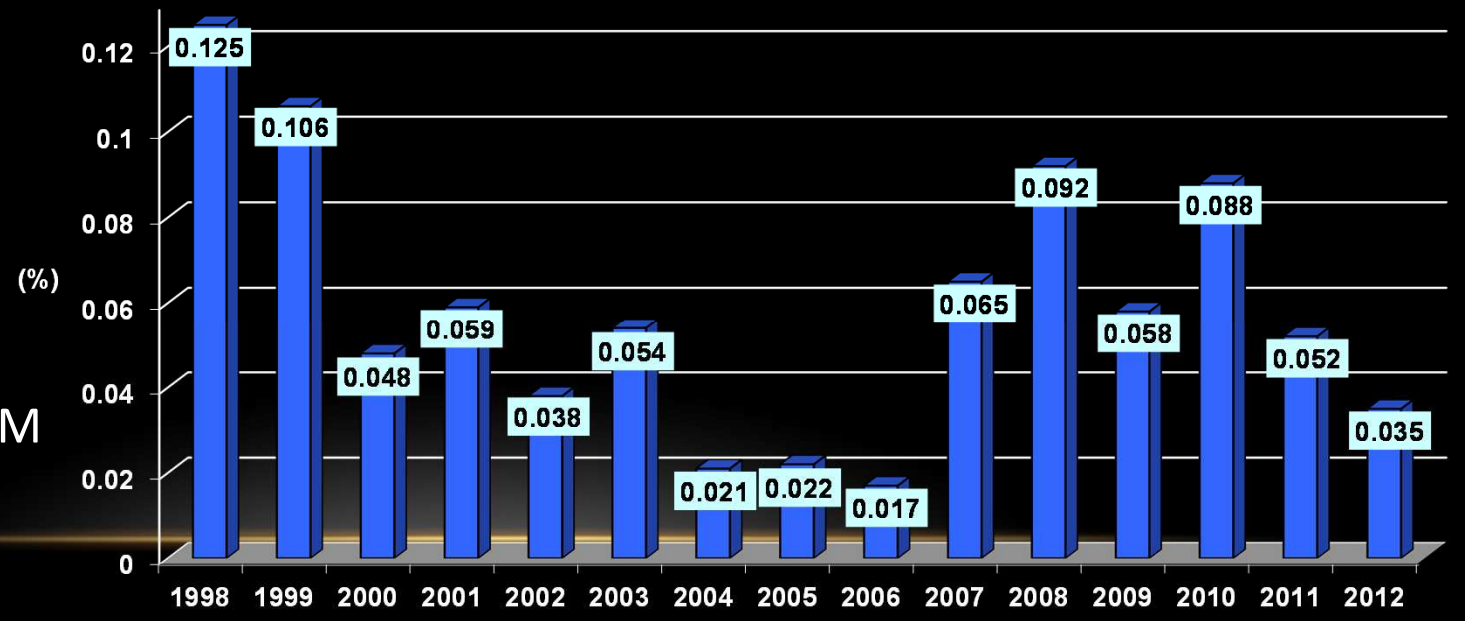
STERILE SEALING

- regularly maintained and controlled sealers
- macroscopic inspection

POOR WELDS ON BLOOD COLLECTION – CITM 1998-2012



SAMPLE COLLECTION

- at the beginning or at the end of blood withdrawal
- no delay in sampling
- properly labelled tubes
- adequate sample volume
- inadequate samples appropriately labelled and the nonconformity recorded

DONATION INSPECTION

- each donation should be inspected for possible damage
- blood bag and the respective samples should not be taken away from the donor’s bed until label conformity has been approved, with due attention paid to ID number on the donation and the respective samples

