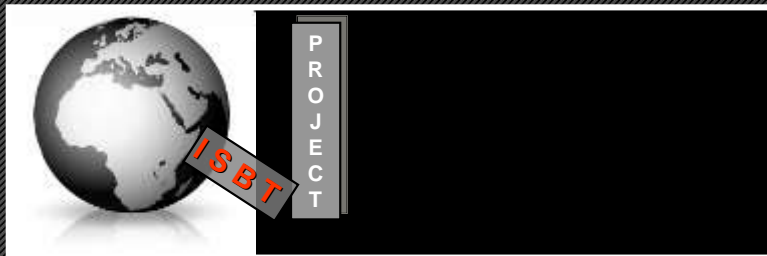


# QUALITY INDICATORS IN TRANSFUSION MEDICINE

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# QUALITY IN HEALTHCARE



- progressive advancement in medical science
- integration of numerous scientific achievements and technological solutions
- development of a series of diagnostic and therapeutic procedures

# QUALITY IN HEALTHCARE



- unequal healthcare quality level
- considerable increase in its costs
- variations in the treatment of the same patient groups
- articles and news on inappropriate treatment and errors

# QUALITY IN HEALTHCARE



## Consequence:

- demands for quality
  - measurement
  - assessment
  - improvement
- various interest groups involved in healthcare system:
  - users
  - service providers
  - regulators
  - insurance companies, etc.

# HEALTHCARE QUALITY MEASUREMENT

- long tradition in some countries
- in the United States, quality measurement dates back to the 1990s
- relative long history of these activities is also found in:
  - Australia
  - Canada
  - Scotland

# HEALTHCARE QUALITY MEASUREMENT

- more recent but often emphasized as successful models of quality measurement are those carried out in:
  - Denmark
  - Germany
  - The Netherlands
  - France
  - United Kingdom
  - Sweden

# HEALTHCARE QUALITY MEASUREMENT

## ORGANIZATIONS AND INSTITUTIONS

- Agency for Healthcare Research and Quality (**AHRQ**) has been actively working on quality indicators for more than ten years;
- 2002: the Organization for Economic Cooperation and Development (**OECD**) initiated the Health Care Quality Indicators project, aimed at healthcare quality measurement and comparison among various countries;
- 2003: the World Health Organization (**WHO**) Regional Office for Europe launched the Performance Assessment Tool for quality improvement in Hospitals (**PATH**) project to collect data on various quality indicators in hospitals across Europe;
- 2005: the Institute for Quality Laboratory Management (**IQLM**) Task Force defined and worked out a series of indicators in the field of laboratory activities

# QUALITY INDICATORS - DEFINITION

- one of the tools of Quality Management System (QMS)
- measurable, objective indicators of the efficiency of the QMS
- monitoring and assessment of the quality of products and services
- comparison of different institutions
- implementation of corrective measures and continuous quality improvement

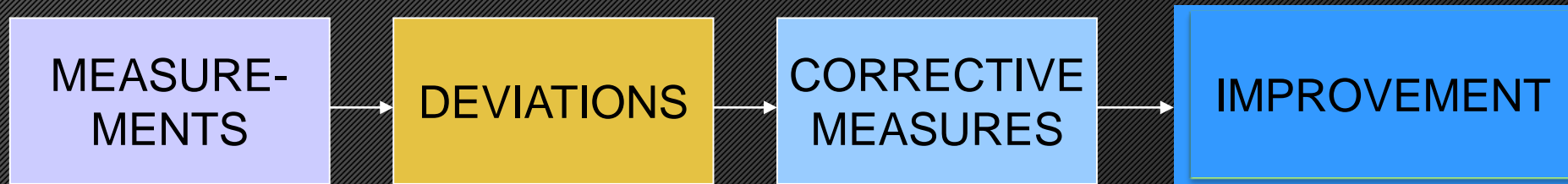


# QUALITY INDICATORS - DEFINITION

- according to the ISO 9001 standard, conformity with the set quality standards and goals, and thus the efficiency of QMS has to be demonstrated by measurement.
- the laboratories accredited according to the EN ISO 15189 standard are obliged to perform systematic analysis of quality indicators
- primarily applying to hospitals
- increasingly introduced in primary healthcare

