

IMPLEMENTATION AND MONITORING OF QUALITY INDICATORS IN BLOOD ESTABLISHMENTS



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Antalya, 2019

SWOT ANALYSIS IN HEALTHCARE

SWOT =

Strengths,

Weaknesses,

Opportunities,

Threats



- tool for the assessment of an organization/system
- positives and negatives, inside and outside of the organization/system
- planning of future initiatives, investments, etc.

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SWOT ANALYSIS IN HEALTHCARE SYSTEM

Example:



STRENGTHS

- integration of scientific achievements and technological solutions in the development of diagnostic and therapeutic procedures
- Informatization
- automation
- educated and skilled staff

WEAKNESSES

- unequal healthcare quality level
- rising costs (disproportionate to the healthcare quality)
- lack of staff and/or time

OPPORTUNITIES

- increased funds
- better communication and collaboration between healthcare institutions

THREATS

- pressure for the reduction of healthcare costs
- political/economic insecurity
- adverse demographic changes
- loss of staff



Positive

Negative

HEALTHCARE SYSTEM UNDER THE PUBLIC SCRUTINY

Doctors, medical staff on drugs put patients at risk (USA TODAY, 2014)

'Deny And Defend' Culture Weakens Trust In Health-Care System (Huffpost Living, 2016)

Editorial: Medical errors are a deadly epidemic, The Des Moines Register 2016

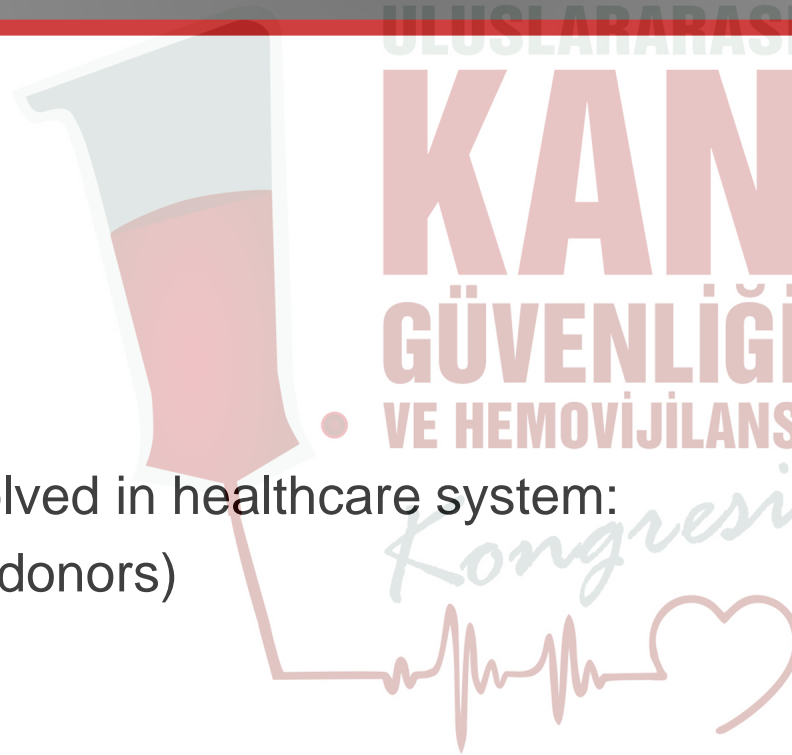
Scandal of 1,000 A&E deaths caused by blunders of over-stretched hospital staff, MIRROR, 2015

Call for royal commission into medical errors in Victorian health system, Herald Sun 2016

The third highest cause of death in the United States is mistakes by medical staff. INDEPENDENT 2016

HEALTHCARE QUALITY

- demands for quality:
 - measurement
 - monitoring
 - assessment
 - improvement
- various interest groups involved in healthcare system:
 - users (e.g. patients / donors)
 - service providers
 - regulators
 - insurance companies, etc.
- although quality measurement and monitoring are important for all of them, their motives vary, resulting in different concepts and thus different definition of quality



HEALTHCARE QUALITY MEASUREMENT/MONITORING

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

QIs are used to identify potential quality concerns (risk identification), and areas that need further analysis and investigation, and to monitor the changes over time

- one of the QM tools
- measurable, objective indicators of the efficiency of the QMS
- monitoring and assessment of the quality of products and services
- comparison of different institutions
- the data collected provide a basis for the implementation of corrective measures and continuous quality improvement

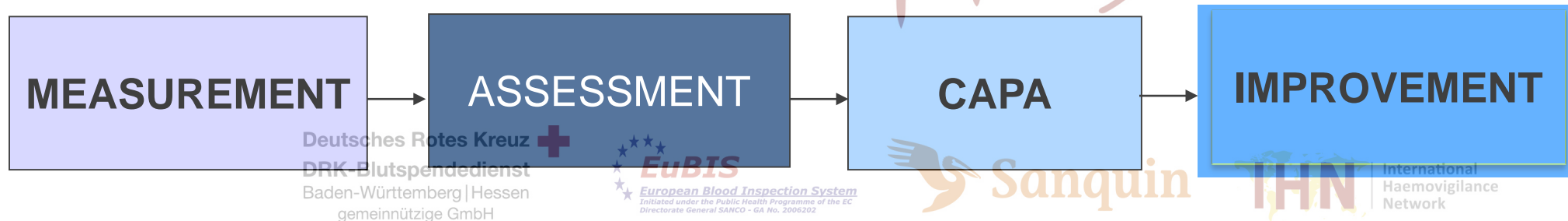
QUALITY INDICATORS - DEFINITION

- 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 **ISO 15189** standard are obliged to perform systematic analysis of quality indicators
- primarily applying to hospitals
- increasingly introduced in primary healthcare



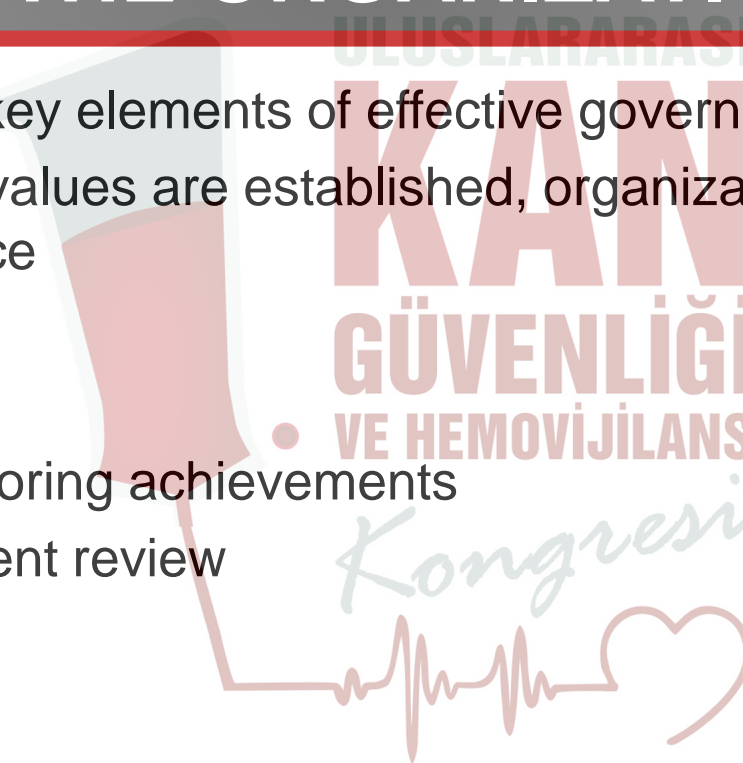
QUALITY INDICATORS - OBJECTIVES

- 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
- comparison of institutions of similar characteristics (benchmarking)
- important prerequisite for the process of accreditation and certification



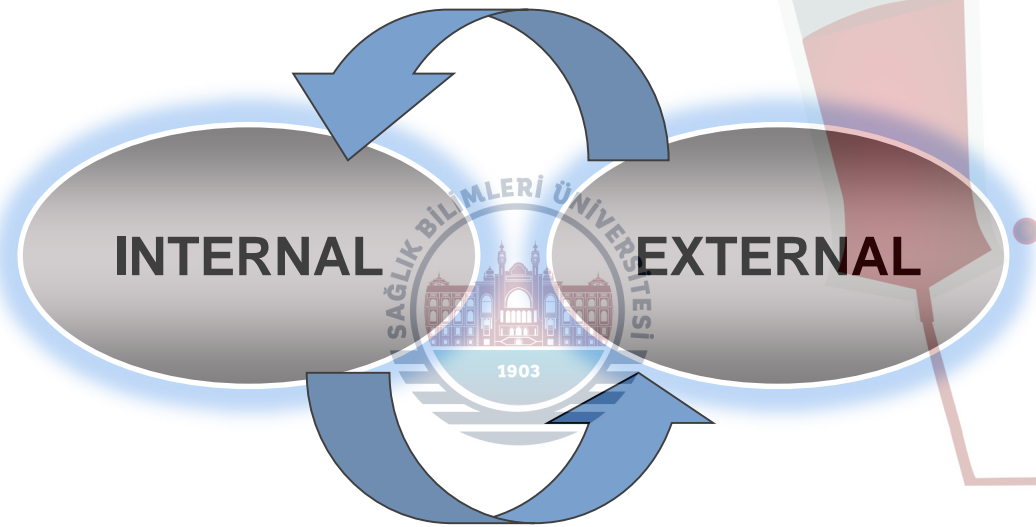
QUALITY INDICATORS AND STRATEGIC FRAMEWORK OF THE ORGANIZATION

- vision, mission and values = key elements of effective governance of the organization
- once the vision, mission and values are established, organizations should develop strategic goals and monitor performance
- Quality indicators:
 - important tool for monitoring achievements
 - input for the Management review



QUALITY INDICATORS - CLASSIFICATIONS

According to the objectives of their establishment and use



INTERNAL

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

EXTERNAL

enable surveillance of the indicators to external partners (regulators, insurance companies, users), to protect their own interest.


