METHOD VALIDATION AND COMPARISON STUDY ON THE DETERMINATION OF BLOOD LIPID PROFILE AND BLOOD GLUCOSE USING CLINICAL CHEMISTRY ANALYZER AND POINT-OF-CARE TEST (POCT)

Rosemarie J. Dumag, Joan M. Castro, Marites V. Alibayan, Maribeth S. Castillo, Joselita Rosario C. Ulanday, Zaril L. Labrague, Leodegaria A. Globio, Zoilo B. Villanueva

Background:
Lipids and glucose play important roles in the energy metabolism of the body. However, abnormal levels of cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides may cause heart-related diseases. Furthermore, in order to function normally, the level of glucose should be maintained. Nowadays, the development of self-monitoring point-of-care apparatus has been acceptable to use because of its convenience and speed.

Objective:
The study aimed to validate the capability of the FNRI Service Laboratory to analyze the blood lipid profile and blood glucose using the clinical chemistry analyzer and POCT.

Materials and Methods:
About 5 mL blood sample were extracted from 79 adult participants. Prior to the analysis of samples, method performance characteristics of the Cobas Integra 400 plus were measured and evaluated using PreciControl Clinical Chemistry (PCCC). Whole blood and serum samples were analyzed using POCT and clinical chemistry analyzer, respectively.

Results and Findings:
Measuring ranges and lower limits of measurement were determined by the manufacturer and were included in the Cobas substrates brochure. Using PCCC1 and PCCC2 for the repeatability and intermediate precision, the method is said to be precise based on the acceptable HorRat value of ≤1.3. In addition, POC controls were analyzed before and after analysis and were found to be within the acceptable control range. The two methods of analysis used were conventional and POCT which gave a statistically different result (P-value ≤ 0.05) for the lipid profile except for glucose with P-value > 0.05. Moreover, the results of the Bland-Altman Plot showed a non-agreement of the results of the analysis.

Conclusion and Recommendation:
Variability of the results can be accounted for the lack of robustness of the POC meter during continuous analysis even in a small sample size. To preserve the integrity of the serum samples, analysis should be conducted in a shorter period of time.