ISBT WORKING PARTY ON QUALITY MANAGEMENT (WP-QM)

QUALITY INDICATORS FOR BLOOD ESTABLISHMENTS AND HOSPITAL BLOOD BANKS – REVISION 2023

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Quality Indicators are objective quality measures of key system elements, used to identify potential quality concerns and risks, and to monitor the changes over time. In 2012, the ISBT Working Party on Quality Management proposed and published a set of quality indicators to assist blood establishments in selection and implementation of quality indicators [1,2,3]. This document has undergone several revisions so far. The current version is supplemented with information on the importance of each quality indicator and the source data required for their calculation.

This document covers the activities of blood establishments (BE), which are collection, testing, processing, storage, release and distribution of human blood or blood components (including source plasma) when intended for transfusion or further industrial manufacturing, as well as activities of hospital blood banks (HBB), mainly related to storage, issue, compatibility tests, and hospital-based transfusion activities. However, in some hospital-based blood services HBB may additionally be engaged in blood collection, processing, and donation testing activities, and thereby function as blood establishments [4].

Quality indicators are usually expressed as a relative frequency, most commonly as a percentage. To calculate relative frequency, the numerator (observations of interest) and the denominator (total number of observations) should be defined, as demonstrated in this document. Quality indicators can also be expressed on the Six Sigma scale.

Contents

The quality indicators proposed in this document are categorized in the following groups:

- Blood donor recruitment, selection and counseling
- Blood/blood component collection
- Blood component preparation
- Donor/blood component testing
- Blood component storage/distribution/issue
- Patient service
- Quality management

BLOOD DONOR RECRUITMENT, SELECTION AND COUNSELING	
Quality indicator	**Implementation of the whole blood collection plan**
Description	Percentage of whole blood donations collected, relative to the planned number.
Importance	This indicator is a measure of success in promoting blood donation and collecting the planned number of whole blood donations, with the aim of supplying hospitals with adequate amounts of blood components.
Numerator	Number of whole blood donations collected.
Denominator	Planned number of whole blood donations.
Quality indicator	**Implementation of the plan for collecting blood components by apheresis**
Description	Percentage of apheresis donations collected, relative to the planned number. This indicator should be used separately for specific component types (blood components for clinical use, source plasma).
Importance	This indicator shows the extent to which the apheresis program can meet the needs for blood components obtained by this technology.
Numerator	Number of apheresis donations collected (according to the blood component type).
Denominator	Planned number of apheresis donations (according to the blood component type).
Quality indicator	**Donations collected from first-time donors**
Description	Percentage of donations collected from first-time donors, relative to the total number of donations.
Importance	This indicator shows the extent to which blood establishment is successful in promoting blood/blood component donation. Continuous recruitment of new donors into the donation system is a guarantee of a sustainable blood component supply.
Numerator	Total number of donations collected from first-time donors (whole blood and/or apheresis).
Denominator	Number of whole blood and/or apheresis donations.
Quality indicator	**Donor deferral rate – total**
Description	The percentage of blood donors temporarily and permanently deferred from donating whole blood and blood components using apheresis procedure. This indicator can be used separately for whole blood donations and for apheresis donations.
Importance	This indicator monitors the trend of donor deferrals over time. Deviations from the predicted frequency may indicate the need for further investigation to verify if deferral criteria are consistently and uniformly applied or if such a deviation indicates an emerging situation. Depending on the results obtained, a more detailed analysis of individual deferral reasons may be indicated. This indicator is also important in planning blood donation sessions, considering seasonal and/or epidemiological variations affecting donor deferrals.
Numerator	All donor deferrals from donating whole blood and/or blood components using apheresis procedure, regardless of the deferral reasons.
Denominator	Number of whole blood and/or apheresis donor attendances.
Quality indicator	**Donor deferral rate – temporary**
Description	The percentage of blood donors temporarily deferred from donating whole blood and blood components using apheresis procedure. This indicator can be used separately for whole blood donations and for apheresis donations.
Importance	This indicator monitors the trend of temporary donor deferrals over time. Deviations from the predicted frequency may indicate the need for the investigation to verify if deferral criteria are consistency and uniformly applied

