The CSCQ pre-analytical EQA scheme

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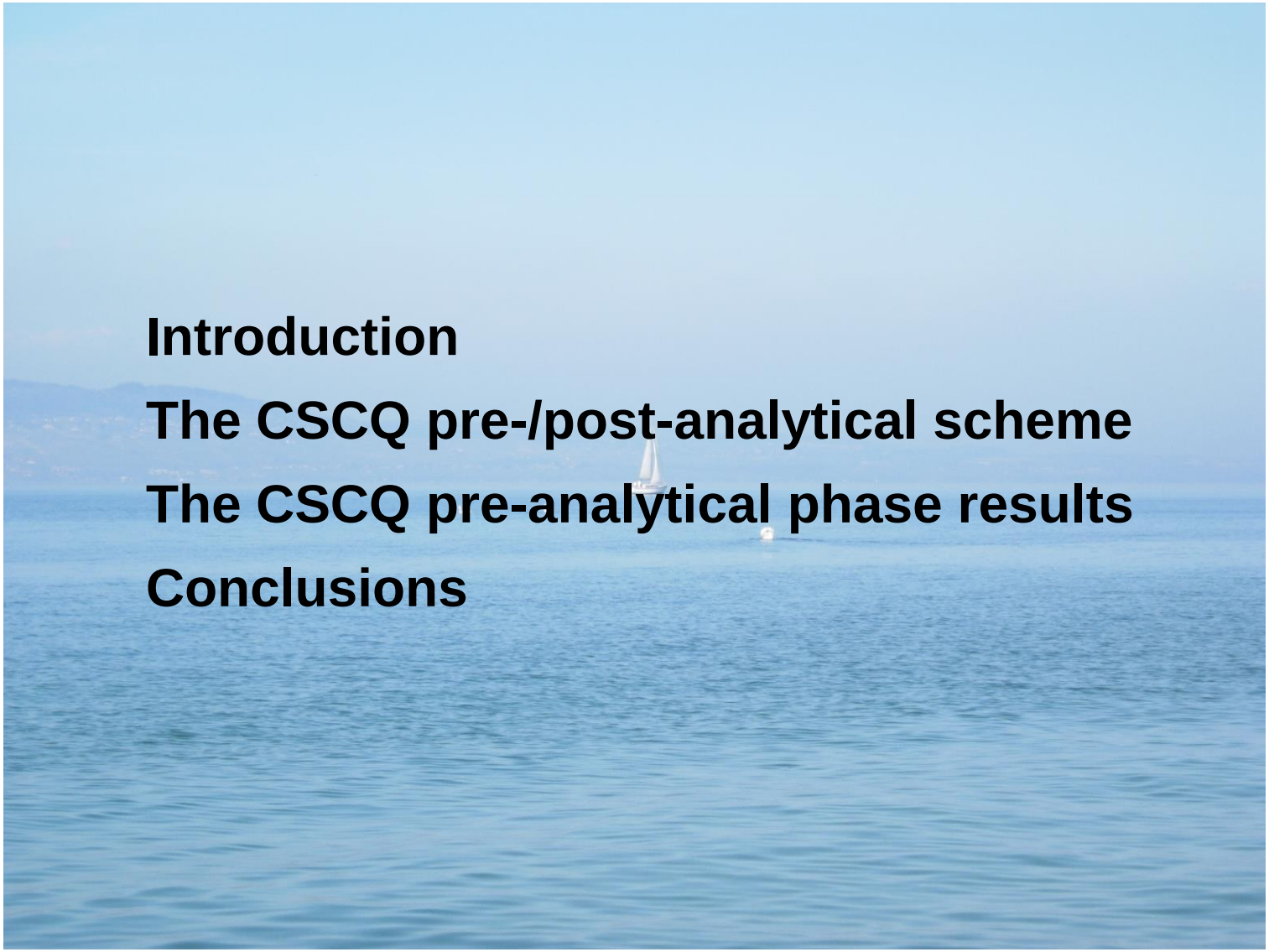


Introduction

The CSCQ pre-/post-analytical scheme

The CSCQ pre-analytical phase results

Conclusions

Introduction: some statements

"Few data are available on the impact of errors in the pre-analytical phase on clinical outcomes. The identification of quality specifications based on the state-of-the art should therefore be considered an essential preliminary step in arousing the awareness in clinical laboratories of the need to measure and improve their performances in extra-analytical quality indicators." [1]

"Whereas the laboratorian may be aware of the possibility of an analytical interference, clinicians are largely unaware of these effects […]. When this information is not given with the result, clinicians may misinterpret test values and take an inappropriate action with their patients." [2]

"Since only laboratorians have detailed knowledge about preanalytical issues this teaching becomes a responsibility of the laboratory physician or scientist." [3]

[1] Plebani M et al., Clin Chem Lab Med 2015
[2] Young DS, in Samples: From the Patient to the Laboratory 1996
[3] Young DS, Clin Chem Lab Med 2003

