How to monitor the quality of the pre-analytical phase?

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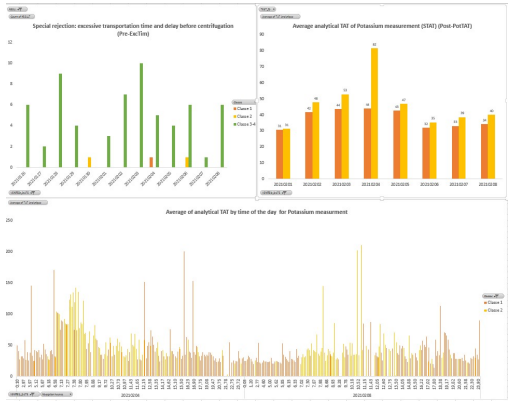
Conflict of interest disclosure

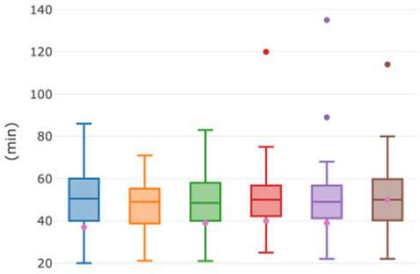
Nothing to disclose.

Let’s start with the conclusion!

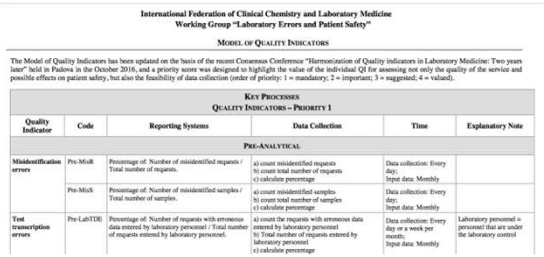
Be proactive, monitor your pre-analytical processes with QIs



Improve your processes through comparison



Get in line with the international guidelines



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

MODEL OF QUALITY INDICATORS

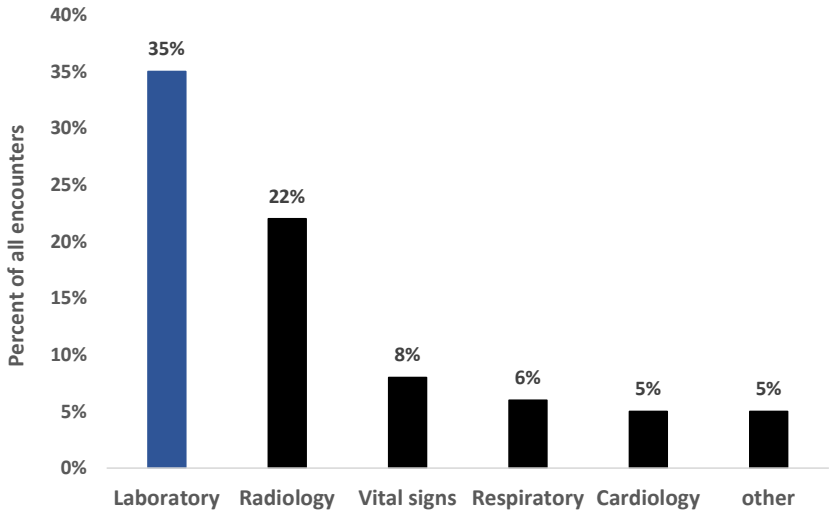
The Model of Quality Indicators has been updated on the basis of the recent Consensus Conference “Harmonization of Quality indicators in Laboratory Medicine: Two years later” held in Padova in the October 2016, and a priority score was designed to highlight the value of the individual QI for assessing 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).

KEY PROCESSES
QUALITY INDICATORS – PRIORITY 1

Quality Indicator	Code	Reporting Systems	Data Collection	Time	Explanatory Note
PRE-ANALYTICAL					
Misidentification errors	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	
Test transcription errors	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

Beside all the challenges we are facing, (COVID-19, pressure for cost reductions, lack of staff …) the patients' safety and quality of care is our priority

More than 35% of medical decisions are based on laboratory testing: As laboratory professionals and directors we have the responsibility to guarantee quality results for each and every patients.



Adapted from 10.1373/jalm.2016.021634 Published December 2016

What is the definition of quality in laboratory medicine

Dr Mario Plebani
Chair of the WG-LEPS, IFCC

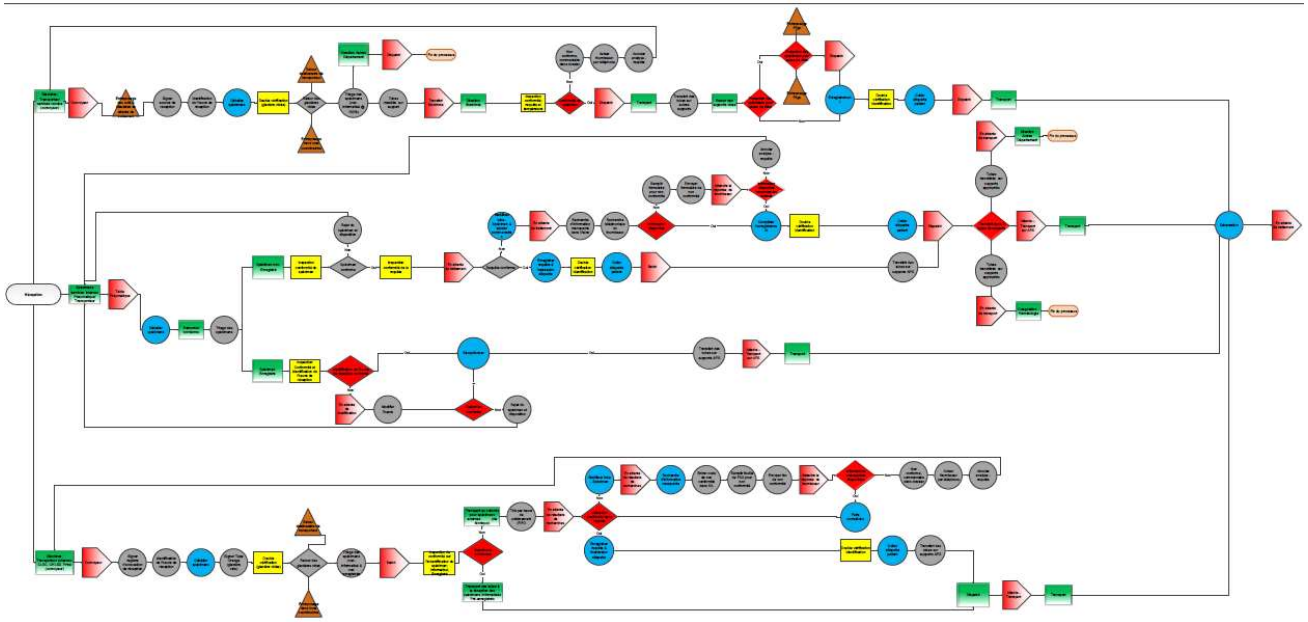
"Quality in laboratory medicine should be defined as the guarantee that each and every step in the total testing process is correctly performed, thus ensuring valuable decision making and effective patient care."

"Wrongs" anywhere compromise test result quality and patients' safety!"

Plebani M. Clin Biochem Rev 2012

The total testing process is quite complex

How can we guarantee quality results over time and every time?



Example of the complexity of the pre-analytical phase for sample management in a laboratory medicine central reception

When it comes to quality in your laboratory and impact on patients:

How do you consider the importance of accurate analytics over robustness of your preanalytical processes?

A) The analytical phase has the most important impact on quality of results.

B) The robustness of laboratory processes including the pre-analytical phase has the most important impact on quality of results.

C) A et B are equally important.

When it comes to quality in your laboratory and impact on patients:

Up to 70% of laboratory errors occur in the pre-analytical phase

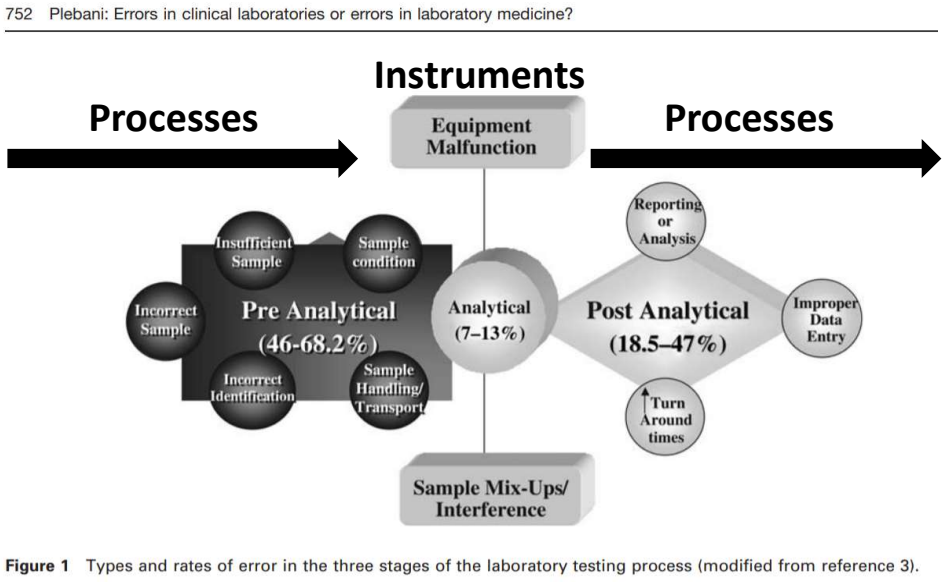


Figure 1 Types and rates of error in the three stages of the laboratory testing process (modified from reference 3).

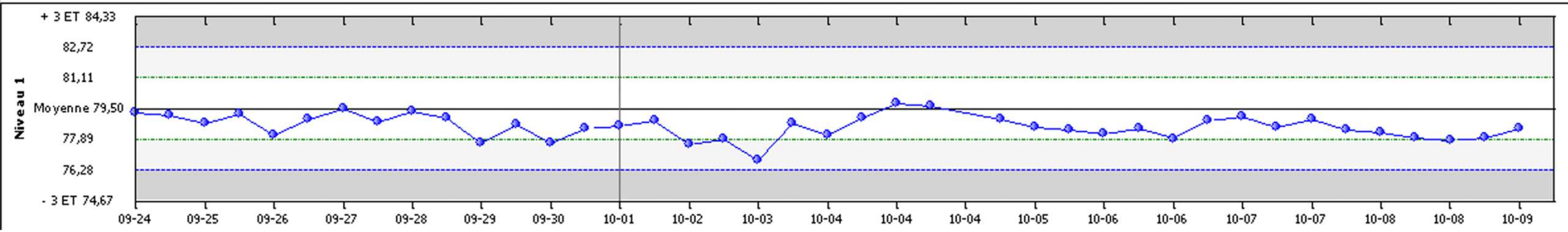
Thanks to Dr M. Plebani

Clin Chem Lab Med 2006;44(6):750–759 © 2006

Controlling processes involving staff and multiple partners can be way more challenging than controlling instruments and the analytical phase

When it comes to quality in your laboratory and impact on patients:

Could you imagine running your lab without any internal QC?



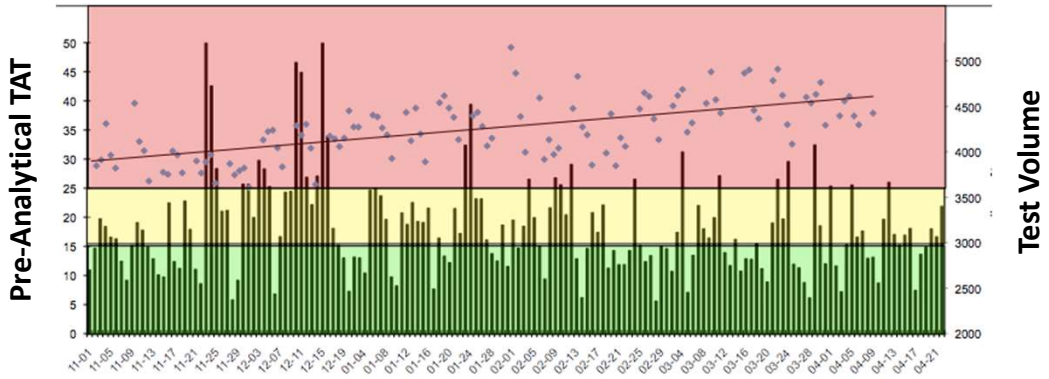
We have internal QC for every single test we run in our laboratories

The WG-LEPS of the IFCC: working towards the standardization in the QIs field

QIs should be :

- **Patient centered** to promote **total quality** and patient safety.
- Cover **the total testing process**: pre-analytic, analytic and post-analytic: **Consistent with ISO 15189:2012 requirements.**
- Applicability to a **wide range of laboratories.**
- **Scientific robustness** with a focus on areas of great importance for quality.
- The definition of **evidence-based thresholds** for acceptance performance.
- Timeliness and possible use as measure of laboratory improvement.

When it comes to quality in your laboratory and impact on patients:



Considering that most of laboratory errors are not coming form the analytical phase, Are you monitoring your preanalytical phase accordingly?

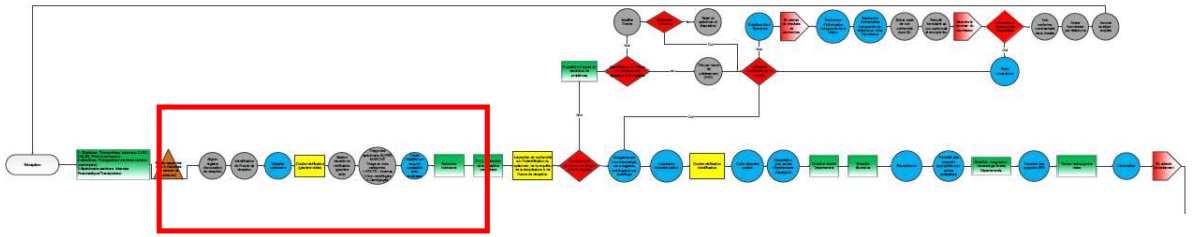
ISO15189:2012: *"The laboratory shall **establish QIs to monitor and evaluate performance** throughout critical aspect **of pre-examination, examination and post-examination processes**."*
*"The process of examining QIs shall be **planned**, which includes establishing the **objectives, methodology, interpretation, limits, action plan and duration of measurement**.*

Monitoring our processes with QIs where should we start?

As laboratory medicine professionals we should do the risk assesment of our processes and prioritize key QIs to assure patient safety no matter what is going on in our lab:

February 2021 in HMR: replacement of our chemistry and immunology instruments with lost of the automation for almost a year.

