Commutability
Improving definitions &
How to deal with

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STT
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Introduction

Reference materials, calibrators, quality control samples

Different from patient samples?
How do we know?
How to deal?
What about patient samples themselves?

1 replicate
Yes, patient samples too!

5 replicates, reduced CI

Reasons: drug interference, antibodies
Related samples (calibrators)

One by one commutable!

Calibration line non-commutable!
Statistics will be elaborated!
Other surprises?

Classical experiment
Measure a minimum of 20 native samples and test samples in one run in replicate (EP 14, n = 3) with at least two measurement procedures.

General interpretation
"Compare the behaviour of the test samples with the native samples"

EP 14 interpretation
Test samples should be within the prediction limits of the regression based on the native samples.
Statistical test (Prediction Interval)

1 replicate
Statistical test (Prediction Interval)

2 replicates
Statistical test (Prediction Interval)

3 replicates
Statistical test (Prediction Interval)

4 replicates
Statistical test \textit{(Prediction Interval)}

5 replicates
Random, Sample-related effects

Importance of sample-related effects for commutability testing according to the EP14 protocol.

Stöckl D, Stepman HC, Van Houcke SK, Thienpont LM.

Solution for sample-related effects

5 replicates, 60 samples
Solution for sample-related effects

5 replicates/2 samples virtual pooling

60 samples → 30 "samples"
Solution for sample-related effects

5 replicates/ 3 samples virtual pooling

60 samples → 20 “samples”
Commutability extent?

Difference = 1.5%

Should be <0.5%; It’s calcium!
Rule of thumb: 1/3 of bias from biology!
Commutability extent?

Can we reach the desired extent?

<table>
<thead>
<tr>
<th></th>
<th>Calcium</th>
<th>Magnesium</th>
<th>Albumin</th>
<th>t-Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Abbott Architect</strong></td>
<td>PI#1 0.4</td>
<td>#1 0.6</td>
<td>#2 1.1</td>
<td>1.4</td>
</tr>
<tr>
<td><strong>Ortho Vitros</strong></td>
<td>PI#1 0.5</td>
<td>ok 0.5</td>
<td>1.3</td>
<td>ok</td>
</tr>
<tr>
<td><strong>Roche Modular</strong></td>
<td>PI#1 0.5</td>
<td>0.5</td>
<td>1.1</td>
<td>ok</td>
</tr>
<tr>
<td><strong>Roche Cobas</strong></td>
<td>PI#1 0.3</td>
<td>0.3</td>
<td>0.7</td>
<td>ok</td>
</tr>
<tr>
<td><strong>Siemens Advia</strong></td>
<td>PI#1 0.4</td>
<td>0.4</td>
<td>0.9</td>
<td>ok</td>
</tr>
</tbody>
</table>

For each EQA sample the deviation (%) from the regression line for the native samples was calculated.

PI#1, PI#2: prediction interval (%) at the concentration of EQA sample #1 and #2.

Ok: EQA material is commutable, because its deviation is smaller than the prediction interval.

Yes, we can!

• Via EQAS &

• All Procedure Trimmed Mean

Commutability assessment by use of external quality assessment surveys – A means to reduce the uncertainty in the commutability decision

Sofie K. Van Houcke¹, Pål Rustad², Hedwig C.M. Stepman¹, Thomas H. Røraas³, Sverre Sandberg³, Linda M. Thienpont¹

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Plan your commutability experiment!

Sample-size calculations

Fig. 1. Power curves illustrating influence of virtual pooling of samples and replication (both CVa and CVsr = 1%) (from left to right): 100 (60) samples, 3 replicates, 5 (3) pooling [blue solid (long dashed) line]; 20 samples, 15 (9) replicates, no pooling [red solid (long dashed) line]; 100 (60, 20) samples, 3 replicates, no pooling [black solid (long, short dashed) line].

Commutability decision?

Work with
Preset specifications!

Limit the magnitude
of the prediction interval, for example!

>Sample size calculations
at given power!
How to deal with it?
How to deal with it?

Avoid it!
How to avoid it in calibration?


"The calibration standards used in the RIA method ... were replaced by a series of human serum samples, in which the concentration of cortisol had been determined by the reference ID-MS method".
How to avoid it in assessment?

**MASTER COMPARISONS**
- EQA with panels of fresh frozen single donation (commutable) sera

**VIRTUAL EQA-1 (Percentiles)**
- Mid- to long-term monitoring of patient percentiles across laboratories and manufacturers

**VIRTUAL EQA-2 (IQC monitoring)**
- Mid- to long-term monitoring of IQC data across laboratories and manufacturers

**EDUCATION**
- Conceptual and statistical education about analytical quality in the medical laboratory