MICROBIOLOGICAL SAFETY

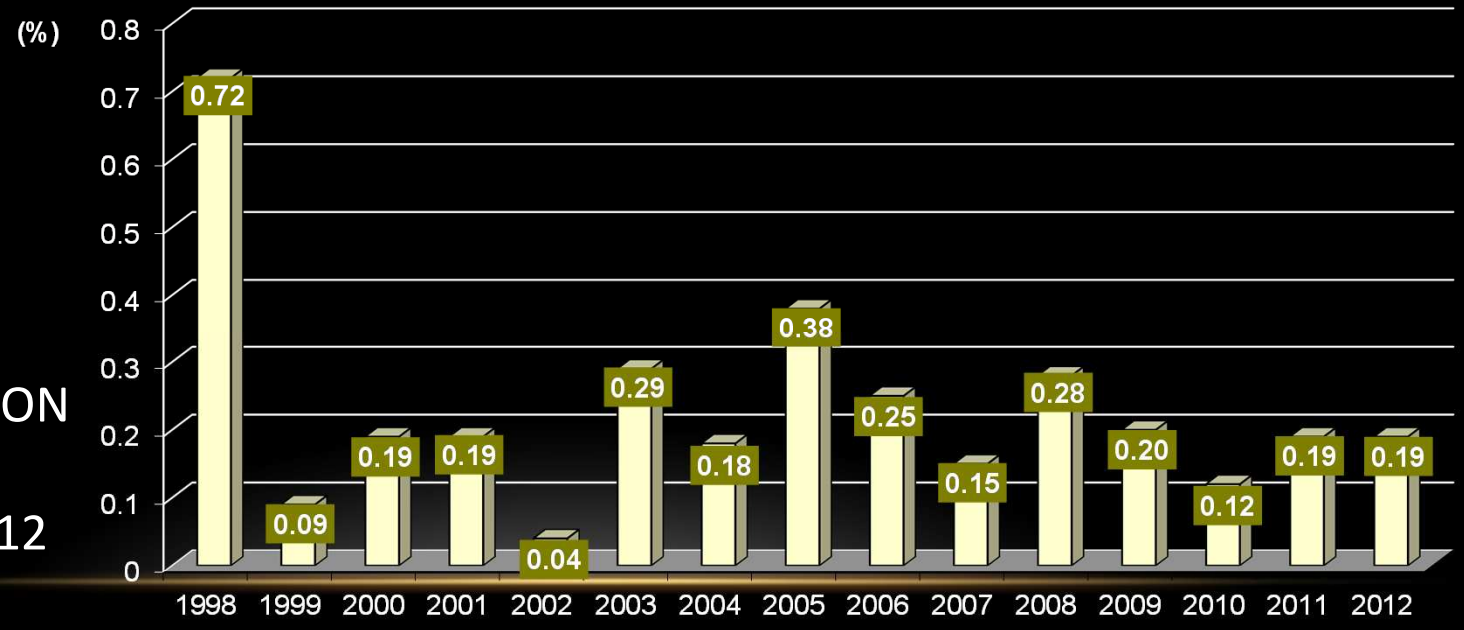
The personnel performing blood withdrawal should be educated on:

- basic hygienic regulations
- need of regular and correct washing and disinfection of hands and accessories
- correct handling and disposal of biological waste

MICROBIOLOGICAL SAFETY

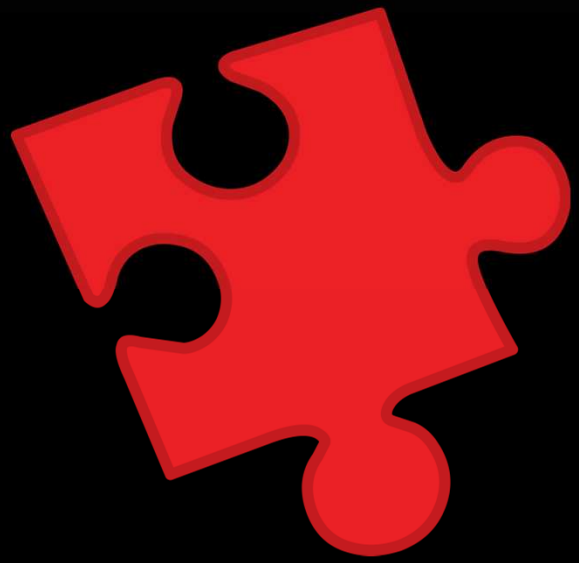
Conditions at blood withdrawal should be regularly surveyed by microbiological control and audits

BACTERIAL CONTAMINATION OF BPs CITM 1998-2012



STORAGE CONDITIONS UNTIL PROCESSING

- records on the time of first and last blood unit collected in a batch referred for processing
- optimal storage temperature immediately upon blood withdrawal
- transportation within the defined temperature range



BLOOD PROCESSING

BC PREPARATION

QA
Planning
Inspection of blood units prior to processing
Preparation of blood components (validation, GMP, ...)
In-process control
Control/monitoring of BC preparation conditions
Labelling
BC release
SPC

HV
Errors
Incidents
BC quality deviation
BC waste
Traceability

BC PREPARATION

Quality indicators:

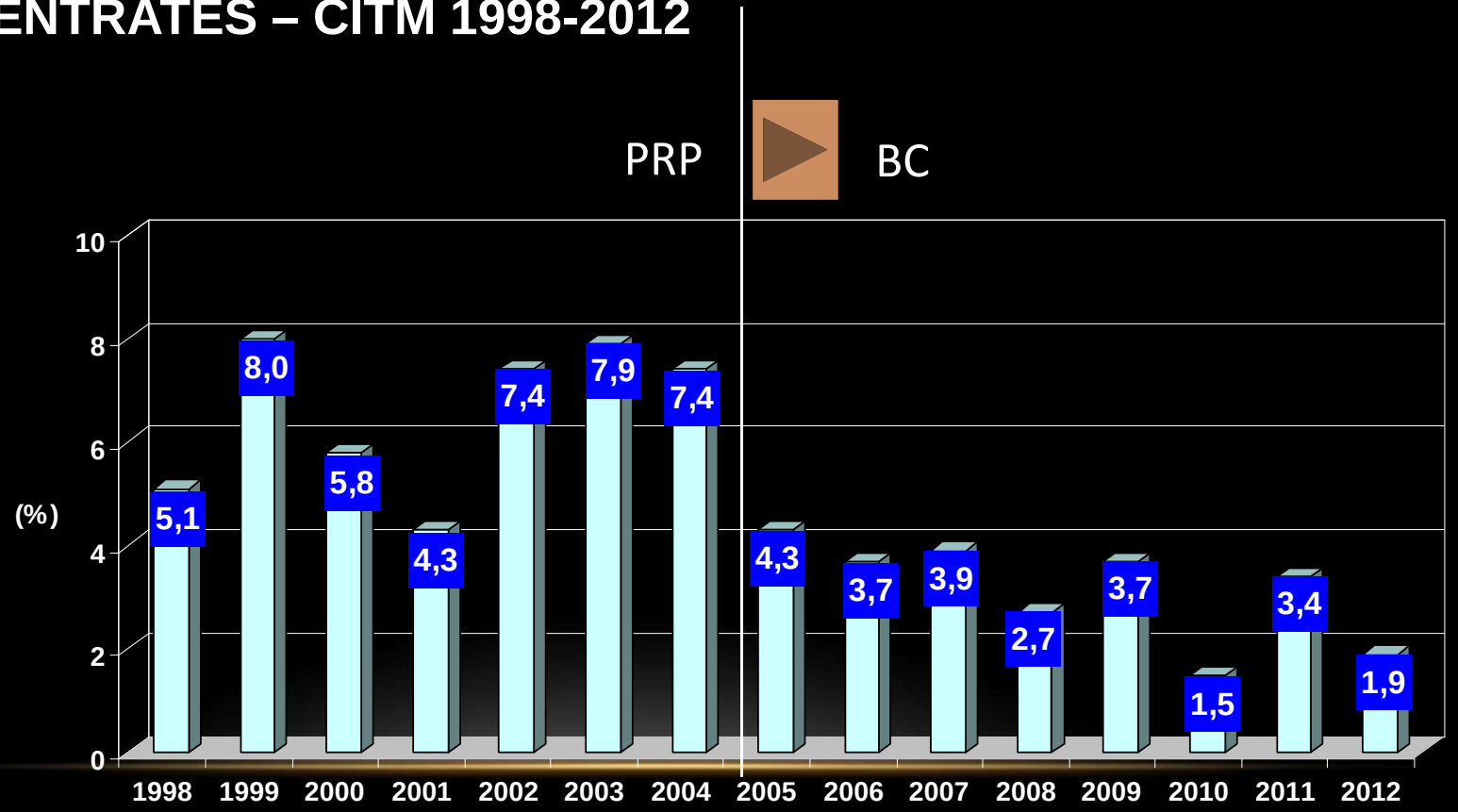
1. *Production index*
2. *Blood component nonconformities*
3. *Hemolytic plasma*
4. *Lipemic plasma*
5. *Expired platelet concentrate shelf life*
6. *Expired RBC concentrate shelf life*
7. *Nonconformities in blood component quality control results*
8. *Poor welds on blood component preparation*
9. *Errors, complaints*

BC PREPARATION PLANNING

- predetermined plan
- the plan is based on data on:
  - particular BC release
  - BC stock according to blood groups
  - hospital BC requirements
- plan development – close collaboration among all those responsible for blood collection and BC preparation

BC PREPARATION PLANNING

OUTDATED PLT CONCENTRATES – CITM 1998-2012



INSPECTION OF BLOOD UNITS PRIOR TO PROCESSING

- prior to entry in the processing area or by the personnel in the processing department
- the amount of blood units received should be compared with the data in the respective documentation
- possible nonconforming material should be separated from blood units entering the production
- macroscopic inspection
- package integriy
- appropriate labelling

