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Dutch lectures in clinical chemistry in Prague 1995

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From May 22-24, 1995 a small delegation of clinical chemists from The Netherlands went to Prague to meet Czech colleagues and to give lectures. The central theme of this series of lectures was total quality management within the field of laboratory medicine. The two lecturers, Dr. H. Baadenhuijsen and dr. H.M.J. Goldschmidt, give a summary of their lectures below. The course was attended by 27 participants. The language used during the course was English. In his opening address professor Engliš called the Dutch lectures in Prague "the gateway to Europe" for Czech clinical chemists. The course, although heavy for speakers and participants, was very much enjoyed by all. As an evaluation the participants filled in a small questionnaire. The results given in table 1 indicate that the course was a success.

We have appreciated the social and touristical aspects of our visit to this beautiful city. We will not easily forget the sightseeing tour in Prague, the official diner with members of the Board of the Czech Society for clinical chemists, and the theatre performances that we were kindly invited to. May I thank professor Engliš, dr. Palicka and professor Kazda for the kind hospitality that we experienced during our stay and especially professor Engliš for all the organizing work that he did to make this course a success. We highly appreciate the invitation of the Czech Society for a next edition of Dutch lectures in clinical chemistry in the spring of 1996. The topic for this course will be endocrinology.

Quality management of medical laboratory data

*H.M.J. Goldschmidt**

Expert systems

The application of expert systems and other forms of artificial intelligence such as neural networks and genetic algorithms, within the laboratory but also in any patient care situation was outlined. An overview of the current state of the art was illustrated by examples. The calculation of cardiac tissue damage, the assessment of a diagnosis based upon laboratory and general patient data, anticoagulants therapy based upon historical laboratory data, were just a few of the explored examples. The general conclusion was that application within the laboratory is rare but will gain in importance in each of the three laboratory limbs: pre-analytical, analytical as well as post-analytical. Application probably will be more effective in monitoring as in screening or diagnostic situations. Sensible applications will probably regard limited, (highly) specialized processes or subjects.

Evaluation techniques

The evaluation of laboratory instruments and tests was presented using various evaluation protocols: ECCLS, NCCLS and industry originated. It was divided into three main sections: analytical, clinical and managerial evaluation. Software (EVAL-kit) covering all three points of view was demonstrated and, where applicable, discussed.

Many analytical characteristics could be estimated through one-at-a-time protocols for imprecision, duplicity, minimal detectable concentration, sample-to-sample carryover, reagent-to-sample carryover, linearity, accuracy, drift, etc., etc.. Special attention was paid to linear regression techniques, parametrical and non-parametrical, and interference protocols. Results of multifactor evaluation designs were compared with one-at-a-time protocols and it was found that in certain situations the multifactor designs could be very useful as a fast and effective evaluation approach.

The involvement of the customer of the laboratory services, the physician, is emphasized in the clinical evaluation point of view such as the estimation of (multivariate) reference ranges, ROC curves and medical allowable errors in comparison with the total analytical error of the test(s) under study. Several concepts are given to account for the medical allowable error: Tonks, Skendzel, Fraser and Westgard. The total analytical error was calculated from the addition of the random and systematic errors; sporadic errors were excluded.

A managerial evaluation including Stockmann's scoring system, cost calculations and organizational impacts, is provided.

Sporadic errors and workflow analysis

The frequency of occurrence of laboratory errors is a controversial subject. A questionnaire regarding this, filled in by the laboratory's customers does not provide much useful information. Studying the formal complaints (internal and external Faults Or Near Accidents) over the last six years reveals only that interchanges between patients and sample ID's are main error causes. How serious the problem is, was shown through blind duplicate experiments between various laboratory sites. Pareto diagrams were used

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Table 1. Evaluation of the course by the participants

Questions	Scale	Average	Range
Can you understand the English language used in the lectures?	1(bad) - 5 (good)	3.68	2 - 5
Were the lectures relevant for your daily practice as clinical chemist?	1 (not at all) - 5 (very much)		
a. Dr. Baadenhuijsen		3.63	1 - 5
b. Dr. Goldschmidt		3.53	1 - 5
How would you score the lectures?	1 (very bad) - 5 (very good)		
a. Dr. Baadenhuijsen		4.58	3 - 5
b. Dr. Goldschmidt		4.95	4 - 5
Did the lectures overestimate or underestimate what you already knew about the topic?	1 (underestimate) - (overestimate)	3.89	2 - 5
Do you think the Dutch lectures in your country should go on in future years?	1 (not at all) - 5 (very much)	4.74	3 - 5

to categorize and order the different error causes. An overall error rate of 1 - 2 % was found. In addition daily turn around time study results (socalled Freckle plots) were given and subsequent Pareto diagrams generated. Delay rates, causes and solutions were discussed. The workflow analysis approach from Lehmann and Leiken leading to consolidated work stations and software programs offering the possibility to simulate dynamically different laboratory settings were shown.

