ROLE AND IMPORTANCE OF QIS IN QM AND HV: FROM MONITORING TO IMPROVEMENT AND SAVING

Tomislav Vuk

Croatian Institute of Transfusion Medicine
Zagreb, Croatia
TRANSFUSION MEDICINE

Special place of transfusion medicine in medical science:

- complex algorithms of donor selection and testing
- variability of the initial material and final products
- specific risks associated with their use
- many inter-connected segments
- numerous participants
- laboratory medicine, clinical medicine, pharmaceutical-like production
- patients and blood donors

Importance of implementing a quality management system (QMS) in transfusion service was early recognized.
QUALITY IN TRANSFUSION MEDICINE

Adequate number of effective and safe blood products for clinically justifiable transfusion treatment.

Quality Management
QM IN TRANSFUSION MEDICINE

Development of transfusion medicine in two main directions:

TRANSFUSION MEDICINE

PHARMACEUTICAL-LIKE PRODUCTION
need of conducting a uniform and strictly controlled process with minimal deviations and waste in the raw material and final products

USE AND MONITORING OF TRANSFUSION THERAPY

economical, justifiable and correct utilization

QUALITY

SAFETY
QM IN TRANSFUSION MEDICINE

- ISO
- GMP
- Professional standards
- Finances
- Human resources
- Information
- Environment
- Health and occupational safety

QMS
HAEMOVIGILANCE

The need of implementing the system of hemovigilance:

- **complexity** of transfusion service processes
- great number of those participating in them
- fatal effects of potential **errors**
- specificity of **risks** associated with blood collection and blood component preparation and use
- constantly pending **new risks**
HAEMOVIGILANCE

- unexpected or undesirable effects (blood safety concept)
- the scope of haemovigilance has evolved
- entire transfusion chain ("vein to vein")
HAEMOVIGILANCE – CURRENT TRENDS

- problem identification
- root-cause analysis
- corrective/preventive actions
- solutions
- recommendations
- monitoring of the effectiveness of the implementation of corrective actions
- standardisation: definitions, indicators
QUALITY INDICATORS

- important QMS tool for accomplishment of the quality goals
- measurable, objective indicators of the efficiency of the key segments of a system
- used to monitor and control process functioning
- the data collected provide a basis for the implementation of corrective measures and continuous quality improvement
- fast and simple insight into the level of product and service quality and their pattern over time
- assessment of the QMS conformity with the set goals
- identification of weak chains in the process
- selection of priorities to be solved
- assessment of the efficiency of corrective measures
- comparison of institutions of similar characteristics (benchmarking)
- important for the process of accreditation and certification
QUALITY INDICATORS

- **ISO 9001**: conformity with the set quality standards and goals, and thus the efficiency of QMS has to be demonstrated by measurement

- **ISO 15189**: laboratories are obliged to perform systematic analysis of quality indicators used for monitoring and assessment of the quality of services offered to patients
  - primarily applying to hospitals
  - increasingly introduced in primary healthcare
  - little data are available on quality indicators in transfusion medicine
    - clinical TM
    - laboratory medicine (EN ISO 15189)
QUALITY INDICATORS

Quality indicators should be focused on:

• basic quality requirements
• product and service safety
• user and provider expectations.

They should also measure:

• satisfaction of the staff members
• performance characteristics
• environment requirements
• etc.
QM, HAEMOVIGILANCE, QI

- HV = risk monitoring system
- HV = quality process
- full integration of hemovigilance in the quality management system
QM, HAEMOVIGILANCE, QI

- QM and HV: activities continuously intertwined
- joint goals of high quality, safe and efficacious transfusion treatment
PROMOTION OF VNBD SELECTION
### PROMOTION

<table>
<thead>
<tr>
<th>QA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of target population</td>
</tr>
<tr>
<td>Promotion directed toward low-risk donors</td>
</tr>
<tr>
<td>Education of prospective donors</td>
</tr>
<tr>
<td>Partnership with blood donors</td>
</tr>
<tr>
<td>Stimulating personal, social and ethical donor’s responsibility for blood safety</td>
</tr>
<tr>
<td>Collaboration with mass-media</td>
</tr>
<tr>
<td>Retaining existing donors</td>
</tr>
<tr>
<td>well structured, planned, professional, continuous, liable to modification, trained staff (nonprofit marketing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HV</th>
</tr>
</thead>
<tbody>
<tr>
<td>HV data about blood donors should be used in promotional and educational activities</td>
</tr>
<tr>
<td>• risks</td>
</tr>
<tr>
<td>• epidemiology of infectious diseases</td>
</tr>
<tr>
<td>• adverse reactions</td>
</tr>
<tr>
<td>• PDI</td>
</tr>
</tbody>
</table>
Dual goal:

1. To protect donor’s health
2. To ensure quality and safe blood products for the recipients
### QA
- Providing the donor with information on all relevant facts related to blood donation (risk behaviours, potential risks and side effects of blood donation)
- Use of uniform questionnaire
- Informed consent form
- Confidential interview with a competent professional
- Medical examination
- Option of self-exclusion
- Donor counselling
- Conditions for apheresis and autologous donors
- Signature (person responsible for donor selection)

### HV
- HV data about blood donors should be used in the process of donor selection
  - risks
  - epidemiology of infectious diseases
  - adverse reactions
  - errors in selection
  - PDI
  - iron status
PROMOTION AND SELECTION: QUALITY INDICATORS

- adequate supply of blood components
- safe and efficacious transfusion treatment

**Quality indicators:**
1. Percentage of voluntary non-remunerated blood donors
2. Accomplishment of the planned number of donors (WB and apher.)
3. Percentage of donations collected from first time donors
4. Number of donations collected per 1000 inhabitants
5. Number of donations per donor (per year)
6. Realization of requests for blood components
7. Donor deferral rate – total, temporary, permanent
8. Errors, complaints, donor satisfaction
BLOOD COLLECTION
BLOOD COLLECTION

- special place and role in the transfusion chain
- many critical sites influencing quality of BC
- skill and experience of the technicians
- venipuncture failures - considerable economic loss for blood collecting institutions
- reputation of the blood establishment
## BLOOD COLLECTION

### QA – CRITICAL POINTS

- Inspection of incoming materials
- Identification and traceability
- Venipuncture
- Sample collection
- Blood mixing with anticoagulant solution
- Duration of blood withdrawal
- Blood volume
- Sterile sealing
- Donor monitoring
- Donation inspection
- Storage conditions until processing

### HV

- Errors
- Bacterial contamination
- Donor reactions and injuries
- Materiovigilance
BLOOD COLLECTION – QUALITY INDICATORS

- donor-related
- product-related

Quality indicators:
1. Venepuncture failures
2. Donor sample nonconformities
3. Incidence of bacterial contamination of blood components
4. Clots in Red Blood Cell (RBC) components
5. Aggregates in platelet concentrates
6. Poor welds on blood collection
7. Donor adverse reactions
8. Donor complaints
9. Customer satisfaction (donors)
10. Error frequency
MATERIOVIGILANCE AT BLOOD COLLECTION

- blood bags – one of the most critical materials
- formal quality control of each batch
- visual inspection of each individual bag
  - blood bag integrity
  - appearance and volume of AC solution
IDENTIFICATION AND TRACEABILITY

- positive identification of blood donor
- unique donation number
  - primary blood bag
  - transfer bags
  - specimens
  - donation form
  - computer system
- each donation traceable to the batch number of the bag used on blood collection
VENIPUNCTURE

- skill and experience of the technicians
- venipuncture failures - considerable economic loss for blood collecting institutions
- reputation of the blood establishment
VENIPUNCTURE

- choice of desinfectant
- validation of desinfection procedure
- education
- pre-donation sampling
- repeat venipuncture at another site with a new needle
BLOOD MIXING WITH AC SOLUTION

- crucial for the quality of BC
- prevention of clot formation
- pH and temperature differences between the two fluids
- manual mixing (30-45 sec) or automated balances-mixers
- validation

CLOTS IN RED CELL PRODUCTS
CITM 1998-2012
DURATION OF BLOOD WITHDRAWAL

- blood flow adequate and uninterrupted
- records on the donations with prolonged duration of blood withdrawal
- **CoE recommendations**
  - > 12 min: no PLT concentrates
  - > 15 min: no plasma for clinical use or for manufacture of coagulation factors
DONOR MONITORING

- personnel adequately educated
- records on all side effects
BLOOD VOLUME

- directly influences the quality of blood components
- regular control of balances