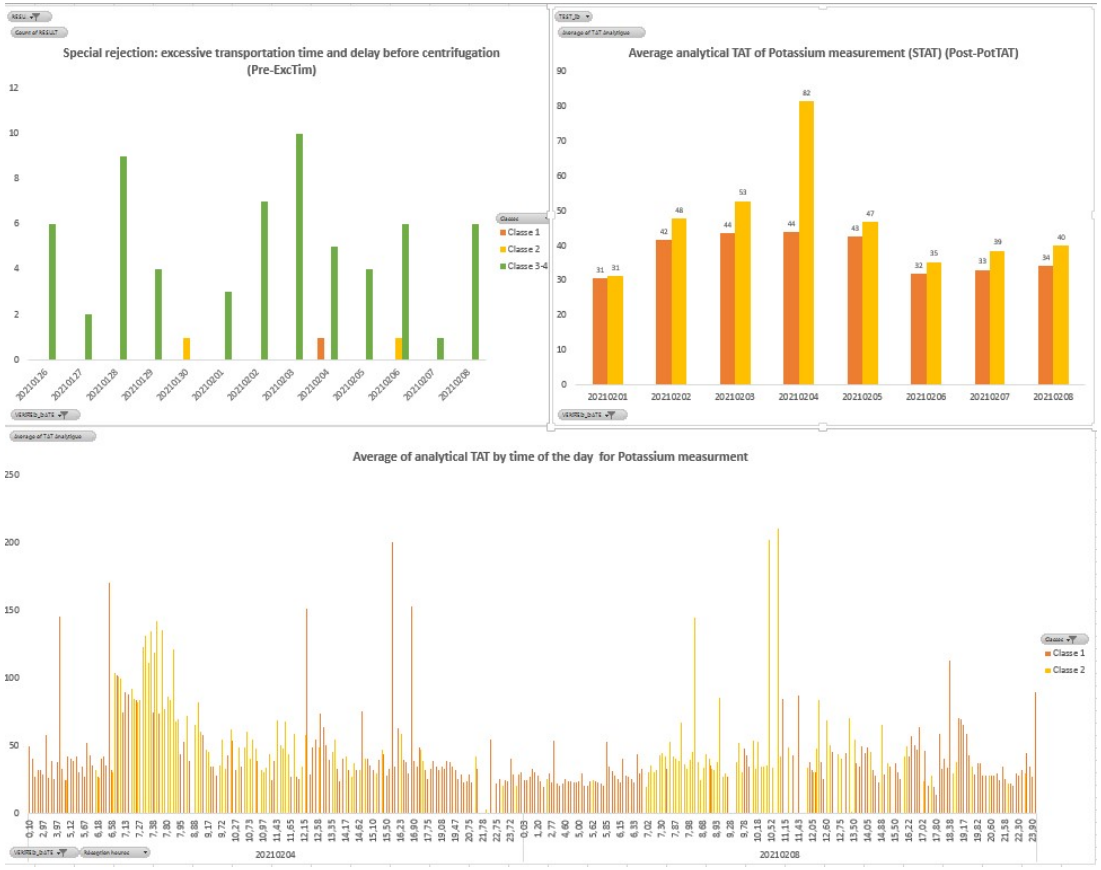
Preanalytical processes
In the lab at high risk!!!



Key QIs from the WG-LEPS list were selected for daily follow up of these important changes:
Monitoring of Post-PotTAT and Pre-ExcTim

Be proactive! Monitor and act on QIs

Dashboard monitoring Post-PotTAT and Pre-ExcTim (WG-LEPS) to monitor the replacement of the chemistry and immunology instruments and lost of automation



Monitoring Potassium TAT based on priority classes of patients (ER, STAT, ICU…) (Post-PotTAT)

Monitoring the number of sample rejection to control the lost of automation and impact on unspun samples (modified Pre-ExcTim)

Extraction of data weekly for daily and hourly monitoring.

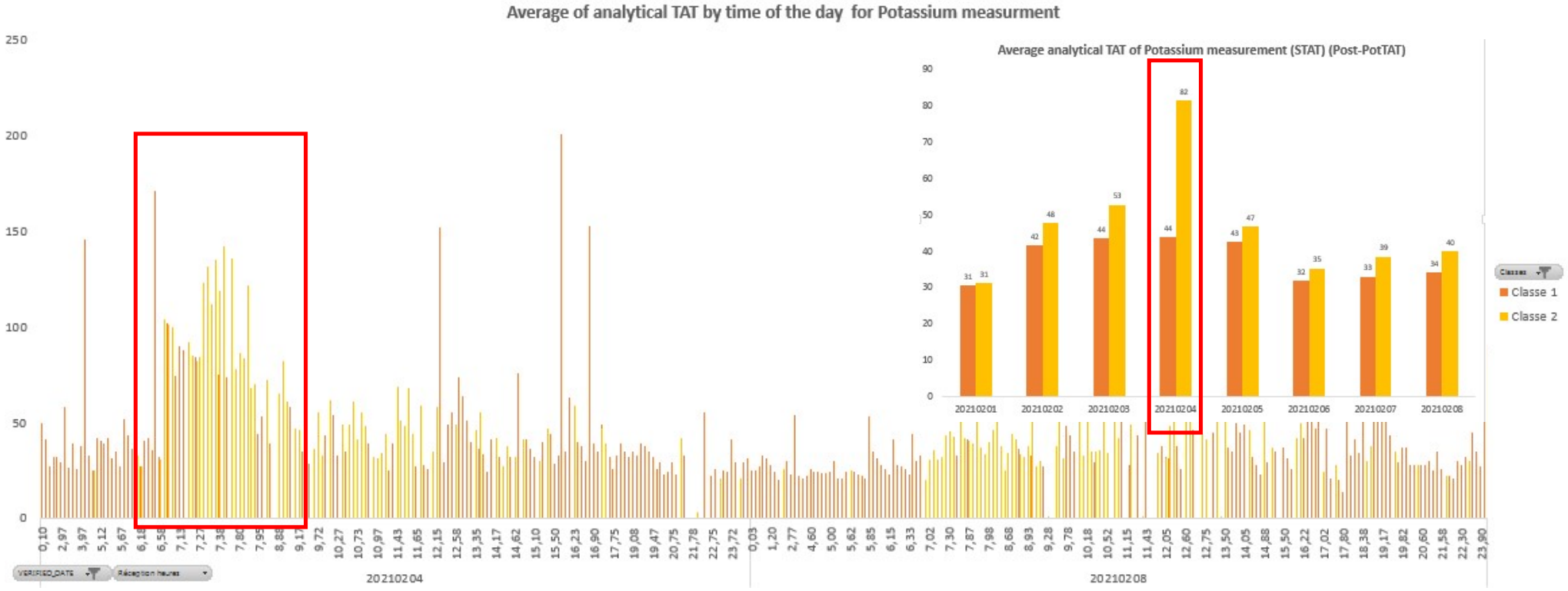
Discussion of results with the lab team on each Friday and brainstorming on solutions for improvement.

Acting on results to improve processes and limit impacts on patients

Be proactive! Monitor and act on QIs

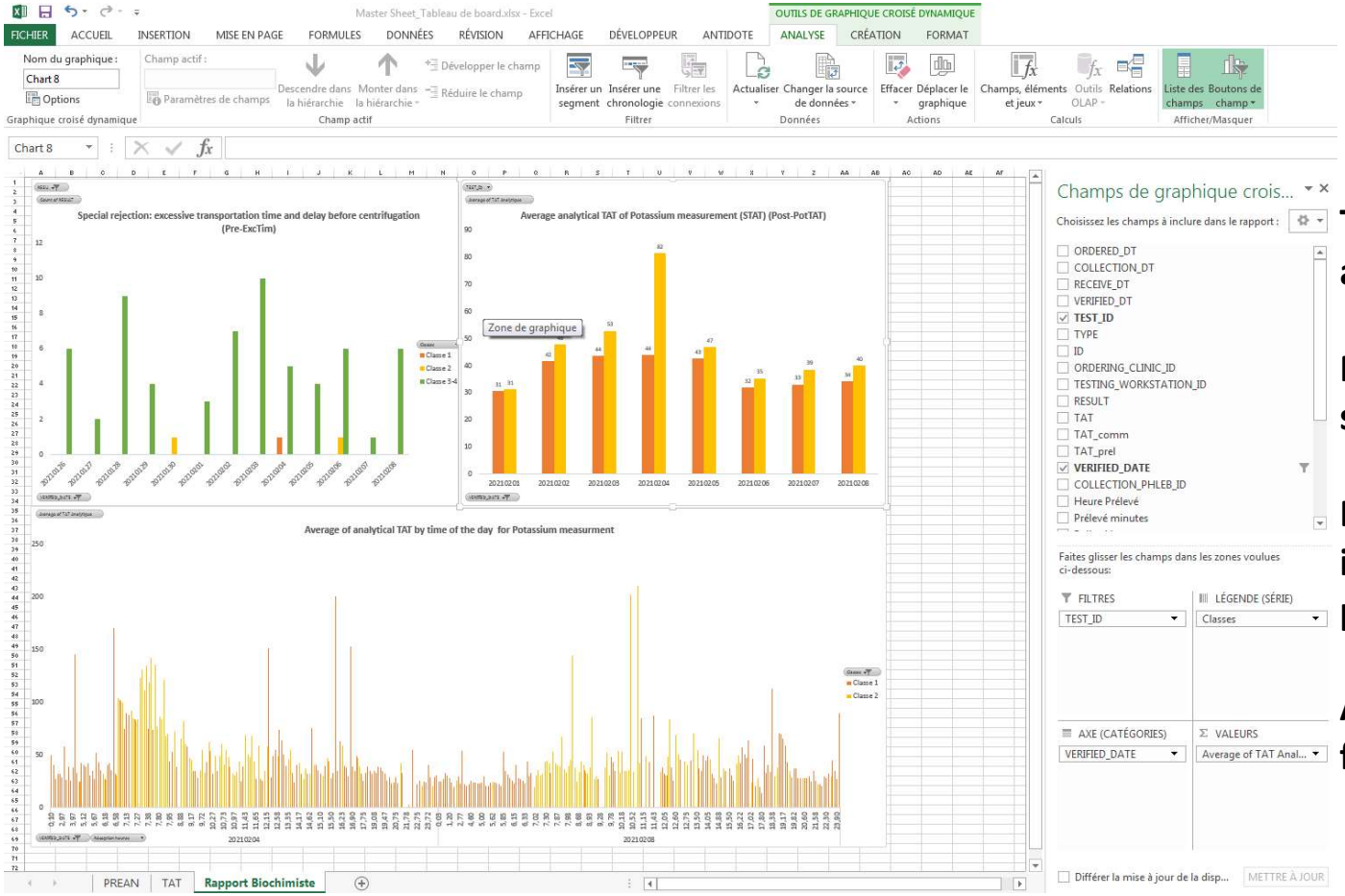
Dashboard monitoring of Post-PotTAT and Pre-ExcTim (WG-LEPS) to monitor the replacement of the chemistry and immunology instruments and lost of automation

Fast identification of a problem in the morning for class 2 samples (care units at shift change)



Be proactive, monitor and act on QIs:

Develop tools to automate QIs monitoring: if it's not fast and easy, you won't do it …



Take the time to develop tools to automate data processing and reports

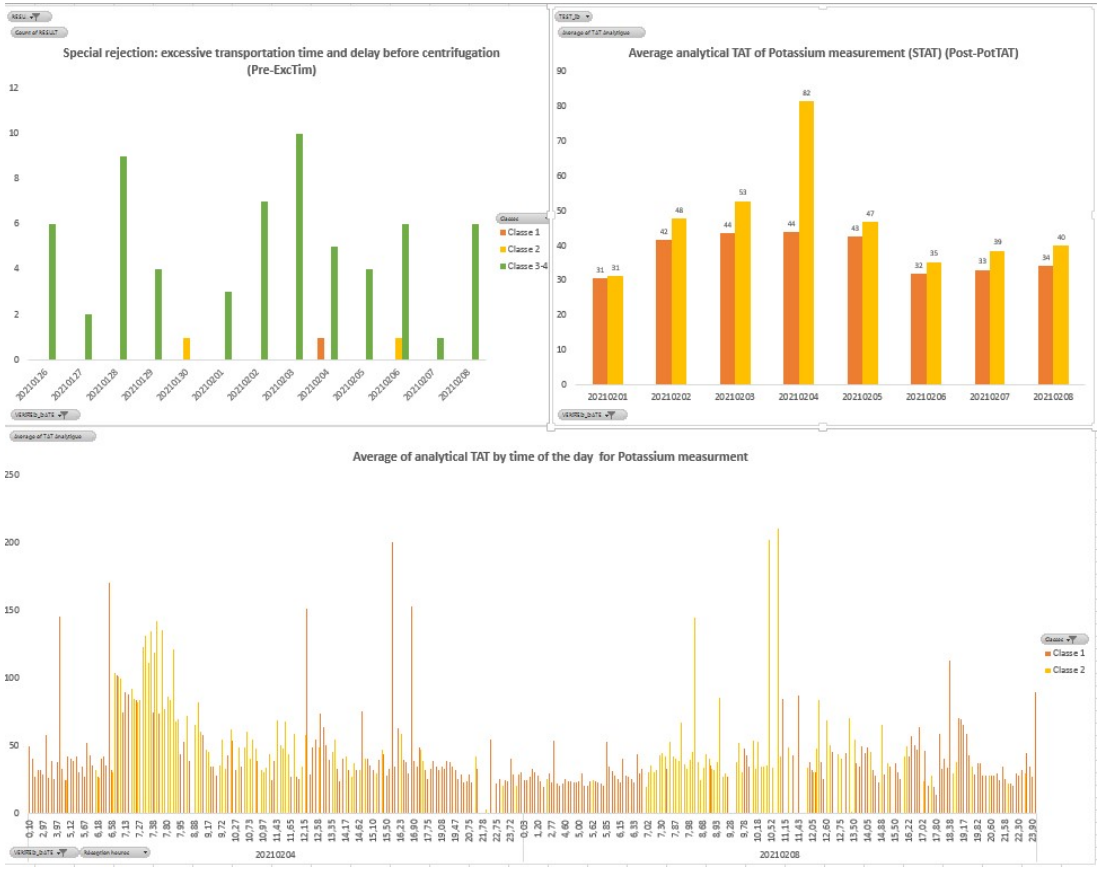
Make sure you are in line with the standardization effort

Discuss results with your team and involve them in the troubleshooting process

Act on result, improve your process and follow your improvement

Be proactive! Monitor and act on QIs

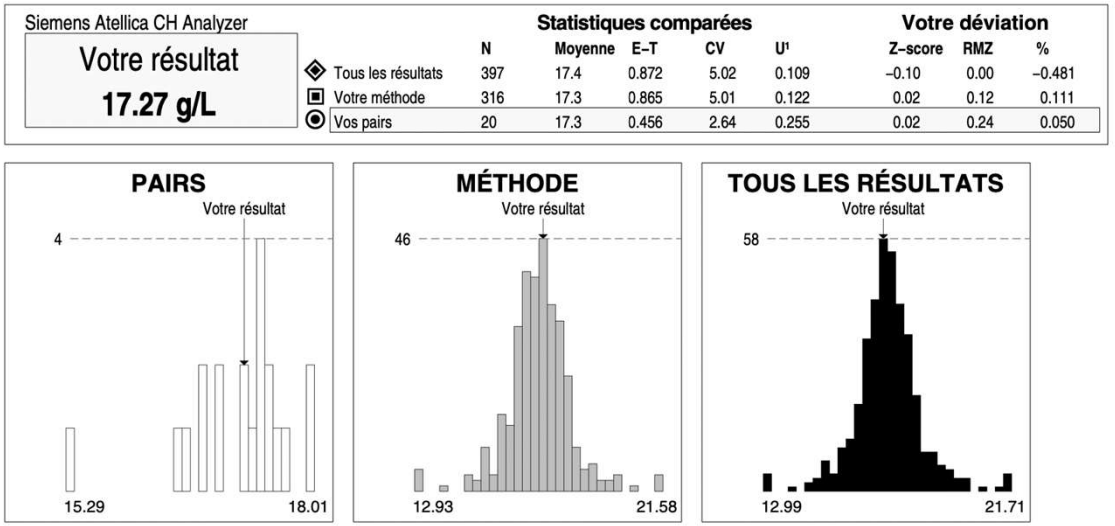
Dashboard monitoring Post-PotTAT and Pre-ExcTim (WG-LEPS) to monitor the replacement of the chemistry and immunology instruments and lost of automation



How can we know if a performance is optimal???

