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Evaluation of hemoglobin testing using the Point-of-Care Testing (POCT) method in blood donor candidates at the Blood Transfusion Unit of the Indonesian Red Cross (IRC), Bekasi Regency

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ABSTRACT

Background: Hemoglobin (Hb) assessment is an essential screening test for prospective blood donors, as it helps safeguard both donor safety and the quality of transfusion components. Accurate testing also supports optimal outcomes for blood recipients. Point-of-care testing (POCT) is one of the hemoglobin measurement methods endorsed by the World Health Organization. This study aimed to evaluate the performance of an Hb meter used in donor screening and to compare Hb values obtained using POCT with those measured using a hematology analyzer as the reference method.

Methods: Precision testing of the Mission HemoPro device was conducted using three levels of control solutions. Accuracy evaluation was performed on 35 venous blood samples collected from donor candidates, measured using the POCT device, and compared with results from a hematology analyzer (Sysmex XN-350).

Results: Precision assessment across low, medium, and high control levels yielded coefficient of variation (CV) values of 0.53%, 0.61%, and 0.40%, respectively. Accuracy evaluation demonstrated a mean bias of 0.15 g/dL, corresponding to a 1.11% bias. Dependent T-test analysis produced $t = 2.061$ with $p = 0.047$ and a mean difference of 0.154 g/dL. Pearson correlation analysis showed a strong positive correlation between the two methods ($r = 0.949$).

Conclusion: Hb measurement using POCT exhibited a statistically significant difference compared with the reference method; however, the numerical discrepancy was small and clinically acceptable. The strong correlation observed indicates that POCT Hb testing is suitable for use in donor screening at blood transfusion units.

Keywords: Hemoglobin, POCT, Hematology Analyzer.
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INTRODUCTION

Hemoglobin (Hb) is a tetrameric erythrocyte protein that binds a non-protein moiety, specifically an iron–porphyrin complex known as heme. It serves two essential transport functions in humans: delivering oxygen to peripheral tissues and carrying carbon dioxide and protons from peripheral sites back to the respiratory organs. When Hb concentration within erythrocytes is reduced, the oxygen-carrying capacity of the blood declines, leading to tissue hypoxia and ultimately resulting in anemia.[1]

Hemoglobin (Hb) testing is a mandatory component of the pre-donation screening process for blood donors. This assessment is critical because a donor's Hb level typically decreases by approximately 1–1.5 g/dL after donating one unit of whole blood. Proper Hb evaluation before donation minimizes the risk of post-donation anemia and simultaneously ensures the quality of transfusion components, thereby contributing to better clinical outcomes for blood recipients.[2]

Accurate and precise Hb screening methods are central to maintaining blood quality and donor safety.[3] Hb measurement can be performed using various approaches, including Point-of-Care Testing (POCT) and hematology analyzers. An ideal Hb screening method for Blood Transfusion Units (BTU/UTD) should exhibit high sensitivity and specificity, with both low false-deferral and low false-acceptance rates. Although automated cell analyzers serve as the gold standard for Hb measurement, their operational time and workflow requirements limit their practicality for rapid donor selection.[4]

POCT is one of the Hb measurement techniques recommended by the World Health Organization. It utilizes a small volume of capillary blood and provides faster turnaround times.[3] The analytical principle commonly employed is spectrophotometry, in which the Hb meter emits light of a specific wavelength through a microcuvette. Part of the light is absorbed by hemoglobin, while the

remainder reaches the optical detector. By comparing the intensity of incident and transmitted light, the device calculates the corresponding Hb concentration.

A hematology analyzer, on the other hand, is an in-vitro diagnostic instrument routinely used in clinical laboratories for patient screening. It enables quantitative analysis, identification, and enumeration of blood and body fluid components, including red blood cells, white blood cells, platelets, and other cellular elements, using electrical impedance, laser light scattering, and fluorescence labelling.[5,6]

Based on those mentioned above, this study aims to evaluate the performance of the Hb meter used in donor screening and to compare POCT-based Hb measurements with those obtained from a hematology analyzer as the reference method.

METODS

The study was conducted in the quality testing laboratory of the Blood Transfusion Unit (BTU) of the Indonesian Red Cross (IRC), Bekasi Regency, in September 2024. All venous blood samples were processed according to established standard operating procedures. To reduce potential operator-related bias when comparing POCT results with those from the hematology analyzer, each specimen was assigned an anonymized barcode. The operator performing the POCT measurements was blinded to the analyzer results, and likewise, the operator of the hematology analyzer was unaware of the POCT findings.

Precision assessment of the Mission HemoPro device was carried out using three levels of control solutions: low, medium, and high. Each control level was measured twenty times, and the mean, standard deviation (SD), and coefficient of variation (CV) were calculated. According to the instrument's specifications, a CV value below 2% was considered acceptable.

Accuracy testing was performed using 35 venous blood samples obtained from donor candidates. Hemoglobin concentrations measured by the POCT device (Mission HemoPro) were compared with those obtained from the reference method, the Sysmex XN-350 hematology analyzer. The analysis included determination of the mean, SD, CV, mean bias, and percentage bias for the two methods.

