

Guidelines and Recommendations

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Recommendations from the IFCC Working Group on Laboratory Errors and Patient Safety for the Global Adoption of an Essential Quality Indicators Panel in Laboratory Medicine

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Abstract

Objectives: To maximize participation in the international standardization effort, this recommendation aims to update the international guidance of the Working Group on Laboratory Errors and Patient Safety of the International Federation of Clinical Chemistry and Laboratory Medicine by identifying a limited and globally applicable panel of Essential Quality Indicators (QIs) focused on patient safety, clinical outcomes, and harmonization across medical laboratories.

Methods: Through a consensus meeting, experts from multiple countries reviewed the IFCC Model of Quality Indicators (MQI) to identify high-priority indicators. Selection prioritized the probability of patient harm, ease of detection,

and feasibility of data collection and implementation within national contexts.

Results: Six essential QIs covering the total testing process were identified and ratified: (1) rate of misidentified requests (Pre-MisR) and misidentified samples (Pre-MisS); (2) rate of sample rejections (Pre-RejS); (3) rate of hemolysis detected either by automated hemolysis index (Pre-HemI) or visual inspection (Pre-HemV); (4) rate of unacceptable results in External Quality Assessment/Proficiency Testing (Intra-Unac); (5) turnaround time of cardiac troponin at the 90th percentile for the emergency room (Post-TnTAT, Post-TnTAT clin); and (6) rate of incorrect laboratory reports (Post-RectRep). Recommendations on calculation, reporting frequency, and integration into IFCC and national comparison programs are provided.

Conclusions: The proposed essential QI panel provides a standardized and feasible framework to support its

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integration into national comparison programs and the IFCC MQI platform. Its implementation will facilitate data consolidation, strengthen the development of national and global quality specifications, and contribute to continuous improvement in patient safety.

Keywords: quality indicators; laboratory errors; patient safety

Introduction

With almost two decades of focused work on reducing laboratory errors in laboratory medicine to improve patient outcome, the Working Group on Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) published multiple recommendations. With consensus meetings organized in 2013 and 2016 and the creation and development of the Model of Quality Indicators (MQI) and the Quality Indicators Comparison Program, multiple tools are available for laboratories across the world to take action and proactively improve patient safety [1, 2]. One central piece of this work is the identification of a list of 53 quality indicators (QIs) covering the total testing process [2]. In addition to being implemented at the national level by multiple countries, the full list of QIs was implemented in the MQI platform and IFCC Quality Indicators comparison program to allow submission, comparison and benchmark of these data from laboratories across the world [3]. Quality specifications based on submitted data are available in multiple publications over the years to provide guidance on management of laboratory errors and performance [4–6].

Despite general adoption of these standardized QIs in multiple countries, participation of laboratories in the IFCC comparison initiative is still limited [3]. Users and national leaders mainly explained this limited participation by the high number of QIs that was challenging to manage, the barriers associated with data accessibility and national comparison program that have been implemented. To address this, and with the purpose of updating the international recommendations of the WG-LEPS, a consensus meeting was organized in Quebec, Canada, on June 17–18th, 2024, with the support of the IFCC and under the auspices of the Canadian Society of Clinical Chemists and the Quebec Society of Clinical Biology. Two follow-up meetings were organized to finalize the recommendations. With a strong representability of WG-LEPS members and experts from all across the world, this publication outlines our 2025 WG-LEPS

recommendations on the adoption of a key panel of essential Quality Indicators for medical laboratories.

A limited set of essential Quality Indicators should be globally adopted by medical laboratories and prioritized to drive harmonization, enhance comparability and strengthen patient safety efforts worldwide

To facilitate and maximize participation in the standardization effort, a smaller set of Quality Indicators covering the total testing process needed to be identified and promoted. This new high priority panel called the “essential QIs” needed to focus on patient safety and outcome while reducing the challenges associated with the barriers of data accuracy and accessibility for laboratories worldwide. While we strongly recommend the adoption of this essential panel, experts still recognize the value of the full panel of the MQI to be used for the selection of key QIs based on risk assessment. The adoption of these essential QIs can be considered as a first step, prior to the embracement of the broader panel.