When it comes to quality in your laboratory and impact on patients:

Could you imagine running your lab without any EQA?



Siemens Atellica CH Analyzer

Votre résultat
17.27 g/L

	Statistiques comparées					Votre déviation		
	N	Moyenne	E–T	CV	U¹	Z–score	RMZ	%
Tous les résultats	397	17.4	0.872	5.02	0.109	–0.10	0.00	–0.481
Votre méthode	316	17.3	0.865	5.01	0.122	0.02	0.12	0.111
Vos pairs	20	17.3	0.456	2.64	0.255	0.02	0.24	0.050

We have EQA programs for every single test we run in our laboratories

The Canadian Program for Quality Indicators Comparison

A new model addressing the needs for standardization to the international guidelines and maximizing participation:

Local (HMR), Provincial (SQBC) and National (CSCC) initiatives part of the standardization model of QIs (WG-LEPS of the IFCC)

More than 85 Laboratories participating across Canada, sharing data with the WG-LEPS of the IFCC

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CSCC

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

The Canadian Program for Quality Indicators Comparison

Data submission and analytical profiles
Editing submitted data

Data submission and analytical profiles
Editing submitted data

Data submission and analytical profiles
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Data submission
Editing submitted data

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The Canadian Program for Quality Indicators Comparison

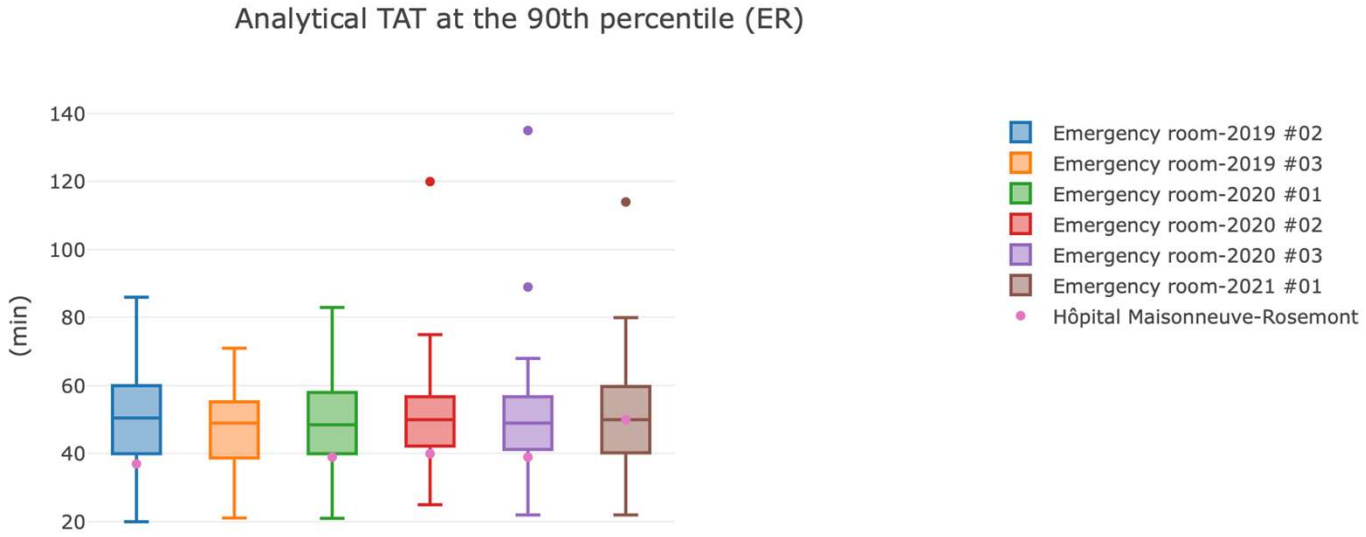
In collaboration with

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

CSCC

Reports: Turnaround Time (TAT) of potassium measurement for patients in the Emergency Room (ER) or outpatients

Analytical TAT: Turnaround time measured from the reception of samples in the laboratory to the release of results.
Clinical TAT: Turnaround time measured from blood sampling to the release of results.



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The Canadian Program for Quality Indicators Comparison

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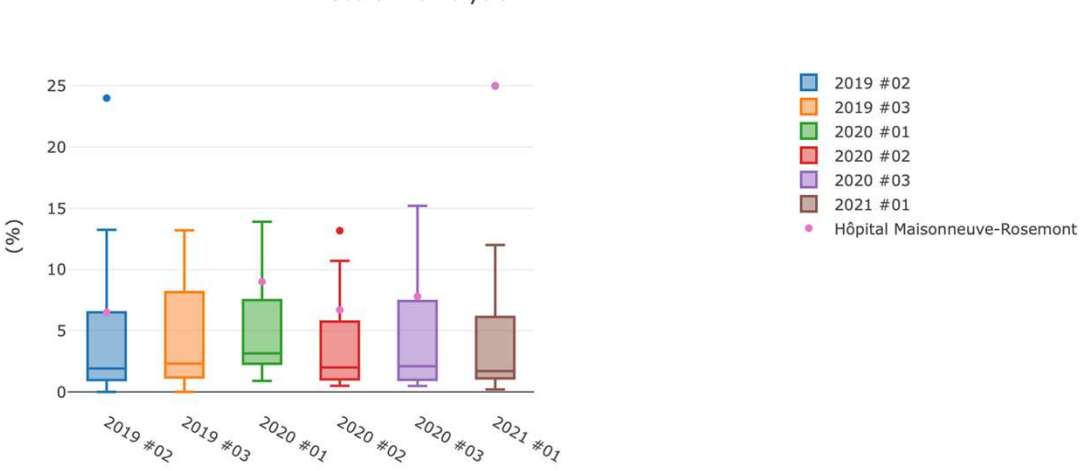

Warning! This is a preliminary comparison including different cut off of free hemoglobin concentration
Recommended cut off based on the IFCC program: 0,5 g/L

Quality Specifications for the rate of hemolysis based on the WG-LEPS program of the IFCC
Established from data submitted by users in 2017 and 2018

Quality Indicators	IFCC code	Year	Number of laboratories	25° percentile	50° percentile	75° percentile
Percentage of: Number of samples with free haemoglobin (Hb) > 0.5 g/L detected by visual inspection/Total number of checked samples for haemolysis	Pre-HemV	2017	147	0,111	0,3	1,435
		2018	130	0,110	0,288	1,105
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	Pre-HemI	2017	177	0,670	2.000	2,760
		2018	146	0,690	1,810	3,230

Sciacovelli et al. Pre-analytical quality indicators in laboratory medicine: Performance of laboratories participating in the IFCC working group "Laboratory Errors and Patient Safety" project. Clinica Chimica Acta 497 (2019) 35–40

Collaborating and sharing data with the WG-LEPS of the IFCC

QUALITY INDICATORS

Post-TnTAT - Turnaround time (minutes), from sample reception in laboratory to release of result, of Cardiac Troponin (TnI or TnT) at 90th

Laboratory code **IMP50** Laboratory Group: **Canadian Laboratories**

Laboratory istitution - **50** - -

	Statistical Data of Laboratory Results				Statistical Data of Laboratory Results				Statistical Data of Laboratory Results			
	Data number	Mean (%)	Median (%)	Sigma mean	Data number	Mean (%)	Median (%)	Sigma mean	Data number	Mean (%)	Median (%)	Sigma mean
All Data	4	44,50	47,50	1,64	142	55,908	56,000	1,349	169	56,975	57,000	1,323

	Laboratory Data				Participants Data							
	Laboratory Value (%)	Laboratory Sigma	Confidence Interval Sigma		Group Sigma		Confidence Interval Group Sigma		Overall Sigma		Confidence Interval Overall Sigma	
			Min	*Max*	*Value*	*N*	*Min*	*Max*	*Value*	*N*	*Min*	*Max*
February 2018	34,00	1,91	1,91	1,91	1,26	34	1,26	1,26	1,26	34	1,26	1,26
April 2018	47,00	1,58	1,58	1,58	1,36	27	1,36	1,36	1,33	48	1,33	1,33
August 2018	48,00	1,55	1,55	1,55	1,37	40	1,37	1,37	1,33	58	1,33	1,33
December 2018	49,00	1,53	1,53	1,53	1,38	41	1,38	1,38	1,38	56	1,38	1,38

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

In collaboration with Drs. Sciacovelli and Plebani

The WG-LEPS of the IFCC:
working towards the standardization in the QIs field

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).

KEY PROCESSES QUALITY INDICATORS – PRIORITY 1					
Quality Indicator	**Code**	**Reporting Systems**	**Data Collection**	**Time**	**Explanatory Note**
PRE-ANALYTICAL					
Misidentification errors	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	
Test transcription errors	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
Post-PotTAT		Turnaround time (minutes), from sample reception in laboratory to release of result, of Potassium (K) at 90th percentile (STAT).	a) estimate all TAT (minutes)), from sample reception in laboratory to release of result, of Potassium STAT) released in the month	Data collection: Every day per a month - three months per year;	

Providing guidance for a set of 53 QIs covering the Total Testing Process.

https://www.ifcc.org/ifcc-education-division/working-groups-special-projects/laboratory-errors-and-patient-safety-wg-leps/quality-indicators-project/

Producing Quality Specifications for promoting improvement

How do you know if the performance of your lab processes are acceptable??
(WG-LEPS of the IFCC)

Clin Chem Lab Med 2017; 55(10): 1478–1488 DE GRUYTER

Opinion Paper

Laura Sciacovelli*, Mauro Panteghini, Giuseppe Lippi, Zorica Sumarac, Janne Cadamuro, César Alex De Oliveira Galoro, Isabel Garcia Del Pino Castro, Wilson Shcolnik and Mario Plebani

Defining a roadmap for harmonizing quality indicators in Laboratory Medicine: a consensus statement on behalf of the IFCC Working Group "Laboratory Error and Patient Safety" and EFLM Task and Finish Group "Performance specifications for the extra-analytical phases"

Performance specifications

The limits for evaluation of laboratory performance are fixed at the 25th and 75th percentile according to the QIs data collected during the previous year. The performance is then classified as follows:

- individual results <25th percentile of value distribution = performance of high quality;
- individual results between 25th and 75th percentile of value distribution = performance of medium quality;
- individual results >75th percentile of value distribution = performance of low quality.

At the end of each year of data collection, QIs data from participating laboratories will be processed and analyzed, so allowing the calculating of the 25th and 75th percentiles to be used as performance limits for the following year (for

Thanks to Dr Mario Plebani

Producing Quality Specifications for promoting improvement

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(WG-LEPS of the IFCC)

Clinica Chimica Acta 497 (2019) 35–40

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IFCC paper

Pre-analytical quality indicators in laboratory medicine: Performance of laboratories participating in the IFCC working group "Laboratory Errors and Patient Safety" project

Laura Sciacovelli[a,*], Giuseppe Lippi[b], Zorica Sumarac[c], Isabel Garcia del Pino Castro[d], Agnes Ivanov[e], Vincent De Guire[f], Cihan Coskun[g], Ada Aita[a], Andrea Padoan[a], Mario Plebani[a], on behalf of Working Group "Laboratory Errors and Patient Safety" of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

Table 1

Pre-analytical quality indicators: 25th, 50th and 75th percentiles of laboratory results and sigma values concerning the 2017 and 2018.

Code	Quality indicator	Year	N.	Laboratory results			Sigma values		
				25th	50th	75th	25th	50th	75th
Misidentification errors									
Pre-MisR	Percentage of: Number of misidentified requests/Total number of requests.	2017	246	0.007 (0–0.010)	0.020 (0.020–0.030)	0.083 (0.067–0.100)	4.64 (4.59–4.70)	5.04 (4.93–5.04)	5.31 (5.22–6)
		2018	211	0.010 (0–0.010)	0.025 (0.020–0.030)	0.070 (0.054–0.100)	4.69 (4.59–4.77)	4.98 (4.93–5.04)	5.22 (5.22–6)
Pre-MisS	Percentage of: Number of misidentified samples/Total number of samples.	2017	214	0 (0–0.005)	0.020 (0.016–0.023)	0.041 (0.039–0.053)	4.84 (4.77–4.86)	5.04 (5.00–5.10)	6 (5.39–6)
		2018	163	0 (0–0)	0.020 (0.010–0.020)	0.040 (0.030–0.040)	4.85 (4.85–4.93)	5.04 (5.04–5.22)	6 (6–6)
Test transcription errors									
Pre-LabTDE	Percentage of: Number of requests with erroneous data entered by laboratory personnel/Total number of requests entered by laboratory personnel.	2017	78	0.002 (0–0.021)	0.166 (0.050–0.266)	0.680 (0.312–3.682)	3.97 (3.33–4.23)	4.44 (4.29–4.80)	5.61 (5.01–6)
		2018	48	0.030 (0–0.128)	0.207 (0.115–0.273)	0.766 (0.256–6.835)	4.03 (2.99–4.30)	4.37 (4.28–4.55)	5.14 (4.52–6)
Pre-OffTDE	Percentage of: Number of requests with erroneous data entered by offside personnel/Total number of requests entered by offside personnel.	2017	72	0.038 (0.020–0.079)	0.151 (0.088–0.227)	0.415 (0.236–0.499)	4.14 (4.08–4.32)	4.46 (4.34–4.63)	4.87 (4.65–5.04)
		2018	45	0.100 (0.100–0.170)	0.210 (0.170–0.250)	0.312 (0.247–0.433)	4.23 (4.12–4.31)	4.36 (4.31–4.43)	4.59 (4.43–4.59)

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A new model addressing the needs for standardization to the international guidelines and maximizing participation:

Local (HMR), Provincial (SQBC) and National (CSCC) initiatives part of the standardization model of QIs (WG-LEPS of the IFCC)

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Pre-analytical nonconformities management: toward a provincial standardization based on the work of the WG-LEPS (IFCC)

Data accessibility is one of the biggest challenge in QIs monitoring. This is particularly true for Pre-analytical non-conformities.

Survey to our participants: *Based on the information you have in your LIS (or other) would you be able to provide the rate of the following pre-analytical NC?*

Misidentification errors
- 73%: yes
- 27%: no

Incorrect sample type:
- 67%: yes
- 33%: no

Incorrect fill volume
- 60%: yes
- 40%: no

Transportation or storage problems
- 60%: yes
- 40%: no

Test Transcription errors
- 47%: yes
- 53%: no

Unintelligible requests
- 40%: yes
- 60%: no

The Committee on Quality Improvement of the SQBC could work on a proposal for a provincial standardization of NC classes and report. Would it be of interest?

