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INTRODUCTION

Module 1
Module 1
The WHO Quality Management Programme
**QMT 1.1 WHO Strategy for Blood Safety**

<table>
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<tr>
<th>Teaching aim</th>
<th>To introduce course participants to the WHO Global Database on Blood Safety and the WHO integrated strategy for blood safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core topics</td>
<td>♦ WHO Global Database on Blood Safety (GDBS) &lt;br&gt;♦ WHO strategy for global blood safety</td>
</tr>
<tr>
<td>Key points</td>
<td>♦ The WHO Global Database on Blood Safety provides the best available information on the global situation &lt;br&gt;♦ The WHO strategy for blood safety defines requirements for the safety, adequacy and accessibility of national blood supplies</td>
</tr>
<tr>
<td>Teaching focus</td>
<td>Ensure participants understand the WHO strategy for safe blood</td>
</tr>
<tr>
<td>Learning outcomes</td>
<td>Participants should be able to: &lt;br&gt;♦ Identify key problems in relation to global blood safety &lt;br&gt;♦ Describe the WHO strategy for blood safety</td>
</tr>
</tbody>
</table>

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<th>Slides</th>
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<td>5 WHO Global Database on Blood Safety (GDBS)</td>
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<td>12 Countries Without 100% Screening: WHO GDBS, 2000–2001</td>
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<td>17 Countries with No Training for Various Categories of BTS Staff: WHO GDBS, 2000–2001</td>
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<td>22 WHO Aide-Mémoire: Blood Safety</td>
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</tbody>
</table>
### Materials
Distribute the following materials at the end of the presentation or at the point at which the topic is introduced:
- WHO Aide-Mémoire: Blood Safety
- WHO Aide-Mémoire: Quality Systems for Blood Safety

### Related presentations and activity
- QMT 1.2 WHO Quality Management Programme (QMP) for Blood Transfusion Services
- QMT 1.3 Introduction to the WHO QMT Course
- QMT 1.4 Participants' Expectations

### Time span
½ hour

### Presentation notes and handling the session

#### Slide 4
Outline of This Presentation
- The three boxes on the slide outline the first two elements of the presentation:
  - Global problems in blood safety
  - The WHO strategy for blood safety
- The QMP element is dealt with in QMT 1.2
- The slides that follow deal with the topic in the highlighted box “What is the problem?”

#### Slide 5
WHO Global Database on Blood Safety (GDBS)
- The WHO Global Database on Blood Safety contains information provided by ministries of health and blood transfusion services in Member States
- The first collection of data covers the period 1998–1999
- The second collection of data covers the period 2000–2001
- 178 out of 192 Member States provided information for the GDBS 2000–2001
- Slides 6–18 summarize some of the key findings from the GDBS for the period 2000–2001

#### Slide 6
- The Human Development Index (HDI) was devised by the United Nations Development Programme (Human Development Report, UNDP, 2002)
- The HDI classifies countries as having a low, medium or high human development index based on life expectancy, educational attainment and adjusted income
- The slide demonstrates the distribution of the global blood supply among the three categories of HDI countries
- 18% of the global population (high HDI countries) has access to 61% of the global blood supply

#### Slide 7
- 82% of the global population (low and medium HDI countries) has access to only 39% of the global supply of safe and tested blood
- This clearly indicates the need for strategies to increase the number of blood donations
Slide 8
- World Health Assembly Resolution WHA28.72 of 1975 urged Member States to promote the development of national blood services based on voluntary, non-remunerated blood donation
- The slide shows the need for further advocacy in many countries to ensure that the resolution is implemented
- Dependence on paid and family/replacement blood donors leads to increased risk to the safety of the blood supply due to an increased risk of transfusion-transmissible infections (TTIs) in these types of donors

Slide 9
- This slide shows that voluntary donation rates are very low in over 60 countries, mostly low and medium HDI countries
- Low and medium HDI countries contribute only 25% of all the donations from voluntary non-remunerated blood donors collected globally
- In contrast, 94% of donations in high HDI countries are from voluntary non-remunerated blood donors
- Only 39 countries have 100% voluntary blood donation, but a further 18 are close to reaching this target; while the majority of them are high HDI countries, some low and medium HDI countries have shown that the goal is achievable

Slide 10
Seroprevalence in Blood Donors (%): WHO GDBS, 2000–2001
- The table shows the range of reported seroprevalence rates of TTIs in donated blood in low, medium and high HDI countries
- These rates are higher in low and medium HDI countries and correlate with the higher percentages of family/replacement or paid donors

Slide 11
- WHO recommends that all donated blood should be tested for the following four markers of infection: HIV, HBV, HCV and syphilis
- In 1998–1999, an estimated 13 million tests were not performed for these four markers
- By 2000–2001, this figure decreased to 6 million, largely due to an improvement in HCV testing

Slide 12
Countries Without 100% Screening: WHO GDBS, 2000–2001
- The chart shows the number of countries (low, medium and high HDI) that carry out 100% testing, less than 100% testing and 0% testing for the four markers recommended by WHO
- 39% of countries still do not test for HCV
- An unacceptable number of countries do not have 100% testing for HIV (the one country that reported 0% testing for HIV collects only 10 units per annum)
- Inadequate testing is often due to erratic supplies of test kits

Slide 13
- In the 178 countries that provided data, ABO (red cell grouping) and RhD testing of donated blood are routinely performed (100% ABO and 98% RhD)
- However, anecdotal information indicates that they are not always performed to a high standard
Slide 14
Percentage Transfused as Whole Blood: WHO GDBS, 2000–2001
- The chart indicates that blood component therapy is not widely available in many countries

Slide 15
Cost of Producing One Unit of Blood: WHO GDBS, 2000–2001
- The slide shows the wide range of costs reported for the production of one unit of blood
- The costs are usually highest in countries that carry out a larger number of tests, perform sophisticated tests (such as NAT testing) and/or use technologies such as universal leukocyte deletion
- Many countries underestimate the real cost of producing a unit of blood
- Many factors contribute to the cost, including all operational costs, such as personnel, premises and utilities, and not only the cost of blood bags, test kits and reagents
- There is no statistical correlation between costs and a country's level of development

Slide 16
Voluntary Blood Donation vs. Units Discarded after Screening for TTIs: WHO GDBS, 2000–2001
- The slide shows how, as rates of voluntary blood donation decrease, a significantly higher proportion of donated blood tests seropositive for infection and is discarded
- The "dip" in the chart is not statistically significant
- The costs of discards contribute to the overall cost of a unit of blood
- An investment in the recruitment of voluntary non-remunerated blood donors will result in a decrease in the cost of a unit of blood

Slide 17
Countries with No Training for Various Categories of BTS Staff
- This slide shows the number of countries with no training available for BTS staff of different categories

Slide 18
What is the Problem?
- The slide summarizes the preceding slides regarding the safety and adequacy of the global blood supply

Slide 19
Outline of This Presentation
- The next slides deal with the topic in the highlighted box – "WHO Strategy for Blood Safety"

Slide 20
WHO Strategy for Blood Safety (1)
- This slide shows the first two elements of the WHO integrated strategy for blood safety

Slide 21
WHO Strategy for Blood Safety (2)
- The first two bullets focus on the testing and processing of donated blood
- The appropriate clinical use of blood involves reducing unnecessary transfusions, promoting safe clinical transfusion practice and encouraging national health authorities to establish strategies and systems to prevent common medical problems that may otherwise result in the need for blood transfusion
<table>
<thead>
<tr>
<th>Slide 22</th>
<th>WHO Aide-Mémoire: Blood Safety</th>
</tr>
</thead>
</table>
| ♦ The Aide-Mémoire is an advocacy document for policy makers that outlines the WHO integrated strategy for blood safety  
♦ It includes a checklist that acts as a reminder of the major elements of the strategy |

<table>
<thead>
<tr>
<th>Slide 23</th>
<th>WHO Aide-Mémoire: Quality Systems for Blood Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The Aide-Mémoire is an advocacy document for policy makers that outlines the steps in implementing quality systems in blood transfusion services</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 24</th>
<th>Blood Saves Lives: Safe Blood Starts with Me!</th>
</tr>
</thead>
</table>
| ♦ This logo was devised for World Health Day 2000 which was dedicated to blood safety with the slogan "Blood Saves Lives: Safe Blood Starts with Me!"  
♦ World Health Day 2000 was celebrated globally and was instrumental in raising awareness about the importance of blood safety  
♦ Following on from the success of World Health Day 2000, World Blood Donor Day (WBDD) was celebrated for the first time on 14 June 2004 to recognize and thank voluntary non-remunerated blood donors throughout the world  
♦ World Blood Donor Day was organized by the World Health Organization, International Federation of Red Cross and Red Crescent Societies, International Federation of Blood Donor Organizations and International Society of Blood Transfusion  
♦ World Blood Donor Day will be held on 14 June each year to promote voluntary non-remunerated blood donation; the date is significant because it is the birthday of Karl Landsteiner, the Nobel prize winner who discovered the ABO blood group system  
♦ Further information is available on the WBDD website: www.wbdd.org |
AIDE-MEMOIRE
for National Blood Programmes

A well-organized blood transfusion service (BTS), with quality systems in all areas, is a prerequisite for the safe and effective use of blood and blood products.

The HIV/AIDS pandemic has focused particular attention on the importance of preventing transfusion-transmitted infections (TTIs). Between 5% and 10% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products. Many more recipients of blood products are infected by hepatitis B and C viruses, syphilis and other infectious agents, such as Chagas disease.

The global burden of disease due to unsafe blood transfusion can be eliminated or substantially reduced through an integrated strategy for blood safety which includes:

- Establishment of a nationally-coordinated blood transfusion service
- Collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

**Words of advice**

- Secure government commitment and support for the national blood programme
- Establish a blood transfusion service as a separate unit with responsibility and authority, an adequate budget, a management team and trained staff
- Educate, motivate, recruit and retain voluntary non-remunerated blood donors from low-risk populations
- Ensure good laboratory practice in screening for transfusion-transmissible infections, blood grouping, compatibility testing, blood component production and the storage and transportation of blood products
- Reduce unnecessary transfusions through the effective clinical use of blood, including alternatives to transfusion
- Establish a quality system for the BTS
- Train all BTS and clinical staff to ensure the provision of safe blood and its effective clinical use
**Key elements**

**Establish a blood transfusion service**

It is the responsibility of governments to ensure a safe and adequate supply of blood. This responsibility may be delegated to a non-profit non-governmental organization, but the BTS should be developed within the framework of the country’s health care infrastructure.

The BTS requires government commitment and support and recognition as a separate unit with an adequate budget, management team and trained staff.

Important activities in establishing a blood transfusion service include:

- Formalization of government commitment and support
- Development of a national blood policy and plan
- Development of necessary legislation/regulation for the BTS
- Formation of an organization with responsibility and authority for the BTS
- Formation of a BTS management committee
- Appointment of a medical director
- Appointment of a quality manager
- Appointment, when necessary, of specialist BTS advisory groups
- Appointment and training of staff experienced in each key aspect of the BTS
- Development and implementation of a budgeting and finance system to ensure a sustainable blood programme through cost recovery and/or annual budget allocation
- Establishment of national quality system, including guidelines, standard operating procedures, accurate records, monitoring and evaluation.

---

**Educate, motivate, recruit and retain low-risk blood donors**

High priority should be given to the elimination of family/replacement and paid blood donor systems, which are associated with a significantly higher prevalence of TTIs.

Voluntary non-remunerated blood donors from low-risk populations who give blood regularly are the foundation of a safe and adequate blood supply.

Important activities include:

- Appointment of an officer responsible for the national blood donor programme
- Establishment of a BTS unit responsible for donor education, motivation, recruitment and retention
- Appointment of a designated blood donor recruitment officer
- Preparation of SOPs in accordance with BTS guidelines
- Training of staff in the blood donor unit
- Identification of donor populations at low risk for TTIs
- Development of educational materials
- Establishment of a register of voluntary non-remunerated blood donors
- Assurance of safe blood collection procedures, including donor selection and deferral, donor care and confidentiality

---

**Donor notification and referral for counselling**

Monitoring of TTIs in the donor population.

---

**Test all donated blood**

The BTS should develop and maintain a national strategy for the testing of all donated blood and blood products, using the most appropriate and effective tests, and for good laboratory practice.

Important activities include:

- Appointment of a designated technical officer
- Development of protocols for the testing, selection and evaluation of appropriate screening assays to be used at each site
- Training of BTS laboratory technical staff
- Screening of all donated blood for TTIs, including HIV, hepatitis viruses, syphilis and other infectious agents, such as Chagas disease
- Blood grouping and compatibility testing
- Good laboratory practice, with effective documentation, including standard operating procedures
- Procurement, supply, central storage and distribution of reagents and materials to ensure continuity in testing at all sites
- Maintenance of an effective blood cold chain for the storage and transportation of blood and blood products.

---

**Reduce unnecessary transfusions by effective clinical use of blood**

Blood transfusion has the potential for acute or delayed complications and the transmission of infection. The risks associated with transfusion can be reduced by minimizing unnecessary transfusions through the effective clinical use of blood and blood products and the appropriate use of simple alternatives to transfusion which are safer and more cost-effective.

Important activities include:

- Development of a national policy and guidelines on the clinical use of blood
- Training in the clinical use of blood for all clinicians involved in the transfusion process and for BTS staff
- Commitment to the prevention, early diagnosis and treatment of conditions that could result in the need for transfusion (obstetrical complications, trauma and other causes of anaemia)
- Availability of intravenous replacement fluids (crystalloids and colloids) for the correction of hypovolaemia
- Availability of pharmaceuticals and devices to minimize the need for blood
- Effective clinical use of blood and blood products in accordance with national guidelines
- Monitoring and evaluation of the clinical use of blood.
Blood transfusion is a key part of modern health care. It is the responsibility of the national blood programme to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood and blood products for clinical use. All products must be safe, clinically effective and of appropriate and consistent quality.

The strategies for achieving this are:

- A well-organized, nationally-coordinated blood transfusion service (BTS)
- Blood collected from regular, voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Appropriate clinical use of blood.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Management commitment and support are essential for the development, implementation and monitoring of a national quality system in order to ensure continuous quality improvement. All staff should understand the importance of quality and the consequences of failure in the quality system.

Words of advice

- Secure the commitment and support of management at all levels
- Identify the need for quality in the national blood policy
- Develop a national quality policy and plan
- Secure adequate resources
- Designate a national quality manager with overall responsibility for the implementation of quality systems in BTSs at all levels
- Develop a quality section, with appropriate staffing and expertise, in each blood centre and hospital blood bank
- Provide training in quality for all BTS staff and other health care professionals involved in blood transfusion
- Assess the effectiveness of the quality system continually

Checklist

**Prerequisites**
- Nationally-coordinated BTS
- Management commitment and support
- Integration of quality in the national blood policy
- National quality policy and plan
- National quality manager
- Adequate resources

**Organizational management**
- Clearly defined organizational structure
- Quality manager in each blood centre and hospital blood bank
- Quality section in each blood centre and hospital blood bank
- Culture of quality
- Commitment and support of all staff
- Identification of processes and procedures and their critical control points

**Standards for quality systems**
- Regulatory or legislative framework
- Appropriate national or international standards
- Standards relevant to BTSs

**Documentation**
- Appropriate, comprehensive documents, including a quality manual and standard operating procedures (SOPs)
- Complete, accurate records
- System for controlling documents

**Training**
- Training policy and plan
- Training of all BTS staff in quality and quality systems
- Training of other health care professionals involved in blood transfusion
- Evaluation of training and its impact

**Assessment**
- Validation
- Ongoing data collection and analysis
- Haemovigilance
- Regular review of all activities
- Internal and external audits
- Error management, corrective and preventive action
- External quality assessment schemes

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Key elements

Requirements for quality systems in blood transfusion

It is the responsibility of governments to ensure that the blood and blood products provided for clinical use by the national blood programme are safe, adequate to meet demand, effective and produced consistently to the appropriate standards.

To achieve this, the blood transfusion service must develop an effective quality system. This should provide a framework within which BTS activities are established, performed in a quality-focused way and continuously monitored to improve outcomes.

The establishment of a quality system will ensure the collection of adequate supplies of blood from regular, voluntary non-remunerated donors, the testing of all blood before use and the appropriate clinical use of blood.

Prerequisites for developing a quality system within the national blood programme include:
- Nationally-coordinated blood transfusion service
- Commitment and support of management at all levels
- Recognition of the importance of quality in the national blood policy

National quality policy and quality plan detailing the strategy, mechanism and resources for their implementation
- Designation of a national quality manager with the necessary responsibility and authority for the development, implementation and monitoring of the quality system
- Provision of appropriate, adequate and sustainable resources to support the development and maintenance of the quality system.

Organizational management

Central to an effective quality system is commitment and support from management at all levels, including:
- Clearly defined organizational structure that defines accountability, authority and responsibility
- Designation of a quality manager, with the necessary skills and expertise, in each blood centre and hospital blood bank
- Formation of a quality section or identified work area in each blood centre and hospital blood bank from which quality activities can be coordinated
- Development of a culture of quality through a management focus on building quality into all activities
- Motivation of staff to ensure their commitment and support for the quality system
- Identification of specific processes and procedures and their critical control points.

Standards for quality systems

Relevant and appropriate standards are required to provide the framework for the development of the quality system:
- The existence of any relevant national legislation or regulations must be acknowledged and incorporated into the framework for quality
- Standards may be national or international: e.g. International Organization for Standardization (ISO) and Good Manufacturing Practice (GMP)

The standards adopted must be relevant to the BTS and its activities.

Documentation

An effective and accurate documentation system that ensures traceability of all BTS activities is the foundation of good quality management.

Important activities include:
- Development of a quality manual: a document describing the quality system, including the organization’s quality policy, standards and procedures
- Production and use of appropriate, comprehensive documents for all activities, including standard operating procedures, forms, labels and any other documents required
- Generation and maintenance of complete and accurate records
- Development of a system to manage the issue, use and retrieval of documents.

