Outcomes from the 2023 Symposium breakout session

Barbara De la Salle, PhD

EQALM Board Member

Objectives of the breakout session

To share our knowledge

To obtain new ideas

To make new friends

Report issued to all EQALM members after the session by the organising committee and speakers.

Contact the EQALM office if you do not have a copy!

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The breakout session 2023

An innovative and experimental activity:

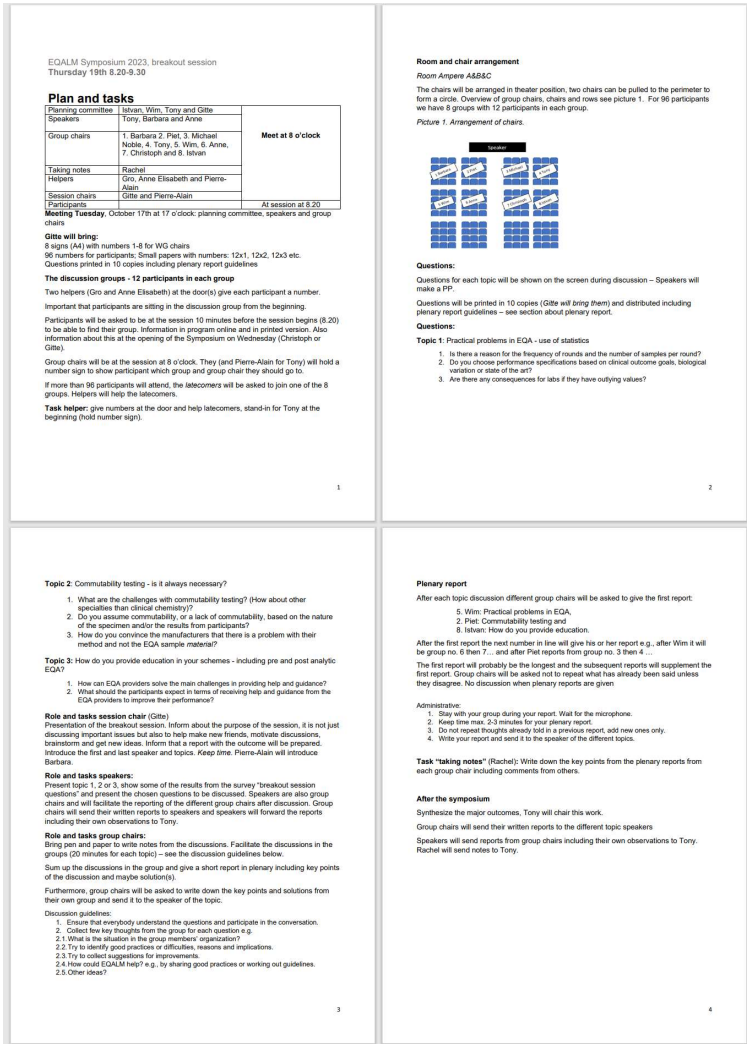
- What did we do?
- What were the outcomes?
- What went well?
- What could be done better?
- Will we do it again?

Before the Symposium

- Topics for discussion chosen by the planning committee
  - Practical problems in EQA – use of statistics
  - Commutability testing – is it always necessary?
  - How do you provide education in your schemes – including pre and post analytical EQA?
- Questionnaire prepared by the committee and expert speakers circulated to all EQALM members in advance
- Selected questions were chosen for discussion on the day

And there was a lot of planning!

- Discussion groups' size and layout
- Allocation of delegates
- Topics and questions
- Roles and tasks for all involved
- Gathering feedback from each group
- Capturing the proceedings
- Reporting outcomes



EQALM Symposium 2023, breakout session
Thursday 19th 8.20-9.30

Plan and tasks

Planning committee	Istvan, Wim, Tony and Gitte	
Speakers	Tony, Barbara and Anne	
Group chairs	1. Barbara 2. Piet, 3. Michael Noble, 4. Tony, 5. Wim, 6. Anne, 7. Christoph and 8. Istvan	**Meet at 8 o'clock**
Taking notes	Rachel	
Helpers	Gro, Anne Elisabeth and Pierre-Alain	
Session chairs	Gitte and Pierre-Alain	
Participants		At session at 8.20

Meeting Tuesday, October 17th at 17 o'clock: planning committee, speakers and group chairs

Gitte will bring:
8 signs (A4) with numbers 1-8 for WG chairs
96 numbers for participants; Small papers with numbers: 12x1, 12x2, 12x3 etc.
Questions printed in 10 copies including plenary report guidelines

The discussion groups - 12 participants in each group

Two helpers (Gro and Anne Elisabeth) at the door(s) give each participant a number.

