The Journal Of The International Federation Of Clinical Chemistry And Laboratory Medicine

eJIFCC

Editorial

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During the last decade quality management systems has gained an increased interest throughout laboratory medicine. This has called for harmonisation of criteria for accreditation and for the wider concept of total quality management. Existing standards like the ISO 9000 series, ISO Guide 25 and the EN 45000 series do not fulfill the need for a comprehensive standard that that goes beyond the technical analytical aspects. The time has now come to evaluate our laboratories using standards that not only focus on the quality of the analytical performance but also on patient related aspects of our activities. A new standard, ISO/FDIS 15189 that is harmonized with the ISO 9001-2000 is under preparation and is likely to be endorsed by the standards organisations during year 2001. This standard is substantially more focused on pre-and post analytical aspects and patient outcome criteria than previous standards.

An example on the need for modernisation of existing standards is the fact that the Clinical Pathology Accreditation (UK) Ltd have published new " Standards for the Medical Laboratory " , January 2001 (**http://www.cpa-uk.co.uk/).** This document is a national standard with cross references to ISO/FDIS 15189, ISO/IEC17024/2000, ISO/DIS 9001(E) and EC4 Essential Criteria. The EC4 Essential Criteria is yet another example.

A number of points of interest in this respect are discussed in this issue of eJIFCC.

The Swedish Society for Clinical Chemistry has, through its expert group, produced a proposal for a protocol, which enhances the clinical and medical aspects on laboratory work. Some of the items will be found in the ISO 15189 but it was originally written to complement the EN 45001. Through the publication of this protocol in this issue we want to start a discussion around these questions. We would like to make use of the possibilities offered by the electronic form of our journal and start a discussion forum and maintain it as an easily accessible platform for discussions.

Please, go to your key-board and give us your views.

All measurements harbor an inherent uncertainty. The ISO definition of uncertainty in measurement is: "parameter, associated with result of measurement that characterises the dispersion of the values that could be reasonably attributed to the measurand". As this definition is rather difficult to live up to in practical laboratory work *Anders Kallner* expands and explains the definition in this issue of *eJIFCC*. A result should not only be described in terms of reproducibility but also how close it is to an assumed "true value". Since we do not know the "true value" we have to work with "assigned values" or what is also called "conventional true value". It is, however, no easy task to determine the " conventional true value " . Should it be done through the creation of " mentor/reference laboratories " or can one use the values obtained from sufficiently large groups in external quality assessment programs? *Bias* will then be the difference between many measurements of the same quantity and the assigned value. The statistic trueness will describe the systematic error. The concept of *accuracy* includes both random and systematic errors and is also often referred to as *total error*. Should bias be included in the so called *total error?* To me that is not absolutely obvious and the main reason for this is the difficulty in defining the " true value " and consequently also the uncertainty of the bias.

After a period of time during which the emphasis has been on the analytical technical/quality of laboratory medicine measurements the time has now come to develop recommendations and standards for the pre- and postanalytical phases in order to come closer to total quality management. *Narayanan and Guder* highlight the importance of knowledge of the preanalytical variables and their influence on the quality of laboratory results. The German Society for Clinical Chemistry and the German Society for Laboratory Medicine have been very active in this field and published their recommendations regarding preanalytical variables as late as last year (1). The authors of the present article anticipate that with the awareness and introduction of strategies to recognise preanalytical errors the goal of achieving total laboratory quality is finally within our grasp.

In the previous issue of this journal we focused on POCT instruments and methodology. The use of POCT has increased enormously during the last decade and will in all probability continue to do so. This has brought forward the need for good quality assessment programs for this type of tests.

Callum G Fraser discusses "Optimal analytical performance for POCT" the hierarchy of strategies to set quality specifications. The hierarchy is the one proposed by him and Hyltoft Pedersen (2) and later approved by expert professionals (3). His conclusion is that there is no reason why POCT analyses and analyses performed at other sites

eJIFCC2001Vol13No1pp001-002

should be judged by different standards. At the top of the hierarchy is assessment of the effect of analytical performance on specific clinical decision making. The discussion on how positive and negative bias can effect the cost of health care in the short run and in the long run and the effectiveness of treatment is very illustrative. Even if it is to be preferred to use strategies at the top of the hierarchy it is argued that those further down are better than none.

It is high time to focus on the quality assessment of the analytical performance of POCT instruments and methods and not only on their speed of analysis. For instance, when will we get a uniform calibration system for POCT glucose analysers?

References

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2. Fraser CG, Hyltoft-Petersen P. Analytical performance characteristics should be judged against objective quality specifications. Clin Chem 1999;45:321-3

3. Hyltoft-Petersen P, Fraser CG, Kallner A, Kenny D, eds. Strategies to set global analytical quality specifications in laboratory medicine. Scand J Clin Lab Invest 1999;59:475-585