Training

Comprehensive, appropriate and effective training is required for all BTS staff and other health care professionals involved in blood transfusion.

Important activities include:
- Training policy and plan
- Training for all BTS staff in general principles of quality, the quality system, documentation and the use of quality monitoring tools

Assessment

Ensuring quality is a continual process. Ongoing assessment of the effectiveness of the quality system is essential through:
- Validation of all processes, procedures, equipment and reagents
- Ongoing collection and analysis of data generated from key activities and their use in quality improvement
- Establishment of haemovigilance through a system of monitoring, reporting and investigation of adverse incidents related to all blood transfusion activities
- Regular review of all activities to assess the overall effectiveness of the quality system and ensure continuous improvement
- Programme of regular internal and external audits of the quality system
- Reporting and analysis of errors with effective corrective and preventive action
- Active participation in appropriate external quality assessment schemes to improve laboratory performance.
WHO Strategy for Blood Safety

Teaching Aim

- To introduce course participants to the WHO strategy for blood safety

Core Topics

- WHO Global Database on Blood Safety (GDBS)
- WHO strategy for global blood safety
Outline of This Presentation

- What is the problem?
- WHO strategy for blood safety
- Quality Management Programme

WHO Global Database on Blood Safety (GDBS)

- Biennial collection of data from Member States to:
  - Accurately assess the global situation on blood safety
  - Obtain the best available information on blood transfusion services in each Member State
  - Identify areas of need
  - Monitor progress and trends

Global Blood Supply by HDI
WHO GDBS, 2000–2001

- Low HDI
  - 2.3 m (3%)
  - (n=26)
- Medium HDI
  - 20.4 m (36%)
  - (n=88)
- High HDI
  - 49.4 m (61%)
  - (n=54)

Total annual blood collection: 81 million (178 countries)
Viral Screening of Whole Blood Donations
WHO GDBS, 2000–2001

**DEVELOPED**
(High HDI)

- 99% tests done
- 49 MILLION DONATIONS
- 1% tests not done

**DEVELOPING**
(Low & medium HDI)

- 81% tests done
- 32 MILLION DONATIONS
- 19% tests not done

Seroprevalence in Blood Donors (%)
WHO GDBS, 2000–2001

<table>
<thead>
<tr>
<th></th>
<th>Low HDI</th>
<th>Medium HDI</th>
<th>High HDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>0.3–14</td>
<td>0–9</td>
<td>0–0.77</td>
</tr>
<tr>
<td>HBV</td>
<td>0.1–21</td>
<td>0–30</td>
<td>0–7</td>
</tr>
<tr>
<td>HCV</td>
<td>0–9.2</td>
<td>0–13.1</td>
<td>0–1.2</td>
</tr>
</tbody>
</table>

Countries Without 100% Screening
WHO GDBS, 2000–2001

- **HIV**: 152, 20
- **HBV**: 145, 24
- **HCV**: 106, 37
- **Syphilis**: 137, 24
Blood Group Serology
WHO GDBS, 2000–2001

- ABO and RhD grouping and compatibility testing are performed in more than 83% of countries
- But there is a lack of:
  - Standardization
  - Documentation
  - Traceability

Percentage Transfused as Whole Blood
WHO GDBS, 2000–2001

Cost of Producing One Unit of Blood
WHO GDBS, 2000–2001
Voluntary Blood Donation vs. Units Discarded after Screening for TTIs

<table>
<thead>
<tr>
<th>Units discarded (%)</th>
<th>Voluntary blood donors (%)</th>
<th>WHO GDBS, 2000–2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>100%</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>75–99%</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>50–74%</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>25–49%</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>0–24%</td>
<td>4</td>
</tr>
</tbody>
</table>

Countries with No Training for Various Categories of BTS Staff

- Medical officers
- Administrative
- Quality management
- Prescribers
- Donor recruitment
- Blood collection/donor care
- Counseling
- Laboratory

What is the Problem?

- Inadequate blood supply and availability of blood components
- Insufficient number of voluntary non-remunerated blood donors
- Risk of transmission of infections through transfusion
- Limited access to training
Outline of This Presentation

- What is the problem?
- WHO strategy for blood safety
- Quality Management Programme

WHO Strategy for Blood Safety (1)

The safety, adequacy and accessibility of blood and blood products depends on:
- The establishment of a well-organized, nationally-coordinated blood transfusion service with quality systems in all areas
- The collection of blood only from voluntary non-remunerated blood donors at low risk of acquiring transfusion-transmissible infections

WHO Strategy for Blood Safety (2)

- Testing of all donated blood, including:
  - Screening for transfusion-transmissible infections
  - Blood grouping
  - Compatibility testing
- Good manufacturing practices in blood component production
- Appropriate clinical use of blood
Key Points

- The WHO Global Database on Blood Safety provides the best available information on the global situation.
- The WHO strategy for blood safety defines requirements for the safety, adequacy and accessibility of national blood supplies.

Learning Outcomes

You should now be able to:

- Identify key problems in relation to global blood safety.
- Describe the WHO strategy for blood safety.
### QMT 1.2

**WHO Quality Management Programme (QMP) for Blood Transfusion Services**

<table>
<thead>
<tr>
<th>Teaching aim</th>
<th>To introduce course participants to the WHO Quality Management Programme (QMP) and Quality Management Training (QMT)</th>
</tr>
</thead>
</table>
| Core topics  | ♦ Quality Management Programme  
♦ Quality Management Training |
| Key points   | ♦ The WHO QMP aims to assist Member States in improving the safety and adequacy of national blood supplies  
♦ QMT courses are held in each region to support the establishment of quality systems in blood transfusion services in all Member States  
♦ QMT course participants will play a central role in establishing national quality systems |
| Teaching focus | ♦ Ensure participants understand the goals of the QMP  
♦ Emphasize the principles of active learning in QMT courses |
| Learning outcomes | Participants should be able to:  
♦ Explain the purpose of the QMP and QMT |
| Slides | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Outline of This Presentation  
5 Goals of the QMP (1)  
6 Goals of the QMP (2)  
7 Components of the QMP  
8 Partners in the QMP  
9 Activities (1)  
10 Activities (2)  
11 Quality Management Training (QMT) for Blood Transfusion Services  
12 Objectives of QMT (1)  
13 Objectives of QMT (2)  
14 Regional Quality Training Centres  
15 Regional QMT Courses (1)  
16 Regional QMT Courses (2)  
17 Active Learning  
18 Development of QMP Materials (1)  
19 Development of QMT Materials (2)  
20 Monitoring and Evaluation of QMP  
21 Indicators for Monitoring and Evaluation of QMP  
22 Indicators for Assessing Progress  
23 Key Points (1) |
Materials
None

Related presentation and activity
QMT 1.3 Introduction to the WHO QMT course
QMT 1.4 Participants’ Expectations

Time span
½ hour

Presentation notes and handling the session

Slide 4
Outline of This Presentation
♦ The slide shows how QMP supports the implementation of the WHO strategy for blood safety

Slide 5
Goals of the QMP (1)
♦ Capacity building is essential for the long-term success of the programme
♦ The transfer of knowledge and, in some cases, technology, will ensure increased national capacity in quality management

Slide 6
Goals of the QMP (2)
♦ Continuous improvement of quality systems is essential for the sustainability of effective BTSs

Slide 7
Components of the QMP
♦ WHO sets the foundation for all QMP activities
♦ Regional Quality Training Centres (RQTCs) have been identified to coordinate QMT courses and act as resource centres for participants after the courses have finished
♦ QMT courses will be described in QMT 1.3
♦ WHO, RQTCs and blood transfusion services form a quality network
♦ Training materials have been developed to support the QMP; some are used during QMT courses and others may be used as open learning materials
♦ The implementation and/or strengthening of External Quality Assessment (EQA) schemes assists in monitoring and also helps to maintain the quality network

Slide 8
Partners in the QMP
♦ RQTCs will start the networking process by ensuring that identified needs for post-training support, follow-up and re-training are met
♦ Certain RQTCs also act as coordinating centres for External Quality Assessment (EQA) schemes
♦ Emphasize that we are all partners in the Quality Management Programme – all of us must participate actively to ensure success
♦ Although the QMP was initiated by WHO, it is essential for all partners to have a sense of ownership in order to achieve the objectives of the programme

Slide 9
Activities (1)
♦ An RQTC has been identified in each region to provide a close and accessible focal point for course participants
<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Activities (2)</th>
</tr>
</thead>
</table>
| ♦ Setting up a "quality area" in each BTS will ensure that there is a specific place for all quality activities  
♦ In countries where no national BTS exists, WHO has strategies in place to:  
  ─ Advocate for the establishment of national quality systems (as shown in QMT 1.1)  
  ─ Work with existing individual blood centres to support them in developing quality systems and promote the spread of quality concepts and procedures to other centres |

<table>
<thead>
<tr>
<th>Slide 11</th>
<th>Quality Management Training (QMT) for Blood Transfusion Services</th>
</tr>
</thead>
</table>
| ♦ This slide introduces Quality Management Training  
♦ QMT was devised to meet the identified need for the training of quality managers/officers and to build capacity at national and centre level |

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Objectives of QMT (1)</th>
</tr>
</thead>
</table>
| ♦ Every participant’s contribution will be important and educational for all involved in the QMP  
♦ Even participants who have some knowledge of quality systems will gain further experience from the course  
♦ The status of quality systems, both current and progressive, is assessed via a questionnaire on key performance indicators  
♦ By comparing baseline data with regular, later reports, progress in implementation can be assessed |

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<thead>
<tr>
<th>Slide 13</th>
<th>Objectives of QMT (2)</th>
</tr>
</thead>
</table>
| ♦ Introduce the fact that participants are expected to prepare a plan of action during the training course and to follow that plan on returning home  
♦ Emphasize that participants will have to obtain agreement and support for their plan from local authorities and BTS medical directors  
♦ Point out to participants that any specific training needs identified during the course will be noted for later action |

<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Regional Quality Training Centres</th>
</tr>
</thead>
</table>
| At least one RQTC has been established in each WHO region with the responsibility for:  
♦ Identifying and enrolling course participants in collaboration with the WHO Regional Adviser, national health authorities and BTS directors  
♦ Modifying the generic training course curriculum in accordance with regional requirements, where required  
♦ Preparing background materials for practical exercises, case studies and working groups  
♦ Organizing and handling logistics, including participants' travel, where applicable  
♦ Acting as a resource centre for the region as well as for course participants  
♦ Assisting participating centres to develop a small "quality area" in the BTS/blood bank to implement and monitor the quality system |
| Slides 15 – 16 | These two slides are an introduction to QMT courses  
Regional QMT Courses (1) and (2)  
Details of the curriculum are covered in QMT 1.3 |
| Slide 17 | This slide emphasizes that the use of activities is known to be the best method of ensuring an effective learning process  
Participants will be expected to be actively involved in group work throughout the course |
| Slide 18 | This slide outlines the main materials being developed to support QMP/QMT  
At the beginning of the course, participants will receive the Participant's Workbook, a file containing:  
- PowerPoint presentations, printed as three slides per page  
- Instructions for activities  
- Course materials, such as examples of documentation  
As the course progresses, the Workbook will fill up with the presentations and activities that have been completed  
All available materials will be handed out at the appropriate time  
Ensure participants understand that they will receive the Facilitator's Toolkit at the end of the course for use in their own BTSs/blood centres |
| Slide 19 | This slide describes the learning materials that are being developed to support learning outside the formal courses |
| Slide 20 | A mechanism for the monitoring and evaluation of the QMP has been established to assess its effectiveness and identify any modifications required  
The evaluation is planned in two phases:  
- Phase 1 covers the first three years of the programme; monitoring will cover the number of countries and participants attending training courses and the number of countries that implement quality systems  
- Phase 2 will assess the impact of the QMP on blood safety |
| Slide 21 | The indicators shown on the slide are some of the process indicators used for monitoring and evaluation |
| Slide 22 | Participants' knowledge and understanding will be assessed throughout the course  
Post-training assessment will be conducted using a standardized questionnaire which will be covered in QMT 9.7  
Some countries will be visited to assess progress in implementing quality systems and provide technical support, where required |
WHO Quality Management Programme (QMP) for Blood Transfusion Services

Teaching Aim

- To introduce course participants to the WHO Quality Management Programme (QMP) and Quality Management Training (QMT)

Core Topics

- Quality Management Programme (QMP)
- Quality Management Training (QMT)
Outline of This Presentation

WHO Strategy for Blood Safety

Quality Management Programme

Outline of This Presentation

What is the problem?

Goals of the QMP (1)

- To assist member states in improving the safety and adequacy of national blood supplies
- To build capacity in quality management (QM) in all aspects of blood transfusion:
  - Through an integrated approach of training and assessment
  - In all Member States of WHO, with regional cooperation

Goals of the QMP (2)

- To support the establishment of sustainable national quality systems in BTSs in each country
Components of the QMP

External Quality Assessment Schemes

Quality Management Training Courses

Regional Quality Training Centres

Re-training & follow-up

Network of National Blood Transfusion Services

External Quality Assessment Schemes

Re-training & follow-up

Activities (1)

- Establishment of Regional Quality Training Centres in each region
- Regional Quality Management Training Courses to train two people from each country as quality managers
- Development of advocacy and learning materials to support the QMP and QMT

Partners in the QMP

WHO

Experts

WHO Collaborating Centres and NGOs

Regional Quality Training Centres

Blood Transfusion Services Network
Activities (2)

- Upgrading of facilities and 'quality desk/area' in BTSs at national level
- Regional External Quality Assessment Schemes for blood group serology and transfusion-transmissible infections (TTIs)
- Post-course support and follow-up courses
- Regional Quality Networks

Objectives of QMT (1)

- To strengthen course participants' knowledge and skills in quality management
- To assess the current status of quality systems in BTSs in participating countries
Objectives of QMT (2)

- To assist participants to develop a plan of action for the establishment of a quality system in their own BTS/blood bank
- To identify future requirements for training and staff development

Regional Quality Training Centres

- At least one centre already identified in each WHO region
- Minimum requirements defined for the selection of RQTCs
- Criteria defined for the selection of external facilitators

Regional QMT Courses (1)
Regional QMT Courses (2)

- Generic curriculum
- Flexibility in the programme of work
- Focus on the principles of quality
- Emphasis on quality in all aspects of transfusion from donor to patient ("vein-to-vein")

Active Learning

Development of QMP Materials (1)

Advocacy
- Aide-Mémoire: Quality Systems for Blood Safety
- Developing a Quality System: for policy makers

Course materials
- Coordinator’s Toolkit: for course coordinators
- Facilitator’s Toolkit: for course facilitators
- Basic QM Workbook: for participants
Development of QMP Materials (2)

Learning materials

- Planning and Implementing a Quality System: for quality managers
- Making Quality Work: for all BTS staff

Monitoring and Evaluation

- Mechanism for monitoring and evaluation of the QMP
  - To assess its effectiveness
  - To identify modifications required in its implementation
- Evaluation to be planned in phases
- Qualitative and quantitative indicators defined

Indicators for Monitoring and Evaluation of QMP

- Number of participants trained per country
- Proportion of countries trained in each region
- Number of training courses held according to plan
- Quality of the training courses
- Use of RQTCs as a resource
Indicators for Assessing Progress

- Course participants' understanding of quality principles and concepts
- Progress made by participating BTSs in establishing national quality systems based on the Quality Status Questionnaire

Key Points (1)

- The WHO QMP aims to assist Member States in improving the safety and adequacy of national blood supplies
- QMT courses are held in each region to support the establishment of quality systems in blood transfusion services in all Member States

Key Points (2)

- QMT course participants will play a central role in establishing national quality systems
### Learning Outcomes

You should now be able to:

- Explain the purpose of the QMP and QMT
### QMT 1.3 Introduction to the WHO QMT Course

| Teaching aim | To introduce the WHO QMT course |
| Core topics | ♦ Modular approach  
♦ Role of the facilitators  
♦ Role of the participants |
| Key points | ♦ The overall structure of the course is modular  
♦ The course will help participants to implement quality systems in their BTS/blood centre  
♦ The role of the facilitators is to ensure that there is active learning |
| Teaching focus | ♦ Ensure participants understand the course objectives and structure  
♦ Ensure participants recognize that they will be expected to play an active role in the learning process  
♦ Encourage participants to ask questions about the course |
| Learning outcomes | Participants should be able to:  
♦ Outline the structure and content of the course  
♦ Identify their role and responsibilities in the QMT course |
| Slides | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 This Training Course  
5 Modular Approach  
6 Introduction  
7 Part 1 (1)  
8 Part 1 (2)  
9 Part 1 (3)  
10 Part 1 (4)  
11 Part 2 (1)  
12 Part 2 (2)  
13 Part 2 (3)  
14 Part 2 (4)  
15 The Facilitators  
16 The Participants  
17 Key Points  
18 Learning Outcomes |
| Materials | ♦ QMT curriculum: Overview  
♦ Course programme of work: daily and weekly |
<p>| Related activity | QMT 1.4 Participants’ Expectations |
| Time span | ½ hour |</p>
<table>
<thead>
<tr>
<th><strong>Presentation notes and handling the session</strong></th>
</tr>
</thead>
</table>
| **Slide 4**  
This Training Course |
| ♦ This training course is designed to enable participants to gain a full understanding of how to introduce quality systems into the BTS  
♦ Implementing quality systems will:  
  ─ Improve blood safety  
  ─ Make everyone’s job easier  
  ─ Increase the motivation of all staff |
| **Slide 5**  
Modular Approach |
| ♦ This slide introduces the modular structure of the course and how each module builds on previous modules  
♦ The modules comprise:  
  ─ Introduction  
  ─ Part 1: Basic Principles of Quality  
  ─ Part 2: Applying Quality Management in the BTS |
| **Slides 6 - 13** |
| ♦ These slides give a broad outline of the QMT course  
♦ Part 1 introduces general principles of quality and quality systems using everyday examples  
♦ Part 2 focuses on the application of quality principles in the BTS |
| **Slide 14**  
The Facilitators |
| ♦ The slide gives a brief description of the role of the facilitators during the course |
| **Slide 15**  
The Participants |
| ♦ This slide summarizes WHO’s and facilitators’ expectations of participants  
♦ Each participant, when embarking on the quality journey, will need to change the way they see things and the way in which they approach their work  
♦ The most important thing for participants to remember is that WHO does not want them to go home simply armed with facts about quality that they cannot use  
♦ The aim of the course is that they should develop knowledge and skills to enable them to establish effective quality systems in their own BTS/blood centre  
♦ They are not expected to memorize all the information presented during the course; it is far more important that they know how to use it  
♦ It is expected that they will constantly return to their notes and other references when implementing their quality systems |
# QUALITY MANAGEMENT TRAINING CURRICULUM

