Q-Probes study of Replicate Specimens at the Clinical Laboratory, The Aga Khan University Hospital, Karachi

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Abstract

Objective: The aim of this Q-probes study was to evaluate the precision of replicate specimens.
Methods: This Q-probes study done at the Clinical Laboratory, The Aga Khan University Hospital Karachi is about routine chemistry analytes because of their importance in critical care patients. The analytes data was collected for six months from April to September 2002.There were total 358 samples, which were given for reanalysis during this period under the constant working conditions. After analysis, results of both the runs on different days, were compared to determine the percent difference between the results. After calculating the percent difference, the results were either accepted or rejected on the basis of guidelines set by CLIA 88(Clinical Laboratories Improvement Amendment 1988).
Results: Among 358 results, 5 were rejected according to the criteria selected. All of these results were then subjected to statistical analysis for calculating statistical significance. As our Null hypothesis was that the prevalence of rejected results were more than 2% with an acceptable limit of less than or equal to 2%. We failed to accept the Null hypothesis that means that it did not exceed the acceptable limits (p-value= 0.962930) with the Confidence Interval range of 0.2 -2.6 where Upper Confidence Interval is still less than 5% for a p-value of 0.05. The rejection of null hypothesis favors high precision between the two sets of results in our studied population.
Conclusion: It is concluded that Q-Probes study of replicate specimens at the Clinical Laboratory at The Aga Khan University Hospital is within the acceptable limits. These figures show that a high quality precision is maintained among the observed specimens. This is an ongoing exercise and studies like these should be a continuous process to maintain and enhance the quality of Laboratory results (JPMA 54:52;2004).

Introduction

The explosion in technology is providing the clinical laboratory professionals a renewed chance to become a productive member of health care providers and changing the concepts regarding chemical pathologist, even in Pakistan. 1 The quality of clinical laboratory testing is important and laboratory replicate sample analysis is used to determine reproducibility or consistency in methods. 2 This Q-probes study has been designed to evaluate precision of replicate specimens as measured by the percent difference of previous day results. Replicate sample analysis is used to determine reproducibility or consistency in methods. Precision has been examined through the repetitive analysis of a series of blind QC materials. 3 Efforts to improve the quality of laboratory testing have been impressive with the variability of analytical performance. It is now less than one twentieth of what it was more than 40 years ago.4 Recent regulatory

and accrediting guidelines now require that, laboratory physicians begin to change their improvement efforts from analytical step to other steps of total testing processes. 5-7 Q-probes, a quality improvement program of The college of American Pathologist (CAP), which has provided almost 100 studies for large numbers of participants in Pathology and laboratory medicine between 1989 and 1999.8

Material and Methods

This is a prospective study with the approach enhance quality of laboratory results to improve patient care. The approach was deployed to identify problems, develop corrective interventions and to evaluate their effectiveness in further studies. This method of quality control focuses on replicate specimen analysis perform on routine basis for monitoring and improving performance.
Our laboratory technologists maintain a record daily replicate specimen analysis. This Q-probes study about routine chemistry analytes because of their importance in critical care patients. The parameters included in our replicate study were blood urea nitrogen creatinine, glucose, sodium and potassium. Regarding specimen storage policy, we used follow recommended protocols, i.e., tubes containing se are closed at all times except at the time of analysis. These tubes are kept in the vertical stopper up position. The se is physically separated from contact with cells as soon possible. After separating the serum, we refrigerate them seven days and this is the policy for all the specimens included in our replicate study. We have done the study our section in which we have looked that these specimens can be refrigerated for a long time and even the glucose sample can be put at the room temperature for two days without any effect on results. The laboratory physician randomly selects specimens from previous day, checks the record of results issued to patients. After obtaining the results from previous day, the Laboratory physician assigns the same sample for analysis (with the same analytes to measure) to the slime bench with anonymous labeling to avoid any bias. This specimen is re-run for the same analytes under similar conditions. The bench technologists are unaware of the previous day results. After analysis, results of both the runs on different days are compared to determine the percentage difference between the results. The analyte data was collected for 6 months from April -September 2002. There was a total of 358 samples analytes that were given for re-analysis during this period. On an average 3 specimens were given for individual analysis each day during the official working days. % Difference was calculated for each pair of results. (% Difference of sample = x-y/z ' 100; where x is result of pervious day, y is re-run result and z = x+y/2). After calculating the % difference, the results were either accepted or rejected on the basis of guidelines set by CLIA, 1988 (Clinical Laboratories Improvement Amendment 1988). Every year, CLIA 1988 guidelines are revised by the center of Disease Control and Prevention which are published in Federal register like for example this year they have added HIPPA compliance Act in 2002.9