In order to evaluate the statistical agreement and relationship between the two measurement techniques, several analytical procedures were undertaken. Normality of the data was examined using the skewness–kurtosis test in SPSS version 24, with distributions considered normal when skewness and kurtosis values fell within the range of 2 to +2. A dependent T-test was subsequently applied to determine whether significant differences existed between Hb values generated by the two instruments, using a significance threshold of $\alpha = 0.05$. A p-value below this threshold indicated a statistically meaningful difference. Pearson correlation analysis was also conducted to assess the strength and direction of the relationship between the two methods, with correlation coefficients interpreted using the general categories of weak (0.1–0.3), moderate (0.3–0.5), and strong (0.5–1.0).[7] Correlation plots were produced using Microsoft Excel to represent the association between the measurement results visually.

RESULTS

Precision testing was performed using three levels of control solutions. At the low control level, the mean value obtained was 9.24 g/dL, with an SD of 0.05 and a CV of 0.53%. At the medium control level, the mean was 14.03 g/dL, with an SD of 0.09 and a CV of 0.61%. At the high control level, the mean measured was 20.44 g/dL, with an SD of 0.08 and a CV of 0.40%. The precision test results are presented in Table 1.

A total of 35 samples were analyzed for hemoglobin levels using both the POCT method and the hematology analyzer. The hematology analyzer produced a mean Hb value of 14.0 g/dL, while the POCT method yielded a mean of 13.9 g/dL. The standard deviation was 1.34 for the hematology analyzer and 1.40 for the POCT device. The lowest value observed for both methods was identical at 11.7 g/dL, whereas the highest value measured was 17.1 g/dL on the hematology analyzer and 16.7 g/dL on the POCT instrument. The calculated mean bias between the two methods was 0.15 g/dL, corresponding to a bias percentage of 1.11%. A summary of the Hb measurement results is presented in Table 2.

Normality testing indicated that the hemoglobin data obtained from both instruments were normally distributed. For the POCT method, the skewness value was 0.337, and the kurtosis value was –1.135. In comparison, the hematology analyzer produced a skewness value of

Table 1. Results of the precision test

Parameters	Control Solution		
	Low (g/dL)	Medium (g/dL)	High (g/dL)
Mean (g/dL)	9.24	14.03	20.44
Standard Deviations (SD)	0.05	0.09	0.08
Coefficient of Variance (CV)	0.53	0.61	0.40

Table 2. Hemoglobin analysis evaluation

Variables	POCT (g/dL)	Hematology Analyzer (g/dL)
Mean (g/dL)	13.90	14.0
Standard Deviations (SD)	1.40	1.34
Minimun	11.70	11.7
Maximum	16.7	17.1
Mean Bias (g/dL)	0.15	
Bias Percentages (%)	1.11	

Table 3. Normality test

Methods	Parameter	Ratio	Conclusion
POCT	Skewness	0,337	Normally Distributed
	Kurtosis	-1,135	Normally Distributed
Hematology Analyzer	Skewness	0,548	Normally Distributed
	Kurtosis	-0,871	Normally Distributed

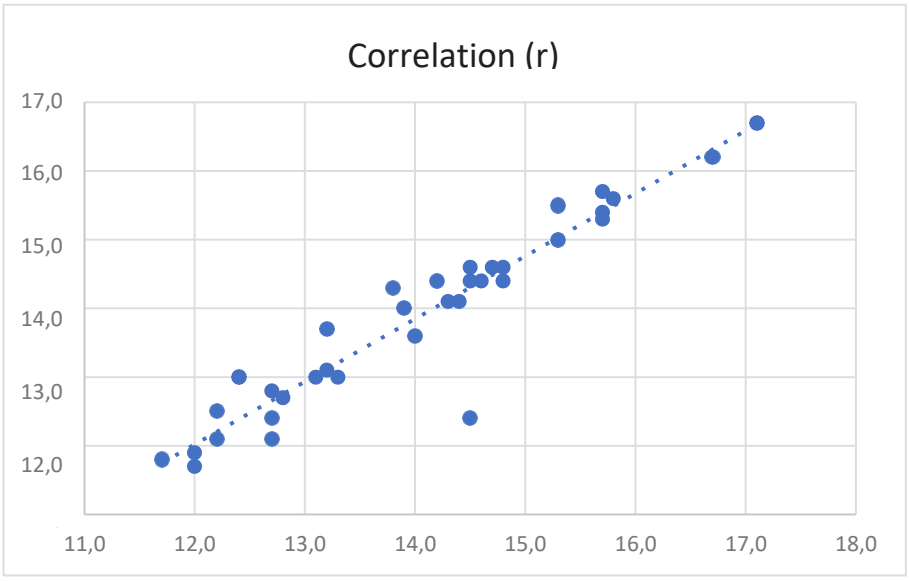

Figure 1. Correlation test of the accuracy test.

0.548 and a kurtosis value of –0.871. These results fall within the acceptable range for normal distribution, and the full normality assessment is presented in Table 3.

