EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

EUROMEDLAB
PARIS 2015
21-25 JUNE
EVOLUTION IN LABORATORY MEDICINE

21st IFCC - EFLM
European Congress of Clinical Chemistry and Laboratory Medicine

EuroMedLab JIB – 2015 exhibition
22-24 June 2015

PARIS, FRANCE – Le Palais des Congrès
21-25 June 2015

Mario Plebani
University-Hospital
of Padova, Italy

QUALITY IN LABORATORY MEDICINE

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***.

Plebani M. Clin Biochem Rev 2012

Criteria for Quality Testing

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

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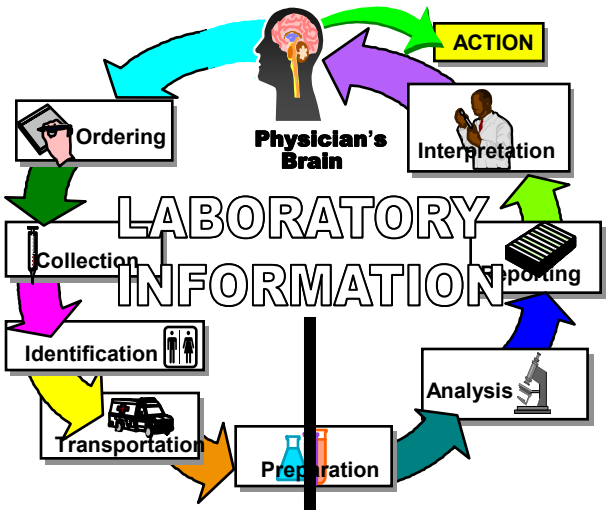
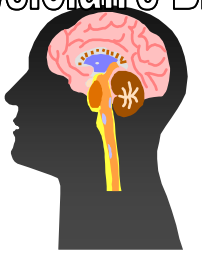
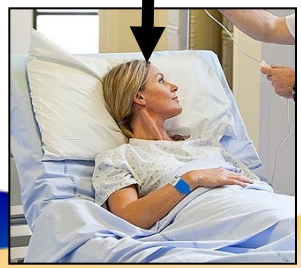


Physician's Brain



DECISION-MAKING



AFTER THE STOCKHOLM CONFERENCE

- Evidence has been collected on the **frequency** and **stratification** of ***errors*** in laboratory medicine.
- The **vulnerability** of both the **pre-analytical phase**, which accounts for approximately 70% of laboratory errors, and of the ***post-analytical phase*** has been highlighted as well as the risk for quality and patient safety.
- Consensually defined criteria for setting **extra-analytical quality indicators** have been developed and data collected.
- This in turn, should provide the way to define reliable **performance criteria** in the pre-and post-analytic phases.

