
  - Monitoring for adverse events

- Records
  - Complete and accurate records of all activities
  - Complete and accurate patient records
Monitoring and Evaluation (1)

- Monitoring and evaluation of the process needs to focus on key indicators
  - Indicators should have a direct relationship to the overall effectiveness of the transfusion process (benefit to the patient)
  - Should be measurable
  - Would be expected to be constant or consistent in an effective transfusion process

Monitoring and Evaluation (2)

Who monitors and evaluates?
- Internal
  - Laboratory
  - Hospital transfusion committee
- External
  - BTS
  - Ministry of Health

Hospital Indicators (1)

- Illegible / incomplete blood request forms
- Number of units requested versus number of unfilled orders
- Number of cancelled operations
- Crossmatched versus transfused ratio (C:T ratio)
Hospital Indicators (2)
- Blood usage per specific condition / intervention
- Adequacy of supply of associated consumables
- Number of adverse incidents reported
- Number of errors found on medical records

BTS Indicators
- Number of units requested
- Number of units issued
- Number of units issued without screening for TTIs
- Number of units returned to stock
- Number of units returned for discard

Adverse Outcomes of Transfusion
- Transfusion reactions
  - May lead to death
  - Most can be prevented
  - Many are due to clerical / checking errors
- Post-transfusion infections
  - May lead to serious disease
  - Majority are preventable through donor selection and screening of blood
  - Mainly due to inadequacy of systems
Analysis and Use of Data (1)

- Analysis of the data to identify
  - Problems and weaknesses
  - Strengths and good practice
- Use the data to build on the strengths
  - Identify why the good practice exists
  - Look at how to apply the principles in other areas

Analysis and Use of Data (2)

- Use the data to change poor practice and solve problems
  - Identify why poor practice has developed
  - Identify changes needed to improve practice

Analysis and Use of Data (3)

- Internal monitoring
  - The major area of activity
  - Ongoing laboratory monitoring of all activities
  - Reporting of monitoring data to hospital transfusion committees (HTC)
  - Review of data and plan of action by HTCs
  - Haemovigilance
Analysis and Use of Data (4)

- External monitoring
  - National haemovigilance system to feed back to all users
  - BTS monitoring to feed back to laboratory and HTC
  - Overall monitoring of practice and outcomes by Ministry of Health

Hospital Transfusion Committee (1)

- Has a key role in maintaining quality standards in transfusion practice in the hospital

Hospital Transfusion Committee (2)

- Members should include
  - Representative of the hospital administration
  - Clinical specialists
  - Representative of the hospital blood bank
  - BTS representative(s)
  - Representative of pharmacy / supply
  - Senior nurse
  - Person responsible for haemovigilance, if available
Role of the Hospital Transfusion Committee

- Implement national guidelines on the clinical use of blood
- Develop and monitor systems and procedures for implementing the guidelines
- Monitor the safety, adequacy and reliability of the supply of blood, blood products and IV fluids
- Promote awareness through training and education

Haemovigilance

- The final monitoring process
  - Covered in detail in QMT 14.9
  - An essential part of the monitoring process
  - Needs to feed back locally and into the national system

Key Points (1)

- All aspects of the process of transfusion should be monitored and the results analysed and acted on
- A hospital transfusion committee should be established in every hospital
Key Points (2)

- The BTS and hospital blood bank should be represented on the hospital transfusion committee
- The clinical use of blood should be monitored using defined indicators

Learning Outcomes (1)

You should now be able to:
- Explain how information from monitoring and evaluation can be used to improve hospital transfusion practice
- Identify the actions required to develop a system for the monitoring and evaluation of the hospital transfusion process

Learning Outcomes (2)

You should now be able to:
- Identify the role of the BTS in the monitoring and evaluation of the hospital transfusion process
QMT 14.9 Haemovigilance

**Teaching aim**
To promote the development of a national reporting system for adverse transfusion events

**Core topics**
- Definition
- Principle
- Requirements
- Benefits

**Key points**
- To be effective, haemovigilance requires open and honest reporting and investigation
- Haemovigilance depends on traceability in the hospital and the BTS
- Haemovigilance is an essential part of the quality system in the BTS/clinical interface
- Information is fed back into the transfusion system to improve the overall safety and quality of transfusion practice in the BTS and the hospital

**Teaching focus**
Emphasize the importance of using the information gathered to improve blood safety

**Learning outcomes**
Participants should be able to:
- Explain how a haemovigilance system can help to improve the quality of every aspect of blood transfusion
- Describe the elements of a haemovigilance system
- Identify the actions required to establish a national haemovigilance system
- Identify the role of the quality manager in developing the national haemovigilance system and utilizing the data to improve transfusion practice

