# Extending the EQA spectrum

POLQM Quality Conference

October 1-3, 2017  Vancouver BC.

# External Quality Assessment

A system for objectively checking the laboratory's performance using an external agency or facility.(1)

*...to ensure their ability to perform to the level of competence and quality required.*

(1) WHO - Laboratory Quality Management System Training Toolkit –Module 10

# EQA benefits

- Provides value as a quality indicator
- Instills confidence in the quality of a laboratory's performance

# EQA benefits

- Provides educational opportunities
- Serves as a tool for evaluation of staff competency
- Allows peer group comparisons of test results

# Quality focus shift

- Analytical quality is not enough
- Assurance of quality has to be extended throughout the total testing process
- Most current EQA programs
  - Measurement of equipment performance
  - Outdated approach

# What most EQA schemes do **not** tend to look at:

- Are negative samples reported as negative?
- Are contaminated samples reported as contaminated?
- Are complex samples submitted for referral?

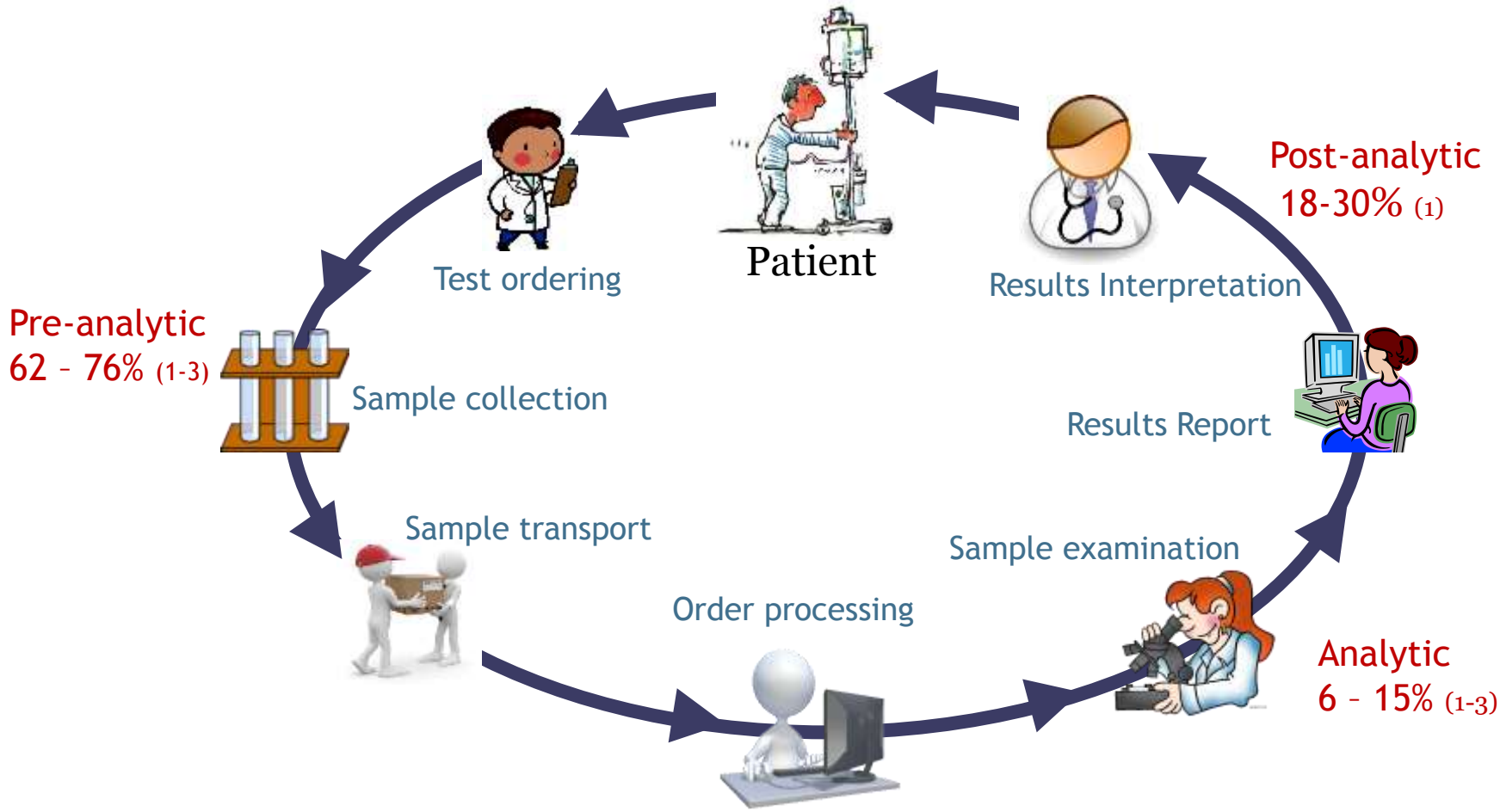
From Noble (Confab 2008)

