

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

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**WP ON QUALITY MANAGEMENT
WP ON HAEMOVIGILANCE**

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

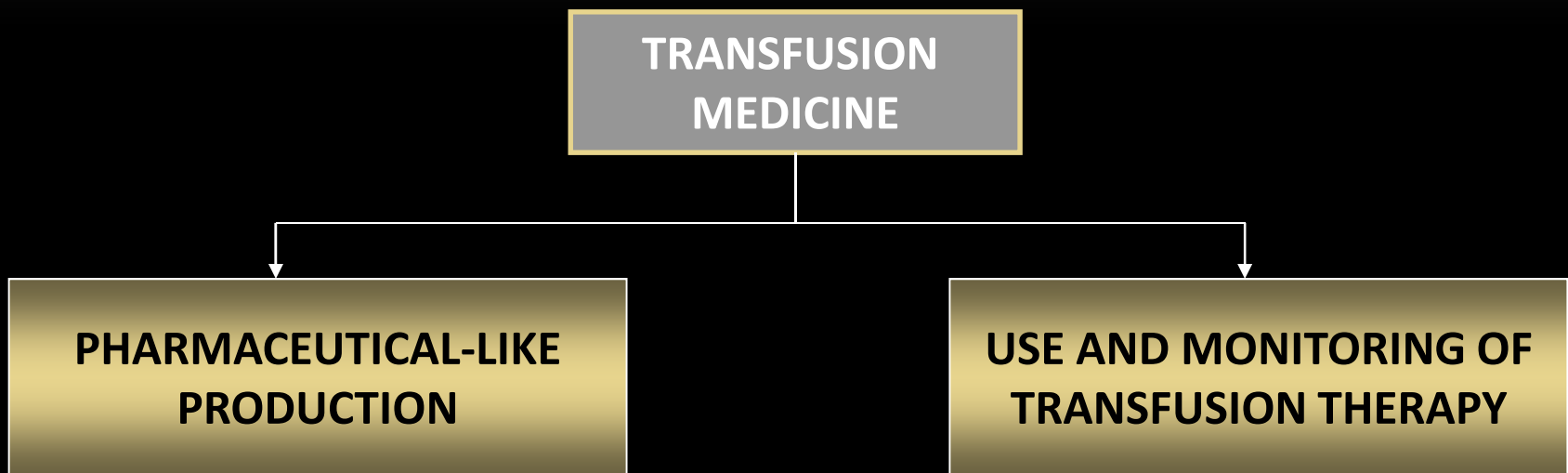
QUALITY IN TRANSFUSION MEDICINE

ADEQUATE NUMBER OF EFFECTIVE
AND SAFE BLOOD PRODUCTS
FOR CLINICALLY JUSTIFIABLE
TRANSFUSION TREATMENT



QM IN TRANSFUSION MEDICINE

Development of transfusion medicine in two main directions:



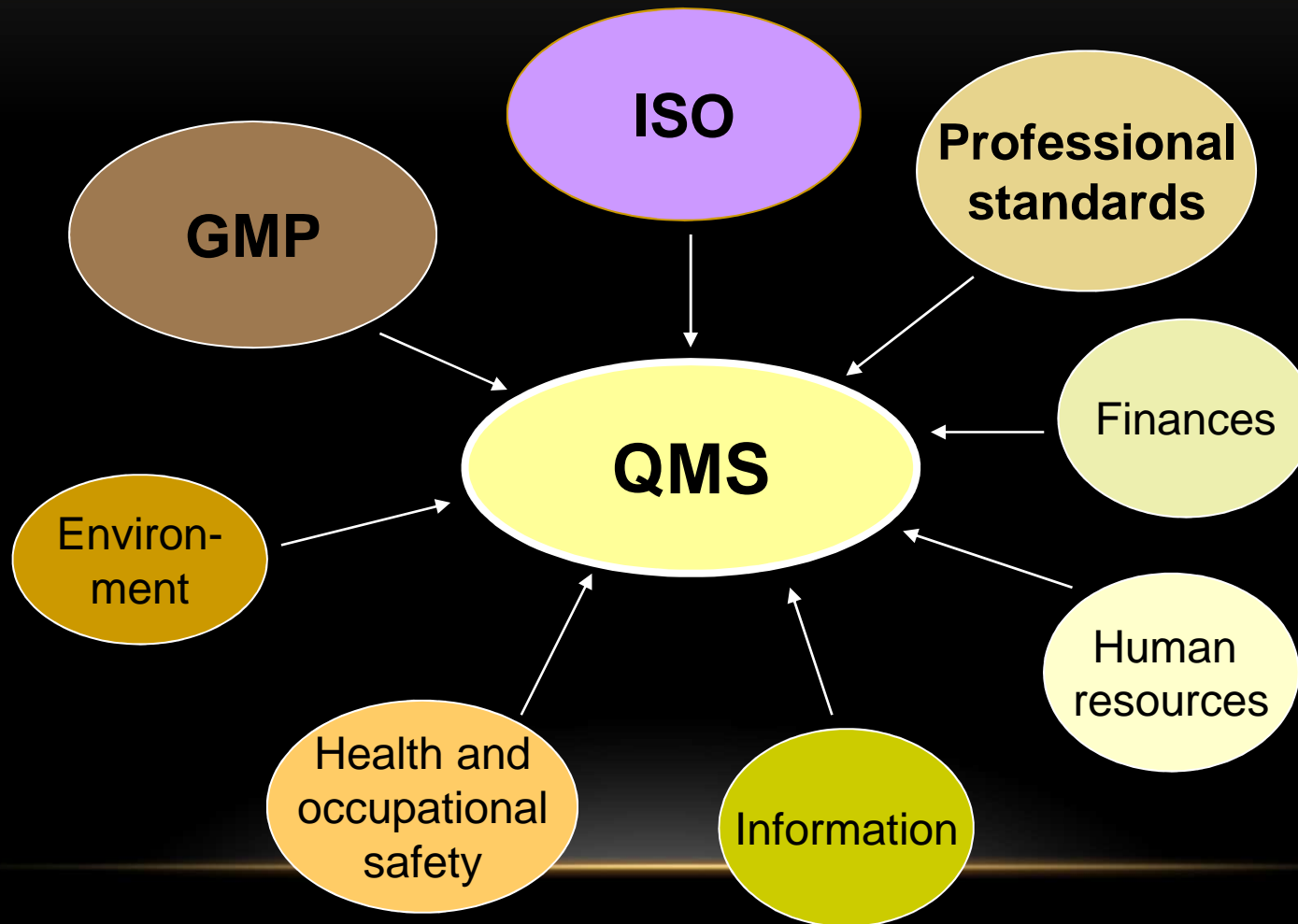
need of conducting a uniform and strictly controlled process with minimal deviations and waste in the raw material and final products

economical, justifiable and correct utilization

← **QUALITY**

SAFETY →

QM IN TRANSFUSION MEDICINE



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”)