## Overview

### INTRODUCTION

| Module 1 | The WHO Quality Management Programme |

### PART 1  BASIC PRINCIPLES OF QUALITY

| Module 2 | Introduction to Quality |
| Module 3 | Quality Systems |
| Module 4 | Organizational Management |
| Module 5 | Standards for Quality Systems |
| Module 6 | Documentation |
| Module 7 | Training |
| Module 8 | Assessment within the Quality System |

### PART 2  APPLYING QUALITY MANAGEMENT IN THE BTS

| Module 9 | Quality Management in the BTS |
| Module 10 | Hygiene and Safety in the BTS |
| Module 11 | Quality Systems in Donor Management and Blood Collection |
| Module 12 | Quality Systems in Laboratory Testing |
| Module 13 | Quality Systems in Component Production and the Issue of Blood |
| Module 14 | Quality Systems and the Clinical Interface |
| Module 15 | Finalization of Participants’ Action Plans and Completion of the Course |
# Example of a Weekly Programme of Work

## Week One

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
</table>
| **QMT 1.1**  
WHO strategies for blood safety                                  | **QMT 2.1**  
The importance of quality in the BTS                          | **QMT 3.1**  
Processes and procedures                                                 | **QMT 4.1**  
Principles of Good Manufacturing Practice                               | **QMT 6.1**  
Deleting a non-compliance procedure                                      | **QMT 7.1**  
Creating a training plan                                                 |
| **QMT 1.2**  
WHO Quality Management Programme (QMP) for blood transfusion services | **QMT 2.2**  
The consequences of poor quality in the BTS                         | **QMT 3.2**  
Flowcharting as a tool for mapping processes                              | **QMT 4.2**  
Documentation in quality systems                                          | **QMT 6.2**  
Creating a training plan                                                 | **QMT 7.2**  
Designing a maintenance and calibration plan                             |
| **QMT 1.3**  
Introduction to the WHO QMT course                                   | **QMT 2.3**  
Introducing quality                                                     | **QMT 3.3**  
Organizational structure and role of the quality manager                 | **QMT 4.3**  
The cost of quality                                                      | **QMT 6.3**  
Validating an SOP                                                        | **QMT 8.1**  
Preparing a validation plan                                              |
| **QMT 1.4**  
Participants’ expectations                                           | **QMT 2.4**  
Quality characteristics                                                  | **QMT 3.4**  
Management responsibility for quality                                    | **QMT 4.4**  
The process in quality systems                                           | **QMT 6.4**  
Validation of training                                                    | **QMT 8.2**  
Maintenance and calibration of equipment                                |
| **QMT 1.5**  
Pre-course assessment                                                   | **QMT 2.5**  
Tour of the Blood Transfusion Centre                                    | **QMT 3.5**  
Flowcharting as a tool for mapping processes                              | **QMT 4.5**  
Introduction to standards for quality systems                            | **QMT 6.5**  
Validation of training                                                    | **QMT 8.3**  
Preparing a maintenance and calibration plan                             |
| **QMT 2.1**  
The importance of quality in the BTS                                                                 | **QMT 3.6**  
Organizational structure and role of the quality manager                 | **QMT 4.6**  
Training needs and plans                                                  | **QMT 7.1**  
Training in the quality system                                            | **QMT 7.3**  
Preparing a maintenance and calibration plan                              | **QMT 8.4**  
Maintenance and calibration of equipment                                 |
| **QMT 2.2**  
The consequences of poor quality in the BTS                                                                  | **QMT 3.7**  
Organization structure and role of the quality manager                   | **QMT 5.1**  
Introduction to standards for quality systems                            | **QMT 7.2**  
Designing a maintenance and calibration plan                              | **QMT 7.4**  
Maintenance and calibration of equipment                                 | **QMT 8.5**  
Validation of training                                                    |

**QMT/Module 1 39**
## Week Two

<table>
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<tr>
<th>Monday</th>
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</thead>
<tbody>
<tr>
<td><strong>QMT 8.6</strong>&lt;br&gt;Quality monitoring tools</td>
<td><strong>QMT 8.12</strong>&lt;br&gt;Steps in developing a quality system in the BTS</td>
<td><strong>QMT 9.3</strong>&lt;br&gt;Steps in developing a quality system in the BTS</td>
<td><strong>QMT 10.1</strong>&lt;br&gt;Introduction to hygiene and safety in the BTS</td>
<td><strong>QMT 11.4</strong>&lt;br&gt;Blood collection</td>
<td><strong>QMT 12.1</strong>&lt;br&gt;Introduction to quality systems in laboratory testing</td>
</tr>
<tr>
<td><strong>QMT 8.7</strong>&lt;br&gt;Steps in developing a quality system in the BTS</td>
<td><strong>QMT 8.13</strong>&lt;br&gt;Identifying non-compliance against a set of standards</td>
<td><strong>QMT 9.4</strong>&lt;br&gt;Costing activities in a BTS</td>
<td><strong>QMT 10.2</strong>&lt;br&gt;Hygiene in the BTS</td>
<td><strong>QMT 11.5</strong>&lt;br&gt;Blood collection</td>
<td><strong>QMT 12.2</strong>&lt;br&gt;Evaluation and use of immunohaematology reagents</td>
</tr>
<tr>
<td><strong>QMT 8.8</strong>&lt;br&gt;Error management</td>
<td><strong>QMT 8.14</strong>&lt;br&gt;Principles of stock control</td>
<td><strong>QMT 9.5</strong>&lt;br&gt;Principles of stock control</td>
<td><strong>QMT 10.3</strong>&lt;br&gt;Biological and chemical safety in the BTS</td>
<td><strong>QMT 11.6</strong>&lt;br&gt;Developing a documentation system for blood donor management</td>
<td><strong>QMT 12.3</strong>&lt;br&gt;Evaluation and use of test kits for transfusion-transmissible infections (TTIs)</td>
</tr>
<tr>
<td><strong>QMT 8.9</strong>&lt;br&gt;Error management</td>
<td><strong>QMT 8.15</strong>&lt;br&gt;Analysing quality system failures</td>
<td><strong>QMT 9.6</strong>&lt;br&gt;Quality aspects of contingency planning</td>
<td><strong>QMT 10.4</strong>&lt;br&gt;Safety issues and minimizing risks</td>
<td><strong>QMT 11.7</strong>&lt;br&gt;Donor care, satisfaction and retention</td>
<td><strong>QMT 12.4</strong>&lt;br&gt;Selecting reagents and test kits</td>
</tr>
<tr>
<td><strong>QMT 8.10</strong>&lt;br&gt;Preparing an SOP on error reporting</td>
<td><strong>QMT 8.16</strong>&lt;br&gt;Mid-course assessment</td>
<td><strong>QMT 9.7</strong>&lt;br&gt;Quality status analysis</td>
<td><strong>QMT 11.1</strong>&lt;br&gt;Introduction to quality systems in blood donor management</td>
<td><strong>QMT 11.8</strong>&lt;br&gt;Donor satisfaction</td>
<td><strong>QMT 12.5</strong>&lt;br&gt;Developing a documentation system for the laboratory</td>
</tr>
<tr>
<td><strong>QMT 8.11</strong>&lt;br&gt;The audit process</td>
<td><strong>QMT 9.1</strong>&lt;br&gt;Applying quality management in the BTS</td>
<td><strong>QMT 9.8</strong>&lt;br&gt;Preparing an action plan</td>
<td><strong>QMT 11.2</strong>&lt;br&gt;Donor recruitment and selection</td>
<td><strong>QMT 11.9</strong>&lt;br&gt;Identifying and monitoring critical control points in blood donor management</td>
<td><strong>QMT 12.6</strong>&lt;br&gt;External Quality Assessment (EQA) schemes</td>
</tr>
<tr>
<td><strong>QMT 8.2</strong>&lt;br&gt;Preparing an SOP on error reporting</td>
<td><strong>QMT 9.2</strong>&lt;br&gt;Identifying critical control points and preparing flowcharts for BTS activities</td>
<td><strong>QMT 9.9</strong>&lt;br&gt;Preparing a draft action plan</td>
<td><strong>QMT 11.3</strong>&lt;br&gt;Donor recruitment and selection</td>
<td><strong>QMT 11.10</strong>&lt;br&gt;Donor recruitment and selection</td>
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<tr>
<td>QMT 12.7 Identifying and monitoring critical control points in laboratory testing</td>
<td>QMT 13.5 Storage and transportation of blood components</td>
<td>QMT 14.1 Introduction to quality systems at the clinical interface</td>
<td>QMT 14.7 Quality in the hospital transfusion process</td>
<td>QMT 15.1 Review of the course</td>
<td>QMT 15.4 Discussion of individual action plans, as appropriate</td>
</tr>
<tr>
<td>QMT 13.1 Introduction to quality systems in blood component production and management</td>
<td>QMT 13.6 Storage and transportation of blood components</td>
<td>QMT 14.2 Policy and guidelines on the clinical use of blood</td>
<td>QMT 14.8 Monitoring and evaluation of the hospital transfusion process</td>
<td>QMT 15.2 Laboratory/clinic visits in BTS</td>
<td>QMT 15.5 Review of quality systems</td>
</tr>
<tr>
<td>QMT 13.2 Quality monitoring of blood component production</td>
<td>QMT 13.7 Blood stock management</td>
<td>QMT 14.3 The role of the BTS at the clinical interface</td>
<td>QMT 14.9 Haemovigilance</td>
<td>QMT 15.3 Completing individual action plans</td>
<td>QMT 15.6 Post-course assessment</td>
</tr>
<tr>
<td>QMT 13.3 Evaluation and monitoring of component production activities</td>
<td>QMT 13.8 Developing a documentation system for the blood components production</td>
<td>QMT 14.4 Documentation in the hospital transfusion process</td>
<td>QMT 14.10 Identifying and monitoring critical control points for the clinical interface and the administration of blood</td>
<td></td>
<td>QMT 15.7 Course evaluation</td>
</tr>
<tr>
<td>QMT 13.4 Quarantine and release</td>
<td>QMT 13.9 Identifying and monitoring critical control points in component production and the issue of blood</td>
<td>QMT 14.5 Designing a blood request form</td>
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<td>QMT 15.8 Final discussions</td>
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<td>QMT 14.6 Quality in the hospital transfusion process</td>
<td></td>
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</tbody>
</table>

| QMT/Module 1 | 41 |
Introduction to the WHO QMT Course

Teaching Aim

- To introduce the WHO QMT course

Core Topics

- Modular approach
- Role of the facilitators
- Role of the participants
This Training Course

- Examines elements of quality systems that will improve the quality and safety of blood
- Will help you to develop a quality system and quality culture in your own BTS
- Is not a technical course

Modular Approach

- The course is divided into three parts:
  - Introduction
  - Part 1: Basic Principles of Quality
  - Part 2: Applying Quality Management in the BTS
- There are fifteen modules
- They are spread out over 18 days
- Each module builds on knowledge gained in previous modules

Introduction

Module 1 - WHO Quality Management Programme

- A small introductory module to:
  - Explain the global programme
  - Identify your expectations
  - Establish your baseline knowledge
Part 1 (1)

Module 2 - Introduction to Quality
- An introduction to quality
  - The need for quality
  - The consequences of poor quality

Module 3 - Quality Systems
- Basic elements of a quality system
  - Generic examples used

Part 1 (2)

Module 4 - Organizational Management
- Organizational structure
  - Quality policy
  - Responsibilities in a quality system

Module 5 - Standards for Quality Systems
- Good Manufacturing Practice
- International Organisation for Standardisation

Part 1 (3)

Module 6 - Documentation
- General concepts
  - Standard operating procedures
  - Document control

Module 7 - Training
- The role of training in a quality system
- Planning training
Part 1 (4)

Module 8 - Assessment Within The Quality System
- Key elements
- Quality is continuous improvement

Part 2 (1)

Module 9 - Quality Management in the BTS
- Applying knowledge gained to the BTS
- Preparing action plans

Module 10 - Hygiene and Safety
- Quality systems in relation to hygiene and safety in the BTS

Part 2 (2)

Module 11 - Quality Systems in Blood Donor Management
- Applying quality systems to the blood donor programme

Module 12 - Quality Systems in Laboratory Testing
- Applying GLP in the laboratory
- Specific examination of immunohaematology and infection screening
Part 2 (3)

Module 13 - Quality Systems in Component Production and Management
- Applying quality systems to blood components production

Module 14 - Quality Systems and the Clinical Interface
- Applying quality systems to the clinical aspects of transfusion

Part 2 (4)

Module 15 - Finalization of Participants' Action Plans and Completion of the Course
- Review of the course
  - Applying continuous improvement (quality principles) to the training course
- Action plan
- Proposed follow up

The Facilitators

- Ensure that you learn
- Not too prescriptive
  - What works for one BTS may not be easily transferred to another
- "Quality is a journey" - we are on the same journey
  - Since good quality comes from continuous improvement, we are also learning and improving
The Participants

- Work hard
- Be active in discussions
  - Most of the learning process is interactive
  - Group work will enhance the learning process
- Return home with the ability to see your BTS with "new eyes", analyse your problems and apply what you have learned, where appropriate

Key Points

- The overall structure of the course is modular
- The course will help you implement to implement quality systems in your BTS
- The role of the facilitators is to ensure that there is active learning

Learning Outcomes

You should now be able to:
- Outline the structure and content of the course
- Identify your role and responsibilities in the QMT course
<table>
<thead>
<tr>
<th><strong>QMT 1.4</strong></th>
<th><strong>Participants' Expectations</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To find out what course participants expect to gain from the QMT course</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Discussion of the objectives and structure of the QMT course  
♦ Identification of participants’ specific interests and learning needs in relation to quality management |
| **Key points** | ♦ QMT is not designed to provide technical training  
♦ Follow-up and support will be provided after the course  
♦ If identified as a need, technical training will be provided after the course |
| **Teaching focus** | Help to keep participants’ expectations realistic and focused on quality rather than on technical issues |
| **Learning outcomes** | Participants should be able to:  
♦ Explain how the QMT course will assist them in applying the principles of quality in their own BTS |
| **Type of activity** | Plenary discussion |
| **Materials** | ♦ Course programme of work: daily and weekly  
♦ QMT curriculum: Overview |
| **Instructions** | 1 Ask participants briefly to review the course programme of work.  
2 Ask participants to spend a few minutes noting down:  
♦ The modules that they think will be most helpful to them  
♦ The modules that they think will be least helpful to them  
♦ What they expect to gain from the course  
♦ Any topics that interest them that are not included in the programme of work.  
3 Ask each participant in turn to:  
♦ Indicate the modules in which they are particularly interested  
♦ Ask questions about the course  
♦ Comment on what they expect to gain from the course. |
| **Review of activity** | ♦ Acknowledge and respond to participants’ particular interests and concerns  
♦ Provide clarification about the course and follow-up activities, as required  
♦ Review participants' comments and explain any issues that need further clarification  
♦ Note down any modules and specific topics where participants may need additional teaching or support |
| **Time span** | 2 hours |
### ACTIVITY

<table>
<thead>
<tr>
<th><strong>QMT 1.5</strong></th>
<th><strong>Pre-Course Assessment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To determine participants' current levels of knowledge and understanding about quality</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Assessment of participants' knowledge and understanding of quality  
♦ Determination of the range of knowledge within the group in order to plan an appropriate level of training |
| **Key points** | ♦ The pre-course assessment aims to generate baseline information about participants  
♦ It will help facilitators to focus the course on areas of particular need |
| **Teaching focus** | ♦ Emphasize that the pre-course assessment is not an examination |
| **Learning outcomes** | Participants should be able to:  
♦ Assess their own level of knowledge and understanding of quality issues |
| **Type of activity** | Multiple-choice questions |
| **Materials** | ♦ QMT 1.5: Pre-Course Assessment Questions for each participant  
♦ Pens  
♦ QMT 1.5: Pre-Course Assessment Answers |
| **Instructions** | 1 Instruct the participants to complete the questionnaire.  
2 Encourage them to try not to guess the answers. |
| **Review of activity** | During your next available free time, mark the participants' responses, using the grid in QMT 1.5: Pre-Course Assessment Answers, to identify participants' individual learning needs |
| **Time** | ¾ hour |
QMT 1.5  
PRE-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
## Answers

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1: b</td>
<td>2: b</td>
<td>3: a</td>
<td>4: a</td>
<td>5: b</td>
<td></td>
</tr>
<tr>
<td>6: a</td>
<td>7: d</td>
<td>8: a</td>
<td>9: b</td>
<td>10: a</td>
<td></td>
</tr>
<tr>
<td>16: a</td>
<td>17: d</td>
<td>18: d</td>
<td>19: d</td>
<td>20: a</td>
<td></td>
</tr>
<tr>
<td>31: a</td>
<td>32: c</td>
<td>33: e</td>
<td>34: a</td>
<td>35: c</td>
<td></td>
</tr>
</tbody>
</table>
PART 1
BASIC PRINCIPLES OF QUALITY

Modules 2–5
Module 2
Introduction to Quality
# QMT 2.1 The Importance of Quality in the Blood Transfusion Service

