"Uncertainty vs. total error in judging performance of participants"

Milano 2015

9th International Meeting, CIRME

Sverre Sandberg, Noklus / EFLM
Bergen Norway

"A pragmatic approach in judging performance of participants"

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The responsibility of the EQA provider

- ✓ The EQA provider is responsible to produce programs for the participants that fulfill the goal to *evaluate measurement procedure performance of* a single laboratory to that of other laboratories and to a true value when possible.
- ✓ EQA providers should strive to use commutable material whenever possible

Adapted from Miller G and Sandberg S Quality Control and the Analytical Examination Process in ***TIETZ TEXTBOOK OF CLINICAL CHEMISTRY AND MOLECULAR DIAGNOSTICS, 6TH EDITION 2016, IN PRESS***

- ✓ The frequency of distribution of samples must address the need of the laboratory.
- ✓ The EQA provider should have the knowledge to be able to *advise the participants* when they have questions regarding their EQA results.

Adapted from Miller G and Sandberg S Quality Control and the Analytical Examination Process in ***TIETZ TEXTBOOK OF CLINICAL CHEMISTRY AND MOLECULAR DIAGNOSTICS, 6TH EDITION 2016, IN PRESS***

Responsibilities

- EQA organiser
  - Inform / judge participants
  - Inform / judge manufacturers
  - Health authorities
- Participant
  - Inform clinicians
- Manufacturer
  - Address problems with the measurement procedure

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Participant feedback/judgement will be dependent on at least four aspects

1. Who are the participants and what background knowledge do they have?
2. What kind of EQAS scheme are they running
3. How is the target value established?
4. How is the EQA result reported?
5. (What are the performance specifications)

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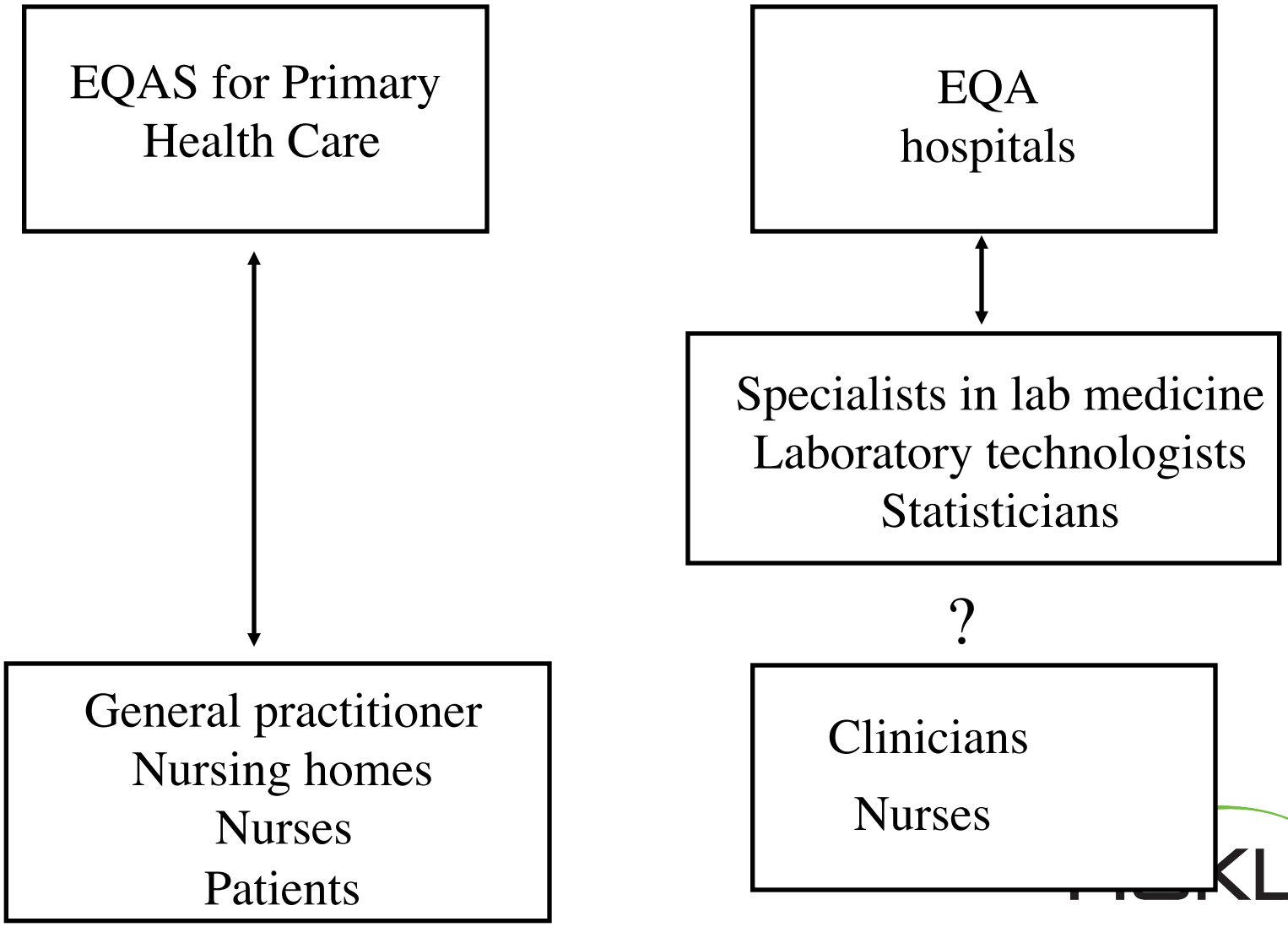
Who are the participants?