They should be clearly defined to obviate differences arising from different practice and approach in data collection and processing.

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

- global
- more general

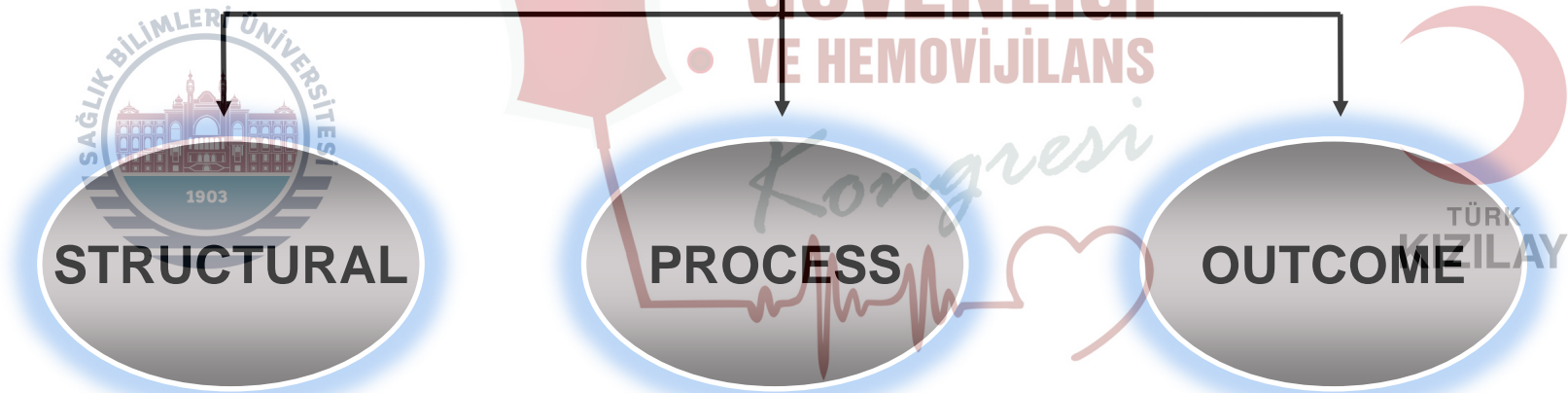
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QUALITY INDICATORS - CLASSIFICATIONS

TRIPARTITE QUALITY MODEL (DONABEDIAN)



STRUCTURAL

how the processes
are organized


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PROCESS

how the activity
is performed

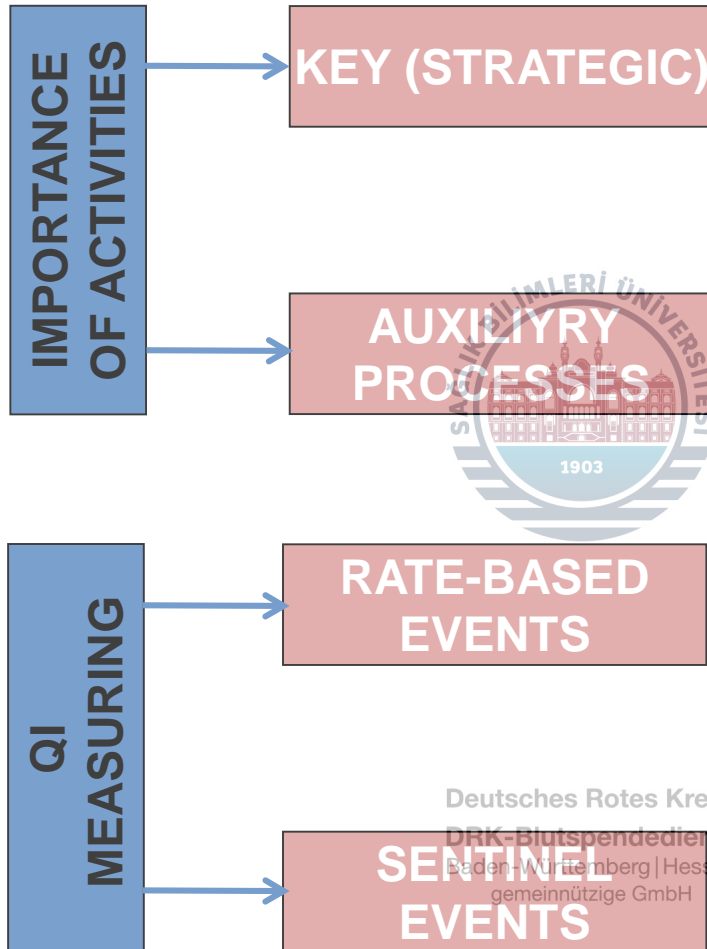

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OUTCOME

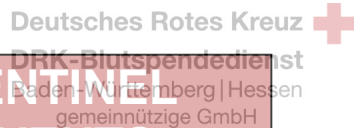
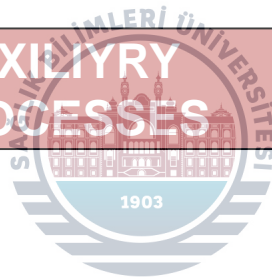
whether appropriate
results have been
achieved


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QUALITY INDICATORS - CLASSIFICATIONS



- part of institution's strategic planning process
- strategic goals and key initiatives
- related to mission and vision
- supportive activities
- occurring with certain frequency
- investigation triggered when the predetermined threshold is exceeded
- rare
- serious
- usually avoidable



QI - CHARACTERISTICS

OBJECTIVITY

→ measurability

IMPORTANCE AND RELEVANCE

→ they should cover relevant events and problems

POTENTIAL FOR USE

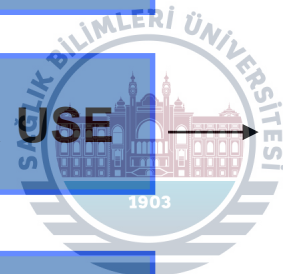
→ when a problem is identified by measurement, it should be possible to respond to it

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

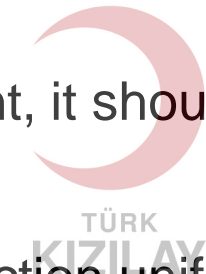


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Pringle *et al.* propose a list of 12 attributes which should be taken into account on QI selection

HOW TO SELECT QUALITY INDICATORS?

- evidence based
- expert consensus and experience
- own experience
- literature review results
- debate with professionals within and outside the institution, etc.



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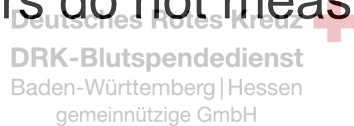
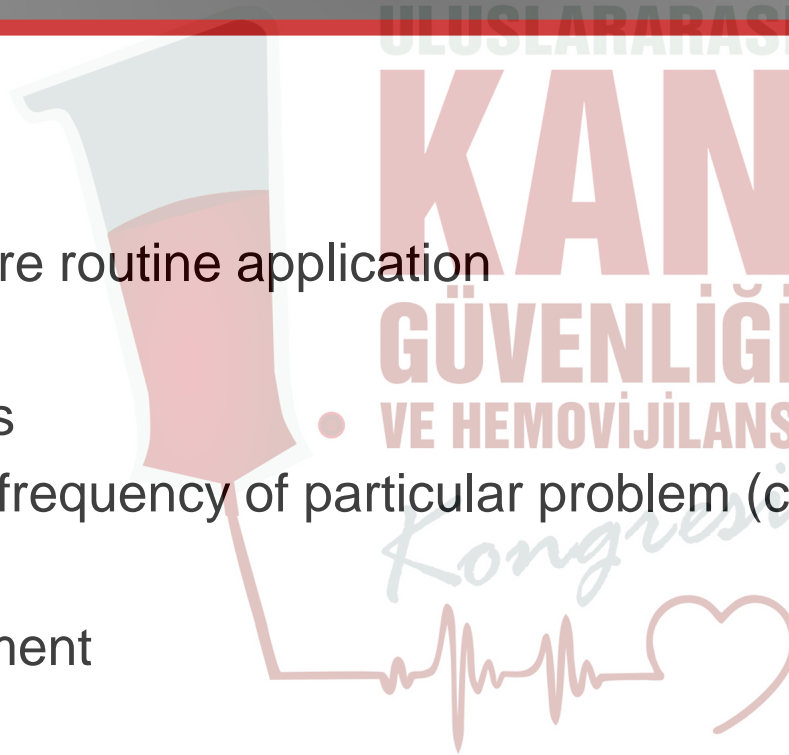
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HOW TO SELECT QUALITY INDICATORS?