## Teaching aim
To introduce the overall concept of quality in the blood transfusion service

## Core topics
- The need for quality in the BTS
- Factors affecting quality
- Results of quality

## Key points
- Quality is essential to ensure that blood transfusion is safe and clinically effective
- Quality applies to all BTS activities
- Quality involves all staff
- Quality benefits all
- Quality improvement is achievable, even when resources are limited

## Teaching focus
- Encourage participants to identify additional positive outcomes of quality
- Emphasize that quality is everybody’s responsibility

## Learning outcomes
Participants should be able to:
- Explain the importance of quality in blood transfusion
- Identify the positive outcomes of quality in the BTS
Related activity  | QMT 2.2  The Consequences of Poor Quality in the Blood Transfusion Service
---|---
Time span  | ½ hour

Presentation notes and handling the session

Slides 4 - 6  | ♦ These three slides present the reasons why quality needs to be introduced in the BTS

Slide 4  
The Need for Quality in the BTS (1)  
♦ The slide introduces the concept of a BTS having “customers”  
♦ Explain that quality focuses on “customers”. Discuss this with the participants, using the following questions:  
  ─ What do the customers of the BTS need?  
  ─ What do the customers of the BTS think they need?  
♦ Quality management systems focus on how best to achieve what customers need, every time they need it  
♦ The second bullet reminds participants that blood is a precious and scarce resource and must be used efficiently and to maximum effect (efficacy)

Slide 5  
The Need for Quality in the BTS (2)  
♦ Stress the importance of ensuring benefit, not harm, to the patient from a blood transfusion  
♦ Point out that adverse effects and errors can never be entirely eliminated; the term “minimize” is therefore used rather than “prevent”  
♦ Any error, regardless of its severity and whenever it occurs in the chain of events leading to a transfusion, can have a detrimental effect on the outcome

Slide 6  
The Need for Quality in the BTS (3)  
♦ All quality activities will help to ensure safety for all concerned in the transfusion process

Slide 7  
Quality is Possible  
♦ The slide shows figures from the 2000 annual report from the National Blood Transfusion Service in Zimbabwe  
♦ The outcome of introducing quality to the donor management programme was a reduction in seroprevalence of infection among donors; the risk of transfusion-transmitted infection was therefore minimized:  
  ─ Lower HIV prevalence in donors due to stringent selection and screening based on appropriate monitoring and evaluation activities  
  ─ Reduced seroprevalence rates in regular donors due to the application of quality principles to donor retention activities  
  ─ A substantial number of regular donors due to good customer care and accurate documentation

Slide 8  
The Basic Transfusion Chain  
♦ The diagram shows how all activities in the BTS are interconnected and therefore how poor quality in one area will result in poor quality in another
<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Factors Affecting Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide shows how all activities in the BTS are processes with inputs and outputs and that there are many factors in each process that can affect the quality of the outputs</td>
<td></td>
</tr>
<tr>
<td>♦ Processes are dealt with in detail in QMT 3.2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Interrelationships</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide demonstrates how there are a number of interested parties (also known as “stakeholders”) in the supply of good quality blood and blood products, each with their own needs and responsibilities</td>
<td></td>
</tr>
<tr>
<td>♦ The three sides of the triangle show the external “customers” of the BTS</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss some of the needs of each “customer” with participants</td>
<td></td>
</tr>
<tr>
<td>♦ The centre of the triangle, the focal area, shows BTS staff who are directly affected by the customers’ needs</td>
<td></td>
</tr>
<tr>
<td>♦ Diagrammatically, the bigger the influence of the external customers, the longer the sides of the triangle become; the area in the middle therefore becomes larger</td>
<td></td>
</tr>
<tr>
<td>♦ As the BTS becomes more quality (customer) focused, the need for quality staff and quality activities increases</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 – 12</th>
<th>Results of Quality for Patients (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The next two slides list some examples of the results of quality for patients</td>
<td></td>
</tr>
<tr>
<td>♦ Invite the participants to suggest a few more</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 13 – 14</th>
<th>Results of Quality for Clinicians &amp; Blood Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These slides list the results of quality for clinicians and blood donors</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that good quality and good clinical outcomes promote voluntary blood donation because the best advertisement is a “satisfied customer” (patients, clinicians, donors)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 15 – 17</th>
<th>Results of Quality for BTS Staff, the BTS &amp; Society</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides give some examples of the results of quality for staff, the BTS and society</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 18</th>
<th>Quality Starts with Me!</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide uses the World Health Day (2000) slogan, “Safe Blood Starts with Me!”, to emphasize that quality in all BTS activities involves everybody, regardless of their role</td>
<td></td>
</tr>
</tbody>
</table>
The Importance of Quality in the Blood Transfusion Service

Teaching Aim

- To introduce the overall concept of quality in the blood transfusion service (BTS)

Core Topics

- The need for quality in the BTS
- Factors affecting quality
- Results of quality
The Need for Quality in the BTS (1)

- To ensure that products and services meet the needs of the “customers”
- To ensure the maximum efficacy of blood and blood products

The Need for Quality in the BTS (2)

- To ensure blood and products benefit — not harm — the patient
  - Prevent the transfusion of unsafe blood or blood products to patients
  - Minimize the risk of adverse effects of transfusion
  - Minimize the occurrence of errors — and their potentially serious or fatal consequences — in the transfusion chain from vein-to-vein

The Need for Quality in the BTS (3)

To protect the health and safety of:
- Blood donors
- Recipients
- Staff
Quality is Possible

Quality is possible, even when resources are limited

Example: HIV prevalence in Zimbabwe, 2000
25.8% General adult population
2.3% New voluntary non-remunerated blood donors
0.7% Regular voluntary non-remunerated blood donors

The strength of the chain depends on the strength of the weakest link — not the strongest link

The quality of the BTS is influenced by the quality of each of the links

Factors Affecting Quality

Equipment, reagents  Personnel

INPUT  

PROCESS  

OUTPUT

Environment  Methods
Interrelationships

Results of Quality for Patients (1)

- Improved health/survival:
  - Effective products
  - Available when required
  - Prescribed appropriately
  - Administered correctly

Results of Quality for Patients (2)

- Lower risk of transfusion-associated morbidity or mortality
  - Fewer adverse transfusion reactions
  - Fewer transfusion-transmitted infections
- Increased confidence in the BTS
- Encourages voluntary blood donation
Results of Quality for Clinicians

- Adequate supplies of products, when required
- Products meet appropriate, defined standards
- Improved clinical outcomes
- Reduction in unnecessary transfusions
- Increased confidence in the BTS
- More likely to encourage voluntary blood donation

Results of Quality for Blood Donors

- Increased confidence in the BTS
- Satisfied donors
  - More likely to become regular donors
  - More likely to promote voluntary non-remunerated blood donation

Results of Quality for BTS Staff

- Improved performance
- More confidence in their own abilities
- Improved morale and job satisfaction
- Fewer errors
- Less time wasted
- Less need for investigation
Results of Quality for the BTS

- Lower seroprevalence of infection among donors
- More cost-effective use of resources
- Positive image
- Increased credibility
- Less risk of legal action

Results of Quality for Society

- More confidence in the BTS
- Positive attitudes towards blood donation and transfusion
- Authorities and general public more likely to support BTS activities

Quality Starts with Me!
Key Points

- Quality is essential to ensure that blood transfusion is safe and clinically effective
- Quality applies to all BTS activities
- Quality involves all staff
- Quality benefits all
- Quality improvement is achievable, even when resources are limited

Learning Outcomes

You should now be able to:

- Explain the importance of quality in blood transfusion
- Identify the positive outcomes of quality in the BTS
<table>
<thead>
<tr>
<th>QMT 2.2</th>
<th>The Consequences of Poor Quality in the Blood Transfusion Service</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To contrast the consequences of poor quality with the benefits of good quality</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>The consequences of poor quality for blood donors, recipients, staff and the BTS</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>Poor quality:</td>
</tr>
<tr>
<td></td>
<td>♦ Endangers patients' lives</td>
</tr>
<tr>
<td></td>
<td>♦ Undermines the credibility of the BTS</td>
</tr>
<tr>
<td></td>
<td>♦ Creates a negative attitude towards blood donation and transfusion</td>
</tr>
<tr>
<td></td>
<td>♦ Contributes to poor staff morale and job insecurity</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Encourage participants to discuss some examples of poor quality in relation to blood transfusion and the reasons why they may occur</td>
</tr>
<tr>
<td></td>
<td>♦ Do not force reluctant participants to reveal deficiencies in their own BTS at this early stage of the course</td>
</tr>
<tr>
<td></td>
<td>♦ Acknowledge the problems and constraints posed by limited staff and resources</td>
</tr>
<tr>
<td></td>
<td>♦ Emphasize that the QMT course will focus in a practical way on how every BTS can work towards quality</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to:</td>
</tr>
<tr>
<td></td>
<td>♦ Identify some reasons for poor quality in the transfusion process</td>
</tr>
<tr>
<td></td>
<td>♦ Identify the consequences of poor quality</td>
</tr>
<tr>
<td><strong>Type of activity</strong></td>
<td>Group work or plenary discussion</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>♦ Flipcharts</td>
</tr>
<tr>
<td></td>
<td>♦ Pens</td>
</tr>
<tr>
<td><strong>Instructions</strong></td>
<td>1 Ask participants to suggest some examples of poor quality and the reasons why these may occur.</td>
</tr>
<tr>
<td></td>
<td>2 Ask them to identify some of the consequences of poor quality for:</td>
</tr>
<tr>
<td></td>
<td>♦ Blood donors</td>
</tr>
<tr>
<td></td>
<td>♦ Patients</td>
</tr>
<tr>
<td></td>
<td>♦ Clinicians</td>
</tr>
<tr>
<td></td>
<td>♦ BTS/blood bank staff</td>
</tr>
<tr>
<td></td>
<td>♦ BTS/blood bank</td>
</tr>
<tr>
<td></td>
<td>♦ Society.</td>
</tr>
<tr>
<td><strong>Review of the activity</strong></td>
<td>Refer to the course programme of work and explain how the course will help participants to identify the causes of poor quality and ways of overcoming them</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>¾ hour</td>
</tr>
<tr>
<td>QMT 2.3</td>
<td>Introducing Quality</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce the concept of quality</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ What is quality?  
♦ Benefits of quality  
♦ Quality as a process of continuous improvement  
♦ Basic quality principles  
♦ Basic quality definition  
♦ Fitness for purpose  
♦ Quality characteristics |
| **Key points** | ♦ Quality is a continual process of striving for improvement to ensure consistently high quality  
♦ Quality products and services are fit for their purpose |
| **Teaching focus** | ♦ Ensure all participants have a clear understanding of basic principles of quality |
| **Learning outcomes** | Participants should be able to:  
♦ Demonstrate an understanding of the broad concepts of quality  
♦ Recognize the importance of quality in everyday life and in the BTS |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 What is Quality?  
5 Benefits of Quality (1)  
6 Benefits of Quality (2)  
7 Quality is a Process  
8 Deming Cycle of Continuous Improvement  
9 Basic Quality Definitions  
10 Quality Characteristics  
11 The Right Product in the Right Place  
12 ..... In the Right Strength  
13 ..... Free of Contamination  
14 ..... Not Deteriorated During Storage  
15 ..... In the Right Container  
16 ..... Correctly Labelled  
17 ..... Properly Sealed  
18 Consistency is Quality  
19 Key Points  
20 Learning Outcomes |
<p>| <strong>Materials</strong> | None |
| <strong>Related activity</strong> | QMT 2.4 Quality Characteristics |
| <strong>Time span</strong> | ¾ hour |</p>
<table>
<thead>
<tr>
<th>Slide 4</th>
<th>What is Quality?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide suggests a simple way of defining quality</td>
<td></td>
</tr>
<tr>
<td>♦ Point out that the key words in the slide are “consistent” and “fit for purpose”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Benefits of Quality (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide lists some general reasons for introducing quality management systems</td>
<td></td>
</tr>
<tr>
<td>♦ Point out that reducing variation in processes (i.e. doing things in the same way, every time) ensures consistency</td>
<td></td>
</tr>
<tr>
<td>♦ This reduces rework and product failure, resulting in cost savings</td>
<td></td>
</tr>
<tr>
<td>♦ Costs are also reduced because of the reduced number of errors/mistakes</td>
<td></td>
</tr>
<tr>
<td>♦ The use of measuring tools to monitor the quality system helps to identify and solve problems</td>
<td></td>
</tr>
<tr>
<td>♦ Monitoring also assists in constant improvement of the service and its products</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Benefits of Quality (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide shows how introducing a quality system will lead to a continuous cycle of improvement</td>
<td></td>
</tr>
<tr>
<td>♦ The continuous cycle of improvement is also discussed on slide 8 in this presentation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Quality is a Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide emphasizes the fact that quality cannot be achieved without a continuous cycle of checking, assessing and responding</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Deming Cycle of Continuous Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide gives a diagrammatic view of the cycle of continuous quality improvement</td>
<td></td>
</tr>
<tr>
<td>♦ By rotating the wheel in the direction of the arrows through the four phases of “Plan, Do, Check, Correct/Improve”, the wheel will continue up the slope</td>
<td></td>
</tr>
<tr>
<td>♦ If there is no progress forward, the tendency is to fall backwards – down the slope – with a consequent loss of quality</td>
<td></td>
</tr>
<tr>
<td>♦ The only way to prevent backwards movement is to keep the wheel moving continually: this is the function of the quality system</td>
<td></td>
</tr>
<tr>
<td>♦ To prevent any backwards movement, a “chuck” in the form of the quality plan is put in place</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Basic Quality Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide states the definitions of quality, fitness for purpose and consistency</td>
<td></td>
</tr>
<tr>
<td>♦ The definition given for quality is that of the International Organisation for Standardisation (ISO)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Quality Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide states the important characteristics of a quality product</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 - 17</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These slides give generic (everyday) and blood transfusion examples of each characteristic</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 18</th>
<th>Consistency is Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide re-emphasizes the points made during the presentation</td>
<td></td>
</tr>
</tbody>
</table>
Introducing Quality

Teaching Aim

- To introduce the concept of quality

Core Topics

- What is quality?
- Benefits of quality
- Quality as a process of continuous improvement
- Basic quality principles
- Basic quality definition
- Fitness for purpose
- Quality characteristics
What is Quality?

Quality is about consistently producing products that are fit for their purpose

- **Safe**
  - Free from infection risk
  - Free from other contamination
  - Correctly labelled
  - “In date”

- **Effective**
  - Contain required bioactive substances
  - Give clinical benefit

Benefits of Quality (1)

- Reduces variation in processes
- Reduces rework
- Prevents problems from occurring
- Reduces costs due to mistakes and errors
- Improves what is done through the use of various measuring tools
- Provides consistent and effective products

Benefits of Quality (2)

- Reliable products
- Confidence in the organization
- Good motivation among staff
- Staff who work towards quality
- Leading to ………
Quality is a Process

- “Quality is an ongoing activity, not a goal to be reached”
  - Continually checking, assessing and responding
  - A continuous cycle of “plan, do, check, act” (Deming cycle)
  - Without continual improvement, quality suffers

Deming Cycle of Continuous Improvement

Basic Quality Definitions

- Quality
  - Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs (ISO)

- Fitness for purpose
  - Suitability of a product for the purpose for which it is intended

- Consistency
  - Doing the same thing time after time, which makes the outcome more predictable and allows for reduced variation in products and processes
Quality Characteristics

- Quality = fitness for purpose
  - Right product
  - Right strength
  - Free of contamination
  - Not deteriorated
  - In the right container
  - Correctly labelled
  - Properly sealed
  - Consistent

The Right Product in the Right Place

Generic example
- Food for a person who is hungry
- A drink for a person who is thirsty

BTS example
- Red cells for a patient with thalassaemia
- Platelet concentrates for a patient with thrombocytopenia

... In the Right Strength

Generic example
- The strength of the drink is appropriate

BTS example
- Adequate platelet count
- Adequate Factor VIII activity in cryoprecipitate
- Adequate haematocrit of packed red cells
... Free of Contamination

Generic example
- No fungus, bacteria or insects in food

BTS example
- No bacterial contamination of blood components
  - Aseptic technique during phlebotomy and component preparation
- No transfusion-transmissible infectious agents

... Not Deteriorated During Storage

Generic example
- Food past its expiry date may be stale
- Inappropriate storage conditions may lead to deterioration of food

BTS example
- Platelet concentrates past their expiry date may be bacterially contaminated
- Incorrect storage conditions may result in haemolysis of red cells

... In the Right Container

Generic example
- Is it appropriate to sell a drink in a plastic bag?
- Is it appropriate to sell food in a bottle?

