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Comparison of Copper (Ii) Sulphate to Hemocue Analyser in the Estimation of Haemoglobin Among Voluntary and Replacement Blood Donors at Bugando Medical Centre

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ABSTRACT

Background

Pre-donation haemoglobin (Hb) screening is among the foremost test done on blood donors to determine whether an individual is fit to donate with the intention of preventing inadvertent donation from an anaemic donor. The National Blood Transfusion Service (NBTS) in Tanzania uses the Copper II Sulphate ($CuSO_4$) gravimetric method to estimate haemoglobin (Hb) in blood donors. The accuracy of the copper II sulphate method for the rapid screening of prospective blood donors has been questioned because this rapid screening method may lead to false deferral of truly eligible prospective blood donors. However, this and other point-of-care method may provide false results.

Methods

This was a cross-sectional study conducted among 236 eligible blood donors attending BMC transfusion centre at Mwanza, Tanzania. The blood donors were asked for their consent to participate in this study from 1st May to 1st August 2024. Capillary blood samples were obtained for Hb estimation by CuSO4 and HemoCue methods, and 3mls of venous blood were also collected for Hb quantification by AHA (gold standard). Descriptive statistics were used to analyse the demographic details of the donor. Kappa statistics were used to determine the level of agreement between the two methods of Hb estimation.

Results

The median age of the study participants was 30 years (IQR: 25-36). The proportion of false eligible donors was 5.5%, and false deferral donors were 2.3% using the CuSO4 gravimetric method. The specificity, sensitivity, positive and negative predictive values, and Kappa agreement for CuSO4 were 53.8%, 94.7%, 93.8%, 58.3%, and 0.51, respectively. In contrast, the specificity, sensitivity, positive and negative predictive values, and Kappa agreement for HemoCue were 63.6%, 97.9%, 96%, 77.7%, and 0.67, respectively.

Conclusion

The current study revealed that, the performance of the CuSO4 gravimetric method is relatively poor, with a high proportion of false eligible donors than the HemoCue method. These findings warrant further studies to evaluate the quality control measures for CuSO4 gravimetric method and explore alternative point-of-care methods for Hb estimation among blood donors in similar resource limited-settings.

CHAPTER ONE

1.0. INTRODUCTION

1.1. Background Information

One of the fundamental purposes of a blood transfusion service is to offer safe and high-quality blood products for patients and to do so, we must avoid collecting blood from an anaemic donor(1). As a result, pre-donation haemoglobin (Hb) testing for blood donors is critical to protect the health of transfusion recipients (2).

According to the Drugs and Cosmetic Act, 1940 and the criteria mentioned in the Directorate General of Health Services Technical Manual, 2003, only blood donors with Hb levels of ≥12.5gm/dl or haematocrit (HCT) of 38% for both males and females are eligible for whole blood donation (3). There are various methods of haemoglobin estimation which vary from simple paper scale reading to measurement by photometer, each with its own advantages and limitations. The copper sulphate ($CuSO_4$) specific gravity method is the traditional method being used for donor screening at many blood centres in Tanzania. Though a cheap and easy method, it does not provide an acceptable degree of accuracy (4). The Cyanmethemoglobin method is the method recommended by the International Council for Standardization in Haematology, but the main disadvantage is the requirement of venipuncture before the actual donation. The HemoCue test system is a portable, battery-operated photometric device for rapid determination of haemoglobin. The WHO haemoglobin colour scale (HCS) is an easy and inexpensive method which measures haemoglobin between 4-14 g/dl in 2 g/dl increments. It is said to provide a reliable indication of the presence and severity of anaemia where laboratory-based haemoglobinometry methods are not available (5)(6).

Despite various methods for Hb estimation, no single technique has emerged as the most appropriate and ideal for a blood donation setup. A highly accurate method in a blood donor setting is more likely to be expensive (7). In a developing country like In Tanzania, it is not possible to use such a method for screening so many blood donors' samples. On the other hand, a less accurate and cheaper method may give false results which may lead to either donation of blood by an anaemic subject or loss of eligible donors. Therefore, there is a requirement to adopt a cost-effective and time-saving Hb estimation method that delivers accurate laboratory results (4).