Integration of the essential QIs in the MQI model and focus on patient outcome and value-based medicine

To be in line with the previous work done by the WG-LEPS, priority 1 QIs from the MQI guidelines were prioritized in the selection process [1]. The size of the essential QIs panel needed to be limited, not exceeding 5–6 QIs. To be consistent with the vision of the importance of the total testing process, essential QIs were identified in each phase, of the total testing process with stronger representation of the pre-analytical phase as most of errors are occurring at this level. The probability of harm for patients and ease of detection by laboratories were prioritized in the selection process. A strategy published by Shaw et al. for QIs selection was adapted and used to assess the value of potential QIs based on frequency of errors, consequence for patients and

Table 1: List of the essential Quality Indicators.

QI	Phase	Calculation	IFCC QIs
#1 Rate of misidentified requests	Pre	%: Number of misidentified requests/Total number of requests	Pre-MisR
Rate of misidentified samples		%: Number of misidentified samples/Total number of samples	Pre-MisS
#2 Rate of samples rejection	Pre	%: Number of samples rejected/Total number of samples	Pre-RejS (new)
#3 Rate of hemolysis	Pre	%: Number of samples with free hemoglobin>0.50 g/L/Number of checked samples for hemolysis	Pre-HemI (auto-mated index) Pre-HemV (Visual inspection) Intra-Unac
#4 Rate of unacceptable performance in EQA-PT schemes per year	Analytical	%: Number of unacceptable performances in EQA-PT schemes in a year/ Total number performances in EQA schemes in a year	
#5 90th percentile of turnaround time of troponin (analytical)	Pre analytical	90th percentile of TAT (min) of cardiac troponin for the ER: From sample reception in the lab to release of results	Post-TnTAT
90th percentile of turnaround time of troponin (clinical)	Post	90th percentile of TAT (min) of cardiac troponin for the ER: From blood sampling to release of results	Post-TnTATclin (new)
#6 Rate of corrected laboratory reports	Post	%: Number of corrected reports by laboratory after release/Total number of reports (requests)	Post-RectRep

Pre-MisR, misidentified requests; Pre-MisS, misidentified samples; Pre-RejS, rate of sample rejections; Pre-HemI, rate of hemolysis detected by automated hemolysis index; Pre-HemV, rate of hemolysis detected by visual inspection; Intra-Unac, rate of unacceptable results in External Quality Assessment/ Proficiency Testing; Post-TnTAT, Post-TnTAT clin, turnaround time of cardiac troponin at the 90th percentile for the emergency room; Post-RectRep, rate of incorrect laboratory reports.

detection capacity [7]. These analyses allowed the consideration of some QIs/errors with lower frequency but higher adverse clinical consequences on patients. Experience shared by WG-LEPS experts representing different national realities was also taken into consideration. Table 1 lists the 6 essential QIs that were identified and ratified by all WG-LEPS members and experts involved in the consensus meetings.

Essential QI#1 (pre-analytical): The rate of misidentified requests and misidentified samples

Based on a Failure Mode and Effects Analysis (FMEA) and opinion of experts, misidentification errors including the rate of misidentified requests and misidentified samples had the highest ranking in terms of potential adverse consequences for patients. Not only applicable for the lab processes but for the whole health system, these QIs provide a good opportunity for alignment with the hospital priorities. Pre-MisR (rate of: number of misidentified requests/total number of requests) and Pre-MisS (Rate of: number of misidentified samples/total number of samples) of the MQI were adopted without modifications. Considering that the origin of errors was not the same between misidentification on requests and samples, both QIs were selected to facilitate root cause analysis. The need for another mode of reporting

other than rate was discussed by experts as numbers are very small and limit commitment from partners to actively reduce the errors. This will be addressed in future work.

