Analytical Performance Specifications: the benefit for the laboratory!

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Performance specifications are extremely important for the laboratory since we know how good performance we need to have for an optimal use of laboratory tests and also not to invest in “too good” quality which can be a waste of money. According to the hierarchy established in the 1the EFLM strategic conference in Milan in 2014, there are three different models to set analytical performance specifications.

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

This can, in principle, be based on different types of studies:

1a. Direct outcome studies – investigating the impact of analytical performance of the test on clinical outcomes;

1b 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.

The advantage of this approach is that it addresses the influence of analytical performance on clinical outcomes that are relevant to patients and society.

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 biological variation data can be established.

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 primary disadvantage with model 1 is that it is only useful for examinations where the links between the test, clinical decision-making and clinical outcomes are straightforward and strong. This means that different performance specifications can apply to the same measurands. For a “clinical guideline” this can be useful, but for a laboratory this can be difficult to handle when it comes for example to setting up rules for internal quality control. What performance specifications should then be used, the strictest or the widest? Concerning the biological variation approach, in principle there is only one number for each measurand. This is very often used by laboratories although they often use different numbers for the same measurand. The reason is that the validity of the biological variation data and the current database has been shown to have important limitations, and the papers on biological variation for the same measurand show great variation. There is however, currently ongoing work in the European Federation of Clinical Chemistry and laboratory medicine to solve this.

Since performance specifications have great implication for what we doing in the laboratory and how we control our analyses, we continuously to find the best way to set the specifications.

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