- 90%: yes
- 10%: no

Pre-analytical nonconformities management: toward a provincial standardization based on the work of the WG-LEPS (IFCC)

We produced a list of standardized non-conformities classes based on the list of pre-analytical QIs of the WG-LEPS (IFCC)

International Federation of Clinical Chemistry and Laboratory Medicine
Working Group "Laboratory Errors and Patient Safety"

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Pre-analytical nonconformities management: toward a provincial standardization based on the work of the WG-LEPS (IFCC)

société québécoise de biologie clinique

Santé et Services sociaux Québec

We produced a list of standardized non-conformities classes based on the list of pre-analytical QIs of the WG-LEPS (IFCC)

Classes générales	Classes de Non-Conformités Pré-analytiques
Ordonnance	Erreur ou absence d'identification de l'usager au niveau de l'ordonnance (Pre-MisR)
Ordonnance	Erreur ou absence d'identification du prescripteur au niveau de l'ordonnance
Ordonnance	Erreur ou absence des coordonnées du prescripteur
	Ordonnance illisible (Pre-InsUn)
Ordonnance	Subdiviser (Usager, prescripteur, coordonnées du prescripteur, préleveur, renseignements cliniques, analyse, site / source)
Ordonnance	Renseignement clinique exigé absent ou incomplet * (Pre-OffReq)
Ordonnance	*Discordance d'identification ordonnance / échantillon*
Ordonnance	*Absence du site anatomique / source du prélèvement lorsqu'exigée*
Saisie de requête	Mauvaise analyse prescrite (pre-LabTDE)
Saisie de requête	Analyse manquante (pre-LabTDE)
Saisie de requête	Ajout d'analyse non-demandé (pre-LabTDE)
Saisie de requête	*Erreur d'enregistrement au niveau de l'usager*
Saisie de requête	*Erreur d'enregistrement au niveau du prescripteur*
Saisie de requête	*Erreur d'enregistrement au niveau du lieu de prescription*
Prélèvement	Mauvais usager prélevé
Prélèvement	Heure de prélèvement inappropriée en fonction des conditions demandées par le laboratoire (pre-InTime)
Prélèvement	Instructions de prélèvement non suivies (ex. : position, jeun, indication sur la prise d'un médicament non respectée)
Prélèvement	Absence de la date et/ou de l'heure réelle de prélèvement
Prélèvement	Absence d'information sur le préleveur

Classes générales	Classes de Non-Conformités Pré-analytiques
Échantillon	Erreur d'identification de l'usager au niveau de l'échantillon (pre-MisS)
Échantillon	Mauvais contenant ou milieu de transport utilisé lors du prélèvement (Pre-WroCo)
Échantillon	Retiré Mauvaise matrice* envoyée au laboratoire (ex: envoi d'un plasma lorsque sang total est requis) (Pre-WroTy)
Échantillon	Volume d'échantillon insuffisant ou inadéquat (Pre-InsV)
Échantillon	Ratio du volume d'échantillon sur volume d'anticoagulant inadéquat (Pre-SaAnt)
Échantillon	Échantillon contaminé (soluté, ordre des tubes, transvasage) (Pre-Cont)
Échantillon	Analyse non-effectuée en raison de l'hémolyse (Pre-HemR)
Échantillon	Échantillon coagulé (Pre-Clot)
Échantillon	Discordance d'identification échantillon / ordonnance
Transport	Échantillon prélevé non reçu au laboratoire (Pre-NotRec)
Transport	Délai de transport de l'échantillon vers le laboratoire non-respecté (Pre-ExcTim)
Transport	Délai entre la réception et l'analyse au laboratoire non-respecté
Transport	Échantillon endommagé, souillé ou déversement lors du transport vers le laboratoire (Pre-DamS)
Transport	Température inadéquate lors du transport de l'échantillon (Pre-InTem)
Transport	Température inadéquate lors de l'entreposage au laboratoire (Pre-NotSt)
Transport	Traitement inadéquat de l'échantillon au laboratoire (stabilisation, tube débouché, aliquotage, tube déversé)
Transport	Échantillon introuvable au laboratoire
Transport	Mode de transport inadéquat (pneumatique, monte-charge)

This list will be integrated in the new provincial LIS: All laboratories across Quebec province (Canada) will use this classification and have access to these pre-analytical QIs.

Pre-analytical nonconformities management: toward a provincial standardization based on the work of the WG-LEPS (IFCC) and in line with the WG-PRE (EFLM) guidelines

Next step:

Promoting the guidelines of the WG-PRE of the EFLM for the ISO15189:2012 Pre-analytical requirements.

Pieter Vermeersch*, Glynis Frans, Alexander von Meyer, Seán Costelloe, Giuseppe Lippi and Ana-Maria Simundic

How to meet ISO15189:2012 pre-analytical requirements in clinical laboratories? A consensus document by the EFLM WG-PRE

Clin Chem Lab Med 2021; 59(6): 1047–1061

Thanks to Dr Ana-Maria Simundic

Table 1: (continued)

ISO paragraph	Question	ISO requirement	Minimal recommendation	Grade	Best-in-class solution	Grade
4.14.7 – Quality indicators	Which QIs should be monitored and in which manner?	Non-binding examples include number of unacceptable samples, numbers of errors at registration and/or accession, number of corrected reports.	Laboratories should at least monitor one of the following quality indicators: number and proportion of misidentification errors, test transcription errors, incorrect sample types, insufficiently filled samples, unsuitable samples, contaminated samples, hemolyzed samples, or clotted samples.	2a	Pre-analytical quality indicators are monitored according to framework provided by the IFCC Model of Quality Pre-analytical Indicators. Laboratories should implement all quality indicators that are relevant for their setting based on risk-assessment. Participation in the IFCC External Quality Assessment program is encouraged.	2a
	At which frequency should QIs be monitored and analyzed?	Not stated.	Yearly.	1	Frequency according to the framework provided by the IFCC Model of Quality Pre-analytical Indicators [8].	2a

Canadian Society of Clinical Chemists initiative: Standardization of QIs in POCT

Why: CSCC members identified a need for the standardization of QIs in the POCT field.

How: Joint Task Force between the CSCC Working Groups on POCT and Quality Improvement through QIs. (Co-Chaired by Dr Julie Shaw and Dr Vincent De Guire) WG of 25 clinical chemists working in different provinces across Canada.

Strategy:

- Mapping processes of glucose meter measurement.
- Risk assessement.
- QIs scoring and selection.
- Field validation of QIs by WG members
- implementation across Canada for comparison between hospitals.
- Establishing Quality Specifications based on the WG-LEPS.

Canadian Society of Clinical Chemists initiative: Standardization of QIs in POCT

Step 1: mapping steps of the process of glucose meter measurement

Step of the process
Preanalytical
Positive patient ID
Operator training - Does a formal program exist?
Operator lock-out - Can only trained operators use the instrument?
Reagent expiry date labeling
Washing of patient hands
Storage of reagent strips
Validation of reagents - Is there a process for this?
Validation of QC material - Is there a process for this?
Storage of meters on the clinical units
Sharing of operator IDs/inappropriate use of emergency operator ID (if applicable)
Proper PPE practices (wearing gloves etc.)
Inventory of management/lot sequestering
Storage of QC solutions on the clinical units
Choice of specimen - Is there awarness by operators of when a capillary specimen may not be appropriate?
Meter validation - Is there a process for this?
Wiping away first drop

Analytical
QC - Are operators performing QC according to the procedure?
QC lock-out - Do the instruments have QC lock-out and is it on?
Follow-up on QC failures by clinical area. Is the follow-up appropriate (eg, do they just repeat and repeat until it's in?)
Testing procedure - Is there a procedure and is it followed by the operators?
Meter interferences - Are operators aware of interferences?
EQA - Is there a formal EQA program?
Regular comparisons with the lab - Are instruments regularly compared to the lab?

Post-analytical
Results reporting - Are operators compliant with charting requirements?
Cleaning of instrument
Meter communication with middleware/LIS - Are there challenges?
Critical results reporting - is there a process for reporting?
Critical results follow-up - Are processes adhered to if they exist?
Periodic review of reference ranges and/or critical values
Lab confirmation for discrepant results. Do clinical areas confirm suspicious results?
Proper disposal of samples/lancets
Docking of meters (if applicable). Clinical compliance with docking for charging and results transmission.

Canadian Society of Clinical Chemists initiative: Standardization of QIs in POCT

Step 2: Assessing risk related to every step of the process taking into account:
Probability of occurrence, consequence on patients and capacity for detection

Step of the process	Risk (CxP)	Detection	Overall Risk
Preanalytical			
Positive patient ID	28,1	2,1	suboptimal
Operator training - Does a formal program exist?	7,5	2,4	acceptable
Operator lock-out - Can only trained operators use the instrument?	9,0	2,1	acceptable
Reagent expiry date labeling	14,7	1,8	acceptable
Washing of patient hands	23,7	1,0	suboptimal
Storage of reagent strips	12,0	1,3	suboptimal
Validation of reagents - Is there a process for this?	2,9	2,8	acceptable
Validation of QC material - Is there a process for this?	3,2	2,6	acceptable
Storage of meters on the clinical units	8,5	2,1	acceptable
Sharing of operator IDs/inappropriate use of emergency operator ID (if applicable)	19,0	1,3	suboptimal
Proper PPE practices (wearing gloves etc.)	15,5	1,2	suboptimal
Inventory of management/lot sequestering	2,1	2,8	acceptable
Storage of QC solutions on the clinical units	10,6	1,4	suboptimal
Choice of specimen - Is there awarness by operators of when a capillary specimen may not be appropriate?	16,3	1,0	suboptimal
Meter validation - Is there a process for this?	1,6	2,8	acceptable
Wiping away first drop	18,3	1,0	suboptimal
Analytical			
QC - Are operators performing QC according to the procedure?	8,3	2,3	acceptable
QC lock-out - Do the instruments have QC lock-out and is it on?	1,5	2,8	acceptable
Follow-up on QC failures by clinical area. Is the follow-up appropriate (eg, do they just repeat and repeat until it's in?)	14,5	2,0	acceptable
Testing procedure - Is there a procedure and is it followed by the operators?	17,6	1,3	suboptimal
Meter interferences - Are operators aware of interferences?	20,7	1,3	suboptimal
EQA - Is there a formal EQA program?	0,7	2,8	acceptable
Regular comparisons with the lab - Are instruments regularly compared to the lab?	8,5	2,8	acceptable
Post-analytical			
Results reporting - Are operators compliant with charting requirements?	13,0	1,8	acceptable
Cleaning of instrument	14,7	1,2	suboptimal
Meter communication with middleware/LIS - Are there challenges?	10,3	2,3	acceptable
Critical results reporting - is there a process for reporting?	17,3	2,0	suboptimal
Critical results follow-up - Are processes adhered to if they exist?	23,5	1,7	suboptimal
Periodic review of reference ranges and/or critical values	3,6	2,8	acceptable
Lab confirmation for discrepant results. Do clinical areas confirm suspicious results?	27,2	1,3	suboptimal
Proper disposal of samples/lancets	7,8	1,2	suboptimal
Docking of meters (if applicable). Clinical compliance with docking for charging and results transmission.	7,8	2,5	acceptable

Methodology based and adapted from Janssens (2014) Annals of Clinical Biochemistry 51 (6): 695-704

Canadian Society of Clinical Chemists initiative: Standardization of QIs in POCT

Step 3: Ranking and prioritizing QIs of interest for comparison between laboratories

Top 10 Ranking of the different scoring strategy

	Risk (CxP)	
Positive patient ID	28,1	Pre-analytical
Lab confirmation for discrepant results. Do clinical areas confirm suspicious results?	27,2	Post-Analytical
Washing of patient hands	23,7	Pre-analytical
Critical results follow-up - Are processes adhered to if they exist?	23,5	Post-Analytical
Meter interferences - Are operators aware of interferences?	20,7	Analytical
Sharing of operator IDs/inappropriate use of emergency operator ID (if applicable)	19,0	Pre-analytical
Wiping away first drop	18,3	Pre-analytical
Testing procedure - Is there a procedure and is it followed by the operators?	17,6	Analytical
Critical results reporting - is there a process for reporting?	17,3	Post-Analytical
Choice of specimen - Is there awarness by operators of when a capillary specimen may not be appropriate?	16,3	Pre-analytical

	Consequence	
Lab confirmation for discrepant results. Do clinical areas confirm suspicious results?	5,8	Post-Analytical
Critical results follow-up - Are processes adhered to if they exist?	5,8	Post-Analytical
Positive patient ID	5,4	Pre-analytical
Washing of patient hands	5,2	Pre-analytical
Meter interferences - Are operators aware of interferences?	4,7	Analytical
Proper PPE practices (wearing gloves etc.)	4,6	Pre-analytical
Critical results reporting - is there a process for reporting?	4,5	Post-Analytical
Testing procedure - Is there a procedure and is it followed by the operators?	4,5	Analytical
Wiping away first drop	4,3	Pre-analytical
Meter validation - Is there a process for this?	4,3	Pre-analytical

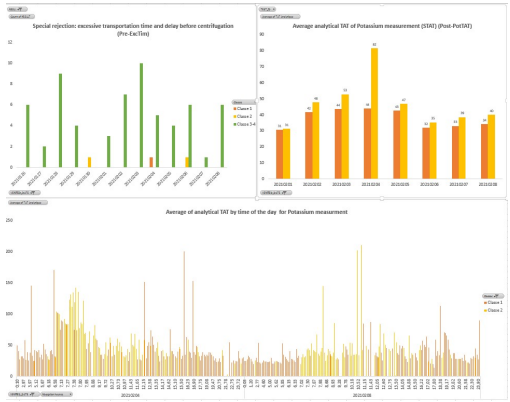
	Detection	
Validation of reagents - Is there a process for this?	2,8	Pre-analytical
Meter validation - Is there a process for this?	2,8	Pre-analytical
QC lock-out - Do the instruments have QC lock-out and is it on?	2,8	Analytical
EQA - Is there a formal EQA program?	2,8	Analytical
Regular comparisons with the lab - Are instruments regularly compared to the lab?	2,8	Analytical
Periodic review of reference ranges and/or critical values	2,8	Post-Analytical
Inventory of management/lot sequestering	2,8	Pre-analytical
Validation of QC material - Is there a process for this?	2,6	Pre-analytical
Docking of meters (if applicable). Clinical compliance with docking for charging and results transmission.	2,5	Post-Analytical
Operator training - Does a formal program exist?	2,4	Pre-analytical

	Risk x Detection	
Positive patient ID	58,5	Pre-analytical
Critical results follow-up - Are processes adhered to if they exist?	39,2	Post-Analytical
Lab confirmation for discrepant results. Do clinical areas confirm suspicious results?	36,2	Post-Analytical
Critical results reporting - is there a process for reporting?	34,5	Post-Analytical
Follow-up on QC failures by clinical area. Is the follow-up appropriate (eg, do they just repeat and repeat until it's in?)	29,0	Analytical
Reagent expiry date labeling	26,9	Pre-analytical
Meter interferences - Are operators aware of interferences?	25,9	Analytical
Meter communication with middleware/LIS - Are there challenges?	24,0	Post-Analytical
Results reporting - Are operators compliant with charting requirements?	23,8	Post-Analytical
Sharing of operator IDs/inappropriate use of emergency operator ID (if applicable)	23,8	Pre-analytical

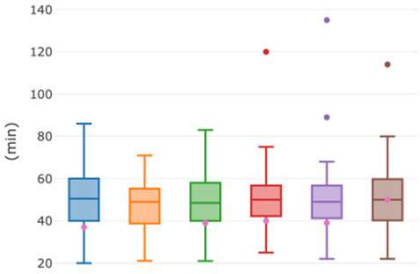
Methodology based and adapted from Janssens (2014) Annals of Clinical Biochemistry 51 (6): 695-704

Let’s finish with the conclusion!

