



**The Milan 2014 consensus document
EQALM meeting 2015, Bergen
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European Commission
Joint Research Centre
IRMM
Institute for Reference
Materials and Measurements



1st EFLM Strategic Conference
**Defining analytical
performance goals
15 years after the
Stockholm Conference**
8th CIRME International Scientific Meeting

Milan (IT)
24-25 November 2014

with the
auspices of 

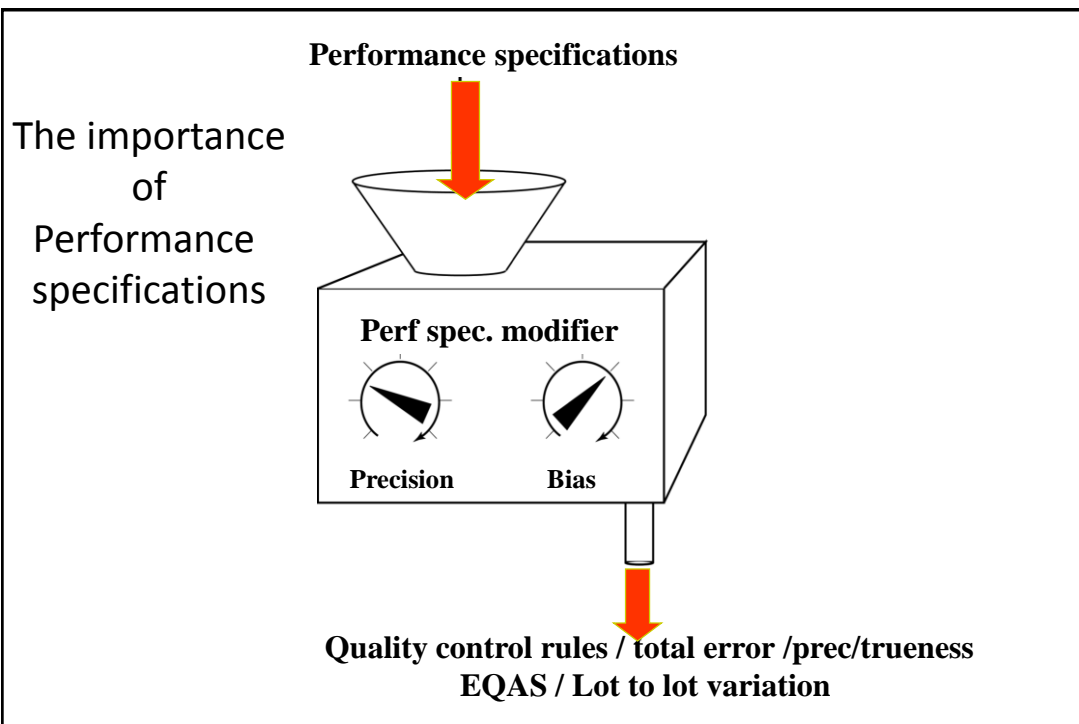


- And to be honest

- We did not know if there was a need for a new approach
- BUT it was a need to re-evaluate the current approach

Nomenclature – three words

1	2	3
Analytical	quality	goals
Measurement	performance	requirements
		specifications
		criteria
		standards



Remember that

- "All models are wrong, but some are useful."
- "The best models are not necessarily the most useful models".

(George Box 1919-2013)

**So – after lengthy discussions
- what models that should be used to set
performance specifications?**

Consensus statement

DE GRUYTER

Clin Chem Lab Med 2015; 53(6): 833–835

Consensus Statement

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**Defining analytical performance specifications:
Consensus Statement from the 1st Strategic
Conference of the European Federation of Clinical
Chemistry and Laboratory Medicine**

Model 1. Based on the effect of analytical performance on clinical outcomes

1a. Direct outcome studies

1b. Indirect outcome studies

Model 2. Based on components of biological variation of the measurand

Model 3. Based on state of the art

So what is new?