How is the target value established?

- what do we compare with

- ✓ True value from a reference method or a certified reference material
- ✓ All participant median
- ✓ Measurement procedure median
- ✓ Lot median

- ✓ You can calculate an ”uncertainty” / ”error zone” around all these values

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How could the result be reported

As a number

As a number with SD if repeated measurements are performed

As a number + information about the SD/CV of the measurement procedure

As a number with the measurement uncertainty

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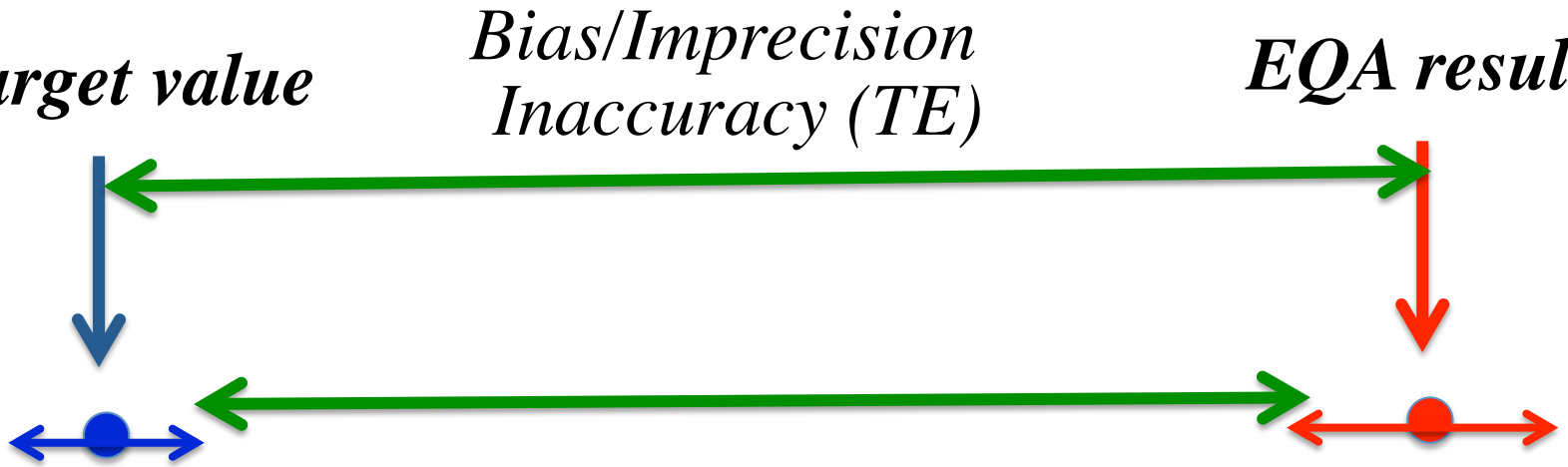
Two numbers



Measurement uncertainty
(reference method)
Confidence interval
(method specific target value)

Measurement uncertainty
(calculated in lab)
Confidence interval
(repeated measurements)

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EQA categories

EQA category	Commutable material	Reference/ CRM target value	Replicate measurements	Assessment of a single laboratory
1	Yes	Yes	Yes	Uncertainty - or CI - of the reference target Repeatability of own results Trueness of own laboratory Comparison own measurement procedure with other measurement procedures
2	Yes	Yes	No	Uncertainty - or CI - of the reference target Accuracy Comparison own measurement procedure with other measurement procedures
3	Yes	No	Yes	CI of the target of the measurement procedure Repeatability of own laboratory Comparison own measurement procedure with other measurement procedures

Modified after Miller et al. Clin Chem 2011

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EQA categories

EQA category	Commutable material	Reference/ CRM target value	Replicate measurements	Assessment of a single laboratory
4	Yes	No	No	CI of the target of the measurement procedure Comparison own measurement procedure with other measurement procedures
5	No	No	Yes	Repeatability Systematic deviation from target value within own measurement procedure
6	No	No	No	Deviation from target value within own measurement procedure

