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Research Article

Point-of-Care Haemoglobin Screening for Prospective Blood Donors – The Role of the User

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Abstract

Determining the haemoglobin (Hb) concentration at the pre-blood donation stage is one of the primary tests that leads to a successful transfusion. Point-of-Care-Testing (POCT) is a commonly used method to measure Hb concentrations. The implementation of such devices is in accordance with the requirements of Blood Donation Centres worldwide and can be considered safe and reliable. However, one of the major drawbacks in using POCT devices is that results obtained are highly User-depended. In this study, important Key Factors for the sampling of capillary blood are highlighted and statistical analysis was used to determine to what extent is the result user-dependent. The results show that POCT devices are indeed user-dependent and the lack of standardisation might further add to the cause of such dependence. The next step is to understand the impact each individual Key Factor has on capillary sampling and train Health Care Professionals on how to minimise such effects.

Keywords: *blood donor, point-of-care-testing, haemoglobin, user-depended*

Introduction

The mission of a blood establishment is to provide a safe and sustainable blood supply. Over the years, stringent guidelines [1] have ensured access to high quality blood products. Generally, when referring to safety, it is the safety of the recipient of the blood product that comes to mind. However, this is only part of the global picture. The safety of the blood donor should also be taken into consideration. One of the many regulations for donating blood requires the prospective blood donor to have a haemoglobin (Hb) level of ≥ 12.5g/dL and ≥ 13.5g/dL respectively for females and males [2]. This requirement prevents asymptomatic anaemic donors from donating blood, who if left to proceed with the donation would otherwise incur potential harm. Hb concentration at the pre-blood donation stage is normally assessed by capillary blood using a Point-of Care (POCT) device and if necessary, this reading is further confirmed from a venous blood sample which is then tested on an automated cell counter (ACC). Like all other analyzers, POCT devices display a number of advantages and disadvantage [3]. They are easy to use [4], provide rapid results with minimal sample volume [5] but are highly susceptible to physiological factors and sampling methodology [6,7] thus making them highly user–dependent. To limit such dependence, apart from designing a tailor-made validation protocol to ensure the effectiveness of such device [8], Blood Transfusion Centres need to standardise the procedure for correct capillary sampling. Such standardisation is only possible if Key Factors for correct capillary sampling are identified and ultimately implemented. This study is intended to provide additional insight on how the User in conjunction with such Key Factors might impact POCT Hb readings.

Method

Ethical approval to perform this study was granted by the Faculty Research Ethical Committee, Department of Applied Biomedical Science, Faculty of Health Sciences, University of Malta. Testing was performed at the National Blood Transfusion Service (Tal-Pietà, Malta). Table 1 summarises the Key Factors which for this study were identified as being critical for the correct sampling of capillary blood.

Table 1. Key Factors for correct sampling of capillary blood.

Allowing the alcohol to air-dry after disinfecting the area
Discarding the first two drops of blood
Retrieval of the cuvette right before using it
Wiping of the cuvette prior to loading onto the analyser

A cohort of 300 random samples were tested for Hb concentration using an automated cell counter (ACC) (Sysmex Europe GmbH, Germany), and the results obtained (referred to as Hb-ACC) were compared to their respective POCT reading (referred to as POCT-Hb). This analysis was categorised by User and then statistically assessed using the Statistical Package for Social Sciences (SPSS) software (SPSS, version 23.0, Chicago, USA). Five trained Health Care professionals (hereon referred to as User) were randomly selected and shadowed while measuring pre-donation Hb concentration of prospective blood donors using a POCT device (EKG Diagnostic GmbH, Germany). A note was taken whether the major Key Factors (Table 1) for POCT Hb testing were being observed. To comply with the General Data Protection Regulation (EU) 2016/679 [9], the data retrieved from the POCT analyser was double blinded, meaning that User may not be identified. In addition, statistical analysis was performed to detect any possible variation present between the multiple POCT devices in use.