CSCQ: organisation of a pre-/post-analytical EQA scheme since 2007

- Xavier Albe & Dagmar Kesseler, EQALM meeting 2011 (Szeged)

Pre-/post-analytical surveys

complementary service of EQA centers and valuable continuing education tool

- Results submission
- Evaluation
- Reporting

- Dagmar Kesseler & Xavier Albe, EQALM meeting 2014 (Toulouse)

EQA in pre-analytics 8 years of experience

- 8 year results
- Statistics
- Standardisation
- Education

Type of EQA scheme

Three types of pre-analytical EQA schemes[1]

I: Registration of procedures (questionnaires) ← CSCQ

II: Circulation of samples simulating errors

III: Registration of errors/adverse events

[1] Kristensen GBB et al., Biochem Med 2014

The CSCQ pre-/post-analytical EQA scheme

- Internet based, multiple choices questionnaire
- 2 surveys per year (>2007)
- 10 questions per survey (the participant can answer 5 questions only)
- Participation is not mandatory, is free of charge, and for education purposes
- Survey period 2007-2017
- 21 surveys
- 210 questions
- 98’866 results
- Report with extensive explanations, recommendations

The CSCQ pre-/post-analytical EQA scheme

- **Questionnaire**

  3 main fields

  1) Pre(pre)-analytical situations, including biological interference

  2) Post(post)-analytical situations

  3) General knowledge

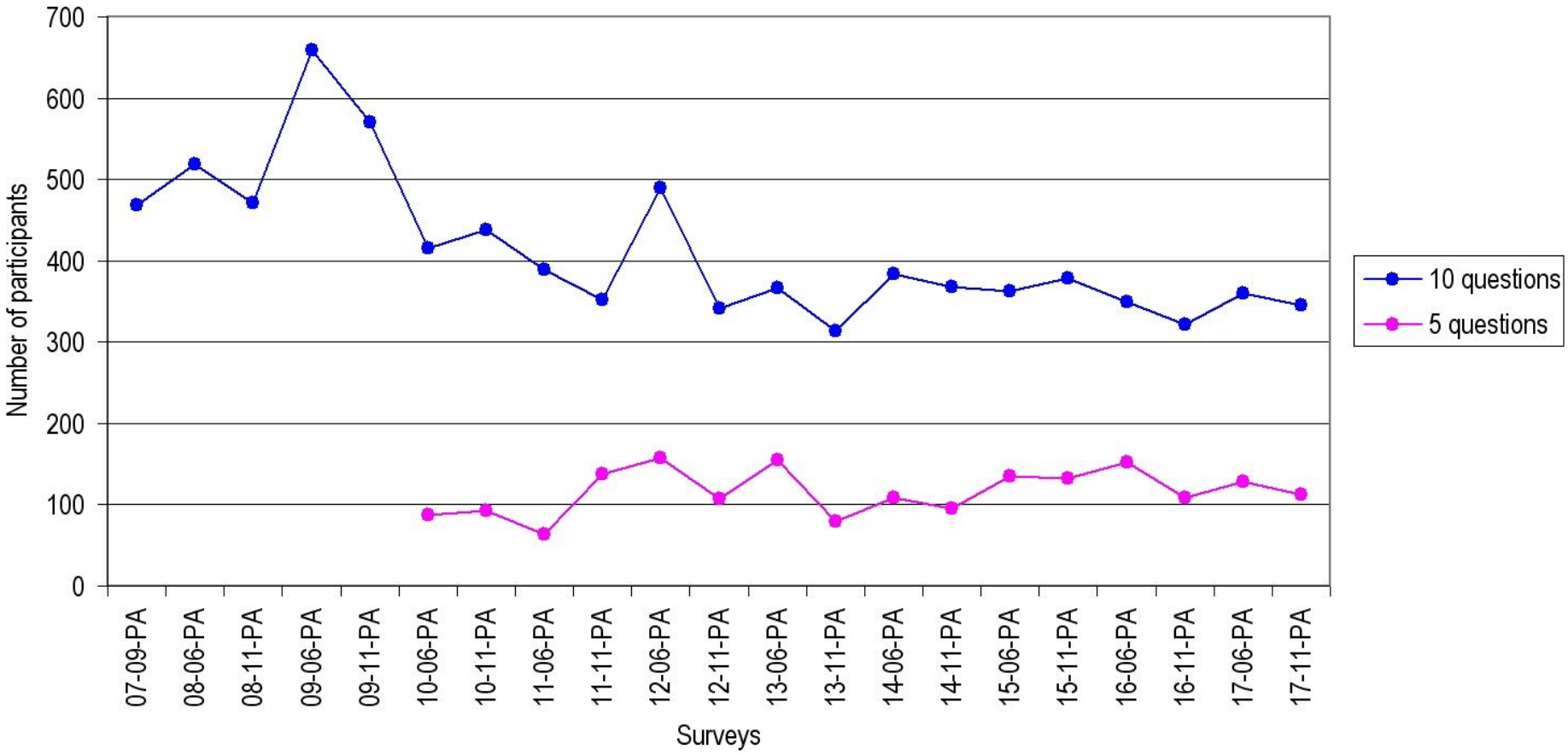
- **Switzerland**

  Laboratory population

  1) Private & Hospital laboratories

  2) Medical Offices (MOs)