Modified after Miller et al. Clin Chem 2011

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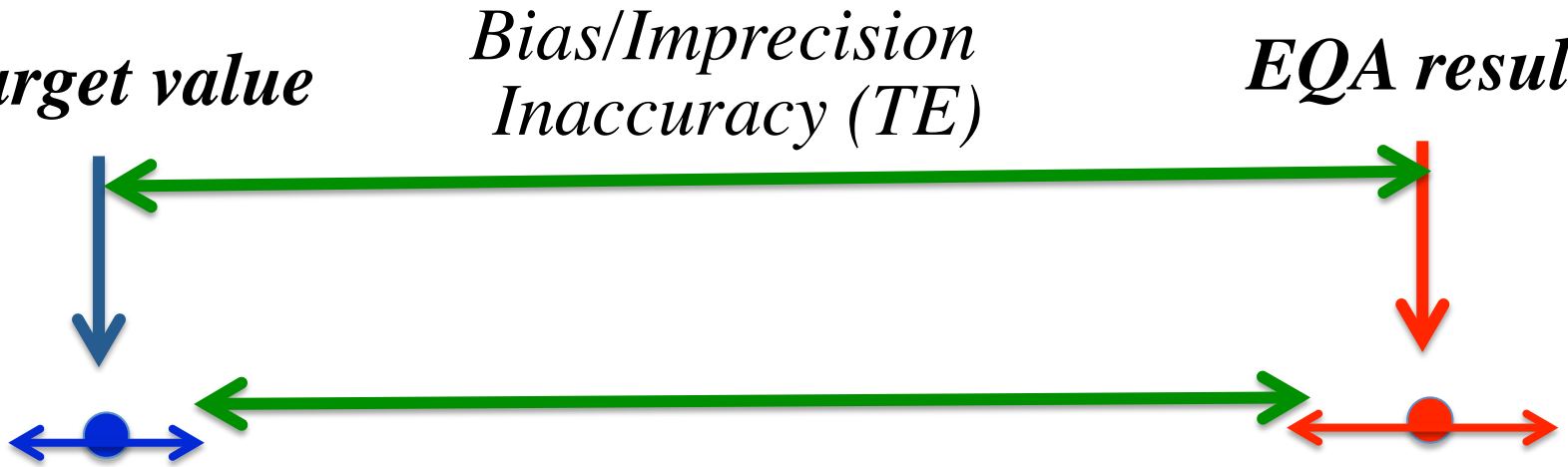
Two numbers



Measurement uncertainty
(reference method)
Confidence interval
(method specific target value)

Measurement uncertainty
(calculated in lab)
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Target value HbA1c
- secondary reference methods -

Resultater fra ERL (DCCT/ NGSP)					
	Metode 1 (Menarini HA 8180)	Metode 2 (Trinity Biotech Hb9210)	Metode 3 (Sebia Capillary 2 FP)	Mean/Fasit Totalt	Unc (k=2)
Kontroll 1	5,03 – 5,03	5,17 – 5,19	4,96 . 4,96	**5,06**	0,09
Kontroll 2	7,17 – 7,16	7,18 – 7,26	7,27 – 7,18	**7,21**	0,04

Target interval for every survey: Target (5.06) ± 0.1
*Thus the target **interval** will be from 4.96 – 5.16*
To each of these limits ± 2% = "good"
and ± 5.4% "acceptable" are added.

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Advantage of a target interval

It is in accordance with the uncertainty of the point estimate (i.e. result from reference method)

Since the “error” is usually not only proportional with a percentage increase but also with an absolute increase, it takes this into account.

(we all know that it is easier to pass the percentage criteria with a high concentration compared to a low concentration)