Important that participants are sitting in the discussion group from the beginning.

Participants will be asked to be at the session 10 minutes before the session begins (8.20) to be able to find their group. Information in program online and in printed version. Also information about this at the opening of the Symposium on Wednesday (Christoph or Gitte).

Group chairs will be at the session at 8 o'clock. They (and Pierre-Alain for Tony) will hold a number sign to show participant which group and group chair they should go to.

If more than 96 participants will attend, the *latecomers* will be asked to join one of the 8 groups. Helpers will help the latecomers.

Task helper: give numbers at the door and help latecomers, stand-in for Tony at the beginning (hold number sign).

1

Room and chair arrangement

Room Ampere A&B&C

The chairs will be arranged in theater position, two chairs can be pulled to the perimeter to form a circle. Overview of group chairs, chairs and rows see picture 1. For 96 participants we have 8 groups with 12 participants in each group.

Picture 1. Arrangement of chairs.

Speaker

Questions:

Questions for each topic will be shown on the screen during discussion – Speakers will make a PP.

Questions will be printed in 10 copies (*Gitte will bring them*) and distributed including plenary report guidelines – see section about plenary report.

Question:

Topic 1: Practical problems in EQA - use of statistics

1. Is there a reason for the frequency of rounds and the number of samples per round?
2. Do you choose performance specifications based on clinical outcome goals, biological variation or state of the art?
3. Are there any consequences for labs if they have outlying values?

2

Topic 2: Commutability testing - is it always necessary?

1. What are the challenges with commutability testing? (How about other specialties than clinical chemistry)?
2. Do you assume commutability, or a lack of commutability, based on the nature of the specimen and/or the results from participants?
3. How do you convince the manufacturers that there is a problem with their method and not the EQA sample *material*?

Topic 3: How do you provide education in your schemes - including pre and post analytic EQA?

1. How can EQA providers solve the main challenges in providing help and guidance?
2. What should the participants expect in terms of receiving help and guidance from the EQA providers to improve their performance?

Role and tasks session chair (Gitte)
Presentation of the breakout session. Inform about the purpose of the session, it is not just discussing important issues but also to help make new friends, motivate discussions, brainstorm and get new ideas. Inform that a report with the outcome will be prepared. Introduce the first and last speaker and topics. *Keep time*. Pierre-Alain will introduce Barbara.

Role and tasks speakers:
Present topic 1, 2 or 3, show some of the results from the survey "breakout session questions" and present the chosen questions to be discussed. Speakers are also group chairs and will facilitate the reporting of the different group chairs after discussion. Group chairs will send their written reports to speakers and speakers will forward the reports including their own observations to Tony.

Role and tasks group chairs:
Bring pen and paper to write notes from the discussions. Facilitate the discussions in the groups (20 minutes for each topic) – see the discussion guidelines below.

Sum up the discussions in the group and give a short report in plenary including key points of the discussion and maybe solution(s).

Furthermore, group chairs will be asked to write down the key points and solutions from their own group and send it to the speaker of the topic.

Discussion guidelines:
1. Ensure that everybody understand the questions and participate in the conversation.
2. Collect few key thoughts from the group for each question e.g.
2.1. What is the situation in the group members' organization?
2.2. Try to identify good practices or difficulties, reasons and implications.
2.3. Try to collect suggestions for improvements.
2.4. How could EQALM help? e.g., by sharing good practices or working out guidelines.
2.5. Other ideas?

3

Plenary report

After each topic discussion different group chairs will be asked to give the first report:

5. Wim: Practical problems in EQA,
2. Piet: Commutability testing and
8. Istvan: How do you provide education.

After the first report the next number in line will give his or her report e.g., after Wim it will be group no. 6 then 7… and after Piet reports from group no. 3 then 4 …

The first report will probably be the longest and the subsequent reports will supplement the first report. Group chairs will be asked not to repeat what has already been said unless they disagree. No discussion when plenary reports are given

Administrative:
1. Stay with your group during your report. Wait for the microphone.
2. Keep time max. 2-3 minutes for your plenary report.
3. Do not repeat thoughts already told in a previous report, add new ones only.
4. Write your report and send it to the speaker of the different topics.

Task "taking notes" (Rachel): Write down the key points from the plenary reports from each group chair including comments from others.

After the symposium

Synthesize the major outcomes, Tony will chair this work.

Group chairs will send their written reports to the different topic speakers

Speakers will send reports from group chairs including their own observations to Tony. Rachel will send notes to Tony.