Participants



Evaluation

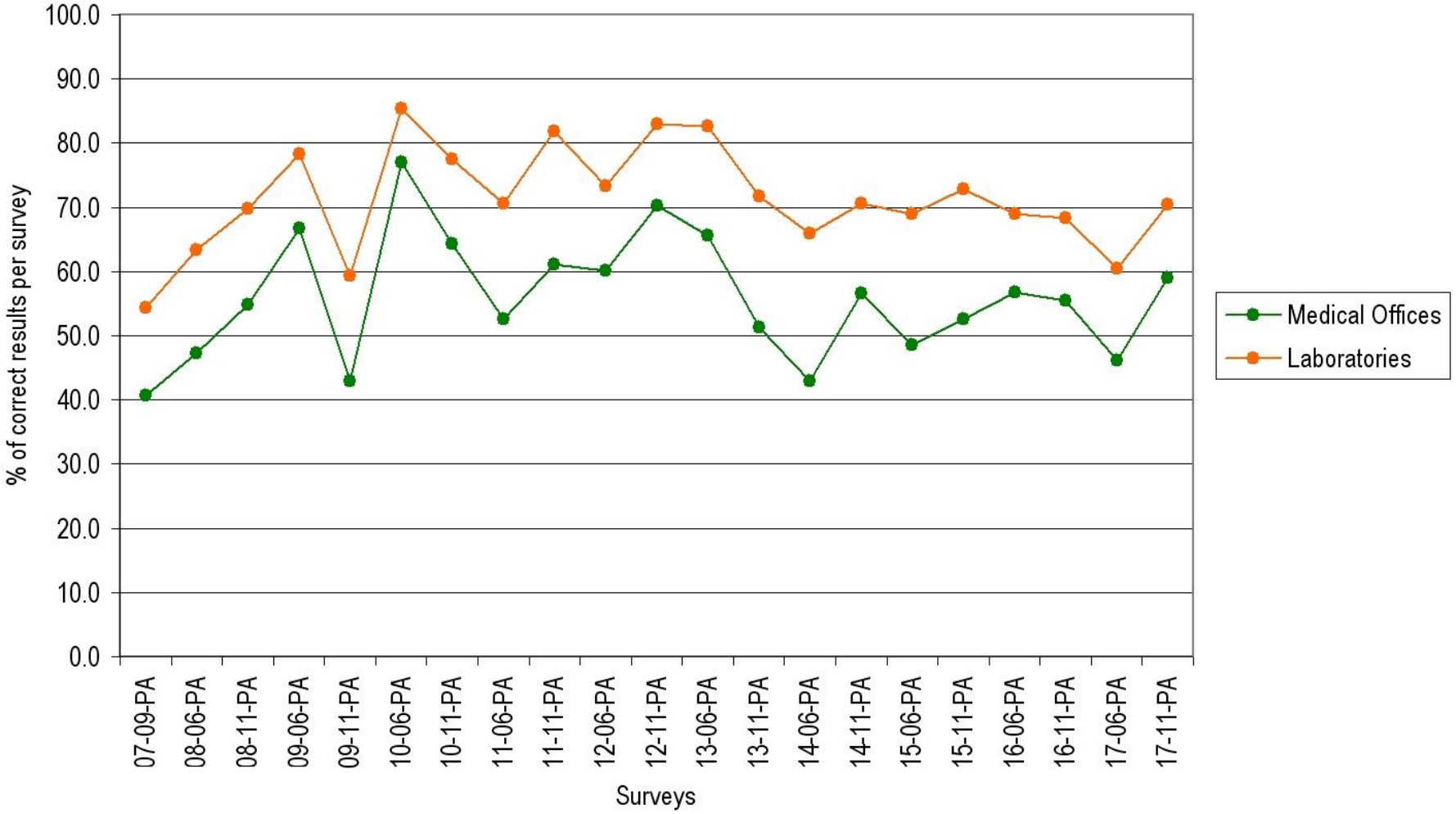
- **Main rules**

Question 1	Question 1	Question 1	Question 1
☐ Answer 1	☐ Answer 1	☐ Answer 1	☒ Answer 1 X
☐ Answer 2	☒ Answer 2 ✓	☐ Answer 2 X	☐ Answer 2
☐ Answer 3	☐ Answer 3	☐ Answer 3	☐ Answer 3
☐ Answer 4	☒ Answer 4 ✓	☒ Answer 4 ✓	☒ Answer 4 ✓
	Correct result	Wrong results	