In order to assess the statistical significance and correlation of the accuracy results, data were analyzed using a dependent T-test and Pearson correlation. The dependent T-test yielded a t value of 2.061 with a probability of 0.047 and a mean difference of 0.154 g/dL. Pearson correlation analysis demonstrated a strong positive correlation, with r = 0.949. The correlation plot for the accuracy test is presented in Figure 1.

DISCUSSION

Pre-donation hemoglobin screening represents a critical step in ensuring both donor safety and the quality of collected blood units. As stipulated in the Indonesian Ministry of Health Regulation No. 91 of 2015, Blood Transfusion Units (UTD) are responsible for maintaining the availability, quality, and safety of blood and its components, and must also ensure that donors are not exposed to harm during the blood collection process.[8] Appropriate selection and validation of screening equipment therefore play an essential role in safeguarding donor welfare and maintaining transfusion quality standards.

This study was designed to assess the performance of an Hb meter used in donor selection and to compare hemoglobin measurements obtained through POCT with those generated by a hematology analyzer, which served as the reference method, within the quality testing laboratory of UTD PMI Bekasi Regency. Precision testing was performed using the Mission HemoPro Hemoglobin Control Solution across three control levels—low, medium, and high, with twenty repeated measurements per level. The resulting mean, SD, and CV values demonstrated strong precision, with CVs of 0.53% for the low level, 0.61% for the medium level, and 0.40% for the high level. All CV values met the instrument's acceptance criterion of <2%, indicating high measurement consistency.

Accuracy testing followed the CLSI EP15-A3 guideline, utilizing 35 venous blood samples collected in EDTA tubes. The mean Hb value obtained via POCT was 13.9 g/dL, compared with 14.0 g/dL from the hematology analyzer. The mean bias of 0.15 g/dL and bias percentage of 1.11% were well within the allowable total error (TEa) for hemoglobin analysis, defined by CLIA as ±7% of the reference value.[9] Consequently, the analytical agreement between the two methods can be considered acceptable.

Normality testing using skewness–kurtosis values confirmed that all data were normally distributed (within the –2 to +2 range), permitting the use of parametric analyses. Dependent T-test results showed a statistically significant difference between POCT and hematology analyzer measurements (t = 2.061, p = 0.047), with a mean difference of 0.1543 g/dL. Although statistically significant, this discrepancy is clinically negligible. The significance observed is likely attributable to the relatively large sample size (n = 35) combined with low data variability, which increases the sensitivity of statistical tests to minor differences.

These findings align with previous work by Fitria et al., who also reported a significant difference between POCT and hematology analyzer Hb measurements, with POCT consistently producing slightly lower mean values.[10] The strong Pearson correlation coefficient observed in the present study (r = 0.949) further supports the comparability of the two methods. The positive linear trend illustrated in Figure 1 indicates that increases in measurements from one method are closely mirrored by the other.

The correlation strength found here is consistent with earlier research. A previous study by Singh et al. reported strong correlations for two invasive POCT hemoglobin devices (r = 0.78 and 0.77), while a noninvasive device demonstrated a moderate correlation (r = 0.43).[3] Similarly, Avcioglu et al. documented a strong correlation (r = 0.908) between invasive POCT measurements and hematology analyzer results, with scatter plots showing a precise positive linear distribution.[4]

This study has several limitations that should be acknowledged. First, the sample size was relatively small (n = 35), which may restrict the precision of subgroup analyses and limit generalizability to broader donor populations. Second, only one POCT device model and one hematology analyzer were evaluated; performance may differ with other instruments or manufacturers. Third, the study utilized venous samples for both methods, whereas POCT devices are typically used with capillary blood in real-world donor screenings, potentially underestimating differences attributable to sample type. Finally, environmental factors such as temperature and humidity, known to influence POCT performance, were not systematically controlled or assessed. These limitations highlight the need for larger, multicenter studies incorporating capillary sampling and

multiple device comparisons to strengthen external validity.

CONCLUSION

Hemoglobin measurement using the POCT method demonstrated a statistically significant difference compared with the reference analyzer; however, the observed discrepancy was small (0.15 g/dL) and clinically acceptable. Both analytical approaches showed a strong positive correlation, indicating that the POCT Hb meter is suitable for assessing hemoglobin levels in prospective blood donors. To maintain the quality and reliability of test results, daily verification using appropriate control solutions, as recommended by the manufacturer, is essential. In addition, periodic requalification of the device should be performed to ensure ongoing accuracy and performance.

ETHICS CONSIDERATION

Ethical approval for the study was obtained from the Blood Transfusion Unit of IRC Bekasi Regency through the Declaration of Blood Source and Ethical Use for Research No. 054/UTD-ADM/UM/X/2025. All procedures were carried out with strict protection of donor confidentiality, and only samples for which BTU IRC Bekasi had granted explicit authorization were used in this research.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest related to the publication of this article.

AUTHOR CONTRIBUTIONS

S was responsible for conducting the experimental procedures, including sample testing, data analysis, and manuscript preparation. DKA contributed to the validation of test results, provided a critical review of data interpretation, and performed substantial revisions to the manuscript. Both authors have read and approved the final version of the article and take full responsibility for all aspects of the work.

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