

**International Federation of Clinical Chemistry and Laboratory Medicine  
Working Group “Laboratory Errors and Patient Safety”**

**MODEL OF QUALITY INDICATORS**

The Model of Quality Indicators has been updated on the basis of the recent Consensus Conference “Harmonization of Quality indicators in Laboratory Medicine: Two years later” held in Padova in the October 2016, and a priority score was designed to highlight the value of the individual QI for assessing not only the quality of the service and possible effects on patient safety, but also the feasibility of data collection (order of priority: 1 = mandatory; 2 = important; 3 = suggested; 4 = valued).

<b>KEY PROCESSES</b>					
<b>QUALITY INDICATORS – PRIORITY 1</b>					
<b>Quality Indicator</b>	<b>Code</b>	<b>Reporting Systems</b>	<b>Data Collection</b>	<b>Time</b>	<b>Explanatory Note</b>
<b>PRE-ANALYTICAL</b>					
<b>Misidentification errors</b>	Pre-MisR	Percentage of: Number of misidentified requests / Total number of requests.	a) count misidentified requests b) count total number of requests c) calculate percentage	Data collection: Every day; Input data: Monthly	
	Pre-MisS	Percentage of: Number of misidentified samples / Total number of samples.	a) count misidentified samples b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly	
<b>Test transcription errors</b>	Pre-LabTDE	Percentage of: Number of requests with erroneous data entered by laboratory personnel / Total number of requests entered by laboratory personnel.	a) count the requests with erroneous data entered by laboratory personnel b) Total number of requests entered by laboratory personnel c) calculate percentage	Data collection: Every day or a week per month; Input data: Monthly	Laboratory personnel = personnel that are under the laboratory control
	Pre-OffTDE	Percentage of: Number of requests with erroneous data entered by offside personnel / Total number of requests entered by offside personnel.	a) count the requests with erroneous data entered by offside personnel b) Total number of requests entered by offside personnel c) calculate percentage	Data collection: Every day or a week per month; Input data: Monthly	Offside personnel = personnel that are not under the laboratory control
<b>Incorrect sample type</b>	Pre-WroTy	Percentage of: Number of samples of wrong or inappropriate sample matrix (e.g. whole blood instead of plasma) / Total number of samples.	a) count samples of wrong or inappropriate type (i.e. whole blood instead of plasma) b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly	
	Pre-WroCo	Percentage of: Number of samples collected in wrong container / Total number of samples.	a) count samples collected in wrong container b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly	

<b>Incorrect fill level</b>	Pre-InsV	Percentage of: Number of samples with insufficient sample volume / Total number of samples.	a) count samples with insufficient sample volume b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly	Insufficient = when the sample volume is less than that requested independently of the possibility to perform the test. It has to measure the incorrect collection (volume inferior than defined), independently of collected volume (50% or 80 % or 90%) Samples of paediatric patients have to be excluded.
	Pre-SaAnt	Percentage of: Number of samples with inappropriate sample-anticoagulant volume ratio / Total number of samples with anticoagulant.	a) count samples with inappropriate sample-anticoagulant volume ratio b) count total number of samples with anticoagulant c) calculate percentage	Data collection: Every day; Input data: Monthly	
<b>Unsuitable samples for transportation and storage problems</b>	Pre-NotRec	Percentage of: Number of samples not received / Total number of samples.	a) count samples not received b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly	
	Pre-NotSt	Percentage of: Number of samples not properly stored before analysis / Total number of samples.	a) count samples not properly stored before analysis b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly	
	Pre-DamS	Percentage of: Number of samples damaged during transportation / Total number of transported samples.	a) count samples damaged during transportation b) count total number of transported samples c) calculate percentage	Data collection: Every day; Input data: Monthly	
	Pre-InTem	Percentage of: Number of samples transported at inappropriate temperature / Total number of samples.	a) count samples transported at inappropriate temperature b) count total number of samples for which the transport temperature is checked c) calculate percentage	Data collection: Every day; Input data: Monthly	This QI has to be collected if the transportation temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature.
	Pre-ExcTim	Percentage of: Number of samples with excessive	a) count samples with excessive transportation	Data collection: Every	This QI has to be collected if the transportation time is