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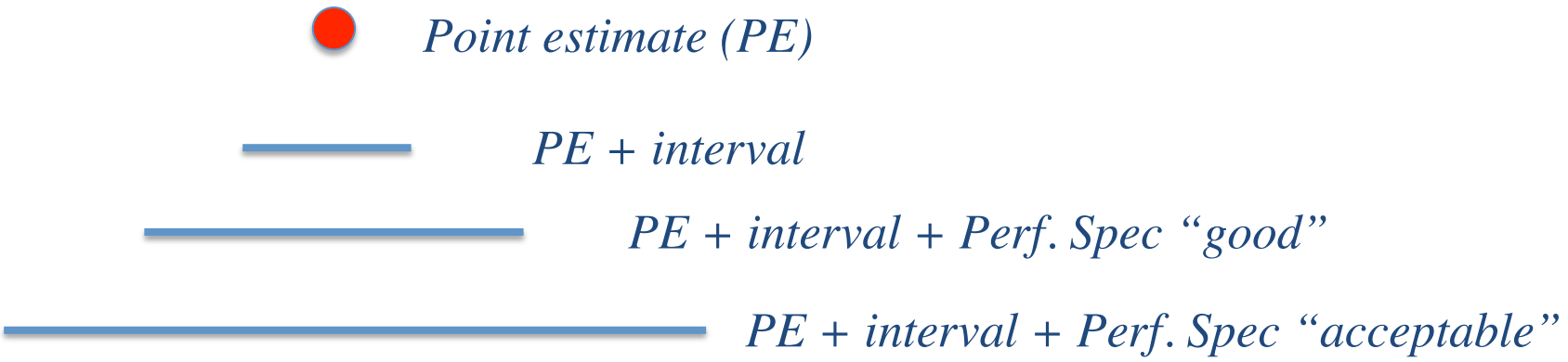
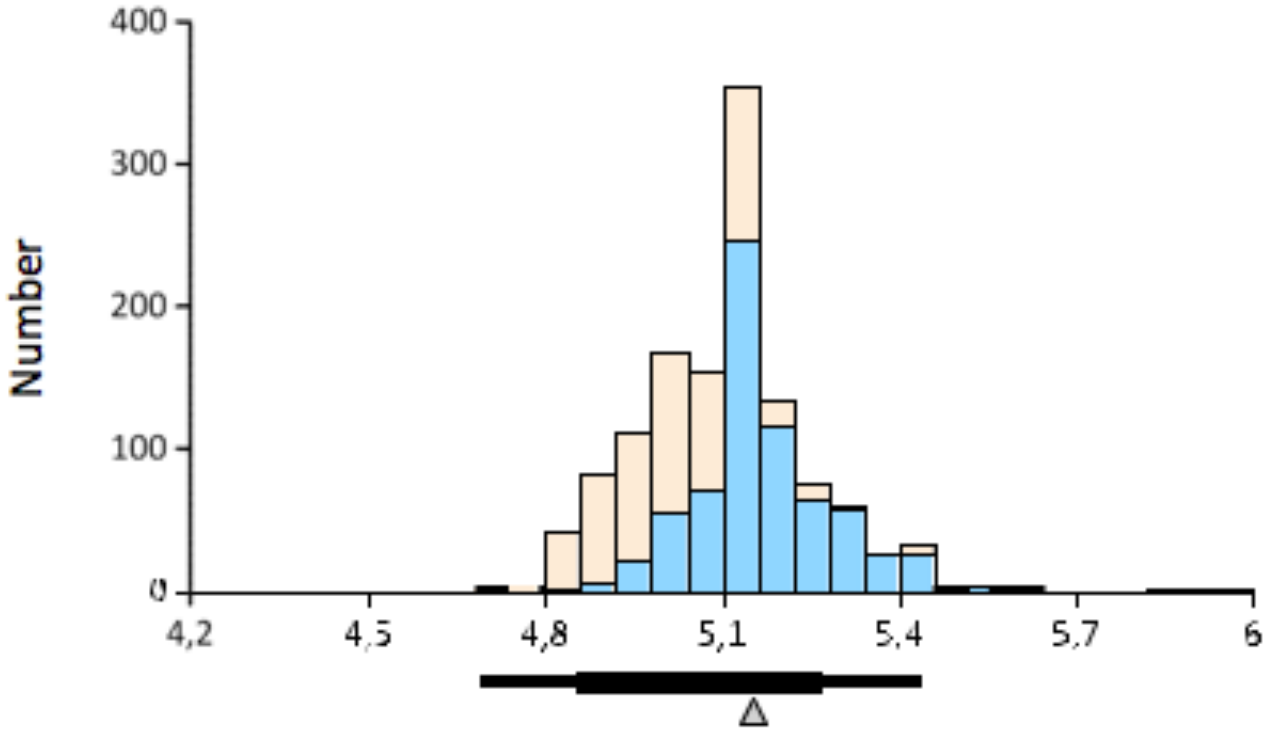
Target interval



HbA1c (%), Control 1:



Trueness:	Target:	5,06	Your result: 5,15
Evaluation:	**Good**		
Precision:	Difference between your two results: 0,1		
Evaluation:	**Good**		

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Non-commutable control material

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EQA categories

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Modified after Miller et al. Clin Chem 2011

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New EQA model for POCT

Clinical Chemistry 59:2
363–371 (2013)

Laboratory Management

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 Sandberg[2,3]

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- ✓ 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.

