EFLM
EUROPEAN FEDERATION
OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE

European Commission
Joint Research Centre
IRMM
Institute for Reference
Materials and Measurements

CIRME
UNIVERSITÀ DEGLI STUDI
DI MILANO

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 **ifcc**
International Federation
of Clinical Chemistry
and Laboratory Medicine

Summary

- Papers in CCLM
- "Consensus" paper
- Task Force
- Discussion and amendments

Draft "Consensus" Document

Approved by the Scientific Programme Committee before the meeting.

Analytical performance goals

There is a general agreement that different models should be available to set performance goals and that some of these are better suited for certain measurands than for others.

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

> *1a. Outcome studies*
>
> *1b. Simulation studies*
>
> *1c. Clinicians´ and/or experts' opinion*

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

Model 3. Based on state of the art

Explanatory notes

- The three models use different principles. The hierarchy applies when high quality studies or data are available for each model.
- Proposed analytical performance goals should always be accompanied by a statement of the source and the quality of the evidence behind the recommendation.

- Some models will be better suited for certain measurands than for others. It is therefore recommended that a list is made allocating measurands to different models.
- Preference should be given to models 1 and 2.

- Models for setting performance goals of assays using ordinal and ratio scales should follow one of the three models outlined above.

Performance goals for the pre- and post-analytical phases

- It is acknowledged that for patient care the quality of the total (preanalytical – analytical - postanalytical) measurement process is the ultimate goal and therefore it would be desirable to go beyond setting analytical performance goals and to establish measurement performance goals. In principle, the performance goals for the pre- and post-analytical phases should follow the same models as for analytical performance goals.

What will happen after the conference
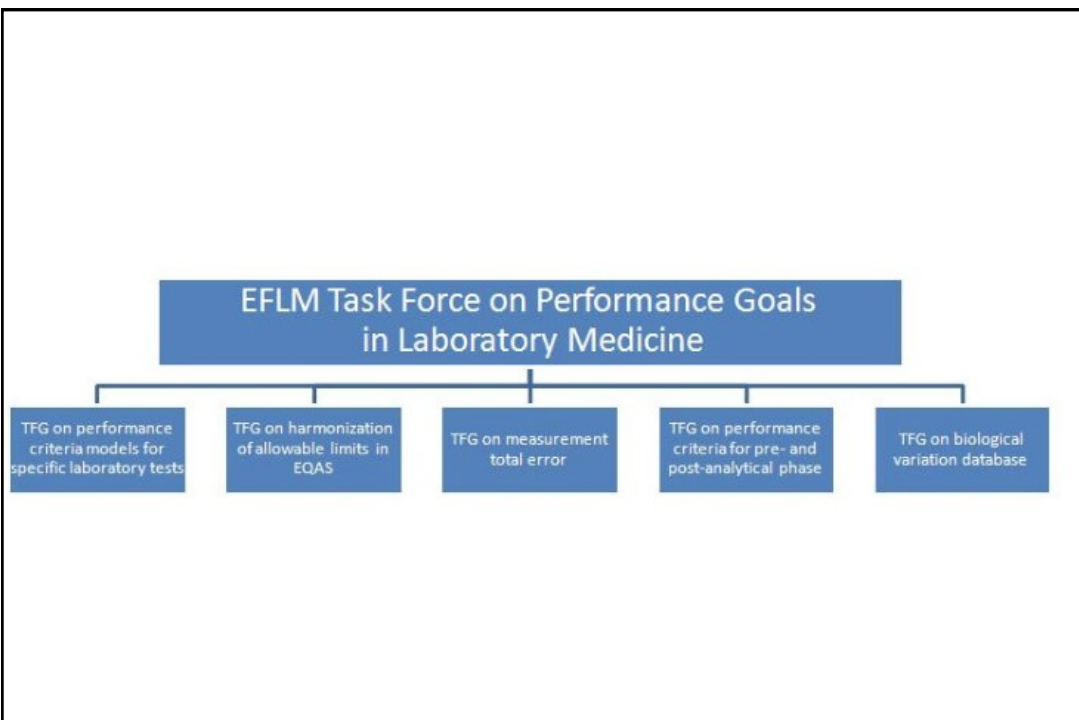
TFG 1: Allocate tests to different models

- *Terms of Reference:* To allocate different tests to different models and give an overview and a reason for why tests are allocated to the different groups. *Deliverable:* To produce a list of proposed models for the different measurands starting with the most common.
- To publish a paper describing the method used for listing different tests in different model groups.

TFG2: Harmonization of allowable limits in EQAS

- *Terms of Reference*: To define performance criteria for the most common analytes that can be used by EQAS organisers (for category I EQAS).
- *Deliverable*: A manuscript dealing with this topic.

TFG 3: Measurement total error

- *Terms of Reference:* To come up with a proposal for how to use the total error concept or if it should be used at all (how can performance criteria for bias and imprecision be combined into performance criteria for total error?)
  Deliverable: A manuscript dealing with this topic.

TFG 4: Performance criteria for pre- and post-analytical (extra-analytical) phases

- *Terms of Reference:* To come up with a general proposal on how to generate performance criteria for the pre- and post-analytical phases (and the total measurement process).
- *Deliverable:* Two papers (one for PRE and one for POST) dealing with this topic.

TFG 5: Biological variation database

- *Terms of Reference:* To use a critical appraisal list to evaluate literature on biological variation. To generate an website with, for each measurand, essential summary information from the selected papers, so that they can be used for setting performance criteria based on biological variation.
- *Deliverable:* A database listing the information for the evaluated analytes

Other?

Discussion of the document and the way forward

- All proposals should be sent to

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The document and TFGs will be amended taking this into account.