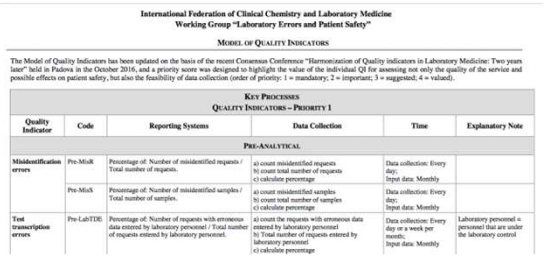
Be proactive, monitor your pre-analytical processes with QIs



Improve your processes through comparison



Get in line with the international guidelines



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).

KEY PROCESSES QUALITY INDICATORS – PRIORITY 1					
Quality Indicator	Code	Reporting Systems	Data Collection	Time	Explanatory Note
PRE-ANALYTICAL					
Misidentification errors	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	
Test transcription errors	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

Acknowledgements

The Working Group On Quality Improvement and the quality office of the

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The WG-LEPS of the IFCC especially Mario Plebani Laura Sciacovelli

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

The CSCC and members of The WG QIs in POCT Especially Julie Shaw

CSCC

The WG-PRE of the EFLM Especially Janne Cadamuro and Ana-Maria Simundic

EFLM EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

The Quebec MSSS and the WG of the provincial LIS for NC standardization

Santé et Services sociaux Québec

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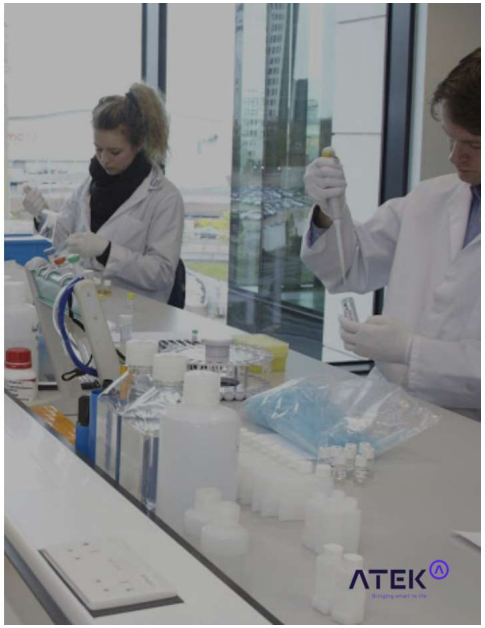
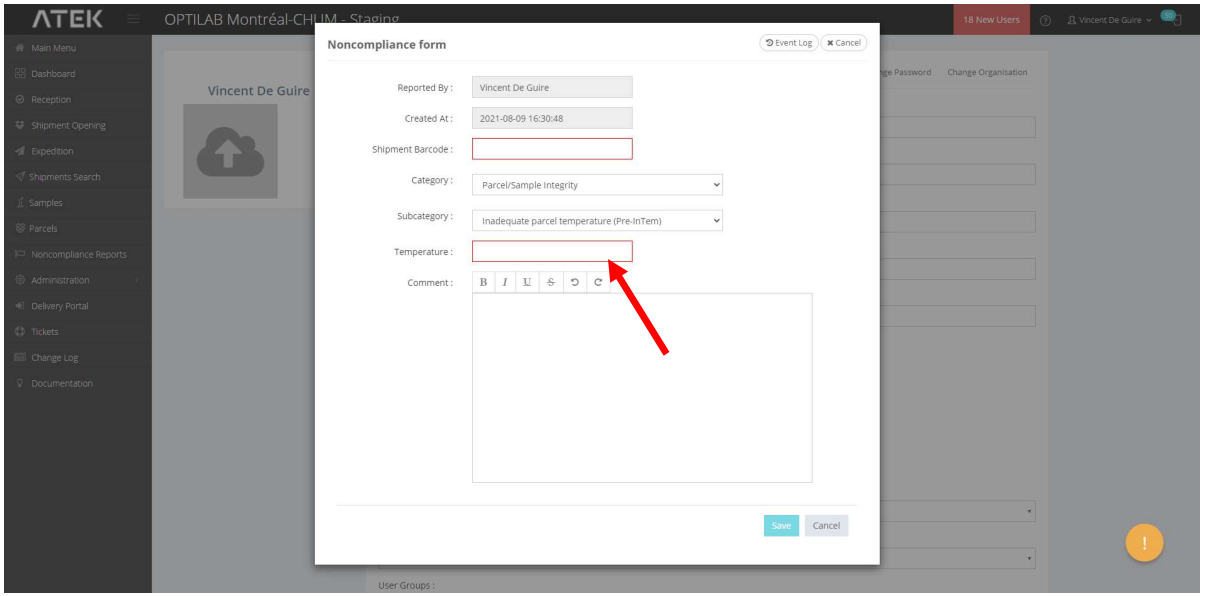
Pre-analytical nonconformities management and QIs: Promoting the international guidelines in our laboratories, but also in the industry

Implementing the WG-LEPS QIs in the non-conformities management module of our sample traceability solution: As laboratory professional we should promote standardization with guidelines as much as possible



Pre-analytical nonconformities management and QIs: Promoting the international guidelines in our laboratories, but also in the industry

Non-conformities classes related to sample transportation are standardized with the WG-LEPS QIs.
All users will be able to have automated reports and compare performance with Quality Specifications.
Laboratories will be able to submit data more easily to the QI comparison program.



The Canadian Program for Quality Indicators Comparison

A new model addressing the needs for standardization to the international guidelines and maximizing participation:

1. **Maximizing adhesion to our program: addressing users needs, involving people**
2. Quality of data is a priority.
3. Addressing the differences between laboratories for accurate comparison.
4. Producing Canadian quality specifications to promote improvement (based on the WG-LEPS).
5. Promoting standardization in the QIs field, sharing data with the WG-LEPS program.
6. Promoting the expertise of Clinical Biochemists in the QIs field.
7. Initiating standardization initiatives using QIs.

1. Maximizing adhesion to our program: addressing users needs, involving people

<u>Survey</u> on pre-analytical non-conformities (NC)
(first survey: 2017)

Which pre-analytical NC should we implement first in our QIs program?

- 55%: misidentification errors
- 35%: Hemolysis rate
- 10%: Incorrect sample type
- 0%: Test transcription errors
- 0%: Incorrect fill volume
- 0%: Samples clotted

The Committee on Quality Improvement of the SQBC could work on a proposal for a provincial standardization of NC classes and report.
Would it be of interest?

- 90%: yes
- 10%: no

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1. Maximizing adhesion to our program: addressing users needs, involving people

Based on the information you have in your LIS (or other) would you be able to provide the rate of the following pre-analytical NC?

Misidentification errors
- 73%: yes
- 27%: no

Incorrect sample type:
- 67%: yes
- 33%: no

Incorrect fill volume
- 60%: yes
- 40%: no

Transportation or storage problems
- 60%: yes
- 40%: no

Test Transcription errors
- 47%: yes
- 53%: no

Unintelligible requests
- 40%: yes
- 60%: no

Data accessibility is one of the biggest challenge in QIs monitoring. Priorizing QIs that are relevant for our patients but not too challenging to extract in most LIS should be a priority to maximize participants enrollment.

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1. Maximizing adhesion to our program: addressing users needs, involving people
2. **Quality of data is a priority.**
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2. Quality of data is a priority.

Working Group: Clinical Biochemists working in different laboratories across the province on different analytical platform, with different laboratory size, different LIS…

New indicators are selected based on **participant's needs** (surveys) and validated by the working group before implementation:

- Plus values of QIs.
- Capacity to access information easily (LIS).
- Identification of factors leading to erroneous values
- **Compatibility with the IFCC program**

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2. Quality of data is a priority.

- **Submission** of data through our **web-based platform**: Documentation available for dates of events, guidelines for QIs…
- Analysis of submitted data by the **Quality Control Office of the SQBC** to identify outliers. Contact laboratories for validation when needed.
- Production of **personalized report** showing **trends** and **comparison** with other laboratories.
- **Data are shared** with the **WG-LEPS of the IFCC** providing an international comparison to our users.

Development of a web-based platform for management of participants, submission of data and automated production of personalised and interactive reports

Log in

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Home

The **Société Québécoise de Biologie Clinique** is pleased to invite you to participate in its new program of quality indicators comparison. Monitoring processes from blood sampling to the communication of results for different types of patients, the program will allow users to follow their improvement and compare their data with the results of other laboratories across Canada.

We have developed a **user-friendly, web-based platform** for the registration of users and the submission of data with associated analytical profiles. Thanks to personalized and interactive reports, users can observe the evolution of their performance over time, and compare it with other laboratories'.

REGISTER

Program in progress

Using tiki wiki and open and free web source solution

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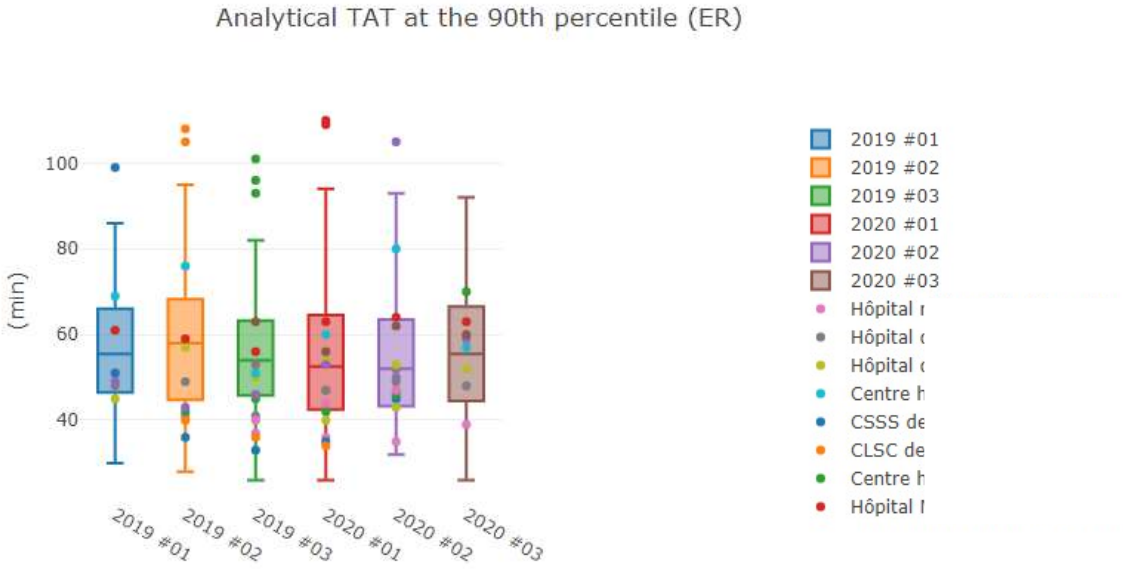
Users can visualize personalized reports showing their trends and comparing their performance with other laboratories

Troponin - Turnaround time

Reports: Turnaround Time (TAT) of troponin measurement for patients in the Emergency Room (ER)

Analytical TAT: Turnaround time measured from the reception of samples in the laboratory to the release of results.
Clinical TAT: Turnaround time measured from blood sampling to the release of results.



Report of the analytical TAT of troponin measurement for patients in the ER at the 90th percentile for a specific user. Values of any box plot can be visualized pointing the mouse on the graph

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Reports are dynamic and can be personalized by users based on needs

Troponin - Turnaround time

Reports: Turnaround Time (TAT) of troponin measurement for patients in the Emergency Room (ER)

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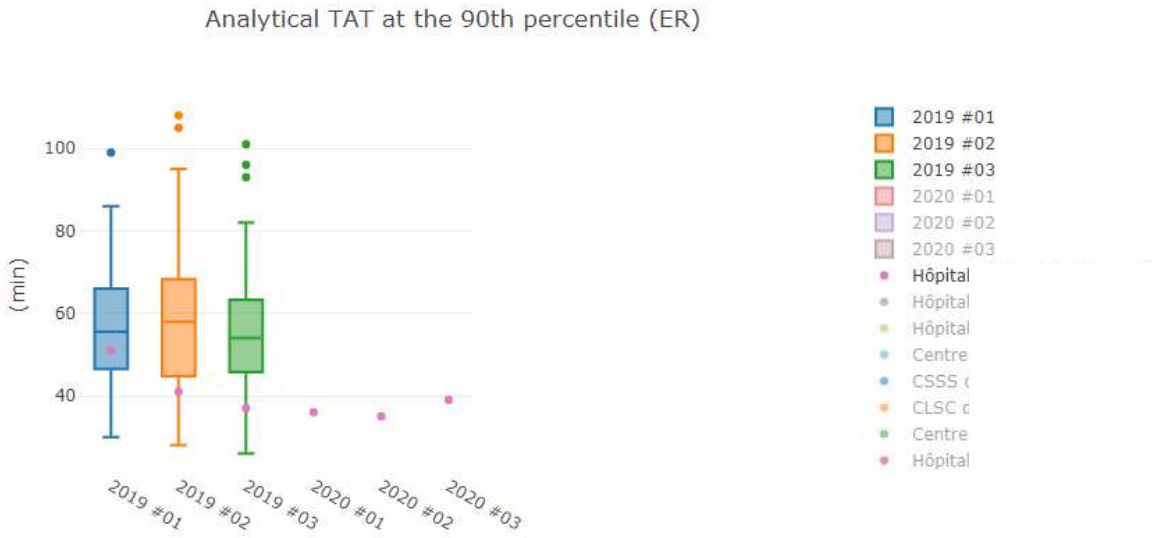

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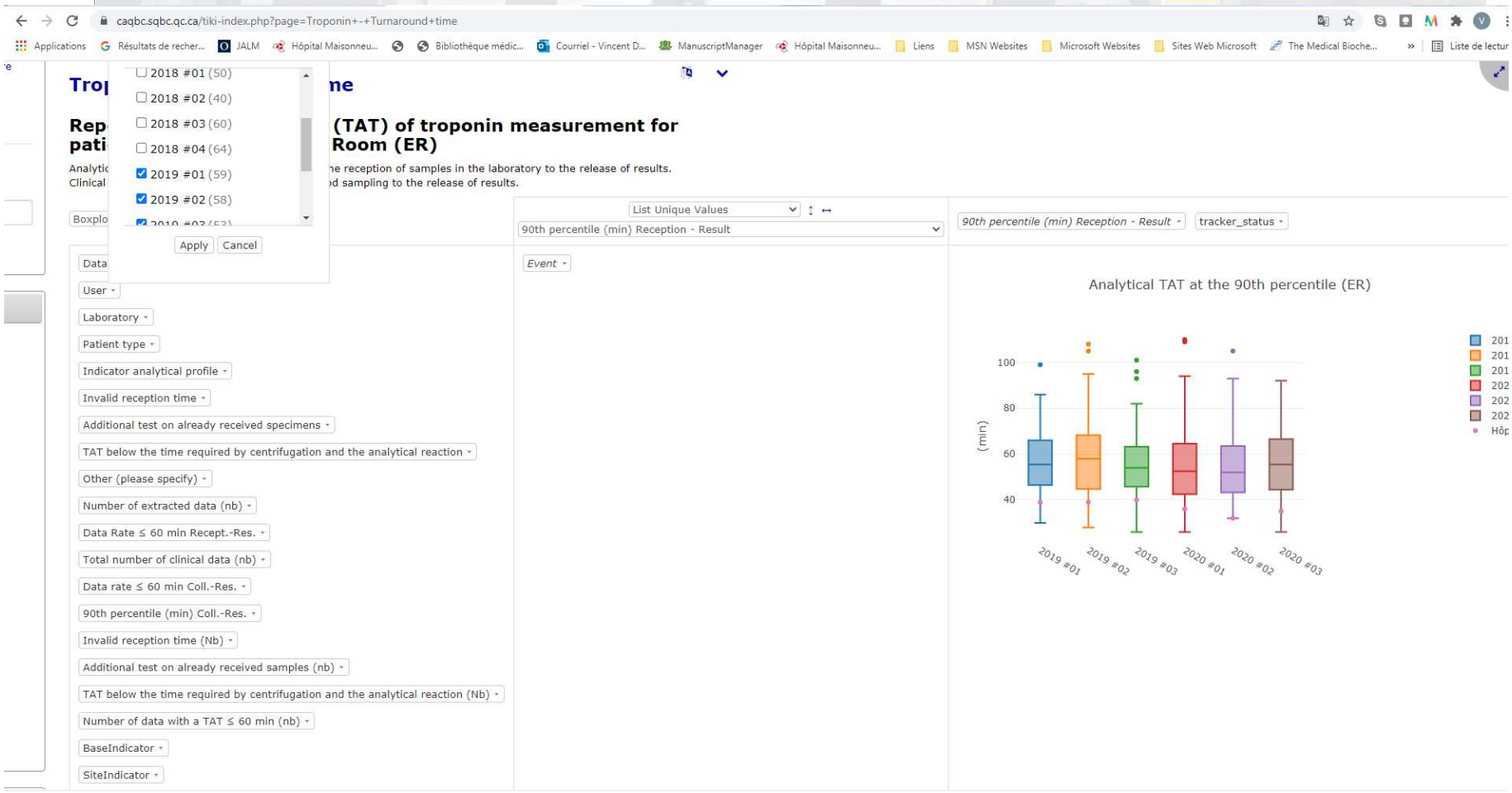
All data related to QIs are accessible for flexible and customized reports



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1. Maximizing adhesion to our program: addressing users needs, involving people
2. Quality of data is a priority.
3. **Addressing the differences between laboratories for accurate comparison.**
4. Producing Canadian quality specifications to promote improvement (based on the WG-LEPS).
5. Promoting standardization in the QIs field, sharing data with the WG-LEPS program.
6. Promoting the expertise of Clinical Biochemists in the QIs field.
7. Initiating standardization initiatives using QIs.