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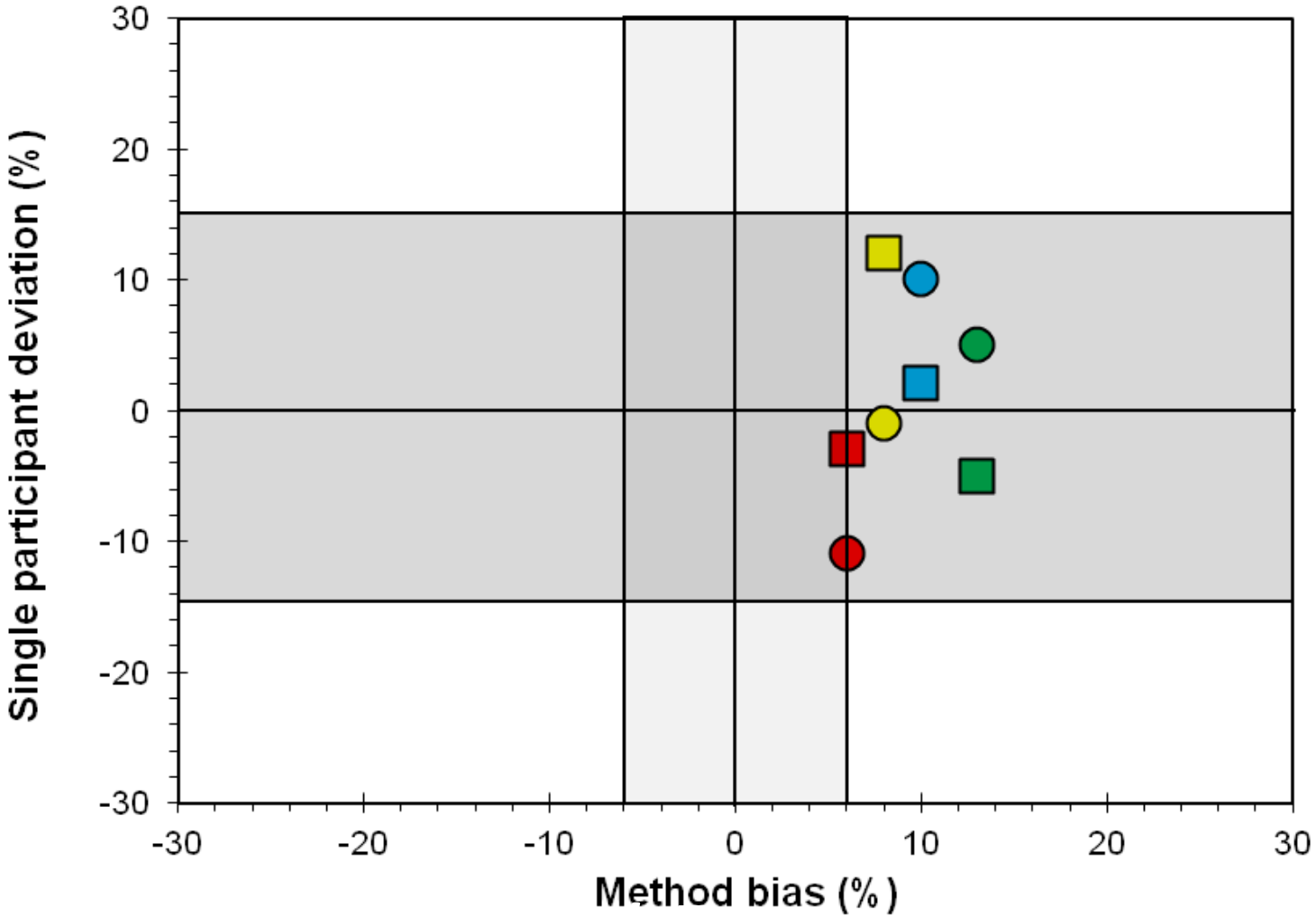
Example 1