**Slides**
1. Title
2. Teaching Aim
3. Core Topics
4. Definition
5. Principle
6. Characteristics of Haemovigilance
7. Requirements — Hospital (1)
8. Requirements — Hospital (2)
9. Requirements — BTS
10. Information Required
11. Presentation of Information
12. Benefits (1)
13. Benefits (2)
14. Key Points (1)
15. Learning Outcomes (1)
16. Learning Outcomes (2)

**Materials**
None
<table>
<thead>
<tr>
<th>Related activity</th>
<th>QMT 14.10 Identifying and Monitoring Critical Control Points for the Clinical Interface and Administration of Blood</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><strong>Definition</strong></td>
</tr>
<tr>
<td></td>
<td>♦ The slide gives a simple definition of haemovigilance</td>
</tr>
<tr>
<td></td>
<td>♦ Explore the meaning of adverse reactions and how these are influenced by all activities in the blood transfusion chain</td>
</tr>
<tr>
<td></td>
<td>♦ Stress the importance of identifying and minimizing all risks and then monitoring the strategies through haemovigilance</td>
</tr>
<tr>
<td><strong>Slide 5</strong></td>
<td><strong>Principle</strong></td>
</tr>
<tr>
<td></td>
<td>♦ Discuss how this principle is in line with the principles of customer satisfaction, such as managing customer complaints, in the quality management system</td>
</tr>
<tr>
<td><strong>Slide 6</strong></td>
<td><strong>Characteristics of Haemovigilance</strong></td>
</tr>
<tr>
<td></td>
<td>♦ Discuss each point with the participants</td>
</tr>
<tr>
<td></td>
<td>♦ Emphasize the importance of ‘professional’ ownership through involvement of all professionals in the blood transfusion chain</td>
</tr>
<tr>
<td></td>
<td>♦ Explore the different concepts behind a mandatory or voluntary system</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss the issue of haemovigilance being non-punitive, reminding participants of the error management system discussed in QMT 8.8</td>
</tr>
<tr>
<td><strong>Slides 7 – 8</strong></td>
<td><strong>Requirements – Hospital (1) &amp; (2)</strong></td>
</tr>
<tr>
<td></td>
<td>♦ These two slides list the main systems that need to be in place in the hospital to assist in establishing a comprehensive haemovigilance system</td>
</tr>
<tr>
<td></td>
<td>♦ Re-emphasize the need for good documentation throughout the transfusion chain</td>
</tr>
<tr>
<td><strong>Slide 9</strong></td>
<td><strong>Requirements – BTS</strong></td>
</tr>
<tr>
<td></td>
<td>♦ The slide lists the main systems that should be in place in the BTS</td>
</tr>
<tr>
<td></td>
<td>♦ Emphasize the need for baseline data for the purposes of comparison and analysis</td>
</tr>
<tr>
<td></td>
<td>♦ Stress the importance of good communication between the BTS and hospitals/clinical teams</td>
</tr>
<tr>
<td><strong>Slide 10</strong></td>
<td><strong>Information required</strong></td>
</tr>
<tr>
<td></td>
<td>♦ The slide lists examples of the information required for the haemovigilance system</td>
</tr>
<tr>
<td></td>
<td>♦ Explore the various details about the patient’s condition on which information may be required</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss the need for immediate action, reporting and investigation</td>
</tr>
<tr>
<td><strong>Slide 11</strong></td>
<td><strong>Presentation of Information</strong></td>
</tr>
<tr>
<td></td>
<td>♦ The slide lists some examples of how the information gathered can be presented</td>
</tr>
<tr>
<td></td>
<td>♦ Explore the need to present information in a transparent manner</td>
</tr>
<tr>
<td></td>
<td>♦ Emphasize the importance of presenting timely reports</td>
</tr>
<tr>
<td><strong>Slides 12 – 13</strong></td>
<td><strong>Benefits (1) &amp; (2)</strong></td>
</tr>
<tr>
<td></td>
<td>♦ The slides list the benefits of implementing a haemovigilance system</td>
</tr>
<tr>
<td></td>
<td>♦ Explore how even negative reports can assist in improving public confidence and trust if presented in a transparent and comprehensive manner</td>
</tr>
</tbody>
</table>
Haemovigilance

Teaching Aim

- To promote the development of a national reporting system for adverse transfusion events

Core Topics

- Definition
- Principle
- Requirements
- Benefits
Definition

- Haemovigilance is a system for the monitoring, reporting and investigation of adverse incidents/near misses related to all blood transfusion activities
  - e.g. SHOT — Serious Hazards of Transfusion (UK)
  - French: comprehensive ‘vein to vein’ concept

Principle

- To detect, collect and analyse information about all adverse incidents related to the transfusion of blood and blood products
  - A system to gather accurate information on adverse transfusion events
  - Information is fed back to improve practice in the BTS and in the hospital
  - Overall effect is to improve transfusion safety and thus public confidence