BTS example
- Blood must be collected in a sterile pack containing an anticoagulant-preservative solution
- Platelet concentrates should be separated into a bag that allows for gaseous exchange
... Correctly Labelled

Generic example
- Product name
- Flavour (e.g. orange-flavoured drink)
- Expiry date

BTS example: blood products
- Product name identification (e.g. whole blood)
- ABO and Rh
- Unique unit number
- Traceability to donor
- Expiry date
- Patient identification on crossmatched blood

... Properly Sealed

Generic example
- Container sealed before purchase
- Free from holes or other defects

BTS example
- Correctly sealed pack with no leaks
- Sampling performed in a closed system with sterile connections and strict aseptic technique

Consistency is Quality

- Doing the right things time after time will ensure product and process predictability
- Reduced variations
- Confidence in the product or service
- Provision of a high quality product or service every time
Key Points

- Quality is a continual process of striving for improvement to ensure consistently high quality
- Quality products and services are fit for their purpose

Learning Outcomes

You should now be able to:
- Demonstrate an understanding of the broad concepts of quality
- Recognize the importance of quality in everyday life and in the BTS
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 2.4</th>
<th>Quality Characteristics</th>
</tr>
</thead>
</table>
| **Teaching aims** | ♦ To demonstrate how the term “fitness for purpose” is a broad definition of quality  
♦ To demonstrate how quality applies to common, everyday situations  
♦ To introduce the concept of quality characteristics |
| **Core topics** | ♦ Quality is “fitness for purpose”  
♦ Quality extends beyond simply producing a product  
♦ Quality relates to products, production, packaging and service |
| **Key points** | ♦ Customers want a high quality product/service  
♦ Everything about a product defines its quality |
| **Teaching focus** | ♦ Ensure that the aim of the activity is clear  
♦ Ensure an understanding of defining and meeting customer needs |
| **Learning outcomes** | Participants will be able to:  
♦ Identify the quality characteristics of a product  
♦ Demonstrate an understanding of fitness for purpose and customer needs |
| **Type of activity** | Group work |
| **Materials required** | ♦ An edible, salty food item contained in some form of packaging: e.g. a packet of potato crisps  
♦ Flipchart  
♦ Pens |
| **Instructions** | 1 Select one participant to assist you in carrying out the brief role play below before dividing the participants into groups.  
2 Role play:  
Facilitator: “Well, Joe, did you have a nice lunch?”  
Participant: “I did, thank you, but I’m still thirsty.”  
Hand the salty food item to the participant.  
3 Divide participants into groups and give each group a packet of the salty food item.  
4 Instruct the groups to:  
♦ Discuss whether the salty food item is a quality item: i.e.:  
   - Is it fit for its intended purpose/use?  
   - Is it the right product to meet the identified need at the right time?  
♦ Identify the quality characteristics of the salty food item and the packaging, based on observation and “tests”  
♦ Define the characteristics used  
♦ Differentiate between “fit for purpose” and acceptable quality characteristics  
♦ Describe the “tests” they have undertaken and the outcomes. |
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Inform participants that they may eat the salty food item.</td>
</tr>
<tr>
<td>6</td>
<td>Ask them to decide what service they would expect from the manufacturer if they file a complaint that the food item is of &quot;poor quality&quot;.</td>
</tr>
</tbody>
</table>

**Review of the activity**

- Guide the discussions to ensure that participants understand that, although the salty food item was not fit for the intended use, it may well be of good quality.
- Ensure that participants list the characteristics of the food item and justify:
  - The characteristics identified
  - The “tests” used to determine quality
- Ensure participants identify the action that they would expect from the manufacturer in response to a complaint.

**Time span**

1 hour
**ACTIVITY**

<table>
<thead>
<tr>
<th>QMT 2.5</th>
<th>Tour of the Blood Transfusion Centre (BTC)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To familiarize participants with the layout and activities of the BTC</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Familiarization with the building  
♦ Opportunity to observe a working blood transfusion centre (BTC)  
♦ Introduction to a working quality system |
| **Key points** | ♦ Quality is visible  
♦ Quality is a continuing process  
♦ Quality involves all staff |
| **Teaching focus** | ♦ Point out areas of particular interest in relation to quality  
♦ Do not get drawn into specifics about the way in which the BTS works |
| **Learning outcomes** | Participants should be able to:  
♦ Identify elements of a working quality system that lead to consistency and fitness for purpose |
| **Type of activity** | Visit to all departments of the BTC |
| **Materials** | Laboratory coats |
| **Instructions** | 1 Liaise with the course coordinator to make arrangements for the tour in advance with the relevant heads of departments and to ask them to designate a member of staff to brief participants on their own areas of activity.  
2 Accompany participants on the tour of the BTC and respond to any questions they may have.  
3 Indicate, where possible, the departmental activities that are related to the quality system: e.g. standard operating procedures.  
4 Indicate the parts of the building that participants will use during the course. |
| **Review of activity** | Ask participants to comment on their observations and identify anything they have noticed that demonstrates that a quality system is in place |
| **Time span** | 1½ hours |
Module 3
Quality Systems
<table>
<thead>
<tr>
<th><strong>QMT 3.1</strong></th>
<th><strong>Quality Systems</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce the concept of quality systems</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Quality and quality systems  
♦ Key elements of a quality system |
| **Key points** | ♦ Quality systems are designed to control processes  
♦ There are five key elements in a quality system:  
  ─ Organizational management  
  ─ Standards for quality systems  
  ─ Documentation  
  ─ Training  
  ─ Assessment |
| **Teaching focus** | ♦ Use examples of simple, generic quality systems to ensure understanding  
♦ Where appropriate, encourage participants to discuss quality systems in their own BTSS |
| **Learning outcomes** | Participants should be able to:  
♦ List the key elements of a quality system  
♦ Demonstrate an understanding of the interrelationship between these key elements |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Quality – the Concept  
5 Quality System – Definition  
6 Elements of a Quality System  
7 Organizational Management  
8 Standards for Quality Systems  
9 Documentation  
10 Training  
11 Assessment  
12 Key Points  
13 Learning Outcomes |
| **Materials** | None |
| **Related activity** | None |
| **Time span** | ½ hour |

**Presentation notes and handling the session**

<p>| <strong>Slide 4</strong> | Quality – the Concept | ♦ The slide shows important points to remember when implementing a quality system |</p>
<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Quality System – Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide gives a definition of a quality system</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that an organizational structure for a quality system may be a single quality officer or a full department with a quality manager</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Elements of a Quality System</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide shows the elements of a quality system that need to be in place to control processes and ensure quality outputs</td>
<td></td>
</tr>
<tr>
<td>♦ Suppliers (e.g. manufacturers of test kits) are the starting point for a quality system</td>
<td></td>
</tr>
<tr>
<td>♦ Inputs are turned into outputs through the use of processes (processes and procedures are dealt with in detail in QMT 3.2)</td>
<td></td>
</tr>
<tr>
<td>♦ Examples of each element are given on slides 7 – 11 in the following order:</td>
<td></td>
</tr>
<tr>
<td>– Organization and management</td>
<td></td>
</tr>
<tr>
<td>– Standards</td>
<td></td>
</tr>
<tr>
<td>– Documentation</td>
<td></td>
</tr>
<tr>
<td>– Training</td>
<td></td>
</tr>
<tr>
<td>– Assessment</td>
<td></td>
</tr>
<tr>
<td>♦ The quality system encompasses all these elements and their associated activities</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 7 – 11</th>
<th>Organization and Management, Standards, Documentation, Training &amp; Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides give examples of each of the elements of a quality system</td>
<td></td>
</tr>
<tr>
<td>♦ Do not go into details at this stage as the principles underlying each element are dealt with in depth in the presentations and activities that follow</td>
<td></td>
</tr>
</tbody>
</table>
Quality Systems

WHO/QMT 3.1

Teaching Aim

- To introduce the concept of quality systems

Core Topics

- Quality and quality systems
- Key elements of a quality system
Quality — the Concept

- Quality does not happen by chance
- Quality needs to be developed in an organization
- Quality needs to be systematic
- Quality systems are the basis on which the quality of the product or service is built

Quality System — Definition

Quality system
- The organizational structure and resources needed to implement quality requirements

Elements of a Quality System

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

Supplier

Processes

Customer
Organizational Management

- Commitment, responsibility and authority
  - Quality policy
  - Organizational structure: organogram
  - Job descriptions

Standards for a Quality System

- Ensure safety and consistency
- National
  - Country-specific
- International: e.g.
  - Good Manufacturing Practice (GMP)
  - International Organisation for Standardisation (ISO)
  - American Association of Blood Banks (AABB)

Documentation

- Information
  - Documents that are informative: e.g. quality policy
- Instruction
  - Documents that are instructive: e.g. standard operating procedures (SOPs)
- Records
  - Documents that allow traceability: e.g. HIV test results
Training

- The quality system is only as good as the staff who actually implement it on a daily basis
- However good the quality system is on paper, quality cannot be achieved if the theory is not translated into practice
- Training must include an understanding of why quality is important

Assessment

Processes, procedures, resources are assessed through:

- Validation
- Calibration and maintenance
- Error management
- Audits
- Quality assessment schemes (QAS):
  - Internal quality assessment schemes (IQAS)
  - External quality assessment schemes (EQAS)

Key Points

- Quality systems are designed to control processes
- There are five key elements in a quality system:
  - Organizational management
  - Standards for quality systems
  - Documentation
  - Training
  - Assessment
### Learning Outcomes

You should now be able to:

- List the key elements of a quality system
- Demonstrate an understanding of the interrelationships between these key elements
<table>
<thead>
<tr>
<th>QMT 3.2</th>
<th>Processes and Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce the concept of processes, procedures and their control</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Processes  
♦ Procedures  
♦ Critical control points  
♦ Indicators |
| **Key points** | ♦ An organization’s operations consist of processes and procedures  
♦ Critical control points need to be identified in each procedure  
♦ Indicators for measuring control of the procedure must be identified and analysed |
| **Teaching focus** | ♦ Check for understanding of the concepts of processes and procedures  
♦ Emphasize that there are critical control points in every procedure |
| **Learning outcomes** | Participants should be able to:  
♦ Define processes and procedures  
♦ Define critical control points and indicators  
♦ List the characteristics of indicators |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Processes and Procedures  
5 Definitions (1)  
6 Definitions (2)  
7 Process Management  
8 Critical Control Points  
9 Indicators (1)  
10 Indicators (2)  
11 Characteristics of Indicators  
12 Key Points  
13 Learning Outcomes |
| **Materials** | None |
| **Related presentation and activity** | QMT 3.3 Flowcharting as a Tool for Mapping Processes  
QMT 3.4 Developing a Process Flowchart |
<p>| <strong>Time span</strong> | ½ hour |</p>
<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Processes and Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide indicates how processes and procedures fit into an organization</td>
<td></td>
</tr>
<tr>
<td>♦ Stress that processes and procedures result in “outputs”: i.e. products and/or services</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Definitions (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use the following example to explain the concept of processes and procedures:</td>
<td></td>
</tr>
<tr>
<td>♦ Example of a process: making biscuits (cookies)</td>
<td></td>
</tr>
<tr>
<td>♦ The process consists of the logical sequence of activities that transform the raw ingredients into biscuits</td>
<td></td>
</tr>
<tr>
<td>♦ Some of the main activities involved include mixing a dough, cooking it in an oven and packing the biscuits into boxes</td>
<td></td>
</tr>
<tr>
<td>♦ The inputs are the ingredients (flour, milk, etc.), used to make the biscuits</td>
<td></td>
</tr>
<tr>
<td>♦ The output is the biscuits</td>
<td></td>
</tr>
<tr>
<td>♦ Example of a procedure: using this example, one procedure would be to add a specified amount of flour, milk, etc., and to mix it in a defined way to form a dough</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Definitions (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use the examples from the scenario:</td>
<td></td>
</tr>
<tr>
<td>— Example of a product: biscuits</td>
<td></td>
</tr>
<tr>
<td>— Example of a service: delivery of the biscuits to a shop</td>
<td></td>
</tr>
<tr>
<td>To help participants understand the concept of a service, describe the following scenario, ask the question below and discuss their answers:</td>
<td></td>
</tr>
<tr>
<td>— <strong>Scenario</strong>: the shop orders a supply of biscuits and is told that they will be delivered tomorrow. The biscuits are delivered one week later</td>
<td></td>
</tr>
<tr>
<td>— <strong>Question</strong>: Is this a quality service?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Process Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide identifies key requirements for the effective management of an organization’s processes</td>
<td></td>
</tr>
<tr>
<td>♦ Stress the importance of understanding that outputs from one process may be the inputs of another process within the same organization</td>
<td></td>
</tr>
<tr>
<td>♦ Cross-refer to the transfusion chain that was presented in QMT 2.1 to make it clear how poor quality outputs in one department result in poor quality inputs for another department</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Critical Control Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives a definition of critical control points</td>
<td></td>
</tr>
<tr>
<td>♦ Stress the importance of identifying indicators that really measure the critical control points in a procedure</td>
<td></td>
</tr>
<tr>
<td>♦ Give some examples of critical control points in a procedure</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Indicators (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives a simple definition of indicators</td>
<td></td>
</tr>
<tr>
<td>♦ Stress the importance of the analysis and use of the data associated with the indicator to improve quality</td>
<td></td>
</tr>
<tr>
<td>♦ Give an example of an indicator at one of the critical control points that you introduced with slide 8</td>
<td></td>
</tr>
<tr>
<td>Slide 10</td>
<td>Indicators (2)</td>
</tr>
<tr>
<td>----------</td>
<td>---------------</td>
</tr>
<tr>
<td>♦ The slide poses a list of questions that should be asked about the indicator(s) that has been identified as the measurement tool for a critical control point</td>
<td></td>
</tr>
<tr>
<td>♦ Using your example of an indicator, ask participants to answer the questions on the slide about the indicator</td>
<td></td>
</tr>
<tr>
<td>♦ Even if the example indicator is not a good example of an indicator, this activity will help participants to realize the value of the careful selection of indicators</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 11</th>
<th>Characteristics of Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives some examples of characteristics of good indicators</td>
<td></td>
</tr>
<tr>
<td>♦ Stress the importance of ensuring that all indicators have some, if not all, of these characteristics</td>
<td></td>
</tr>
</tbody>
</table>
Processes and Procedures

Teaching Aim

- To introduce the concept of processes, procedures and their control

Core Topics

- Processes
- Procedures
- Critical control points
- Indicators
Processes and Procedures

- All activities in an organization consist broadly of processes and procedures, which generally result in a product or service.

Definitions (1)

<table>
<thead>
<tr>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>A system of activities which use resources to transform inputs into outputs (products or services)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>A specified way to carry out a process</td>
</tr>
</tbody>
</table>

Definitions (2)

<table>
<thead>
<tr>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result of a process (service or processed material)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>An intangible product that is the result of at least one activity performed at the interface between the supplier and the customer</td>
</tr>
</tbody>
</table>
Process Management

For an organization to operate effectively, it should:
- Identify and manage all processes and the interrelationships between them
- Acknowledge the significance of:
  - Suppliers who provide the inputs
  - "Customers" who use the outputs

Critical Control Points

- All steps in a procedure that, without control, will lead to a poor quality outcome
- Identify indicators that measure the degree of control of the process at critical control points
  - Are the indicators appropriate to prevent a poor quality outcome?
  - How are the data collected?
  - How are the data used?

Indicators (1)

- Information gathered directly or indirectly at the critical control points in a procedure
- Analysis of this information indicates whether the procedure is being performed in accordance with the quality system
Indicators (2)

- What are we measuring?
- Why are we measuring it?
- How often do we measure it?
- How does the measurement help in making a decision?
- What is the acceptable range?

Characteristics of Indicators

- Simple
- Appropriate
- Reproducible
- Valid
- Measurable

Key Points

- An organization's operations consist of processes and procedures
- Critical control points need to be identified in each procedure
- Indicators for measuring control of the procedure must be identified and analysed
# Learning Outcomes

You should now be able to:

- Define processes and procedures
- Define and identify critical control points
- List the characteristics of indicators
### QMT 3.3 Flowcharting as a Tool for Mapping Processes

| **Teaching aim** | ♦ To introduce the use of flowcharts for analysing processes  
♦ To illustrate the use of flowcharts for identifying critical control points |
| **Core topics** | ♦ Main elements of the analysis of processes and procedures  
♦ Preparing flowcharts |
| **Key points** | ♦ Processes and procedures must be analysed in order to identify critical control points  
♦ Several important questions should be asked when analysing a process:  
  ─ Is the task critical to the outcome?  
  ─ Can the task (or the outcome of the task) be measured?  
♦ Flowcharting provides a simple picture (map) of the overall process |
| **Teaching focus** | ♦ Use simple examples of processes  
♦ Use conventional flowcharting symbols and terminology |
| **Learning outcomes** | Participants should be able to:  
♦ List factors that need to be considered in process analysis  
♦ Design a flowchart of a process |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Maps  
5 Map the Process (1)  
6 Map the Process (2)  
7 Main Tasks (1)  
8 Main Tasks (2)  
9 Critical Control Points  
10 Are You Ready?  
11 Flowcharts (1)  
12 Flowcharts (2)  
13 Use of Symbols  
14 Key Points  
15 Learning Outcomes |
| **Materials** | QMT 3.3: Example of a Process Flowchart  
For ease of reference, it is advisable to have the example flowchart visible on another audio-visual teaching aid: e.g. an overhead projector |
<p>| <strong>Related activity</strong> | QMT 3.4 Developing a Process Flowchart |
| <strong>Time span</strong> | 1 hour |</p>
<table>
<thead>
<tr>
<th>Presentation notes and handling the session</th>
</tr>
</thead>
</table>
| **Slide 4**  
Maps  
♦ The slide lists the characteristics of a map  
♦ Stress that the map of a process or procedure should also have these characteristics |
| **Slide 5**  
Map the Process (1)  
♦ The slide shows the first step in mapping (analysing) a process  
♦ A short list is given of some of the questions that should be asked  
♦ Use the example of a flowchart (QMT 3.3: Example of a Process Flowchart) to discuss the questions and possible answers  
♦ Stress the importance of identifying the ownership of a process and demonstrate how this assists in defining its scope  
♦ Emphasize the importance of keeping process analysis simple |
| **Slide 6**  
Map the Process (2)  
♦ The slide gives some tips on ensuring that the body of the process is well-defined before drawing the map  
♦ Use the example to demonstrate the use of the questions and possible answers |
| **Slide 7**  
Main Tasks (1)  
♦ Use the example to demonstrate how to ensure that each task is still within the scope of the process |
| **Slide 8**  
Main Tasks (2)  
♦ Use the example to examine the tasks and discuss the questions on the slide and relate them, and possible answers, to the example |
| **Slide 9**  
Critical Control Points  
♦ Stress the importance of identifying all critical control points and appropriate indicators  
♦ Stress that a task that is not a critical control point in a process (i.e. not a procedure) may not be a main task; to leave the task in the process flowchart may complicate the process  
♦ Stress the importance of keeping the analysis simple  
♦ Discuss how the flowchart should guide the user on what happens when a failure occurs at a critical control point |
| **Slide 10**  
Are You Ready?  
♦ This slide is a summary of the preceding slides and reminds participants that all aspects must be covered before they can define the process and draw the flowchart |
| **Slides 11 - 12**  
Flowcharts (1) & (2)  
♦ These two slides outline some simple steps in drawing a flowchart  
♦ Use the example to demonstrate how to apply the steps |
| **Slide 13**  
Use of Symbols  
♦ The slide shows some examples of symbols that can be used for flowcharts  
♦ Emphasize that some symbols are used internationally, especially those found in computer software packages  
♦ However, the decision on which symbols to use is up to the organization  
♦ Once the symbols to be used have been decided, their use should be consistent |
Decide to go to Zimbabwe

Select airline

- Air Zimbabwe
- South African Airlines
- British Airways

Phone airline

Is plane full?