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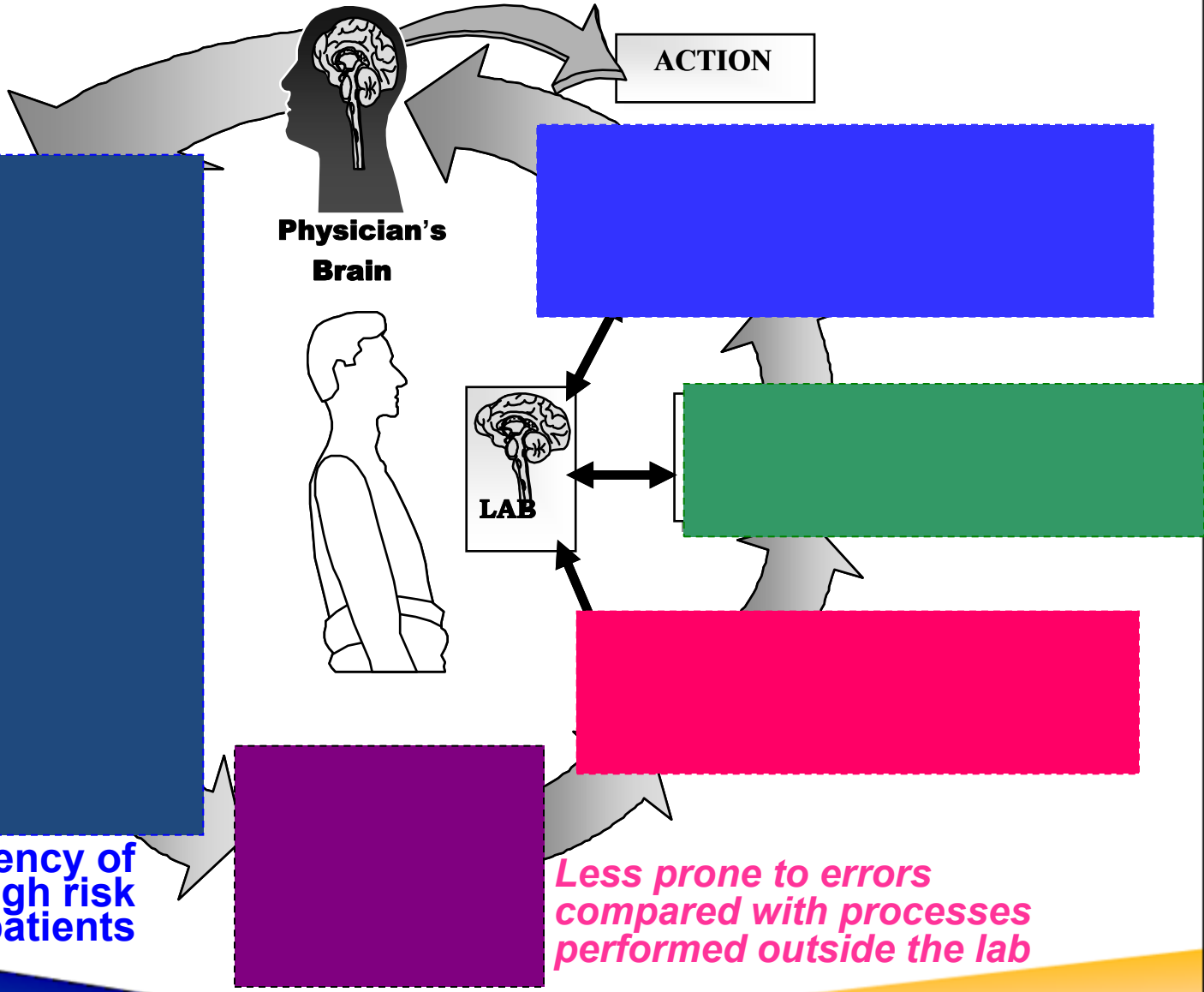

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DE GRUYTER

Clin Chem Lab Med 2015; 53(6): 833–835

Consensus Statement

Sverre Sandberg*, Callum G. Fraser, Andrea Rita Horvath, Rob Jansen, Graham Jones, Wytze Oosterhuis, Per Hyltoft Petersen, Heinz Schimmel, Ken Sikaris and Mauro Panteghini

Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine

Performance specifications for pre- and post-analytical phases

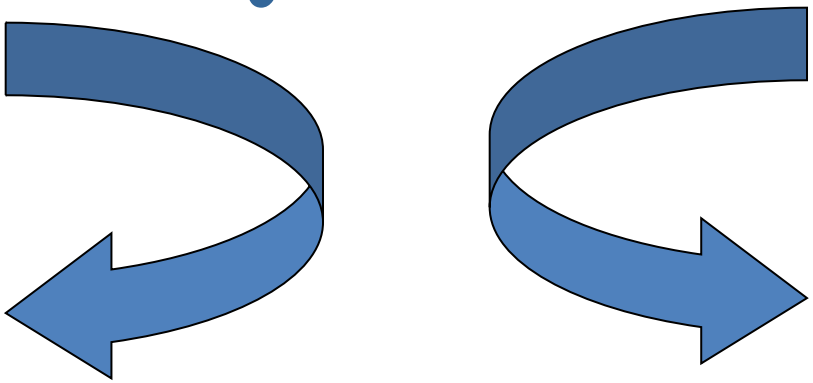
It is acknowledged that, for patient care, optimizing the quality of the total (pre-analytical/analytical/post-analytical) examination process is the ultimate goal and therefore it would be desirable to go beyond setting analytical performance specifications and to establish examination performance specifications. In principle, the performance specifications for the pre- and post-analytical laboratory processes should follow the same models as for analytical performance specifications. When components of these additional phases can be expressed in numerical terms, they should be added in defining examination performance specifications. In other situations, pre- and post-analytical performance specifications will be best represented by separate quality indicators that should reflect models 1 and 3 listed above.