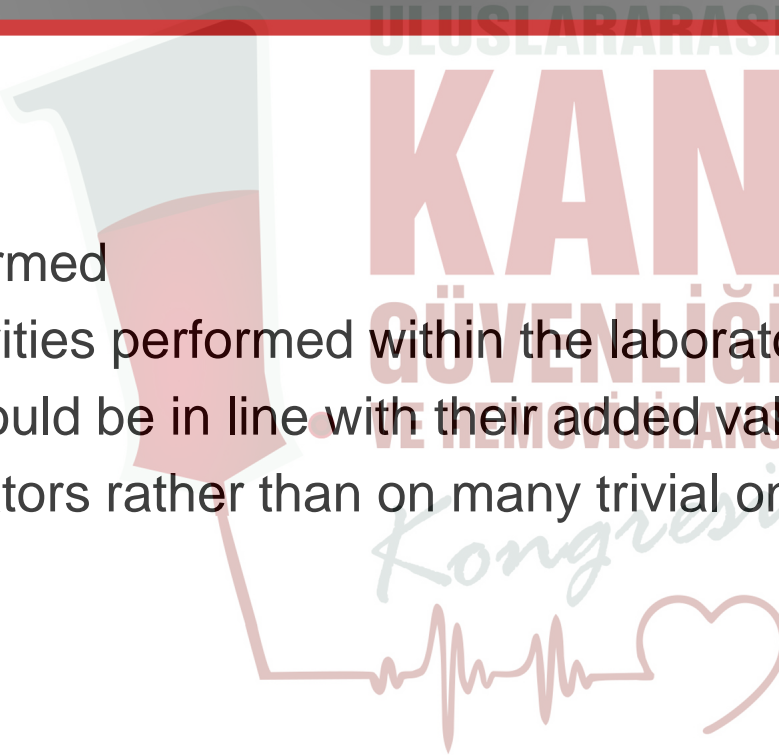
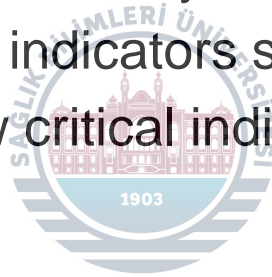
- complex process
- scientific approach
- testing and verification before routine application
- exploration of the processes
- assessment of the risk and frequency of particular problem (criticality, relevance)
- institution priorities
- the possibilities of improvement
- selection of indicators is closely related to critical control points and key elements
- some indicators do not measure quality directly



HOW TO SELECT QUALITY INDICATORS?

Number of quality indicators:

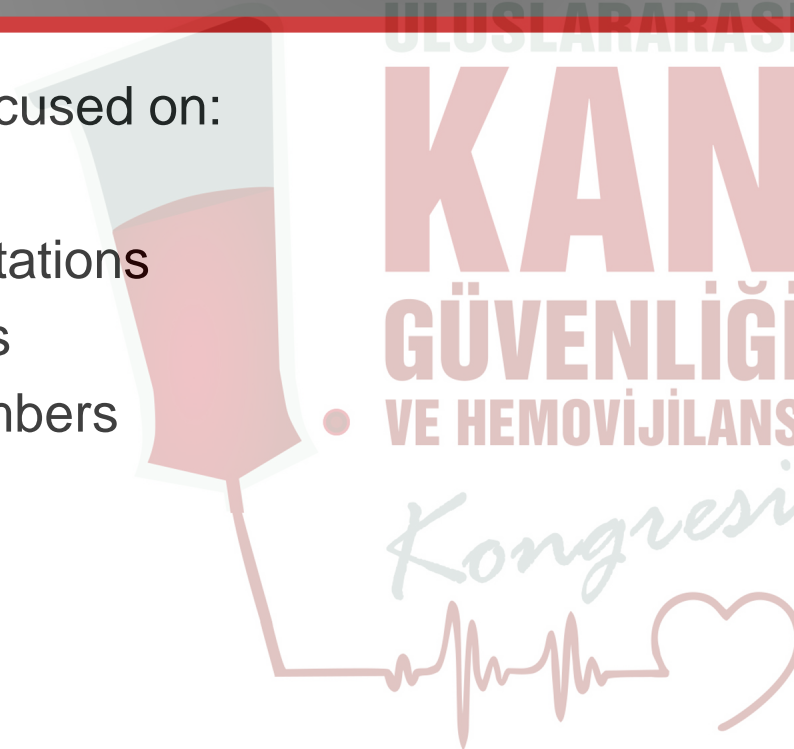
- the size of the institution
- extent of the activities performed
- QI should cover all key activities performed within the laboratory or institution
- the number of indicators should be in line with their added value
- focus on a few critical indicators rather than on many trivial ones



HOW TO SELECT QUALITY INDICATORS?

Quality indicators should be focused on:

- quality/safety requirements
- customer needs and expectations
- characteristics of processes
- satisfaction of the staff members
- etc.



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DEFINING NUMERATORS AND DENOMINATORS

- the numerator and denominator should be precisely defined

Numerator

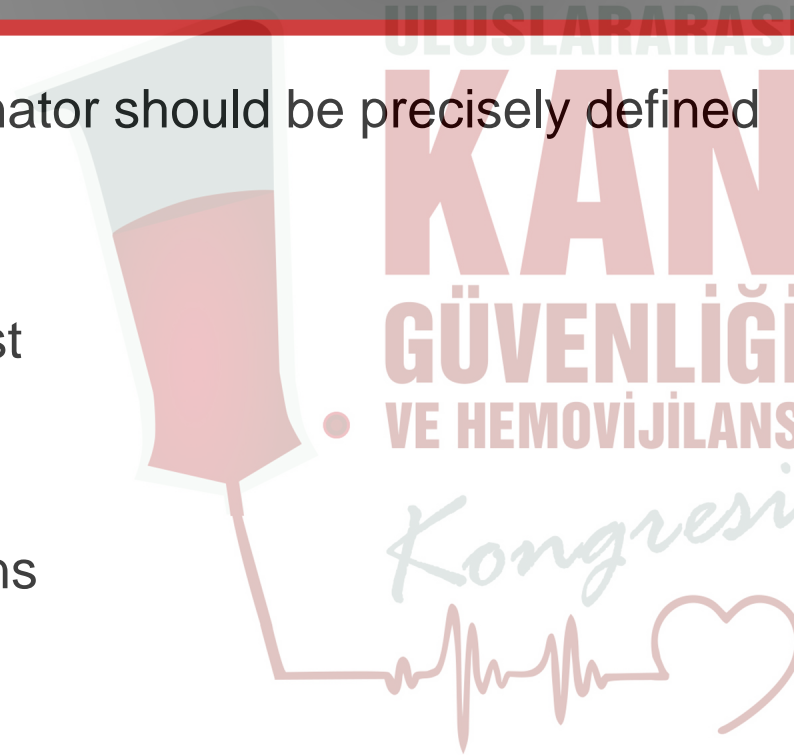
- Number of events of interest

Denominator

- Total number of observations

QI (expressed as %)

- Numerator divided by the denominator x 100



SETTING QUALITY OBJECTIVES

SMART – acronym for setting objectives

Doran GT. (1981). "There's a S.M.A.R.T. way to write management's goals and objectives". Management Review. 70 (11): 35–36.

Specific

- target a specific area for improvement.

Mesurable

- quantify or at least suggest an indicator of progress

Assignable

- specify who will do it

Realistic

- state what results can realistically be achieved, given available resources

Time-related

- specify when the result can be achieved

SETTING QUALITY OBJECTIVES AND 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



SETTING QUALITY OBJECTIVES AND ACTION LIMITS

- quality objectives reflect the quality policy in a organization
- liable to both qualitative and quantitative modifications
- not fixed - adjustments based on regular evaluation
- they can be changed or terms of their achievement redefined by the management decision
- redefining of objectives is also necessary in case of process changes that profoundly modify the process characteristics and consequently its stability



DEFINING THE METHOD OF DATA COLLECTION AND PROCESSING

- source of data (computer reports, record books, forms, etc.)
- responsible persons
- statistical methods



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MONITORING, INTERPRETATION (TRENDS) AND REPORTING

- continuous survey
- trends
- deviations (significance?)
- CAPA
- 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)

CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

- quality improvement – ultimate goal of QI monitoring
 - improved product and service quality
 - reduction of non-conformities and errors
- Implementation of CAPA

Systematic data:

- collection
- processing
- analysis



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Current level
of quality?

Potential
for quality
Improvement?



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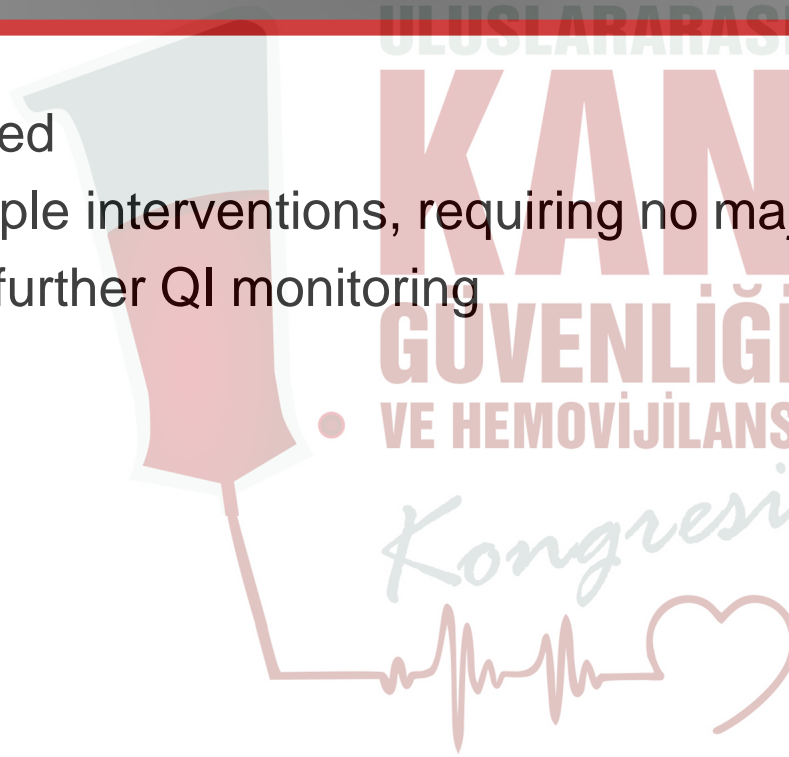


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CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

- CAPA have to be documented
- sometimes achieved by simple interventions, requiring no major financial investment
- effectiveness monitored by further QI monitoring



