External Quality Assurance of POC instruments

13th EFLM Continuous Postgraduate Course in Clinical Chemistry and Laboratory Medicine
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What I will talk about

✓ What is special with EQA for POC
✓ What is important with EQA
✓ The total testing process
✓ Examples of how it can be done
Analytical quality assurance

- Everything is different
- Should we use internal quality control, for which analytes, what rules $2\sigma$, $3\sigma$ / split sample?
- Can we show that this is of importance?
- What do we do with the alarms?
- How to perform EQAS, how often?
- How to perform quality assurance of self-measurement?
Analytical quality assurance of POCT - challenges

• Challenges
  – Easy to use
  – “Everybody can do it”
  – “No mistakes can be done”
  – “The instrument will give an error message if something is wrong”
  – Often used by people with little or no lab experience
  – Expensive to perform controls
Differences in EQAS for POC testing and hospital laboratories

EQAS for Primary health care

General Practitioners
Office personell, Nurses / Patients

EQAS for Laboratories

Clinical chemists
Statisticians
Med. lab. tech.

?  

Clinicians
Nurses
EQA and POC - what is the difference from usual EQA?

- Often many participants / user
- Situated in remote areas
- Users with little knowledge about the laboratory
- Direct communication with patients, nurses, clinicians, GP-offices
## EQA categories

<table>
<thead>
<tr>
<th>EQA category</th>
<th>Commutable material</th>
<th>Reference target value</th>
<th>Replicate measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>2</td>
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<td>3</td>
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<td>5</td>
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<td>6</td>
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*Modified after Miller et al. Clin Chem 2011*

Quality specifications should be given
External quality assessment programmes 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.
Analytical quality specificaitons

Similar or different compared to hospital laboratories?

Dependent on the use of the test.
Guidelines Recommendation to participate in EQA schemes


## Example POCT INR

### European countries that do not provide EQA for POC INR testing (n=19):
- Belgium, Bulgaria, Croatia, France, Germany, Iceland, Ireland, Italy, Latvia, Luxemburg, Poland, Portugal, Romania, Russia, Slovakia, Slovenia, Spain, Sweden, Turkey.

<table>
<thead>
<tr>
<th>European country</th>
<th>External Quality Assessment organizer</th>
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</thead>
<tbody>
<tr>
<td>Austria</td>
<td>ÖQUASTA Austrian Society of Quality Assurance and Standardization</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>SEKK External quality assessment system for clinical laboratories</td>
</tr>
<tr>
<td>Denmark</td>
<td>DEKS Danish Institute for External Quality Assurance for Laboratories in Health Care</td>
</tr>
<tr>
<td>Finland</td>
<td>Labquality Labquality</td>
</tr>
<tr>
<td>Hungary</td>
<td>QualiCont In Vitro Diagnostic Quality Control Nonprofit Public Utility Ltd.</td>
</tr>
<tr>
<td>Netherlands</td>
<td>ECAT External quality Control of diagnostic Assays and Tests</td>
</tr>
<tr>
<td></td>
<td>FNT Federation of Netherlands Thrombosis services</td>
</tr>
<tr>
<td>Norway</td>
<td>NOKLUS The Norwegian Quality Improvement of Primary Care Laboratories</td>
</tr>
<tr>
<td>Switzerland</td>
<td>CSCQ The Quality Control Center Switzerland</td>
</tr>
<tr>
<td></td>
<td>MQ Association of Medical Quality Control</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>UKNEQAS United Kingdom National External Quality Assessment Scheme</td>
</tr>
<tr>
<td></td>
<td>WEQAS Welsh External Quality Assessment Schemes</td>
</tr>
</tbody>
</table>

In Norway:
Government and the Norwegian Medical Association established an organization to take care of improving laboratory quality of POC instruments
2879 participants in NOKLUS
1755 GPs offices (99.8%)
928 (92 %) nursing homes
Others, oil platforms, military, police etc

Laboratory consultants visit the participants

518 courses with 7192 participants
36 schemes for EQAS
How to do it

• Traditional EQA by circulating samples
  – Often non-commutable samples

• Split sample with GP office / hospital
  – Will include also preanalytic factors + additional factors/errors related to “master” instrument(s)
  – Native samples
New EQA model for POCT

External Quality Assessment of Point-of-Care Methods: Model For Combined Assessment of Method Bias and Single-Participant Performance by the Use of Native Patient Samples and Noncommutable Control Materials

Anne Stavelin,1,2 Per Hyltoft Petersen,1 Una Ø. Sølvik,2 and Sverre Sandberg2,3
✓ Method bias is established by split sample analyses of patients samples e.g. 100 samples for each method.

✓ Participant performance is estimated by deviation from method specific target value using non-commutable control material.
Example 1

The POCT method: Too high values

The participant: OK
Example 2

The POCT method: OK
Too high values
Example 3

The POCT method: OK
The participant: Both high and low values
Between-Lot Variation in External Quality Assessment of Glucose: Clinical Importance and Effect on Participant Performance Evaluation

Gunn B.B. Kristensen,* Nina Gade Christensen, Geir Thue, and Sverre Sandberg
Selection of lot numbers for the study from the routine EQAS, shown for the Ascensia Elite glucometer (n= 262 instruments).
Different lots and different control materials

The material we used
Should there be quality specifications depending on the source of the target values?

- Commutable material with target value
  - Method variation
  - Lot variation
  - Participants performance

- Method median
  - Lot variation
  - Participants performance

- Lot median
  - Participants performance
Should target limits be set depending on a common target value, method specific target value or lot specific target value?
EQAS for self-monitoring glucose

Post-analytical quality assurance

• How to report the result?
• How does the co-worker or patient interpret the result?
• How do the physicians interpret the result?
• What are the actions?
Interpretation and action

Patient A is a 76-year-old man with permanent atrial fibrillation and hypertension who is treated with warfarin and antihypertensives. The therapeutic interval for this patient is INR 2,0-3,0 (target INR 2,5). He is otherwise healthy and is feeling well at the moment. His INR results have been stable, and have varied between 2,0 and 2,8 during the last months. His INR today is 2,3, and you decide not to change the warfarin dose.

If you were to decrease his warfarin dose, how high must this next INR value be? ____.
Create a process for EQA of POC devices

1. Control material, target values, replicates.
2. Frequency
3. Follow up
4. Pre- and post-analytical aspects.
Thank you