- **Other rules**

☒ or ☐ Answer 2 ✓ Correct result

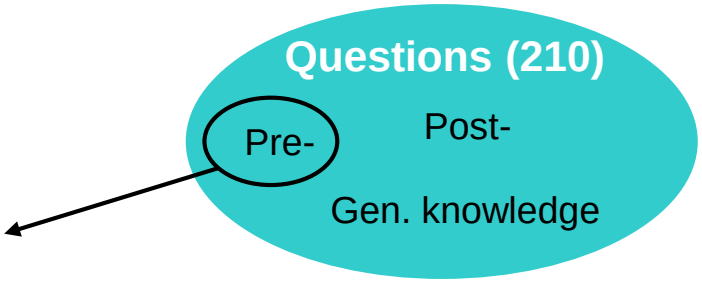
Performances (per survey) - All questions (n=210)



Types and relative frequency of errors in the different phases of the total testing process[1]

Phase of the TTP	Type of error	Relative frequency (%)
Pre-pre-analytical	Inappropriate test request	
	Order entry	
	Patient/specimen misidentification	
	Sample collected from infusion route	
	Sample collection (haemolysis, clotting, insufficient volume, etc.)	46–68.2%
	Inappropriate container	
	Handling, storage and transportation	
Pre-analytical	Sorting and routing	
	Pour-off	
	Aliquoting, pipetting and labelling	3.0–5.3%
	Centrifugation (time and/or speed)	
Analytical	Equipment malfunction	
	Sample mix-ups	7.0–13%
	Interference (endogenous or exogenous)	
	Undetected failure in quality control	
Post-analytic	Erroneous validation of analytical data	
	Failure in reporting/ addressing the report	
	Excessive turn-around-time	12.5–20%
	Improper data entry and manual transcription error	
	Failure/delay in reporting critical values	
Post-post-analytic	Delayed/missed reaction to laboratory reporting	
	Incorrect interpretation	
	Inappropriate/inadequate follow-up plan	25–45.5%
	Failure to order appropriate consultation	

[1] Plebani M, Ann Clin Biochem 2010



The pre-analytical phase[1]

- Are the patient and the anatomic site of origin correctly prepared?
- Is the type of sample correct?
- Is the sample correctly taken?
- Is the sample correctly stored? How long?
- Is the sample correctly processed?
- Is there an interference in the analytical procedure?
- Is there a biological variable influencing the laboratory result?

[1] Guder WG and Narayanan S, Pre-examination procedures in laboratory diagnostics 2015

122 questions regarding the pre-analytical phase

Overall performances (Laboratories and Medical Offices)

Performance for a question	% of correct results
Worst	10.7
Best	99.6

Performance for all questions	% of correct results
Mean	59.5
Median	62.1

Worst performances - Example 1

Age and cholesterol

	% of correct results
Labs	16.2
MOs	8.6

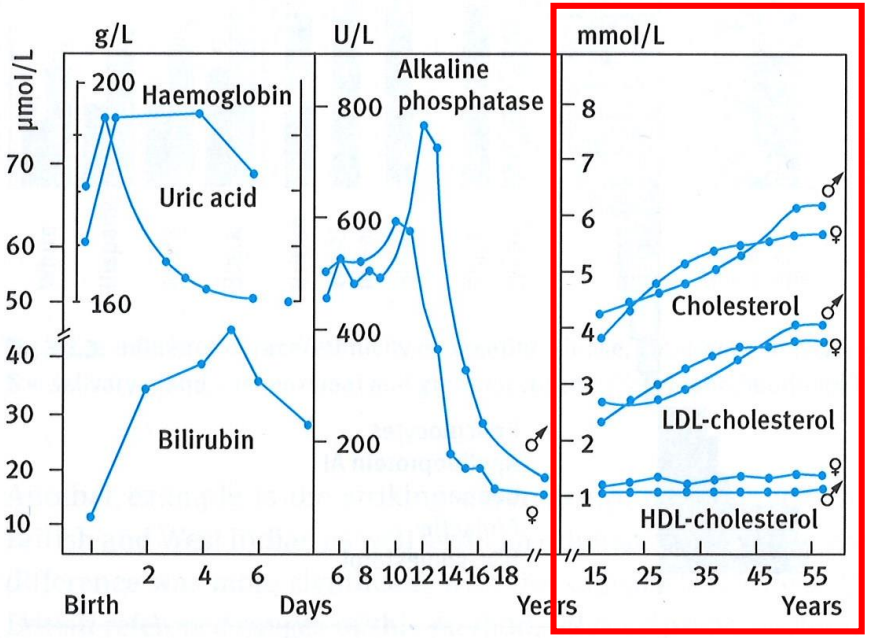
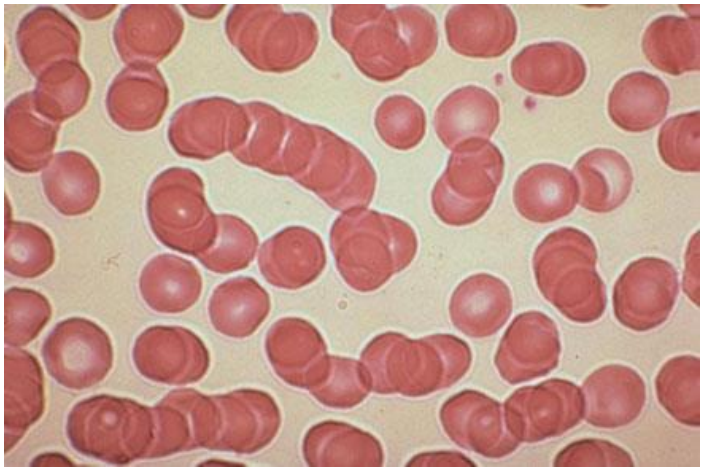


