HOW TO MANAGE QUALITY PROBLEMS AND COMPLAINTS IN TRANSFUSION MEDICINE?

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Antalya, 2019
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
• great responsibility of transfusion services to provide accessible and safe transfusion therapy
• tremendous progress in terms of quality and safety in transfusion medicine
• most of the activities in transfusion chain take place without any problems
• some risks are still present
• the biological origin of blood products
  - transfusion-transmissible infections
  - immune-mediated transfusion reactions
• complexity, numerous participants in transfusion chain
  - errors

Importance of implementing a QMS in transfusion medicine was early recognized.
• 1991 - France
• unexpected or undesirable effects of transfusion treatment (blood safety concept)
• the scope of haemovigilance has evolved
• entire transfusion chain ("vein to vein")
• HV = risk monitoring system
• HV = quality process
• full integration of haemovigilance in the quality management system
ROLE AND IMPORTANCE OF QM/HV

- QM and HV: activities continuously intertwined
- joint goals of high quality, safe and efficacious transfusion treatment
- proper functioning of all activities in the entire process of transfusion medicine
- continuous monitoring
- CAPA
- improvement
PREVENTIVE APPROACH

- preventive approach
  - preventing things from getting badly
  - when things go badly - preventing and mitigating damage by a correct and rapid response

Preventive strategies:
- comprehensive risk management
- education
- definition of critical control points
- permanent quality monitoring and vigilance
- audits
- identification of opportunities, etc.
• quality – responsibility of all employees
• team work and cooperation

• knowledge and professional competence
• human qualities

• structured protocol
• each decision should be properly documented
DECISION MAKING

• process of choosing among different action options (alternatives)
• intuition vs. reasoning
• knowledge, experience, facts, relevant information

• difficulties on making decisions:
  - complex problems
  - situations when we feel uncertainty
  - lacking or inadequate data
  - serious consequences of decisions
COMMUNICATION

• inappropriate communication = misunderstandings and conflicts
• written and verbal communication skills
• two-way process
• ability of active listening
• transfer of information and education
• effective problem solving
• better management of conflict situations
• the skill of written communication:
  - responding to complaints
  - making complaints
TEAM WORK

- important tool in achieving common goals
- the scope of tasks to cover is steadily increasing and growing ever more complex

“None of us is as smart as all of us”
*Japanese proverb*

"Coming together is a beginning; keeping together is progress; working together is success."
*Henry Ford*
CAUSES OF QUALITY PROBLEMS

Blood banks
quality problems are often manifested on blood products
• biological origin of blood products
• human errors
• poor quality of materials and equipment used in product realization
• suboptimal planning and organization of work

Hospital transfusion units
problems are most commonly related to pre-transfusion testing
• errors in pre-analytical phase
• selection or issue of blood components for transfusion

Clinical transfusion practice
• many activities that are not directly under the jurisdiction of BTS
• BTS can affect them through hospital transfusion committees, education of clinical staff, and so on
BLOOD COLLECTION

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


“Overall data suggest that optimal initial education of staff members performing blood collection should take 5-6 months, while taking into account that up to one year is needed to acquire desired skill and experience.”
Venipuncture failures (CITM)
- failed insertion of the needle into the vein
- interrupted collection (hematoma, poor/absent flow, donor reaction...)

Croatian Institute of Transfusion Medicine – 2017 data

IMPORTANT QUALITY INDICATOR!
VENIPUNCTURE FAILURES – CITM 1998-2017

%
Croatian Institute of Transfusion Medicine (CITM)
Zagreb, Croatia
Year: 2017
269 PDI

**During donation (blood withdrawal) or immediately after**

EARLY
58 (21.6%)
Infections/contact: 27 (46.6%)

**After donation but before next donation/attendance**

LATE
211 (78.4%)

**Subsequent donation(s)**

Tattoo/piercing: 50 (23.7%)
Surgical procedures: 48 (22.7%)
Travel: 41 (19.4%)
Endoscopy: 31 (14.7%)
Infections/contact: 8 (3.8%)
Other medical conditions: 33 (15.6%)
• risk assessment
  - quality/safety of blood components
  - safety of blood donors
• cooperation with HBB and clinicians
  - recall
  - look-back
• cooperation with fractionators
  - contracts
• counseling blood donors
  - further donations
• education
  - blood donors
  - staff
OUTDATED BLOOD COMPONENTS

- BC - valuable resource
- responsible management
- careful planning of blood collection
- stock management
- low discard rate: savings, better allocation of resources

Figure: Outdated PLT concentrates
CITM 1998-2017
LIPEMIC PLASMA

CITM – lipemic FFP for clinical use 1998-2017

Corrective actions
- donor factors
- testing problems
- product loss
MANAGEMENT OF NONCONFORMING QC RESULTS (SPC)

Nonconforming QC result(s) → Initial investigation → Decision on BC(s)

- Accidental process variation
- System problem

Accidental process variation or System problem → Root cause analysis → Corrective action
Repeat testing according to quality protocol

- e.g. in QC
- (influence on the result?)

