Quality Assurance in Transfusion Medicine

Dr. Hakan Buyukdere
Division of Hematopathology
The Ottawa Hospital
Objectives

At the end of this session, participants will be able to:

• Explain the purpose and basic principles of a quality assurance program in Transfusion Medicine

• List at least six (6) basic components of a Transfusion Medicine QA program

• Describe at least three (3) strategies through which error identification can lead to quality improvement as part of a quality assurance program in transfusion medicine
Objectives

- Accreditation Standards
- Components of a Quality Management System
- Quality System Essentials
- Role and responsibility of TM Medical Director
• **Quality**: The ability to consistently provide products and services that meet customer and regulatory requirements
Quality Management System

- Accreditation Programs and Inspections:
  - Federal and accreditation standards
    - Health Canada Regulations
    - CSTM -AABB Standards
    - IQMH Requirements
  - Identified deviations and deficiencies must be corrected
  - Measures the state of the facility's program at a single point in time
  - These inspections mostly find deviations after they occur
  - Accreditations and Inspections are the best friend of TM Lab. Medical Director !!
Quality Management System

• For Successful Quality Management:
  • Actively and continuously practiced throughout all activities
  • Always ready for inspections
  • Everyone’s job all the time!
<table>
<thead>
<tr>
<th>STAGE</th>
<th>ACTIVITIES PERFORMED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Quality Management 2000s</td>
<td>Management approach centered around “Client Satisfaction”</td>
</tr>
<tr>
<td>Quality Management 1990s</td>
<td>All of the below plus the economic aspects of “Cost of Quality”</td>
</tr>
<tr>
<td>Quality System 1990s</td>
<td>“Comprehensive and Coordinated” efforts to meet quality objectives</td>
</tr>
<tr>
<td>Quality Assurance 1980s</td>
<td>Systematic activities to provide “Confidence” that the organization meets requirements for quality</td>
</tr>
<tr>
<td>Quality Control 1970s</td>
<td>Operational techniques applied to “Specific Tasks” for quality and regulatory compliance</td>
</tr>
</tbody>
</table>
Quality Control

- Planned systematic activities that prove confidence
- Monitors the accuracy and precision of analytical method on a daily basis
- Reveals when a method, piece of equipment or procedure is not working as expected
- Frequency determined by regulations, standards and manufacturers’ instructions

**Accuracy:** Degree of closeness of determined value to the true value

**Precision/imprecision:** Dispersion of repeated measurements about the mean

- Not accurate:
- Not precise:
Quality Control in TM

- Daily testing of reactivity of blood typing reagents
- Calibrating centrifuges
- Monitoring temperatures of fridges, freezers and thawing devices

Monitoring QC
- Use QC rules which detect clinically important errors while minimizing false rejections, assess probabilities for error detection and false rejection
- Have at least one rule for random error and one rule for systematic error
- Track QC with standardized control chart (Levey-Jennings chart, radar plot), QC software: readily available for review by all staff
Quality Assurance

• Planned actions which assure systems and elements that influence quality are working as expected
• Looks beyond the performance of a test or piece of equipment
• Addresses how well the entire process is functioning
# Quality Assurance Indicators

## TRANSFUSION MEDICINE QUALITY INDICATORS

**Campus:** GENERAL  
**Year:** 2018

### CLIENT SATISFACTION

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Complaints</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CBS Directed Complaints</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

### INTERNAL INDICATORS - Errors in TM

<table>
<thead>
<tr>
<th>Error Description</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood grouping errors</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Incorrect blood issued</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>IQMH discordant results</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CAP / HC discordant results</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>ABO Procedures performed</td>
<td>3264</td>
<td>2993</td>
<td>3280</td>
<td>3052</td>
<td>3352</td>
<td>3145</td>
<td>3215</td>
<td>3238</td>
<td>2565</td>
<td>2662</td>
<td>2614</td>
<td>2625</td>
<td></td>
</tr>
</tbody>
</table>