PREPARATION OF BLOOD COMPONENTS

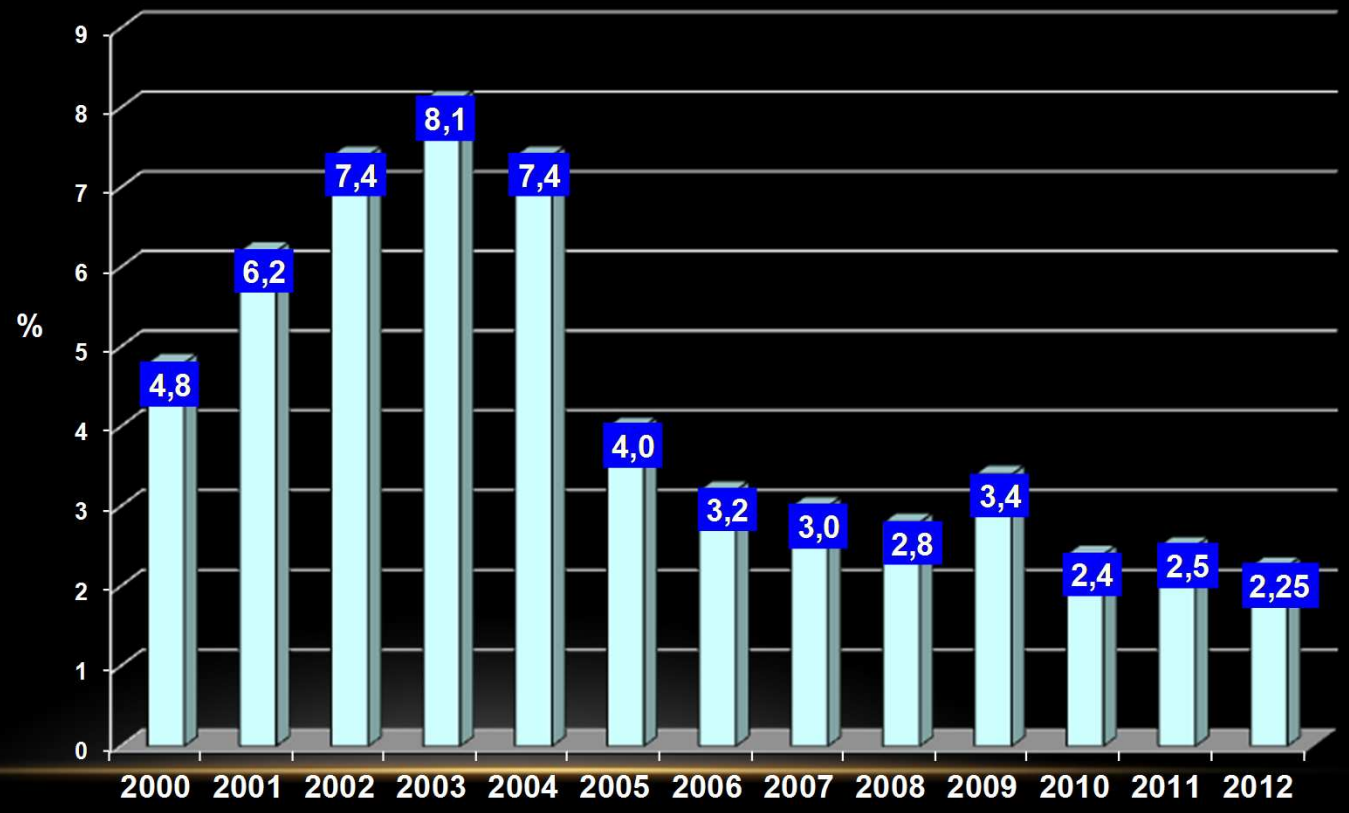
- according to GMP, SOPs and preparation procedure protocols
- validation – new procedures or significant changes
- the personnel in processing department should strictly comply with all regulations on wearing protective clothes and shoes, cleaning and sanitation of the premisses, and regular hand washing and desinfection
- the time elapsed from the time of blood withdrawal to the component production should be strictly controlled
- processing automation = better standardization
- traceability
- closed system production
- special requirements for “open” system production

IN-PROCESS CONTROL

- production department
- every component
- volume control
- macroscopic inspection of intermediate and final BC
- control of critical parameters (leakage, damage to the container, excessive air, suspicion of microbial contamination, unusual turbidity, aggregation, haemolysis or other colour change)
- nonconforming products reported to QC/QA department