# What most EQA schemes do **not** tend to look at:

- Are pre-analytic factors addressed?
  - Improper containers and transport
  - Compromised samples.
  - Mislabeled samples.
  - Rejection criteria

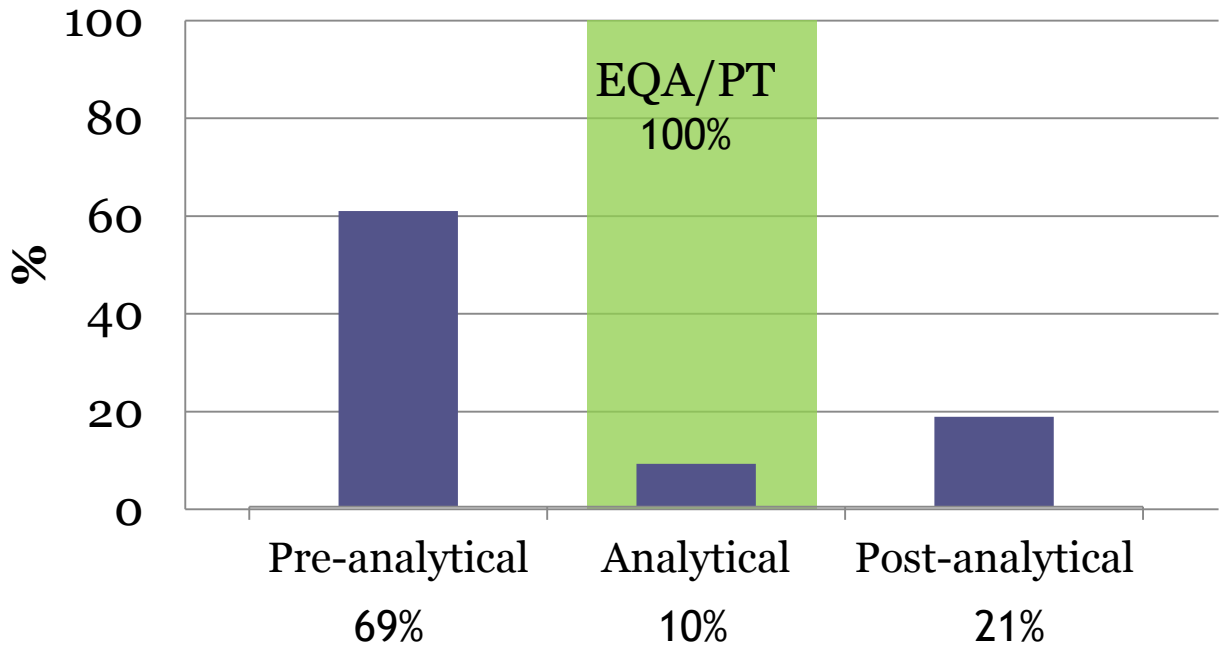
- Are post-analytic factors addressed?
  - Interpretive commentary not included or wrong interpretation included.
  - Reports reaching the incorrect physician
  - Results reported on the incorrect patient

# Total Laboratory Testing Process - Errors




(1) Restelli V., Taylor A., Cochrane D., Noble M. (2017) Medical laboratory associated errors: the 33-month experience of an on-line volunteer Canadian province wide error reporting system. Diagnosis (aop); (2) Carraro, P. (2007) Errors in a Stat Laboratory: Types and Frequencies 10 Years Later. Clin. Chem. 53(7) (3) Plebani, M. (2006) Errors in clinical laboratories or errors in laboratory medicine? Clin. Chem. Lab. Med. 44 (6)750-759

# Medical Laboratory EQA/PT
# Total Laboratory Testing Process



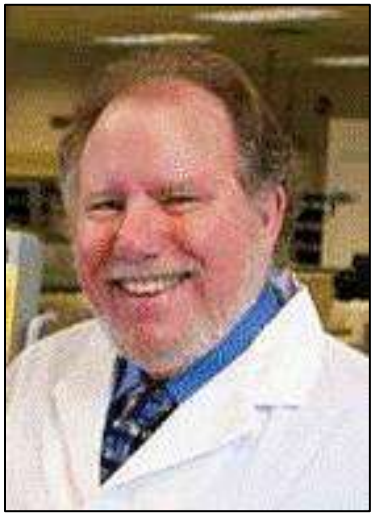

Areas where 90% of errors occur are not tested by most EQA programs

# If it makes sense here…

Willie Sutton

"I rob banks because that's where the money is."