### EXTERNAL INDICATORS - Errors outside of TM

<table>
<thead>
<tr>
<th>Error Description</th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>Oct</th>
<th>Nov</th>
<th>Dec</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood infused to wrong patient</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Duplicate specimens</td>
<td>49</td>
<td>42</td>
<td>49</td>
<td>42</td>
<td>34</td>
<td>38</td>
<td>33</td>
<td>25</td>
<td>28</td>
<td>27</td>
<td>27</td>
<td>21</td>
<td>415</td>
</tr>
<tr>
<td>Mislabeled/Wrong patient collected</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>31</td>
</tr>
<tr>
<td>Hemolysed / IV contaminated specimen</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Specimen/requisition not match</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Incorrect specimen type</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Inadequate volume</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>Unlabelled/incomplete labelled sample</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>No sample received</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Unlabelled/incomplete requisition</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>delay in receipt of sample</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Requisition not signed (drawing)</td>
<td>4</td>
<td>6</td>
<td>4</td>
<td>6</td>
<td>6</td>
<td>3</td>
<td>6</td>
<td>10</td>
<td>12</td>
<td>14</td>
<td>4</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Total rejected specimens</td>
<td>12</td>
<td>14</td>
<td>7</td>
<td>12</td>
<td>19</td>
<td>12</td>
<td>13</td>
<td>19</td>
<td>20</td>
<td>20</td>
<td>19</td>
<td>9</td>
<td>176</td>
</tr>
<tr>
<td>T/S samples received</td>
<td>2513</td>
<td>2308</td>
<td>2471</td>
<td>2328</td>
<td>2436</td>
<td>2294</td>
<td>2399</td>
<td>2408</td>
<td>2251</td>
<td>2459</td>
<td>2506</td>
<td>2495</td>
<td></td>
</tr>
</tbody>
</table>
Quality System

- Organizational structure, procedures, processes and resources that are needed to implement quality
- Provides the framework for applying quality principles and practices
Quality Management System Essentials

1. Organization
2. Customer Satisfaction
3. Facilities and Safety
4. Personnel
5. Purchasing and Inventory
6. Equipment
7. Process Management
8. Documents and Records
9. Information Management
10. Non-conformance Management
11. Assessments - Audits
12. Continual Improvement
1. Organization

- Relationship of lab personnel by job title
# 1. Organization

**Pathology and Laboratory Medicine**  
**Hematopathology & Transfusion Medicine**  
**Administration Manual**

**Quality Assurance & QC**

<table>
<thead>
<tr>
<th>Medical/Scientific</th>
<th>Management</th>
<th>Charge/Senior/Other</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td><strong>Back-up/Alternate</strong></td>
<td></td>
</tr>
<tr>
<td>REVIEW OF QMELS AND EXTERNAL QUALITY PROGRAMS - PATIENT SAFETY</td>
<td>AG (overall), All</td>
<td>DN, TM, Civ &amp; Gen, DN, Riv</td>
</tr>
<tr>
<td>DEPARTMENTAL QUALITY MANAGEMENT COMMITTEE</td>
<td>AG</td>
<td>DN, TM, Civ &amp; Gen, DN, Riv</td>
</tr>
<tr>
<td>DIVISIONAL QUALITY MANAGEMENT COMMITTEE (Hematology)</td>
<td>AG, Chair</td>
<td>DN</td>
</tr>
<tr>
<td>DIVISIONAL QUALITY MANAGEMENT COMMITTEE (TM &amp; TT)</td>
<td>AG, HB</td>
<td>DN</td>
</tr>
<tr>
<td>QC DATA MANAGEMENT AND OLA COORDINATION</td>
<td>AG, Special Hematology, All</td>
<td>DN</td>
</tr>
<tr>
<td>AG for TM, General and</td>
<td>All</td>
<td>DN for Transfusion Medicine, General</td>
</tr>
</tbody>
</table>

All Charge Techs. at their respective campus

All Charge Techs. in Hematology (3 campuses)

Charge Tech.

Charge Tech.

Charge tech.