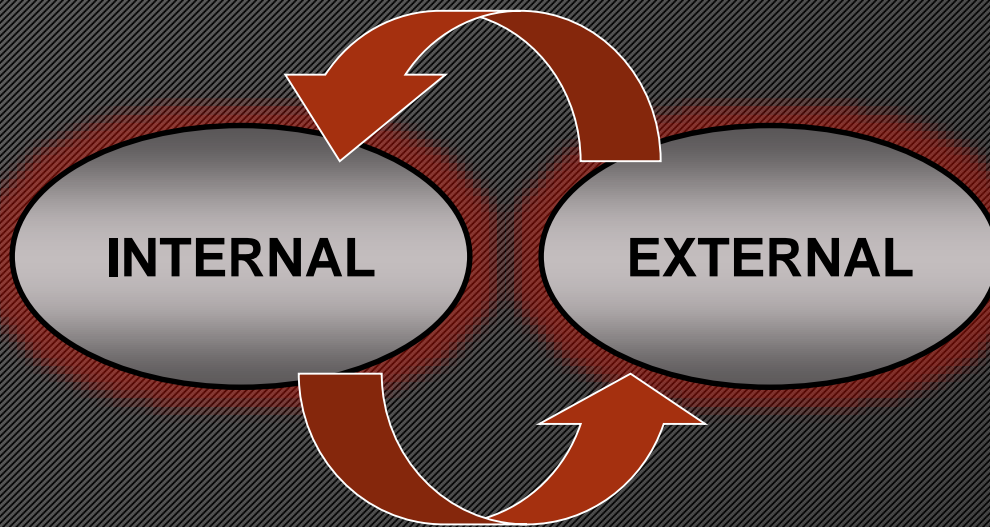
# QUALITY INDICATORS - OBJECTIVES

- 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
- benchmarking
- important for the process of accreditation and certification



# QUALITY INDICATORS - CLASSIFICATIONS

According to the objectives of their establishment and utilization



- detailed
- specific
- addressing problems and specificities of local interest

- global
- more general

## INTERNAL

defined by the institution management to control their own processes, to upgrade their quality, and to achieve better management results

## EXTERNAL

they enable surveillance of the indicators to external partners, to protect their own interest.

They should be clearly defined

# QUALITY INDICATORS - CLASSIFICATIONS

## TRIPARTITE QUALITY MODEL (DONABEDIAN)

**STRUCTURAL**

how the processes  
are organized

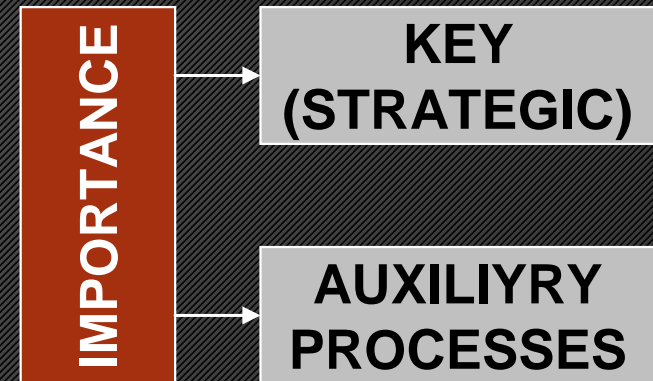
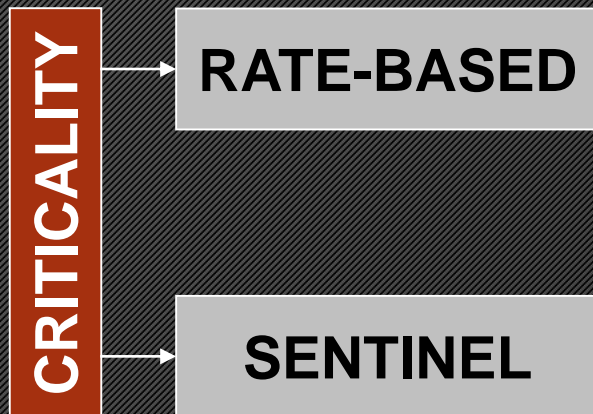
**PROCESS**

how the activity  
is performed

**OUTCOME**

whether appropriate  
results have been  
achieved

# QUALITY INDICATORS - CLASSIFICATIONS



# QI - CHARACTERISTICS

**OBJECTIVITY**

→ measurability

**IMPORTANCE AND  
RELEVANCE**

→ they should cover more common events and problems

**POTENTIAL FOR USE**

→ when a problem is identified by measurement, it should be possible to respond to it

