

5th EFLM Conference on Preanalytical Phase

Preanalytical challenges - time for solutions



Zagreb (Croatia), 22-23 March 2019

Saturday, 23 March, 2019

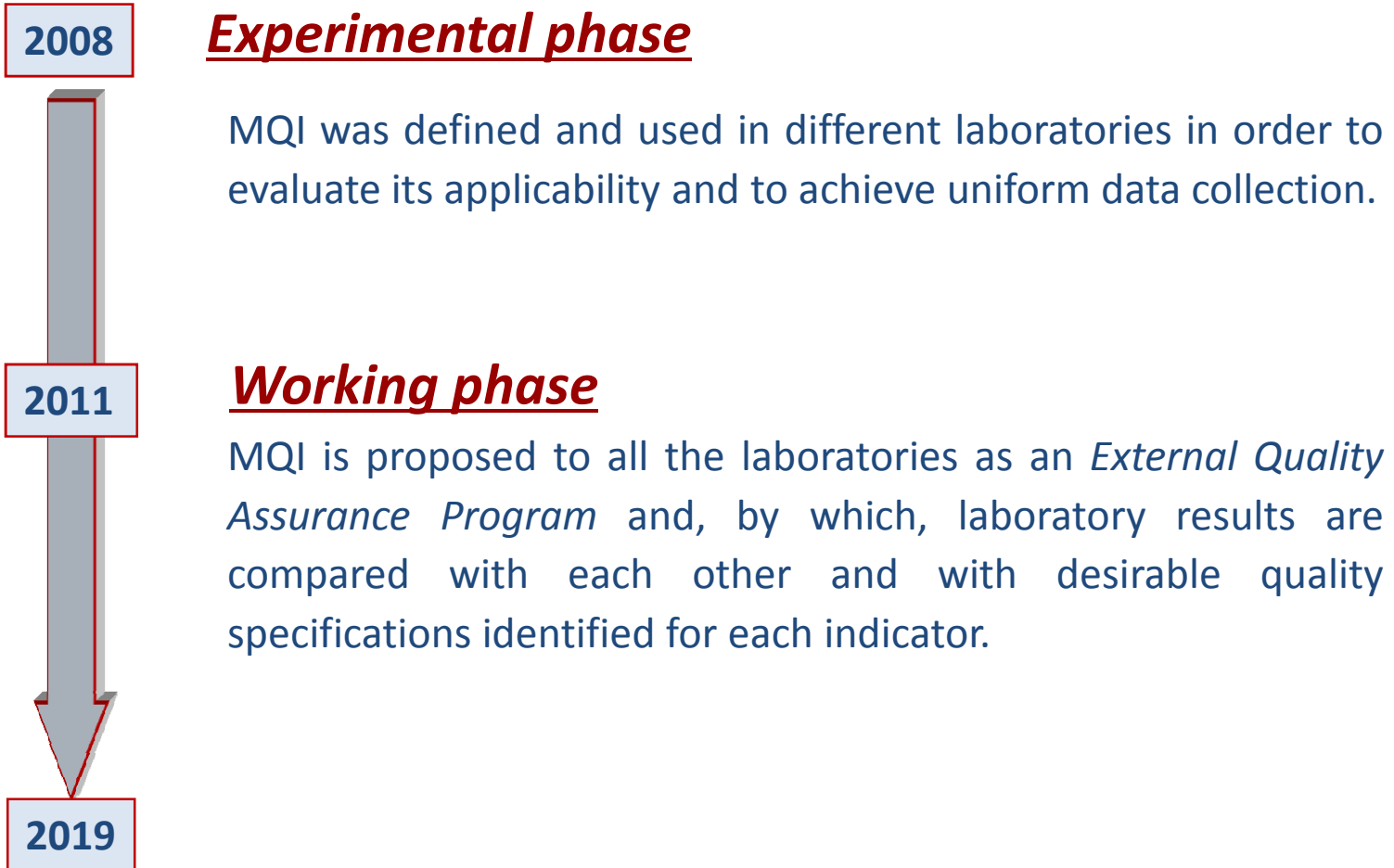
Session: Preanalytical phase and patient safety

Chairs: Mads Nybo and Mercedes Ibarz

09:00 - 09:30	Preanalytical phase, patient safety and its impact on hospital management Steve McManus
09:30 - 10:30	Roundtable on Preanalytical quality indicators Mario Plebani and Laura Sciacovelli
10:30 - 11:15	Coffee break

IFCC Working Group “Laboratory Errors and Patient Safety”

Project on Model of Quality Indicators



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Project on Model of Quality Indicators

Harmonization of Quality Indicator management in clinical laboratories all over the world

The participation in the External Quality Assurance Program includes the:

- use of a common list of Quality Indicators;
- collection of results from participating laboratories;
- processing of results;
- release of a report with the evaluation of laboratory results and statistical data calculated per group and related to all results.