MTISL-Gen
1. Organization

- Solicit feedback from end users
  - Good and bad
- Interprofessional collaboration
- Membership on committees
  - TOH Transfusion Committee
  - Stem Cell Committee
  - Joint Hospital/ORBCoN/CBS Committee
  - EORLA Discipline Specific Working Group
  - Hospital Emergency Blood Management Committee
2. Customer Satisfaction

- **Physicians and nurses**
  - Expect timely and safe transfusions
- **Patients**
  - Demand safe, correct products
3. Facilities and Safety

Occupational Health and Safety Act
Regulations for Health Care and Residential Facilities
Regulations for Industrial Establishments

- Joint Health and Safety Committee
- Environment temp control
- Electrical safety/Fire protection
- Training programs for emergency preparedness and infection control
4. Personnel

- Job descriptions
- Educational requirements
- Licensing
- Training and feedback
- Ongoing competency assessments
  - Direct observation
  - Written practical tests
  - Unknowns

- Employees
  - Training
  - Safe work environment
  - Compensation
  - Satisfaction
4. Personnel

TM Competency Schedule 2018/2019:
Jan – Feb: Neonatal Transfusion Quiz
Mar – Apr: Review of IQMH Sect VI
May – Jun: Reconstitution of PPP
Jul – Aug: Summer break
Sept – Oct: IQMH Dry Cases
Nov – Dec: ORBCON Advance Competency
Jan – Feb: ORBCON Basic Competency
5. Purchasing and Inventory

- Process for selection of vendors, equipment and supplies
- Vendor qualifications
- Identification of critical supplies
- Required to perform pre-transfusion testing and issuing of blood products:
5. Purchasing and Inventory

Critical Reagents:
- ABORh antisera
- Antihuman globulin
- Antibody screening cells

Critical Supplies:
- Glass tubes
- Pipettes

Supplies for Activities under Blood Regs:
- Transfer Pack Container
- Blood Transfer Set
- Welding Wafers
6. Equipment

- Process for installation, ensure proper functioning before daily operation
- Schedule for calibration, preventative maintenance and QC
  - Regulations/accreditation requirements
  - Manufacturers’ written instructions
- Defective equipment
- Records: date of purchase, new vs used, calibration, maintenance and repair
7. Process Management

- Interrelated activities that transforms inputs and outputs
  - Standard operating systems (SOPs)
  - Work instructions
  - Validation
  - Process control
  - Proficiency Testing
7. Process Management - SOPs

• Provides instruction for each activity in a larger process
  • To provide physician with ABORh type
    • Ordering of the test
    • Collecting of the appropriate sample
    • Delivering to lab
    • Perform ABORh
    • Reporting of the results
7. Process Management – Work Instructions

- ABORh typing

1. **PRINCIPLE**

To determine the ABO group in human blood.

ABO blood groups are determined by the presence or absence of A and B antigens on the red cells and by the presence or absence of anti-A and anti-B in the plasma.
7. Process Management - Validation

- To ensure new process will work as intended in the live environment
- Comparison to established method
- Training
- Documentation
7. Process Management - Validation
7. Process Management – Process Control

- Correct problems before they affect the product
- Improves processes to meet the changing needs and technologies
- Monitor the process to ensure performing as required
  - Daily review of work
  - Review QC records
  - Capture and act on occurrences when the process didn’t perform as expected

- Methods and procedures are compared to other labs for the ability to get the same result on unknown samples
  
  - IQMH
    - blood typing
    - detecting and identifying of antibodies
    - donor compatibility
  
  - CAP
    - Rosette
  
  - Interlab Comparison
    - Cold antibody workup
8. Documents and Records

Documents:

- Approved information contained in written or electronic format
- Policies, procedures, forms, manufacturers’ inserts

Records:

- A capture of the results of performing procedures and tests
- Worksheets, instrument printouts, electronic resulting

As per CPSO recommendation, records must be kept for 10 years from the date of last entry! For TM Lab, CSA Standards gives specific retention time for specific documents!
8. Documents and Records – Document Control System

- Links the policies, processes and procedures
- Ensures only the latest approved versions are available
- Specifies who can make changes
- How the changes are relayed to staff
- Documentation of training of new change
9. Information Management

- Patient information and test results
- Maintenance of confidentiality
- Must ensure the integrity of the info
- Release of information
  - Internal and external
- Who has access
10. Nonconformance (Occurrence) Management