**RELIABILITY**

→ clear numerator and denominator, data collection uniform and comprehensible the results obtained should be reliable to be correctly interpretable and comparable

**VALIDITY**

→ the indicator should be adequately related to the problem monitored

Pringle *et al.* propose a list of 12 attributes which should be taken in account on indicator selection

# HOW TO SELECT QUALITY INDICATORS?

1. Evidence based
  2. Expert consensus and experience
- scientific concepts
  - own experience
  - literature review results
  - debate with professionals within and outside the institution, etc.

# HOW TO SELECT QUALITY INDICATORS?

- complex process
- scientific approach
- testing and verification before routine usage
  
- exploration of the processes underlying particular service
- assessment of the risk and frequency of particular problem (criticality, relevance)
- institution priorities
- the possibilities of improvement



# HOW TO SELECT QUALITY INDICATORS?

Number of quality indicators:

- the size of the institution
- extent of the activities performed
- quality indicators should preferably cover all services performed within the laboratory or institution

# HOW TO SELECT QUALITY INDICATORS?

Quality indicators should be focused on:

- basic quality requirements
- product and service safety
- user expectations.

They should also measure:

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

# DEFINING THE INDICATORS

- the numerator and denominator should first be precisely defined
- liable to modifications

# SETTING QUALITY OBJECTIVES AND CRITICAL ACTION LIMITS

- experiences of other institutions
- literature data
- results of own process measurements, i.e. through monitoring and analysis of own data over a period of time
- goals should be realistic
- SOP documenting all activities related to QIs

# SETTING QUALITY OBJECTIVES AND CRITICAL ACTION LIMITS

- quality goals reflect the quality policy in a organization
- they can be changed or terms of their achievement redefined by the management decision
- redefining of objectives in case of process changes

# DEFINING THE METHOD OF DATA COLLECTION AND PROCESSING

- source of data
- responsible persons
- statistical methods

# MONITORING, INTERPRETATION (TRENDS) AND REPORTING

- continuous survey
- trends
- deviations (significance?)
- corrective actions
- periodic reports to the management
- quality indicators should be available to all employees

# MONITORING, INTERPRETATION (TRENDS) AND REPORTING

- data should be timely processed and forwarded to the interested parties
- not all QIs are equally significant for all subjects
- a part of the QI are used by the institution management to assess the quality system and its further planning
- some indicators are relevant for heads of particular departments or laboratories and for their employees
- a part of the indicators have to be reported to the competent authority and/or other regulatory bodies
- sentinel events are liable to notification to the national surveillance systems (haemovigilance in TM)



# MONITORING, INTERPRETATION (TRENDS) AND REPORTING

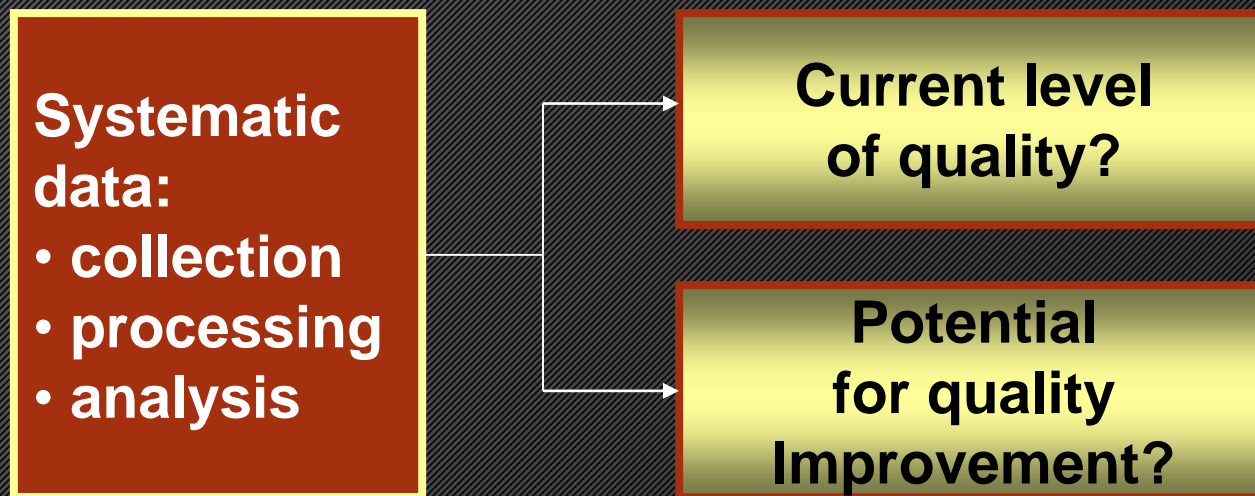
- all persons involved in the quality indicator management should have appropriate education and training in this segment of QM
- actively included
- comments, criticism and suggestions