4

BD0

On the day

Delegates:

- Approximately **90 delegates attended**
- Delegates were allocated at random to **8 groups**, each of around 12 people
- **Each group had a chair**
  - Barbara De la Salle, Piet Meijer, Michael Noble, Tony Badrick, Wim Coucke, Anne Stavelin, Christoph Buchta and Istvan Juhos

The topics were each introduced by an 'expert' speaker

Speakers:

- **Tony Badrick** : Practical problems in EQA - the use of statistics
- **Barbara De la Salle**: Commutability testing – is it always necessary
- **Anne Stavelin**: How do you provide education in your schemes – including pre and post analytic EQA

Tony – photo

Diapositive 6

BD0 Tony - do you have a photo?
Barbara De la Salle; 2024-09-22T11:00:38.886

The discussions

The purpose was not to define EQALM policy but to assess the state of the art and members' opinions

- Participants answered pre-set questions
- The participants did not choose the questions
- BUT the chairs and the group members were flexible over how and even if all the questions were discussed
- Each group provided feedback verbally and as notes

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Guidance for each breakout group chair

Ensure that all members of the group understand the questions

Ensure each participant is heard

Keep notes

Give a summary at the end of the session

Guidance for the discussion:

- What is the situation in the member's organisation
- Identify good practices or difficulties and their reasons
- Collect suggestions for improvement
- How could EQALM help?

Topic 1 – *Tony Badrick*

PRACTICAL PROBLEMS IN EQA – THE USE OF STATISTICS

Practical problems in EQA – the use of statistics

There are some common issues faced by all EQA providers in developing their programs. One of these is the criteria used for acceptability of results from EQA challenges. The Milan model provides three broad options for these criteria, though they are all closely related. They are 1) clinical outcomes, 2) using a Total Allowable Error based on biological variation, or 3) State of the Art. In some jurisdictions, achieving satisfactory EQA performance is a prerequisite for a laboratory to remain operating.

Tony Badrick

Practical problems in EQA – the use of statistics

Q1: Do you choose analytical performance specifications (APS) based on clinical outcome goals, biological variation or state of the art or expert opinion? (or something else)

Q2: Are there any consequences for labs if they have outlying values? (and manufacturers)

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Delegate feedback on APS

- APS structure has been defined from the Milan conference; EQA providers generally follow this.
- BV defined by the EFLM now dominates, which is now strengthened by science/papers.
- BV is not always available. If BV does not work, step back to state-of-the-art and see what is achievable.
- Depends on the design of the scheme. There does need to be different APS for different concentrations. APS may exist, even within a programme, depending on the clinical need.
- They may be driven by Regulation.
- What is the best practice?

Delegate feedback on consequences for outlying values

- Feedback is essential for labs.
- Some EQA providers have their own rules and may proactively contact the laboratory.
- Vigilance reporting for manufacturers, positive and negative.
- Oversight beyond the EQA provider: in some countries, there is an escalation process; in others, there isn't. It is up to the EQA provider. Look at overall responsibility.
- Consequences depend on the country of origin.

Key Takeaways – Use of Statistics

- **Summary from the topic expert**
- It is good to have a definition of what state of the art means — suggest to APS working group

Topic 2 – *Barbara De la Salle*

COMMUTABILITY TESTING – IS IT ALWAYS NECESSARY?

Commutability Testing – is it always necessary?

Commutability is central to the harmonisation and standardisation of laboratory results. IVDD manufacturers should demonstrate traceability of their methods to commutable reference materials or methods to ensure the equivalence of laboratory investigations, regardless of the method principle. Post market surveillance of IVDD performance is an important function of EQA but relies on the demonstration of commutability of the EQA survey materials, which is a challenge for EQA providers.

Barbara De la Salle

Commutability Testing – is it always necessary?

Q1: What are the challenges with commutability testing? (How about other specialities than clinical chemistry)?

Q2: Do you assume commutability, or a lack of commutability, based on the nature of the specimen and/or the results from participants?

Q3: How do you convince the manufacturers that there is a problem with their method and not the EQA sample material?

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Delegate feedback on the challenges of commutability testing

Methods

There is a lack of reference methods.
The sensitivity and specificity of assays is an issue.
The range of instruments and methods on the market.
POCT instruments.

Materials

Fixed and spiked samples are a challenge.
Conflict between commutability, stability and homogeneity.
Commercial material claims.

Resources

Cost.
Staff time to repeat testing.
The amount of evidence required.
Participants are not interested.

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Delegate feedback on the assumption of commutability/lack of commutability

- Testing is costly and impractical so, “yes”
- Are the established protocols the only acceptable methods, can indirect evidence be used?
- The nature of the sample is important but ‘nothing added’ is not defined – what about freezing or pooling?
- If all methods show equivalent results, the assumption is that the material is probably commutable.