- All employees need to participate
- Should not be perceived as a tool for finger pointing
- Represents that the processes don’t work as they should
- Creates opportunities for improvement
10. Nonconformance Management

• Charge techs record nonconformance in spreadsheet
• Nonconformances are reviewed and investigated
  • Process is amended
  • Retraining
  • Opportunity for competency
## 10. Nonconformance Management

### INTERNAL INCIDENTS

<table>
<thead>
<tr>
<th>Campus: General</th>
<th>Year: 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Staff</td>
</tr>
<tr>
<td>2018-01-10</td>
<td></td>
</tr>
<tr>
<td>15-Jan</td>
<td></td>
</tr>
<tr>
<td>15-Jan</td>
<td></td>
</tr>
<tr>
<td>15-Jan</td>
<td></td>
</tr>
<tr>
<td>08-Feb</td>
<td></td>
</tr>
<tr>
<td>09-Feb</td>
<td></td>
</tr>
<tr>
<td>08-Jan</td>
<td></td>
</tr>
<tr>
<td>25-Jan</td>
<td></td>
</tr>
<tr>
<td>19-Feb</td>
<td></td>
</tr>
<tr>
<td>19-Feb</td>
<td></td>
</tr>
<tr>
<td>17-Mar</td>
<td></td>
</tr>
<tr>
<td>25-Mar</td>
<td></td>
</tr>
<tr>
<td>13-Apr</td>
<td></td>
</tr>
<tr>
<td>18-Apr</td>
<td></td>
</tr>
<tr>
<td>28-May</td>
<td></td>
</tr>
<tr>
<td>10-Mar</td>
<td></td>
</tr>
<tr>
<td>22-Jul</td>
<td></td>
</tr>
<tr>
<td>23-Jul</td>
<td></td>
</tr>
<tr>
<td>25-Jul</td>
<td></td>
</tr>
<tr>
<td>26-Jul</td>
<td></td>
</tr>
<tr>
<td>09-Aug</td>
<td></td>
</tr>
<tr>
<td>25-Aug</td>
<td></td>
</tr>
<tr>
<td>04-Sep</td>
<td></td>
</tr>
<tr>
<td>04-Sep</td>
<td></td>
</tr>
<tr>
<td>19-Sep</td>
<td></td>
</tr>
<tr>
<td>21-Sep</td>
<td></td>
</tr>
<tr>
<td>02-Nov</td>
<td></td>
</tr>
<tr>
<td>28-Dec</td>
<td></td>
</tr>
<tr>
<td>28-Dec</td>
<td></td>
</tr>
</tbody>
</table>
Health Canada mandates:

- Blood banks must report any error or accident that may affect the safety, purity, potency or effectiveness of the blood component

**Error:**

- Nonconformance attributed to a human or system problem
- Failure to follow procedure

**Accident:**

- Not attributed to a person’s mistake
11. Assessments - Audits

- Measures the state of the quality program
- Identifies opportunities for improvement
- Internal vs External

  - **Internal assessments:**
    - Review of compliance inspection checklists
    - Tracking of QI
    - Incident Reviews

  “The establishment must perform internal audits to assess ALL activities performed under the Blood Regulations”

  *Health Canada*
11. Assessments – Audits

**Internal Audits**
- RBC Transfusion Practice
- Bedside Audit
- O negative RBC Audit
- Informed Consent Audit
- Reduced Platelet Audit
- Cryoprecipitate Audit

**External Audits**
- Proficiency testing
- External assessments
  - IQMH
  - Health Canada
  - FACT
  - External Studies
Internal Audit

Audit of RBC Transfusion Practice – General Campus

Audit Period: 2018 Jan, Nov

Background: An audit was performed to identify inappropriate red blood cell (RBC) transfusions at the General Campus by reviewing pre-transfusion hemoglobin (hgb) and single unit transfusions using the ORBCON QIP toolkit.

Method: Using LIS records from the month of January and November 2018, hgb data was collected for 50 RBC transfusions, selecting only the first RBC transfusion for each patient during the audit period. Each patient was also tabulated as receiving one or more RBC units. The percentages of transfusions with a pre-transfusion hgb less than 80 g/L as well as single unit RBC transfusions are reported.