- NO
  - Phone another airline
- YES
  - Get price of ticket

Is price acceptable?

- NO
- YES
  - Book ticket
Flowcharting as a Tool for Mapping Processes

Teaching Aim

- To introduce the use of flowcharts for analysing processes
- To illustrate the use of flowcharts for identifying critical control points

Core Topics

- Main elements of the analysis of processes and procedures
- Preparing flowcharts
Maps

Maps are pictures that:
- Tell us where we are
- Show us where we want to get to
- Illustrate the steps we must take and the direction in which we need to go
- Show us the various problems we may encounter
- Show us the choices available

Map the Process (1)

Identify the scope — clear start and finish events that show the boundaries of the process
- Which department owns the process?
- What are the inputs?
  - Do the inputs need to be controlled?
- What do you want to produce (the output)?
  - What are the specifications of the output (product/service)?
  - Who uses the output (customer)?

Map the Process (2)

Describe the process
- What are the main tasks (steps) to get from input to output?
  - Put the main tasks into logical order
- Are some of the tasks sub-processes?
  - If there are sub-processes, cross-refer to them
Main Tasks (1)

- Are all the outcomes of the tasks identified within the scope of this process?
- If the answer is YES, ensure the decisions and their outcomes are included in the flowchart
- If the answer is NO, cross-refer to another process/flowchart

Main Tasks (2)

- Ask the following question about each main task:
  - Is the task dependent on another process?
- If the answer is YES, this task needs to be cross-referenced to the other process
- If the answer is NO, no further action is required

Critical Control Points

- Is the task critical to the outcome of the process?
  - If the answer is YES, this is a critical control point
  - If the answer is NO, check whether this is definitely a main task
- Can the task or outcome of the task be measured?
  - What is the indicator?
- What happens when there is a failure at the critical control point?
Are You Ready?

- You can flowchart the process only when:
  - You know exactly what the process does
  - You have a list of sequential steps that are critical to the outcome of the process
  - You know the input and output of the process
  - You have identified sub-processes
  - You have clear start and finish points
  - The flow of tasks is what actually happens

---

Flowcharts (1)

- Illustrate the process with a diagram — draw a map
- Ensure all the main steps and choices are identified
- Ensure there is a logical sequence of:
  - Beginning and end points
  - Key tasks
  - Choices
  - Decisions
- Use symbols

---

Flowcharts (2)

- Start the diagram with the box showing the input
- Put the main steps in boxes in a logical sequence and connect by arrows that show the flow of work
  - Ensure steps that are choices or decisions are clearly shown (use different symbols)
- End the diagram with the output
  - Include control for specifications
Use of Symbols

- Some organizations use a standard set of symbols for flowcharts: e.g.

  ![Symbols for Flowcharts]

- Symbols can be used to indicate the type of step

Key Points

- Processes and procedures must be analysed in order to identify critical control points
- Important questions to ask when analysing a process
  - Is the task critical to the outcome?
  - Can the task (or the outcome of the task) be measured?
- Flowcharting provides a simple picture (map) of the overall process

Learning Outcomes

You should now be able to:

- List factors that need to be considered in process analysis
- Design a flowchart of a process
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 3.4</th>
<th>Developing a Process Flowchart</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To demonstrate to participants that the concept of process flow can be applied to any given situation</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Breakdown of a specific process  
♦ Analysis of the process using a flowchart |
| **Key points** | ♦ Processes are made up of individual procedures  
♦ Flowcharts help to clarify the individual elements of processes and procedures, including critical control points |
| **Teaching focus** | ♦ Focus on the basic processes, from raw materials to final product and distribution  
♦ Emphasize the need for simplicity  
♦ Provide a specimen flowchart for the process (QMT 3.3: Example of a Process Flowchart) |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the individual elements in a specific process  
♦ Develop a simple process flowchart |
| **Type of activity** | Group work |
| **Materials** | ♦ Instructions on flowcharting symbols (QMT 3.3: slide 13).  
♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 Instruct participants to analyse and draw a flowchart for the manufacturing process used in a generic organization. Examples are:  
♦ A biscuit (cookie) factory  
♦ A bread factory (bakery).  
2 Instruct them to follow the steps given in QMT 3.3.  
3 Remind them to use conventional flowcharting symbols. |
| **Review of the activity** | ♦ Discuss the flowcharts, emphasizing the identification of critical control points and decision-making steps  
♦ Ensure the process flowchart closes: i.e. there is a definite endpoint  
♦ The steps in the flowchart should include:  
   ─ Receipt of raw materials  
   ─ Approval of supplier (Yes/No)  
   ─ Quarantine of raw materials  
   ─ Testing of raw materials  
   ─ Meets specifications (Yes/No)  
   ─ Process of raw materials into final product  
   ─ Testing of final product  
   ─ Meets specifications (Yes/No)  
   ─ Release, reject, re-work steps |
| **Time span** | 1½ hours |
Use of Symbols

- Some organizations use a standard set of symbols for flowcharts: e.g.

- Symbols can be used to indicate the type of step
Module 4
Organizational Management
<table>
<thead>
<tr>
<th>QMT 4.1</th>
<th>Management Responsibility for Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce management’s responsibilities for the quality system</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Quality management terminology  
♦ Organizational responsibility for quality  
♦ Quality policy as a part of the organization’s strategic plan  
♦ Planning and implementing a quality system  
♦ Managing a quality system |
| **Key points** | ♦ Commitment by management to quality is essential  
♦ Responsibility for quality should be outlined in the quality policy and plan  
♦ Management should take responsibility for the planning and implementation of the quality system  
♦ The involvement and commitment of all staff is essential to develop a “culture of quality” |
| **Teaching focus** | ♦ Emphasize the importance of top-level support and action  
♦ Emphasize the role of all staff in ensuring quality |
| **Learning outcomes** | Participants should be able to:  
♦ Define management’s responsibilities for quality  
♦ Define commonly used quality management terminology  
♦ List the key elements of a quality policy |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Evolution of the Concept of Quality  
5 Definitions (1)  
6 Definitions (2)  
7 Definitions (3)  
8 Definitions (4)  
9 Organizational Responsibility (1)  
10 Organizational Responsibility (2)  
11 Quality Policy (1)  
12 Quality Policy (2)  
13 Quality Policy (3)  
14 Management Responsibility for Quality  
15 Planning a Quality System (1)  
16 Planning a Quality System (2)  
17 Planning a Quality System (3)  
18 Implementing a Quality System (1)  
19 Implementing a Quality system (2)  
20 Monitor and Modify  
21 Key Points  
22 Learning Outcomes |
**Materials**
None

**Related activity**
QMT 4.2 Developing a Quality Policy

**Time span**
½ hour

**Presentation notes and handling the session**

**Slide 4**
Evolution of the Concept of Quality
- The slide shows a diagrammatic representation of how the concept of quality systems has developed over the years
- Emphasize how quality control monitors only the end product and how this evolved to cover a larger area through quality assurance measures
- Discuss the differences between quality management and total quality management and how the latter focuses on customer needs and satisfaction

**Slides 5 – 8**
Definitions (1), (2), (3) & (4)
- The four slides give definitions related to quality management
- Discuss the steps in the evolution of the concepts, demonstrating how each step covers a wider area and finally encompasses all aspects of an organization’s activities

**Slide 9**
Organizational Responsibility (1)
- This slide states three principles regarding the broad responsibilities of an organization in relation to quality and, in particular, demonstration of commitment through a quality policy

**Slide 10**
Organizational Responsibility (2)
- The slide states three major activities that demonstrate the commitment of senior management to quality

**Slides 11 – 13**
Quality Policy (1), (2) & (3)
- The following three slides describe the concept of a quality policy and its key elements
- An example of a simple quality policy is included

**Slide 14**
Management Responsibility for Quality
- The slide states the three main regular responsibilities of management in ensuring that a quality system is implemented

**Slides 15 – 17**
Planning a Quality System (1), (2) & (3)
- The first slide introduces the concept of a quality plan
- The next two slides identify essential elements of a quality plan

**Slides 18 – 19**
Implementing a Quality System (1) & (2)
- The slides outline some basic steps in implementing a quality system and offer tips for success

**Slide 20**
Monitor and Modify
- Emphasize that constant monitoring and modification, where necessary, are the key to a successful quality plan and ultimately, to an effective quality system
Management Responsibility for Quality

Teaching Aim

- To introduce management’s responsibilities for the quality system

Core Topics

- Quality management terminology
- Organizational responsibility for quality
- Quality policy as a part of the organization’s strategic plan
- Planning and implementing a quality system
- Managing a quality system
Evolution of the Concept of Quality

- Quality Assurance
- Total Quality Management
- Quality Control
- Quality Management

Definitions (1)

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

Quality assurance
- Range of activities and systems that provide confidence within the organization and authorities that all quality requirements are met

Definitions (2)

Quality management
- Coordinated activities to direct and control an organization with regard to quality, including:
  - Quality control
  - Quality assurance
  - Planning
  - Improvement
Definitions (3)

Total Quality Management
A management approach:
- Centred on quality
- Based on the participation of all staff
- Aims at long-term success through
  - Customer satisfaction
  - Benefits to all staff
  - Benefits to society

Organizational Responsibility (1)

- The overall responsibility for quality in any organization lies with senior management
- The commitment of senior management and their involvement in quality-related activities is communicated through a quality policy
- The quality policy communicates the direction of the organization with regard to quality

Definitions (4)

Quality management system
- System to establish a quality policy and quality objectives and to achieve these objectives

Quality policy
- Overall intentions and direction of an organization related to quality, as expressed by senior management
Organizational Responsibility (2)

Senior management must ensure that:
- Sufficient and appropriate resources are available to achieve the required quality of product/service
- A policy is in place stating the commitment to quality
- The quality system covers all aspects of the organization

Quality Policy (1)

- A document that outlines the quality system
  - How quality is to be delivered (assured)
  - Its relevance to the activities of the organization
  - Its relevance to customers' needs
- Must be
  - Understood, implemented and maintained by all staff at all levels

Quality Policy (2)

- Statement of intent
  - Statement that says what you are going to do to achieve quality
- Signed and dated by Director or Chief Executive Officer
Quality Policy (3)

Example of a quality policy

- Management and staff are committed to setting up and maintaining a quality management system
- Quality is achieved by:
  - Adhering to national blood transfusion standards and generic quality standards
  - Ongoing training of staff
  - Measuring compliance and acting on deficiencies

Management Responsibility for Quality

- Planning a quality system
- Implementing the quality system
- Monitoring and modifying the quality system, as required

Planning a Quality System (1)

- Careful planning is essential for the success of a quality system
- The quality plan is based on the needs of the organization and its customers
Planning a Quality System (2)

The quality plan includes

- Quality policy
- Organizational structure, responsibilities and authority
- Defined processes and procedures that lead to the final product
- Methodology

Planning a Quality System (3)

- Raw materials used
- Product specifications
- Training
- Monitoring
- External regulation

Implementing a Quality System (1)

- Start with an action plan
- Communicate the objectives of the plan to all staff
- Achieve staff commitment
  - Implementation will fail without staff involvement and understanding of what is happening and why
  - Quality is the responsibility of all staff
- Generate a culture of quality
Implementing a Quality System (2)

- Implement the quality system gradually and in a systematic way
- Deal with key areas and issues first
- Set targets and record implementation

Monitor and Modify

- Monitor the performance of the quality system
  - Customer complaints
  - Internal complaints
  - Audits
- Modify the system, if required

Key Points

- Commitment by management to quality is essential
- Responsibility for quality should be outlined in the quality policy and plan
- Management should take responsibility for the planning and implementation of the quality system
- The involvement and commitment of all staff is essential to develop a "culture of quality"
<table>
<thead>
<tr>
<th>Learning Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>You should now be able to:</td>
</tr>
<tr>
<td>- Define management’s responsibilities for quality</td>
</tr>
<tr>
<td>- Define commonly used quality management terminology</td>
</tr>
<tr>
<td>- List the key elements of a quality policy</td>
</tr>
<tr>
<td><strong>QMT 4.2</strong></td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td><strong>Teaching aim</strong></td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Full and active support from senior management  
♦ Formal approval and acceptance of the policy  
♦ Key quality principles upon which the policy is based  
♦ Identifying appropriate standards |
| **Key points** | ♦ The quality policy must reflect the needs of the organization’s customers as well as its own structure and capabilities  
♦ Whatever standards are adopted, they must be relevant and appropriate to the organization  
♦ The support of senior management is central to the successful implementation of the quality policy |
| **Teaching focus** | ♦ Ensure that the policies developed by participants reflect the organization and its customers  
♦ Focus on simplicity and the use of simple wording  
♦ Ensure there is a section for senior management to sign the policy |
| **Learning outcomes** | Participants should be able to:  
♦ Write a quality policy for a generic organization  
♦ Write a quality policy for their own BTS |
| **Type of activity** | Group work |
| **Materials** | ♦ QMT 4.2: Examples of Quality Policies  
♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 Select an example of a small manufacturing organization that has a simple production process, preferably the same example as that used in QMT 3.4.  
2 Instruct participants to write a quality policy for the organization. This should outline:  
♦ The standard(s) that the organization will follow in order to ensure a good quality product  
♦ The key principles that will be used to achieve a good quality product: e.g.  
    ─ Well-trained staff  
    ─ Use of good quality raw materials purchased from approved suppliers.  
3 Remind participants to consider the following issues:  
♦ Commitment by the head of the organization to quality systems  
♦ Whether the policy is appropriate to the core business.  
4 Ensure that the statement of quality includes a section for the signature of a member of senior management and the date when it was signed. |
<table>
<thead>
<tr>
<th><strong>Review of the activity</strong></th>
<th>Ensure that the policies developed by the groups have simple statements that are easy to understand and apply to the core business</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time span</strong></td>
<td>1½ hours</td>
</tr>
</tbody>
</table>
Examples of Quality Policies for Blood Transfusion Services

Example 1
The National Blood Transfusion Service is dedicated to a system of quality management that will ensure that its blood products and services meet the requirements of clinicians and their patients. Because our products are administered to patients, our quality system will be comparable in excellence to those used in the pharmaceutical industry by licensed manufacturers.

The quality policy rests on four principles:
♦ Our definition of quality is conformance to requirements. We will carefully specify our requirements to our suppliers (donors and manufacturers), our processes (collection, laboratory, distribution) and our product users
♦ We will improve and maintain quality through a planned system of quality management, which will cover every part of our activity; audit and review will be an essential part of this system
♦ We will ensure that, under the guidance of trained quality management, each member of our staff recognizes their responsibility for quality improvement
♦ We will ensure that the education and training of staff are sufficient to maintain and improve quality.

Example 2
Management and staff of the Blood Transfusion Service are committed to a total quality management system for its products and services.

Quality is achieved by:
♦ Integrating quality with overall business and strategic plans
♦ Adhering to current good laboratory and manufacturing practice, satisfying the requirements of the authoritative national standard for the practice of blood transfusion and, where appropriate, those of the Medicines Control Council of the Department of Health
♦ Ongoing training of people and continuing improvement of products, processes and services
♦ Measuring the effectiveness of, and compliance with, the quality system through proficiency test programmes and internal quality audits
♦ Accepting measurement of the quality of products as an effective means of minimizing costs to the consumer.
<table>
<thead>
<tr>
<th>QMT 4.3</th>
<th><strong>Organizational Structure and the Role of the Quality Manager</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To highlight the importance of a reporting structure in an organization and the role of the quality manager</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Authority and responsibility for the organization’s activities  
♦ Importance of a clear definition of all activities and responsibilities in an organization  
♦ Role and responsibilities of the quality manager |
| **Key points** | ♦ Every organization needs a formal structure  
♦ The structures that is developed should maintain and strengthen the organization as a whole  
♦ A clear organizational structure is essential for smooth functioning  
♦ Authority and responsibility within the organization must be defined  
♦ The quality manager should be independent of operational activities  
♦ The quality manager reports directly to the head of the organization/institution  
♦ The quality manager is responsible for the implementation and maintenance of the quality system |
| **Teaching focus** | ♦ Emphasize that organizational structures need to be well-defined to be effective  
♦ Ensure participants understand the definitions of authority and responsibility and how the two are related in an organization |
| **Learning outcomes** | Participants should be able to:  
♦ Explain why a clear organizational structure is an important part of a quality system  
♦ Prepare a basic organizational chart (organigram)  
♦ List the responsibilities of the quality manager |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Terms Relating to Organization  
5 Authority and Responsibility (1)  
6 Authority and Responsibility (2)  
7 Example of an Organigram (1)  
8 Example of an Organigram (2)  
9 Staff and the Organization (1)  
10 Staff and the Organization (2)  
11 The Quality Manager  
12 Responsibilities of the Quality Manager  
13 Key Points (1) |
### Key Points (2)

15 Learning Outcomes

<table>
<thead>
<tr>
<th>Materials</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related activity</td>
<td>QMT 4.4 Developing an Organigram</td>
</tr>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
</tbody>
</table>