Essential QI#2 (pre-analytical): The rate of sample rejections: Pre-RejS (new)

The MQI includes a high number of priority 1 pre-analytical QIs capturing different errors leading to sample rejection. To be better aligned with patient outcome and consequence of errors, a more global essential QI was needed. In line with this goal, the rate of sample recollection, a priority 1 QI part of the outcome measure panel of the MQI, was considered. However, experts agreed on the fact that challenges of data extraction on the number of samples recollected following sample rejection were limiting the broad adoption of this QI. It was identified that the overall rate of rejected samples would be more aligned with outcomes for patients and easier to monitor for laboratories.

This global essential QI could notably include pre-analytical errors leading to sample rejection due to: samples of wrong or inappropriate sample matrix (Pre-WroTy), samples collected in wrong container (Pre-WroCo), samples with insufficient sample volume (Pre-InsV), samples with inappropriate sample-anticoagulant volume ratio (Pre-SaAnt),

samples not received (Pre-NotRec), Number of samples not properly stored before analysis, (Pre-NotSt), samples damaged during transportation (Pre-DamS), samples transported at inappropriate temperature (Pre-InTem), samples with excessive transportation time (Pre-ExcTim), contaminated samples rejected (Pre-Cont), samples rejected due to hemolysis (Pre-HemR), samples with anticoagulant clotted (Pre-Clot).

As experts acknowledged that the rate of sample rejection may vary based on national and internal policies, clear guidance on what should be included in this calculation should be provided. Furthermore, many members mentioned the challenge of having access to the number of samples in their Laboratory Information System (LIS). Despite the use of the number of tests or requests was considered as a denominator to facilitate data accessibility, the total number of samples was selected to be in line with the existing MQI pre-analytical QIs. Future collaboration with LIS companies will be needed to facilitate this process.

In addition to monitoring patient outcomes and safety, tracking the rate of rejected samples also provides clear value for hospitals by helping assess the organizational costs associated with pre-analytical errors. Strengthening collaborations with health economics experts will be a priority for WG-LEPS to better support the case for quality improvement, not only in terms of patient benefit but also in terms of institutional efficiency and resource optimization.

QI#3 (pre-analytical): The rate of hemolysis: Pre-HemI and Pre-HemV (0.50 g/L cut off)

This essential QI is designed to monitor the quality of blood sampling procedures and aligns with the MQI indicators Pre-HemV (percentage of: number of samples with free hemoglobin (Hb) >0.50 g/L detected by visual inspection/total number of checked samples for hemolysis) and Pre-HemI (percentage of: number of samples with free hemoglobin (Hb) >0.50 g/L detected by automated hemolytic index/total number of checked samples for hemolysis), which are widely used in both the MQI program and national comparison initiatives. While the use of automated HIL (hemolysis, icterus, lipemia) indices is strongly recommended by experts, the inclusion of a visual assessment QI was maintained, as many laboratories in certain countries continue to rely on visual evaluation. This indicator also offers an opportunity to strengthen collaboration with middleware providers to support broader implementation and data capture.

Essential QI#4 (analytical): Intra-Unac: Rate of unacceptable results in External Quality Assessment/Proficiency Testing (EQA/PT)

Although most errors occur in the pre and post analytical phases, it was considered essential to address the Total Testing Process by including an analytical QI. Monitoring the analytical phase was identified as a high priority to ensure accurate test results and reduce laboratory errors. The selected indicator, Intra-Unac (percentage of: number of unacceptable performances in EQAS-PT schemes, per year/total number of performances in EQA schemes, per year), is also directly aligned with laboratory accreditation requirements. Experts discussed several limitations, including discrepancies between external quality assessment (EQA) programs, such as differences in group size, comparison models, and the use of commutable samples, which will need to be considered. Strengthening collaboration with proficiency testing providers was highlighted as a key priority to support the implementation of this QI. Intra-Unac may also serve as an entry point for broader integration of IFCC extra analytical QIs into external quality assessment frameworks.

