Upsala J Med Sci 95: 275–277, 1990

Plans for Obtaining a "NORDIC LIST" of Specifications

Carl-Henric de Verdier

Department of Clinical Chemistry, University of Uppsala, Uppsala, Sweden

In several countries work is going on in order to establish numerical values for quality specifications for clinical chemical (and haematological) analyses and investigations. In some countries this work is connected with proficiency testing organized by a controlling authority or a professional society as proficiency test must have specified rules for approval (2,4). In the Nordic countries several different programs for external quality assurance have been running (1). What is acceptable quality is, however, left to the head of the laboratory - as a head physician - to decide. New trends within laboratory medicine with more decentralized laboratories, more economical responsibility delegated to the laboratory and more competition between laboratories call for guidelines for quality specifications. This new attitude has also influenced the new Scandinavian Recommendations for Quality Control and Quality Assurance (5) as indicated in the third chapter of this report.

CONSIDERATIONS IN THE PREPARATION OF A NORDIC LIST

The Board of the Nordic Clinical Chemistry project (NORDKEM) has earlier and in the preliminary work for this project expressed its wish to let the professionals of the clinical laboratories, the doctors in primary care and the clinicians prepare a list of quality specifications.

A lot of questions must be ventilated in connection with the preparation of such a list. Table 1 presents a checklist which might be of value when preparing a list of quality specifications for the Nordic countries.

Table 1.

Checklist for the preparation of a Nordic list of quality specifications for clinical chemical laboratories.

The list of quality specifications must be structured around:

* **System--Component**, Testing/evaluation of different methods/investigations
* **Clinical situations** (concentration ranges)
* **Type of quality specification:** 1) Clinical Needs 2) Clinical Quality Specifications 3) Analytical quality goals (TE_a) and in the local laboratory 4) Laboratory Quality Specifications (see more in chapter 3, Fig. 1).
* **The expression of the quality specifications.** The 95 % probability range within which results of investigations should be localized.

  Starting from the <u>analytical</u> side that means e g

  $$TE_a = \text{bias} + SE_c \cdot s + [\text{component of } RE_c]$$

  (where the abbreviations have the following meaning: TE_a total allowable error = AAE, SE_c critical systematic error expressed as a factor times s, RE_c critical random error and s inherent random imprecision).

  Starting from the side of <u>clinical needs</u> that means e g

  $$\Delta > \sqrt{2} \cdot 1.65 \, (CV_P^2 + CV_A^2 + CV_B^2)^{\frac{1}{2}} \qquad (3)$$

  (where CV means coefficient of variation, B within-individual, P pre-analytical and A analytical sources of variation; Δ is an significant difference in serial results during a monitoring situation). Also other ways of calculating clinical needs and clinical quality specifications - using e g decision analysis or biomedical models (see chapter 3) - are of interest.
* In accordance with "International Vocabulary of Basic and General Terms in Metrology" (**VIM**) (6) and other relevant standards and guidelines.
* Complementation with **matrix effects (specified)** and **unspecific reactions (specified).** Existing guidelines for the measurement of such effects should be improved.

* Presentation of the list in a standardized form and possibly also as a data base. Which components should be included? Primarily the 40 most frequently analyzed components and some more analytes of principal interest. Only investigations that have a significant role in the clinical process.
* Evaluation of the list with quality specifications? Submission to the Scand J Clin Lab Invest and to the Newsletters of the national societies of clinical chemistry in Scandinavia and of the Nordic Society of Clinical Chemistry? Sending draft for consideration to the national Societies for Clinical Chemistry in the Nordic countries? Discussion at the next Nordic congress in 1992?

REFERENCES

1. In de Verdier C-H, Aronsson T, Nyberg A: (eds): Quality Control in Clinical Chemistry - Efforts to Find an Efficient Strategy, Helsinki, NORDKEM, 1984, p 1-241

2. Ehrmeyer SS, Laessig RH. Use of alternative rules (other than the 1 2s) for evaluating interlaboratory performance data. Clin Chem (1988);34:250-256.

3. Fraser CG, Hyltoft Petersen P, Larsen ML. Setting analytical goals for random analytical error in specific monitoring situations. Clin Chem (1990);36:1625-1628.

4. Laessig RH, Ehrmeyer SS. Use of computer modelling to predict magnitude of interlaboratory error tolerated by proposed CDC interlaboratory proficiency testing performance criteria. Clin Chem (1988);34:1849-1852.

5. Scandinavian Society for Clinical Chemistry. General Scandinavian Recommendation on Quality Control an Quality Assurance in Clinical Chemistry. Scand J Clin Lab Invest (1990);50:225-227.

6. Zender R. Measurements in Biological Systems. Metrological Principles and Terminology. Scand J Clin Lab Invest (1989);49 suppl 193:3-10.

Correspondence:
Professor Carl-Henric de Verdier
Department of Clinical Chemistry, Uppsala University
Postal address: University Hospital
S-751 85 Uppsala, Sweden.