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3. Addressing the differences between laboratories for accurate comparison.

What Is the best description for troponin measurement in your laboratory?

1. **Registered in ED and measured on a stand alone instrument using HS troponin**
2. **Registered in the lab and measured on a stand alone instrument using HS troponin**
3. **Registered in ED and measured on a POCT**
4. **Registered in ED and measured on an automated track using HS troponin**
5. **other**

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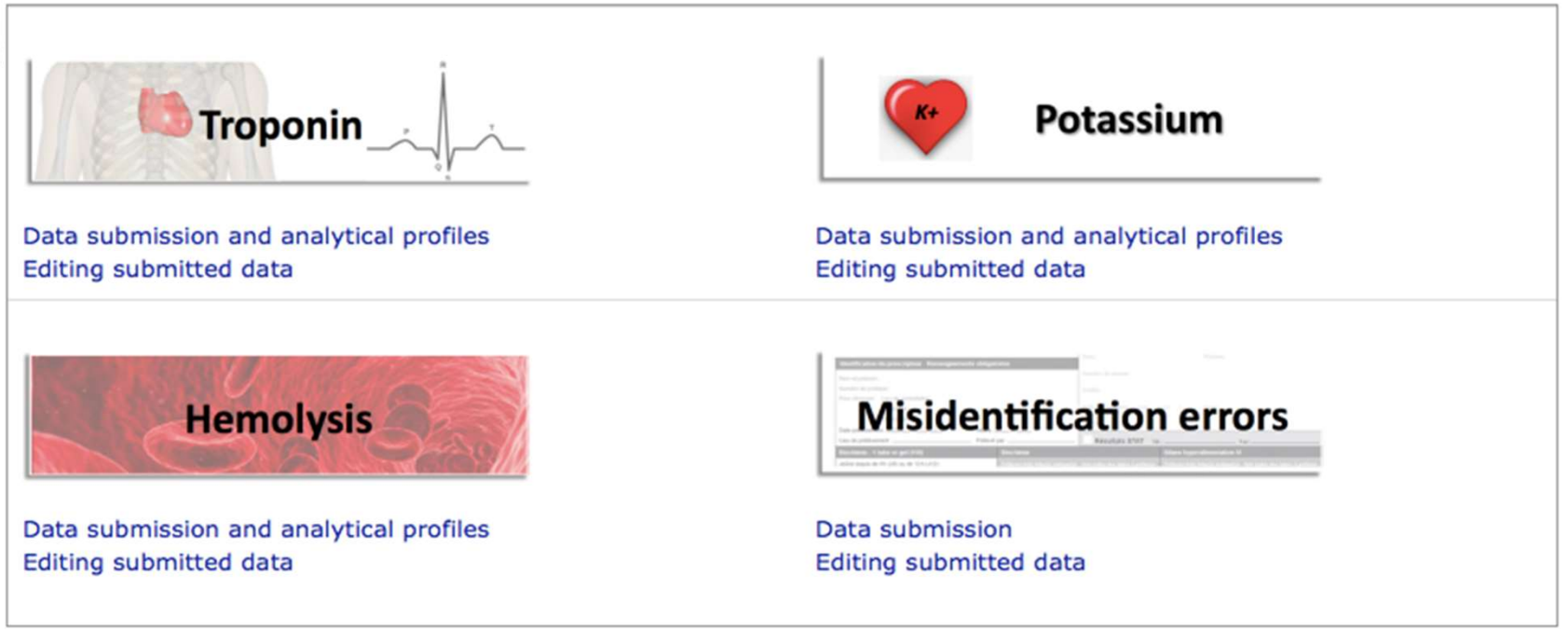
3. Addressing the differences between laboratories for accurate comparison: the analytical profile



In the same line of EQA programs, participants need to provide information related to the QI in evaluation

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3. Addressing the differences between laboratories for accurate comparison: the analytical profile

Comparison of performance based on the analytical profile: *Automation vs stand alone vs POCT*

Analytical profile	Automation	Stand alone	POCT
Number of laboratories	14	54	1
Average of 90th percentile	60 min	55 min	26 min
Standard deviation	8,3	11,2	N/A

LABORATORY : Hôpital Maisonneuve-Rosemont

Supplier : Roche diagnostics	**Instrument model** : Cobas411	
Analytical approach : Instrument isolé	**Reagent number** : 05092728 119	**Analytical reaction time** : 8,0 min
Centrifugation time (if applicable) :	4min	
Laboratory information system (LIS) :	SCC	

In the same line of EQA programs, participants need to provide information related to the QI in evaluation

1. Maximizing adhesion to our program: addressing users needs, involving people
2. Quality of data is a priority.
3. Addressing the differences between laboratories for accurate comparison.
4. **Producing Canadian quality specifications to promote improvement (based on the WG-LEPS).**
5. Promoting standardization in the QIs field, sharing data with the WG-LEPS program.
6. Promoting the expertise of Clinical Biochemists in the QIs field.
7. Initiating standardization initiatives using QIs.

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4. Producing Canadian Quality Specifications for promoting improvement

How do you know if the performance of your lab processes are acceptable??
(Based on the WG-LEPS)

Troponin measurement for the ER should be less than 60 minutes, but:

A) From blood sampling?

B) From reception in the lab?

4. Producing Canadian Quality Specifications for promoting improvement

How do you know if the performance of your lab processes are acceptable??
(Based on the WG-LEPS)

Clinical Chemistry 64:4
645–655 (2018)

Special Report

Clinical Laboratory Practice Recommendations for the Use of Cardiac Troponin in Acute Coronary Syndrome: Expert Opinion from the Academy of the American Association for Clinical Chemistry and the Task Force on Clinical Applications of Cardiac Bio-Markers of the International Federation of Clinical Chemistry and Laboratory Medicine

Alan H.B. Wu,[1*] Robert H. Christenson,[2] Dina N. Greene,[3] Allan S. Jaffe,[4] Peter A. Kavsak,[5] Jordi Ordonez-Llanos,[6] and Fred S. Apple[7]

Recommendation 9: Cardiac troponin results should be reported within 60 minutes or less of when a sample is received. There should be continued efforts to improve this to a time of 60 minutes from when the sample was collected.

Thanks to Drs Alan Wu and Peter Kavsak

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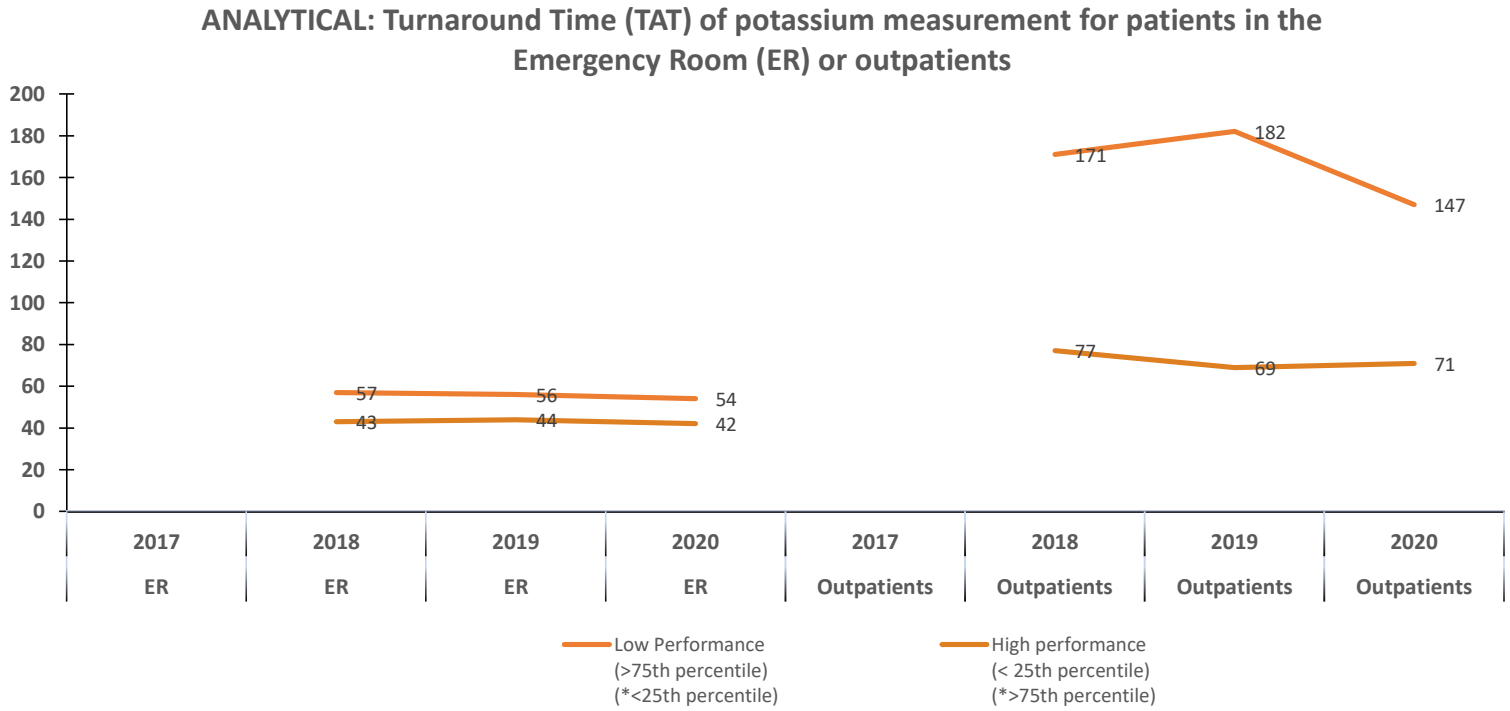
4. Producing Canadian Quality Specifications for promoting improvement

How do you know if the performance of your lab processes are acceptable??
(Based on the WG-LEPS)

Quality Indicator	Type of TAT	Type of patients	Year	High performance (< 25th percentile) (*>75th percentile)	Acceptable Performance (25th-75th percentile)	Low Performance (>75th percentile) (*<25th percentile)	% of lab with 90e percentile < 60 minutes	Number of participants
Troponin : Rate of TAT ≤ 60 min	Analytical	ER	2017	*> 87%	87-96%	*< 96%	N/A	56
Troponin : Rate of TAT ≤ 60 min	Analytical	ER	2018	*> 89%	89-96%	*< 96%	N/A	70
Troponin : Rate of TAT ≤ 60 min	Analytical	ER	2019	*> 88%	88-96%	*< 96%	0%	66
Troponin : Rate of TAT ≤ 60 min	Analytical	ER	2020	*> 88%	88-97%	*< 97%	0%	73
Troponin : Rate of TAT ≤ 60 min	Clinical	ER	2017	N/A	N/A	N/A	N/A	0
Troponin : Rate of TAT ≤ 60 min	Clinical	ER	2018	*> 57%	57-81%	*< 81%	N/A	61
Troponin : Rate of TAT ≤ 60 min	Clinical	ER	2019	*> 52%	52-81%	*< 81%	37%	60
Troponin : Rate of TAT ≤ 60 min	Clinical	ER	2020	*> 52%	52-79%	*< 79%	34%	64
Troponin : TAT 90th percentile	Analytical	ER	2017	< 49 min	49-64 min	> 64 min	68%	56
Troponin : TAT 90th percentile	Analytical	ER	2018	< 47 min	47-61 min	> 61 min	74%	70
Troponin : TAT 90th percentile	Analytical	ER	2019	< 48 min	48-63 min	> 63 min	73%	66
Troponin : TAT 90th percentile	Analytical	ER	2020	< 48 min	48-64 min	> 64 min	64%	85
Troponin : TAT 90th percentile	Clinical	ER	2017	N/A	N/A	N/A	N/A	0
Troponin : TAT 90th percentile	Clinical	ER	2018	< 70 min	70-90 min	> 90 min	11%	61
Troponin : TAT 90th percentile	Clinical	ER	2019	< 71 min	71-97 min	> 97 min	15%	60
Troponin : TAT 90th percentile	Clinical	ER	2020	< 72 min	72-100 min	> 100 min	5%	76