Staff performing audit: Heather Maddison/Jennifer O’Neil/Melanie Tokessy
Performed: 2018-02-15 and 2018-11-20

Results:

To determine % of RBC transfusions with pre-transfusion hgb <80g/L (target 80%):

<table>
<thead>
<tr>
<th></th>
<th>January</th>
<th>November</th>
</tr>
</thead>
<tbody>
<tr>
<td># of consecutive transfusions audited</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td># of transfusions with a pre-transfusion hgb</td>
<td>49</td>
<td>50</td>
</tr>
<tr>
<td># of transfusions with a pre-transfusion hgb &lt;80 g/L</td>
<td>40</td>
<td>46</td>
</tr>
<tr>
<td>% of RBC transfusions with pre-transfusion hgb &lt;80 g/L</td>
<td>80%</td>
<td>92%</td>
</tr>
</tbody>
</table>

To determine % single unit RBC transfusions:

<table>
<thead>
<tr>
<th></th>
<th>January</th>
<th>November</th>
</tr>
</thead>
<tbody>
<tr>
<td># of consecutive transfusions audited</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td># of single unit transfusions</td>
<td>25</td>
<td>27</td>
</tr>
<tr>
<td>% of single unit RBC transfusions</td>
<td>50%</td>
<td>54%</td>
</tr>
</tbody>
</table>

Conclusion: As per ORBCON, the best performing site in the 2013 Ontario RBC Audit for adult inpatients was 80% of transfusions with a pre-transfusion hgb of <80 g/L and 80% for single unit transfusions. The results from January to November showed a small improvement.

Results will be shared with the TM staff, Transfusion Medicine and QA Committees.

Reviewed/Approved by: ___________________________  Date: ___________________
12. Continual Improvement

- Benchmarking and evidence-based practices
- Audits and assessment results, including IQMH, HC
- Feedback from staff or stakeholders
- Results from quality control programs (internal and external), proficiency testing etc.
- Regulatory requirements and changes to requirements
12. Continual Improvement

- **Code Bleed ED**
  - Need for Code Bleed at General
  - Delays in getting blood to patient

- **Code Bleed OBS**
  - Delays in getting blood patient urgently
  - What products to give and when
  - Worked with OB-Anaest. to determine products to be issued
Quality System Essentials:
Foundations that apply to all operations in the path of workflow
Canadian Association of Pathologists position statement 1996, 2004

- The medical director of the laboratory is
  - a suitably qualified physician who is legally, morally, and ethically responsible for the scope, standards, and quality of service.

Choose the correct answer:

- The medical director is responsible for
  1- The test results he/she reports.
  2- the test results reported by the laboratory medical staff.
  3- the test results reported by the laboratory.
  4- the test results issued by the technologists.
Canadian Association of Pathologists position statement
1996, 2004

The Laboratory Director (non medical) is responsible

- for the overall operation and administration of the laboratory, including areas of
  - personnel competency,
  - equipment,
  - safety,
  - laboratory policies,
  - Quality assurance,
  - proficiency testing, and reporting and delivery of results (see Code of Federal Regulations at 42 CFR 493.1407 and 493.1445) [1].
Summary

• A quality management system is needed to achieve the standard of excellence that patients and doctors/nurses expect

• Ensures safe, timely and efficacious transfusions to patients and it is a never ending prospect

• Quality should be built into day-to-day activities and is everyone’s responsibility

• TM Medical Directors is responsible for the scope of work, standards and quality of service TM Lab. generates
1- Laboratory Management, Textbook of Laboratory Hematology Practice, ISLH, 2012
2- Quality Systems for the Laboratory, ASCP Press
3- IQMH Accreditation, version 7.1
4- Astion ML et al.; Am J Clin Pathol 2003;120:18-26
5- CSA Standards - 2017, Blood and Blood Components, CSA-Z902
6- Henry’s Clinical Diagnosis and Management of Laboratory Methods, 23rd Edition, 2017
7- Quality Management in Clinical Laboratories, CAP Press, 2005
8- AABB – Standards for Blood Banks and Transfusion Services, 31st Edition