Sandberg S et al CCLM 2015

Performance criteria

	Analytical Phase	Pre/Post-Analytical Phase
Hierarchy of criteria	***Well defined***	***Not defined*** Possibly based on the State-of-the-Art and on Outcome Measures
Quality Specifications	***Well defined*** Bias and Reproducibility	***Under development***
Metrics	***Well defined***	***Proposed*** - Percentage - Parts per million (ppm) - Six sigma
Tools of measures	***Well defined*** - Internal Quality Control (IQC) - External Quality Assessment (EQA)	***Recently defined*** Quality indicators (QI)

Quality Indicators



Process Measures

-Harmonization
-Metric
-Performance specifications

Outcome Measures

- Work in progress

Quality Indicators

Key Processes

Priority	1	2	3	4
Pre-analytical phase	22	2	2	2
Intra-analytical phase	5	0	1	0
Post-analytical phase	8	0	0	3

Performance Specifications

	Range	Median	Specifications	
Specimen not received	2.0 - 6.1	2.9	2.0	Optimum
			4.0	Desirable
			6.0	Minimum
Specimen insufficient	0.07 - 0.8	0.15	0.07	Optimum
			0.44	Desirable
			0.8	Minimum
Wrong container	0.02 - 0.2	0.03	0.02	Optimum
			0.11	Desirable
			0.2	Minimum

Quality Indicators

Post-Analytical Processes

Quality Indicators		Quality Specifications *on the basis of 25° -50° - 75° percentile*		
		Minimum	**Desirable**	**Optimum**
Percentage of: Number of reports with interpretative comments impacting positively on patient's outcome/ Total number of reports with interpretative comments **(Post-Comm)**	*Percentage*	0.12	32.2	62.5
	Sigma	1.699	1.967	4.429
Percentage of: Number of incorrect reports issued by the laboratory / Total number of reports issued by the laboratory **(Post-IncRep)**	*Percentage*	0.035	0	0
	Sigma	4.621	4.791	4.932
Percentage of: Number of reports delivered outside the specified time/ Total number of reports.**(Post-OutTime)**	*Percentage*	0.13	0	0
	Sigma	3.782	4.508	4.793

OUTCOME MEASURES
pre-analytical phase

Measure	*Causes*
1) **Inappropriate test ordered**	- Cognitive problem - Defensive medicine issues - Misspelt test name - Misunderstanding of physician's request
2) **Appropriate test not ordered**	- Cognitive problem - Misspelt test name - Misunderstanding of physician's request - Test lost in translation (from physician's request to electronic or hard copy)

OUTCOME MEASURES
intra-analytical phase

Measure	*Causes*
3) Result of appropriately ordered test inaccurate	- Patient/sample misidentification - Pre-analytical errors in sample collection and handling - Instrumentation failure, analytical interference and poor analytical performances

OUTCOME MEASURES
post-analytical phase

- **Appropriate test ordered, but delay in TTP occurs**
  - Delayed sample collection or transportation
  - Delayed analytical performance
  - Delayed trasmission of results
  - Delayed acknowlegement by care operators/ physicians
- **Appropriate test result misapplied**
  - Cognitive failure of clinicians
  - Available information incomplete
  - Wrong reference ranges or decision levels
  - No interpretative comment
- **Outpatients called back for wrong procedures**
  - Suspected patient/sample misidentification
  - Unsuitable samples
  - Incorrect results
  - Suspected interference

TFG-PSEP: the project

1) Enrollment of the members of the TFG-PSEP **done**
2) Project planning
3) Spread of the information
4) Collection of data
5) Proposal of preliminary performance specifications
6) Further steps