Essential QI#5 (pre, analytical and post-analytical): Turnaround time of cardiac troponin (TnI or TnT) at the 90th percentile for the emergency room from reception in the laboratory to release of result (Post-TnTAT) and from blood sampling to release of result (Post-TnTAT clin)

QIs assessing the turnaround time of laboratory testing are broadly used globally and have a very high level of participation in the MQI comparison programs and national initiatives. These metrics assess multiple parameters of laboratory processes, aligning directly with the quality and efficiency of patient care. In line with our priority to focus on patient safety and outcomes, turnaround time (TAT) for the measurement of cardiac troponins for the emergency room

(ER) was selected in the MQI list and complemented with an additional QI. Post-TnTAT measures the 90th percentile of TAT (minutes) from sample reception in the laboratory to release of results to the stakeholders for results which require a short TAT (STAT) and is highly useful to assess laboratory processes for urgent testing. Post-TnT does, however, not reflect the whole processes including steps before reception in the lab and after release of results including consequent actions undertaken by the requesting physician. Therefore, considering the primary focus on direct patient outcomes, the experts agreed that the total testing process for cardiac troponins measurement needs to be better assessed. A second QI measuring the 90th percentile of TAT (minutes) from blood sampling to release of result was also integrated into the essential QIs list. Challenges related to availability of accurate blood sampling time data in many laboratories were acknowledged. This new QI is of high value for outcomes and patient safety but remains optional for laboratories that cannot yet access accurate data on blood sampling time. Improving the traceability of sampling time should remain a priority for these laboratories to enable future integration of this QI.

Essential QI#6 (post-analytical): Post-RectRep: Rate of incorrect laboratory reports and consideration of communication of critical results (Post-InsCR)

Two QIs were considered for monitoring the post-analytical phase. Although the notification of critical results (Post InsCR) was acknowledged as having a strong impact on patient outcomes, experts highlighted major limitations in current data accessibility. In fact, most laboratories do not have easy access to data on critical value communication, which significantly limits their capacity to participate. As a result, despite its clinical relevance, this QI was not included in the list of essential QIs at this stage. Targeted efforts will be made in 2025 and 2026 to collaborate with LIS providers to improve data traceability and enable its future implementation.

Conversely, the QI related to the rate of corrected reports (Post-RectRep) was selected and formally included in the list of essential QIs. It is well recognized that errors in laboratory reports can have a direct and significant impact on patient safety. Furthermore, monitoring of corrected reports is aligned with requirements of laboratory accreditations. This QI was considered both clinically relevant and feasible to implement across laboratories, supporting its

prioritization within the MQI framework. As stated in the MQI framework, reports may be corrected due to erroneous results, inappropriate or missing interpretative comments, or incorrect patient identification details. Clear guidance will be needed to ensure consistent and standardized data collection. In line with the MQI this QI should be calculated as the percentage of corrected reports after release on the number of reports (requests) (Post-RectRep).

Applicability of the essential QIs in the IFCC and national comparison initiatives

The identification of a limited set of essential QIs, in line with patient safety and outcome, is expected to consolidate international efforts, maximize participation in both IFCC and national comparison programs, and significantly increase the number of laboratories contributing to the development of robust quality specifications. While this focused panel supports global harmonization and feasibility, the full list of QIs within the MQI framework remains entirely legitimate and should continue to be used by laboratories based on their specific needs and risk assessments. To strengthen adherence to benchmarking initiatives and enable meaningful data aggregation for generation of global quality specifications by the IFCC, the frequency of data submission for these essential QIs has been reduced within the MQI program to three times per year, aligned with some existing QIs. This adjustment was made to facilitate participation and to increase the number of laboratories contributing to each comparison cycle, thereby enhancing the statistical robustness of performance benchmarks. A triannual reporting cycle is therefore recommended for all essential QIs, except for the rate of unacceptable performance in EQA/PT (Intra-Unac), which should be collected and analyzed on an annual basis (Table 2). In parallel, ongoing efforts are being made to streamline data exchange between national initiatives and the IFCC program, with the objective of improving data consolidation and strengthening the validity of global quality specifications.

Applicability of essential QIs across laboratory disciplines and opportunities for expansion

Among the six essential QIs identified, four were recognized as broadly applicable across multiple fields of laboratory

Table 2: Recommended frequency of evaluation to support standardized implementation of the essential QIs in the comparison programs.