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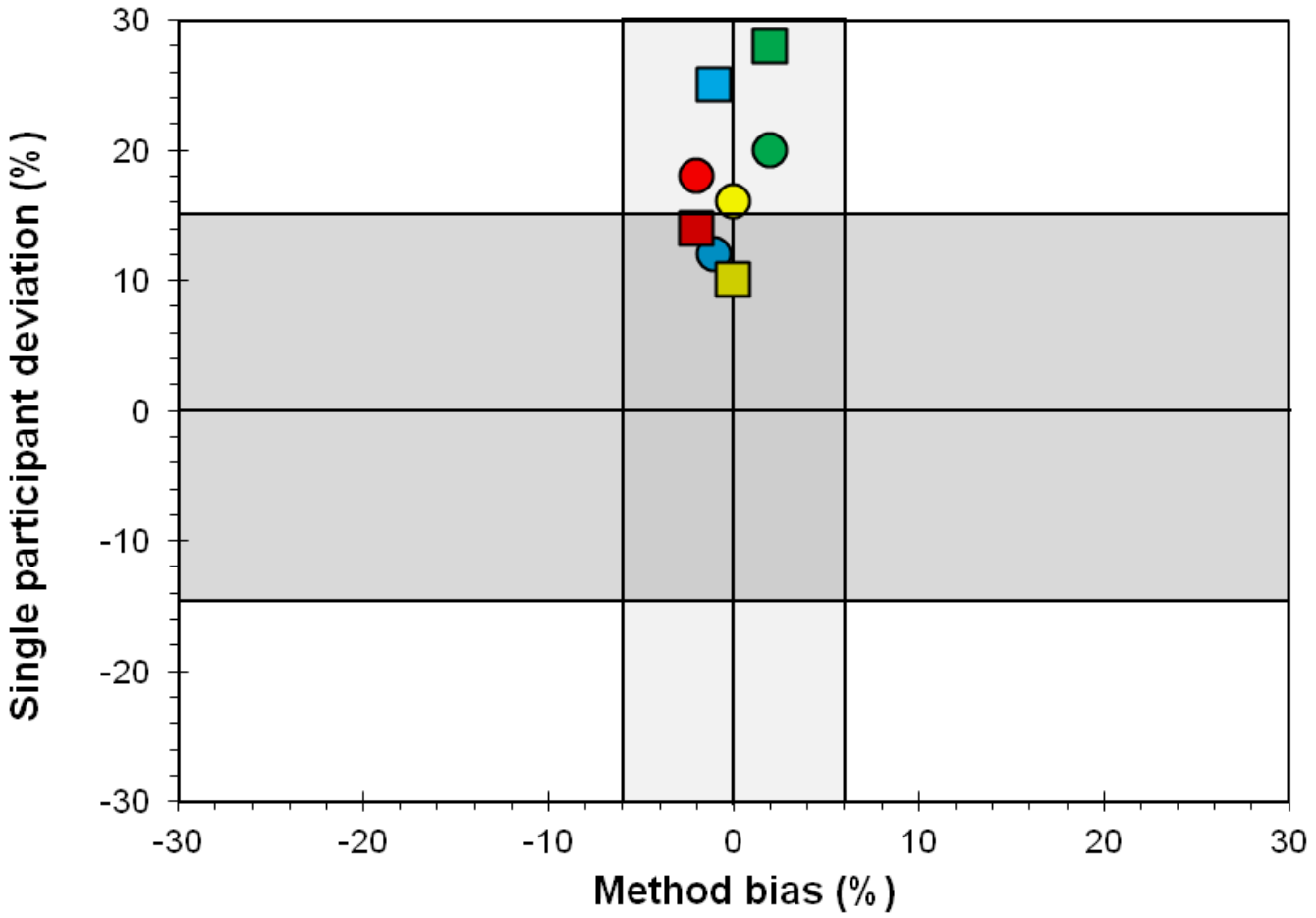
Example 2


Single participant deviation (%)
30
20
10
0
-10
-20
-30
-30
-20
-10
0
10
20
30
Method bias (%)

Non-commutability between lots of a measurement procedure

This is not covered in the categories of EQA schemes but can be a serious problem that is not uncovered unless a system with native EQA controls are established

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Non-commutability within a measurement procedure

Clinical Chemistry 51:9
1632–1636 (2005)