Characteristics of Haemovigilance

- Confidential
- Professionally owned
- Voluntary / mandatory
- Not punitive
Requirements - Hospital (1)

- System for reporting any adverse incident related to the transfusion of blood and blood products
  - Awareness amongst clinicians / nurses / laboratory staff regarding the need to identify adverse reactions
  - Simple and effective system

Requirements - Hospital (2)

- System for monitoring transfusion
  - Hospital practice
  - Transfused patients
- Full documentation
  - Guidelines and procedures
  - Reporting forms

Requirements - BTS

- BTS system for the investigation of all reports
  - Willingness to investigate incidents
  - Traceability of all products from donor to patient(s)
  - Re-call of implicated units of blood / products
  - Re-call of implicated donors
- Full documentation
  - Guidelines and procedures
  - Investigation outcome forms
Information Required

- Details of the incident or event
- Patient identity (coded, if necessary)
- Details of patient's condition and treatment regimen
  - Full transfusion history
  - Results of laboratory tests before and after transfusion
- Details of action taken as a result of the incident
  - Immediate
  - Local
  - National

Presentation of Information

- Full analysis of each reported incident
  - Type of incident
  - Cause
  - Outcome
  - Any other relevant information
  - Feedback to reporting site, as appropriate
- Presentation of collected information
  - Annual report
  - Impartial analysis
  - Broad dissemination of information
  - Anonymity and confidentiality at all times

Benefits (1)

- Understanding of the frequency and range of transfusion-related events
  - Where they occur
  - Why they occur
- Improved understanding of transfusion consequences
  - Natural history of transfusion-transmitted infections
  - Effects of transfusion on the body
Benefits (2)

- Opportunity to take action and improve transfusion practice
- Improved public confidence and trust

Key points

- To be effective, haemovigilance requires open and honest reporting and investigation and depends on traceability in the hospital and the BTS
- Haemovigilance is an essential part of the quality system at the BTS / clinical interface
- Information is fed back into the transfusion system to improve the overall safety and quality of transfusion practice in the BTS and hospital

Learning Outcomes (1)

You should now be able to:

- Explain how a haemovigilance system can help to improve the quality of every aspect of blood transfusion
- Describe the elements of a haemovigilance system
Learning Outcomes (2)

- Identify the actions required to establish a national haemovigilance system
- Identify the role of the quality manager in developing a national haemovigilance system and utilizing the data to improve transfusion practice
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 14.10</th>
<th>Identifying and Monitoring Critical Control Points for the Clinical Interface and the Administration of Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To identify critical control points at the clinical interface and plan systems for monitoring</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Identifying the monitoring points available  
♦ Identifying the monitoring strategies and evaluation methods |
| **Key points** | ♦ Critical control points in the hospital transfusion process must be identified |
| **Teaching focus** | ♦ Emphasize the importance of good communication between the BTS/blood bank and the hospital  
♦ Emphasize the role of the hospital transfusion committee in ensuring the safety of the patient requiring transfusion |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the critical control points in the process at which monitoring should take place  
♦ Identify the kind of monitoring that should take place |
| **Type of activity** | Group work |
| **Materials required** | ♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 Allocate one of the following activities to each group:  
♦ Issue of blood for transfusion  
♦ Administration of blood to the patient  
♦ Monitoring the transfused patient  
♦ Reporting and investigating adverse transfusion reactions.  
2 Instruct the participants to:  
♦ Identify the critical control points in the process  
♦ Prepare a flowchart  
♦ Identify the personnel involved  
♦ Design a plan for monitoring and evaluation of the process  
♦ Identify the documentation required |
| **Review of the activity** | Ensure that participants:  
♦ Produce simple but effective flowcharts  
♦ Correctly identify the critical control points  
♦ Identify both hospital and BTS staff involved in the process  
♦ Prepare a comprehensive plan for monitoring and evaluation  
♦ Include data that should be obtained for a comprehensive haemovigilance system |
| **Time span** | 1 hour |
Module 15
Finalization of Participants' Action Plans and Completion of the Course
### QMT 15.1 Review of the Course

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To enable participants to identify any areas where clarification or additional work is needed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core topics</strong></td>
<td>Review of any aspects of the course that require clarification or additional discussion</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Teaching focus** | Identify the specific issues requiring further discussion  
|                  | Clarify and explain, using relevant examples where possible |
| **Learning outcomes** |                                                                                          |
| **Type of activity** | Plenary session |
| **Materials required** | All presentations, in case they are needed for cross-reference |
| **Instructions** | 1 Invite the participants to identify any areas that require clarification.  
|                  | Keep the discussions brief and to the point  
|                  | Invite other participants to clarify the issues raised, if they wish  
|                  | Keep the discussions open |
| **Review of the activity** |  
| **Time span** | 1 hour |
## QMT 15.2 Laboratory/Clinic Visits in the BTS