	or if such a deviation indicates an emerging situation. Depending on the results obtained, more detailed analysis of individual deferral reasons may be indicated. This indicator is also important in planning blood donation sessions considering seasonal and/or epidemiological variations affecting donor deferrals.
Numerator	Number of temporary deferrals of blood donors from donating whole blood and/or blood components using apheresis procedure, regardless of the deferral reasons.
Denominator	Number of whole blood and/or apheresis donor attendances.
Quality indicator	**Donor deferral rate – permanent**
Description	The percentage of blood donors permanently deferred from donating blood or blood components. This indicator can be used separately for whole blood donations and for apheresis donations.
Importance	This indicator monitors the frequency of permanently deferred donors over time. Deviations from the predicted frequency may indicate the need for the investigation to verify if deferral criteria are consistently and uniformly applied, or a modification of the criteria is required.
Numerator	Number of permanently deferred donors (all donors permanently deferred from donating whole blood and/or blood components using apheresis procedure, regardless of the reasons for deferral).
Denominator	Number of whole blood and/or apheresis donor attendances.
Quality indicator	**Donor deferral due to low hemoglobin concentration**
Description	The percentage of blood donors temporarily or permanently deferred from donating blood and/or blood components, due to low hemoglobin concentration. This indicator can be used separately for whole blood donations and for apheresis donations.
Importance	This indicator monitors the trend of donor deferrals due to low hemoglobin concentration, the most common cause of blood donor temporary deferral. Deviations from the predicted frequency may indicate seasonal variations, accuracy of the methods used for hemoglobin determination, skills of the blood establishment staff, the success of strategies aimed at reducing iron loss in donors, etc.
Numerator	Deferred donors (all donor deferrals from donating whole blood and/or blood components using apheresis procedure, due to low hemoglobin concentration).
Denominator	Number of whole blood and/or apheresis donor attendances.
Quality indicator	**Post-donation information (PDI)**
Description	Percentage of donations of suspected quality/safety due to reported PDI.
Importance	PDI reflects the shortcomings, limitations, and complexity of the donor selection process. Knowledge of the causes of PDI events, their types and frequency, is a prerequisite not only for their effective management, but also for the implementation of measures to improve the selection process and the safety of donated blood.
Numerator	Number of donations of suspected quality/safety due to reported PDI.
Denominator	Number of donations collected (whole blood and apheresis donations).
Quality indicator	**Lipemic donations**
Description	Percentage of donations where the entire donation or any of the related blood components (most often plasma) was discarded due to the lipemia.
Importance	Lipemic donations reduce supply of blood component for direct clinical use and for fractionation. Donor education on dietary habits prior to blood/plasma donation is very important, not only for improving the quality of blood components but also for donor health status.