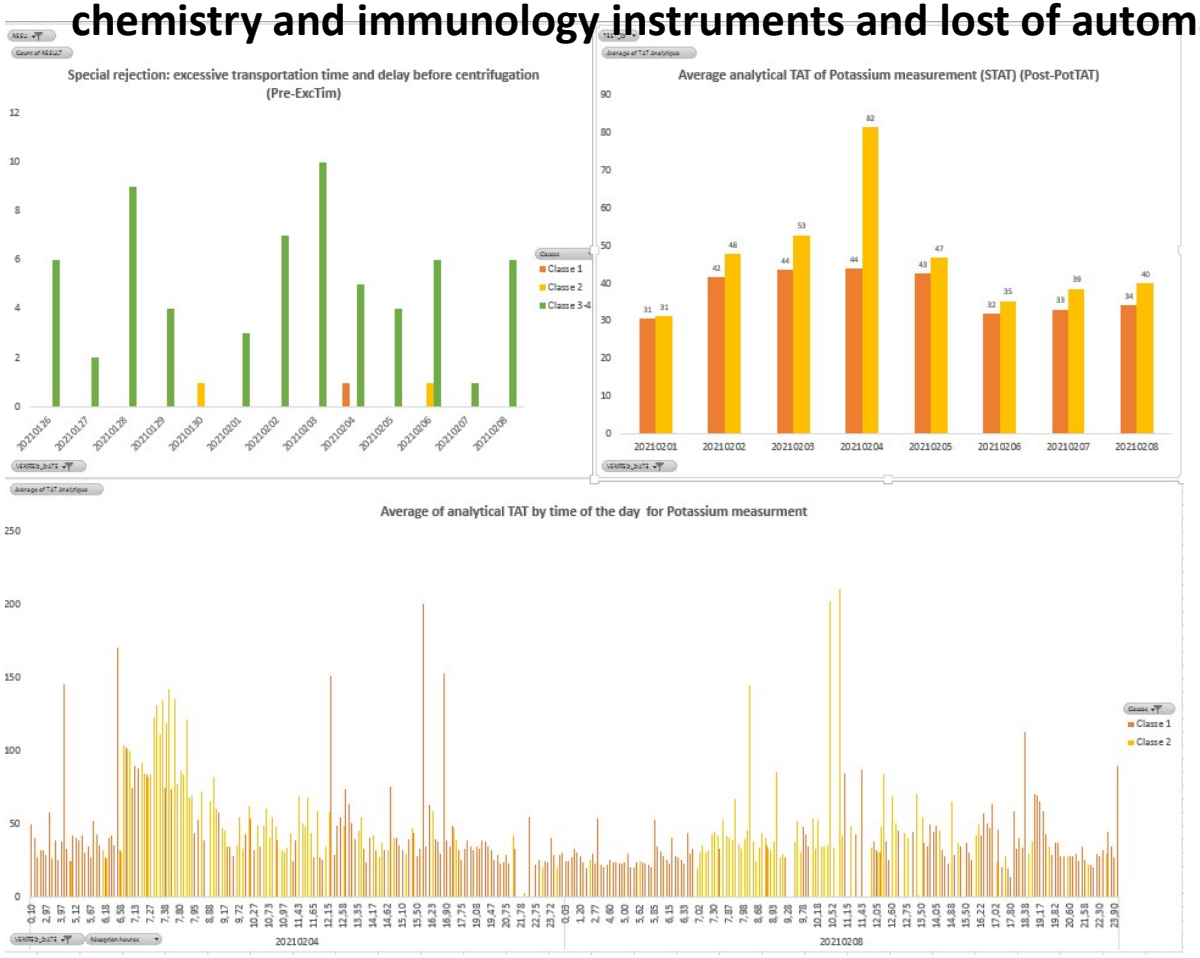
4. Producing Canadian Quality Specifications for promoting improvement

Follow up of improvement through years for Canadian laboratories



Be proactive! Monitor and act on QIs

Dashboard monitoring Post-PotTAT and Pre-ExcTim (WG-LEPS) to monitor the replacement of the chemistry and immunology instruments and lost of automation



Monitoring Potassium TAT based on priority classes of patients (ER, STAT, ICU…) (Post-PotTAT)

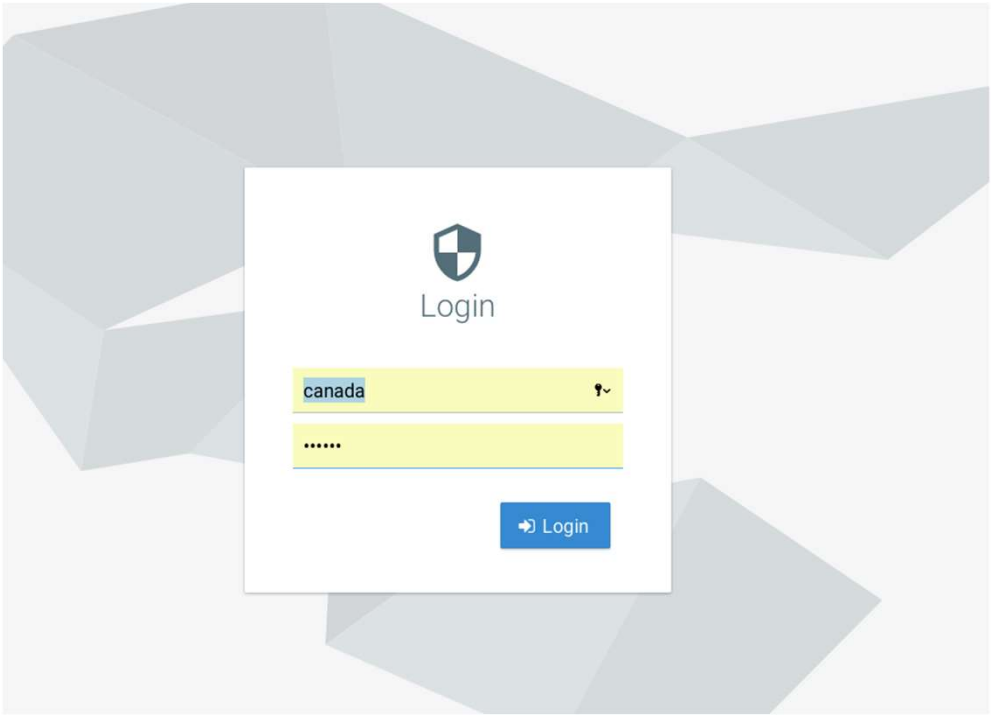
Benchamarking against Quality Specifications for Post-PotTAT

Our performance is optimal even with the construction and lost of automation!

The Canadian Program for Quality Indicators Comparison

1. Maximizing adhesion to our program: addressing users needs, involving people
2. Quality of data is a priority.
3. Addressing the differences between laboratories for accurate comparison.
4. Producing Canadian quality specifications to promote improvement (based on the WG-LEPS).
5. **Promoting standardization in the QIs field, sharing data with the WG-LEPS program.**
6. Promoting the expertise of Clinical Biochemists in the QIs field.
7. Initiating standardization initiatives using QIs.

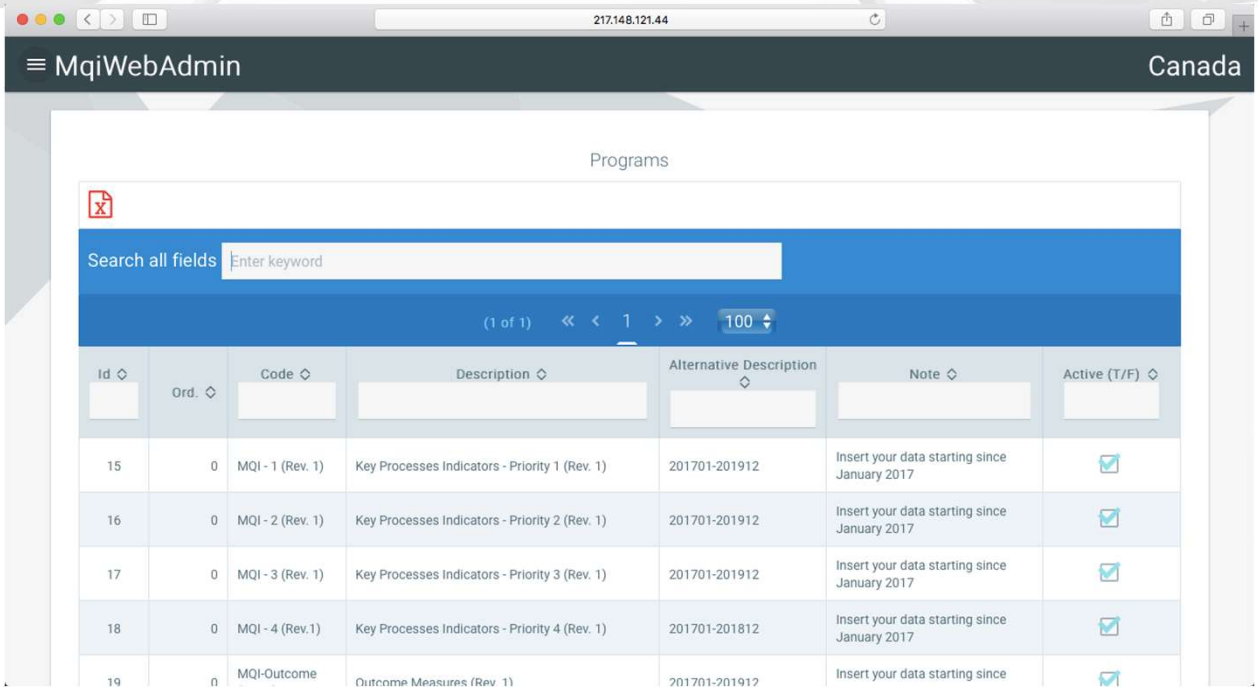
5. Promoting standardization in the QIs field.
Sharing data with the MQI program of the WG-LEPS (IFCC)



In collaboration with Drs. Plebani and Sciacovelli (WG-LEPS)

5. Promoting standardization in the QIs field.
Sharing data with the MQI program of the WG-LEPS (IFCC):

We can share data on specific QIs of interest

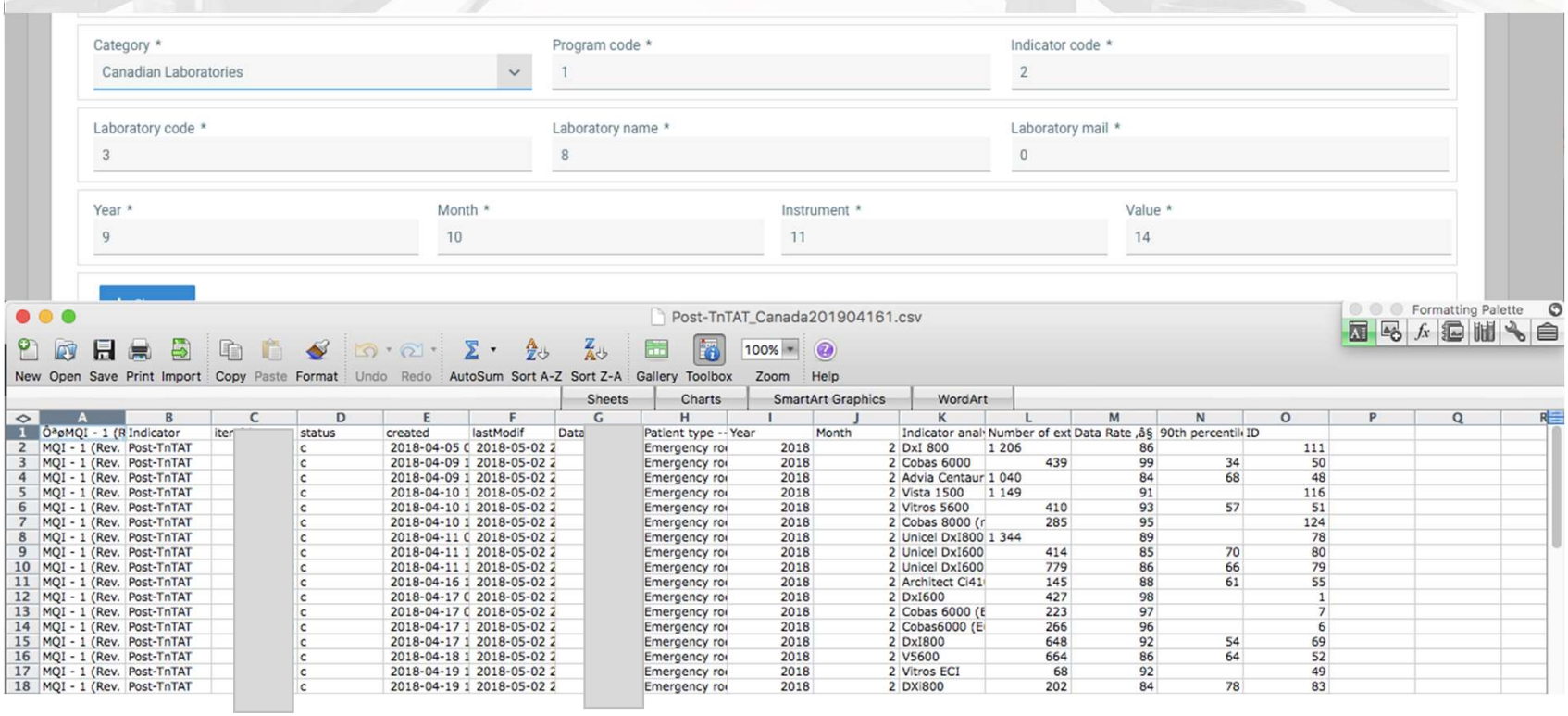


Id	Ord.	Code	Description	Alternative Description	Note	Active (T/F)
15	0	MQI - 1 (Rev. 1)	Key Processes Indicators - Priority 1 (Rev. 1)	201701-201912	Insert your data starting since January 2017	☑
16	0	MQI - 2 (Rev. 1)	Key Processes Indicators - Priority 2 (Rev. 1)	201701-201912	Insert your data starting since January 2017	☑
17	0	MQI - 3 (Rev. 1)	Key Processes Indicators - Priority 3 (Rev. 1)	201701-201912	Insert your data starting since January 2017	☑
18	0	MQI - 4 (Rev.1)	Key Processes Indicators - Priority 4 (Rev. 1)	201701-201812	Insert your data starting since January 2017	☑
19	0	MQI-Outcome	Outcome Measures (Rev. 1)	201701-201912	Insert your data starting since	☑

In collaboration with Drs. Plebani and Sciacovelli (WG-LEPS)

5. Promoting standardization in the QIs field.
Sharing data with the MQI program of the WG-LEPS (IFCC):

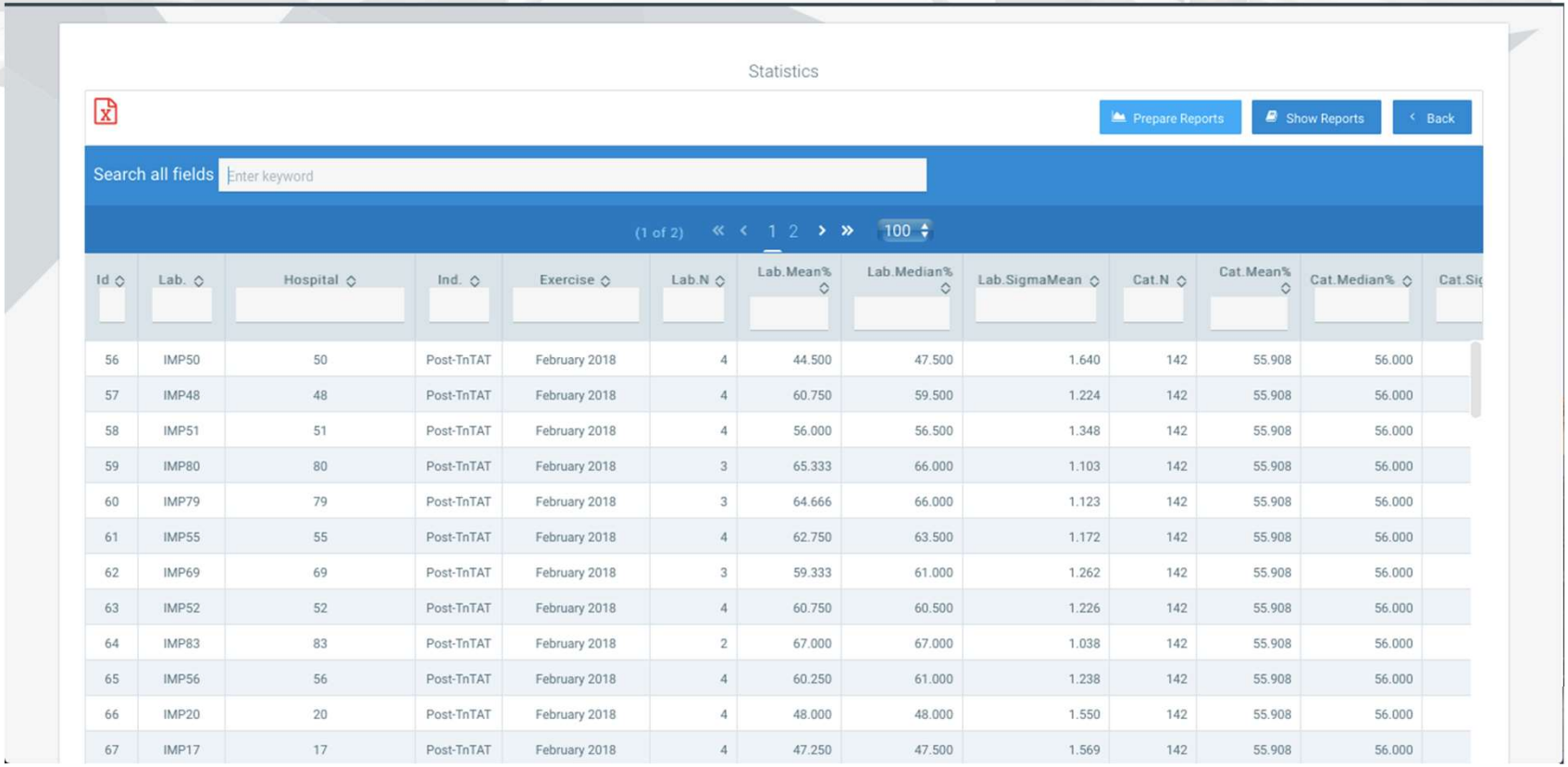
Transfer of data is automated, flexible and in batch



