Original Article

Evaluation of the total analytical error in the flame photometry method

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ABSTRACT

Background and Objectives: For total analytical error, imprecision (SD) and bias, performance goals for laboratory tests have most often been developed. A total analytical error goal requires that the combination of errors from all sources (random and systematic errors) be within some acceptable limit.

Materials and Methods: Fifty vials of sodium and potassium standards (Sandos Company) were chosen. Then, the concentration of sodium and potassium in these standards were daily measured using flame photometry for 50 days at biochemistry laboratory (Ghaem hospital, Mashhad). Thereafter, the mean, standard deviation, random and systematic analytical errors, and total analytical error from these values were calculated.

Results: The systematic and random analytical errors for standard specimens using flame photometry method for sodium and potassium are $\mu\epsilon$ (Na) = 0.36, $\mu\epsilon$ (k) = 0.012, $\sigma\epsilon$ (Na) = 0.69 and $\sigma\epsilon$ (k) = 0.11 respectively. Meanwhile, the total analytical error of flame photometry for measurement of sodium and potassium was 1.74 mM/l and 0.232 mM/l respectively.

Conclusion: In this study, it was found out that flame photometry system has good precision and accuracy and its total analytical error for measuring of sodium and potassium are within the acceptable range.

Key words: Sodium, Potassium, Flame photometry, Total analytical error

Introduction

Performance goals for laboratory tests have been argued for many years with perhaps the best known starting point being Tonks (1). A collection of ideas on performance goal strategies has been published in the proceedings of a related conference (2). Many of these efforts to develop goals have produced valuable insights in understanding quality requirement for laboratory tests. Performance goals for laboratory testing have most often been developed for total analytical error, imprecision (SD), and bias. A total analytical error goal

requires that the combination of errors from all sources be within some acceptable limit. Various approaches have been recommended for defining and estimating the analytical performance of analyzer systems in clinical chemistry. An appropriate approach should describe the magnitude and likelihood of errors in measurements of standard specimens (3). Systematic error is a measure of the agreement between the measured quantity and the true value. This aspect of accuracy is usually estimated by a comparison of experimental methods in which the clinical specimens are assayed by the method under evaluation and by a method whose accuracy has been established and validated. The terms inaccuracy and bias are often used to emphasize the lack of agreement among methods that are being compared (3). The distribution of values around a central value represents random error. Total analytical error considers all types of errors, both random and systematic ones. The total error demonstrates how large the error can be when the random and systematic components occur in the same direction (3).

On this basis, valid data are essential for making medical decisions. The two most important concepts used in judging analytical performance are analytical accuracy and analytical precision (3). The College of American pathologists has combined the assessment of accuracy and precision into the concept of total error for many assays, which is the sum of bias and imprecision. This approach has the advantage of providing clinicians with only a single term for total analytical error and has been suggested as more useful in medical practice.

Flame emission photometry is most commonly used for the quantitative measurement of sodium and potassium in body fluid. The total analytical error of a system at a particular concentration is defined as the maximum absolute error for 95% of measurements on standard specimens. In this study, it was tried to determine the total analytical error of the flame emission photometry system for sodium and potassium measurement.

Materials and methods

According to the recommendation of the National Committee for clinical laboratory standards (NCCLS), a minimum of 40 specimens analyzed over a minimum of 5 days with suggested distributions of specimens over the clinically meaningful range for many analyses. In this study, 50 vials of sodium and potassium standards (Sandos Company) were selected. The electrolytes were measured using ion selective electrode (reference method). True concentration of sodium and potassium in these vials was 140 mM/l and 5 mM/l respectively. The concentration of sodium and potassium in these standards was also daily measured using flame photometry (SEAC-FP20) for 50 days at Biochemistry Laboratory (Ghaem hospital, Mashhad). Then, daily values were recorded and after the omission of outlier counts (4), the mean and standard deviation after 50 days was calculated. Thereafter, random and systematic analytical errors and total analytical error were calculated.