Results

From the 300 random samples tested, 31 samples were eliminated because the Users performing the test were sporadic. The remaining samples represent testing performed by five Users (identified here on as User 1 – User 5). The Spearman correlation was performed to measure the degree of association between the ACC-Hb and POCT-Hb categorised by the User. Table 2 indicates that the Spearman correlation coefficient is positive across all the different Users. Out of these five Users, User 2 produced the most correlated Hb values, whilst User 1 produced the least correlated Hb values, having a correlation coefficient of 0.877 and 0.435 respectively. Furthermore, there is less than 5% chance that the positive correlation between the POCT-Hb values obtained by each user and the ACC-Hb values happened by chance, since the p-values are all less than the 0.05 level of significance.

Table 2. Spearman correlation between the POCT-Hb and ACC-Hb based on User.

			Spearman Correlation	
			ACC-Hb	**N**
POCT-Hb	**User 1**	Correlation Coefficient	0.877	26
		Significance	0	
	User 2	Correlation Coefficient	0.598	32
		Significance	0	
	User 3	Correlation Coefficient	0.709	86
		Significance	0	
	User 4	Correlation Coefficient	0.797	92
		Significance	0	
	User 5	Correlation Coefficient	0.435	33
		Significance	0.011	

ACC: Automated Cell Counter; POCT: Point-of-Care Testing; Hb: Haemoglobin; N: Sample Size

Using the data from Table 2, so as to determine the level of significant difference between User, the *Z*-score was calculated for each pair of correlation coefficients. As highlighted in Table 3, a statistical significance ($p<0.05$) was noted when User 1 was compared with Users 2, 3 and 5; between User 3 and User 5 and between User 4 and 5.

Table 3. Significance of Correlation Difference between paired Users.

		POCT-Hb				
		User 1 (N=26)	User 2 (N=32)	User 3 (N=86)	User 4 (N=92)	User 5 (N=33)
POCT-Hb	User 1 (N=26)		0.016	0.043	0.244	0.001
	User 2 (N=32)			0.366	0.061	0.390
	User 3 (N=86)				0.179	0.049
	User 4 (N=92)					0.003

POCT: Point-of-Care Testing; Hb: Haemoglobin; N: Sample Size

Table 4 summarizes which Key Factors determined as essential for the POCT device to accurately estimate the Hb level in capillary blood from a finger-prick were followed by the User. The successful performance of each step by each User is marked (✓) accordingly.

Table 4. Key Factors performed by the User during capillary sampling.

	User A	User B	User C	User D
Gentle massaging of the finger	✓			
Use of Alcohol Wipe	✓	✓	✓	✓
Alcohol residue left to air-dry		✓	✓	✓
Discarded 1st drop of blood	✓	✓	✓	✓
Discarded 2nd drop of blood		✓	✓	
Cuvette retrieved right before use				✓
Wiped under-surface of cuvette			✓	✓

Since multiple POCT devices are in use at any given time, the Spearman correlation was once again used to determine whether there may be a statistically significant difference between the POCT-Hb values and ACC-Hb values based on which device was used. Table 5 indicates the presence of a positive correlation between all the POCT devices tested. The highest correlation between the POCT- and ACC- Hb values (0.861) was observed with the EKF-010 device, whilst the least correlated Hb values were obtained with the POCT-008 device. Nonetheless, the POCT-008 device still produced moderately correlated results with those of the ACC, with a Spearman correlation coefficient of 0.513. Moreover, the positive correlation that is observed between the POCT-Hb values obtained with each device and the ACC-Hb values is 95%. This was not attributed to chance since for all devices the *p*-value is less than the 0.05 level of significance.

Table 5. Spearman correlation between the POCT-Hb and ACC-Hb based on EKF- analyser.