		transportation time / Total number of samples.	time b) count total number of samples for which the transport time is checked c) calculate percentage	day; Input data: Monthly	measured through appropriate measuring devices or a procedure that guarantees the detection of the times.
<b>Contaminated samples</b>	Pre-MicCon	Percentage of: Number of microbiological contaminated samples rejected / Total number of microbiological samples.	a) count microbiological contaminated samples rejected b) count total number of microbiological samples c) calculate percentage	Data collection: Every day; Input data: Monthly	Microbiological samples: blood culture, urine, sputum, pharyngeal, etc.
	Pre-Cont	Percentage of: Number of contaminated samples rejected / Total number of not microbiological samples.	a) count contaminated samples rejected b) count total number of blood culture samples c) calculate percentage	Data collection: Every day; Input data: Monthly	Contaminated samples = samples which are contaminated by infusion, drugs, anticoagulants (EDTA, citrate), parenteral nutrition, X-ray contrast material, etc.
<b>Haemolysed sample</b>	Pre-HemV	Percentage of: Number of samples with free haemoglobin (Hb) >0.5 g/L detected by visual inspection / Total number of checked samples for haemolysis	a) count samples with free Hb>0.5 g/L detected by visual inspection b) count total number of checked samples for haemolysis c) calculate percentage	Data collection: Every day; Input data: Monthly	Checked samples = all samples verified for haemolysis have to be included (clinical chemistry, immunochemistry, coagulation, etc.).
	Pre-HemI	Percentage of: Number of samples with free haemoglobin (Hb) >0.5 g/L detected by automated haemolytic index / Total number of checked samples for haemolysis.	a) count samples with free Hb>0.5 g/L detected by automated index haemolysis b) count total number of checked samples for haemolysis c) calculate percentage	Data collection: Every day; Input data: Monthly	Checked samples = all samples verified for haemolysis have to be included (clinical chemistry, immunochemistry, coagulation, etc.).
	Pre-HemR	Percentage of: Number of samples rejected due to haemolysis / Total number of checked samples for haemolysis.	a) count samples rejected due to haemolysis b) count total number of checked samples for haemolysis c) calculate percentage	Data collection: Every day; Input data: Monthly	Checked samples = all samples verified for haemolysis have to be included (clinical chemistry, immunochemistry, coagulation, etc.).
<b>Clotted samples</b>	Pre-Clot	Percentage of: Number of samples clotted / Total number of samples with an anticoagulant checked	a) count samples clotted b) count total number of samples with an	Data collection: Every day;	Checked samples = all samples verified for clots

		for clots.	anticoagulant checked for clots c) calculate percentage	Input data: Monthly	have to be included (haematology, coagulation clinical chemistry, etc.)
<b>INTRA-ANALYTICAL PHASE</b>					
<b>Test uncovered by an IQC</b>	Intra-IQC	Percentage of: Number of tests without IQC / Total number of tests in the menu.	a) count number of tests without IQC b) count total number of tests in the menu c) calculate percentage	Data collection: Every year; Input data: December	IQC: Internal Quality Control.
<b>Unacceptable performances in IQC</b>	Intra-UnIQC	Percentage of: Number of IQC results outside defined limits / Total number of IQC results	a) count number of IQC results outside defined limits b) count total number of IQC results c) calculate percentage	Data collection: Every day; Input data: Monthly	IQC: Internal Quality Control.
<b>Test uncovered by an EQA-PT control</b>	Intra-EQA	Percentage of: Number of tests without EQA-PT control / Total number of tests in the menu.	a) count number of tests without EQA-PT control b) count total number of tests in the laboratory menu c) calculate percentage	Data collection: Every year; Input data: December	EQA: External Quality Assessment; PT: Proficiency Testing.
<b>Unacceptable performances in EQA-PT schemes</b>	Intra-Unac	Percentage of: Number of unacceptable performances in EQAS-PT Schemes, per year / Total number of performances in EQA Schemes, per year.	a) count number of unacceptable performances in EQA Schemes b) count total number of performances in EQA Schemes c) calculate percentage	Data collection: Every year; Input data: December	EQA: External Quality Assessment; PT: Proficiency Testing.
<b>Data transcription errors</b>	Intra-ErrTran	Percentage of: Number of incorrect results for erroneous manual transcription / Total number of results that need manual transcription.	a) count incorrect results for erroneous manual transcription b) count results that need manual transcription c) calculate the percentage	Data collection: Every day; Input data: Monthly	
	Intra-FailLIS	Percentage of: Number of incorrect results for information system problems / Total number of results.	a) count incorrect results for information system problems b) count total number of results c) calculate the percentage	Data collection: Every day; Input data: Monthly	
<b>POST-ANALYTICAL PHASE</b>					
<b>Inappropriate turnaround times</b>	Post-OutTime	Percentage of: Number of reports delivered outside the specified time / Total number of reports.	a) count reports delivered outside specified time b) count total number of reports c) calculate the percentage	Data collection: Every day; Input data: Monthly	Specified time = this concerns the reports (not results)
	Post-PofTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of Potassium (K) at 90 <sup>th</sup> percentile (STAT).	a) estimate all TAT (minutes), from sample reception in laboratory to release of result, of Potassium (K) at 90 <sup>th</sup> percentile (STAT) released in the month	Data collection: Every day per a month - three months per year;	