Results

It was supposed that values in this study follow a Gaussian distribution. The mean value of sodium and potassium measurement using flame photometry was 140.36 and 5.012 respectively. We subtract the true value of sodium and potassium (140 and 5 mM/l) from each of these values and in this way, the probability distribution of the analytical measurement errors $\varepsilon 1 = X_{i(Na)} - 140$ for sodium and $\varepsilon 2 = X_{i(k)} - 5$, which is Gaussian with a mean of $\mu\varepsilon_{(Na)} = 0.36$ for sodium, $\mu\varepsilon_{(K)} = 0.012$ for potassium and standard deviation $\sigma\varepsilon = 0.69$ for sodium and $\sigma\varepsilon = 0.11$ for potassium was obtained. This probability distribution contains all the information about the magnitude and likelihood of the analytical errors of measurements of these specimens, with a true concentration of 140 mM/l for sodium and 5 mM/l for potassium. The systematic analytical error of measurements on standard specimens with a true concentration of 140 mM/l for sodium and 5 mM/l for potassium by flame photometry method

were $\mu\varepsilon_{(Na)}$=0.36 and $\mu\varepsilon_{(k)}$=0.012 for sodium and potassium respectively. The random analytical error of measurement on standard specimens with a true concentration of 140 mM/l for sodium and 5 mM/l for potassium by flame photometry method for sodium and potassium wre $\sigma\varepsilon_{(Na)}$=0.69 and $\sigma\varepsilon_{(k)}$=0.11 respectively.

According to data, it was found out that the central 95% of the distribution of measurement errors was $0.36 \pm 2(0.69)$ mM/l for sodium and $0.12 \pm 2(0.11)$ mM/l for potassium (Figure 1). Thus, the total analytical errors of flame photometry for measurement of sodium and potassium were 1.74 and 0.232 mM/l respectively.
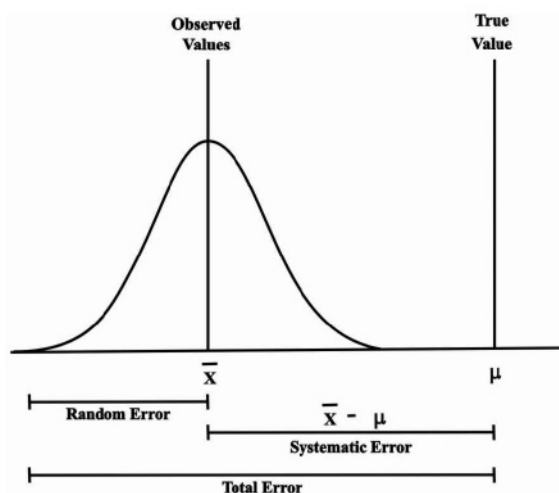
Figure 1: The total analytical error concept of accuracy

Discussion

Several sources of information can be used to establish limits for total analytical error. These include professional judgment based on experience with regard to the medical use of laboratory tests, surveys of clinicians, the inter-individual biological variation of the analysis, limits based on state-of-the-art performance, and limits calculated from fractions of the reference interval of the analysis. Several guidelines have been published in the literature. Barnett was one of the first investigators in the field and published the results of his survey of physicians in the mid 1960 (5). He has continued his efforts by updating

some goals and by adding other working goals (6). These and most other recommendations present only precision goals of allowable SD and must be converted to total error goals. Fraser (7) has advocated the concept that no analytical bias is allowable; he has also championed the view that maximum goals should be derived from inter-individual biological variation data. Recently, regulations (8) have been issued by the Health Care Finance Administration to implement the Clinical Laboratory Improvement Amendment of 1988 (CLIA 88). One of the most striking impacts on these CLIA regulations on the process of method selection and evaluation is their establishment of fixed limits for assessing method and laboratory performance for specific analytes as regulated by proficiency testing. Given the legal and punitive ramifications of the CLIA regulations, these limits have now become de facto, the maximum limits for allowable error. Consequently, in practice, the total allowable error for a given analytical method must be less than the respective CLIA fixed limits for the analyte in question. Barnett and Westgard have suggested that method coefficient of variation not exceed one fourth of CLIA limits so as to include possibility of unstable method performance and the utilization of cost-effective quality control procedures (9).

According to CLIA 88 recommendations, maximum total error (fixed limit goal) for sodium and potassium in decision level of 140 mM/l (sodium) and 5 mM/l (potassium) are 4 mM/l and 0.5 mM/l respectively, and maximum standard deviation (precision goals) for sodium and potassium in decision level of 140 mM/l (for sodium) and 5 mM/l (for potassium) are1 mM/l and 0.13 mM/l respectively.

Conclusion

Flame photometry system have good precision and accuracy and its total analytical error for measuring of sodium and potassium are acceptable. It is also recommended that each biochemistry laboratory evaluates its method and

calculation of total analytical error for analytes measurement. It is also an endeavor to calculate total analytical error in every method.

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