The relationship between measurement uncertainty and reporting interval

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ABSTRACT

Background

Measurement uncertainty (MU) estimates are used by clinicians in result interpretation for diagnosis and monitoring and by laboratories in assessing assay fitness for use and analytical troubleshooting. However MU is not routinely used to assess the appropriateness of the analyte reporting interval. We describe the relationship between MU and the analyte reporting interval.

Methods and Results

The Reporting Interval R is the smallest unit of measurement chosen for clinical reporting. When choosing the appropriate value for R, it is necessary that the reference change values and expanded MU values can be meaningfully calculated. Expanded MU provides the tighter criterion for defining an upper limit for R. This limit can be determined as $R \leq k. SDa / 1.9$ where SDA is the analytical standard deviation and k is the coverage factor (usually 2)

Conclusion

Using MU estimates to determine the reporting interval for quantitative laboratory results ensures reporting practices match local analytical performance and recognises the inherent error of the measurement process.

Introduction

The release and adoption of the latest 2012 revision of ISO 15189 has seen greater attention paid by many laboratories to Measurement Uncertainty (MU) and its estimation.[1] The previous version required laboratories to determine the uncertainty of results, where relevant and possible, allowing for individual interpretation and implementation of this requirement. Under the 2012 standard, laboratories "shall determine measurement uncertainty for each measurement procedure in the examination phases used to report measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty".[1] MU estimation has thus become a required procedure for ISO 15189 accredited laboratories and is an increasingly common practice. MU estimates are used by clinicians in result interpretation for diagnosis and monitoring and by laboratories in assessing assay fitness for use and analytical troubleshooting.

In the Foreword to the CLSI document "Expression of Measurement of Uncertainty in Laboratory Medicine; Approved Guideline" it states that "Uncertainty estimates … can be important in defining the measuring interval of measurement systems to ensure that the quality of results issued meets clinical requirements".[2] However MU is not routinely used to assess the appropriateness of the analyte reporting interval. In this brief note we describe the relationship between MU and the analyte reporting interval.

Methods and Results

The Expanded Uncertainty, U, defines the interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.[3] The true value of the measurand lies within the confidence interval given by the stated uncertainty and centred on the reported value with the stated level of confidence.[4]

$$U = k \,.\, u_c(y)$$

Where $u_c(y)$ is the combined standard uncertainty of measurand y and k is the coverage factor, which is the number of standard deviations required to include a stated proportion of values. If the laboratory uses a Type B method of determining U, then the combined standard uncertainty can be determined from the standard deviation of the assay, usually calculated using the analytical standard deviation of internal quality control samples (SDa).

This uncertainty can be communicated to users by reporting laboratory results together with the appropriate U as $x \pm U$ where x is the measured concentration of measurand y and U is calculated using an agreed coverage factor (usually 2).[5]

$$U = k \,.\, SDa$$

The Reporting Interval R is the smallest unit of measurement chosen for clinical reporting. When choosing the appropriate value for R, it is necessary that the following parameters can be meaningfully calculated:

a) Reference change value RCV

$$RCV = 2 . \sqrt{2} . SDa$$

b) Expanded measurement uncertainty U

$$U = k . SDa \text{ (where } k = 2)$$

Of these two, the latter, expanded measurement uncertainty U provides the tighter criterion for defining R. The importance of U in determining R is illustrated by considering the reporting of MU when U is less than R. This would require rounding up or down of U at the final reporting step. Rounding up will communicate inflated values of U to users, causing potential false negatives in diagnosis and result monitoring. Rounding down will produce values of zero, which are clinically and scientifically absurd.

Thus U provides an upper limit for R. An additional factor of 1.9 is required to account for potential information loss due to rounding.[6]

$$R \leq U / 1.9 \quad or$$

$$R \leq k. SDa / 1.9$$

If k =2, then R should be approximately less than or equal to SDa. SDa itself is an ideal choice for R as it allows simple calculation of MU (2 x R) and RCV (3 x R). So using the example of a serum sodium measurement of 130 mmol/L with an SDa of 1 mmol/L, the MU of 2 mmol/L and RCV of 3 mmol/L are easily calculated.

Discussion

It should be noted that our definition of R refers to the reporting rather than the measuring phase of the analytical process. The measuring unit size used in the measuring phase must be smaller than the analytical standard deviation to allow accurate calculation of the standard deviation itself. Thus in the example of serum sodium measurement used above, given SDa of 1 mmol/L, we would recommend measuring in 0.1 mmol/L increments but reporting using an R of 1 mmol/L. We appreciate that in practice SDa rarely matches the decile (e.g. 0.01, 0.1, 1) increments used in most laboratory information system so the closest decile should be selected.[6] When in doubt, the larger decile should be chosen over the smaller (e.g. 1 rather than 0.1) given that the use of SDa as the sole contributor to U undoubtably excludes other real sources of uncertainty, leading to a probable underestimate of U and hence an of the true value of R.

We have described a novel approach to the determination of the reporting interval for an assay, one that is determined by the uncertainty of the measurement process and therefore provides useful information to the clinician about the interpretation of the result. With widespread routine calculation of MU by clinical laboratories, this information is readily available and ensures that the local reporting practice matches the local analytical performance of the assay. We would advocate that laboratories use the MU process to assess the reporting intervals of the results and ensure that they are appropriate given the inherent error of the measurement process.

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