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To explore specific aspects of BTS activities in detail.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Detailed look at the BTS from a quality perspective</td>
</tr>
<tr>
<td></td>
<td>♦ Discussion of approaches taken by the BTS and the reasons for them</td>
</tr>
<tr>
<td></td>
<td>♦ Review of any areas or activities of specific interest</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Ensure as best as possible that participants’ information needs are met</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Type of activity</strong></td>
<td>Group visits to departments</td>
</tr>
<tr>
<td><strong>Materials required</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Instructions</strong></td>
<td>1 The QMP coordinator should already have asked the participants, prior to the actual activity, which departments they wish to visit and which specific aspects they wish to view.</td>
</tr>
<tr>
<td></td>
<td>2 Allow the coordinator to time-manage the participants and their visits.</td>
</tr>
<tr>
<td><strong>Review of the activity</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>1 – 2 hours</td>
</tr>
</tbody>
</table>
### QMT 15.3 Completing Individual Action Plans

<table>
<thead>
<tr>
<th>Teaching aim</th>
<th>To ensure each participant produces an appropriate and achievable action plan</th>
</tr>
</thead>
</table>
| Core topics  | • Producing an appropriate and realistic action plan  
               • Planning: what, how often and when  
               • Defining the timescale for the plan (i.e. short, medium and long-term) |
| Key points   | • Plans need to be appropriate and realistic |
| Teaching focus | • Ensure plans are realistic and achievable  
                  • Emphasize the value of developing short, medium and long-term plans |
| Learning outcomes | Participants will be able to:  
                            • Identify needs  
                            • Prepare an action plan for their BTS |
| Type of activity | Individual work |
| Materials required | • Draft action plans prepared in QMT 9.7  
                                • Comments from facilitators on the drafts |
| Instructions | 1 Discuss the comments made by the facilitator(s) on the draft plans.  
               2 Assist participants to adjust their plans accordingly, where appropriate. |
| Review of the activity | Individual discussions |
| Time span | 2 – 3 hours |
### Discussion of Individual Action Plans

<table>
<thead>
<tr>
<th>QMT 15.4</th>
<th>Teaching aim</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To assist participants to finalize their action plans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Core topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Overall strengths and weaknesses of participants’ action plans</td>
</tr>
<tr>
<td>♦ Finalization of action plans</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Teaching focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ If possible, obtain the input of the facilitators who gave comments on the draft plans</td>
</tr>
<tr>
<td>♦ Guide discussions to ensure they are positive and constructive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Learning outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants will be able to:</td>
</tr>
<tr>
<td>♦ Produce an amended action plan for their BTS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentations by participants followed by plenary session</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Materials required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action plans prepared by participants</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Invite the participants in turn to present their action plans.</td>
</tr>
<tr>
<td>2 Allocate 5–10 minutes for each participant to make their presentations. Ask them simply to give an overview of their plans rather than explaining them in detail.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review of the activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ After each presentation, invite comments from other participants</td>
</tr>
<tr>
<td>♦ Encourage constructive criticism</td>
</tr>
<tr>
<td>♦ Point out, where appropriate, how different approaches may sometimes be necessary in action planning and what factors may have determined those approaches</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time span</th>
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</thead>
<tbody>
<tr>
<td>1½ hours</td>
</tr>
</tbody>
</table>
### QMT 15.5 Review of Quality Systems

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To review the role of quality in blood transfusion</th>
</tr>
</thead>
</table>
| **Core topics** | ♦ Review of key aims and principles of quality systems  
    ♦ Quality in all BTS activities |
| **Key points** | ♦ All BTS activities contribute to quality  
    ♦ Quality is only as good as the weakest link in the chain |
| **Teaching focus** | ♦ Summarize the key elements of the course  
    ♦ Bring everything to a suitable conclusion |
| **Learning outcomes** | Participants should be able to:  
    ♦ Outline the reasons for establishing quality systems in a BTS  
    ♦ List the major elements in establishing quality systems |

| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Quality  
5 Quality System Elements  
6 Aim of Quality Systems in the BTS  
7 Quality Failures  
8 Consequences of Poor Quality  
9 Consequences of Good Quality  
10 Key Points  
11 Learning Outcomes |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Materials</strong></td>
<td>All presentations (these should already have been distributed)</td>
</tr>
<tr>
<td><strong>Related activity</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>½ hour</td>
</tr>
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#### Presentation notes and handling the session

- The presentation is a summary of the 15 modules in the course
- Re-visit the elements of the quality system
- Emphasize the reasons for establishing quality systems in the BTS
Review of Quality Systems

