Automated hematology analyzers have evolved to improve workflow and precision. Precision, defined as the closeness of agreement between replicate measurements, on the same sample under specified conditions, is expressed quantitatively in terms of imprecision either as the Standard Deviation (SD) or the coefficient of variation (CV). Results from the Institute for Quality Management in Healthcare (IQMH) patterns-of-practice survey demonstrated considerable variation in precision goals reported by laboratories. A literature review provided limited guidance in setting precision goals for analytical performance of hematology analyzers. Precision is an important component of a laboratory’s internal quality control ( IOC) plan to ensure the reliability of the results provided by the laboratory. The IQMH Hematology Scientific Committee developed precision goals to provide guidance for laboratories in setting appropriate precision limits for routine hematology parameters.

The following process was used in the determination of the precision goals:

1. A search was performed of current published literature for setting precision goals and the following data was collected for review:
   - Published precision goals including the Desirable Biological Variation Database specifications published by Ricos C, et al. (Table 1)
   - Precisions goals from IQMH Hematology Scientific Committee members’ laboratories (Table 1)
   - Precision goals reported in the IQMH patterns-of-practice survey of 184 hematology laboratories (Table 1)
   - Manufacturers’ precision claims.
   - CV (%) and SD values obtained in a recent IQMH proficiency testing survey grouped by hematology instruments from 201 CBC results (Table 2 and 3).

2. Data collected from the steps were compared with the IQMH Allowable Performance Limits (APLs).
   The IQMH APLs represent the total allowable error (TEa) that is a combination of measurement bias and imprecision. The imprecision component of total error is characterized by CV or standard deviation multiplied by a z-value. Z-value is a standard score that represents the number of standard deviations from the mean in a Gaussian distribution. For example, when a z-score of three is used, the probability of observations falling into the mean ± 3 standard deviation range is 99.7%. The IQMH APLs with a z-value of three were used in this study to set the precision goals.

3. Medical decision points and clinical needs were also considered by the Scientific Committee.

Conclusion

Precision goals are an important consideration when selecting and validating new instruments. Setting appropriate precision limits are useful for monitoring QC and for ongoing analytical performance of established methods. Our results showed that setting a precision equivalent to one-third of the APLs could be useful for laboratories. If laboratories are able to achieve the IQMH precision goals they can verify analytical performance and reasonably ensure the likelihood of passing the proficiency testing surveys.