Exceptional circumstances - properly explained and documented

- product recall
- donor counseling
- repair of the equipment
- staff re-education
- testing of other components
• causes
• influence on other products from the same donation
• influence on blood products from other donations of the donor
• influence on the other blood components from the same “batch”
BC NONCONFORMITY - INVESTIGATION

Depends on the type of the nonconformity

**Donor-related factors**
- CBC parameters (HGB, WBC, PLT...)
- lipemia
- protein content
- other laboratory findings

**Collection/processing/storage**
- length of blood withdrawal
- flow
  - venipuncture technique (technician)
  - veins
- apheresis procedure; alarms and messages
- filtration time, separation time
- storage conditions
BC NONCONFORMITY - INVESTIGATION

Equipment
• HGB determination system
• blood mixers
• sealers/SCD
• apheresis machines
• blood centrifuges and separators
• refrigerators/freezers...

Materials
• blood bags
• filters
• solutions
• labels/adhesives...

Human errors
ERRORS IN TRANSFUSION MEDICINE

• one of the leading causes of morbidity and mortality associated with transfusion therapy
• may have disastrous consequences for the patients
• frequently of multifactor nature

• danger of serious/fatal outcomes
• cost of lost products
CAUSES OF ERRORS

- inexperienced staff
- lack of staff
- lack of knowledge
- complexity of procedures
- inappropriate design of equipment and procedures
- poor communication
- poor co-ordination
- improper documentation
- stress
- distractions...

Even well trained individuals are at risk of making serious errors while working in poorly designed systems (Singh H et al. Qual Saf Health Care. 2006)
INVESTIGATION OF ERRORS/EVENTS

- systematic, comprehensive, efficient

Data collection

Classification Analysis

CA/PA

Quality improvement

Uniform

Formal protocol (e.g. MERS-TM)
Responsible professionals
Focus on system-based issues
Risk assessment
SHOT/MHRA

SHOT - 2018
• 3326 total reports
• 2905 errors = 87.3%
• 1667 no harm (1451 near miss + 216 right blood right patient)

MHRA - 2018
• 1606 reports
• 408 SAR
• 1198 SAE (98.3% human errors)

MHRA = Medicines and Healthcare products Regulatory Agency

EC. Summary of the 2017 annual reporting of serious adverse reactions and events for blood and blood components (data collected from 01/01/2016 to 31/12/2016)

Ref. Ares(2019)1077383 - 21/02/2019
ERROR PREVENTION

• establishment of such an organizational structure and working environment where recognized errors can be reported without fear
• the use of simple, clear and intelligible documentation
• initial and continuous education
• defining critical sites in the work process and intensified surveillance of these sites
ERROR PREVENTION

- use of SOPs
- clear rules and policies
- systematic analysis of nonconformities, errors, complaints, and implementation of corrective and preventive measures
- internal audits
- automation and computerization
- checklists
- duplicate checks
- suggestions to be more careful – low potential
In addition to already mentioned preventive measures:

• avoidance of unnecessary transfusions
• identifications bracelets
• radiofrequency ID systems
• fingerprint sensors
• palm vein scanning technology
• blood testing at bedside
• double grouping
• transfusion registry
• careful monitoring of the recipient
• Haemovigilance systems
ERROR MONITORING

- important quality indicator
- trend analysis
- quality objectives
- UCL (upper control limit)

Error monitoring: example CITM
COMPLAINT MANAGEMENT

• some products and services fail to meet the customer requirements/expectations, in spite of:
  - maximal institution commitment to quality
  - optimal results of internal quality measurements
• efficient complaint management provides valuable information on:
  - customer satisfaction
  - perception of the product and service quality
• precondition for undertaking appropriate CAPA and continuous quality improvement
• tool for continuous quality harmonization with customer requirements and expectations
• clearly defined
• described in a document defining:
  - the course of activities
  - the persons responsible for their performance
COMPLAINT MANAGEMENT