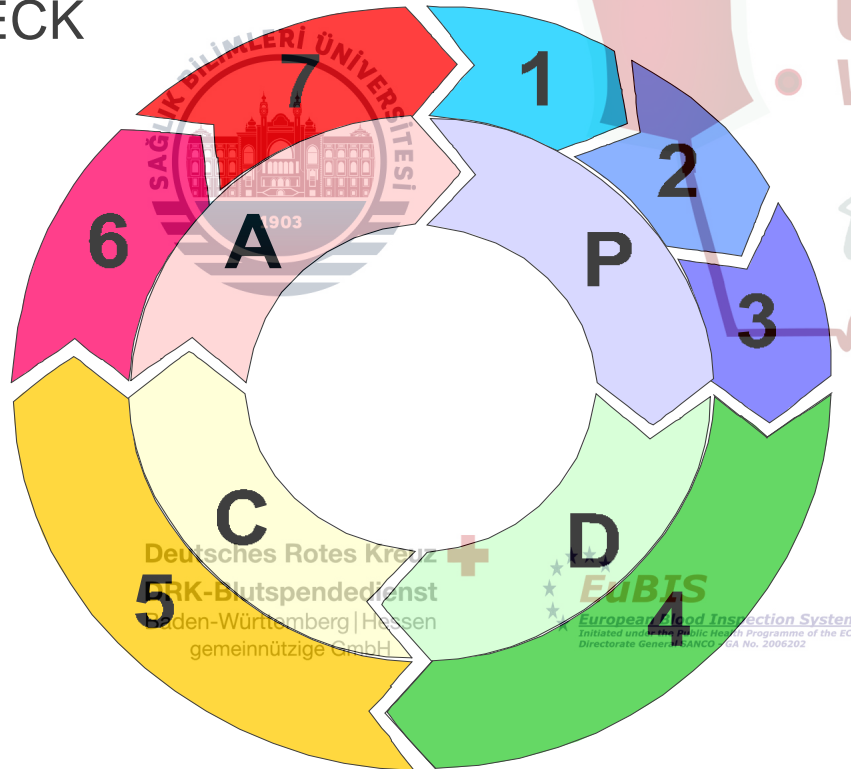
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QUALITY IMPROVEMENT STRATEGIES

PDCA (Deming circle)

- P = PLAN
- D = DO
- C = CHECK
- A = ACT



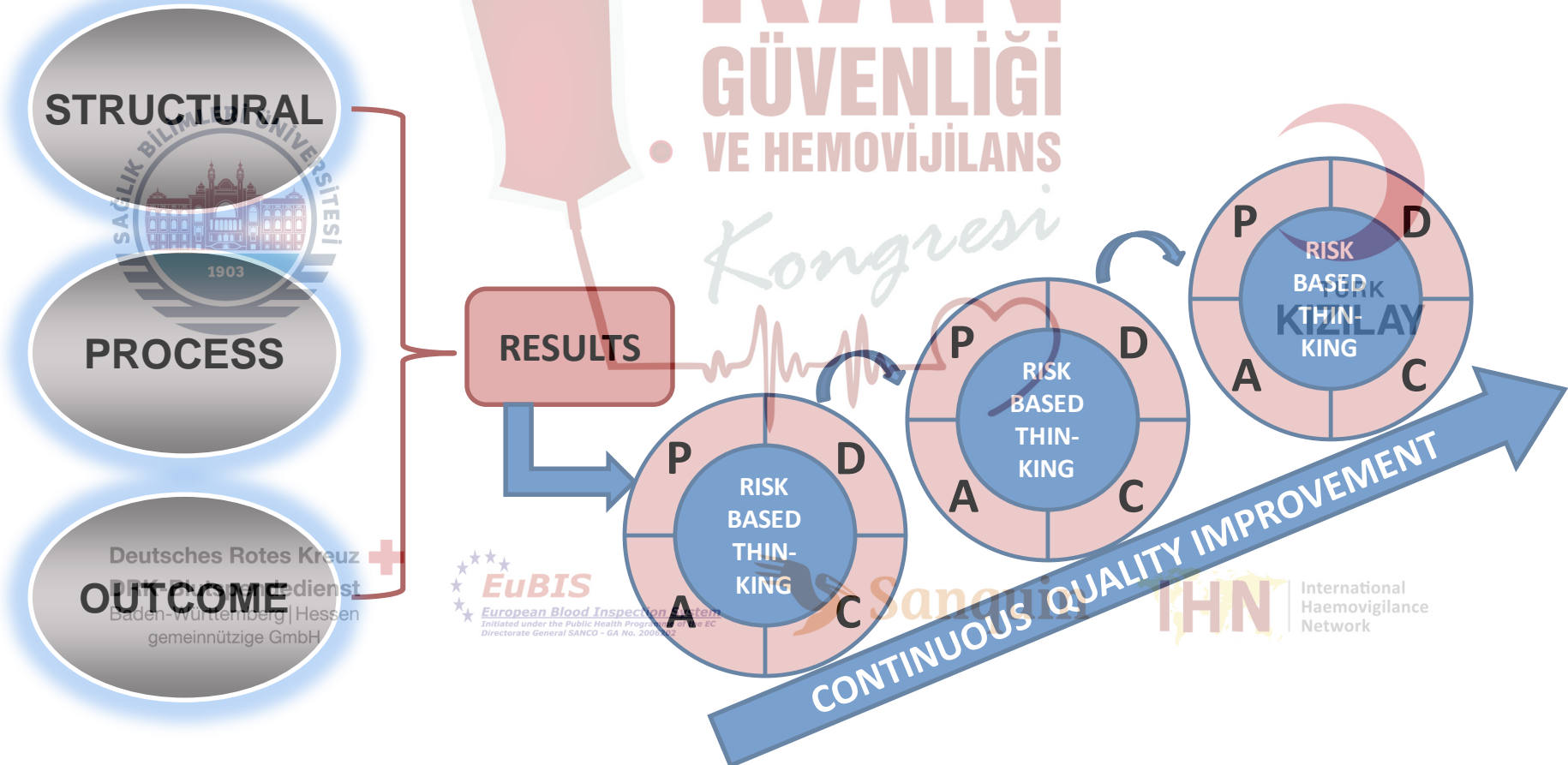
1. define problem
2. analyze problem
3. analyze causes
4. implement the plan
5. monitor effectiveness of actions taken
6. document changes
7. plan further improvement

Requirements:

- data-guided
- cyclical

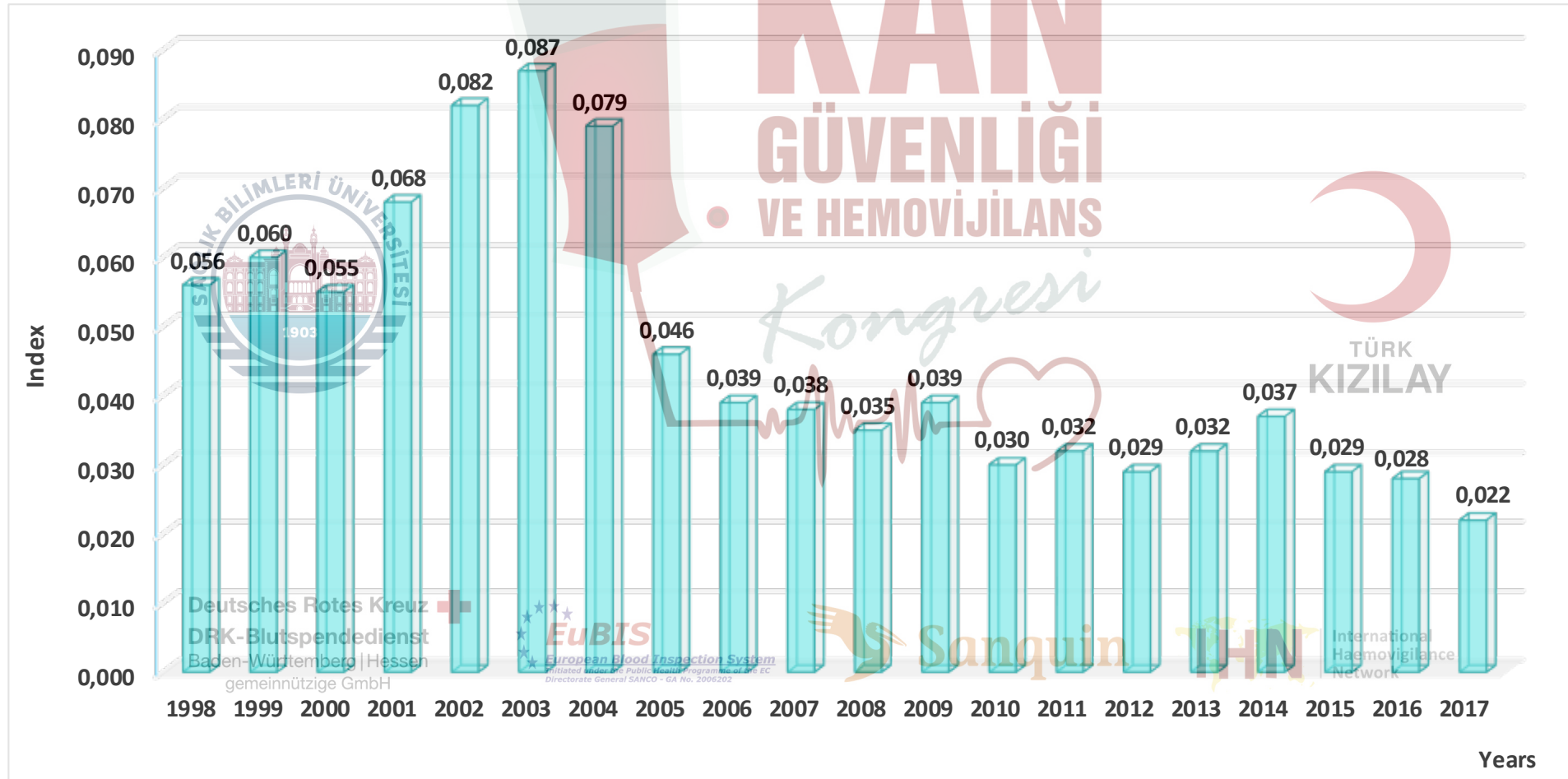
QI AND CONTINUOUS QUALITY IMPROVEMENT

Quality indicators
(Donabedian model)



