Upsala J Med Sci 95: 305–307, 1990

Glossary of Terms

Many of the terms are defined according to an earlier reference (1).

Value of quantity

value of a quantity. The expression of a quantity in terms of a number and an appropriate unit of measurement (2).

numerical value (of a quantity). The number in the value of a quantity (2).

true value of a quantity. Is the value which characterizes a quantity perfectly defined, in the conditions which exist when that quantity is considered (2).

conventional true value (of a quantity). A value of a quantity which , for a given purpose, may be substituted for the true value (2).

Analytical Performance Characteristics

imprecision of the measurement procedure (s). The inherent imprecision of the measurement procedure is estimated from replication studies. By analysis of variance techniques the within-run and the between-run components of variation may be estimated; s_w and s_b denote the corresponding standard deviations, and s_t stands for the total standard deviation of the measurement procedure (1).

bias. The average systematic error of the measurement procedure, as estimated by a comparison of method, e. g. comparison of patient values between the test method and a definitive method or a reference method (1). Bias has obtained the meaning of the difference between the conventional true value and the expected value of the local laboratory.

total error (TE)(4) = absolute error of measurement (3). TE is the "sum" of the systematic error and a component of the random error.

systematic shift (SE). A systematic shift is the systematic error that occurs in the measurement procedure. It is expressed direct in units or as a factor times the inherent imprecision of the measurement procedure (1).

increase in random error (RE). An increase in the inherent random error of the measuremnt procedure is expressed as a factor by which the inherent imprecision is multiplied to give the imprecision of the measurement procedure under the influence of an analytical disturbance (1).

frequency of errors. Refers to the incidence rate of analytical disturbances, which occur in addition to the inherent errors. It is here expressed in percent of runs having analytical disturbances (1).

Analytical Quality Specifications

allowable analytical error (AAE) = total allowable error (TE_a) = Analytical Quality Goal. AAE is a 95 % limit of error, i. e. 19 out of 20 test results should have errors less than this amount. AAE is a 1.96·s limit of error, thus a recommended allowable s must be multiplied by 1.96 to express the error specification in the form of AAE (1).

critical systematic shift (SE_c). A term in the equation:

$$AAE = \text{bias} + SE_c \cdot s + (\text{component of } RE_c)$$

which must be small enough so that the numerical value of AAE is not exceeded.

critical increase in random error (RE_c). See above.

laboratory quality specification = analytical quality specification of the laboratory. This is the specification given by the laboratory to its customers. If not otherwise stated it means that 95 % of the results delivered should be located within the specification limits.

Quality Specifications including both analytical and non-analytical components

clinical needs. This term is preferred to the term medical needs. It generally includes analytical limits but may also include non-analytical characteristics as turnaround time.

clinical quality specifications. This term includes components of variation as preanalytical and analytical errors. It also assumes standardized treatment and care of the patient.

Non-analytical Quality Specifications

Turnaround time (t_{max})

Utilization of analyses (investigations)

Result interpretation

Supply of available analyses and other services

Cost of analyses

Laboratory Quality Management

≈ good laboratory practice (GLP)

Quality laboratory practices

Quality control

Quality assurance

Internal quality assurance

External quality assurance

REFERENCES

1. Westgard J O, Groth T, de Verdier C-H. Principles for developing improved quality control procedures. In: de Verdier C-H, Aronsson T, Nyberg A, eds. Quality control in clinical chemistry - Efforts to find an efficient strategy. Scand J Clin Lab Invest 1984;44 Suppl 172: 19-41.

2. Zender R.Measurements in biological systems. Metrological principles and terminology. In: Kallner A, Bangham D, Moss D, eds. Improvment of comparability and compatibility of laboratory assay results in life sciences. IFCC Master Discussion, 1. Bergmeyer Conference 1988. Scand J Clin Lab Invest 1989;49 Suppl 193: 3-10.

3. Dybkaer R, Martin D V, Rowan R M eds. Good Practice in decentralized analytical clinical measurement. Scand J Clin Lab invest 1991;51 Suppl. In press.

4. Westgard, J. O., Barry, P. L. Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes. p. 1-231. AACC Press. Washington, DC 1986.