Numerator	Number of donations where the entire donation or any of the related blood components (most often plasma) was discarded due to the lipemia (whole blood and apheresis donations).
Denominator	Total number of donations: from whole blood and obtained by apheresis.
BLOOD/BLOOD COMPONENT COLLECTION	
Quality indicator	**Failed collections**
Description	Percentage of failed collections. Separate data on whole blood and apheresis donations is more informative.
Importance	Blood collection is one of the key processes in the transfusion chain affecting both donor satisfaction and blood component quality and safety. Collection failures represent one of the leading nonconformities in blood establishments. Apart from being a negative motivating factor for blood donors, they also affect the blood components supply and have a negative financial impact.
Numerator	Failed collections: 1. Venipuncture failures in the narrow sense (failure to introduce the needle into the donor's vein): no blood is collected at all. 2. Interrupted blood collection due to: a. slow (inadequate) flow b. hematoma c. donor adverse reaction d. other (technical factors...).
Denominator	Total number of donations (whole blood and/or apheresis, commenced collections).
Quality indicator	**Clots in red blood cell (RBC) components**
Description	Percentage of red blood cell components (whole blood, red cell concentrates, buffy coats) with clots, relative to the total number of whole blood donations (complete donations).
Importance	This is an important indicator for assessing the quality of blood collection process. Slow or intermittent blood flow during donation may induce clot formation and often depends on the vein selection and the position of the needle in the vein. This indicator is also used to assess the efficiency of blood mixing with anticoagulant solution on blood collection. At institutions employing manual mixing it is an indicator of correct staff technique and in case of automated scales/mixers this indicator points to the correct device operation.
Numerator	Number of RBC components with clots.
Denominator	Number of whole blood donations (complete collections).
Quality indicator	**Aggregates in platelet (PLT) concentrates obtained by apheresis**
Description	Percentage of PLT concentrates obtained by apheresis discarded due to the presence of aggregates (persistent aggregates after the mandatory rest period and throughout the storage).
Importance	This indicator points to the factors contributing to the formation of aggregates (apheresis procedure, donor related factors, storage conditions).
Numerator	Number of apheresis PLT concentrates discarded due to the presence of aggregates.
Denominator	Total number of PLT concentrates obtained by apheresis (complete collections).
Quality indicator	**Aggregates in PLT concentrates obtained from whole blood**
Description	Percentage of PLT concentrates obtained from whole blood, discarded due to the presence of aggregates (persistent aggregates after the mandatory rest period and throughout the storage).
Importance	This indicator points to the factors contributing to the formation of aggregates in whole blood-derived PLT concentrates (collection systems, temperature

	during collection and storage of whole blood, preparation method, storage conditions).
Numerator	Number of whole-blood-derived PLT concentrates discarded due to the presence of aggregates.
Denominator	Total number of PLT concentrates produced from whole blood.
Quality indicator	**Poor welds in blood collection**
Description	Percentage of donations found to be nonconforming due to the poor weld.
Importance	This indicator largely points to the process ability to meet the requirements of microbiological safety of blood components by maintaining the weld integrity. Its monitoring enables timely service or repair/renewal of the sterile welding devices, or indicates inappropriate quality, handling, or maintenance of these devices.
Numerator	Blood components with poor welds (no matter how they were detected: during collection, in process control).
Denominator	Total number of blood donations (whole blood + apheresis donation, commenced collections).
Quality indicator	**Inadequate volume of whole blood collected**
Description	Percentage of underweight or overweight whole blood collections (completed donations).
Importance	In overweight blood donations, the amount of anticoagulant is not sufficient to prevent blood clotting while in underweight units there is an excess of anticoagulant and compromised quality of blood components.
Numerator	Number of underweight or overweight whole blood collections. Failed collections where donation process has been interrupted should not be calculated.
Denominator	Total number of whole blood donations collected.
Quality indicator	**Donor adverse reactions/complications**
Description	Incidence of donor adverse reactions/complications expressed as a percentage.
Importance	For most people, donating blood and blood components is a safe and well-tolerated procedure. However, some blood donors may experience reactions or complications during or after donation. By monitoring the frequency and trends of these events it is possible to identify opportunities for improvement through the education of staff and blood donors, improved communication, and implementation of strategies proved to be effective in decreasing the incidence of such events.
Numerator	The number of donor adverse reactions/complications recorded before, during or after donation (whole blood and/or apheresis donations).
Denominator	Total number of donations (whole blood and/or apheresis, commenced donations).
BLOOD COMPONENT PREPARATION	
Quality indicator	**Nonconforming blood components**
Description	Percentage of nonconforming blood components relative to the total number of blood components produced. This indicator includes all types of blood component nonconformities and indicates the total amount of blood components discarded due to the various reasons.
Importance	The primary role of blood establishments is to ensure adequate supplies of quality and safe blood components, with minimal waste of this valuable resource. The achievement of this goal is assessed by monitoring various indicators. Reducing the number of nonconforming blood components can be achieved by modifying and optimizing the preparation process, better production planning, timely preventive maintenance of equipment, continuous