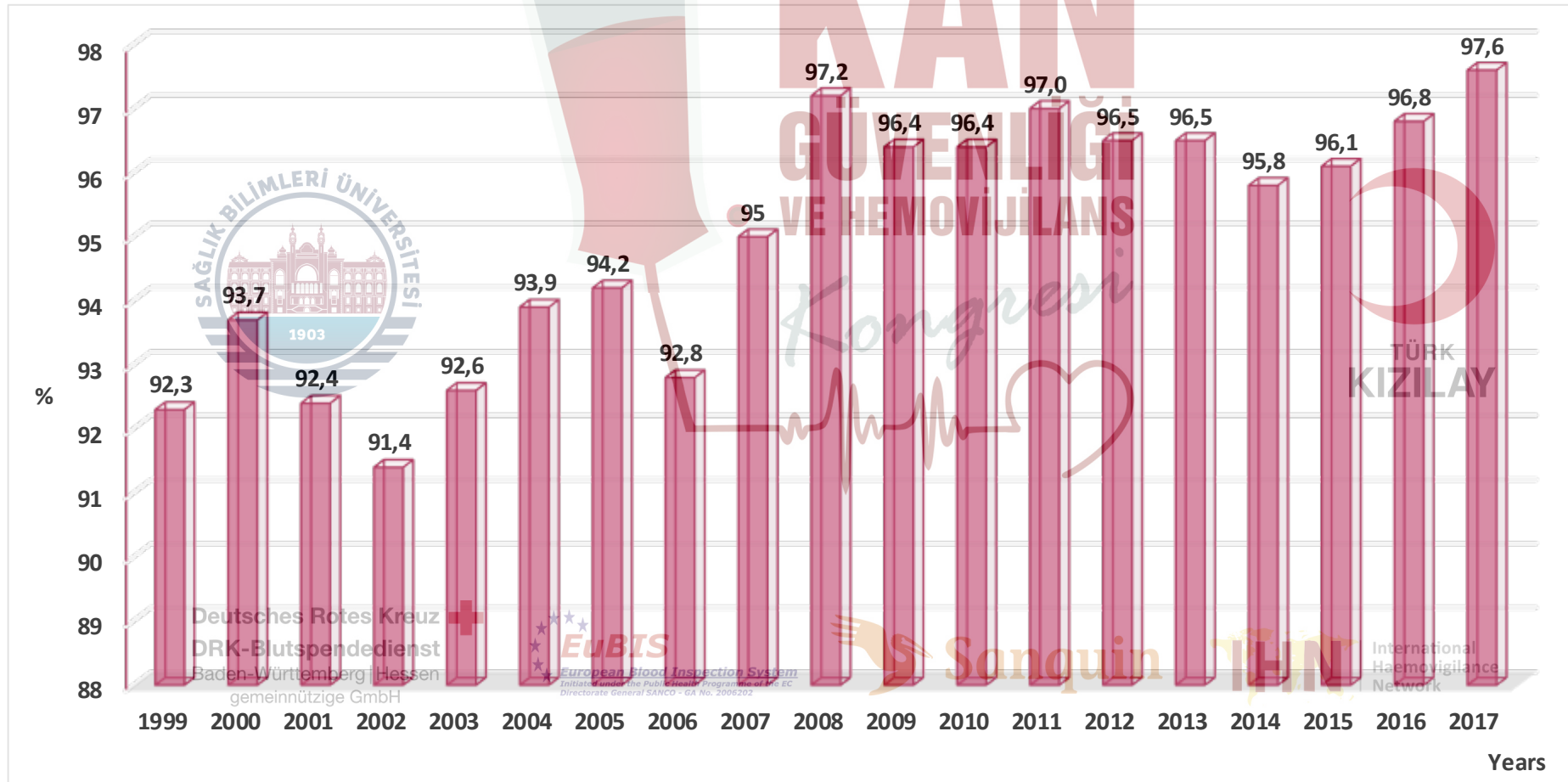
QI AND CONTINUOUS QUALITY IMPROVEMENT

NONCONFORMITIES / BLOOD COMPONENTS INDEX – CITM 1998-2017



QI AND CONTINUOUS QUALITY IMPROVEMENT

QC BLOOD COMPONENTS – % OF CONFORMING RESULTS (CITM 1998-2017)



QUALITY INDICATORS IN TRANSFUSION MEDICINE

- QM in transfusion medicine – long history
- quality indicators as a QMS tool did not receive due attention until few years ago
- 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 (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

- **ISBT** Working Party on Quality Management
- **36 QI** defined in all segments of transfusion service activities

Vuk T. Quality indicators: a tool for quality monitoring and improvement. ISBT Science Series 2012;7:24-8.

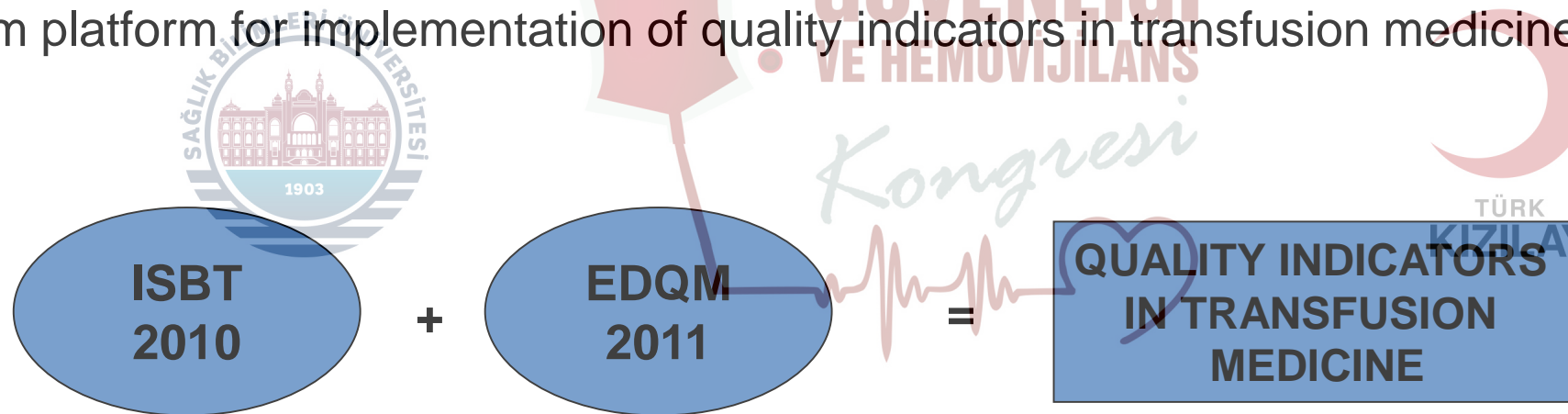
Vuk T. Implementation of ISBT quality indicators in the quality management and haemovigilance systems. ISBT Science Series 2015;10:371–375.

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

- the last version of these indicators published on ISBT website
- QI project Croatia since 2012 (21/36 indicators)

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

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MONITORING OF QUALITY INDICATORS

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



n - CHARTS

→ absolute values

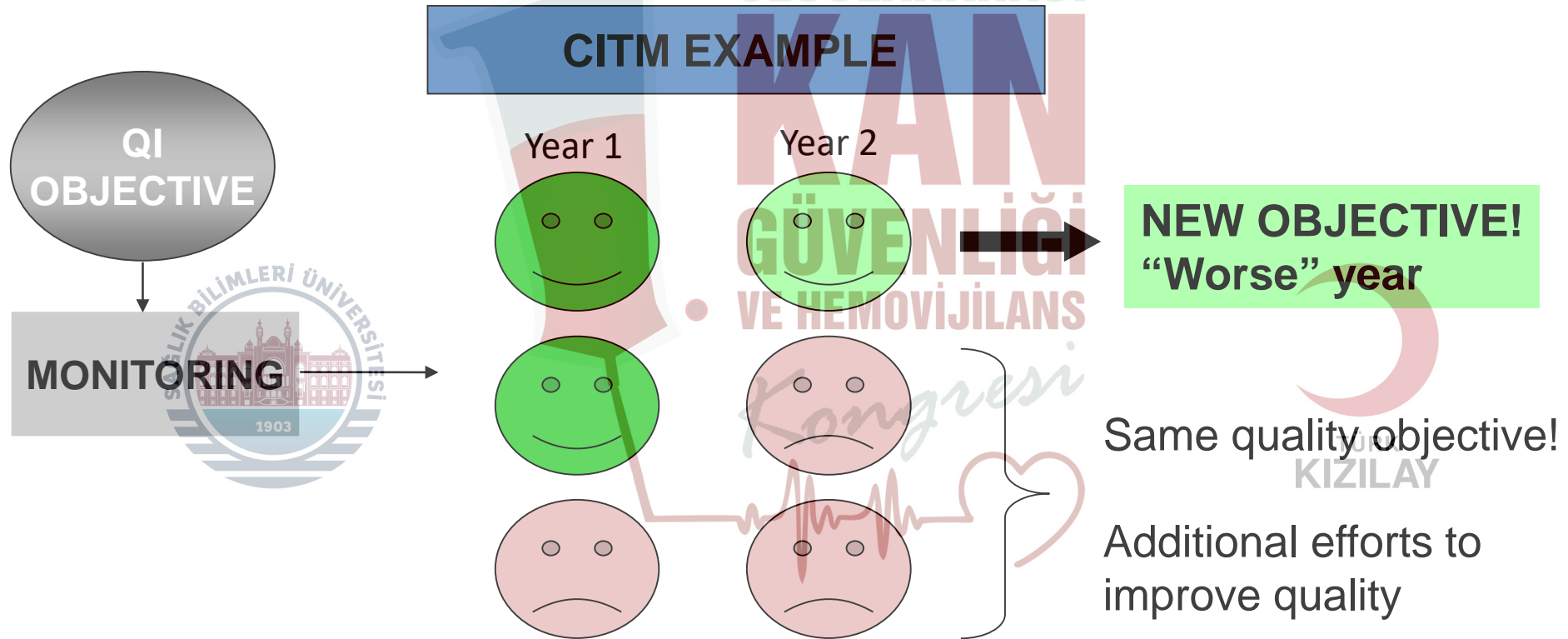
p - CHARTS

→ proportions

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QI AND CONTINUOUS QUALITY IMPROVEMENT



quality objective modifications:

- less dynamic
- more realistic and feasible

QI PROJECT CROATIA 2012

Reorganization of BTS in Croatia
from 21 to 7 centers collecting blood and producing BC

Objectives:

- performance standardization
- upgrading the quality and safety of transfusion treatment in Croatia

Questionnaire:

- QI – 21/36
- brief description
- numerator
- denominator
- result

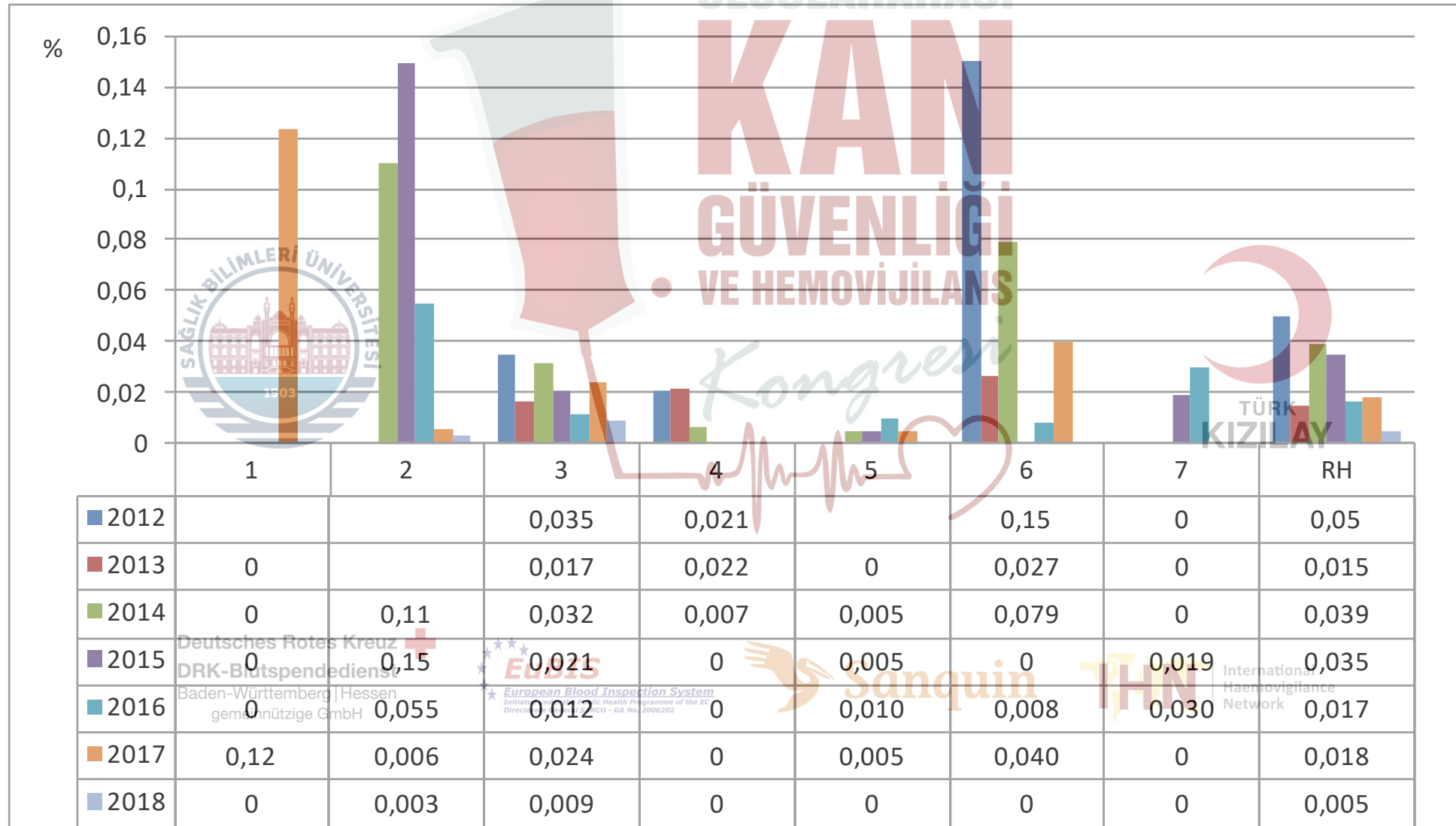


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QI PROJECT CROATIA

EXAMPLE – POOR WELDS ON BLOOD COLLECTION



ISBT WP-QM SURVEY ON QUALITY INDICATORS

First results presented at ISBT congress 2016

98 total responses

Complete responses: 59

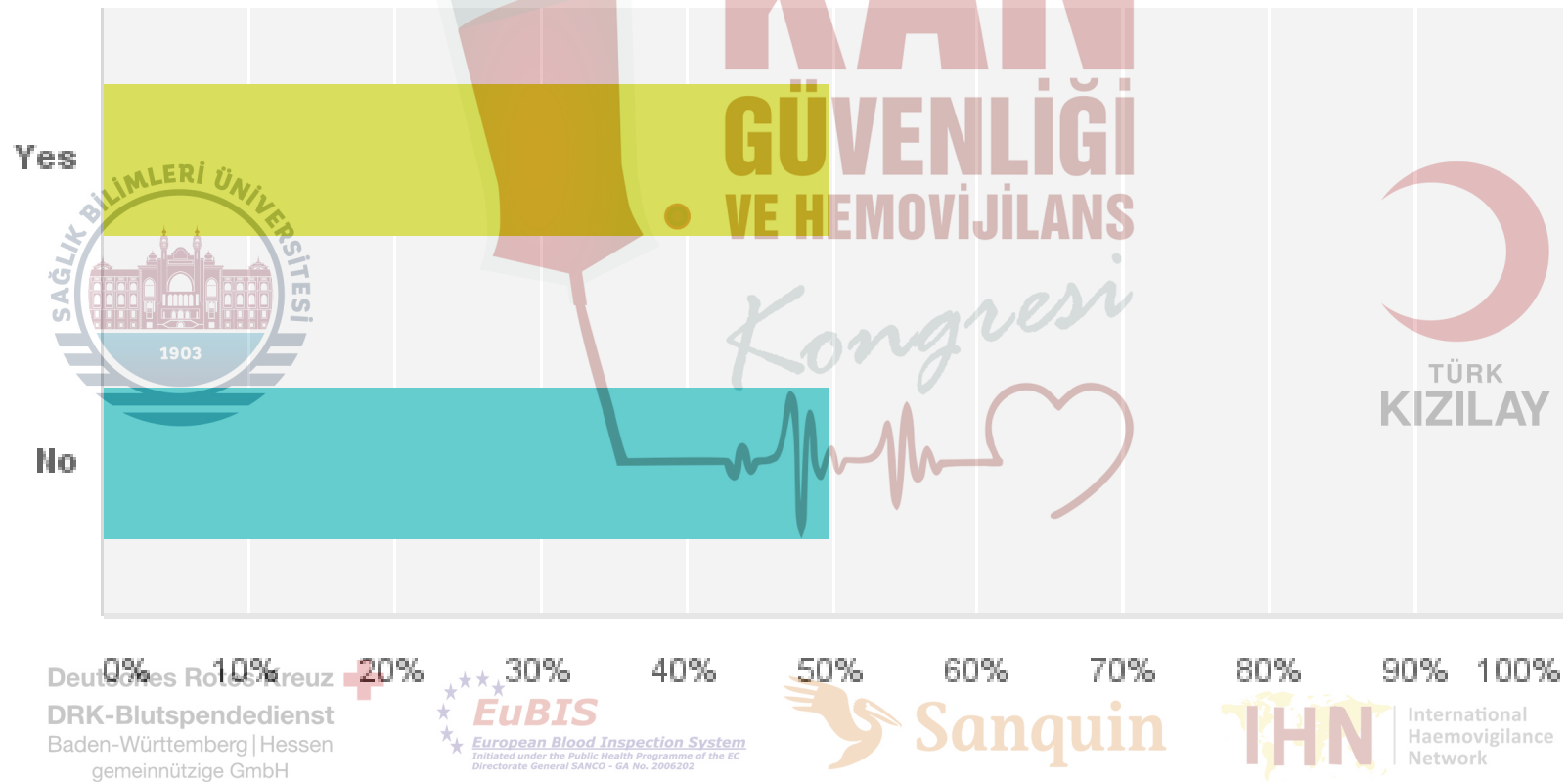
Some of the data presented in the following slides