WHO/QMT 15.5

Teaching Aim

- To review the role of quality in blood transfusion

Core Topics

- Review of key aims and principles of quality systems
- Quality in all BTS activities
Quality

- Fitness for purpose
- Blood transfusion that is safe and efficacious
- A process — not a goal
- Continuous improvement
  A new way of looking at what you do, understanding it and searching for improvement

Quality System Elements

- Organizational management
- Referential (quality) standards
- Documentation
- Monitoring & evaluation
- Training

Aim of Quality Systems in the BTS

- To reduce the risk of serious or fatal consequences throughout the whole transfusion chain (from "vein to vein")
Quality Failures

- Can result in death
  - Failure to identify patient
  - Failure to identify donor
  - Incorrect results
  - Unscreened blood

Consequences of Poor Quality

- Inappropriate action
- Inappropriate inaction
- Delayed action
- Loss of credibility
- Legal action

Consequences of Good Quality

- Life or improved “quality of life”
- Delighted customers
- Minimal risk
Key Points

- All BTS activities contribute to quality
- Quality is only as good as the weakest link in the chain

Learning Outcomes

You should now be able to:

- Outline the reasons for establishing a quality system in a BTS
- List the major elements in establishing a quality system
<table>
<thead>
<tr>
<th>QMT 15.6</th>
<th>Post-Course Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching aim</td>
<td>To determine participants' levels of knowledge and understanding of quality and quality systems</td>
</tr>
<tr>
<td>Core topics</td>
<td>✦ Determining participants' knowledge and understanding of quality in comparison with the pre-course assessment</td>
</tr>
</tbody>
</table>
| Key points    | ✦ The post-course assessment is not an examination  
✦ It will help in planning subsequent courses by identifying how to strengthen areas of weakness or gaps in the curriculum |
| Teaching focus| ✦ Ensure that participants understand that the assessment is not an examination |
| Learning outcomes | Participants should be able to:  
✦ Demonstrate increased knowledge and understanding of quality and quality systems in the BTS |
| Type of activity | Multiple-choice questions |
| Materials     | ✦ QMT 15.6: Post-Course Assessment Questions  
✦ QMT 15.6: Post-Course Assessment Answers  
✦ Pens |
| Instructions  | 1 Instruct the participants to answer the questions on the assessment questionnaire.  
2 Encourage them not to guess the answers. |
| Review of activity | ✦ Mark the participants’ responses while participants are completing QMT 15.7  
✦ Note the results  
✦ Return the marked sheets to participants |
| Time          | ½ hour |
QMT 15.6

POST-COURSE ASSESSMENT QUESTIONS

Name:

Total Questions: 35

Time: 45 minutes

Mark the correct answer to each question

1. The quality of a product or a service denotes:
   a. High cost
   b. Fitness for the purpose
   c. Quick results and efficacious products
   d. Sophistication and complexity of the process

2. ISO is:
   a. Internal Services Office
   b. International Organisation for Standardisation
   c. International Safety Organization
   d. Instant Solutions Offer

3. The relationship between the results achieved and the resources used is:
   a. Efficiency
   b. Effectiveness
   c. Precision
   d. Verification

4. The initial draft of a standard operating procedure should be written by:
   a. Person performing the procedure
   b. Quality manager
   c. Technical head of the blood bank
   d. An expert committee

5. A system of activities that uses resources to transform inputs into outputs is defined as:
   a. Procedure
   b. Process
   c. Plan
   d. Performance
6 The fulfilment of a requirement is defined as:
   a Conformity
   b Characteristic
   c SOP
   d Audit

7 The implementation of quality in blood banks is the responsibility of:
   a The quality manager only
   b The technical head of the blood bank only
   c External auditors
   d All staff members of the blood bank

8 A quality policy is officially endorsed and approved by the:
   a Top management of the blood bank
   b Quality Manager
   c Customer
   d Technical professionals of the blood bank

9 The overall intentions and direction of an organization in relation to quality, as formally expressed by top management is:
   a Quality objective
   b Quality policy
   c Quality management system
   d Quality planning

10 A document stating the quality policy and describing the quality system of an organization is called:
   a Quality manual
   b Guidelines
   c Specifications
   d Quality plan

11 A job description includes all of the following except:
   a Key tasks to be performed
   b Minimum qualifications and experience
   c Position in the organization’s organogram
   d Career advancement prospects
12 **Standard operating procedures (SOPs):**
   a. Are guidelines for screening of transfusion-transmissible infections
   b. May be used by some staff members sometimes
   c. Are designed to help newly recruited and inexperienced technical staff to develop confidence and acquire skills
   d. Must be followed strictly by all staff members at all times

13 **SOPs should be accessible to:**
   a. Senior staff only
   b. All relevant staff all the time
   c. Staff when they encounter problems in performing procedure
   d. All staff only on demand

