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Point-of-Care Testing for Blood Donor Haemoglobin Screening

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Abstract

Haemoglobin (Hb) testing is a pre-blood donation requirement essential to identify borderline or anaemic asymptomatic donors, which would otherwise experience anaemic symptoms after donating a unit of blood. At the blood donation stage, Hb is estimated by means of a Point-of-Care Testing (POCT) device. POCT devices, have become increasingly popular for screening Hb in blood banks, are time saving and easy to operate but may lack reliability in certain circumstances. The efficacy of a POCT device, as with any other analyzer, is determined by its ability to produce accurate and repeatable results. However, it is important to acknowledge the fact that the accuracy of POCT can be greatly influenced by various methodological and physiological factors.

Keywords: POCT, Blood Donor, Haemoglobin

Abbreviations

Hb: Haemoglobin; POCT: Point-of-Care Testing; WHO: World Health Organization; EDQM: European Directorate for Quality of Medicine and Health-Care; CBC: Complete Blood Count

Introduction

The Haemoglobin (Hb) concentration is estimated in prospective blood donors as an initial screening test prior to donation [1]. This procedure is a well-established requirement and integral part of donor assessment in most countries [2]. The rationale for this screening is to:

- **Evaluate the donor's health status:** Assessing the donor's health serves as an important public health sentinel [3]. Hb screening aims to identify asymptomatic or borderline anaemic individuals. The donor is safeguarded by providing immediate medical evaluation and treatment [4], preventing the aggravation of anaemic symptoms which are most likely not as apparent prior to blood donation. The World Health Organization (WHO), defines anaemia as condition in which the number of healthy erythrocytes or their oxygen-carrying capacity is reduced, failing to meet physiological needs. The '1993-2005 WHO database' reports a global prevalence of anaemia of 25% (1.62 billion people) [6]. People suffering from anaemia may experience fatigue, shortness of breath, dizziness, headaches, cold hands and feet, pale skin and chest pain. The graveness of such symptoms depends on the severity and duration of anaemia.

- **Identify individuals which would be rendered anaemic post-donation:** The Hb level of a blood donor drops by 1-1.5 g/dL, after donating a single unit of whole blood [3,5]. Having said that, it is essential to identify those individuals with a borderline Hb level, as these are at risk of experiencing anaemic symptoms after losing a unit of blood.

- **Ensure good-quality blood products:** The recipients' health is also safeguarded by ensuring that the required therapeutic dose is met or exceeds an objective standard [5].

According to the European Directorate for Quality of Medicine and Health-Care (EDQM), a female and male Hb level of ≥13.5g/dL and ≥12.5g/dL respectively renders the individual as eligible for blood donation. Standard guideline requirements for blood donor eligibility recommend that, a Complete Blood Count (CBC) must be carried out using sampled venous blood on donors whose Point-of-Care Testing (POCT) reading is abnormally low or high [7]. Such a scenario would expose the donor to a second needle prick increasing discomfort. The CBC is generally carried out on an automated cell counter, and although each test only takes a few minutes to perform, the blood donor must be kept waiting, prolonging the overall blood donation process. Additionally, the donor is referred to a doctor for further medical management. Normally, it is advised that low iron levels should be replenished, generally by eating a nutritious, well-balanced diet with foods rich in iron and vitamin C [8].

Point-of-Care Testing

POCT is the act of performing diagnostic tests at or near the site of patient care, outside a laboratory setting, with the aid of "point-of-care" devices. Such devices are portable and, in most cases, easy to operate and deliver results within a few seconds or minutes. POCT can be extremely useful at the community level, operating rooms or in complex emergency settings where effective clinical decisions need to be made [9,10]. The growth in popularity and uptake of POCT devices throughout the world entails that results obtained from these analysers must be comparable to those of local reference laboratories [11].

Employing Point-of-Care Testing Devices for the Screening of Blood Donors

Hb levels are usually assessed prior to a blood donation by means of a POCT device. A drop of capillary blood is obtained by a finger prick, which is drawn into a dry reagent cuvette by capillary action. Erythrocytes are then lysed, and the haemoglobin is converted to azide-methaemoglobin, which is then quantified using spectrophotometry. Ideally, the method employed for Hb screening should have a high

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specificity and high sensitivity. Sensitivity is a measure of the test's ability to indicate and defer significantly anaemic prospective donors, whilst specificity indicates the test's ability to accurately classify healthy, non-anaemic prospective donors [12]. In other words, a Hb screening method should present with low false failure (deferral) rates and low false pass rates [5].

The selection of donors is extensively dependent on the accuracy of the Hb screening method [2]. Blood shortage is a constant struggle; therefore, any POCT analyser which is employed should accurately discriminate between eligible and non-eligible donors, thus avoiding unnecessary deferrals of healthy donors [13].