In Tanzania and other resource-limited settings, use the $CuSO_4$ gravimetric method to estimate Hb among blood donors. This method is known to be easy to perform, quick and cost-effective. However, the method is known to be affected by high serum protein, high leucocyte count, and high ambient temperature, while waste disposal of the solution used is considered a biohazard, and in some countries, it is regarded as an environmental toxin; and most importantly the method cannot quantify the exact amount of Hb. Moreover, there is a lack of a generally accepted quality control for the method and the fact that it cannot quantify the exact amount of Hb, therefore, it is not feasible to detect an abnormally low or high Hb level.5-7 Hence, it may potentially provide false results, leading to donation-induced iron deficiency anemia8-11 and the loss of blood donors (8)(9,10).

1.2 Problem Statement

The $CuSO_4$ gravimetric method has been traditionally used and is still being used for donor screening at many blood centres in Tanzania because of its availability and cost-effectiveness. However, it does not provide an acceptable degree of accuracy. Using Copper Sulphate as the main standard in the donation units can be the leading cause of ejection of reliable donors or the wrong selection of blood donors hence

the scarcity of blood in the health centres (4). The proposed mechanism for this shortcoming is that Copper Sulphate ($CuSO_4.5H_2O$), when poorly reconstituted, can precipitate Hb, other proteins, and leukocytes. Many studies have shown that the subjects deferred because of failing the test may not actually be anaemic. It is, therefore, important to determine anaemia amongst them using the standard diagnostic method so that there is no loss of any potential donors. Due to these shortcomings, blood transfusion centres in other developed countries have shifted towards other point-of-care methods of Hb estimation such as HemoCue (4) (11,12).

1.3 Rationale of the study

The study aimed to compare the efficacy of Hb estimation methods, namely, the CuSO4 method and HemoCue photometer in reporting the Hb levels of blood donors at BMC compared to the Automated Haematological Analyser to come up with a better and more efficient method in the determination of Hb among the donors and setting reliable criteria in the selection and rejection of the blood donors as far as Hb estimation is of concern.

Also, the study has come up with new ways of correctly interpreting Hb and is shifting to new ways of Hb interpretation, leaving behind the traditional Hb estimation method, which has posed a greater effect on donor selection due to low efficacy and led to low blood collection due to increased rejection criteria.

1.4. Research question

What is the utility of Copper Sulphate and HemoCue in the determination of Hb among blood donors at BMC using an Automated Haematological Analyser as the gold standard?

1.5. Research Objectives

1.5.1 General Objectives

To determine the utility of Copper Sulphate and HemoCue in the determination of Hb among blood donors at BMC using an Automated Haematological Analyser as the gold standard.

1.5.2 Specific Objectives

1. To determine the specificity of Copper Sulphate and HemoCue in the detection of Haemoglobin using an Automated Haematological Analyser as a gold standard.
2. To determine the sensitivity of Copper Sulphate and HemoCue in the detection of Haemoglobin using an Automated Haematological Analyser as a gold standard.
3. To determine the Positive Predictive Value of Copper Sulphate and HemoCue in the detection of Haemoglobin using an Automated Haematological Analyser as a gold standard.
4. To determine the Negative Predictive Value of Copper Sulphate and HemoCue in the detection of Haemoglobin using an Automated Haematological Analyser as a gold standard.

CHAPTER TWO

2.0. LITERATURE REVIEW

2.1. Background Information

Blood donation is a vital part of worldwide healthcare. It allows for blood transfusion as a life-sustaining and life-saving procedure. Over one hundred million units of blood are donated each year throughout the world. This activity reviews donor eligibility and selection, adverse effects of donation, and pathogen reduction and inactivation for donated blood. This activity highlights the role of the interprofessional team

in ensuring appropriate protocol is followed. The Hb estimation of blood donors is the only laboratory test performed before blood donation and is of paramount importance. Blood donation is relatively a safe procedure when stringent measures are put in place in donor selection. Of all the criteria in donor selection, the most crucial and significant is the level of hemoglobin of the prospective donors. This is because the donation should not cause harm to the donor and the recipient of such blood should benefit maximally from the blood transfusion (13,14).

Various methods of hemoglobin estimations are available depending on the setting and how buoyant institutions are. The methods vary from simple paper scale reading, especially in rural setting to a more advanced method of Photometry. Each of these methods has its advantages and limitations. The $CuSO_4$ gravimetric test has been the method of choice for the primary Hb screening of potential blood donors for many years. Although very anemic donors can, on occasion, pass the $CuSO_4$ test, there are reports suggesting that the $CuSO_4$ method tends to give inappropriate failures. The deferred blood donor has been a subject of concern in the present decade of frequent blood shortages (14,15). The blood donor deferral rate has been reported to be as high as 24% and the largest single cause of deferral (approx. 20–50%) is a low hemoglobin (Hb) level. Approximately 80% of these deferred donors are females (2,3).