14 **The following documents need to be controlled:**
   a. Quality manual
   b. Standard operating procedures
   c. Donor records
   d. List of approved suppliers
   e. All of the above

15 **The part of quality assurance that ensures that products are consistently produced and controlled to quality standards appropriate to their intended use is called:**
   a. Good Manufacturing Practice (GMP)
   b. Good Laboratory Practice (GLP)
   c. Good Clinical Practice (GCP)
   d. Internal quality control

16 **A quality audit is:**
   a. A systematic, independent and documented examination to determine whether quality activities comply with planned arrangements
   b. An evaluation of conformity by observation and judgement
   c. An activity that ensures correct financial procedures

17 **Competency assessment of staff includes all the following except:**
   a. Written evaluation
   b. Review of work records
   c. Testing of unknown samples
   d. Gross salary received
   e. Problem solving skills
18 A stock card is characterized by the following except:
   a A simple and efficient stock control system
   b A record of the order, delivery and use of each item
   c Decides next order and quantity to order
   d Ensures excessive stocks are always available
   e Helps at each time of issue, order or delivery of stock

19 The following essential information should be retained for stock control except:
   a Minimum stock level
   b Minimum order
   c Code number of consumables
   d Test in which consumable is to be used

20 The method most suitable for ordering consumables with a long expiry period if you have sufficient resources and storage space is:
   a Bulk order
   b Standing order
   c Order as required

21 Which of the following does not apply to an external quality assessment (EQA) scheme?
   a Organized by an external agency
   b Does not require follow up
   c Periodic
   d Compares performance at different sites

22 Material received by a participating blood bank for external quality assessment should be analyzed:
   a By the quality manager alone
   b By the most skilled worker
   c With specially procured and exclusive reagents
   d In the same manner as routine work

23 A unique number must be assigned to each donation of blood. To which of the following should this number be attached?
   a The primary collection bag only
   b The primary and all secondary collection bags only
   c The primary, all secondary collection bags and all specimen tubes used only
   d The primary, all secondary collection bags, all specimen tubes used and donation record
24 The following applies to storage areas for blood and blood components:
   a Quarantined components should be stored with non-conforming blood components
   b Tested (available) units should be stored separately from partially tested or untested (quarantined) blood components
   c Quarantined components should be stored with expired blood components

25 Quality monitoring of processed blood components is performed to:
   a Find reasons not to make blood components
   b Research new techniques for making blood components
   c Ensure that the final product meets specifications and that the process is "in control"
   d Keep the quality manager happy

26 The identification of a patient receiving transfusion should be carried out:
   a By the patient’s bedside immediately before transfusion
   b At the nurses’ station before transfusion
   c During the transfusion
   d After the transfusion

27 The documentation required in the preparation of blood components includes:
   a Approved SOPs and records of all key activities ranging from the receipt of whole blood to the distribution of released components to hospitals and blood banks for compatibility testing
   b Validation protocol for testing for transfusion-transmissible infections
   c Crossmatching results
   d Training records for staff working in the Quality Department

28 Documented procedures for the recall of blood components must enable:
   a Recall of all components/component pool related to the donation that caused an adverse reaction
   b Recall of the initial component that caused the adverse reaction
   c Awareness that the component caused an adverse reaction

29 Recall of a product should lead to:
   a Notification of the donor staff
   b No further action
   c An investigation, with corrective action to prevent recurrence
   d Notification of the components preparation staff
30 **It is important to have a stock control system for reagents because:**
   a. It ensures that reagents are validated properly
   b. It helps you in monitoring the rate of usage of items, and the reliability of your supplier which, in turn will help prevent an out-of-stock situation
   c. It is an extra system to keep people busy
   d. It is a new system that management wants implemented

31 **Record-keeping in the laboratory is essential in meeting the requirements of:**
   a. Good laboratory practice
   b. Good record-keeping practice
   c. Good testing practice
   d. Good housekeeping practice

32 **A "blood cold chain" is:**
   a. A metal link that is kept in the refrigerator
   b. The storage of products in a refrigerator and/or freezer
   c. A system for storing and transporting blood and plasma in an appropriate way to maintain all its functions
   d. A cold climate

33 **The following are NOT essential parts of the blood cold chain:**
   a. Equipment for the storage and transportation of blood
   b. People who manage the storage and transportation of blood
   c. People and equipment, resulting in an adequate blood cold chain
   d. Maintenance of blood storage equipment
   e. Control of the stock of blood available for use

34 **A haemovigilance programme is concerned with:**
   a. Investigation of transfusion-related incidents
   b. Haemoglobin level of a donor
   c. Haemoglobin test
   d. Efficiency of staff

35 **The customers of the BTS at the clinical interface are:**
   a. Patients
   b. Clinicians
   c. Patients and clinicians
   d. Donors
QMT 15.6