Fig. 3.1.1 Guder WG and Narayanan S, in Pre-examination procedures in laboratory diagnostics 2015

07-09-PA Q3

Worst performances - Example 2

Blood smear with erythrocytes roll of coins (smear thickness, pregnancy, etc.)



	% of correct results
Labs	13.0
MOs	11.3

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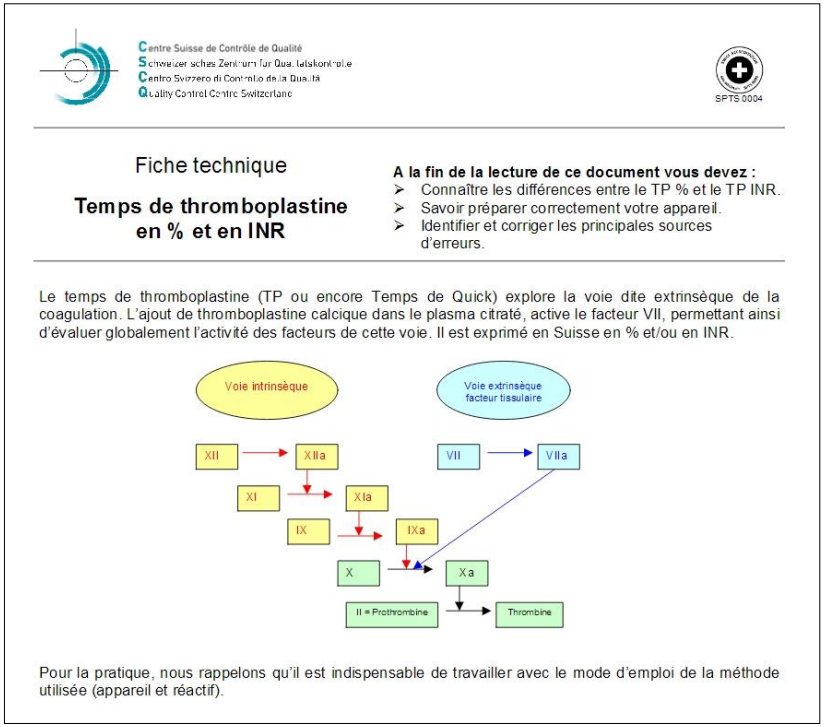
Worst performances - Example 3

Coagulation (INR): time, anticoagulant concentration

	% of correct results
Labs	18.6
MOs	17.6



Centre Suisse de Contrôle de Qualité
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Centro Svizzero di Controllo della Qualità
Quality Control Centre Switzerland

SPTS 0004

Fiche technique

Temps de thromboplastine en % et en INR

A la fin de la lecture de ce document vous devez :
- Connaître les différences entre le TP % et le TP INR.
- Savoir préparer correctement votre appareil.
- Identifier et corriger les principales sources d'erreurs.

Le temps de thromboplastine (TP ou encore Temps de Quick) explore la voie dite extrinsèque de la coagulation. L'ajout de thromboplastine calcique dans le plasma citraté, active le facteur VII, permettant ainsi d'évaluer globalement l'activité des facteurs de cette voie. Il est exprimé en Suisse en % et/ou en INR.

Pour la pratique, nous rappelons qu'il est indispensable de travailler avec le mode d'emploi de la méthode utilisée (appareil et réactif).

www.cscq.ch/SiteCSCQ/SiteCSCQ_FR/PublicationFR.html

17-06-PA Q11

Best performances

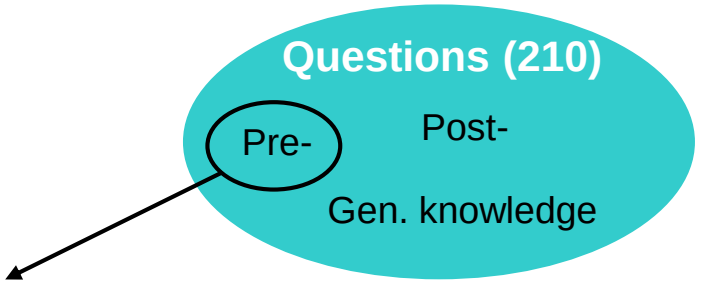
For Laboratories and Medical Offices

Topics:

- When a patient sample has to be identified
- Interference caused by the light
- Important information to be mentioned before the coagulation test
- Which analytes can be tested with an EDTA blood sample
- Higher concentration of analytes in new-borns as compared with adults

Is there any improvement?