	education of staff and donors, careful stock management and other appropriate measures.
Numerator	Total number of non-conforming blood components, regardless of the non-conformity type (positive lab tests, inadequate quality, outdating, etc.).
Denominator	Total number of blood components produced including primary and modified components (filtered, washed, volume reduced, etc.), conforming and non-conforming.
Quality indicator	**Poor welds in blood component preparation**
Description	The percentage of blood components discarded due to poor welds relative to the total number of blood components produced.
Importance	This indicator largely points to the process ability to meet the requirements of microbiological safety of blood components by maintaining weld integrity. Its monitoring enables timely service or repair/renewal of the sterile welding devices or of sterile connection devices, or indicates inappropriate quality, handling, or maintenance of these devices.
Numerator	Total number of non-conforming blood components due to the poor weld in blood component preparation.
Denominator	Total number of blood components produced including primary and modified blood components (filtered, washed, volume reduced, etc.), conforming and non-conforming.
Quality indicator	**Hemolysis in whole blood**
Description	Percentage of collected whole blood with hemolysis.
Importance	Abnormal hemolysis of RBCs may occur during blood collection, transportation and processing. It may also be caused by bacterial contamination, antibodies and other factors related to blood donors. Hemolysis in blood unit can be observed by visual inspection of supernatant plasma after whole blood centrifugation.
Numerator	Number of collected whole blood with hemolytic aspect of plasma (complete collections).
Denominator	Total number of collected whole blood (complete collections).
DONOR/BLOOD COMPONENT TESTING	
Quality indicator	**Donor sample nonconformities**
Definition	Percentage of non-conforming donor samples.
Importance	Reliable and accurate results of laboratory testing are a precondition for safe transfusion treatment. Automation of laboratory testing and continuous upgrading of the test quality has resulted in high analytical process dependability, so errors generally occur in preanalytical and postanalytical phase of laboratory testing. Accordingly, the quality of donor samples and the accuracy of their labeling should be strictly controlled, each non-conformity reported, and unacceptable samples excluded from testing.
Numerator	Non-conforming blood donor samples (unacceptable due to lipemia, hemolysis, dilution, inadequate/erroneous labeling etc.).
Denominator	Total number of donor samples.
Quality indicator	**Internal quality control (IQC) failures in laboratory testing**
Definition	Quality indicator of the analytical phase of the laboratory process, monitoring the frequency of IQC results that are outside defined acceptance criteria.
Importance	IQC is an activity that monitors and evaluates the analytical process, detects errors, and ensures the reliability and accuracy of test results. A poor approach to IQC can result in validation of incorrect results or excessive investigations of falsely rejected test runs. Monitoring IQC failures and identifying their causes