QI	IFCC QIs	Evaluation schedules
#1 Rate of misidentified requests	Pre-MisR	Data collection: Everyday for a month
Rate of misidentified samples	Pre-MisS	April – August – December
#2 Rate of samples rejection	Pre-RejS (new)	
#3 Rate of hemolysis	Pre-HemI (automated index)	
	Pre-HemV (Visual inspection)	
#5 90th percentile of turnaround time of troponin (analytical)	Post-TnTAT	
90th percentile of turnaround time of troponin (clinical)	Post-TnTATclin (new)	
#6 Rate of corrected laboratory reports	Post-RectRep	
#4 Rate of unacceptable performance in EQA-PT schemes per year	Intra-Unac	Data collection: Every year

Pre-MisR, misidentified requests; Pre-MisS, misidentified samples; Pre-RejS, rate of sample rejections; Pre-HemI, rate of hemolysis detected by automated hemolysis index; Pre-HemV, rate of hemolysis detected by visual inspection; Intra-Unac, rate of unacceptable results in External Quality Assessment/Proficiency Testing; Post-TnTAT, Post-TnTAT clin, turnaround time of cardiac troponin at the 90th percentile for the emergency room; Post-RectRep, rate of incorrect laboratory reports.

medicine. These include: the rate of misidentified requests and samples (Pre-MisR and Pre-MisS, QI#1), the overall sample rejection rate (Pre-RejS, QI#2), the rate of unacceptable results in external quality assessment or proficiency testing (Intra-Unac, QI#4), and the rate of corrected laboratory reports (Post-RectRep, QI#6). These indicators are not specific to clinical chemistry and can be meaningfully implemented in other disciplines such as hematology, pathology, microbiology, transfusion medicine, molecular diagnostics, immunology and others. Their broader adoption supports consistency in quality monitoring across laboratory specialties and fosters a system-wide approach to improving patient safety. Experts also emphasized the potential to enhance the essential QI panel by incorporating discipline-specific TAT indicators. As an example, in hematology, the MQI includes a discipline-specific TAT indicator Post-WBCTAT for the TAT for white

blood cell count at the 90th percentile, which can be used to evaluate timely reporting of urgent tests. Beyond hematology, other easy and clinically significant tests could also be identified for the development of discipline-specific QIs relevant to various fields of laboratory medicine. The WG-LEPS strongly encourages future collaborations with international scientific societies representing microbiology, pathology, transfusion medicine, molecular diagnostics, and others. These partnerships will be essential to enrich the MQI framework by identifying key indicators that reflect the clinical priorities, workflows, and quality challenges unique to each discipline. Such efforts will support the broader vision of the WG-LEPS to establish a harmonized, yet adaptable, set of QIs that strengthen quality assurance across the full spectrum of laboratory services.

Conclusions

This panel of essential quality indicators strongly aligned with the core principles of value-based medicine [8]. It focuses on maximizing clinical impact by prioritizing indicators that reflect patient outcomes and clinical needs, while also ensuring feasibility through automation and ease of detection. By enhancing traceability across the total testing process (TTP) and promoting standardized data collection, this approach enables more effective benchmarking and supports continuous quality improvement across laboratories, ultimately reinforcing patient safety. As quality indicators are a moving target in laboratory medicine, their aim is to provide effective benchmark, evidence of quality levels and allow improvement initiatives as technological, organizational and professional issues developments require continuous reappraisal and improvement of the indicators [9]. To achieve this, concerted efforts and clear guidance will be required to ensure standardization and high-quality benchmarking for each quality indicator.

As a first step toward international implementation, a call to action is made to national societies to actively collaborate in the promotion and adoption of the essential QIs panel. This involves integrating the panel into national comparison programs, contributing to the development of national quality specifications and participating in the MQI model and comparison platform. National Quality specifications should be shared with the WG-LEPS of the IFCC to support the establishment of robust quality benchmarks, built on standardized, high-quality data from a large and internationally representative cohort of laboratories. All of these efforts ultimately converge toward a common purpose,

collectively reducing laboratory errors through value-based medicine to ensure patient safety.

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