		b) estimate the 90 <sup>th</sup> percentile	Input data: April - August - December	
	Post-INRTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of International Normalized Ratio (INR) value at 90 <sup>th</sup> percentile (STAT). a) estimate all TAT (minutes) , from sample reception in laboratory to release of result, of International Normalized Ratio (INR) (STAT) released in the month b) estimate the 90 <sup>th</sup> percentile	Data collection: Every day per a month - three months per year; Input data: April - August - December	
	Post-WBCTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of White Blood Cell (WBC) count at 90 <sup>th</sup> percentile (STAT). a) estimate all TAT (minutes) , from sample reception in laboratory to release of result, of White Blood Cell (WBC) count ( STAT) released in the month b) estimate the 90 <sup>th</sup> percentile	Data collection: Every day per a month - three months per year; Input data: April - August - December	
	Post-TnTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of Cardiac Troponin (TnI or TnT) at 90 <sup>th</sup> percentile (STAT). a) estimate all TAT (minutes) , from sample reception in laboratory to release of result, of Cardiac Troponin I (TnI or TnT) (STAT) released in the month b) estimate the 90 <sup>th</sup> percentile	Data collection: Every day per a month - three months per year; Input data: April - August - December	
	Post-TATPotH	Percentage of: Number of Potassium results (STAT) released after 1 hour/Total number of Potassium results (STAT) a) count number of Potassium results (STAT) released after 1 hour b) count total number of Potassium results (STAT) c) calculate the percentage	Data collection: Every day; Input data: Monthly	
<b>Incorrect laboratory reports</b>	Post-RectRep	Percentage of: Number of rectified reports by laboratory after the release / Total number of released reports. a) count number of rectified reports after the release b) count total number of released reports c) calculate the percentage	Data collection: Every day; Input data: Monthly	For example: Reports could be rectified for erroneous results or inappropriate/missed interpretative comments or wrong patient's details, etc
<b>Notification of critical results</b>	Post-InsCR	Percentage of: Number of critical results of inside patients notified after a consensually agreed time (from result validation to result communication to the clinical ward) / Total number of critical results of inside patients to communicate. a) count critical results of inside patients notified after a consensually agreed time (from result validation to result communication to the clinical ward) b) count total number of critical results of inside patients to communicate c) calculate percentage	Data collection: Every day for a month - three months per year; Input data: April - August - December	Critical results = results that are so "extremely" abnormal and are considered life threatening because they may be associated with a significant dangerous event unless a medical action is promptly established. Consensually agreed time = time established by laboratory in which the critical result has to be effectively reported to the

					clinical ward. Inside patients = hospitalized Patients
	Post-OffCR	Percentage of: Number of critical results of offside patients notified after a consensually agreed time (from result validation to result communication to the general practitioner) / Total number of critical results of offside patients to communicate.	a) count critical results of offside patients notified after a consensually agreed time (from result validation to result communication to the general practitioner) b) count total number of critical results of offside patients to communicate c) calculate percentage	Data collection: Every day for a month - three months per year; Input data: April - August - December	Critical results = results that are so “extremely” abnormal and are considered life threatening because they may be associated with a significant dangerous event unless a medical action is promptly established. Consensually agreed time = time established by laboratory in which the critical result has to be effectively reported to the general practitioner Offside patients = not hospitalized Patients