	(reagents, hardware, software…) are important for timely implementation of appropriate corrective actions.
Numerator	Number of internal QC results outside defined limits.
Denominator	Total number of internal QC results.
Quality indicator	**Proficiency testing**
Definition	Percentage of correct results in proficiency testing.
Importance	Proficiency testing is important for continuous surveillance of laboratory testing performance, identification of weak points in processes and implementation of corrective actions with the final goal of improving quality and safety of transfusion.
Numerator	Correct results obtained in proficiency testing.
Denominator	Total numbers of tests performed in proficiency testing.
Quality indicator	**Positive results of bacterial screening of PLT concentrates**
Definition	Incidence of bacterial contamination of PLT concentrates.
Importance	Despite significant advances in the microbiological safety of blood components, bacterial contamination remains a threat to transfused patients and is the most common infectious risk of blood transfusion. The incidence of bacterial contamination of blood components is an indicator of the process ability to meet the requirements of microbiological safety of blood components.
Numerator	PLT concentrates confirmed to be positive on bacterial screening.
Denominator	Total number of platelet components subjected to bacterial screening.
Quality indicator	**Non-conformities in blood component quality control results**
Definition	Percentage of non-conforming quality control results relative to the total number of analyses/measurements performed.
Importance	The overall results of statistical process control are presented here with one single indicator. Although a deficiency in one product or parameter can be masked by a good overall value, monitoring this indicator is a simple way to assess the overall quality of blood components and trends in quality over time.
Numerator	The number of QC results (for example: PLT content, residual WBCs, hemoglobin content, volume, etc.), which do not comply with specified requirements.
Denominator	Total number of blood component QC results.
BLOOD COMPONENT STORAGE/DISTRIBUTION/ISSUE	
Quality indicator	**Expired PLT concentrates**
Description	Percentage of PLT concentrates discarded due to expiry.
Importance	This indicator is important in assessing the effectiveness of measures implemented for platelet stock management, including planning of collection and production, cooperation with clinicians in assessing the need for transfusion treatment, etc. This indicator should be interpreted together with indicators that assess the fulfillment of requests for PLT concentrates.
Numerator	Expired PLT concentrates (pools + apheresis components). PLT concentrates expired for the purpose of QC testing should be excluded for the calculation.
Denominator	Total number of platelet components (pools + apheresis) produced.
Quality indicator	**Expired RBC concentrates**
Description	Percentage of RBC concentrates discarded due to expiry.
Importance	This indicator is important in assessing the effectiveness of measures implemented for RBC stock management, including planning of collection and production, cooperation with clinicians in assessing the need for transfusion treatment, etc. This indicator should be interpreted together with indicators that assess the fulfillment of orders for RBC concentrates.
Numerator	Expired RBC units (excluding units expired for the purpose of QC testing).
Denominator	Total number of RBC units produced.

Quality indicator	**Realization of requests for blood components**
Description	Percentage of blood components distributed/issued in relation to the blood components requested.
Importance	This indicator assesses the degree to which a blood establishment meets the requirements for blood components set by customers.
Numerator	Number of blood components requested.
Denominator	Number of blood components distributed/issued.
Quality indicator	**Wrong blood component issue**
Description	Percentage of wrong blood components issued.
Importance	This indicator may point to a deficiency in the blood component issuing procedure. According to many studies, transfusion reactions are often caused by errors in blood component issuing. For this reason, this indicator is important in assessing the safety of transfusion practice.
Numerator	Number of wrong blood components distributed/ issued (wrong blood group or wrong blood component type).
Denominator	Total number of blood components distributed/issued.
Quality indicator	**Returned blood components**
Definition	Percentage of blood components returned for confirmed or suspected non-conformity, relative to the total number of blood components distributed/issued from the blood establishments.
Importance	This indicator refers to problems with the quality of blood components delivered to hospitals (or hospital blood banks). The blood components returned within the frame of regular stock rotation are not included in the calculation of this indicator. The pattern of this indicator is greatly influenced by the number of complaints and of blood component withdrawal/recall.
Numerator	Blood components returned because of confirmed or suspected non-conformity.
Denominator	Total number of blood components distributed/issued.
Quality indicator	**Damaged blood components**
Definition	Percentage of damaged blood components.
Importance	Blood bags can be damaged during the preparation, handling, storage and transportation of blood components. A visual inspection to assess the integrity of the packaging is extremely important. Monitoring this indicator helps in detecting the causes of damage (bag quality, handling errors, inadequate storage, etc.) and effectively removing them.
Numerator	Blood components damaged during preparation, storage and handling.
Denominator	Total number of blood components produced.
Quality indicator	**Component wastage rate (RBC concentrates, PLT concentrates, fresh frozen plasma - FFP) at the hospital**
Definition	Percentage of blood components discarded in hospitals due to non-utilization.
Importance	This indicator is important in assessing blood ordering and utilization practice. Based on the results obtained by monitoring this indicator, it is possible to implement adequate corrective action and preventive action (CAPA). They should be based on education and organizational changes aimed at responsible and rational use of blood components.
Numerator	Number of wasted units (RBC concentrates, PLT concentrates, FFP).
Denominator	Total number of units (RBC concentrates, PLT concentrates, FFP) received from the blood bank.
PATIENT SERVICE	
Quality indicator	**Patient sample non-conformities**