#### Presentation notes and handling the session

| Slide 4 Terms Relating to Organization | ♦ The slide states the definitions of an organization and organizational structure  
♦ Give some examples of groups of staff in an organization |
| Slides 5 - 6 Authority and Responsibility (1) & (2) | ♦ The slides give definitions related to quality management  
♦ Emphasize that an organizational structure is a formal system of communication and authority and is usually expressed in the form of an organigram  
♦ Explain how the organigram, a diagrammatic representation of the organizational structure, also defines the level at which a member of staff/position operates, relative to others |
| Slides 7 - 8 Example of an Organigram (1) & (2) | ♦ Two structures are shown on these slides:  
— The first slide shows a simple structure for a BTS  
— The second slide is a structure for a generic organization  
♦ Discuss the structures with participants  
♦ Promote discussion with participants by asking them about the structure of their own BTSs |
| Slides 9 - 10 Staff and the Organization (1) & (2) | ♦ Stress that staff need induction training about the structure of the organization in which they work  
♦ Training as part of the quality system is dealt with in Module 7 |
| Slides 11 - 12 The Quality Manager & Responsibilities of the Quality Manager | ♦ These slides outline the position and functions of a quality manager  
♦ Emphasize that the quality manager in any organization should never work in isolation, but should involve all staff in quality |
Organizational Structure and the Role of the Quality Manager

Teaching Aim

- To highlight the importance of a reporting structure in an organization and the role of the quality manager

Core Topics

- Authority and responsibility for the organization's activities
- Importance of a clear definition of all activities and responsibilities in an organization
- Role and responsibilities of the quality manager
Terms Relating to Organization

Organization
- Group of people and facilities, with an orderly arrangement of responsibilities, authorities and relationships

Organizational structure
- Orderly arrangement of responsibilities and relationships between staff of the organization

Authority and Responsibility (1)
- All staff within an organization need clearly defined lines of authority and responsibility
- Responsibility should not be given without authority
- Reporting structures are developed to assist the organization in achieving its objectives

Authority and Responsibility (2)
- The structure should encourage the organization to work as a coordinated unit, not just as individual sections
- The organizational structure should be documented as an organigram
- The quality manager should be independent of those having direct responsibility for the work performed
Example of an Organigram (1)

Example of an Organigram (2)

Staff and the Organization (1)

- The role of the organization must be made clear to all staff
  - What it does
  - Who its customers are
Staff and the Organization (2)

- A clear structure and focus is essential to enable all staff to understand their role in the organization
  - Who they are responsible to
  - What they do
  - Why they do it
  - What the outcomes may be, if done incorrectly
  - How different parts of the organization interact

The Quality Manager

- A management representative
- Reports directly to the head of the organization/institution
- Independent of manufacture or service delivery
- Given authority and responsibility for implementing and maintaining the quality system

Responsibilities of the Quality Manager

- To develop, implement and maintain an effective quality system
- To involve all BTS staff in quality
- To develop a culture of quality in the organization
- To train staff in quality and quality systems
- To encourage and support individual departments in implementing their own quality systems
Key Points (1)

- Every organization needs a formal structure
- The structure should maintain and strengthen the organization as a whole
- A clear organizational structure is essential for smooth functioning
- Authority and responsibility within the organization must be defined

Key Points (2)

- The quality manager should be independent of operational activities
- The quality manager reports directly to the head of the organization/institution
- The quality manager is responsible for the implementation and maintenance of the quality system

Learning Outcomes

You should now be able to:

- Explain why a clear organizational structure is an important part of a quality system
- Prepare a basic organizational chart (organigram)
- List the responsibilities of the quality manager
# ACTIVITY

<table>
<thead>
<tr>
<th>QMT 4.4</th>
<th>Developing an Organigram</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To train participants in preparing a simple organizational chart (organigram)</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Preparation of organizational charts  
♦ Consolidation of the use of organigrams |
| **Key points** | ♦ Organigrams simplify the presentation of organizational structures |
| **Teaching focus** | ♦ Ensure the participants keep to a simple organizational structure for a generic organization |
| **Learning outcomes** | Participants should be able to:  
♦ Draw an organizational chart  
♦ Demonstrate their knowledge of lines of responsibility and reporting structures |
| **Type of activity** | Group work |
| **Materials** | ♦ Flipcharts  
♦ Pens  
♦ QMT 4.4: Examples of Organigrams (Note: Distribute these after the activity) |
| **Instructions** | 1 Instruct participants to draw an organizational chart for the generic organization used in QMT 4.2.  
2 Ensure that participants:  
♦ First agree on the size of the organization  
♦ Decide on the various managers/supervisors (key personnel) that need to be present in the organization and their positions  
♦ Include the reporting structure. |
| **Review of the activity** | ♦ Discuss the functions and responsibilities of the various managers/supervisors named in the charts. Ensure that the roles of the following personnel are included in the discussion:  
— Chief Executive Officer (CEO)/Director/General Manager  
— Quality Manager/Officer  
— Financial Manager/Officer  
— Personnel Manager/Officer  
— Maintenance  
— Production  
— Marketing  
♦ Ensure the discussion covers the positioning of the quality manager/officer in the organizational structure  
♦ Distribute the examples of organigrams; ask participants to compare these with the ones they have produced and consider whether they can improve their own organigrams |
<p>| <strong>Time span</strong> | 1 hour |</p>
<table>
<thead>
<tr>
<th>QMT 4.5</th>
<th>Job Descriptions, Responsibility and Delegation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To highlight the importance of job descriptions that outline authority, responsibility and delegation</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Job descriptions  
♦ Person specifications  
♦ Competence  
♦ Authority and responsibility  
♦ Effective personnel management  
♦ Delegation |
| **Key points** | ♦ All organizations must ensure that they employ the right person for the right job  
♦ Staff should be well-trained and competent  
♦ Job descriptions and person specifications set out precisely what a job involves and the kind of person needed  
♦ Delegation enables managers to make the best use of their time and develop junior staff  
♦ Delegation is the sign of a good manager and a good quality system |
| **Teaching focus** | ♦ Emphasize the importance of clear and specific job descriptions and person specifications  
♦ Reinforce the importance of the delegation of authority |
| **Learning outcomes** | Participants should be able to:  
♦ List the key elements of job descriptions and person specifications  
♦ Identify the importance of authority and responsibility  
♦ Explain the importance of delegation |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Job Description (1)  
5 Job Description (2)  
6 Person Specification  
7 Importance of Defining Job Descriptions  
8 Preparing a Job Description and Person Specification  
9 Competence  
10 Effective Personnel Management (1)  
11 Effective Personnel Management (2)  
12 Delegation (1)  
13 Delegation (2)  
14 Key Points (1)  
15 Key Points (2)  
16 Learning Outcomes |
### Materials
Examples of job descriptions and person specifications. See QMT 4.5: Examples

### Related activity
QMT 4.6 Writing a Job Description

### Time span
1 hour

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Job Description (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives a broad outline of what a job description is and its main functions</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Job Description (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide states the basic elements of a job description</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each element with the participants</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that a job description should:</td>
<td></td>
</tr>
<tr>
<td>─ Correlate with the position as outlined in the organigram</td>
<td></td>
</tr>
<tr>
<td>─ Enable the organization to define the experience and skills required to do the job</td>
<td></td>
</tr>
<tr>
<td>─ Enable the person holding the post to understand the qualifications, skills and experience needed to do the job and what the job activities are</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Person Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the basic elements of a person specification</td>
<td></td>
</tr>
<tr>
<td>♦ Outline the similarities and differences between a job description and a person specification, emphasizing the fact that a person specification focuses on the person</td>
<td></td>
</tr>
<tr>
<td>♦ Use the examples to illustrate the points discussed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Importance of Defining Job Descriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the benefits of defining jobs and positions within an organization</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Preparing a Job Description and Person Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the questions that should be asked and answered when writing a job description</td>
<td></td>
</tr>
<tr>
<td>♦ Using the examples provided, discuss the topic with the participants</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Competence</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Stress that qualifications alone are insufficient to ensure a person’s competence</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that on-the-job training is essential to ensure that all staff achieve competence in their work</td>
<td></td>
</tr>
<tr>
<td>♦ Competency based training is dealt with in Module 7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 10 – 11</th>
<th>Effective Personnel Management (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The following two slides address some elements of effective personnel management and introduce the concept of delegation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 12 – 13</th>
<th>Delegation (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides outline the broad concept of delegation and reasons why some managers are reluctant to delegate</td>
<td></td>
</tr>
</tbody>
</table>
THE BLOOD SERVICE

Document for training only

JOB DESCRIPTION

Job title: Technologist, TTI screening laboratory
Grade: Technologist B 12–14
Department: General Laboratories
Main function: To undertake the TTI testing of blood donation samples

Note: In addition to these functions, employees are required to carry out other such duties as may reasonably be required

Accountable to: Head of TTI screening laboratory
Liases with: Blood grouping laboratory, other sections of the general laboratories, blood issue department

Minimum qualifications: Degree in a biological science or equivalent, with some previous experience of TTI testing or virus serology

Staff responsibilities: Together with senior laboratory staff, supervision and training of junior technical staff, as required

1 Key tasks

1.1 Perform TTI testing of blood donation samples referred to the laboratory.

1.2 Ensure that all testing is performed to defined standards and that the quality system within the laboratory is maintained at all times.

1.3 Play an active role in any other relevant areas of work undertaken by the laboratory.

1.4 As required by the head of the laboratory, check and authorize final results.

1.5 As required by the head of the laboratory, maintain and calibrate the equipment used in the laboratory.

2 General

The post holder is required to:

2.1 Keep himself/herself informed about developments and best practices in his/her areas of activity and to apply such information to the benefit of the Service, as appropriate.
2.2 Promote and implement the spirit and intention of the Service’s Mission Statement and to comply with and promote all the Service’s policies and supporting procedures.

2.3 Make positive efforts to promote his/her own personal safety and that of others by taking reasonable care at work, by carrying out the requirements of the law or following recognized codes of practice provided or advised by management to ensure safe working practices.

2.4 Observe the Service’s standards on confidentiality of information at all times.

2.5 Observe, maintain and promote quality standards in accordance with the Service’s policy and continuously improve the quality of patient support and donor care provided.

2.6 To undertake ad hoc duties and/or hours of work as may be required at his/her initial place of work or at any of the Service’s other establishments.

Terms and conditions
All other terms and conditions of employment are subject to Administrative and Clerical terms and conditions of service unless otherwise indicated in your Statement of Main Terms and Conditions of Employment.
PERSON SPECIFICATION

<table>
<thead>
<tr>
<th>Feature sought</th>
<th>Essential</th>
<th>Desirable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional/work</td>
<td>Experience in TTI screening of blood donations or</td>
<td>Experience in the detection of microbial genomes</td>
</tr>
<tr>
<td>experience</td>
<td>experience in virus serology</td>
<td></td>
</tr>
<tr>
<td>Skills</td>
<td>Comprehensive relevant bench skills</td>
<td>Computer skills; ability to analyse critically</td>
</tr>
<tr>
<td>Qualifications</td>
<td>BSc in a biological science or equivalent</td>
<td></td>
</tr>
<tr>
<td>Aptitude</td>
<td>Flexible and quick to learn; work well in a team</td>
<td>Willing to take responsibility, when necessary</td>
</tr>
<tr>
<td>Disposition</td>
<td>Calm; responsive rather than reactive; able to work</td>
<td></td>
</tr>
<tr>
<td></td>
<td>under pressure</td>
<td></td>
</tr>
<tr>
<td>Motivation</td>
<td>Self-motivated; must have the desire to produce high</td>
<td></td>
</tr>
<tr>
<td></td>
<td>quality work</td>
<td></td>
</tr>
</tbody>
</table>
Teaching Aim

- To highlight the importance of job descriptions that outline authority, responsibility and delegation

Core Topics

- Job descriptions
- Person specifications
- Competence
- Authority and responsibility
- Effective personnel management
- Delegation
Job Description (1)

- A statement of the duties and working conditions for a particular job
- Defines the skills, abilities, qualifications and experience required for the job
- Defines the job holder’s authority and responsibility within the organization

Job Description (2)

- Defines the basic elements of the job
  - Job title
  - Department
  - Main activities
  - Responsibility and authority
  - Liaisons
  - Qualifications
  - Grade/salary
  - Other requirements

Person Specification

- Outlines the essential/desirable skills, qualifications, experience and personal characteristics required for a specific job
  - Skills/competence
  - Experience
  - Qualifications
  - Aptitude
  - Disposition
  - Motivation
Importance of Defining Job Descriptions

- Clearly define the job
- Clearly define the person specification
- Simplify interviewing, selection and assessment
- Ensure a consistent approach to all appointments
- Help to ensure you get the staff you want
- Help to ensure people get the job they can do

Preparing a Job Description and Person Specification

- What is the job?
- Where is it located?
- What does it involve?
- What kind of person would be best to do the job?
- What skills and experience should that person have?
- What level of responsibility and authority does the job have?
- What is the grade/salary?

Competence

- Ability of an individual to do a particular job
- Ability of an individual to apply relevant skills and knowledge to the job
- Competence is gained by training
Effective Personnel Management (1)

- Management can be defined as the art of getting things done through people
- No single person can do everything
- Managers need to get the most from others
- Managers must help others to achieve their potential
- Managers need to know their own job

Effective Personnel Management (2)

- Team building
- Delegation
  - What can be done by others?
  - Who can do it?
  - How many people can do it?
  - What training is needed?
  - What resources are needed?
  - What are the benefits?
- Inspiring others to increase their motivation

Delegation (1)

Delegation of both authority and responsibility
- Delegation of responsibility on its own is not ideal
- Authority should not be abused
- It is only when staff are given responsibility and authority that they can develop confidence and skills
Delegation (2)

- Many managers do not delegate
  - They want to be in control of everything
  - They see delegation as lessening their position
  - They see it as encouraging others to seek their job
  - They do not trust their staff
- Delegation is the key to building a quality system
- The quality manager cannot – and should not – do everything

Key Points (1)

- All organizations must ensure that they employ the right person for the right job
- Staff should be well-trained and competent
- Job descriptions and person specifications set out precisely what a job involves and the kind of person needed

Key Points (2)

- Delegation enables managers to make the best use of their time and develop junior staff
- Delegation is the sign of a good manager and a good quality system
Learning Outcomes

You should now be able to:

- List the key elements of job descriptions and person specifications
- Identify the importance of authority and responsibility
- Explain the importance of delegation
### QMT 4.6 Writing a Job Description

<table>
<thead>
<tr>
<th>Teaching aim</th>
<th>To train participants in preparing a job description</th>
</tr>
</thead>
</table>
| Core topics  | ♦ The job description as a structured document  
♦ Key elements of a job description  
♦ Appropriate responsibilities and duties for a job |
| Key points   | ♦ All job descriptions in an organization should have the same format and should include the key elements of the job |
| Teaching focus | ♦ Ensure key elements are included in the job descriptions  
♦ Emphasize the quality manager’s role in ensuring a standardized approach to the development of job descriptions |
| Learning outcomes | Participants should be able to:  
♦ Prepare a simple job description and person specification  
♦ Include the appropriate duties and responsibilities in the job description |
| Type of activity | Group work |
| Materials | ♦ Examples of job descriptions and person specifications. See QMT 4.5: Examples  
♦ Flipcharts  
♦ Pens |
| Instructions | 1 Instruct participants to write a job description for the quality manager/officer of the generic organization they have discussed in QMT 4.2 and QMT 4.4.  
2 Instruct them to include the following essential elements:  
♦ Main job title  
♦ Minimum qualifications  
♦ Additional qualifications and experience  
♦ 10 duties or responsibilities  
♦ To whom they report  
♦ Who reports to them. |
| Review of the activity | ♦ Discuss the various formats for job descriptions presented by participants, concentrating on the merits of each one  
♦ Discuss the selection of minimum qualifications and experience, with particular reference to the responsibilities listed |
| Time span | 1½ hours |
### The Cost of Quality

<table>
<thead>
<tr>
<th><strong>QMT 4.7</strong></th>
<th><strong>Teaching aim</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core topics</strong></td>
<td>To demonstrate that a quality-based approach saves money</td>
</tr>
<tr>
<td>♦ Definition of the cost of quality</td>
<td></td>
</tr>
<tr>
<td>♦ Cost of quality</td>
<td></td>
</tr>
<tr>
<td>♦ Elements of quality costs</td>
<td></td>
</tr>
<tr>
<td>♦ Poor quality costs more</td>
<td></td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>Poor quality leads to failures and rejected products</td>
</tr>
<tr>
<td>♦ Poor quality increases operational costs</td>
<td></td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>Give a range of examples where the actual cost is higher than expected due to poor quality</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Analyse processes and procedures to identify where poor quality increases costs</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</td>
</tr>
<tr>
<td></td>
<td>4 Definition</td>
</tr>
<tr>
<td></td>
<td>5 Costs of Quality (1)</td>
</tr>
<tr>
<td></td>
<td>6 Costs of Quality (2)</td>
</tr>
<tr>
<td></td>
<td>7 Elements of Quality Costs (1)</td>
</tr>
<tr>
<td></td>
<td>8 Elements of Quality Costs (2)</td>
</tr>
<tr>
<td></td>
<td>9 Interaction of the Elements</td>
</tr>
<tr>
<td></td>
<td>10 Cost of Quality</td>
</tr>
<tr>
<td></td>
<td>11 Aims</td>
</tr>
<tr>
<td></td>
<td>12 Costing and the Clinical Interface</td>
</tr>
<tr>
<td></td>
<td>13 Minimum Overall Costs</td>
</tr>
<tr>
<td></td>
<td>14 Key Points</td>
</tr>
<tr>
<td></td>
<td>15 Learning Outcomes</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>None</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>
</tbody>
</table>

**Presentation notes and handling the session**

| **Slide 4** |
| Definition | The slide gives a broad definition of the cost of quality |
| | Emphasize that quality costs are the costs involved in ensuring that quality products meet required standards |
| | Discuss how the cost of quality refers only to defects/rejects: i.e. during the making, finding the defect, repairing the defect (if possible) or the cost of avoiding the defect |
### Slide 4
**Definition (continued)**
- Use some examples to explain this, such as:
  - During the making: e.g. a blood pack breaking in the centrifuge
  - Finding the defect: e.g. during routine quality control of platelet concentrates: platelet counts, pH etc.
  - Repairing the defect: e.g. all the HIV tests have to be re-done
  - Avoiding the defect: e.g. producing SOPs, training staff, etc.