# How about here?



We should  be challenging laboratories in the Pre and Post Examination Phases…

***because that's where the errors are.***

| | |
|---|---|
| **Pre-analytic - collections** | Improperly labeled sample<br>Delay in sample collection/delivery<br>Compromised sample<br>Incorrect patient/body part/sample type |
| **Pre-analytic - clerical** | Incorrect information in order/requisition<br>Incorrect test/product ordered |
| **Analytical** | Incorrect sorting or handling of sample in lab.<br>Delay in processing<br>Procedure not followed<br>Instrument / analyzer error |
| **Post-analytical** | Incorrect results reported<br>Higher than expected turnaround times<br>Results reported to or on incorrect person |

# Accreditation agencies

- Increasingly requiring laboratories to go beyond the analytical quality

Joint Commission International

- Improve patient identification
- Improve communication among caregivers

CAP

- Monitor certain QI that deal with extra-analytical phase

# ISO15189:2012

*Medical laboratories – Particular requirements for quality and competence*

- "EQA programs should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures."

# Challenges

- Many EQA programs lack the tools for it.
- Variety of locations and staff groups involved
- Outside of the laboratory’s control

# Methods to perform extra-analytical EQA*

- Type I: Registration of procedures
- Type II: Circulation of samples simulating errors
- Type III: Registration of errors/adverse events.

*__Kristensen et al.__ How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochemia Medica 2014;24(1):114-22

# Type I: Registration of procedures

- Questionnaires, registration of procedures, evaluation of reports.
  - Advantages:
    - Limited resources,
    - Broad reach,
    - Several aspects of the TTP can be addressed
  - Limitations:
    - Questionnaires should be validated by experts
    - Queuing of answers

# Type I - Examples

1. **Questionnaires, registration of procedures, evaluation of report**

| | |
|---|---|
| ECAT (Netherlands) | Pre- and post-analytical electronic surveys in haemostasis |
| NKK (Norway) | Effects of hemoglobin on some common serum analysis |
| LabQuality (Finland) | Pre-analytical questionnaires. Participants are asked to find pre-analytical error(s) in the cases. |
| CSCQ (Switzerland) | Questionnaires on pre-post analytical phases |
| WEQAS (UK) | Case scenario with EQA sample: analytical and interpretative elements are examined |
| CMPT (Canada) | Paper/Video challenges – Clinically relevant reports |

Modified from: **Kristensen et al.** How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochemia Medica 2014;24(1):114-22

# Type II: Circulation of samples simulating errors

- Similar to classic PT samples with errors / interferences
  - Advantages
    - More representative of 'real samples'
  - Disadvantages
    - Requires expertise on sample preparation
    - Bias (labs expect a sample with an error)
    - Limited number of aspects of TTP

# Type II - Examples

2. **Circulation of samples simulating errors**

| | |
|---|---|
| European Commission | Circulates samples for extraction of RNA/DNA |
| WEQAS | Chemistry samples with interferences (lipemic, icteric, hemolysis) |

Modified from: **Kristensen et al.** How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochemia Medica 2014;24(1):114-22

# Type III: Registration of errors

- Monitoring of QI representing areas prone to errors during a period of time
  - Advantages
    - Use labs own systems for registration of errors
  - Disadvantages
    - Requires harmonization of QI for inter laboratory comparison.
    - Extra resources to register errors.

# EQA programs with extra-analytical schemes

3. **Registration of errors/adverse events**

| | |
|---|---|
| CAP (US) | (Q Track) registration of error rates |
| SEQC (Spain) | Registration of samples rejected over a period of time |
| KIMMS QA (Australasia) | Monitors the pre- and post-analytical phase / measurement and monitoring of key incident quality indicators. |

Modified from: **Kristensen et al.** How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochemia Medica 2014;24(1):114-22

# CMPT: Clinically relevant report

- Final report is evaluated in context (1997)
  - Interpretation, clarity, appropriateness of report
  - Normal flora is reported as such
  - Contamination is reported as such
  - Adherence to current guidelines
  - Appropriate set of antimicrobial agents reported

# CMPT: Clinically relevant report

- Examples:
  - Sputum, vaginal swabs, throat swabs
    - normal flora vs identification of organisms
  - Susceptibility reporting in the context of bacterial meningitis
    - **M091-5**: 31% of the laboratories reported antimicrobial agents that are not recommended for treatment of CSF infections.
  - Adherence to new guidelines
    - **M114-3** (Feb 2012) GBS vaginal screen: 2010 CDC guidelines on prevention of group B streptococcal disease in neonates ~60% laboratories reported erythromycin results.