Definition	Percentage of non-conforming patient samples for pretransfusion testing. Sample nonconformities refer to labeling issues (unlabeled samples, sample label errors, missing information on samples) or sample quality (wrong container, insufficient sample volume, damaged samples, incorrect sample type, hemolyzed samples, samples with anticoagulant that are clotted or have inappropriate sample to anticoagulant ratio, inadequately transported or stored samples).
Importance	Reliable and accurate results of laboratory tests are of crucial importance for the safety of transfusion treatment. Adequate labeling and sample quality, prevention of errors and continuous monitoring of all activities from collection, storage and transport to receipt, inspection and processing of samples are very important in achieving this goal. The data collected by monitoring this indicator is a useful tool in the education of clinical staff who administer transfusion therapy.
Numerator	Non-conforming samples for pretransfusion testing (wrong or incomplete labeling or inadequate sample quality).
Denominator	Total number of samples for pretransfusion testing.
Quality indicator	**Non-conformities in the requests for pretransfusion testing**
Definition	The percentage of non-conforming requests for pretransfusion testing.
Importance	Reliable and accurate results of laboratory testing are a precondition of safe transfusion treatment. Accuracy and completeness of data on the requests and matching of identification data on request form and the sample label are among the most important parameters to be monitored. The data collected by monitoring this indicator is a useful tool in the education of clinical staff who administer transfusion therapy.
Numerator	Non-conforming requests for pretransfusion testing (wrong or incomplete data resulting in rejection of the request).
Denominator	Total number of requests for pretransfusion testing.
Quality indicator	**Internal quality control (IQC) failures in laboratory testing**
Definition	Quality indicator of the analytical phase of the laboratory process, monitoring the frequency of IQC results that are outside defined acceptance criteria.
Importance	IQC is an activity that monitors and evaluates the analytical process, detects errors, and ensures the reliability and accuracy of test results. A poor approach to IQC can result in validation of incorrect results or excessive investigations of falsely rejected test runs. Monitoring IQC failures and identifying their causes (reagents, hardware, software…) are important for timely implementation of appropriate corrective actions.
Numerator	Number of internal QC results outside defined limits.
Denominator	Total number of internal QC results.
Quality indicator	**Test turnaround time (TAT) – urgent requests**
Definition	Percentage of emergency laboratory tests completed within prescribed TAT (the period from receipt of the sample at the laboratory until the release of the report).
Importance	In addition to providing reliable, precise, and accurate reports, the quality of laboratory services is also measured by the timely delivery of test reports. This is especially important in emergency situations. TAT is therefore one of the key indicators of laboratory efficiency. By monitoring and analyzing TAT, the laboratory can identify factors that affect reporting time and implement measures to improve the quality of services.
Numerator	Total number of emergency laboratory tests completed within prescribed TAT.
Denominator	Total number of emergency laboratory tests.