### Slides 5 - 6
**Costs of Quality**
- The slides list the main elements of quality costs
- Emphasize that costs related to quality result from two types of quality failure: internal failure and external failure
- Use examples to illustrate these points, such as:

  **Internal failure**
  - Discards: how much it costs in labour and materials for each unit that is discarded, for whatever reason
  - Retest: the cost in labour and materials of re-doing the work: e.g. repeating all the HIV tests in a particular run
  - Downtime: the costs of labour (Note: staff may have to do overtime to catch up) and the cost of repairs if one of the machines is not working

  **External failure**
  - Complaints: the cost of investigating a complaint, including staff costs, social/community costs and public health costs
  - Returned/rejected products: all costs related to blood products that are returned for whatever reason
  - Law suits: in industry, this cost would be the cost of the guarantee of the product. In the BTS setting, we could be sued if we fail to provide safe, effective products to the patient

### Slides 7 - 8
**Elements of Quality Costs**
- The slides list the major elements of quality costs
- Give examples for each, such as:

  **Appraisal costs**
  - Incoming goods inspection: quality checks on ABO reagents for avidity, titre, etc.
  - Product testing: cost of testing (e.g. a platelet concentrate) to ensure it meets specifications
  - Equipment: cost of calibration and maintenance of all equipment
  - Materials consumed during testing: e.g. the cells used to quality control ABO reagents
  - Evaluation: cost of participating in an external quality assessment scheme

  **Prevention costs**
  - Quality planning
  - Training
  - Test kit evaluations
  - Process control
  - Data collection and analysis
  - Reporting
<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Interaction of the Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide explains how the elements of quality costs interact</td>
<td></td>
</tr>
<tr>
<td>♦ Use the following example to assist in the explanation:</td>
<td></td>
</tr>
<tr>
<td>♦ If the BTS has no appraisal or prevention costs, there will be many rejects leading to high external failures. There will therefore be many more customer complaints and returns of products. In the case of the BTS, the highest failure is the death of the patient. For example, if the BTS does no appraisal of the ABO reagent being used and has no SOPs for the staff to follow, the patient/unit may be incorrectly tested. This could result in a transfusion reaction. Costs incurred would include those related to investigating the transfusion reaction and a possible law suit</td>
<td></td>
</tr>
<tr>
<td>♦ If the BTS introduces appraisal (e.g. it now carries out some tests on the reagent just before use) and finds the reagent is not working, it will have an increased number of internal failures. It will have to find a different reagent to use, which wastes time and money</td>
<td></td>
</tr>
<tr>
<td>♦ The last and most beneficial step is to introduce prevention, through quality planning. If the BTS has full control over the selection of the supplier of the reagent, its staff are fully trained and certified as competent to SOPs, and all processes are well documented, it will reduce the overall cost of performing an ABO group and provide a quality service/product to patients</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Cost of Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide shows a graph that demonstrates how, as the costs of appraisal and prevention increase, failure costs reduce – thus reducing the total cost of quality</td>
<td></td>
</tr>
<tr>
<td>♦ Demonstrate how an optimum point is eventually reached (the arrow labelled “This is where you want to be”) where input costs from appraisal and prevention start to contribute to the total cost of the product without significantly reducing failure costs. The optimum point is where the organization wants to be</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 11</th>
<th>Objectives of quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the two main objectives of an organization in relation to quality</td>
<td></td>
</tr>
<tr>
<td>♦ Explain how “zero defects” is an impossible goal, but that the aim should be to make the number of failures as few as possible. Link this concept to how error analysis (see QMT 8.8) can be used to motivate staff</td>
<td></td>
</tr>
<tr>
<td>♦ Introduce the concept of “Do It Right First Time” (DIRFT) – and every time</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Costing and the Clinical Interface</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists important points regarding the role of the BTS at the clinical interface</td>
<td></td>
</tr>
<tr>
<td>♦ This topic is dealt with in detail in Module 14</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants, using generic and BTS examples</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Minimum Overall Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide states two important principles regarding the cost of quality</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that poor quality ALWAYS increases overall costs</td>
<td></td>
</tr>
</tbody>
</table>
The Cost of Quality

Teaching Aim

- To demonstrate that a quality-based approach saves money

Core Topics

- Definition of the cost of quality
- Cost of quality
- Elements of quality costs
- Poor quality costs more
Definition

The cost of quality
The total cost incurred by the organization in meeting specified quality standards

Costs of Quality (1)

Internal failure
- Discards
- Retest/rework
- "Downtime" - costs related to equipment breakdown
- Additional staff time

Costs of Quality (2)

External failure
- Complaints
- Returned/rejected products
- Law suits
Elements of Quality Costs (1)

Appraisal costs
- Incoming goods inspection
- Product testing
- Equipment (calibration)
- Materials consumed during testing
- Evaluation

Elements of Quality Costs (2)

Prevention costs
- Quality planning
- Training
- Test kit evaluations
- Process control
- Data collection and analysis
- Reporting

Interaction of the Elements

- Lack of investment in both appraisal and prevention leads to very high external failures
- Increasing appraisal costs may initially result in higher detection of internal failures, but ultimately decreases internal failures
- Introducing prevention costs leads to:
  - Improved quality
  - Lower overall costs
Cost of Quality

Objectives of Quality

- Zero defects
- Do It Right First Time (DIRFT) — and every time

Costing and the Clinical Interface

- Do quality costs end at the point of issue?
  - Ensure users are trained
  - "After sales service"
  - Complaints
Minimum Overall Costs

Achieve the required standards as economically as possible

Quality costs — but poor quality costs more

Key Points

- Poor quality leads to failures and rejected products
- Poor quality increases operational costs

Learning Outcomes

You should now be able to:
- Analyze processes and procedures to identify where poor quality increases costs
Module 5
Standards for Quality Systems
### QMT 5.1 Introduction to Standards for Quality Systems

#### Teaching aim
To introduce various quality standards that may be used by blood transfusion services

#### Core topics
- Quality standards
- National and international standards
- Regulatory standards
- Quality standards and audits

#### Key points
- Quality standards are key elements of the quality system
- Quality standards help to ensure a systematic and consistent approach to the development of quality systems
- Quality standards must be relevant to the BTS

#### Teaching focus
- Explain the usefulness of quality standards to the BTS
- Emphasize the importance of identifying appropriate standards for a particular BTS

#### Learning outcomes
- Explain the role of quality standards
- Describe the benefits to the BTS of using quality standards
- Explain the role of the quality manager in ensuring that relevant quality standards are identified and implemented

#### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Quality Standards (1)
5. Quality Standards (2)
6. Quality Standards (3)
7. Standards in Use
8. Regulatory Standards
9. Quality Standards and Audits (1)
10. Quality Standards and Audits (2)
11. Key Points
12. Learning Outcomes

#### Materials
Examples of quality standards from countries in the region. Liaise with the Course Coordinator in advance to identify suitable examples.

#### Related activity
None

#### Time span
½ hour
<table>
<thead>
<tr>
<th>Presentation notes and handling the session</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Slides 4 - 6</strong></td>
</tr>
<tr>
<td>Quality Standards (1), (2) &amp; (3)</td>
</tr>
<tr>
<td>✦ The three slides outline the definition of quality standards and the reasons for using them</td>
</tr>
<tr>
<td>✦ Involve participants in a discussion on the differences between practice-focused standards and system-focused standards</td>
</tr>
<tr>
<td>✦ Emphasize the differences between voluntary-based standards and regulatory-based standards</td>
</tr>
<tr>
<td>✦ Ensure that participants understand the need for selecting the appropriate standards for an organization</td>
</tr>
</tbody>
</table>

| Slide 7                                   |
| Standards in Use                          |
| ✦ The slide lists some examples of standards available for BTSs  |
| ✦ Using the examples from countries in the region, select some standards to discuss with the participants  |

| Slide 8                                   |
| Regulatory Standards                      |
| ✦ Discuss the points with the participants and involve them by asking about any regulatory standards that may exist in their countries  |

| Slide 9                                   |
| Quality Standards and Audits (1) & (2)     |
| ✦ The slides list some important points of the use of standards directly related to quality audits  |
| ✦ Quality audits are dealt with in detail in Module 8  |
Introduction to Standards for Quality Systems

WHO/QMT 5.1

Teaching Aim

- To introduce various quality standards that may be used by blood transfusion services

Core Topics

- Quality standards
- National and international standards
- Regulatory standards
- Quality standards and audits
Quality Standards (1)

- Defined sets of minimum quality requirements for an organization or institution (including healthcare organizations)
- Ensure that all activities consistently meet a minimum standard
- Different types of standards exist:
  - Practice focused: e.g. GMP
  - System focused: e.g. ISO

Quality Standards (2)

- May be applied on a voluntary or regulatory basis
  - The organization wants to adopt best practice
  - A customer may require an organization to meet certain standards
  - A customer, professional body or other higher authority may encourage/requires registration or accreditation
  - A national regulatory system may legally require all similar organizations to meet certain standards

Quality Standards (3)

- Quality standards must be appropriate to the activities of the organization
## Standards in Use

- **General international standards:** e.g.
  - Good Manufacturing Practice (GMP)
  - International Organisation for Standardisation (ISO)
  - International Laboratory Accreditation (ILAC)

- **Specific national standards:** e.g.
  - UK "Red Book" guidelines for National Blood Service
  - AABB guidelines for American Blood Banks
  - French regulations for blood transfusion services

## Regulatory Standards

- **Legal requirements in individual countries**
  - Must be met
  - Subject to regular inspection and licensing

- **May be regulated by government or designated non-governmental organization:** e.g.
  - Relevant specialized government department
  - National accreditation body

- **Are applied to all organizations in the same field**

## Quality Standards and Audits (1)

- **Audits are performed against relevant standards**
  - Voluntary
  - Mandatory

- **Enable the quality systems of an organization to be assessed**
  - Do the written procedures match the standards?
  - Are the written procedures actually followed?
## Quality Standards and Audits (2)

- Enable direct comparison between different organizations in the same field
  - Benchmarking

## Key Points

- Quality standards are key elements of the quality system
- Quality standards help to ensure a systematic and consistent approach to the development of quality systems
- Quality standards must be relevant to the BTS

## Learning Outcomes

You now should be able to:

- Explain the role of quality standards
- Describe the benefits to the BTS of using quality standards
- Explain the role of the quality manager in ensuring that relevant quality standards are identified and implemented
### QMT 5.2 Principles of Good Manufacturing Practice

| Teaching aim | To introduce Good Manufacturing Practice (GMP) within the quality system |
| Core topics | ♦ The BTS as a manufacturer  
♦ GMP as a part of the quality system  
♦ The key elements of GMP |
| Key points | ♦ BTSs are manufacturers of therapeutic products  
♦ Implementing GMP is essential to assure good quality products |
| Teaching focus | ♦ Focus on the BTS as a manufacturer  
♦ Ensure an understanding of the concept of manufacture applied to blood and blood products |
| Learning outcomes | ♦ Describe the role of GMP within the quality system  
♦ List the elements of GMP |
| Slides | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 GMP within the Quality System  
5 Definition - GMP  
6 Good Manufacturing Practice  
7 BTS Manufacturing Activities  
8 Elements of GMP  
9 Quality Management  
10 Personnel  
11 Contracts  
12 Purchasing  
13 Premises and Equipment (1)  
14 Premises and Equipment (2)  
15 Documentation  
16 Key Areas in Production (1)  
17 Key Areas in Production (2)  
18 Key Areas in Product Testing  
19 Quality Control of Products  
20 Complaints and Recall (1)  
21 Complaints and Recall (2)  
22 Self-Inspection (Audit)  
23 Key Points  
24 Learning Outcomes |
<table>
<thead>
<tr>
<th>Slide 4</th>
<th>GMP within the Quality System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The slide gives a diagrammatic representation of where GMP fits into the quality system and emphasizes how it is part of quality assurance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 5 - 6</th>
<th>Definition – GMP &amp; Good Manufacturing Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The slides give the definition of GMP and the main reasons for applying GMP principles to a manufacturing organization</td>
</tr>
<tr>
<td></td>
<td>Emphasize that GMP is related to the manufacture of products</td>
</tr>
<tr>
<td></td>
<td>The definition of GMP used here is from the European Union publication, <em>GMP Guidelines in Pharmaceutical/Medicinal Products</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>BTS Manufacturing Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The slide asks some questions regarding using GMP principles in a BTS</td>
</tr>
<tr>
<td></td>
<td>Discuss the questions and answers with the participants</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Elements of GMP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The list on the slide comes from the main sections of the EU publication, <em>GMP Guidelines in Pharmaceutical/Medicinal Products</em> and covers the main activities of any manufacturer</td>
</tr>
<tr>
<td></td>
<td>Point out to the participants that some elements of GMP overlap with those of the overall quality management system such as documentation</td>
</tr>
<tr>
<td></td>
<td>The following slides look at each of these points in greater detail</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Quality Management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Emphasize the need for participants to understand how GMP fits into the quality management system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Discuss how some of the elements of GMP principles are already covered by the quality system such as organograms and job descriptions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 11</th>
<th>Contracts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Discuss the use of contracts within the BTS</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Purchasing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The slide lists the main areas that must be controlled when purchasing any goods</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 13 – 14</th>
<th>Premises and Equipment (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The following two slides list areas of concern regarding premises and equipment in any manufacturing organization</td>
</tr>
<tr>
<td></td>
<td>Discuss these points with the participants, particularly their applicability to BTSs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 15</th>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The slide details the specific documents related to the manufacturing process</td>
</tr>
<tr>
<td></td>
<td>Discuss these with the participants. Emphasize the various documents in a BTS that fall into these categories</td>
</tr>
<tr>
<td>Slides 16 - 17</td>
<td>Key Areas in Production (1) &amp; (2)</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>♦ The two slides give a list of the key areas in production</td>
<td></td>
</tr>
<tr>
<td>♦ Outline the applicability of each area to the BTS</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 18</th>
<th>Key Areas in Product Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The points stated relate directly to product testing</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that the quality principles applied here to controlling product manufacture are the same as those applied to testing for transfusion-transmissible infections and blood group serology (dealt with in Module 12)</td>
<td></td>
</tr>
<tr>
<td>♦ Outline the application of each point to the BTS blood component department</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 19</th>
<th>Quality Control of Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the main area of control for product manufacture</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss these points related to the BTS</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 20 - 21</th>
<th>Complaints and Recall (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These slides outline the main elements of a complaints and recall system</td>
<td></td>
</tr>
<tr>
<td>♦ Errors/quality incidents are dealt with in detail in Module 8</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 22</th>
<th>Self-Inspection (Audit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ GMP principles focus on internal quality audits</td>
<td></td>
</tr>
<tr>
<td>♦ Quality audits are dealt with in Module 8</td>
<td></td>
</tr>
</tbody>
</table>
Teaching Aim

- To introduce the principles of Good Manufacturing Practice (GMP) within the quality system

Core Topics

- The BTS as a manufacturer
- GMP as a key part of the quality system
- Key elements of GMP
Definition - GMP

- GMP is “that part of QA that ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use”
  - Safety
  - Consistency

Good Manufacturing Practice

- GMP is about all the things we do and the care we take to ensure the quality of our products
- It is concerned with both production and quality control
- It ensures that the product testing results obtained are accurate and precise
BTS Manufacturing Activities

- Do you consider that we are a manufacturer?
- What do we manufacture?
- What are the key steps in the manufacture of blood and blood products for transfusion?

Elements of GMP

- Quality management
- Personnel
- Contracts
- Purchasing
- Premises and equipment
- Documentation
- Production
- Quality control
- Complaints and recall
- Self-inspection

Quality Management

- For GMP to be effective, it should be part of the quality management system of the organization
- All the elements related to quality systems are still relevant in GMP guidelines
Personnel

- Qualified
- Trained
  - Health & safety
  - Hygiene
- Sufficient number
- Organizational chart
  - Job descriptions
  - Authority

Contracts

- Must be correctly defined
- Written contract
- Must ensure satisfactory quality
  - Stipulate quantities
  - Stipulate quality requirements

Purchasing

- Specifications
- Quantities
- Delivery times
- Verify the quality of the incoming goods
Premises and Equipment (1)

- Located, designed and maintained to suit the operations to be carried out
- Layout and design to minimize errors and allow cleaning and maintenance
- Lighting and temperature controlled appropriately

Premises and Equipment (2)

- Protection against insects, vermin, etc.
- Prevent unauthorized access to building and work areas
- Defined areas for different activities
- Staff areas

Documentation

- Adequate and clear documentation
  - Control the manufacturing process: e.g. standard operating procedures (SOPs)
  - Specifications
  - Comprehensive records with dates and signatures
  - Despatch/transport records
  - Maintenance/calibration records
  - Training records
### Key Areas in Production (1)
- Follow clearly defined procedures
- Ensure procedures are performed and supervised by competent staff
- Identify the status of product: e.g. quarantine
- Correct storage
- Quality control at appropriate stages

### Key Areas in Production (2)
- Prevent contamination and deterioration
- Periodic review of processes and procedures
- Test packaging materials
- Identify rejected materials and remove from the system

### Key Areas in Product Testing
- Define strategies and methodology
- Follow clearly defined procedures
- Evaluate and validate test methods/reagents
- Include quality control
  - Test methodology
- Quality assessment schemes
  - To monitor effectiveness of testing methodology
Quality Control of Products

- Specifications
- Sampling
  - How many
  - How often
- Testing
- Analysis
- Documentation
- Non-conformance

Complaints and Recall (1)

Develop a system
- Identify responsible person
- Prepare documented procedures
- Inform customers about the complaints system

Complaints and Recall (2)

- Requires good production records and product traceability
- Reporting and recording of problems/incidents
- Review and analysis of problems
- Recall of defective products
- Corrective and preventive action
Self-Inspection (Audit)

- Regular internal audits
- Recording of audits
- Training of staff to audit

Key Points

- BTSs are manufacturers of therapeutic products
- Implementing GMP is essential to assure good quality products

Learning Outcomes

You should now be able to:

- Describe the role of GMP within the quality system
- List the elements of GMP