# CORRECTIVE ACTIONS

- most important ultimate goal of QI monitoring
- upgrading the product and service quality
- reduction of non-conformities and errors to an acceptable level
- corrective actions have to be documented
- re-education or additional education of the personnel, changes in the working process, establishment of additional administrative controls, etc.
- effectiveness is monitored by further indicator surveillance

# QI AND CONTINUOUS QUALITY IMPROVEMENT

- continuous quality improvement - one of the main goals of the QMS
- Quality indicators - major role in achieving this goal



# QI AND CONTINUOUS QUALITY IMPROVEMENT

- sometimes achieved by simple interventions, requiring no major financial investment:
  - education of the employees
  - organizational changes, etc.

# QUALITY MANAGEMENT IN 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

# HAEMOVIGILANCE

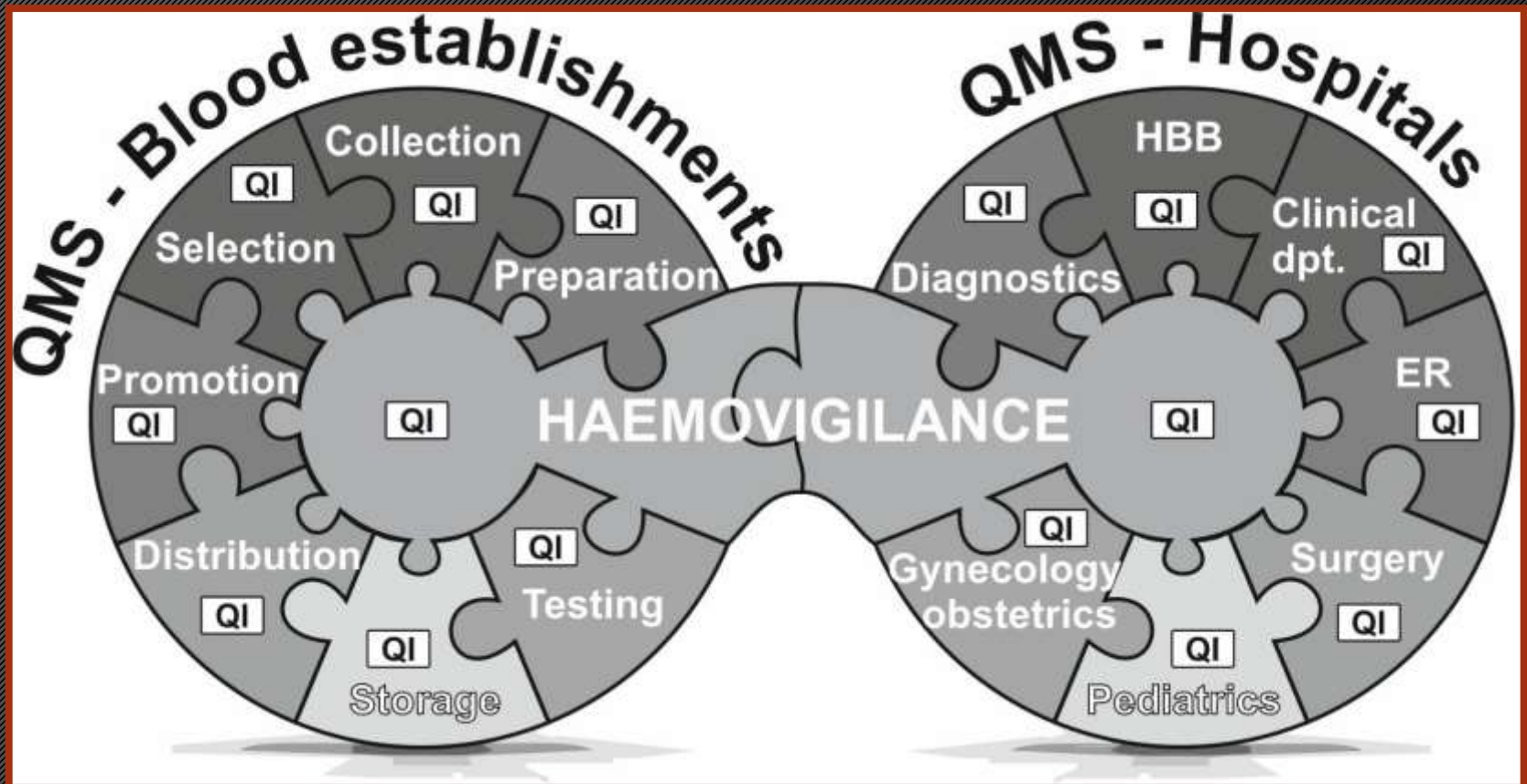
The need of implementing the system of hemovigilance:

- complexity of transfusion service processes
- fatal effects of potential errors
- specificity of risks associated with blood collection and blood component preparation and use
- constantly pending new risks

# QI IN QUALITY MANAGEMENT AND HAEMOVIGILANCE?

- Haemovigilance should be integrated in the QMS!
- activities and goals are closely intertwined
- the level to which these goals have been achieved?
- continuous **measurement**
- quality **indicators** as a QMS tool
- identification of problems, priorities to solve, possibilities of improving the quality and safety

# QM, HAEMOVIGILANCE, QI





# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- QM in transfusion medicine – long history
- quality indicators as a QMS tool did not receive due attention until recently
- QI in transfusion medicine – employed at the institutional or local level
- large-scale discussion on the importance of the implementation, monitoring and comparison of quality indicators seems to have failed
- data on the selection and implementation of quality indicators, and on the results of their monitoring in particular, are quite insufficient
- little data are available on quality indicators in transfusion medicine
  - clinical TM
  - laboratory medicine (EN ISO 15189)

# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- during the [IHN](#) seminar held in Dubrovnik 2010, implementation of quality indicators in blood establishments at the international level was initiated
- Objectives:
  - to stimulate BE to introduce quality indicators
  - to help them select the most appropriate QI
  - to introduce a standardized method of data collection and processing
  - benchmarking on international level

# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- discussion on the project continued at the [ISBT](#) Quality Management and Haemovigilance working parties meetings

# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- 36 QI defined in all segments of transfusion service activities
- the last version of these indicators published in Transfusion Today 2013

Vuk T. Quality indicators in blood establishments: ISBT Working Party on Quality Management Project. Transfusion Today 2013;96:10-11.

# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- Percentage of voluntary non-remunerated blood donors
- Accomplishment of the planned number of donors (whole blood and apheresis)
- Percentage of donations collected from first time donors
- Number of donations collected per 1,000 inhabitants
- Number of donations per donor (per year)
- Donor deferral rate – total, temporary, permanent
- Venipuncture failures
- Clots in red blood cell (RBC) products
- Aggregates in platelet concentrates obtained by apheresis
- Poor welds on blood collection and poor welds on blood product manufacture

# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- Lipemic plasma
- Donor adverse reactions
- Production index
- Product non-conformities
- Hemolytic plasma
- Expired platelet concentrate shelf life and expired RBC concentrate shelf life
- Realization of requests for blood components
- Wrong blood product issue
- Returned blood products
- Component wastage rate (RBC, PLT, FFF) at the hospital
- Donor sample non-conformities

# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- Proficiency testing – performance evaluation
- Positive findings on blood product bacteriological testing
- Contamination rate of blood product cultures
- Non-conformities in blood product quality control results
- Blood product complaints and donor complaints
- Serious adverse events (SAE)
- Product withdrawal from the market
- Corrective measures completed on time (from internal audits, external audits and initiated by QA department)
- Change controls completed on time
- Customer satisfaction

# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- Patient sample non-conformities and non-conformities in the requests for pretransfusion testing
- Test turnaround time (TAT) – urgent requests
- C:T ratio
- AB0/Rh(D) discrepancies
- RBC units issued in emergency without testing



# QUALITY INDICATORS IN TRANSFUSION MEDICINE

- quality indicators related to the efficacy and outcome of transfusion treatment were not included in the project
- **EDQM 2011**: incentive known as “Quality Indicators for the Evaluation and Monitoring the Optimal Use of Blood and Blood Components”
- uniform platform for implementation of quality indicators in transfusion medicine



# SELECTION OF ISBT QUALITY INDICATORS

- the ISBT quality indicators help blood establishments in choosing **what** to monitor but not the objectives and limits of action
- Why?

# SELECTION OF ISBT QUALITY INDICATORS

Blood establishments differ among themselves according to the:

- availability and structure of blood donors,
- criteria of donor selection,
- method of blood product preparation,
- clinical practice (different requirements for blood products),
- availability of material and human resources

# HOW TO DEFINE QUALITY OBJECTIVES AND ACTION LIMITS?

CITM experience:

**MONITORING**



2-3 years  
retrospectively (historical data?) or prospectively

**INITIAL  
GOAL**



mean value of measurements for the respective period  
correction factor (certain degree of improvement  
e.g., 5%-10%).