ISBT WP-QM

SURVEY ON QUALITY INDICATORS

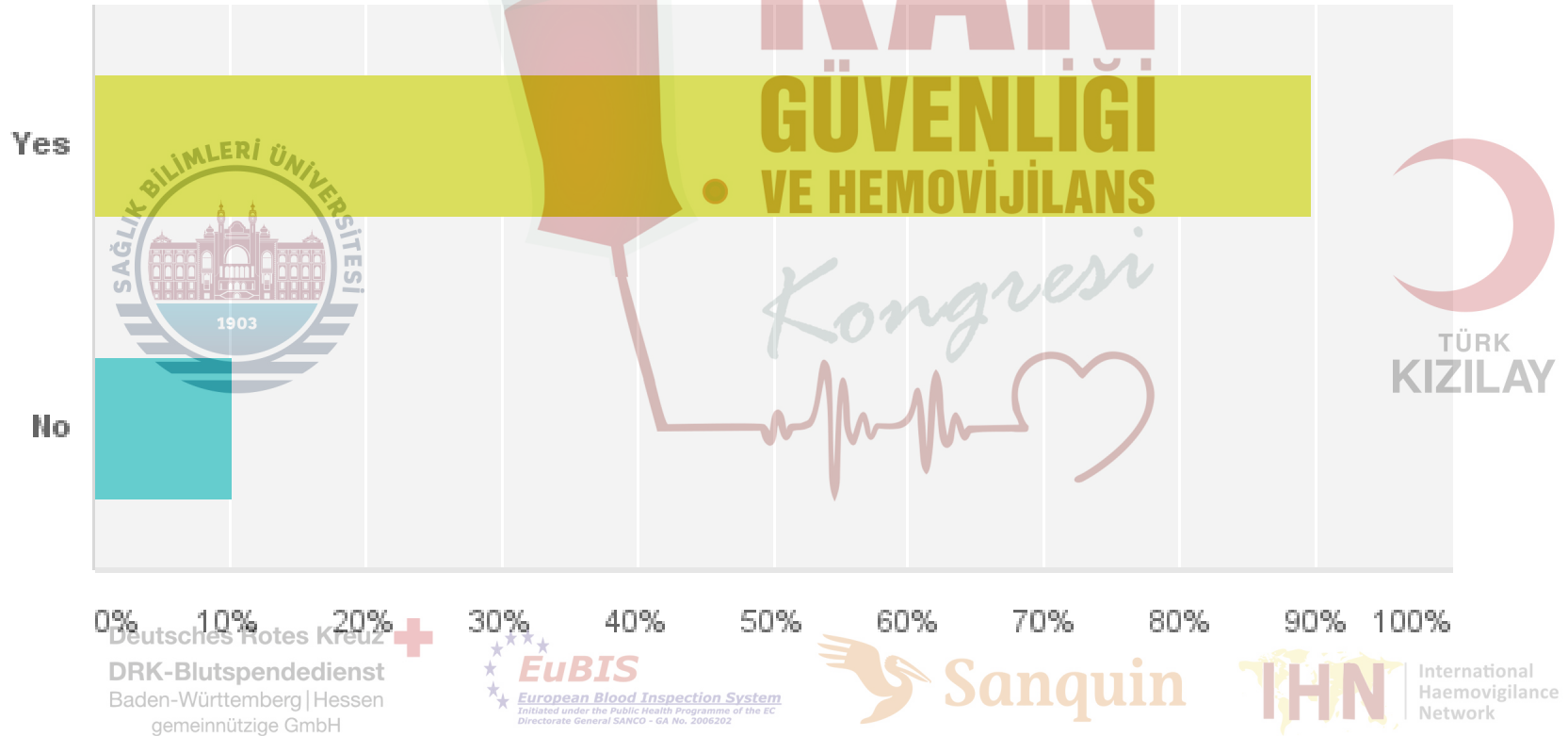
Q4: Do you have a national program of quality indicators (QI) in transfusion medicine?



Answered: 82 Skipped: 16

ISBT WP-QM SURVEY ON QUALITY INDICATORS

Q6: Do you consider the proposed ISBT quality indicators helpful for your institution?

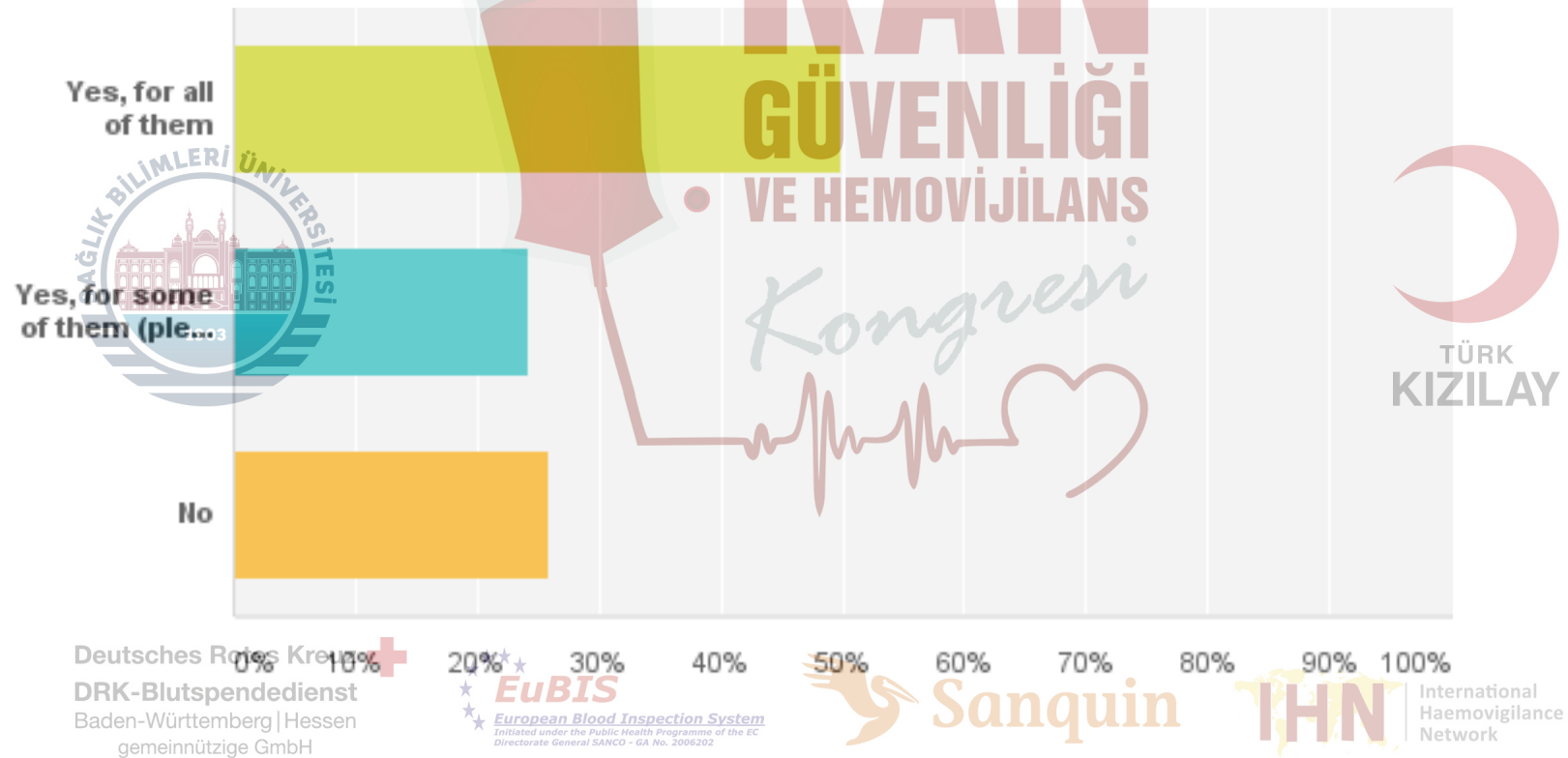


Answered: 69 Skipped: 29

ISBT WP-QM

SURVEY ON QUALITY INDICATORS

Q32: Have you established quality objectives / specifications for quality indicators in use?