**KEY PROCESSES**  
**QUALITY INDICATORS – PRIORITY 2**

Quality Indicator	Code	Reporting Systems	Data Collection	Time	Explanatory Notes
<b>PRE-ANALYTICAL</b>					
<b>Inappropriate test requests</b>	Pre-OffQue	Percentage of: Number of requests without clinical question (offside patients) / Total number of requests (offside patients)	a) count requests without clinical question (offside patients) b) count total number of requests question (offside patients) c) calculate percentage	Data collection: A week per month - three months per year; Input data: April - August - December	Offside patients = not hospitalized patients
<b>Inappropriate time in sample collection</b>	Pre-InTime	Percentage of: Number of samples collected at inappropriate time of sample collection / Total number of samples requiring a specified time for data collection.	a) count samples collected at inappropriate time of sample collection b) count total number of samples requiring a specified time for data collection. c) calculate percentage	Data collection: Every day; Input data: Monthly	This QI has to be collected if time of sample collection is required (e.g. Cortisol).

**KEY PROCESSES**  
**QUALITY INDICATORS – PRIORITY 3**

Quality Indicator	Code	Reporting Systems	Data Collection	Time	Explanatory Notes
<b>PRE-ANALYTICAL</b>					
<b>Unintelligible requests</b>	Pre-OffUn	Percentage of: Number of unintelligible offside patients requests / Total number of offside patients requests	a) count unintelligible offside patients requests b) count total number of offside patients requests c) calculate percentage	Data collection: A week per month; Input data: Monthly	Offside patients = not hospitalized patients
	Pre-InsUn	Percentage of: Number of unintelligible inside patients requests / Total number of inside patients requests	a) count unintelligible inside patients requests b) count total number of inside patients requests c) calculate percentage	Data collection: A week per month; Input data: Monthly	Inside patients = hospitalized patients



**KEY PROCESSES**  
**QUALITY INDICATORS – PRIORITY 4**

<b>Quality Indicator</b>	<b>Code</b>	<b>Reporting Systems</b>	<b>Data Collection</b>	<b>Time</b>	<b>Explanatory Notes</b>
<b>PRE-ANALYTICAL</b>					
<b>Inappropriate test requests</b>	Pre-OffReq	Percentage of: Number of inappropriate requests, with respect to clinical question (offside patients) / Number of requests reporting clinical question (offside patients)	a) select and count offside patients requests with clinical question b) count the selected requests with inappropriate tests in relation to clinical question and on the basis of guidelines and scientific recommendations c) calculate percentage	Data collection: A week per month - three months per year; Input data: April - August - December	Offside patients = not hospitalized patients
	Pre-InsReq	Percentage of: Number of inappropriate requests, with respect to clinical question (inside patients) / Number of requests reporting clinical question (inside patients)	a) select and count inside patients requests with clinical question b) count the selected requests with inappropriate tests in relation to clinical question and on the basis of guidelines and scientific recommendations c) calculate percentage	Data collection: A week per month - three months per year; Input data: April - August - December	Inside patients = hospitalized patients
<b>POST-ANALYTICAL</b>					
<b>Notification of critical results (TAT)</b>	Post-InsCRT	Median value of time (from result validation to result communication to the clinical ward) to communicate critical results of inside patients (minutes)	a) estimate the time (minutes) to communicate critical results of inside patients b) calculate the median value of estimated times	Data collection: Every day for a month - three months per year; Input data: April - August - December	Critical results = results that are so “extremely” abnormal and are considered life threatening because they may be associated with a significant dangerous event unless a medical action is promptly established. Inside patients = hospitalized Patients.
	Post-OffCRT	Median value of time (from result validation to result communication to the general practitioner) to communicate critical results of offside patients (minutes)	a) estimate the time (minutes) to communicate critical results of offside patients b) calculate the median value of estimated times	Data collection: Every day for a month - three months per year; Input data: April - August - December	Critical results = results that are so “extremely” abnormal and are considered life threatening because they may be associated with a significant dangerous event unless a medical action is promptly established. Offside patients = not hospitalized Patients

<b>Interpretative comments</b>	Post-Comm	Percentage of: Number of reports with interpretative comments impacting positively on patient's outcome / Total number of reports with interpretative comments	a) select a test, or group of tests, that often requires a comment for the correct interpretation of the result b) select a clinical ward and contact a physician in order to analyse together the reports with interpretative comments c) evaluate the clinical actions undertaken on the basis of interpretative comments d) evaluate the patients outcome e) count the positive outcomes f) count the total number of reports with interpretative comments g) calculate the percentage	Data collection: A week per month - three months per year; Input data: April - August - December	
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