The CSCQ pre-analytical phase results



The questions are nearly always different, with few exceptions

Four identical questions (pre-analytical phase)

% of correct results (n)

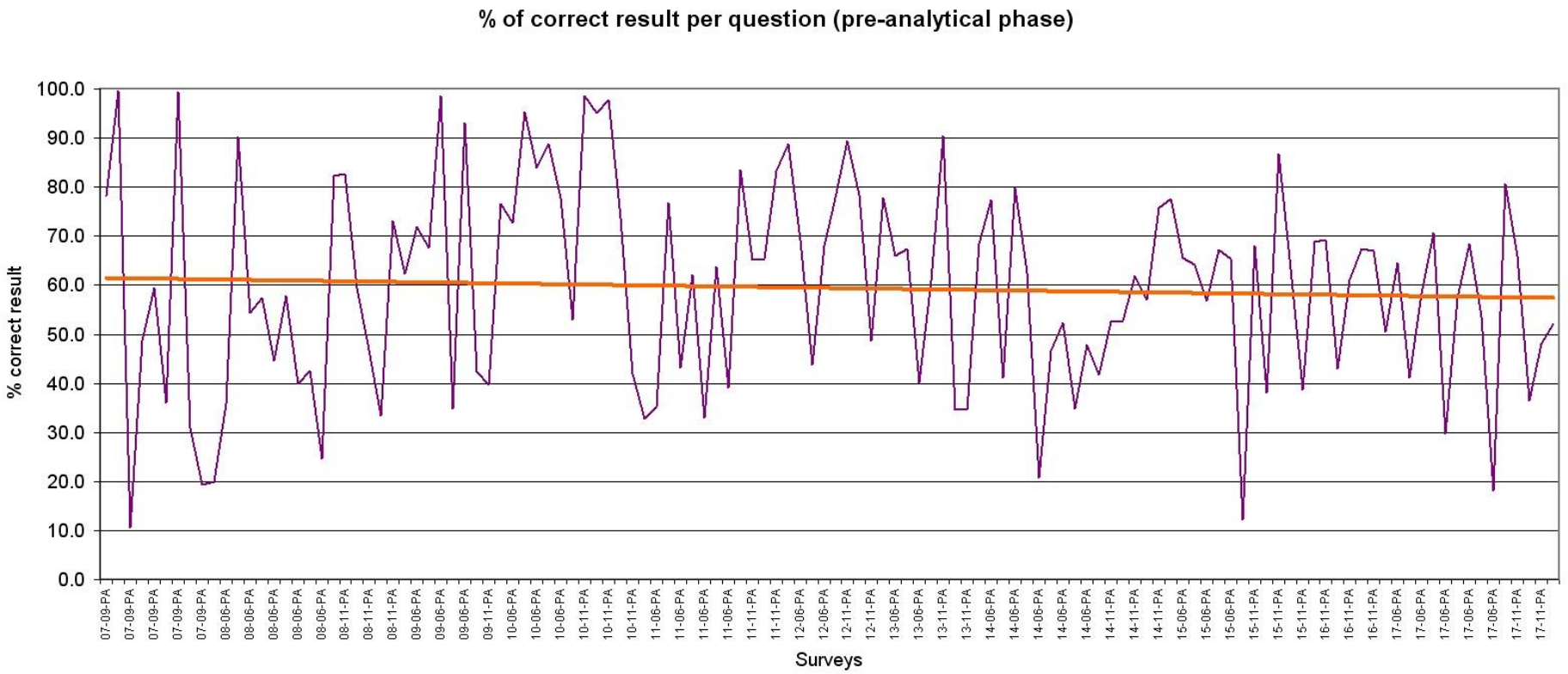
	Ammonium: pre-analytical conditions			Effect of the light			Effect of the gender			Pregnancy: quick test		
Survey	07-09	10-06		07-09	10-11		08-06	10-11		12-06	15-11	
Labs	40.8	87.4	↑	99.2	100	~	94.7	98.1	~	93.7	89.4	~
MOs	12.1	72.8	↑	99.4	97.8	~	88.7	93.1	~	87.1	85.1	~

Four very similar questions (pre-analytical phase)

% of correct results (n)

	Sample conservation (duration)		Effect of the altitude		Sampling: supine or upright position		Sampling: errors leading to K increase	
Survey	07-09	14-06	07-09	14-06	08-06	14-06	07-09	14-06
Labs	26.2	67.5 ↑	70.8	68.9 ~	67.9	61.2 ~	58.5	63.2 ~
MOs	16.8	35.2 ↑	55.2	41.6 ↓	53.9	37.1 ↓	20.4	16.4 ~

Is there any improvement?