In the pre-blood donation phase, the purpose of Hb testing is to identify individuals with abnormally low Hb levels. However, the effectiveness of this analyser is still yet to be established. False POCT results subjects the potential blood donor to another needle prick and prolongs the overall blood donation procedure. This may cause both discomfort and inconvenience to the potential donor who might decide not to donate blood next time around, thus further dwindling the future blood supply.

Challenges of the Point-of-Care Testing

POCT minimizes the Total Testing Process since it reduces the length of both the pre-analytical and post-analytical phases, sometimes even eliminating certain activities within these stages reducing the possibility of further errors [14]. The effectiveness of a device is characterized by its ability to present with accurate and precise results. However, the accuracy and precision of POCT analyzers may be influenced by several biological and methodological factors [15]. POCT analysers are generally considered less sensitive than traditional laboratory testing [5], and like all analyser is affected by the sample source, type and acquisition, quality control measures and user dependent. Hb POCT analysers are highly susceptible to sample acquisition as explained hereunder:

- **Biological variation:** The physiological need for oxygen varies greatly between individuals, and so Hb levels vary depending on the age, sex, altitude, pregnancy status and cigarette smoking [16]. Smokers and individuals residing at higher altitudes have higher normal Hb levels. Pregnant females and colored-skin people have lower normal Hb levels [5]. The Hb cut-off criterion is hence designed for different populations around the world; however there is no single technique or methodology which has been deemed as most suitable for Hb estimation in blood screening in Transfusion Medicine [17].

- **Finger-stick:** The finger-stick technique is a commonly used method for sampling at POC. However, this is met with a low acceptance by prospective blood donors due to the associated pain and discomfort. The loop capillaries are the major source of blood from a finger-stick. The concentration of Hb within these loops fluctuates with skin temperature and depth. Applying pressure on the donor's skin will cause extracellular tissue fluid to exude, diluting the capillary blood even further [3]. Patel et al. [18] has also demonstrated that the size, style and manner of how a lancet is used may also influence the Hb concentration.

- **Venous *vs* Capillary Blood:** The use of capillary blood for Hb determination prior to blood donation is said to be controversial, and conflicting data has been reported. Various studies in the past, including those conducted by Coburn et al., and Ross et al. have reported no significant difference between finger stick and venous samples [19,20]. A substantial amount of studies, including those from Wood et al. and Radtke et al. have demonstrated that capillary blood overestimated the Hb level [4,21]. This was due to the arterial source of the capillaries which per se contain a higher Hb content than venous blood [22]. Contrasting studies by Darragh et al. [23] and Ardin et al. [24] have shown that capillary blood underestimates Hb levels. Capillary blood is therefore said to provide only an estimated Hb concentration rather than an actual measure as that obtained by the venous blood sample. Regardless, most studies comparing capillary and venous blood are carried out using different haemoglobinometers and automated haematology analysers, introducing an inherent component of bias. Moreover, cut-off criteria for Hb levels and hence interpretation of results varies with the geographic location of the study [3]. The use of venous samples for Hb testing is considered as the golden standard. Nonetheless, sampling venous blood at the pre-donation stage is impractical, time consuming and less likely to be accepted by the donors [4].

- **Postural effect:** Another factor which possibly influences Hb concentration is the donor's posture. In his study, Eisenberg [25] has demonstrated that results from samples taken in a standing position showed signs of hemoconcentration, whilst sitting or lying down gave hemodiluted readings. This is because on standing, body fluids pool to the lower extremities, consequently intravascular fluid moves into the interstitial spaces increasing the blood concentration, and on the other hand in a sitting or recumbent position, interstitial fluid flows back into the circulation, diluting the blood [3].

A concern over the quality of results obtained outside a traditional laboratory has originated after a dramatic increase in availability of POC devices. It is undeniable that POCT provides a rapid means for test results [14], but the question arises spontaneously whether these results are comparable to those obtained from a local reference laboratory [13]. POCT devices are nowadays widely available. They can be purchased at pharmacies, supermarkets and even through the internet. This broad accessibility may seem as an advantage; however, it has a down-side effect on the quality of results. The average operator of POCT for home-use does not have any formal laboratory training, the education to fully comprehend the complexity of the testing process, lacks knowledge about the many variables which could possibly influence the final test result [14], and the importance for quality control and quality assurance [26].

Conclusion

Recent advances in technology have made it possible to perform laboratory tests at the bedside of the patient. However, the POCT device remains highly user depended and therefore additional standardisation is required to further reduce variation in the results from the true Hb value. Efforts to accurately measure pre-donation Hb are very important for donor safety and component quality. The next step to ensure the reliability of such devices is to establish validation protocols to ensure their effectiveness.

References

1. Singh A, Dubey A, Sonker A, Chaudhary R. Evaluation of various methods of point-of-care testing of haemoglobin concentration in blood donors. Blood Transfus. 2015;13: 233-229.