Evidence-Based
Laboratory Medicine
and Test Utilization

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

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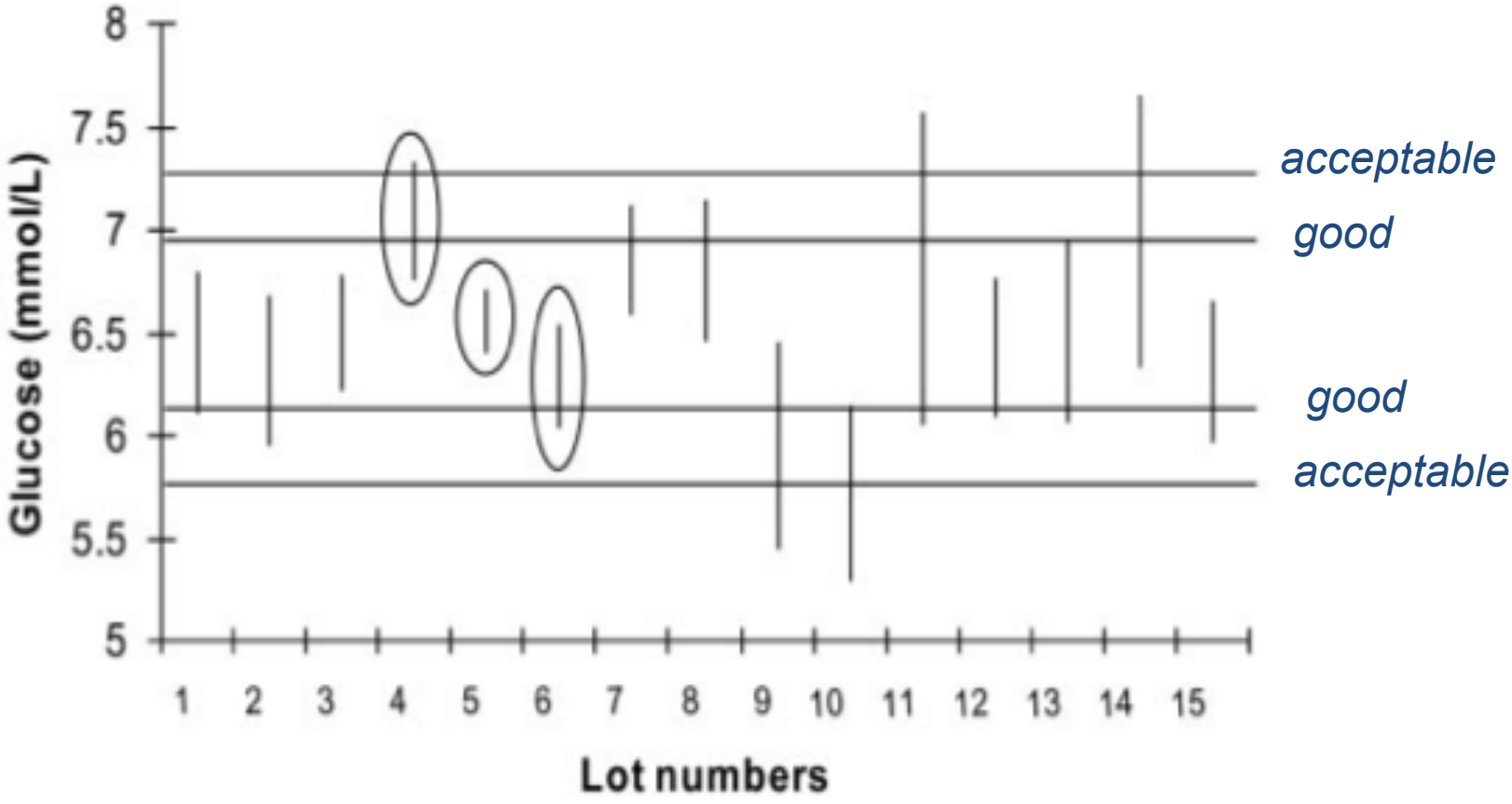
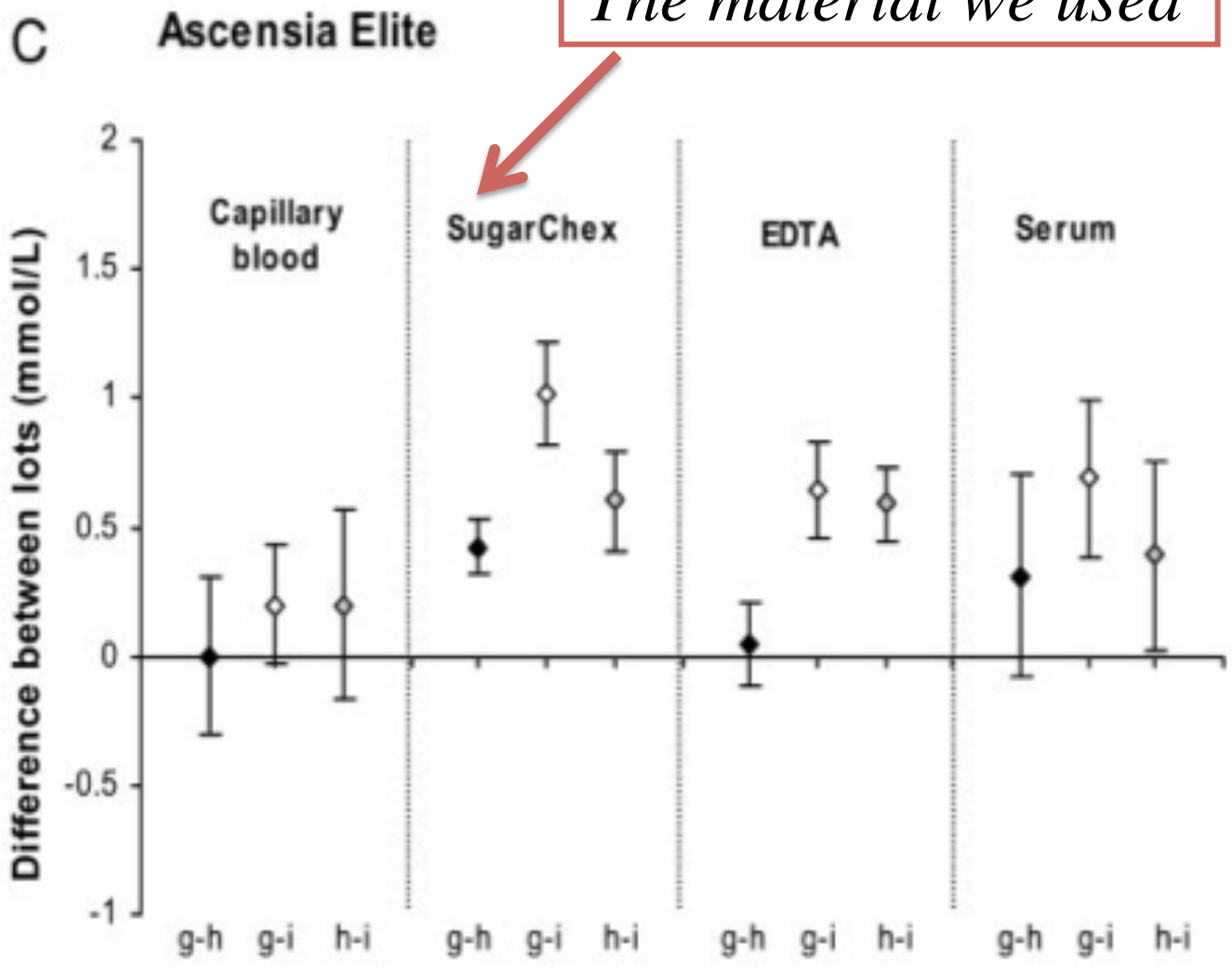
Lot numbers for the routine EQAS shown for the Ascensia Elite glucometer (n= 262 instruments).

