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Accuracy and Precision of Blood Glucose Level Examination Using the POCT Method on a New Device with an Old Device Agains the GOD-PAP Method

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ABSTRACT
Blood glucose testing using the POCT method is currently often used because it uses capillary blood samples with a small volume. Quality control of POCT equipment is needed to see the accuracy value and precision value so that the feasibility of the method used is known. The accuracy value is a precise measurement in accordance with the correct value while the precision value is the accuracy of the examination results when replicated with the same sample. This study aims to determine the accuracy and precision of blood glucose testing using the POCT method on new devices and old devices against the GOD-PAP method. This study used analytic observational method with cross sectional approach. This research was conducted in the clinical chemistry laboratory of the Surabaya kemenkes polytechnic and the GOD-PAP examination at the Surabaya health laboratory. It was carried out on November, 2023-February, 2024. Using 30 test materials from Surabaya poltekkes kemenkes students. The results of the study obtained the accuracy value of the POCT method on the new device against the GOD-PAP method obtained an average percentage inaccuracy of 0.87%. While the POCT method on the old device obtained an average percentage of inaccuracy of -2.87%. The results of the precision value of blood glucose levels of the POCT method on the new device obtained an average KV of 3.71% and on the old POCT method obtained a KV of 8.52%. This conclusion is that the accuracy value of the POCT method on new device and old device is accurate because it is still in the range of 10%. While the precision value on the new device has high accuracy because it has an imprecision value that is lower than the maximum CV limit of blood glucose examination, which is 5%. The old device has lower precision because it has an imprecision value that is higher than the maximum CV limit of blood glucose examination.

Keywords: Accuracy, Precision, POCT method, Glucose, GOD-PAP method

INTRODUCTION
Blood glucose monitoring is an integral part of diabetes care, but has some limitations in terms of accuracy and precision (Barry H, 2009). POCT (Point of care testing) has gained importance in healthcare in recent decades (Ferreira et al., 2017). Accuracy and precision are used to verify or validate the method. Each investigation method produces different result data, but good precision does not necessarily guarantee that the data can be described as accurate. Even if an investigative method provides data of high precision or accuracy, this does not guarantee that it is of good precision. Moreover, it may also provide equally good precision and accuracy (Ulfiati et al., 2018). If the results of the data obtained are not good, A check can be carried out to find any irregularities in the pre-analytical, analytical and post-analytical. Monitoring quality indicators is an important part of quality assurance in the laboratory (Shaw et al., 2023). POCT can sometimes be misleading if the sources of error in the measurements are overlooked. There are a number of factors that can affect the

accuracy of blood glucose strips (Panda et al., 2021). The blood used in the POCT system is capillary blood, the biochemical content of which is in equilibrium with the mediastinal fluid (Mehdizadeh Torghadar et al., 2018). POCT device can be used for all types of samples (Kafesa et al., 2022).

The Centers for Medicare & Medicaid Services has questioned the accuracy of POCT glucose meters in critically ill patients (Pilackas et al., 2020), so research on accuracy and precision is needed.Research conducted by (Arini, 2021) for uric acid analysis, a bias value of 12.30% and a recovery percentage of 110.88%. The coefficient of variation of the POCT method was 3.50%, and the coefficient of variation of the enzymatic colorimetric uric acid method was 5.37%. In previous studies using POCT and uricase enzymatic colorimetric uric acid parameters, the authors were interested in conducting further studies using glucose parameters. Point-of-care testing (POCT) is defined as a type of laboratory testing that is performed near the patient, as opposed to laboratory testing in the main hospital laboratory (Mukunya fridah muthoni, 2018). It was in this context that this study was carried out, examining blood glucose parameters, as diabetes mellitus is its complications have become a worldwide problem that negatively affects human health and even leads to death (Zhang et al., 2021). Worldwide, up to 20% of hospital patients suffer from diabetes mellitus (Olsen et al., 2024). Currently, blood sugar checks in hospitals are carried out using POCT, which can produce quick results (Umpierrez, 2019).