1. Only three models with different principles

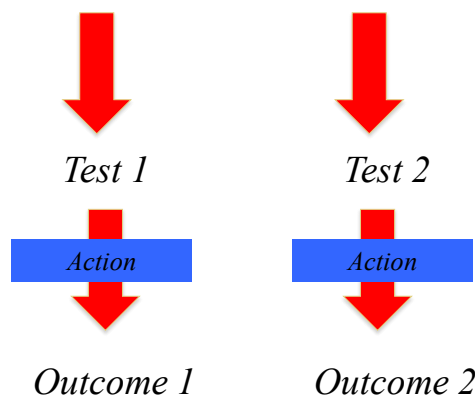
Model 1. Based on the effect of analytical performance on clinical outcomes

This can, in principle, be done using different types of studies:

1. *Direct outcome studies* – investigating the impact of analytical performance of the test on clinical outcomes;
2. *Indirect outcome studies* – investigating the impact of analytical performance of the test on clinical classifications or decisions and thereby on the probability of patient outcomes, e.g., by simulation or decision analysis.

Outcome

Patient with a disease



The advantage of this approach is that it addresses the influence of analytical performance on clinical outcomes that are relevant to patients and society. The primary disadvantage is that it is only useful for examinations where the links between the test, clinical decision making and clinical outcomes are straightforward and strong.

Model 2. Based on components of biological variation of the measurand

This attempts to minimize the ratio of 'analytical noise' to the biological signal.

The advantage is that it can be applied to most measurands for which population based or subject-specific biological variation data can be established.

The limitations are that much of the current data/studies have not been carried out in a proper scientific way and therefore contains flaws.

Model 3. Based on state-of-the-art

This relates to the highest level of analytical performance technically achievable. Alternatively, it could be defined as the analytical performance achieved by a certain percentage of laboratories.

The advantage of this model is that state-of-the-art performance data are readily available. The disadvantage is that there may be no relationship between what is technically achievable and what is needed to minimize the ratio of 'analytical noise' to the biological signal or needed to obtain an improved clinical outcome.

Model Based on	Study	Advantage	Disadvantage
Clinical outcomes	Outcome studies	Address the needs of patients and society	Difficult to perform studies. Limited number of measurands
Biological variation	Studies on biological variation Analytical noise vs biological signal	Can be applied to most measurands	Current data is not good enough
State of the art	Empirical data	Easy to obtain data	Does not relate to what is needed or to noise/signal minimalisation

Explanatory notes

- It should be noted that the three models use different principles.
- The hierarchy assumes that high quality studies or data are available for each model.
- Proposed analytical performance specifications should therefore always be accompanied by a statement of the rationale, the source and the quality of the evidence behind the recommendation.

After the meeting

- A series of papers from the Strategic conference is published in CCLM 2015;53 issue 6
- 5 Task and Finish Groups (TFG) are established that will take the ideas from the Strategic conference onwards and try to address problems that have not been addressed or solved during the conference.

TFG: Allocate tests to different models

Ferruccio Ceriotti

To allocate different tests to different models

To produce a list of proposed models for the different measurands starting with the most common.

TFG: Performance criteria for pre- and post-analytical (extra-analytical) phases

Mario Plebani

To come up with a general proposal on how to generate performance criteria for the pre- and post-analytical phases

TFG: Biological variation database

Sverre Sandberg

To use a critical appraisal check list to evaluate literature on biological variation.

To evaluate existing papers, categorize to A, B, C and D

To establish a database listing the information for the evaluated analytes

TFG: Measurement total error

Wytze Oosterhuis

To come up with a proposal for how to use the total error concept or if it should be used at all (e.g. Is it possible to combine performance specifications for bias and imprecision into performance specifications for total error?)

TFG: Harmonization of allowable limits in EQAS

Graham Jones

To define performance specifications for the most common analytes that can be used by EQAS organisers (for category I EQAS).