Delegate feedback on convincing manufacturers that there is a problem

Communication

Establish good communications with manufacturers. Encourage participants to go to manufacturers.

Collaboration

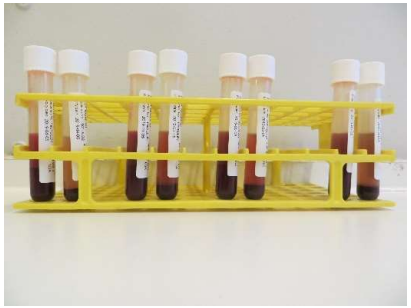
Work with participants and other EQA providers.

Commutability

Is the same seen with fresh samples? Can you use historical trends or patients' results?

Key Takeaways - Commutability Testing

- We should not dismiss EQA that cannot demonstrate commutability, the programmes remain useful with peer group assessment.
- We should prioritise and support reference material/method development.
- Is there a means to streamline commutability testing?
- Can EQALM provide guidance or training on commutability testing and assumption of commutability?
- Can data or materials be shared within EQALM?
- Can EQALM provide a platform for sharing data about performance of different methods, to improve work with manufacturers?
- Is there a role or position for manufacturers within EQALM?



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Topic 3 – *Anne Stavelin*

HOW DO YOU PROVIDE EDUCATION IN YOUR SCHEMES, INCLUDING PRE AND POST ANALYTICAL EQA?

How do you provide education in your schemes, including pre and post analytical EQA?

According to ISO/IEC 17043:2023, one of the purposes of doing EQA is to educate participants on the results of the studies. The PT provider shall give opinions and interpretations as well as advice to the participants. The PT provider shall provide expert commentary including possible sources of error and suggestions for improving performance.

Anne Stavelin

How do you provide education in your schemes, including pre and post analytical EQA?

Q1: How can EQA providers solve the main challenges in providing help and guidance?

Q2: What should the participants expect in terms of receiving help and guidance from the EQA providers to improve their performance?

Topic 3: Education and guidance

EQA provider should strive to give

Clear and concise expert commentary, tailored guidance, timely feedback

The labs should expect to get

General advice, relevant educational resources (webinars, courses, newsletters)

Challenges

Limited human resources, different training needs, communication

Key takeaways –Education in EQA

- **Proactive Education**: EQA providers should offer regular education, such as webinars and newsletters, to ensure participants understand EQA results.
- **Personalized Feedback**: Participants should receive tailored feedback and guidance based on their specific needs and performance.
- **Accessible Resources**: EQA providers should offer accessible resources, including online learning platforms and AI chatbots, to support participants.
- **Collaboration**: EQA providers should collaborate with other organizations to ensure consistent standards and expectations.

What went well?

- We talked to each other
- We listened to each other
- We learnt from each other
- We identified differences in our opinions and our knowledge
- We provided feedback to EQALM
- We provided knowledge for the WGs to follow up
- We organized the event well

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What could have been done better?

- The room was noisy and it was difficult to hear what was being said – *noted but a single room was the most efficient use of time*
- There was not enough time for the discussions – *noted but this kept the discussion brief and focused*
- The room was too hot – *noted but this was beyond our control*
- The group was too big for the room – *noted but we did not wish to limit the number of people*
- A follow-on session for delegates to speak to the experts individually should be considered - *noted*

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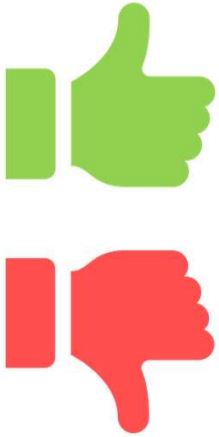
WOULD YOU LIKE TO DO IT AGAIN?



Future suggested topics

Planning committee:

- What's wrong with ISO17043
- How can EQA help labs identify risk for ISO15189
- COMET project guidelines
- Traceability and EQA post-market surveillance
- Educating young scientists in EQA

WGs/Scientific Committee:

- Digital Technology and EQA
- IVD regulations and EQA
- Will AI change the landscape of EQA?
- Assessing individual competency in EQA

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Thank You

Planning Committee

Wim Coucke, Istvan Juhos, Tony Badrick, Gitte Henriksen

Group chairs

Barbara De la Salle, Piet Meijer, Michael Noble, Tony Badrick, Wim Coucke, Anne Stavelin, Christoph Buchta, Istvan Juhos

Session chairs

Gitte Henriksen, Pierre-Alain Morandi

'Expert' speakers

Tony Badrick, Barbara De la Salle, Anne Stavelin

Session notes

Rachel Marrington

Session report co-ordinator

Tony Badrick

Group photo needed