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Achievements

- Three different Models of Quality Indicators (QIs) have been tested and now the Model of Quality Indicators discussed and approved in the Consensus Conference held in Padova (Italy) in 2016 is in use, through an External Quality Assurance Program (EQAP).
- A dedicated website (www.ifcc-mqi.com) is available to collect laboratory results and provide a report to each participant.
- A criterion to define the performance specifications for each Indicator has been defined.

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Model of Quality Indicators



26 Indicators → 53 Measurements

	<i>Indicators</i>	<i>Measurements</i>
Key Processes	20	43
<i>Pre-analytical phase</i>	11	25
<i>Intra-analytical phase</i>	5	6
<i>Post-analytical phase</i>	4	12
Support Processes	3	5
Outcome Measures	3	5

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Priority order

- 1 *Mandatory*
- 2 *Important*
- 3 *Suggested*
- 4 *Valued*



Model of Quality Indicators = 53 Measurements

Key Processes = 43

	<i>Priority</i>	1	2	3	4
Pre-analytical phase	⇒	19	2	2	2
Intra-analytical phase	⇒	6	0	0	0
Post-analytical phase	⇒	9	0	0	3

Support Processes = 5

<i>Priority</i>	1	2	3	4
	0	4	1	0

Outcome Measures = 5

<i>Priority</i>	1	2	3	4
	5	0	0	0

1

Haemolysed sample	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
	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.

2

Inappropriate test requests	Pre-OffQue	Percentage of: Number of requests without clinical question (offside patients) / Total number of requests (offside patients)
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3

Unintelligible requests	Pre-OffUn	Percentage of: Number of unintelligible offside patients requests / Total number of offside patients requests
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4

Inappropriate test requests	Pre-OffReq	Percentage of: Number of inappropriate requests, with respect to clinical question (offside patients) / Number of requests reporting clinical question (offside patients)
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WEAKNESSES

- ✓ Many labs used the Qis proposed by the WG-LEPS, but they do not submit data
- ✓ Laboratories have difficulties to submit the results in compliance with the deadlines (monthly, every three months, every years, etc.)

Pre-analytical Quality Indicators

- Priority 1 -

Misidentification errors

- ✓ Misidentified requests
- ✓ Misidentified samples

Test transcription errors

- ✓ requests with erroneous data entered by laboratory personnel
- ✓ requests with erroneous data entered by offside personnel

Samples with Incorrect sample type

- ✓ Samples of wrong or inappropriate type (e.g. whole blood instead of plasma)
- ✓ Samples collected in wrong container

Samples with Incorrect fill level

- ✓ Samples with insufficient volume
- ✓ Samples with inappropriate sample-anticoagulant volume ratio

Unsuitable samples for transportation and storage problems

- ✓ Not received
- ✓ Not properly stored before the analysis
- ✓ Damage during the transportation
- ✓ Transported at inappropriate temperature
- ✓ With excessive transportation time

Contaminated sample

- ✓ Microbiological contaminated samples
- ✓ Contaminated samples rejected

Haemolysed samples

- ✓ Samples with free haemoglobin (Hb) > 0.5 g/L detected by visual inspection
- ✓ Samples with free haemoglobin (Hb) > 0.5 g/L detected by automated haemolytic index
- ✓ Samples rejected due to haemolysis

Clotted sample

Inappropriate time in sample collection

Pre-analytical Quality Indicators

Priority 2

Inappropriate test requests

- ✓ Requests without clinical question (offside patients)
- ✓ Requests without clinical question (inside patients)

Priority 3

Unintelligible requests

Priority 4



Inappropriate test requests

- ✓ Inappropriate requests with respect to clinical question (offside patients)
- ✓ Inappropriate requests with respect to clinical question (inside patients)