IN-PROCESS CONTROL

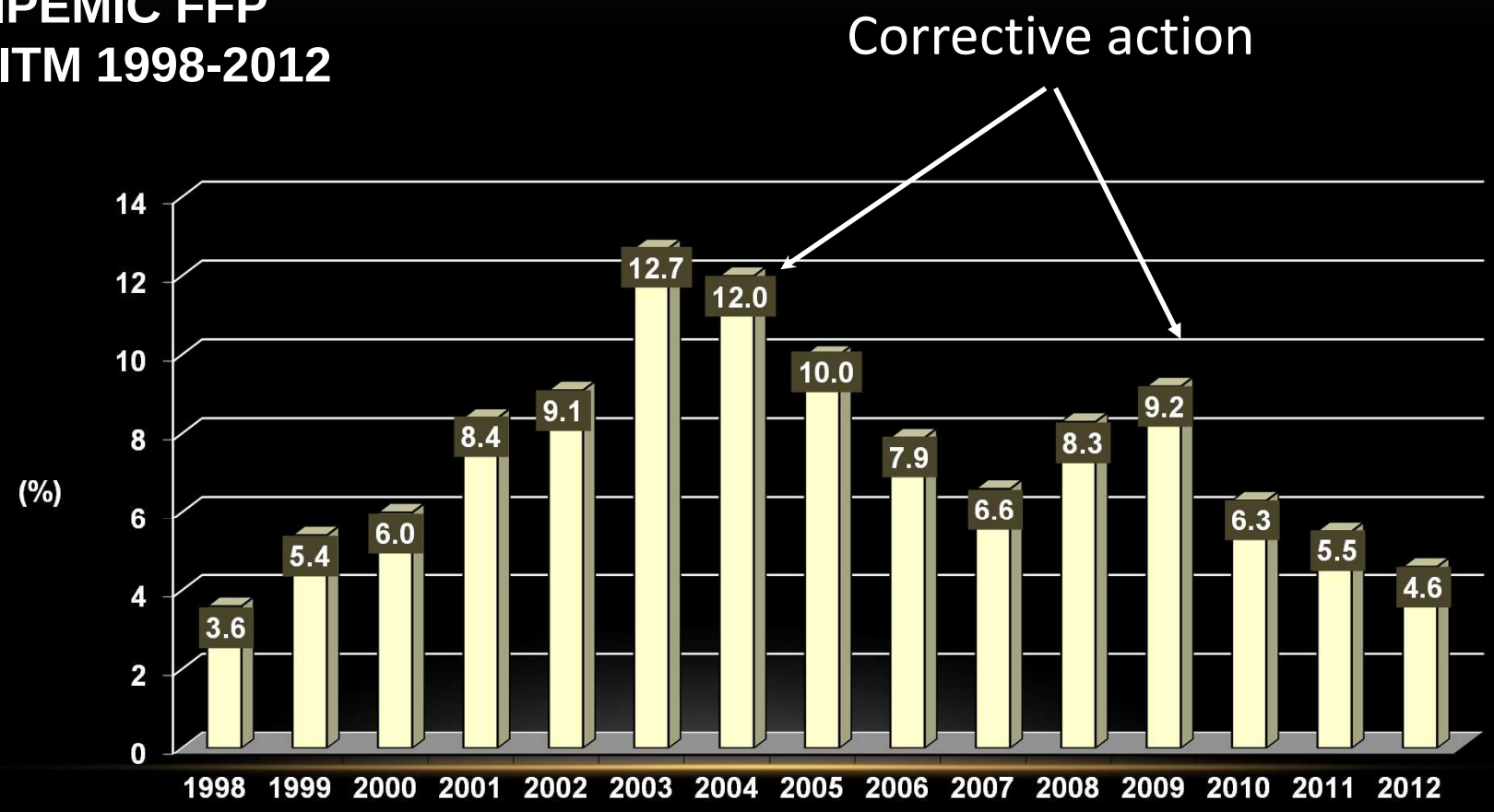
NONCONFORMING BLOOD PRODUCTS CITM 2000-2012



SAVING !