2. Rudolf-Oliveira RCM, Gonçalves KT, Martignago ML, Mengatto V, Gaspar PC, Ferreira J dos S, et al. Comparison between two portable hemoglobinometers and a reference method to verify the reliability of screening in blood donors. Transfus Apher Sci. 2013; 49: 578-582.

3. Chaudhary R, Dubey A, Sonker A. Techniques used for the screening of hemoglobin levels in blood donors: current insights and future directions. J Blood Med. 2017; 8: 75-88.

4. Wood EM, Kim DM, Miller JP. Accuracy of predonation Hct sampling affects donor safety, eligibility, and deferral rates. Transfusion. 2001; 41: 353-359.

5. Cable RG. Hb screening of blood donors: how close is close enough? Transfusion. 2003; 43: 306-308.

6. World Health Organiztion. Worldwide prevalence of anaemia 1993-2005. WHO. 2008.

7. Council of Europe. Good Practice Guidelines for blood establishments - European Directorate for the Quality of Medicines. 2018.

8. American Society of Haematology. Anemia. 2019.

9. Raja M, Musi R, Fattorini M, Piva E, Putoto G. Point of Care Testing and Transfusion Safety in Resource Limited Settings: A Review. Journal of Blood Disorders & Transfusion. 2015; 6.

10. Sanchis-Gomar F, Cortell-Ballester J, Pareja-Galeano H, Banfi G, Lippi G. Hemoglobin point-of-care testing: the HemoCue system. J Lab Autom. 2013; 18: 198-205.

11. Briggs C, Kimber S, Green L. Where are we at with point-of-care testing in haematology? Br J Haematol. 2012; 158: 679-690.

12. Parker M, Han Z, Abu-Haydar E, Matsiko E, Iyakaremye D, Tuyisenge L, et al. An evaluation of hemoglobin measurement tools and their accuracy and reliability when screening for child anemia in Rwanda: A randomized study. PLoS ONE. 2018; 13:e0187663.

13. Briggs C, Guthrie D, Hyde K, Mackie I, Parker N, Popek M, et al. Guidelines for point-of-care testing: haematology. Br J Haematol. 2008; 142: 904-915.

14. Nichols JH. Quality in point-of-care testing. Expert Rev Mol Diagn. 2003; 3: 563-572.

15. Tatsumi N, Miwa S, Lewis SM. International Society of Hematology, and the International Council for Standardization in Haematology. Specimen collection, storage, and transmission to the laboratory for hematological tests. Int J Hematol. 2002; 75: 261-268.

16. Srivastava T, Saxena R, Negandhi H, Neogi SB, Sharma J. Methods for Hemoglobin Estimation: A Review of 'What Works'. Journal of Hematology & Transfusion. 2014.

17. Mohan G, Bhaskaran R, Sudha S, Thomas T. Comparison of Pre donation Hemoglobin Screening Methods - Implications of Quality and Cost. International Journal of Contemporary Medical Research. 3: 2064-2067.

18. Patel AJ, Wesley R, Leitman SF, Bryant BJ. Capillary versus venous haemoglobin determination in the assessment of healthy blood donors. Vox Sang. 2013; 104: 317-323.

19. Coburn TJ, Miller WV, Parrill WD. Unacceptable variability of hemoglobin estimation on samples obtained from ear punctures. Transfusion. 1977; 17:265-268.

20. Ross DG, Gilfillan AC, Houston DE, Heaton WA. Evaluation of hemoglobin screening methods in prospective blood donors. Vox Sang. 1986; 50: 78-80.

21. Radtke H, Polat G, Kalus U, Salama A, Kiesewetter H. Hemoglobin screening in prospective blood donors: comparison of different blood samples and different quantitative methods. Transfus Apher Sci. 2005; 33: 31-35.

22. Daae LN, Halvorsen S, Mathisen PM, Mironska K. A comparison between haematological parameters in 'capillary' and venous blood from healthy adults. Scand J Clin Lab Invest. 1988; 48: 723-726.

23. Darragh E, McSweeney E, Ekin C, Kinsella A, Murphy WG. SI25 The Capillary Haemoglobin Level is a More Physiological Measure than the Venous Level and is Less Susceptible to Seasonal Fluctuation When the Donor Haemoglobin Level is Close to the Regulatory Cut-Off. Transfusion Medicine. 2006; 16: 13-14.

24. Ardin S, Störmer M, Radojska S, Oustianskaia L, Hahn M, Gathof BS. Comparison of three noninvasive methods for hemoglobin screening of blood donors. Transfusion. 2015; 55: 379-387.

25. Eisenberg S. Effect of posture and position of the venous sampling site on the haematocrit and serum protein concentration. Journal of Laboratory and Clinical Medicine. 1963; 61: 755-760.

26. Shaw JLV. Practical challenges related to point of care testing. Pract Lab Med. 2016; 4: 22-29.

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