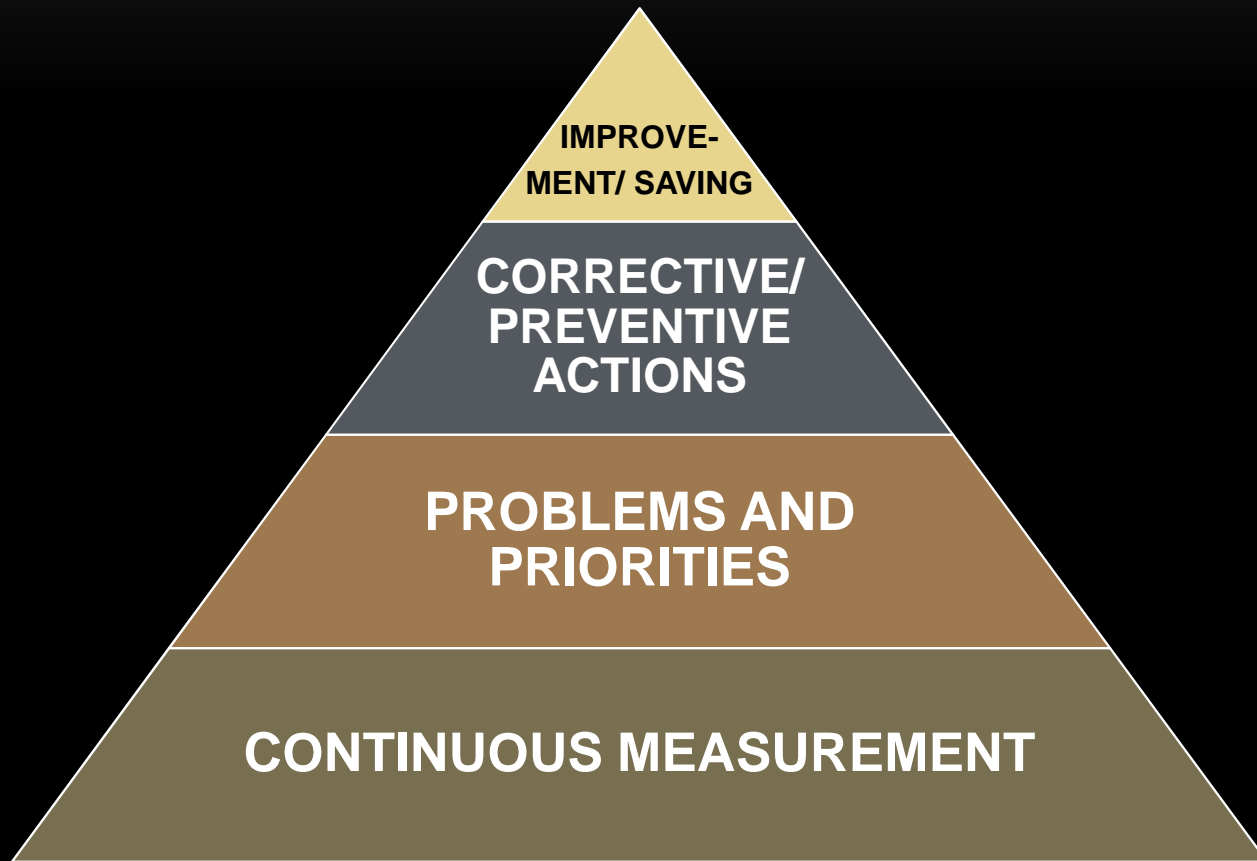
HAEMOVIGILANCE – CURRENT TRENDS

- 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



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:

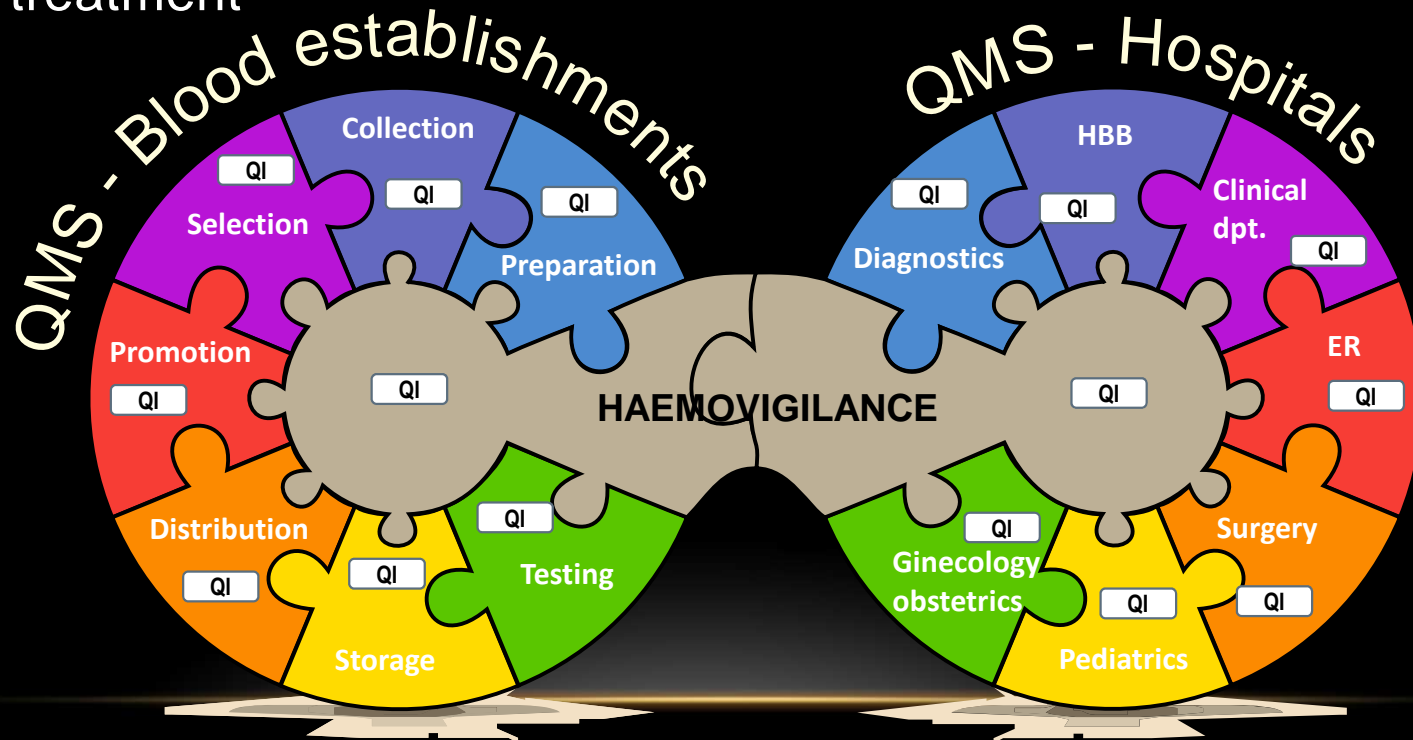
- satisfaction of the staff members
- performance characteristics
- environment requirements
- etc.

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

QA

Identification of target population

Promotion directed toward low-risk donors

Education of prospective donors

Partnership with blood donors

Stimulating personal, social and ethical donor's responsibility for blood safety

Collaboration with mass-media

Retaining existing donors

well structured, planned, professional, continuous, liable to modification, trained staff (nonprofit marketing)

HV

HV data about blood donors should be used in promotional and educational activities

- risks
- epidemiology of infectious diseases
- adverse reactions
- PDI

SELECTION

Dual goal:

1. To protect donor's health
2. To ensure quality and safe blood products for the recipients

SELECTION

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

Nonconformity



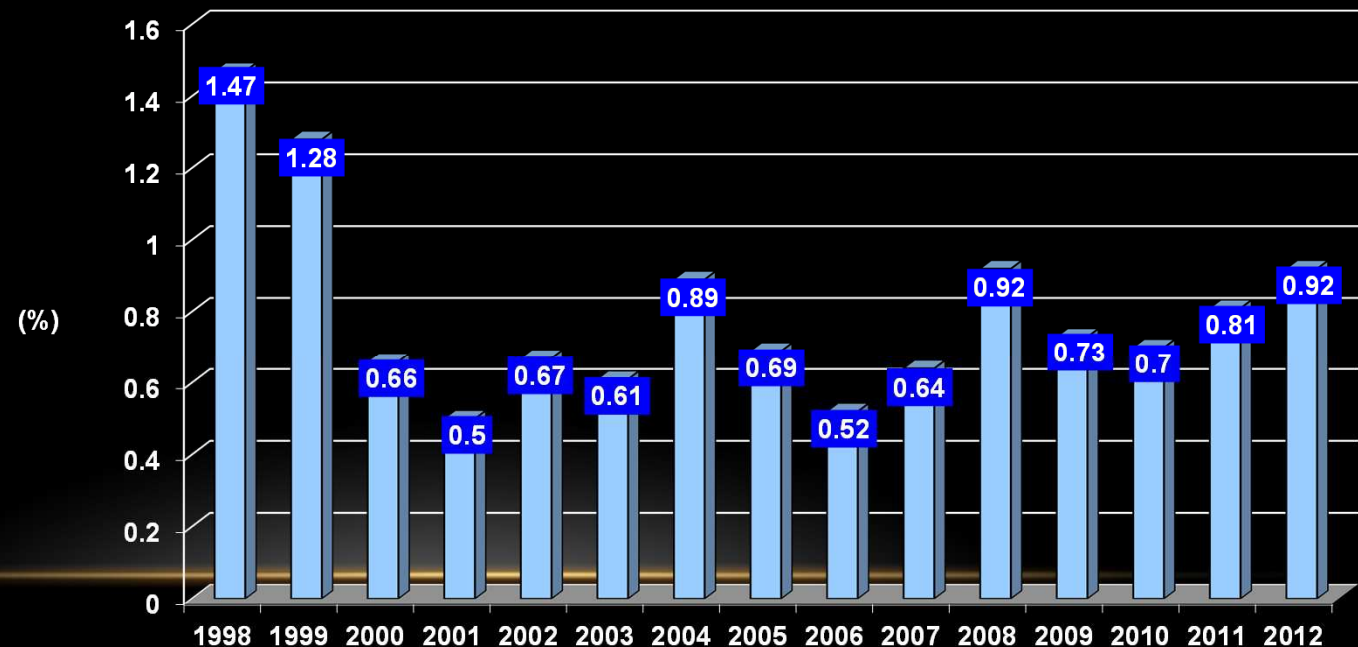
IDENTIFICATION AND TRACEABILITY

- 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

COLLECTION
FAILURES
CITM 1998-2012



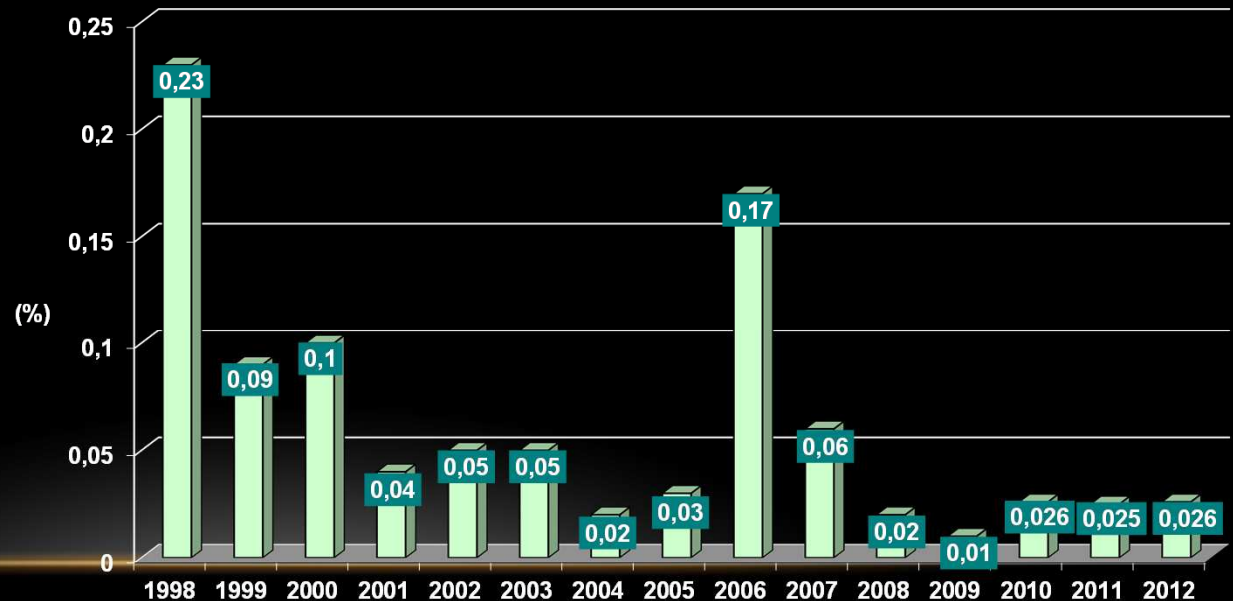
VENIPUNCTURE

- choice of disinfectant
- validation of disinfection 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