IN-PROCESS CONTROL

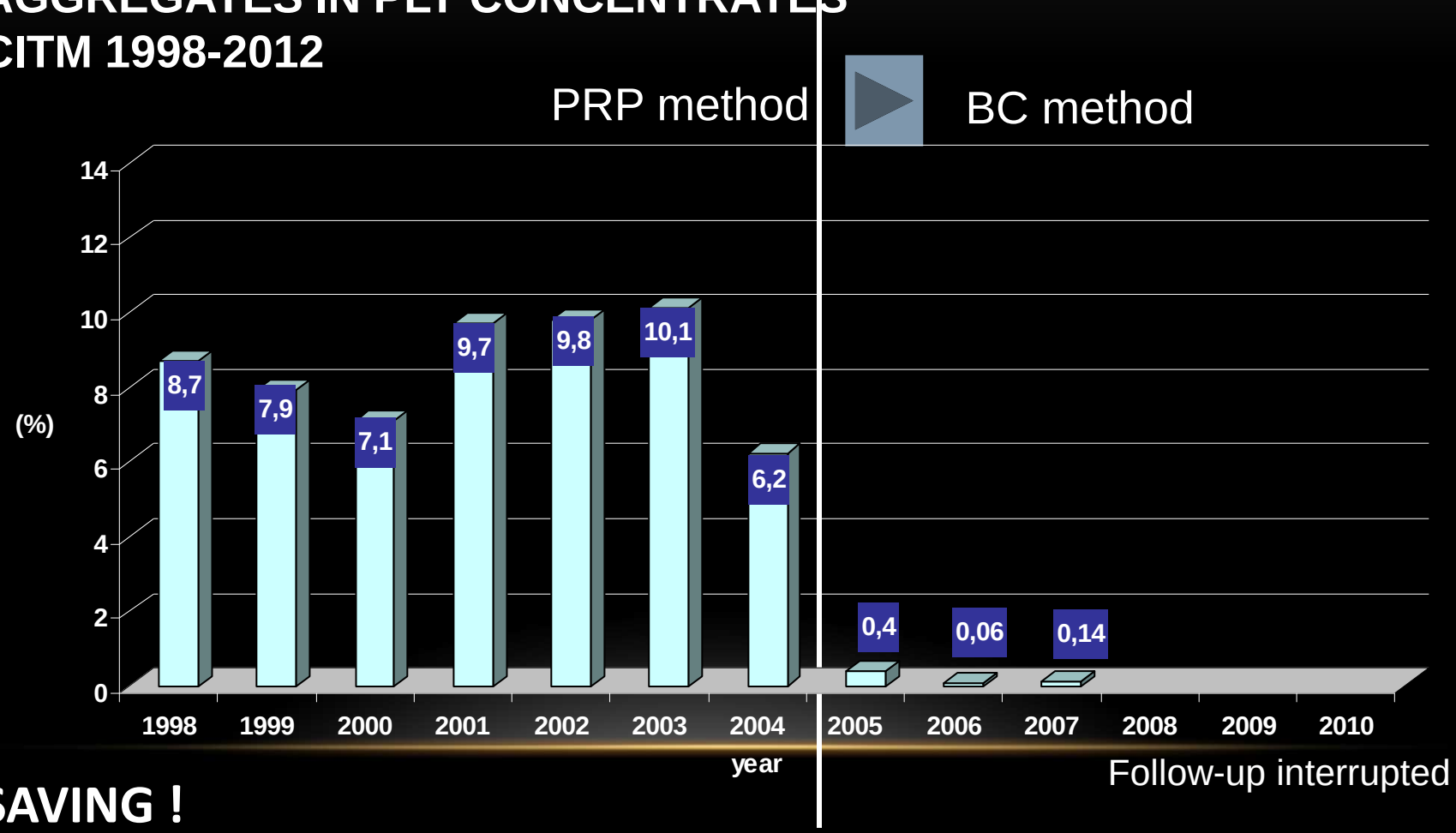
LIPEMIC FFP
CITM 1998-2012



SAVING !

IN-PROCESS CONTROL

AGGREGATES IN PLT CONCENTRATES
CITM 1998-2012



SAVING !

LABELLING

- critical point in the chain of blood product safety
- clear product identification in all phases of the production process
- written instructions
- computer-assisted and controlled labelling is preferred
- labels should contain all necessary data on the BC
- critical data should be in the machine-readable format

CONTROL/MONITORING OF BC PRODUCTION CONDITIONS

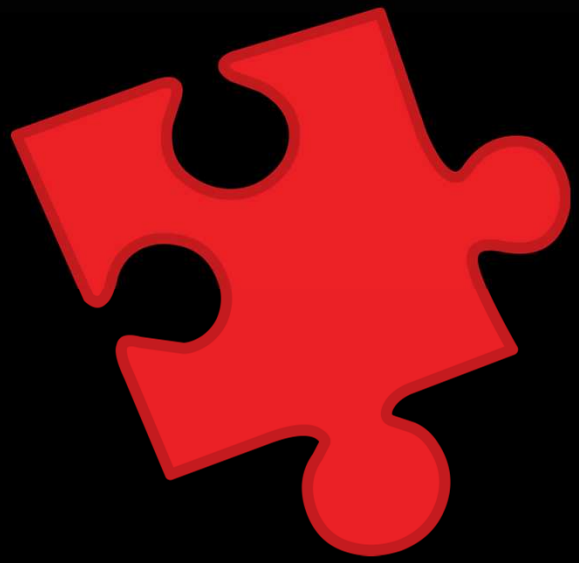
- documented procedure
- methods
- limits of warning and action
- procedure in case of particular condition deviation

BLOOD COMPONENT RELEASE

- administrative and/or physical quarantine until decision on the release
- responsible person for QA
- documented and validated procedure
- quality records for each work segment
- computer-assisted release (if possible)

SPC

- quality plan
- specifications for component quality monitoring
- parameters and limits
- validated methods for sampling and testing
- SOP’s
- continuous monitoring, analysis and reporting
- appropriate statistical methods
- out of specification results – corrective measures



STORAGE AND DISTRIBUTION

STORAGE AND DISTRIBUTION/ISSUE OF BLOOD COMPONENTS

QA
STORAGE
Storage conditions maintained and controlled at regular time intervals
Safe manipulation with BCs
BCs easily accessible („firs in-first out”)
Storage area should be regularly cleaned and maintained
Separate storage area for nonconforming, returned, quarantined BCs
RELEASE AND DISTRIBUTION
Macroscopic inspection
Re-checking of all relevant BC data
Documented delivery: time and responsible person

HV
Errors
Incidents
Traceability, identification
Monitoring of storage and transport conditions
Policies for pick-up and delivery of BCs