Laboratory automation
Shortly different ways of laboratory automation were given; a layered model with a local area network seems the way to go for the near future. It provides the best opportunities for the instrumental couplings and the fastest, most secure data flow for the laboratories customers.

Time dependencies
The concept of autocorrelation was given and used to quantify the coherence of time series of calibration, quality control data and patient monitoring data. These time dependent processes could be characterized as first order, autoregressive, stochastic, stationary processes. This enables us to predict within certain confidence limits the signal under study. And by doing so it can simply be shown that particular calibration, control and monitoring frequencies are either too low or too high. In the example of the vitamin B12 control data the frequency could be reduced by 75% without loosing any essential information. The reconstructed signal and the reconstruction error can be used to verify such as often as one wants.

Conclusions by multicriteria analysis
Through the simultaneous consideration of analytical, medical and managerial items, decisions are undertaken that take all of these into account. Through the distinction between operational, tactical and strategical and specific techniques applicable in each of these domains, optimal decision strategies can be chosen. It was emphasized that total quality management is a key issue for the coming years in the medical laboratory.

Quality management of medical laboratory data.
*H. Baadenhuijsen***

External Quality Control programmes in The Netherlands
An overview of the existing activities in the field of external QC was given. The theoretical fundaments of the coupled internal/external Combi-scheme (Steigstra et al. Clin Chem 1991; 37: 1196-1204) were explained. Important part of this scheme is the scoring system which is based on the constraints given by the intra-individual biological variation. Practical elaboration yields examples of limits for analytes which, with the present state of the art, are too narrow (Na, Ca, Total protein, Albumin) and others which are too wide (Enzymes, Triglycerides). Solution of this problem has been sought in the use of so-called limit scores.
The non-commutability of part of the control sera used in external QC schemes remains a big problem for correct participant assessment. Examples of this problem were discussed and the data of the recent study (Baadenhuijsen et al. Clin Chem 1995;41:724-730) on the cholesterol analysis were given as an example of how to tackle the problem of denaturation of lipoproteins in control sera by the lyophilization procedure.

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The use of electronic data transfer techniques
The principles and the practical use of the data-transfer and data-management program Qbase were demonstrated by means of a PC-overhead projection session. The program supports not only the electronic data transfer of the participant's QC data to the central SKZL computer but also gives the opportunity to manage the daily internal QC procedures (statistics, Shewart charts). The participants are also able to consult the central database for statistical details of the cumulated results. The integrity of the local user's environment is cared of by automated updating of relevant local tables each time the user has activated modem contact with the central computer.

Indirect estimation of reference intervals with the Bhattacharya procedure
By means of PC-overhead projection, the program "Refvalue" (Baadenhuijsen, Smit. J Clin Chem Clin Biochem 1985; 23: 829-839) was demonstrated. In contrast to the officially recommended IFCC procedure for establishing reference ranges, this procedure does not start from a very well-defined reference population, but uses the total amount of laboratory results generated for each analyte to be studied. The underlying principle is the deconvolution of (not too much) overlapping Gaussian distributions by the sequential logarithmisation and numerical differentiation of the observed frequency distribution. The modification as described by Baadenhuijsen and Smit enables not only the use of underlying symmetrical distributions, but also skewed distributions by incorporating an iterative Ln(x+c) transformation procedure. Advantages and limitations of the procedure were discussed.

Geriatric reference ranges
Starting with an overview of some general available data of biological and clinical chemical nature, the concept of the elderly growing population was discussed. Results of own experience with the generation of geriatric reference ranges were given. This was done on the basis of the indirect procedure for establishing reference ranges by the method of Bhattacharya, as explained above). Use was made of the recently published contribution to the AACC handbook on geriatric reference values (Baadenhuijsen H. Reports on reference values in the elderly for 16 analytes in serum. In: Faulkner WR, Meites S, eds, Geriatric Clinical Chemistry, Washington: AACC Press 1993: 189-583).

Analytical performance goals in relation to medical and biological constraints
This lecture was focussed on the influence of random errors of different origin on the process of clinical decision making and laboratory management, taking into account the intra-individual biological variation. Several worked-out examples taken from literature (Fraser et al. Clin Chem 1990; 36: 1625-1628) were demonstrated. Included were cases of hyperparathyroidism, diabetes management by analysis of HbA1c and the analytical goals to be used for cholesterol analysis.