**ACTION  
LIMITS**



2 SD: critical indicators  
3 SD: less critical indicators

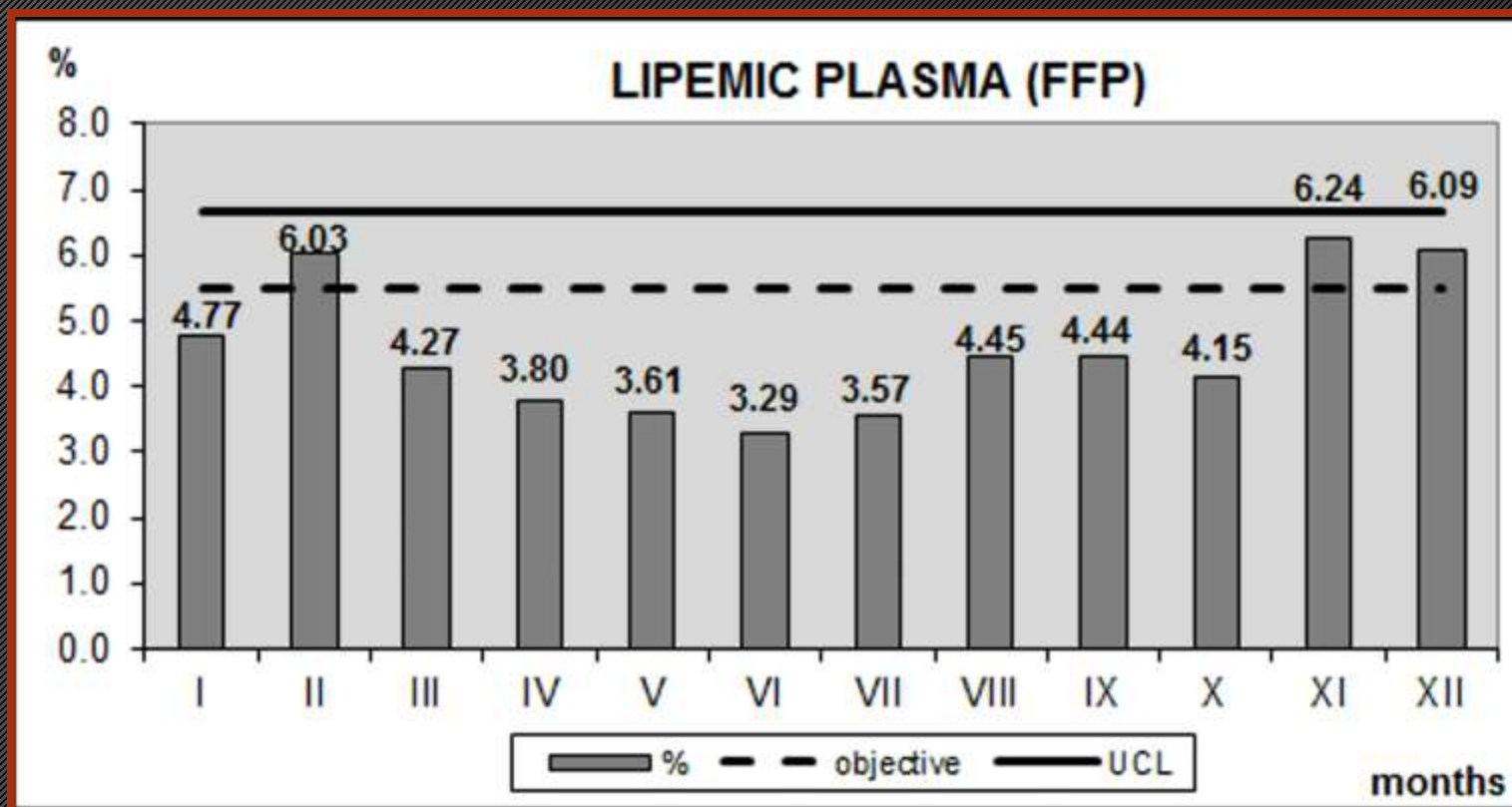
# MONITORING OF QUALITY INDICATORS

- continuous
- simple, practical and informative
- various graphic tools
- CITM:

**n - CHARTS** → absolute values

**p - CHARTS** → proportion

# MONITORING OF QUALITY INDICATORS – CITM EXAMPLE

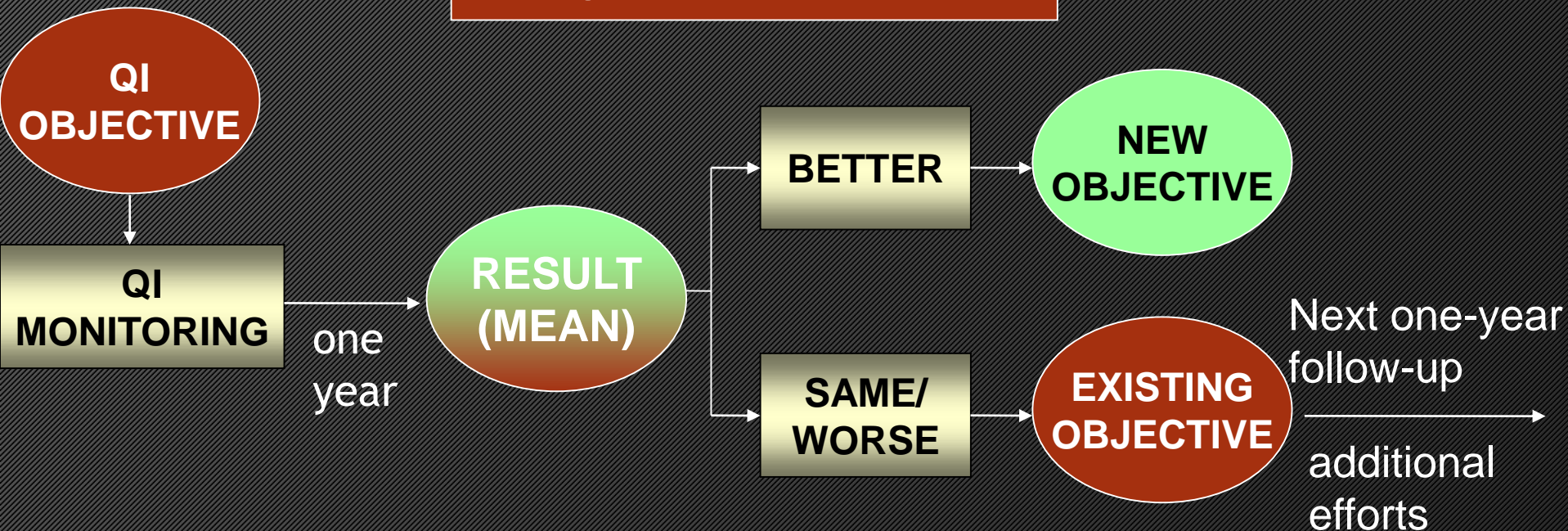


Lipemic fresh frozen plasma quality indicator  
(Croatian Institute of Transfusion Medicine, 2012)