POST-COURSE ASSESSMENT ANSWERS

Answers

<p>| | | | | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
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<tr>
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<td>d</td>
<td>8</td>
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<tr>
<td>11</td>
<td>d</td>
<td>12</td>
<td>d</td>
<td>13</td>
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<tr>
<td>16</td>
<td>a</td>
<td>17</td>
<td>d</td>
<td>18</td>
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<tr>
<td>21</td>
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<td>b</td>
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<td>19</td>
<td>d</td>
<td>20</td>
<td>a</td>
<td>24</td>
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<tr>
<td>29</td>
<td>c</td>
<td>30</td>
<td>b</td>
<td>34</td>
</tr>
</tbody>
</table>
### Teaching aim
To obtain feedback on the quality and overall effectiveness of the course

### Core topics
- Evaluating the effectiveness of the training: presentations, activities, facilitators, facilities and general arrangements
- Follow-up courses

### Key points
- Feedback is needed about course methods and effectiveness
- Honest opinions are needed

### Teaching focus
Make clear to the participants that their views are genuinely required

### Learning outcomes
Participants should be able to:
- Freely express their views and/or concerns about the course

### Type of activity
Individual work

### Materials
- QMT 15.7: Course Evaluation forms
- Pens

### Instructions
1. Ask the participants to complete the evaluation form as honestly and as openly as possible.

### Review of activity
- Hand the completed evaluation forms to the course coordinator

### Time
½ hour

<table>
<thead>
<tr>
<th>QMT 15.7</th>
<th>Course Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To obtain feedback on the quality and overall effectiveness of the course</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Evaluating the effectiveness of the training: presentations, activities, facilitators, facilities and general arrangements  
♦ Follow-up courses |
| **Key points** | ♦ Feedback is needed about course methods and effectiveness  
♦ Honest opinions are needed |
| **Teaching focus** | Make clear to the participants that their views are genuinely required |
| **Learning outcomes** | Participants should be able to:  
♦ Freely express their views and/or concerns about the course |
| **Type of activity** | Individual work |
| **Materials** | ♦ QMT 15.7: Course Evaluation forms  
♦ Pens |
| **Instructions** | 1. Ask the participants to complete the evaluation form as honestly and as openly as possible. |
| **Review of activity** | ♦ Hand the completed evaluation forms to the course coordinator |
| **Time** | ½ hour |
Please answer the following questions

**Section One**

**Course**

1. List the subjects that were of most value to you in the course.

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

2. List any subjects that you think should have been covered in more depth.

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

3. List any subjects that you think should have been covered in less depth.

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________

   ___________________________________________________
4 List any additional subjects that you felt should have been included.

_________________________________________________________________________
_________________________________________________________________________
_________________________________________________________________________
_________________________________________________________________________
_________________________________________________________________________

5 List any subjects that you felt could have been omitted.

_________________________________________________________________________
_________________________________________________________________________
_________________________________________________________________________
_________________________________________________________________________
_________________________________________________________________________

Section Two

6 How would you rate the effectiveness of:

♦ Presentations
♦ Activities
♦ Material
♦ Level of each presentation and activity?

Use the following rating systems to grade them.