STORAGE AND DISTRIBUTION/ISSUE

Quality indicators:

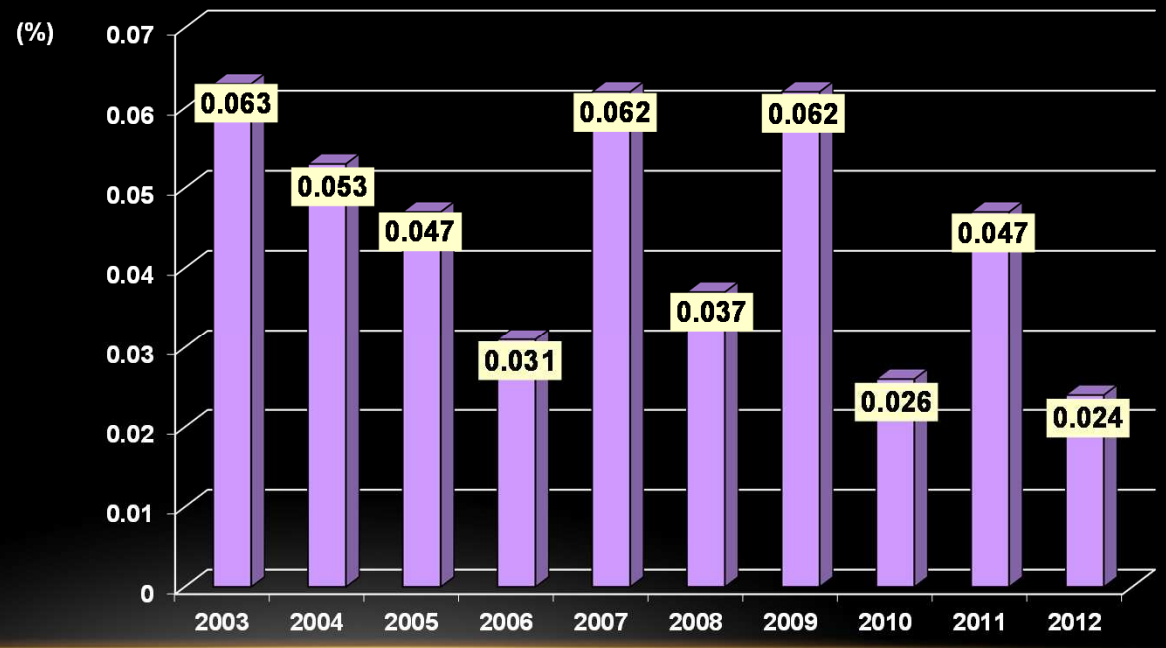
1. ***Wrong blood component issue***
2. ***RBC units issued in emergency without testing***
3. ***Errors, events, complaints, costumer satisfaction***

Blood component issuing in emergency

- life-saving
- possible occurrence of errors with fatal consequences

THE RETURN OF BC

- only if defined by contract
- documented evidence for the BCs to have been transported and stored in accordance with the respective regulations



RETURNED BCs
CITM 2003-2012

Quality indicator:

1. Returned blood components

PRODUCT RECALL/WITHDRAWAL

- defective blood components or blood components suspected of being defective issued to the hospitals
- written procedure
- head of QA or other responsible person
- quality indicators – frequency and effectiveness of the procedure

Quality indicator:

1. ***Blood component withdrawal from the market***

TESTING

LABORATORY TESTING

QA
All segments of laboratory testing
Testing procedures and reagents validated before their routine use
Each donation tested according to respective legal requirements
Written procedure describing procedures to resolve discrepant results
Internal control of laboratory testing
External QC (proficiency testing)
Automation, robotics, computer validation
GLP, error management
Accreditation

HV
Error monitoring and prevention, including „near-misses”
Investigation of discrepaciens and incidents
Traceability, identification
Epidemiological surveillance of TTI (prevalence, incidence)
Trace-back and look-back
Materiovigilance in testing

LABORATORY TESTING

Quality indicators:

1. *Donor sample nonconformities*
2. *Patient sample nonconformities*
3. *Nonconformities in the requests for pretransfusion testing*
4. *AB0/Rh(D) discrepancies*
5. *Test turnaround Time (TAT) – urgent requests*
6. *Wrong blood component issue*
7. *Proficiency testing – performance evaluation*
8. *Contamination rate of blood component cultures*
9. *SAE (lab)*

OPTIMAL USE OF BLOOD

OPTIMAL USE OF BLOOD

- IHN – 10th meeting in Frankfurt: optimal use of blood products adopted as a new objective
- International forum „Haemovigilance for the optimal use of blood products in the hospital" (Vox Sang 2010)

- integral part of the national HS in Belgium, Ireland and the Netherlands

- important role of hospital TCs and TOs

- education of clinicians and laboratory personnel

- development of clinical guidelines in hospitals

OPTIMAL USE OF BLOOD

Insufficient data on blood and blood product usage:

Who?