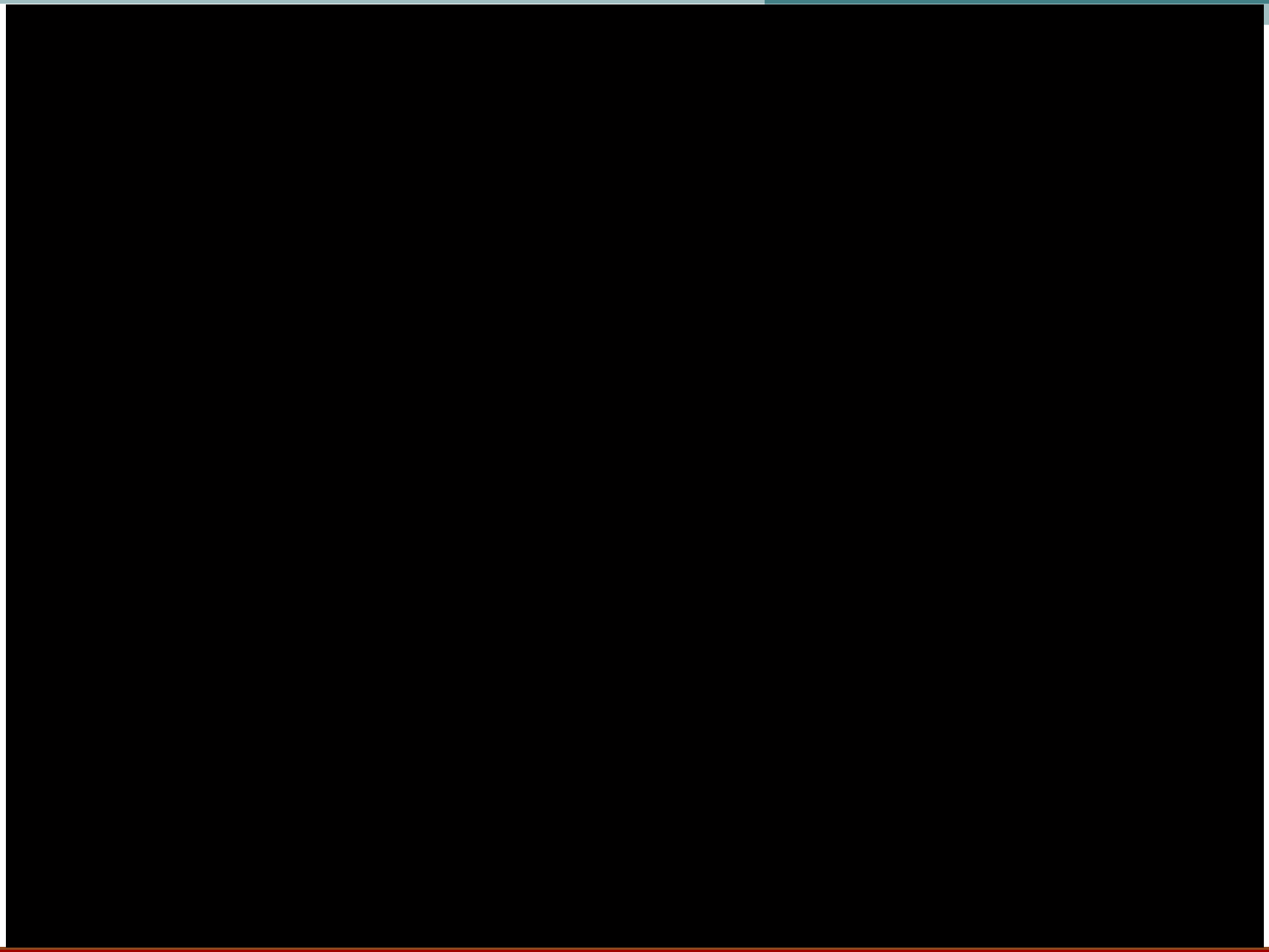
# CMPT Paper Challenge program

- Creation
  - selection of a topic,  description of a case scenario,
  - the design of possible answers,
  - selection of best response, and unacceptable ones .
- Feedback
  - Group analytics
  - Informative critique with results and inter-laboratory comparison.

