EQA of POCT methods: how to interpret results?

Anne Stavelin, Ph.D. NOKLUS, Bergen, Norway

External quality assurance (EQA) is both a tool to compare the analytical performance of different methods and a tool for the individual laboratory to compare results with others with the same or different methods. EQA is administered by an external part (an EQA organizer) and the result is assessed retrospectively. The time period between the reported result and the feedback should be as short as possible. It is recommended that users of point-of-care testing (POCT) methods should participate in EQA schemes whenever available (1) and it has been shown that participation over time have the potential to improve the participant performance (2). However, it is a challenge for the EQA organizers to provide such schemes because of the often large number of participants and that the different methods cannot use the same control materials. In addition, it is a challenge to obtain suitable control materials. A study performed within the European countries (3) showed that only some countries offer EQA schemes for POCT international normalized ratio (INR) because of these challenges.

EQA schemes can be divided into 6 categories where category 1 is considered the best (4). Here we have commutable or native control materials, reference target values and replicate measurements. In this category, the trueness of methods and the trueness for each single laboratory can be assessed. The harmonization of methods can be evaluated, and each single participant can compare results with other methods as well as within own method. It is important that the laboratory know which aspects of analytical quality that can be assessed in the different EQA schemes in order to interpret the results correctly.

EQA schemes for POCT is most commonly in category 6, meaning that we cannot compare results between different POCT methods (the trueness cannot be evaluated). A novel model has therefore been established in order to improve EQA schemes for POCT (5). The principle is that a POC method bias is established using native patient samples (about 100 for each POC method), and this is combined with the result from the regular EQA scheme. In this way, the combined assessment of the POC method bias and each single participant performance can be assessed. The POCT bias is established by a selected group of participants (approx. 25 general practitioners for each POCT method) by analyzing approx. five native patient samples each. The reagent lot variation can also be evaluated by this model. In general, if differences between reagent lots are detected in the regular EQA scheme with non-commutable control materials (category 6), we cannot know whether this also reflect patient samples. However, by performing the novel model, we can evaluate lot-to-lot differences with native patient samples.

Safe patient treatment is not only dependent on the analytical quality of the instrument. There are several factors that can influence the process from clinical findings to diagnosing, monitoring and treatment of patients. This process is called the total testing process, and all steps are important. Noklus offers an overall quality assurance system for laboratories in primary health care. In addition to the EQA schemes, over 40 laboratory consultants arrange courses and visit the participants, they examine their procedures and provide practical advice and education regarding the use of different instruments.

In summary, in order to interpret EQA results correctly it is important for the laboratories to know the design of the EQA scheme (the nature of the control materials and target values, i.e. the category of EQA schemes). The laboratories should preferably participate in EQA schemes where it is easy to interpret whether an unacceptable EQA result is due to a poor method performance or poor participant performance.