# QI AND CONTINUOUS QUALITY IMPROVEMENT

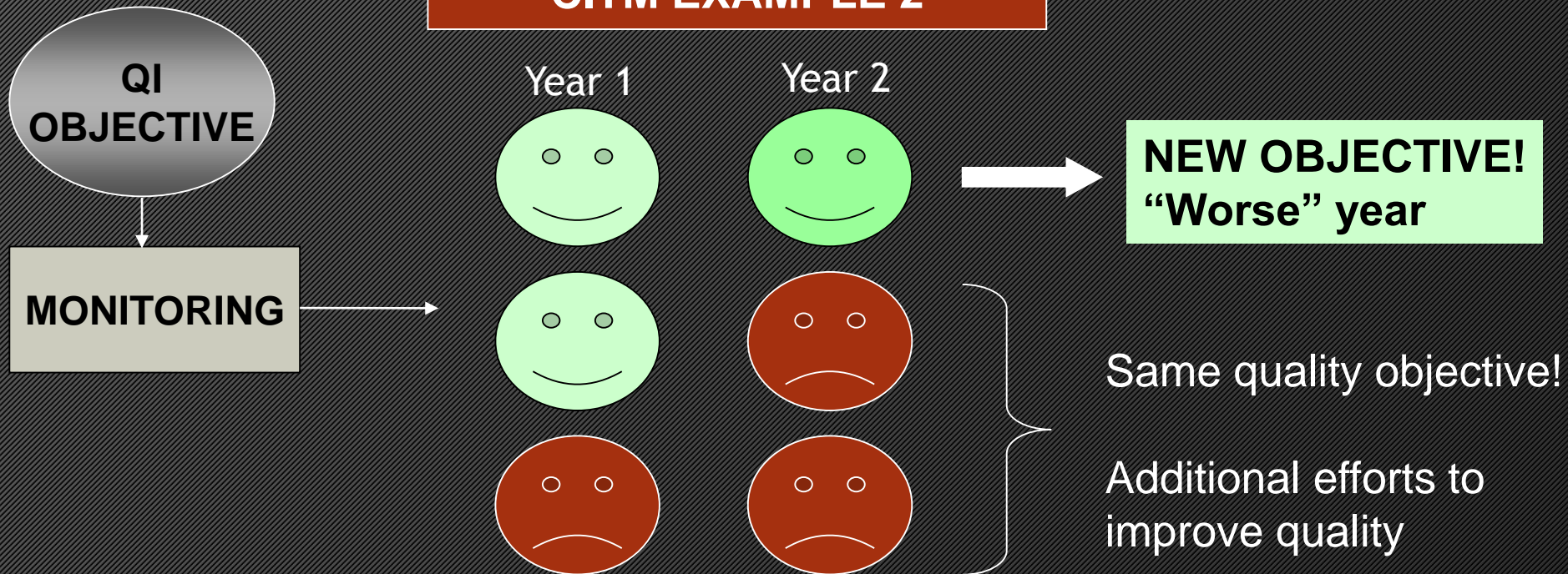
- QI
- dynamic
  - liable to modifications
  - how do we change them?

## CITM EXAMPLE 1



# QI AND CONTINUOUS QUALITY IMPROVEMENT

## CITM EXAMPLE 2



quality objective modifications:

- less dynamic
- more realistic and feasible



# FUTURE OF ISBT QUALITY INDICATORS

- the activities undertaken to date have considerably changed the perception of QI in transfusion medicine
- QI: subject of professional lectures, topic of articles and congress reports, graduation theses, etc.
- The activities of ISBT have greatly contributed to popularizing this important issue, having increased the professional awareness of their role and need of their implementation and monitoring

# FUTURE OF ISBT QUALITY INDICATORS

## Two studies:

1. The use of quality indicators in blood establishments worldwide (questionnaire)
2. QI monitoring at the international level: data collection for benchmarking

activities for clearly defining the numerators and denominators to make the collected data reliable!

# CONCLUSION

- continuous and ever more stringent quality and safety requirements
- continuous monitoring of the processes
- identification of the possibilities for improvement
- risk prevention
- timely response to the risks
- quality measurement - availability of accurate and relevant data

# CONCLUSION

- quality indicators: important tool for accomplishment of the quality goals
- efficient utilization of this tool:
  - quality and safety of products and services
  - rational management of the resources and savings
- quality culture where monitoring of quality indicators is perceived as a necessity rather than an imposed obligation

**THANK YOU!**