LABORATORY ACCREDITATION: THE VALUE OF QUALITY IMPROVEMENT

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Today, many medical laboratories demonstrate their competence by accreditation. This formal recognition of the reliability of the test results means medical laboratories have to fulfill the requirements laid down in the international standard ISO 15189.
This ISO document stress the importance of assuring the quality of examination procedures such as validation of methods, quality control procedures , calibration and estimation of uncertainty of measurements. At this moment 220 medical Laboratories are accreditated by the *Raad voor Accreditatie-Divisie Zorg (RvA), Stichting ter Bevordering van de Kwaliteit van het Laboratoriumonderzoek en voor de Accreditatie van Laboratoria in de Gezondheidszorg (CCKL)*, the accreditating body in The Netherlands for medical laboratories and 290 medical laboratories are registered. The improvements of several years of accreditation are the use of appropriate methods, better service from the instrument and kit suppliers, better control of traceable elements (i.e. temperature, volume and weight) and more adequate process control on first, second and third quality control, leading to general understanding and acceptance of the accreditation standard ISO 15189.
Since many medical laboratories are accreditated, the developments are now focusing on the process of continuous quality improvement by implementing models from the industry for example Lean (Toyota), Six Sigma metrics (Motorola) and DMAI^{2}C (Johnson & Johnson) in relation with increased productivity and cost reduction.
Understanding the theoretical characteristics of Westgard Rules means insight in the probability of false rejections (P_{fr}) of control measurements and the probability of error detection (P_{ed}). Several tools are available, e.g. the program Westgard Advisor and the use of Operational Specifications Charts. Application of these these tools implies the development of procedures describing the design of the process of quality control for each test procedure in terms of control rules and frequency of control measurements.
This knowledge of models like Sigma Sigma metrics and Lean was introduced in our laboratory in 2006, leading to a procedure to evaluate new analytical systems with significant reduction of costs. Planning the evaluation of an analyzer started with the calculation of the Sigma Score for 43 different test procedures using the Te_a from the database of Ricos et al. and the CV analytical as described by the supplier. Only 8 tests showed Sigma Score <3 meaning that these were poor performing processes. Only these 8 tests were evaluated using the Evaluation Procedure EP5a (from the CLSI) for estimation of the precision. Method comparison was carried out using plasma pools. Following this procedure the evaluation time was reduced with 60 % and the overall costs (i.e. expenses for technical assistents and less depreciation as a result of decreased evaluation time and a lower number of test measurements) were reduced by almost 70%. Another useful spinoff is the reduced costs of control materials as a result of reduced fail costs by applying the appropriate control rules.

1 Ricos C. et al. Scand J Clin Invest 1999;59 491 – 500
2 James O Westgard . Assuring the Right Quality Right 2007 ISBN 1-886958-24-6