<p>| Section A | | Section B |
|-----------|-----------|
| Grade     | Grade     |
| 1         | Excellent |
| 2         | Good      |
| 3         | Satisfactory |
| 4         | Poor      |
| 5         | Very poor |
| 1         | Too advanced |
| 2         | About right |
| 3         | Too basic  |</p>
<table>
<thead>
<tr>
<th>Subject</th>
<th>Section A</th>
<th>Section B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Presentation Number</td>
<td>Presentation Rating</td>
</tr>
<tr>
<td><strong>Module 1: The WHO Quality Management Programme</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO Strategies for Blood Safety</td>
<td>QMT 1.1</td>
<td></td>
</tr>
<tr>
<td>WHO Quality Management Project (QMP) for Blood Transfusion Services</td>
<td>QMT 1.2</td>
<td></td>
</tr>
<tr>
<td>Introduction to the WHO QMT Course</td>
<td>QMT 1.3</td>
<td></td>
</tr>
<tr>
<td>Participants’ Expectations</td>
<td></td>
<td>QMT 1.4</td>
</tr>
<tr>
<td>Pre-Course Assessment</td>
<td></td>
<td>QMT 1.5</td>
</tr>
<tr>
<td><strong>Module 2: Introduction to Quality</strong></td>
<td></td>
<td></td>
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<tr>
<td>The Importance of Quality in the Blood Transfusion Service</td>
<td>QMT 2.1</td>
<td></td>
</tr>
<tr>
<td>The Consequences of Poor Quality in the Blood Transfusion Service</td>
<td></td>
<td>QMT 2.2</td>
</tr>
<tr>
<td>Introducing Quality</td>
<td>QMT 2.3</td>
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<tr>
<td>Quality Characteristics</td>
<td></td>
<td>QMT 2.4</td>
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<td>Tour of the Blood Transfusion Centre (BTC)</td>
<td></td>
<td>QMT 2.5</td>
</tr>
<tr>
<td>Subject</td>
<td>Section A</td>
<td>Section B</td>
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<tr>
<td><strong>Module 3: Quality Systems</strong></td>
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<tr>
<td>Quality Systems</td>
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<tr>
<td>Processes and Procedures</td>
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<tr>
<td>Flowcharting as a Tool for Mapping Processes</td>
<td>QMT 3.3</td>
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<tr>
<td>Developing a Process Flowchart</td>
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<tr>
<td><strong>Module 4: Organizational Management</strong></td>
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<tr>
<td>Management Responsibility for Quality</td>
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<tr>
<td>Developing a Quality Policy</td>
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<tr>
<td>Organizational Structure and Role of the Quality Manager</td>
<td>QMT 4.3</td>
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<tr>
<td>Developing an Organogram</td>
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<tr>
<td>Job Descriptions, Responsibility and Delegation</td>
<td>QMT 4.5</td>
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<tr>
<td>Writing a Job Description</td>
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<tr>
<td>The Cost of Quality</td>
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<tr>
<td>Subject</td>
<td>Module 5: Standards for Quality Systems</td>
<td>Module 6: Documentation</td>
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<tr>
<td></td>
<td>Introduction to Standards for Quality Systems</td>
<td>Documentation in Quality Systems</td>
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<tr>
<td></td>
<td>Principles of Good Manufacturing Practice</td>
<td>Standard Operating Procedures</td>
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<td>Writing an SOP</td>
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<td>Validating an SOP</td>
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<td>Document Control</td>
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<td>Controlling a Document</td>
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<td>QMT 5.1</td>
<td>QMT 6.1</td>
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<tr>
<td>Module 8: Assessment</td>
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<tr>
<td>Assessment within Quality Systems</td>
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<tr>
<td>Validation</td>
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<tr>
<td>Preparing a Validation Plan</td>
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<td>Developing a Maintenance and Validation Plan</td>
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<td><strong>Evaluation and Use of Test Kits for Transfusion-Transmissible Infections</strong></td>
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<td><strong>External Quality Assessment (EQA) Schemes</strong></td>
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<td>Evaluation and Monitoring of Blood Component Production Activities</td>
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<td>Quarantine and Release</td>
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<td>Storage and Transportation of Blood Components</td>
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<td>Blood Stock Management</td>
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<td>Module 14: Quality Systems at the Clinical Interface</td>
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<td>Introduction to Quality Systems at the Clinical Interface</td>
<td>QMT 14.1</td>
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<td>Policy and Guidelines on the Clinical Use of Blood</td>
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<td>The Role of the BTS at the Clinical Interface</td>
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<td>Documentation in the Hospital Transfusion Process</td>
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<td>Designing a Blood Request Form</td>
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<td>Quality in the Hospital Transfusion Process</td>
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<td>Monitoring and Evaluation of the Hospital Transfusion Process</td>
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<td>Haemovigilance</td>
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<tr>
<td>Identifying and Monitoring Critical Control Points for the Clinical Interface and Administration of Blood</td>
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<td>QMT 14.10</td>
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</tbody>
</table>
7 List your suggestions for improving the training course.

_________________________________________________________________________
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8 List your suggestions for improving the materials used.

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_________________________________________________________________________
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9 List your suggestions for improving the learning activities.

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_________________________________________________________________________
10 List the topics you would like to see covered in follow-up courses.

_________________________________________________________________________
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### QMT 15.8 Final Discussions

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To provide a forum for final discussion and clarification</th>
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<tbody>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Outstanding issues&lt;br&gt;♦ Follow-up courses and other QMP/QMT activities&lt;br&gt;♦ Strengthening the links and collaboration between the Quality Training Centre and other countries in the region</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>♦ The final forum for discussion</td>
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<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Clear up any outstanding issues, queries or problems</td>
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<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to:&lt;br&gt;♦ Identify any final issues that require clarification or discussion</td>
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<tr>
<td><strong>Type of activity</strong></td>
<td>Plenary session</td>
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<tr>
<td><strong>Materials</strong></td>
<td>None</td>
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<tr>
<td><strong>Instructions</strong></td>
<td>1 Ask the participants if there are any further issues they wish to discuss.&lt;br&gt;2 Keep the discussions informal.</td>
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<tr>
<td><strong>Review of activity</strong></td>
<td>None</td>
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<tr>
<td><strong>Time</strong></td>
<td>1 hour</td>
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