How much?

Why? (indications)

Levels of wastage?

- benchmarking and demand forecasting not easy task

OPTIMAL USE OF BLOOD

René de Vries, Blood Matters 2009:

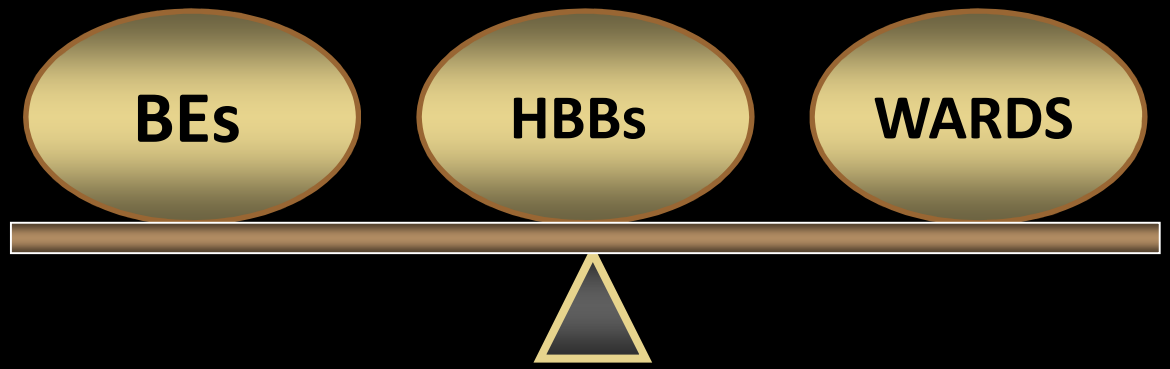
- efficacy of blood transfusions often unknown, or not established or even negative
- result: significant reduction of the use of blood products as documented by many haemovigilance systems
- next step: surveillance for appropriate or optimal use of blood products: indicators

OPTIMAL USE OF BLOOD

- In 2010, **EDQM** initiated the project “Quality indicators for the evaluation and monitoring the Optimal Use of Blood and Blood Components” (2010)
- quality indicators related to efficacy or outcomes of transfusion therapy

BLOOD COMPONENT ORDERING AND UTILIZATION

- availability of blood components is limited
- supplies should be handled with extreme responsibility



- assessment of ordering practice and blood utilization

Quality indicators:

1. ***Component wastage rate (RBC, PLT, FFP) at the hospital***
2. ***C:T ratio***

MONITORING OF TRANSFUSION ADVERSE REACTIONS

- the first subject tackled through the system of hemovigilance
- considerable improvements over years
- reduced prevalence of TRALI
- reduced bacterial infection

Quality indicator:

1. ***SAE/SAR***

QMS

- functionality of the quality management system at the institution
- commitment for continuous quality improvement

Quality indicators:

1. ***timely implementation of Change controls***
2. ***timely implementation of Corrective actions from internal and external audits***

QI PROJECT:
INTERNATIONAL SURVEY (CURRENT STATUS)

QUALITY INDICATORS		Score
1.	Donor deferral rate (total, temporary, permanent)	14/18
2.	Serious adverse events (SAE)	12/18
3.	Donor adverse reactions	11/18
4.	Product non-conformities	11/18
5.	Expired PLT and RBC concentrate shelf life	11/18
6.	Percentage of voluntary non-remunerated blood donors	9/18
7.	Wrong blood product issue	9/18
8.	Blood product complaints and donor complaints	9/18
9.	Non-conformities in BP quality control results	8/18
10.	Percentage of donations collected from first time donors	7/18

QI PROJECT – CROATIA (2012-)

QUALITY INDICATORS		Score
1.	Donor deferral rate (total, temporary, permanent)	14/18
2.	Serious adverse events (SAE)	12/18
3.	Donor adverse reactions	11/18
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7.	Wrong blood product issue	9/18
8.	Blood product complaints and donor complaints	9/18
9.	Non-conformities in BP quality control results	8/18
10.	Percentage of donations collected from 1st time donors	7/18

QUALITY INDICATORS		Score
1.	Collection failures	6/18
2.	Production index	4/18
3.	Positive findings on blood product bacteriological testing	4/18
4.	Product withdrawal from the market	4/18
5.	Lipemic plasma	2/18
6.	Clots in red blood cell (RBC) products	1/18
7.	Poor welds on blood collection and poor welds on blood product manufacture	1/18
8.	Returned blood products	1/18
9.	Hemolytic plasma	0/18

CONCLUSION

- full integration of hemovigilance in the quality management system
- in order to exchange and to compare data standardized collection and analysis is required
- definitions, indicators
- monitoring of quality indicators and implementation of appropriate corrective measures influence not only the quality and safety of products and services, but also the rational resource management and saving