Diabetics' blood sugar levels rise and fall according to their medication, diet and physical activity. Glucose is the most abundant carbohydrate in the bloodstream, and blood glucose is the most commonly performed analysis in clinical laboratories (Swift, 2023). As a result, the POCT can be used to monitor the patient's state of health to avoid a sudden drop in blood sugar levels. The point-of-care blood glucose testing (POCT) system is important for decision-making in patients with suspected hypoglycemia (Feng-fei Li, Bing-yin shi, Min Niu, 2018). Diabetes guidelines recommend performing capillary POCT tests at the bedside before meals to assessing blood glucose control and adjusting insulin therapy in hospital (Umpierrez, 2019). POCT blood glucose measurement enables a graphical-visual comparison of glucose control (Ahmed et al., 2020).

Point-of-care tests (POCT) are increasingly being used in primary care (Smits et al., 2022). Based on the above description of the problem, the POCT method is still widely used in laboratories, hospitals and by patients themselves to determine blood glucose levels in the body, as it is easy to use. This assertion is in line with data from studies conducted by (Konoralma et al., 2018), according to which an average of 1,846 blood glucose tests are requested every month in the RSU GMIM Pancaran Kasih laboratory in the city of Manado. For this reason, POCT blood glucose meters need to be properly set up or maintained, and perform a standard evaluation method, so that results are delivered error-free.

RESEARCH METHOD

This research uses analytic observational research with cross sectional method of observation. The time of the study was carried out in November 2023 - May 2024 in the laboratory of the Medical Laboratory Technology Department of the Surabaya Ministry of Health Polytechnic, and blood glucose levels were monitored in the Surabaya City Regional Health Laboratory. Capillary blood was used as test material, as many as 30 test materials for the POCT method on a new device with an old device, and venous blood test materials were tested for blood glucose using the GOD-PAP method to determine the true value. Precision test with venous blood test material on 3 test materials and repeated 10 times.

In this study, primary data obtained from blood glucose level testing using POCT on new devices with old devices and GOD-PAP method were used. Then the results of the examination were analyzed by dividing the accuracy value by the average value of the POCT method performed by the examination minus the average true value obtained from the GOD-PAP examination results, then divided by the average true value and multiplied by 100%. While the precision value is determined by determining the standard deviation (SD) of the replication. Then it can be expressed in the form of a coefficient of variation (CV) with units of percent.

RESULT AND DISCUSSION

This study was conducted with 30 test materials. The accuracy value was determined from the blood glucose measurement using the POCT method of the new device versus the GOD-PAP method, using the blood glucose measurement results of the POCT method of the new device for the measurement result and the blood glucose measurement of the GOD-PAP method for the correct value. The results of the calculation of the accuracy value of the blood glucose measurement of the POCT method on the new device compared to the GOD-PAP method are shown in Table 1 below.
Key Findings:

Table 1. Accuracy of blood glucose test using the POCT method on the new device compared to the GOD-PAP method

	Blood glucose levels (mg/dL)		% inaccuracy	%Recovery
	New device POCT	True Value		
Average	83,93	83,37	0,87	100,87

The new POCT device achieved an average inaccuracy value of 0.87 %. A positive result for the average inaccuracy value indicates a higher than true value. The accuracy value can also be expressed as a percentage of recovery. A good accuracy value is in the range of 80-110% (Putra & Wardhana, 2016). The percentage recovery result of the new POCT device was 100.51%. This shows that the new POCT device has good accuracy and has met the criteria of the specified limit. The accuracy value of the POCT method for testing blood glucose levels with the old device compared to the GOD-PAP method gave the results in Table 2 below.

Table 2. Accuracy of blood glucose test using the POCT method on the old device compared to the GOD-PAP method

	Blood Gkucose levels (mg/dL)		%inaccuracy	%Recovery
	Old device POCT	True Value		
Average	80,63	83,37	-2,87	97,13

The average inaccuracy value is -2.87 %. These negative results indicate that the results of the tests performed are below the true value. The percentage recovery results of the POCT method with the old device give a recovery percentage of 97.05 %. From this percentage, it can be seen that the POCT method on the old device has a good accuracy value, as it fulfills the criteria within the specified limits in the range of 80-110%.