Data Analysis 2014 - 2018

Error rate over the years:  decreasing  stable  increasing



Misidentification errors

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- ✓ Misidentified samples 



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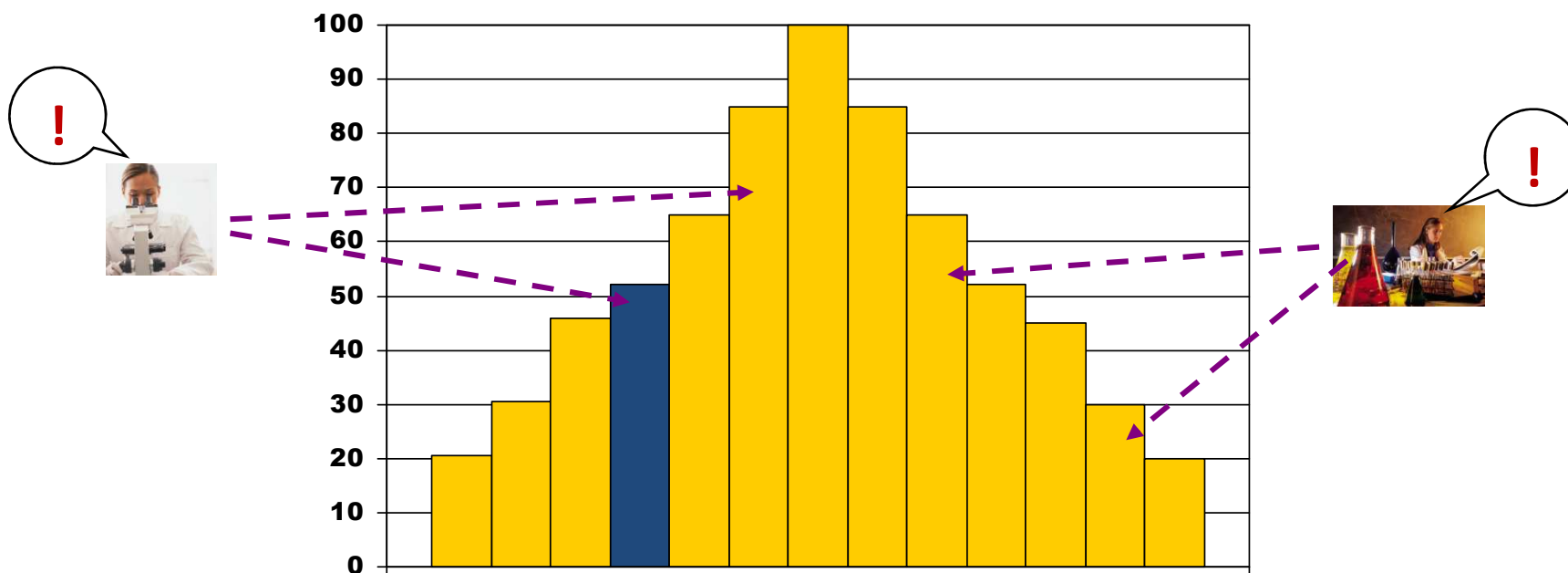
Clotted sample

Inappropriate time in sample collection



Benchmarking process

Comparison of the performance of each laboratory
with that of other laboratories!



STRENGTHS

Different Laboratories can:

- use the same Quality Indicators
- collect results according to the same procedure
- compare their results with those of other labs



STRENGTHS

Collection and analysis of QIs results allows to:

- know the error rate
- define the State-of-the-Art of Laboratories performances
- define the targets that is possible to reach



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Project on Model of Quality Indicators



In progress

Future goals



In progress



Participation is free

Confidentiality is guaranteed

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In progress

Future goals



In progress

- Involvement of the **international Providers of EQAS/PT** (i.e. NEQAS, INSTAND, RfB, SEKK, IEQAS, NKK, DEKS etc.), in the External Quality Assurance Program of the WG-LEPS in order to harmonize the use of QIs;
- Identification of **National Leaders** to coordinate the participation of laboratories in their Countries with the involvement of national Scientific Societies;
- Involvement of **Accreditation Bodies**, so that the MQI may be identified as a suitable tool complying with the ISO 15189:2012 requirements.

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In progress

Future goals



In progress

The success of the project depends on
a management organized at a national/regional level,
so that all peculiarities of laboratories are understood and respect national
practices.

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Project on Model of Quality Indicators



In progress

Future goals



In progress

Identification of National Leaders to coordinate the participation of laboratories in their Countries in order to increase the number of participants and stimulate their active involvement. In particular:

- promote the Model as a tool that supports process improvements, errors reduction and patient safety;
- select the Indicators that are more appropriate in respect to national practices, requirements and regulatory rules;
- promote and support the participation of clinical laboratories;

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In progress

Future goals



In progress

Identification of National Leaders to coordinate the participation of laboratories in their Countries in order to increase the number of participants and stimulate their active involvement. In particular:

- co-operate with the chairman and co-workers of the WG-LEPS;
- provide suggestions to improve the current MQI so that it is applied to all clinical laboratories aside from number and type of tests, staff, and country/region

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In progress

Future goals



In progress

To favourite this goal, the web application (www.ifcc-mqi.com) has been updating so that is possible that each “National Leader”

- can autonomously manage QIs data from laboratories of its country, sharing the QIs and the criteria and procedures that are defined in agreement with the WG-LEPS.
- will be able to collect and processing data from "local" laboratories and release to them the report,
- will also be able to visualize, in anonymous form, the data collected from laboratories around the world.

Quality Indicators in Laboratory Medicine



*All of you are invited
to use Quality Indicators in your own laboratory
in order to
improve the quality of laboratory performances
and
guarantee patient safety*