• complaint receipt
• complaint processing (analysis)
  - justifiability
  - risk level
• informing the complainant on the activities performed and results obtained
• implementation of corrective/preventive actions
• periodical statistical analysis of data produced by the procedures of complaint management
• monitoring efficiency of the corrective actions undertaken for complaints
COLLABORATION WITH CUSTOMERS

- partnership
- good communication
- proposals, suggestions, needs
- important in the process of complaint management
COMPLAINT MANAGEMENT

DOMAIN project:
• system of donor complaint management has been established in the majority of transfusion institutions
• the number of complaints received varies considerably among institutions
  - waiting time
  - inappropriate staff communication
  - donor deferral
  - technique of venipuncture

Northern Ireland Blood Transfusion Service
• annual 2017 report
• 17 formal complaints out of 54954 donations
• Scottish National BTS – donors
• around 204,000 donors
• 97 complaints per 100,000 attendances at blood donation services
• 281 complaints (total) in 2008/09 (peak)
• 231 complaints in 2011/12
  - donor selection/health and safety
  - donor communications
  - staff attitudes and behavior
  - waiting times
COMPLAINT MANAGEMENT

- Croatian Institute of Transfusion Medicine (CITM)
- 13-year period (1998-2010)
- ~ 1 million donations
- ~ 2.5 million blood components
- laboratory testing performed in 600,000 patients
- 817 complaints

### Complaint Management – Croatian Experience

**CITM 1998-2010**

<table>
<thead>
<tr>
<th>Complaint category</th>
<th>n</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>Positive direct antiglobulin test (DAT) in RBC products</td>
<td>334</td>
<td>40.9</td>
</tr>
<tr>
<td>Blood product distribution/issuing</td>
<td>105</td>
<td>12.9</td>
</tr>
<tr>
<td>Blood product quality</td>
<td>77</td>
<td>9.4</td>
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<tr>
<td>Laboratory test findings</td>
<td>69</td>
<td>8.4</td>
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<tr>
<td>Blood product labeling</td>
<td>59</td>
<td>7.2</td>
</tr>
<tr>
<td>Bacterial contamination of blood product suspected</td>
<td>48</td>
<td>5.9</td>
</tr>
<tr>
<td>Transfusion virus transmission suspected</td>
<td>31</td>
<td>3.8</td>
</tr>
<tr>
<td>Providing service to donors</td>
<td>21</td>
<td>2.6</td>
</tr>
<tr>
<td>Providing service to patients</td>
<td>20</td>
<td>2.4</td>
</tr>
<tr>
<td>Other</td>
<td>53</td>
<td>6.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>817</td>
<td>100.0</td>
</tr>
</tbody>
</table>
PRODUCT RECALL - CHARACTERISTICS

- efficient system
- timely recall
- products that are known or suspected of being nonconforming
- questionable quality and/or safety
- complete traceability throughout the transfusion chain
PRODUCT RECALL

- as soon as possible
- at any time

- written procedure
  - all activities
  - degree of responsibility of each individual involved
  - harmonized with the existing professional standards and legal provisions
PRODUCT RECALL - REASONS

• PDI (donor risks)
• aberration from the prescribed product/service quality detected upon issuing
• results of donor testing may suggest possible risk of issued blood components
• reported AE/AR pointing to nonconformity of other products from the same donation/batch;
• user's complaint;
• when requested by inspection or respective regulatory bodies...
PRODUCT RECALL - FREQUENCY

- relatively frequent in transfusion medicine
  - biological origin of blood products
  - specific risks associated with their use
  - not all risks can be predicted, some of them cannot be prevented

- 1/700 units available to hospitals (1990-1997) – Ramsey & Sherman 1999
- 1/2,000 units in US in the late 1990s (Ramsey G, 2004)
- 1/250 BC involved in market withdrawals and quarantines, 1/5800 formally recalled (Ramsey G, 2014)
Recall initiated by suppliers

Recall of:
- equipment
- reagents
- other incoming materials

Procedure:
- written instructions
- responsible persons
- etc...
NONCONFORMITIES OF MATERIALS AND EQUIPMENT

- timely detection, labeling and separation (putting out of use) of nonconforming materials/equipment
- assessment of the effect of nonconforming materials/equipment on product and service quality
- properly documented
- supplier/manufacturer should be contacted
- whenever possible, defective incoming material should be sent to the manufacturer
- report to the CA/regulatory bodies as appropriate
- evaluation and selection of manufacturers
- good collaboration with the manufacturers
CONCLUSIONS

• timely detection of quality problems
• comprehensive analysis and risk assessment
• structured protocol
• properly documented
• monitoring trends
• implementation of corrective/preventive actions
• quality improvement
• continuous process
• team work
THANK YOU!