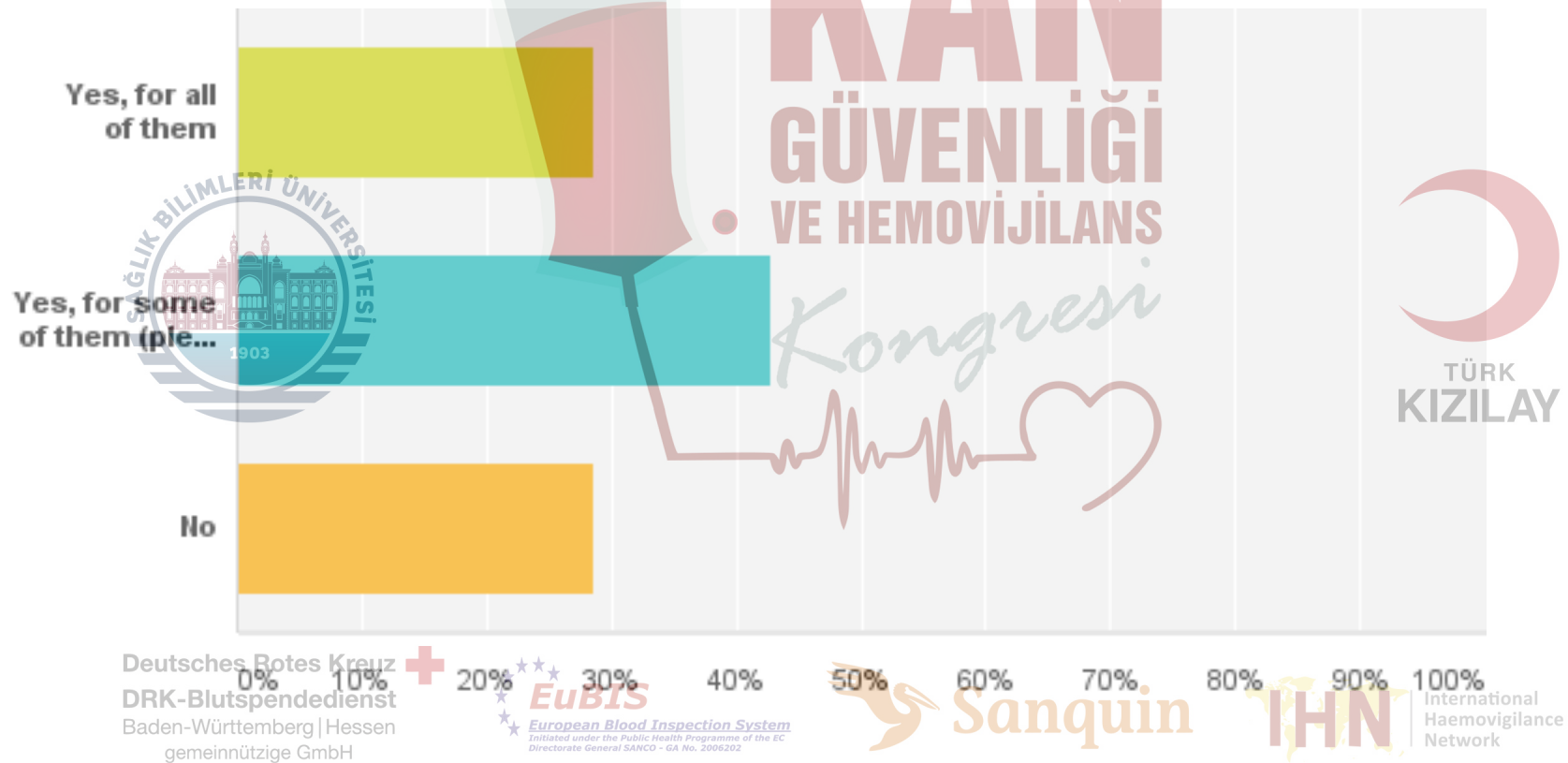


Answered: 58 Skipped: 40

ISBT WP-QM

SURVEY ON QUALITY INDICATORS

Q34: Have you established control limits (lower or upper) for quality indicators in use?

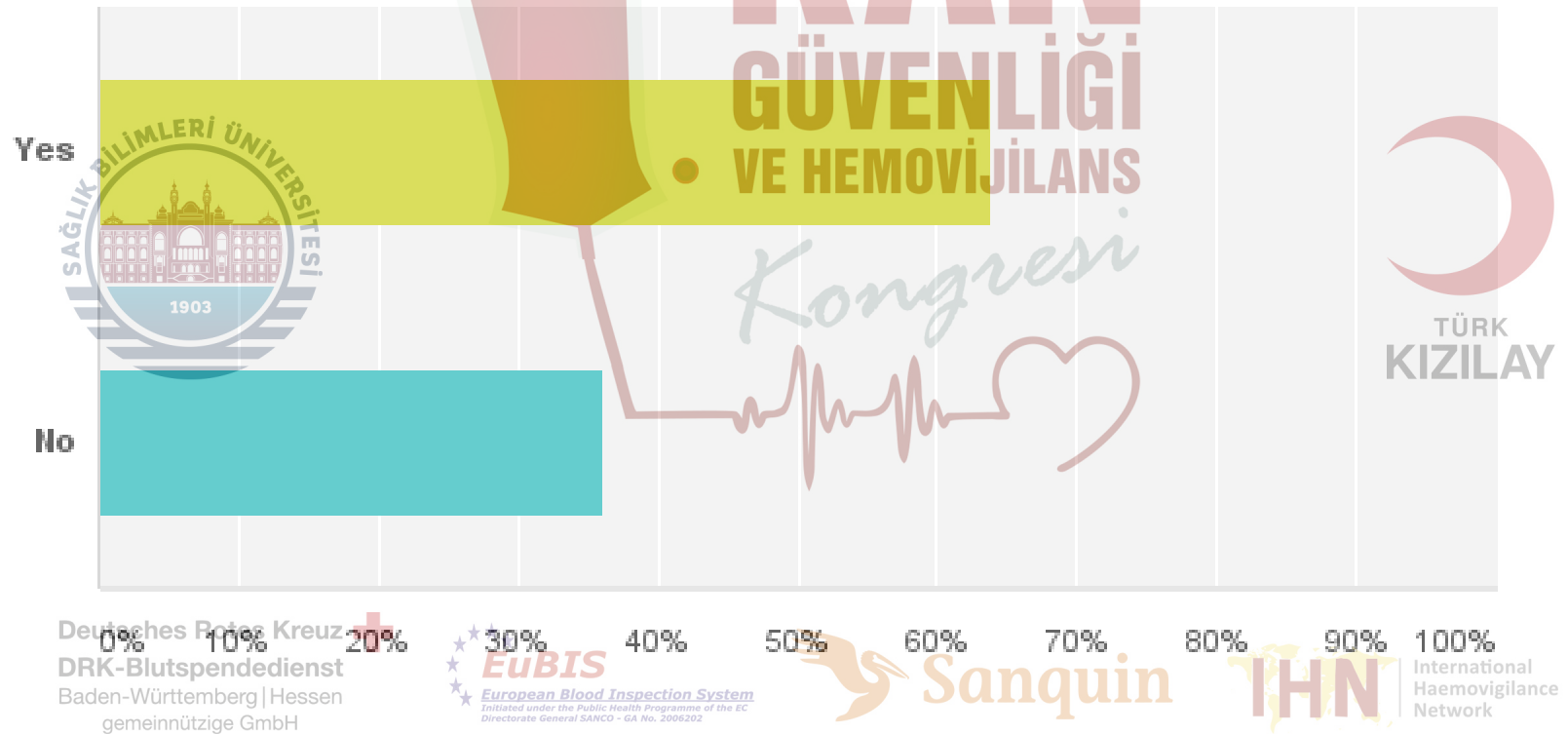


Answered: 56 Skipped: 42

ISBT WP-QM

SURVEY ON QUALITY INDICATORS

Q36: Do you have SOPs for monitoring quality indicators?

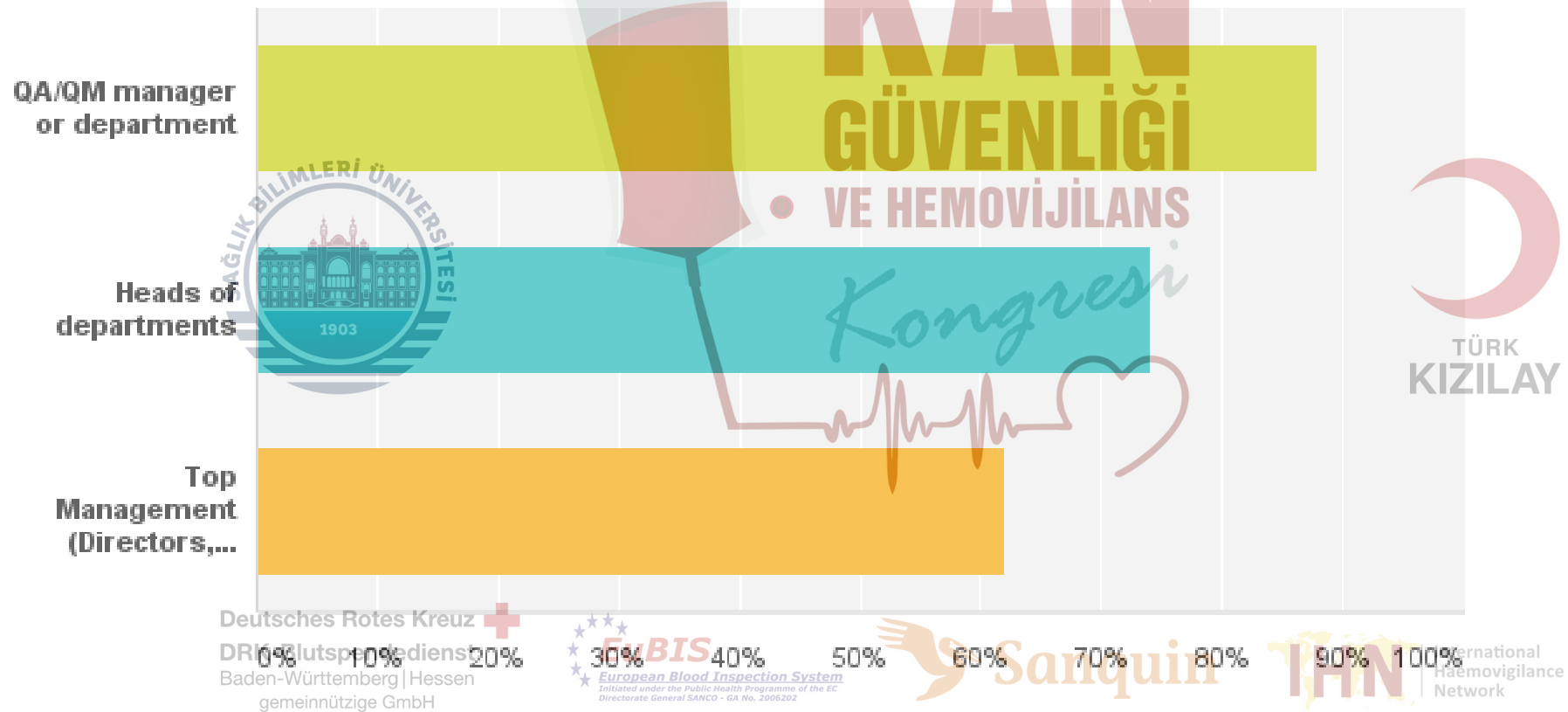


Answered: 58 Skipped: 40

ISBT WP-QM

SURVEY ON QUALITY INDICATORS

Q37: Quality indicators are monitored by (select one or more answer)



Answered: 58 Skipped: 40

ISBT QUALITY INDICATORS

- the activities undertaken to date have considerably changed the perception of QI in transfusion medicine
- QI are topic of :
 - presentations
 - articles
 - congress reports
 - graduation theses, etc.
- the activities of ISBT have greatly contributed to the increase of awareness of their role and need of their implementation and monitoring

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
- 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





THANK YOU!

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