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1	Ô²øMQI - 1 (R	Indicator	iter	status	created	lastModif	Data	Patient type --	Year	Month	Indicator anal	Number of ext	Data Rate ,§§	90th percentil	ID			
2	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-05 0	2018-05-02 2		Emergency ro	2018	2	DxI 800	1 206	86		111			
3	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-09 1	2018-05-02 2		Emergency ro	2018	2	Cobas 6000	439	99	34	50			
4	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-09 1	2018-05-02 2		Emergency ro	2018	2	Advia Centaur	1 040	84	68	48			
5	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-10 1	2018-05-02 2		Emergency ro	2018	2	Vista 1500	1 149	91		116			
6	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-10 1	2018-05-02 2		Emergency ro	2018	2	Vitros 5600	410	93	57	51			
7	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-10 1	2018-05-02 2		Emergency ro	2018	2	Cobas 8000 (r	285	95		124			
8	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-11 0	2018-05-02 2		Emergency ro	2018	2	Unicel DxI800	1 344	89		78			
9	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-11 1	2018-05-02 2		Emergency ro	2018	2	Unicel DxI600	414	85	70	80			
10	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-11 1	2018-05-02 2		Emergency ro	2018	2	Unicel DxI600	779	86	66	79			
11	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-16 1	2018-05-02 2		Emergency ro	2018	2	Architect Ci41	145	88	61	55			
12	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-17 0	2018-05-02 2		Emergency ro	2018	2	DxI600	427	98		1			
13	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-17 0	2018-05-02 2		Emergency ro	2018	2	Cobas 6000 (E	223	97		7			
14	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-17 1	2018-05-02 2		Emergency ro	2018	2	Cobas6000 (E	266	96		6			
15	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-17 1	2018-05-02 2		Emergency ro	2018	2	DxI800	648	92	54	69			
16	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-18 1	2018-05-02 2		Emergency ro	2018	2	V5600	664	86	64	52			
17	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-19 1	2018-05-02 2		Emergency ro	2018	2	Vitros ECI	68	92		49			
18	MQI - 1 (Rev.	Post-TnTAT		c	2018-04-19 1	2018-05-02 2		Emergency ro	2018	2	DXI800	202	84	78	83			

In collaboration with Drs. Plebani and Sciacovelli (WG-LEPS)

5. Promoting standardization in the QIs field.
Sharing data with the MQI program of the WG-LEPS (IFCC)



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Id	Lab.	Hospital	Ind.	Exercise	Lab.N	Lab.Mean%	Lab.Median%	Lab.SigmaMean	Cat.N	Cat.Mean%	Cat.Median%	Cat.Sig
56	IMP50	50	Post-TnTAT	February 2018	4	44.500	47.500	1.640	142	55.908	56.000	
57	IMP48	48	Post-TnTAT	February 2018	4	60.750	59.500	1.224	142	55.908	56.000	
58	IMP51	51	Post-TnTAT	February 2018	4	56.000	56.500	1.348	142	55.908	56.000	
59	IMP80	80	Post-TnTAT	February 2018	3	65.333	66.000	1.103	142	55.908	56.000	
60	IMP79	79	Post-TnTAT	February 2018	3	64.666	66.000	1.123	142	55.908	56.000	
61	IMP55	55	Post-TnTAT	February 2018	4	62.750	63.500	1.172	142	55.908	56.000	
62	IMP69	69	Post-TnTAT	February 2018	3	59.333	61.000	1.262	142	55.908	56.000	
63	IMP52	52	Post-TnTAT	February 2018	4	60.750	60.500	1.226	142	55.908	56.000	
64	IMP83	83	Post-TnTAT	February 2018	2	67.000	67.000	1.038	142	55.908	56.000	
65	IMP56	56	Post-TnTAT	February 2018	4	60.250	61.000	1.238	142	55.908	56.000	
66	IMP20	20	Post-TnTAT	February 2018	4	48.000	48.000	1.550	142	55.908	56.000	
67	IMP17	17	Post-TnTAT	February 2018	4	47.250	47.500	1.569	142	55.908	56.000	

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

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In collaboration with Drs. Plebani and Sciacovelli (WG-LEPS)

5. Promoting standardization in the QIs field.
Sharing data with the MQI program of the WG-LEPS (IFCC):

Providing IFCC reports to our users to increase the number of participants for specific QIs.

QUALITY INDICATORS

Post-TnTAT - Turnaround time (minutes), from sample reception in laboratory to release of result, of Cardiac Troponin (TnI or TnT) at 90th

Laboratory code **IMP50** Laboratory Group: **Canadian Laboratories**

Laboratory istitution - **50** - -

	Statistical Data of Laboratory Results				Statistical Data of Laboratory Results				Statistical Data of Laboratory Results			
	Data number	Mean (%)	Median (%)	Sigma mean	Data number	Mean (%)	Median (%)	Sigma mean	Data number	Mean (%)	Median (%)	Sigma mean
All Data	4	44,50	47,50	1,64	142	55,908	56,000	1,349	169	56,975	57,000	1,323

	Laboratory Data				Participants Data							
	Laboratory Value (%)	Laboratory Sigma	Confidence Interval Sigma		Group Sigma		Confidence Interval Group Sigma		Overall Sigma		Confidence Interval Overall Sigma	
			Min	*Max*	*Value*	*N*	*Min*	*Max*	*Value*	*N*	*Min*	*Max*
February 2018	34,00	1,91	1,91	1,91	1,26	34	1,26	1,26	1,26	34	1,26	1,26
April 2018	47,00	1,58	1,58	1,58	1,36	27	1,36	1,36	1,33	48	1,33	1,33
August 2018	48,00	1,55	1,55	1,55	1,37	40	1,37	1,37	1,33	58	1,33	1,33
December 2018	49,00	1,53	1,53	1,53	1,38	41	1,38	1,38	1,38	56	1,38	1,38

In collaboration with Drs. Plebani and Sciacovelli (WG-LEPS)

The Canadian Program for Quality Indicators Comparison

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6. Promoting the expertise of laboratory professional in the QI field.

•The **credibility of our program** (high number of participants and collaboration with WG-LEPS and CSCC) gives the **opportunity to Clinical Biochemists to be involved** in **QIs initiative** (laboratory network leaders).

•**Clinical Biochemists are highly considered** in **quality improvement committee** within their organization (there is a lot of competition!)

•**Laboratory professionals** are recruited in **key provincial committee** for QIs evaluation and quality improvement initiatives.

• **Consideration of our standardization initiatives** by the provincial government to be implemented all across the laboratories.

1. Maximizing adhesion to our program: addressing users needs, involving people
2. Quality of data is a priority.
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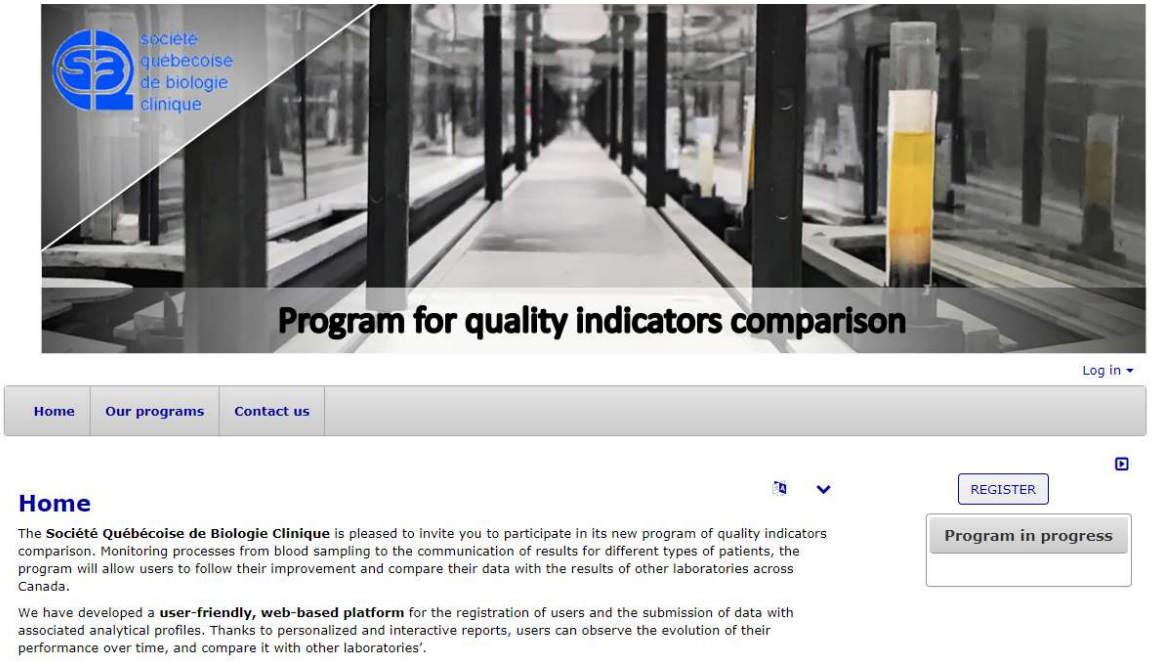
7. **Initiating standardization initiatives using QIs.**

Canadian Society of Clinical Chemists initiative: Standardization of QIs in POCT

Step 4: Implementing these QIs in the Quality Indicators Comparison Program



Recommended literature

- **WG-LEPS website for the QIs comparison project:** *https://www.ifcc.org/ifcc-education-division/working-groups-special-projects/laboratory-errors-and-patient-safety-wg-leps/quality-indicators-project/*
- Sciacovelli L et al. Defining a roadmap for harmonizing quality indicators in Laboratory Medicine: a consensus statement on behalf of the IFCC Working Group "Laboratory Error and Patient Safety" and EFLM Task and Finish Group "Performance specifications for the extra-analytical phases". Clin Chem Lab Med. 2017 Aug 28;55(10):1478-1488. doi: 10.1515/cclm-2017-0412. PMID: 28688224.
- Sciacovelli L et al; Working Group “Laboratory Errors and Patient Safety” of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Pre-analytical quality indicators in laboratory medicine: Performance of laboratories participating in the IFCC working group "Laboratory Errors and Patient Safety" project. Clin Chim Acta. 2019 Oct;497:35-40. doi: 10.1016/j.cca.2019.07.007. Epub 2019 Jul 8. PMID: 31295446.
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- Vermeersch P et al. How to meet ISO15189:2012 pre-analytical requirements in clinical laboratories? A consensus document by the EFLM WG-PRE. Clin Chem Lab Med. 2021 Jan 15;59(6):1047-1061. doi: 10.1515/cclm-2020-1859. PMID: 33554545.
- Janssens PM. Practical, transparent prospective risk analysis for the clinical laboratory. Ann Clin Biochem. 2014 Nov;51(Pt 6):695-704. doi: 10.1177/0004563214521160. Epub 2014 Feb 19. PMID: 24553437.

Test your knowledge

If you have carefully followed this lecture, you will know the answers to these questions:

- Is there any international guidelines for Quality Indicators monitoring? Which one?
- What is the value of comparing quality indicators performance between laboratories?
- What is Quality Specifications and how can it help you in your quality improvement initiatives?
- Name different standardization initiatives that can make the difference for our patients.
- What would be the best strategy if you need to implement quality improvement initiatives in your hospital to maximize adhesion?

Learning outcomes

If you attend this lecture, at the end you will know/understand/learn:

1. Understand the value of monitoring our laboratory processes to improve the safety of our patients.
2. Be aware of the international guidelines on Quality Indicators monitoring and quality improvement.
3. Understand how local, provincial and national initiatives in line with the international guidelines can enroll laboratory medicine professionals in quality improvement initiatives.
4. Understand the value of Quality Indicators comparison between laboratories and Quality Specifications for benchmarking.
5. Understand how standardization initiatives can improve quality in our laboratories.

Are we all measuring the same thing in regards of process monitoring?

What Is the best description of your potassium TAT in your laboratory?

- **From blood sampling or from reception in the lab?**
- **Calculating the average of TAT or the 90th percentile?**
- **For the ER only or all your patients?**
- **Are you using POCT, stand alone instruments or automation?**
- **…**

Quality indicators for laboratory diagnostics: consensus is needed

Mario Plebani[1], Laura Sciacovelli[1] and Giuseppe Lippi[2]

There is now a compelling need to reorganize and possibly unify these ongoing projects, as well as establish an international consensus for producing joint recommendations focused on the adoption of universal quality indicators and common terminology.

Ann Clin Biochem 2011;48:479

Thanks to Dr Mario Plebani

The WG-LEPS of the IFCC: working towards the standardization of the QIs field

DE GRUYTER DOI 10.1515/cclm-2014-0142 — Clin Chem Lab Med 2014; aop

Opinion paper

Mario Plebani*, Michael L. Astion, Julian H. Barth, Wenxiang Chen, César A. de Oliveira Galoro, Mercedes Ibarz Escuer, Agnes Ivanov, Warren G. Miller, Penny Petinos, Laura Sciacovelli, Wilson Shcolnik, Ana-Maria Simundic and Zorica Sumarac

Harmonization of quality indicators in laboratory medicine. A preliminary consensus

However, while some interesting programs on indicators in the total testing process have been developed in some countries, there is no consensus for the production of joint recommendations focusing on the adoption of universal QIs and common terminology in the total testing process. A preliminary agreement has been achieved in a Consensus Conference organized in Padua in 2013, after revising the model of quality indicators (MQI) developed by the Working Group on "Laboratory Errors and Patient Safety" of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The consensually

Before 2013 there was no consensus on joint recommendations for universal QIs. In other words, it was almost impossible to compare the robustness of our process at the international level.

Don't forget! Comparison of our processes means improvement!

Thanks to Dr Mario Plebani