Quality indicator	**Crossmatch/transfusion (C/T) ratio**
Definition	Crossmatch to transfusion ratio = number of units cross matched/number of units transfused.
Importance	This is an important quality indicator of blood ordering and utilization. It is used for assessment of pretransfusion test ordering appropriateness and benchmarking between departments and hospitals. Monitoring this indicator can improve the efficacy of the ordering system for cost-effective testing and minimal wastage of blood components. Note: There are also other methods available to assess efficiency of blood requesting and its utilization, as Transfusion index (TI) = number of units transfused/number of patients cross-matched) and Transfusion Probability (TP) = number of patients transfused /number of patients cross-matched x 100
Numerator	Total number of red blood cell units cross-matched.
Denominator	Total number of red blood cell units transfused.
Quality indicator	**ABO/Rh(D) discrepancies**
Definition	Differences between results of ABO/Rh(D) determination in two independent patient samples.
Importance	ABO/Rh(D) discrepancies may result from different causes, such as misidentification of patients, labeling errors, technical errors etc. It is a common practice in many blood establishments to perform ABO and Rh(D) testing of the patient on two independently collected samples. Such a policy is a precondition for the implementation of electronic cross-match, but also the measure for improving the safety of transfusion therapy. Monitoring this indicator is important for the assessment of blood transfusion safety and improvement through implementation of appropriate corrective actions.
Numerator	The number of ABO/Rh(D) discrepancies.
Denominator	Total number of patients whose ABO/Rh(D) blood type was determined two or more times.
Quality indicator	**Incorrect laboratory reports issued**
Definition	The percentage of issued laboratory reports that were found to be erroneous. The error can be discovered in the laboratory, or after a customer complaint.
Importance	Although issuing incorrect test results is a rare event, the consequences for the patient can be very serious. For this reason, maximum attention should be paid to the prevention of such events. Evaluation/validation of the results is of critical importance here. The monitoring of this indicator is important in the assessment of the overall quality and safety of the laboratory process.
Numerator	Number of incorrect reports issued by the laboratory.
Denominator	Total number of reports issued by the laboratory.
Quality indicator	**RBC units issued in emergency without testing**
Definition	The percentage of RBC units issued without pretransfusion testing due to emergency.
Importance	In patients who urgently require transfusion therapy, it is sometimes necessary to transfuse RBC products before the completion of routine pretransfusion testing. These are lifesaving procedures where benefits for the patient outweigh possible risks. Group O RBCs are typically issued to prevent hemolytic transfusion reaction due to ABO incompatibility. Emergency issuing of RBC units before completion of routine pretransfusion testing carries a risk of hemolytic transfusion reactions due to clinically significant alloantibodies.
Numerator	Number of RBC units issued in emergency without pretransfusion testing or before completion of all required tests, including ABO type, antibody detection

	test, antibody identification (if applicable) antigen typing of RBC unit and crossmatch.
Denominator	Total number of RBC units issued for transfusion therapy.
Quality indicator	**Proficiency testing**
Definition	Percentage of correct results in proficiency testing.
Importance	Proficiency testing is important for continuous surveillance of laboratory testing performance, identification of weak points in processes and implementation of corrective actions with the aim of improving quality and safety of transfusion treatment.
Numerator	Correct results obtained in proficiency testing.
Denominator	Total number of tests performed in proficiency testing.
Quality indicator	**Serious adverse reactions (SAR) in patients**
Description	Incidence of SAR in patients (expressed usually as % or n/1000). This indicator can be monitored separately for different types of blood components, for certain types of reactions or different groups of patients.
Importance	Transfusion treatment is a safe procedure, and transfusion reactions, especially serious ones, are very rare. However, some risks of transfusion treatment cannot be predicted, and some of the known risks cannot always be successfully prevented. Systematic monitoring, reporting and analysis of transfusion reactions is important in assessing the safety of transfusion treatment and the success of measures implemented with the aim of increasing the safety of blood components.
Numerator	The number of SAR recorded in transfused patients.
Denominator	Total number of blood components transfused (or issued for transfusion).
QUALITY MANAGEMENT	
Quality indicator	**Complaints on blood components**
Definition	Percentage of blood components for which complaints were received, relative to the total number of blood components distributed/issued.
Importance	Continuous customer satisfaction with the quality of products and services provided is one of the basic goals of quality management in blood establishments. Systematic recording and processing of complaints enables insight into the degree of fulfillment of customer expectations and detection of areas in which appropriate CAPA needs to be undertaken. Therefore, complaints should be considered as a valuable tool for continuous quality improvement and customer satisfaction.
Numerator	Number of blood components for which a complaint was received.
Denominator	Number of blood components distributed/ issued.
Quality indicator	**Donor complaints**
Definition	Percentage of blood donors who complained about the service provided by a blood establishment.
Importance	Blood donor satisfaction is an important factor in donor recruitment and is positively correlated with the intent to return for future donation. Donor complaints make an important indicator of customer satisfaction and results of their monitoring and analysis are essential for implementation of appropriate CAPA.
Numerator	Number of donor complaints.
Denominator	Number of donors who attended the donor center.
Quality indicator	**Serious adverse events (SAE)**
Definition	Frequency of serious adverse events recorded.
Importance	Transfusion treatment is generally a safe procedure, but there are numerous risks that can cause harm to the patient. Most SAE occur due to errors, which

