Representatives from 38 European and extra-European Countries are attending the event

Australia	Iran	Czech Rep.
Austria	Ireland	Romania
Belgium	Italy	Russia
Bulgaria	Latvia	Serbia
Canada	Lebanon	Slovenia
Croatia	Lithuania	Spain
Denmark	Malaysia	USA
Estonia	Norway	South Africa
Finland	The Netherlands	Sweden
France	Poland	Switzerland
Germany	Portugal	Turkey
Ghana	Qatar	Ukraine
Greece	UK	

EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

Profession (e.g., JCTLM, EFLM): Define analytical objectives: reference measurement systems (traceability chain) and associated clinically acceptable performance (fitness for purpose)

↓

Diagnostic manufacturers: Implement suitable analytical systems (platform, reagents, calibrators, controls) fulfilling the above established goals

↓

End users (clinical laboratories): Survey assay and laboratory performance through:
- IQC component I: testing system controls to confirm and verify manufacturer's declared performance (CE marked – virtually unbiased)
- EQA: true value in commutable materials for defining performance of laboratory measurements

Adapted from
Panteghini M, Clin Chem Lab Med 2010;48:7

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The definition and use of the reference system concept for standardization of measurements must be closely associated with the setting of targets for uncertainty and error of measurement in order to make it clinically acceptable

If these goals are not objectively defined and fulfilled, there is a risk of letting error gain the upper hand, thus obscuring the clinical information supplied by the result and possibly nullifying the theoretical advantages of metrological traceability and even causing negative effects on patients' outcome.

L Thienpont et al., Clin Chem Lab Med 2004;42:842
Braga F & Panteghini M, Clin Chim Acta 2014;432:55

STRATEGIES TO SET GLOBAL QUALITY SPECIFICATIONS IN LABORATORY MEDICINE

WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

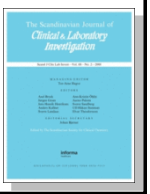
International Union of Pure and Applied Chemistry

ifcc *International Federation of Clinical Chemistry and Laboratory Medicine*

Nobelforum,
Karolinska Institutet
Stockholm April 24-26, 1999

1999 Stockholm Consensus Conference on Quality Specifications in Laboratory Medicine

1. **Evaluation of the effect of analytical performance on clinical outcomes in specific clinical settings (e.g. misclassification in diagnosis)**
2. **Evaluation of the effect of analytical performance on clinical decisions in general**
   a. **Data based on components of biological variation**
   b. **Data based on analysis of clinicians opinions**
3. **Published professional recommendations from national and international expert bodies**
4. **Performance goals set by**
   a. **Regulatory bodies**
   b. **EQAS organizers**
5. **Goals based on the current state of the art (e.g. as demonstrated by data from EQAS)**



Scan J Clin Lab Invest 1999;49:475-585

Acceptable performance 1999-2014

[definition & application]

...is like teenage sex

- Everybody is talking about it
- Everybody thinks everybody else is doing it
- Few people are doing it
- And those who are, are doing it badly

1999 Stockholm Consensus Conference
revised in 2014

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1999 Stockholm Consensus Conference revised in 2014

Effect of analytical performance on clinical outcomes

- Advantage: to directly address the influence of measurement performance criteria on clinical outcomes.
- Disadvantage: it is only useful for examinations that inherently exert crucial effects on clinical decision-making. Furthermore, it may be influenced by the current measurement quality and results may vary according to the population investigated.

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1999 Stockholm Consensus Conference revised in 2014

Performance goals based on biological variation of the measurand

- Advantage: it can be applied to most measurands for which a “steady state” biologic model can be established.
- Disadvantage: need to carefully assess the relevance of the biological variation data.

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revised in 2014

Performance goals based on the state of the art

- Advantage: numbers are readily available.
- Disadvantage: there may be no relationship between what is achievable and what is needed clinically.

2014 Milan Consensus Conference
will also discuss:

Performance criteria for extra-analytical phases

Performance criteria for qualitative test procedures

Publication of Proceedings of the Conference