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
more recent but often emphasized as successful models of quality measurement are those carried out in:

- Denmark
- Germany
- The Netherlands
- France
- United Kingdom
- Sweden
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

**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

- detailed
- specific
- addressing problems and specificities of local interest
- global
- more general
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

- KEY (STRATEGIC)
- AUXILIARY PROCESSES
- CRITICALITY
  - RATE-BASED
  - SENTINEL
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 an 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

Systematic data:
- collection
- processing
- analysis

Current level of quality?

Potential for quality improvement?
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
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

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?
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:

\begin{align*}
\text{n - CHARTS} & \rightarrow \text{absolute values} \\
\text{p - CHARTS} & \rightarrow \text{proportion}
\end{align*}
MONITORING OF QUALITY INDICATORS – CITM EXAMPLE

Lipemic fresh frozen plasma quality indicator
(Croatian Institute of Transfusion Medicine, 2012)
QI AND CONTINUOUS QUALITY IMPROVEMENT

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

CITM EXAMPLE 1

QI

QI OBJECTIVE

RESULT (MEAN)

Better

New Objective

Same/Worse

Existing Objective

Next one-year follow-up

Additional efforts

QI MONITORING

one year
QI AND CONTINUOUS QUALITY IMPROVEMENT

CITM EXAMPLE 2

QI OBJECTIVE

MONITORING

Year 1

Year 2

NEW OBJECTIVE! “Worse” year

Same quality objective!

Additional efforts to improve quality

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
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!