No improvement. Why? Questions are, with rare exceptions, always different, personnel turnover in the lab/MO over the years, participating labs/MOs turnover.

Is there a link between Participation and Performance?

- 2014-2017 : 8 surveys (all questions)
- Selection of Laboratories and Medical Offices that received 8 questionnaires and participated in 1 or >1 survey :
  - 475 Medical Offices (and 724 with <8 questionnaires and participated 1 or >1)
  - 198 Laboratories (and 268 with <8 questionnaires and participated 1 or >1)

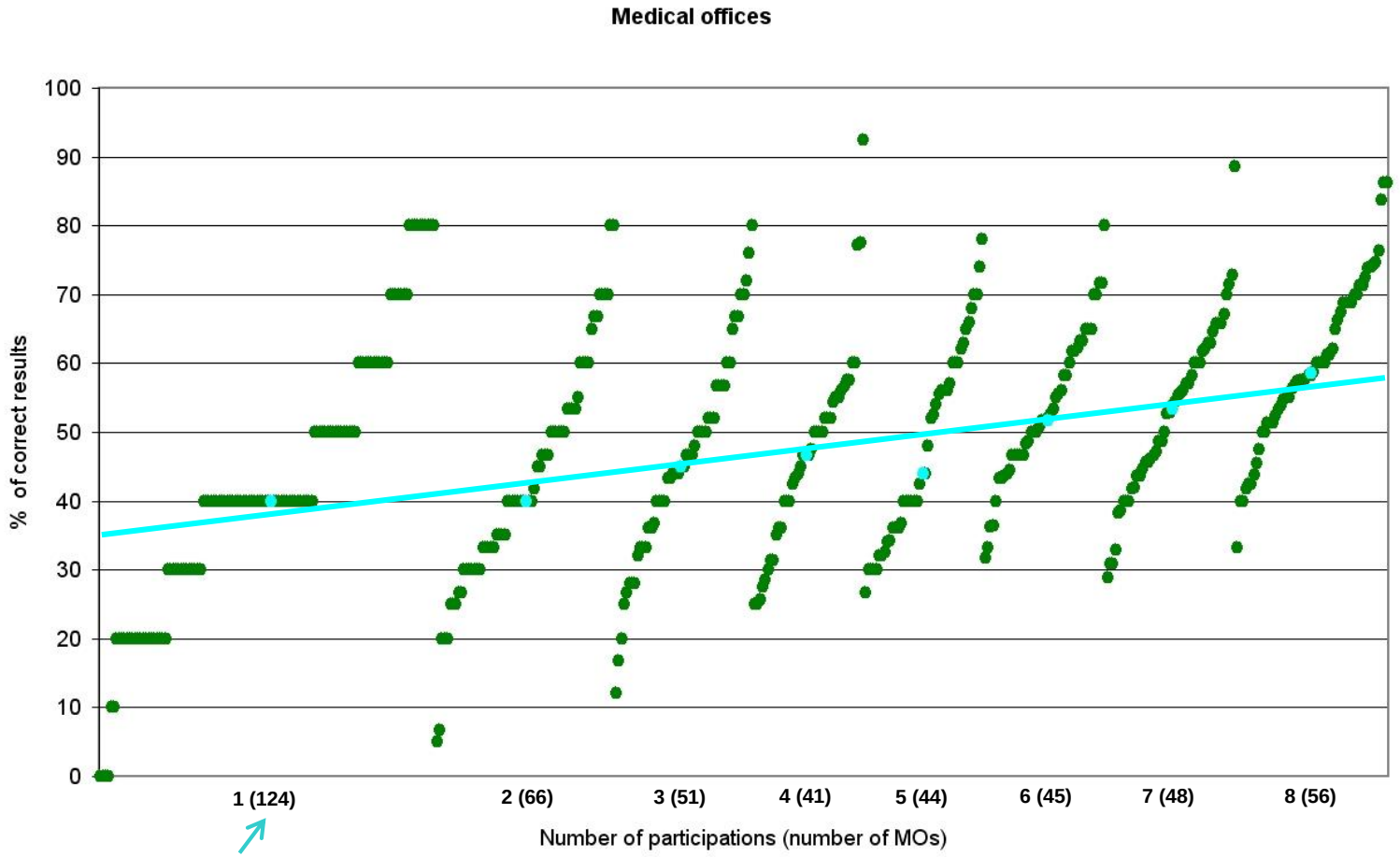
Joined or quit the scheme

↑

Turnover!