			Spearman Correlation	
			ACC-Hb	N
POCT-Hb	POCT-007	Correlation Coefficient	0.782	7
		Significance	0.038	
	POCT -008	Correlation Coefficient	0.513	91
		Significance	0	
	POCT -009	Correlation Coefficient	0.842	15
		Significance	0	
	POCT -010	Correlation Coefficient	0.861	79
		Significance	0	
	POCT -011	Correlation Coefficient	0.787	58
		Significance	0	
	POCT -013	Correlation Coefficient	0.658	50
		Significance	0	

ACC: Automated Cell Counter; POCT: Point-of-Care Testing; Hb: Haemoglobin; N: Sample Size

The Z-score and the p-values for each POCT devices was determined and Table 6 shows the p-values obtained between each pair of correlations. A significant difference is observed between the analyzers as highlighted in Table 6, since the *p*-value is less than the 0.05 level of significance.

Table 6: Significance of Difference between paired POCT EKF analysers

		POCT-Hb					
		POCT -007 (N=7)	POCT -008 (N=91)	POCT -009 (N=15)	POCT -010 (N=79)	POCT -011 (N=58)	POCT -013 (N=50)
POCT-Hb	POCT -007 (N=7)		0.344	0.758	0.631	0.980	0.616
	POCT -008 (N=91)			0.032	0	0.004	0.218
	POCT -009 (N=15)				0.824	0.605	0.175
	POCT -010 (N=79)					0.187	0.006
	POCT -011 (N=58)						0.167

POCT: Point-of-Care Testing; Hb: Haemoglobin; N: Sample Size

Discussion

The User who performs the POCT procedure is a critical variable and may influence the Hb level obtained. Bahadur et al. [10], explain that capillary Hb level is affected by the drop used, exposure of cuvette to sunlight and the gentle massaging of the finger prior to sampling. Indeed, the Key Factors observed during this study where selected because messaging of the finger increases blood flow to the area, however this should be performed gently as too much pressure can cause the blood to haemolyse. After disinfecting the area with alcohol, this should be left to dry to prevent both haemolysis and risk of bacterial infections by increasing the contact time of the alcohol on the skin. The first few drops of blood should be discarded as they may be contaminated with tissue fluid or debris. The microcuvettes used during the analysis are light sensitive and therefore should be kept in their appropriate container and retrieved only right before use. Finally, the wiping of the microcuvette removes excess blood and prevents contamination/soling of the POCT optical component. The correlation between the POCT-Hb in capillary blood and the corresponding ACC-Hb in venous blood was assessed based on the User performing the POCT technique. User 2 produced highly correlated results (r=0.877), followed by User 5 (r=0.797), User 4 (r=0.709), User 3 (r=0.598) and User 1 (r=0.435); the latter being the User which produced the least correlated Hb values. Moreover, statistically significant difference was obtained between the correlation coefficient of User 1 and 2 (p=0.001), User 1 and 4 (p=0.049), User 1 and 5 (p=0.003), User 2 and 3 (p=0.016) and User 2 and 4 (p=0.043). These findings provide strong evidence that the sampling technique for POCT creates variation in the capillary Hb level measured and there is possibility that the lack of standardisation has also contributed to such a variation. From observing the Users performing capillary Hb testing, one may notice a variation in the sampling. All POCT devices are subjected to rigorous Quality Control Checks which confirm that these devices are both accurate and precise (data not shown). To further confirm that the variation observed in this study is User-depended, the correlation between the POCT-Hb in capillary and the corresponding ACC-Hb in venous blood was also assessed based on the specific POCT device used. All devices produced moderate to highly correlated Hb values. Agreement between the POCT-Hb and ACC-Hb values was observed best when the POCT-010 device was used, whilst the least agreement was observed with the POCT-008 device. Nonetheless, the lack of agreement between the two measurements is not entirely due to the different POCT-device utilised nor the User performing the POCT technique but may also be due to the different sample type (capillary vs venous blood) - venous blood was shown to be much more accurate than capillary blood [8]. The next stage would be to determine which Key Factor has the most impact on POCT readings and how to mitigate such outcomes. In conclusion, once further elucidation is made available it is fundamental that all Health Care Professionals involved in pre-blood donation Hb

testing be advised to strictly adhere to the sampling protocol and most of all they should be made aware of the importance of each step and how to further reduce potential incorrect sampling.

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