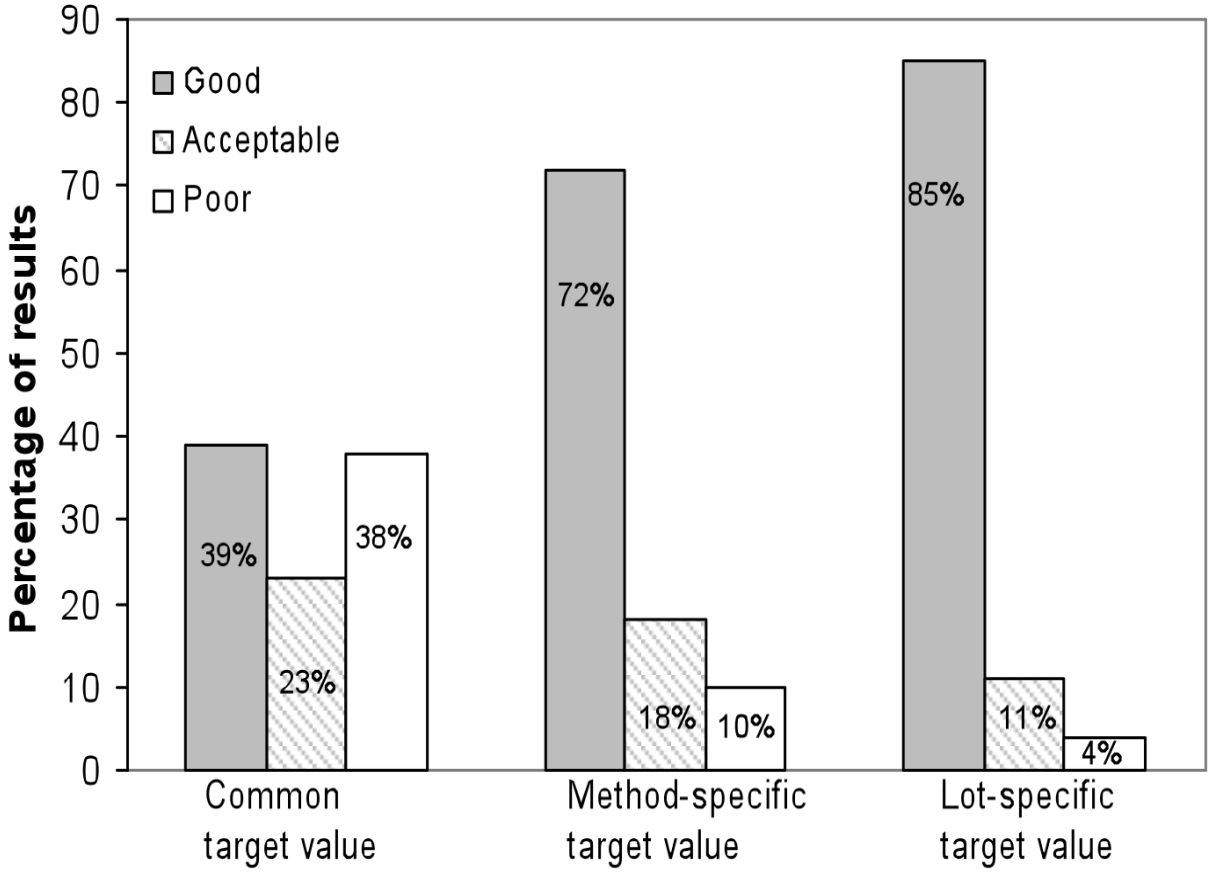


Different lots and different control materials

The material we used



Should target limits be set depending on a common target value, method specific target value or lot specific target value



Conclusion

- “Measurement uncertainty” in the target value can be used to obtain a target interval
- The “measurement uncertainty” of the EQA result is not reported. Sometimes imprecision is reported.
- EQA result can be compared to the target value and reported as a total error or as bias (and imprecision)
- EQA results can be compared to a reference value (or overall mean), mean of measurement procedure or mean of lot

Thank you