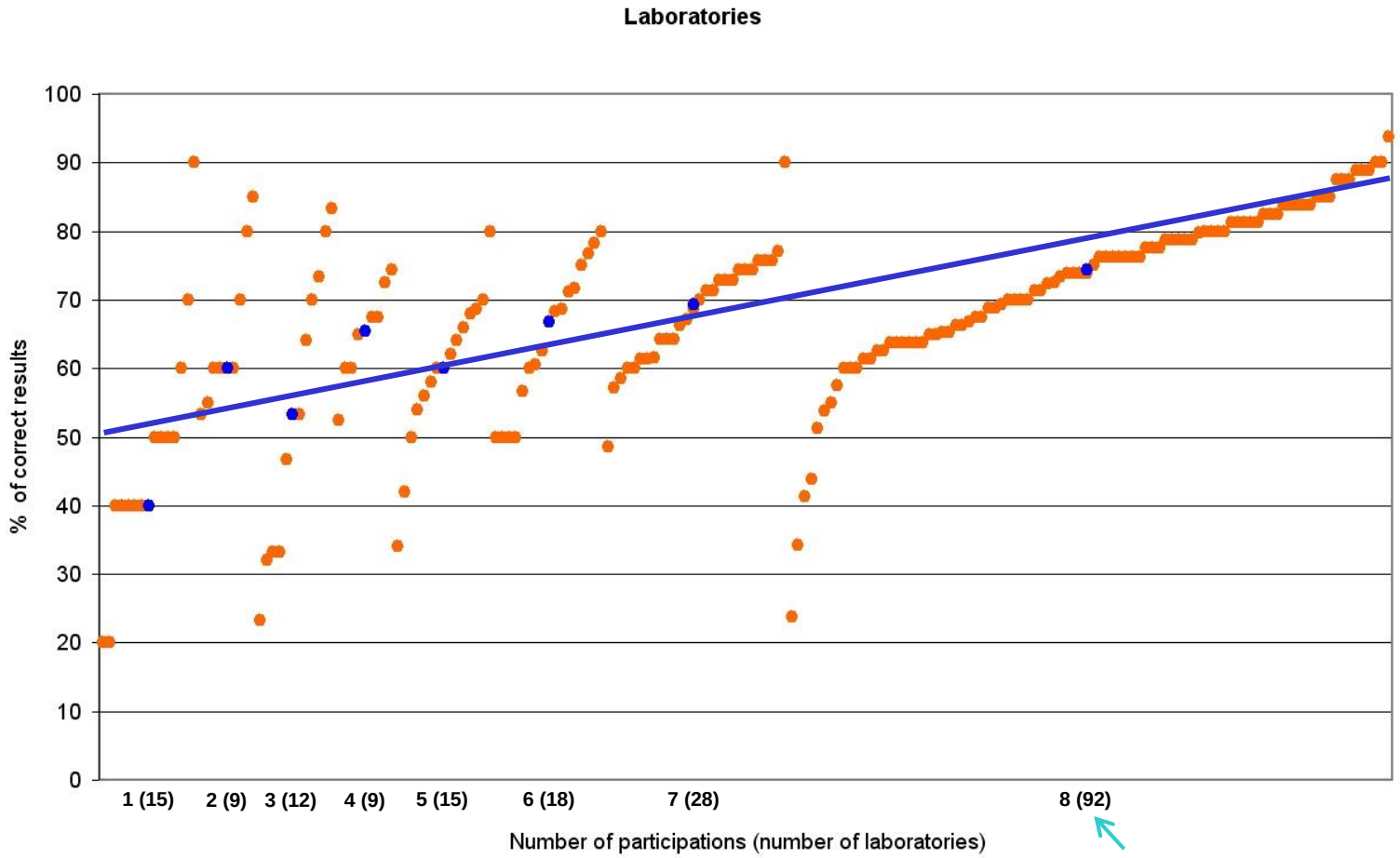
Participation vs Performance

● = 1 MO
● median



Participation vs Performance

● = 1 laboratory
● median



Type of EQA scheme

Three types of pre-analytical EQA schemes[1].

I: Registration of procedures (questionnaires) ← CSCQ

II: Circulation of samples simulating errors ← CSCQ: once

III: Registration of errors/adverse events

Circulating sample: many problems

[1] Kristensen GBB et al., Biochem Med 2014

Perspectives & Challenges

- Pre-analytical survey: valid educational tool for laboratory technicians and medical office staff. Given the positive link between participation and performance, it would be highly recommended to encourage a high and regular participation in the scheme.
- The survey is useful to promote standardised procedures, especially (but not only) in the pre-analytical phase (definition of fasting status, patient and blood identification, color-coding tubes, quality indicators, etc.)[1]
- Repeat the circulation of samples simulating errors.

[1] Lippi et al., Clin Chem Lab Med 2017

Conclusions

We observe:

- variable performance (from 10.7 to 99.6 % of correct results)
- no improvement over time (possible reasons: personnel within the lab/MO and lab/MO turnover, questions are nearly always different)
- positive correlation between participation and performance
- few studies published regarding the pre-analytical phase

We need:

- promote this type of EQA scheme (continuous education)
- encourage regular participation in this scheme


Thank you for your attention