	highlights the importance of root cause analysis to identify appropriate measures in avoiding SAE recurrence. Timely reporting and analysis of SAE is therefore of critical importance for assessment and improvement of transfusion safety.
Numerator	Number of SAE.
Denominator	Total number of blood components processed.
Quality indicator	**Recall/withdrawal of blood components**
Definition	Percentage of blood components recalled due to confirmed or suspected non-conformity.
Importance	This indicator is important in assessing the risk to the safety of transfusion treatment arising from the distribution of blood products for which a quality/safety problem has subsequently been identified or suspected.
Numerator	Blood components recalled due to confirmed or suspected non-conformity.
Denominator	Total number of blood components distributed/issued.
Quality indicator	**CAPA completed on time (initiated by quality department)**
Definition	Percentage of corrective/preventive actions (CAPA) initiated by quality department, completed on time.
Importance	Continuous quality improvement is a key principle and goal of QMS. Achievement of this goal depends on the timely and consistent implementation of CAPA. They are initiated to correct and prevent recurrence of existing nonconformity or prevent occurrence of potential nonconformity. Monitoring the implementation of CAPA is a tool that evaluates the effectiveness of the QMS and staff commitment to continuous quality improvement.
Numerator	CAPA completed on time.
Denominator	Total number of CAPA initiated by quality department.
Quality indicator	**Corrective actions from external audits/inspections completed on time**
Definition	Percentage of corrective actions initiated during external audits/inspections, completed on time.
Importance	Continuous quality improvement is the basic goal of QMS. Achievement of this goal depends on the timely and consistent implementation of corrective actions. They are initiated to prevent the recurrence of non-conformities, errors, deviations detected in routine practice or during internal or external audits. Monitoring the implementation of corrective measures is a tool that evaluates the functioning of the QMS and staff commitment to continuous quality improvement.
Numerator	Corrective actions from external audits/inspection completed on time.
Denominator	Total number of corrective actions initiated.
Quality indicator	**Corrective actions from internal audits completed on time**
Definition	Percentage of corrective actions initiated during internal audits, completed on time.
Importance	Continuous quality improvement is the basic goal of QMS. Achievement of this goal depends on the timely and consistent implementation of corrective measures. They are initiated to prevent the recurrence of non-conformities, errors or deviations detected in routine practice or during internal or external audits. Monitoring the implementation of corrective measures is a tool that evaluates the functioning of the QMS and staff commitment to continuous quality improvement.
Numerator	Corrective actions from internal audits completed on time.
Denominator	Total number of corrective actions initiated during internal audits.
Quality indicator	**Change controls completed on time**
Definition	Percentage of change controls completed on time.

Importance	The change control system enables timely planning, evaluation, implementation, and documentation of all changes that may affect the quality, safety and availability of blood components, as well as the safety of blood donors and patients. The timely implementation of all required activities is important for undisturbed functioning of processes in blood establishments.
Numerator	Change controls completed on time.
Denominator	Total number of change controls initiated.
Quality indicator	**Donor satisfaction / Customer satisfaction**
Definition	Donor satisfaction is a measure of donor satisfaction with the service provided by a blood establishment (availability of donation sites, kindness of the staff, comfort, hygiene, etc.). Customer satisfaction is a measure of how products or services delivered meet customer needs and expectations. This quality indicator is expressed as a percentage of responses in a donor/customer satisfaction survey with acceptable scores.
Importance	Focusing on donors/customers and meeting their needs and expectations is the highest priority of the quality system. The level to which this requirement is fulfilled can be assessed in different ways. One of the most common is a questionnaire. Based on the results obtained, blood establishments should initiate appropriate CAPA in order to improve customer satisfaction.
Numerator	Number of responses with acceptable score.
Denominator	Total number of survey responses.

References

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