Carried out by Advisory Committee

# Video Challenge program

- Scenario introduced via video (~1.5 min)
- Participants answer a questionnaire provided
- Design and feedback process similar to the one used for the Paper Challenges



# VC MRSA - Issues

- Samples ordered not optimal (hands) for MRSA screen
- Date or test missing in requisition
- Three samples labelled with same body part

# Questionnaire

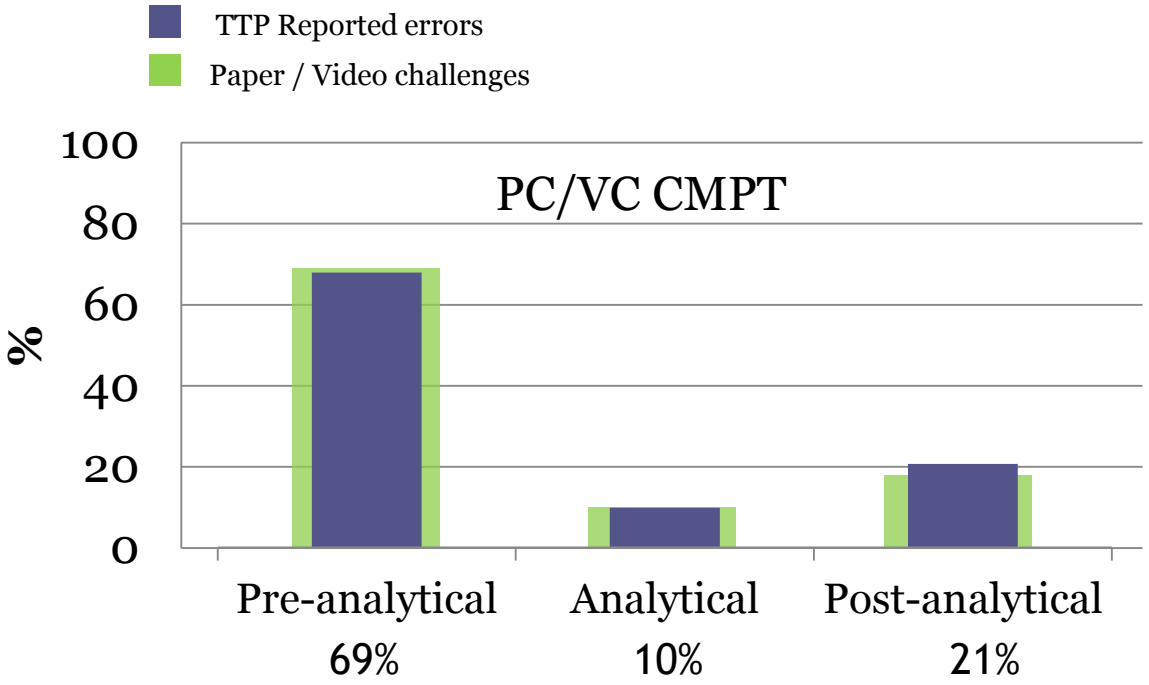
- **PART A -** Indicate the source or error in the clip
- **PART B –** Select possible consequences of this error
- **PART C –** Check the proper action to remediate this error and reduce the probability of this error to happen again

# Video Challenge program

- Advantages
  - Allows for more complex scenarios to be presented
  - The error is not stated to the participants
  - Less prone to misinterpretations?
  - More fun? – personal opinion -

# Paper / Video challenges (1998 – 2017)

| Phase | No | % |
|---|---|---|
| pre-analytical | 27 | 69 |
| analytical | 4 | 10 |
| post-analytical | 7 | 18 |
| lab safety | 1 | 3 |
| Total | 39 | 100 |



# In Summary

- It is important to extend PT/EQA to cover a broader view of the total laboratory testing cycle.
- Approaches may be “less technical”; there is room for developing creative ways to address the extra-analytical phases

# In Summary

- Lab professionals, EQA programs, and accreditation bodies must increase their efforts to ensure quality is extended throughout the total testing process

# In Summary

- EQA is a valuable tool for Quality Improvement ONLY if it is applied for change.