Results

Among 358 results, 5 were rejected according to the criteria selected. The results rejected included I Potassium, 2 Sodium and 2 Creatinine. All of these were then subjected to

statistical analysis for calculating significance. As our Null hypothesis was that the prevalence for the proportion of rejected results was more than 2%. (An acceptable limit is less then or equal to 2%). We fail to accept the Null hypothesis that means that it did not exceed the acceptable limit (p-value = 0.962930) with the Confidence Interval range of 0.2 -2.6 where Upper Confidence Interval is still less then 5% for a p-value of 0.05 which is within acceptable limits.

Discussion

Earlier in Q-probes quality monitoring experience, it has been recognized that quality is not a static phenomena. 10 Our study describes an approach to quality improvement for replicate sample analysis, that permits a continuous process monitoring and performance improvement. The QC procedures adopted from those performed in centralized laboratory testing (e.g. imprecision, linearity and interpreter variability) as in our lab still needs further evaluation to improve quality control. Continuous quality improvement requires e.ffective data management. 11 We have used the statistical procedures recommended by the National committee for clinical laboratory standards (NCCLS) EP-9A. 12 Moreover the formula for calculating the percent difference is by dividing the difference between the two results by their average as follows: (Where the "x" is the previous day result, "y" is rerun result while13. In our study the results are accepted or rejected on the basis of recommendations defined by American Medical Association and as such includes tests classified as moderately complex under the Clinical Laboratory Improvement Amendments of 1988 (CLIA' 88). Testing personnel quality control, proficiency testing and other operation facets must conform to accreditations regulations and rules applicable under local state laws l4 that unfortunately do not exist in our part of the world. The fact that the strict performance improvement program of CAP (college of American Pathologist) for routine chemistry analytes is required independently form other laboratory tests emphasizes the importance of routine chemistry results in critical care patients, as erroneous chemistry reports would not only lead to incorrect clinical diagnosis but also would affect management of critical care patients. Biological availability of the concentration of different analytes were evaluated at a conference on analytical goals held in Aspen, Colorado, in 1976. For the analytes included in our study, CLIA 1988 guidelines recommended that analytical goals should be at least as stringent as the current performance of laboratories. That is why the samples rejected in our replicate study were showing more percent variation than the acceptable range while the samples accepted in our study were within the recommended range of percent variation. While doing this study, we accounted for the inherent variability and the substance interference during the analysis of parameters. In addition to routine chemistry and other enzyme assays, proficiency testing provided by CAP surveys, a model of blind QC (quality control) as part of Extensive External Quality control Program has also been instituted in our laboratory for diagnostic standardization of clinical chemistry. Re-examination of randomly selected samples by different technologists and by instruments is periodically performed. The timely maintenance of equipments, proper training of staff, regular quality assurance meeting with technical staff and the strict vigilance are the key reasons of these good results in our laboratory.

Recommendations

A follow up study of similar nature with statistical analysis is required to improve above hypothesis. This exercise should be an integral part of Internal Quality Assurance programs all labs on continuous basis. A broad base lab data should be maintained with an effective External Quality Assurance Program on National basis.

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