Interpretation of EQA results and EQA-based trouble shooting

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What I will talk about

- How to interpret EQA results
  - Key factors/challenges
- How to handle an EQA error
  - History
  - The flowchart

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Aims of EQA

- **To identify poor performance, detect analytical errors, and make corrective actions**
- To monitor the analytical quality
- To document the analytical quality

- Evaluation of each individual laboratory
- Evaluation of the methods

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How to interpret the EQA result?

Key factors

1. Control material
2. Target value assignment
3. Number of replicates
4. Between lot variation

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Control material

- **Commutable**
- Stable
- Homogeneous
- Clinical relevant concentrations

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Assignment of target value

- Commutable sample
  - Reference method/Value transfer
  - (Overall mean/median)
  - Method specific target value
- Commutablity unknown
  - Method specific target value

ISO 13528

Number of replicates

- One – most common
  - Assessment of total error
- Two or more
  - Assessment of bias and imprecision

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Between lot variation

- Will influence participant assessment
- Lot variation in non-commutable EQA samples may NOT reflect native samples

EQA organizer should register lot numbers and comment on lot variation in feedback reports

Kristensen Clin Chem 2005, Stavelin Clin Chem 2016

EQA-based troubleshooting

WHY?

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ISO 15189: 2012; 5.6.3

- An accredited laboratory shall:
  - participate in EQA programs
  - monitor and document the results
  - implement corrective actions when predetermined performance criteria are not fulfilled

Little aid in the process of finding the sources of errors when they appear

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The History

- Group works at NKKs annual meeting in 2008 and 2009
- Further processed by NKKs Expert group
  - Resulted in a flowchart with additional comments (2010)

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Evaluation in 2012-2013

- Participants in Labquality's 2-level Clinical Chemistry scheme (2050) were asked to use the flowchart to assess and state the cause of the error for 180 deviating EQA results (56%)
  - Most errors were the laboratories responsibility (81%), 15% EQA provider, 4% a mix
  - About 60% used the flowchart regularly
  - Comprehensive and a bit complicated, but very useful in training/educational situations
  - Change the order and start with transcription errors (most common)

Revised version in 2016

FLOWCHART 2.0

Ideal EQA sample

- Commutable
- Reference value with small uncertainty

<u>Not fulfilled</u>: Errors NOT related to the quality of the laboratory may arise GENERATING COST WITHOUT BENEFIT!

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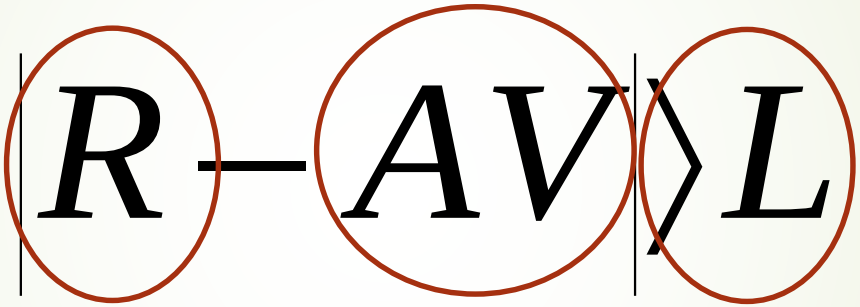
An EQA-error is defined by the following relation:



R = Laboratory result
AV = Assigned value
L = Acceptable limits

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Flowchart 2.0

Order of the flowchart

Transcription error

Pre-survey issues

Sample receipt/handling

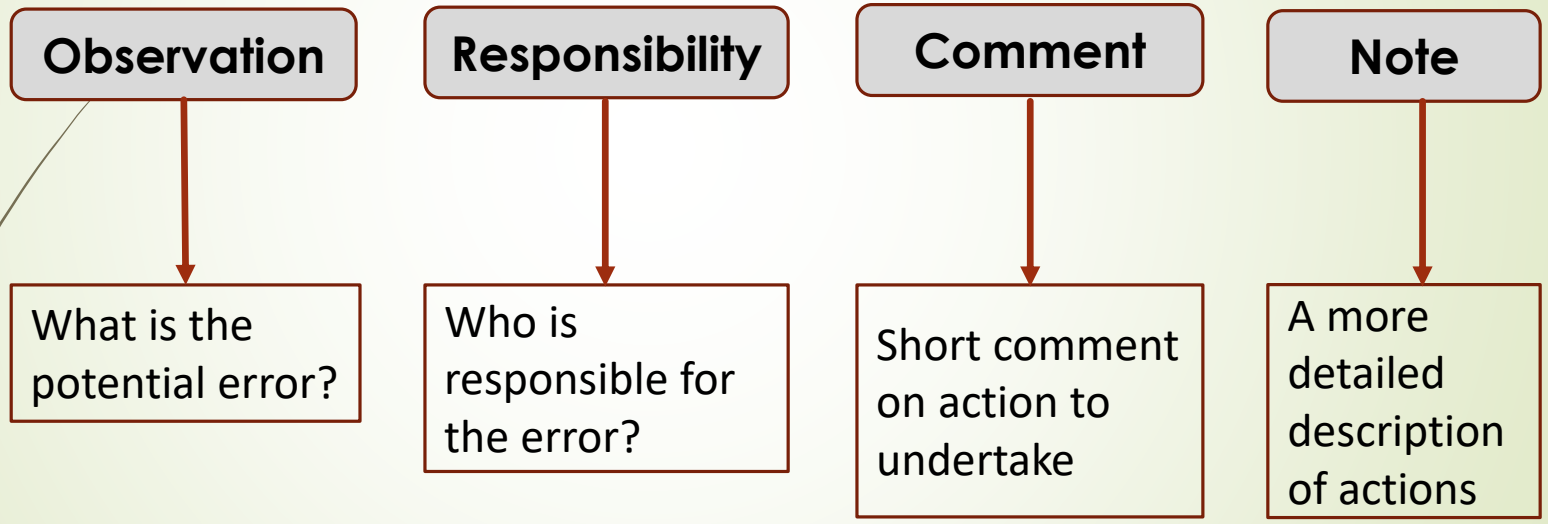
Test Performance

Data Handling EQA Provider

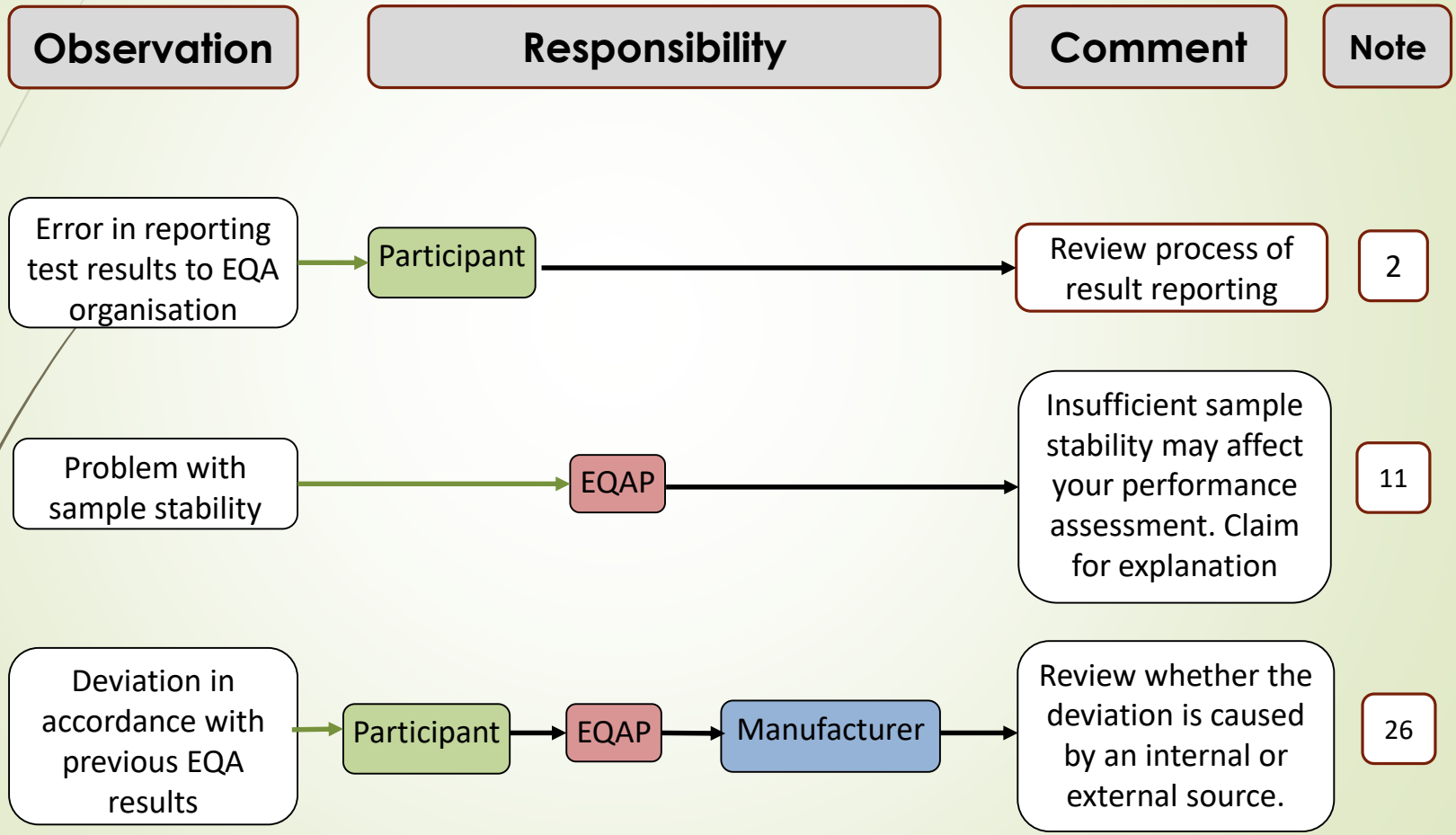
Report and interpretation

Flowchart 2.0

Structure of the flowchart



Examples


Observation
Responsibility
Comment
Note
Error in reporting test results to EQA organisation
Participant
Review process of result reporting
2
Problem with sample stability
EQAP
Insufficient sample stability may affect your performance assessment. Claim for explanation
11
Deviation in accordance with previous EQA results
Participant
EQAP
Manufacturer
Review whether the deviation is caused by an internal or external source.
26

Errors related to the EQA provider

Pre-survey issues

- Poor EQA sample (non-commutable, unstable, inhomogeneous)
- Errors in labelling, packaging or distribution of EQA samples
- Errors in instruction letter

Data Handling EQA Provider

- Inappropriate statistical procedure
- Error in assignment of target value
- Error in presentation of results
- Between lot variation

Should be commented on in the report or comment letter!!

Incitement!!

- In order to improve their schemes, the EQA provider should create a **checklist based on this flowchart** as a tool to make ongoing EQA schemes more useful for the participant.

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Future plans

- The flowchart should become available in the public domain - e.g. EQALM's website
  - **"Dynamic" document -** continuously being improved and revised according to comments from the users

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