The precision value of the POCT method on the new device was replicated ten times on 3 test materials. The results of the blood glucose precision of the POCT method on the new device are shown in Table 3 as follows.

Table 3. Precision of the blood glucose on the new POCT device

Test material code	Replication average	SD	%KV
P1	75,30	2,54	3,37%
P2	72,20	3,39	4,70%
P3	77,50	2,17	2,80%
Average	75,00	2,75	3,71%

Three test materials in the blood glucose test using the new POCT device gave an average standard deviation of 2.75 and an average coefficient of variation of 3.71%. The percentage of the impression of a good blood glucose measurement is less than 5%, expressed in the coefficient of variation (Siregar et al., 2018). The average coefficient of variation of the blood glucose test using the new POCT device is 3.71%, which means that it has a good precision value, as the coefficient of variation achieved is no more than 5%. However, the precision value of the old POCT method is shown in Table 4 below.

Table 4. Precision of the blood glucose test on an old POCT device

Test material code	Replication average	SD	%KV
P1	76,20	7,00	9,19%
P2	66,10	4,63	7,00%
P3	73,30	6,72	9,16%
Average	71,87	6,21	8,52%

The precision of the POCT on the old device showed an average standard deviation on 3 test materials of 6.21 and an average coefficient of variation on 3 test materials of 8.52%, which means that it has a low precision value compared to the POCT on the new device, which showed a coefficient of variation of 3.71%.

POCT enables rapid delivery of test results with the ability to provide a result quickly so that appropriate treatment can be initiated, leading to improved clinical or economic outcomes (Larkins & Thombare, 2023). Research by (Satyanarayan, 2019) The comparison of the POCT glucose meter with the GOD-POD laboratory reference method produced acceptable results that can be very helpful in monitoring glucose concentrations. The blood glucose test results of the POCT on the new device and the old device show differences in the test results, but these are not significant, so they still have a good accuracy value compared to the correct value. Point-of-care blood glucose monitoring can be useful for screening diabetics and assessing blood glucose level (Andriankaja O.M. et al., 2019). According to research from (Yan et al., 2022), homemade human control material for POC glucose testing has good homogeneity, stability and applicability, which meets the requirements of quality control.Pre-analytical factors that may cause this difference in results are the lack of skills of medical staff in using the POCT devices at the point of care, patients who are tested unconscious are often difficult to test because the blood vessels are fragile or the fingers are wrinkled or bent, it may also occur because the new device has never been used and the batteries used are still sealed, while the old device has been used for blood glucose testing for more than two years with a frequency of two times per week. POCT blood glucose monitoring can be useful for screening diabetics and check blood glucose levels (Andriankaja O.M. et al., 2019).

Meanwhile, according to (Hartono, 2011). The device is calibrated at least once every 6 months. At the time of storage, the owner has not removed the battery and has not taken care to choose a storage location that is not exposed to sunlight. Analytical errors that can lead to different results are the way capillary blood is drawn or finger pricks where the alcohol swab is not allowed to dry so that it mixes with blood. Post-analytical errors that can occur include not writing down the results of the test after the swab has been removed so that the device switches off automatically and the test results are not recorded, which can lead to errors in recording the test results.

CONCLUSION AND RECOMMENDATION

The results of the research on the new POCT device showed an average inaccuracy value of 0.87% and the old device of -2.87%. The results of the percentage recovery of the POCT with the new device showed a value of 100.51%. The POCT old device value of 97.13%, which means that the accuracy is good as it is in the range of 80-110%. The precision value of the new POCT device reached an average of 3.71%, which means that it has a good precision value as the good coefficient of variation is not more than 5%. Meanwhile, the average coefficient of variation of the old POCT tool is 8.52%, which means that it has a low precision value compared with the POCT method of the new device.

Future researchers can use different brands of POCT device and add certain criteria for respondents, such as respondents with diabetes.

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