Low haemoglobin is one of the major reasons for the deferral of blood donors amongst the various others. The American Association of Blood Banks recommends for minimum Hb of 12.5 g/dl or haematocrit of 38%. For blood transfusion services in India, the Drug & Cosmetics Act 1940, amended in 1999, has specified the minimum Hb level of 12.5 g/dl for male and female blood donors. If the method used for Hb estimation is not accurate, it can lead to increased deferral rates thereby adding to the already existing blood shortage. On the other hand, if a person with low Hb is allowed to donate it could affect the donor adversely (7).

The finger-stick $CuSO_4$ method is the time-honoured pre-donation screening procedure at the discriminating value of 12.5 g/dl (8). Even with strict quality control the $CuSO_4$ method fails healthy donors and passes those with abnormal proteins and leucocytosis. Lack of specificity of this test can result in unnecessary donor deferral. The $CuSO_4$ method has been used traditionally for Hb screening of blood donors at our centre as it has low rate of false positive results. The present study has planned to analyse the impact of inaccuracies of the $CuSO_4$ method on donor deferral and also to evaluate other alternative methods of Hb estimation for blood donor screening taking specificity and sensitivity into account (4,16).

2.2 Methods for estimation of Hb among blood donors

2.2.1 Copper sulphate gravimetric method

This method is based on the estimation of the specific gravity of blood, assuming that the donor has normal protein levels. The Specific gravity of 1.053 corresponds to an Hb level of 12.5 g/dL. A drop of blood, allowed to fall into a copper sulphate solution of specific gravity 1.053, becomes encased in a sack of copper proteinate, which prevents dispersion of fluid for 15 seconds. If the specific gravity of blood is higher than the solution, the drop will sink or else it will remain suspended for some time. In most cases, this method is capable of estimating Hb within ~0.5 g/dL, which is comparable to a coefficient of variation (CV) of 2%

Although the method has withstood the test of time in ease of performance and cost, it is criticized for having a subjective end point. This test also gives false-negative results, very commonly leading to large amounts of inappropriate donor deferrals (50%–70%). Common sources of error leading to determination of falsely low Hb are incorporation of air bubbles and the use of an inadequate height for dropping the

blood. Several studies have advocated the implementation of a supplementary method, such as microhematocrit or portable hemoglobinometer (PH), in order to recover the inappropriate deferrals (17–19).

2.2.2 Cyanmethemoglobin (HiCN) method

This is the reference method for Hb determination in laboratories and for the calibration of hemoglobinometers. The principle is a conversion of Hb to HiCN by the addition of potassium cyanide and ferricyanide whose absorbance is measured at 540 nm in a photoelectric calorimeter against a standard solution. The main cause of error in this method is sample dilution and presence of turbidity when measured at a single wavelength. As this method is time-consuming, tedious and dependent on toxic cyanide reagents, it is no longer used in blood banks for Hb estimation (20).

2.2.3 Automated Haematology Analysers

Automated Haematology Analysers (AHA) can provide high precision and enable high-sample throughputs but require regular maintenance, control of calibration, trained personnel and stable climatic conditions to operate them. A high cost of equipment and reagents is another constrain in developing countries. Hb determination is done by HiCN or the oxy-haemoglobin method. In the former, the blood specimen is diluted with a reagent containing ferricyanide and cyanide, which converts Hb to HiCN. The absorbance of the HiCN at 540 nm wavelength is then used for quantitation. In the latter, the blood specimen is diluted with an aqueous solution tetrasodium salt of ethylenediaminetetraacetic acid (EDTA) and mixed with air to convert Hb to oxyhaemoglobin. The absorbance of oxyhaemoglobin at 540 nm is then measured. A typical analyser working on venous blood has a CV of ≤1.2% for Hb measurement (20,21).

2.2.4 Haemoglobin Colour Scale (HCS)

It was developed in 1995 as an inexpensive, simple alternative, intended for initial screening of anaemia in field conditions where elaborate laboratory equipment was not available. The HCS uses a strip of chromatography paper and a standard colour chart. The method compares the colour of a drop of blood absorbed onto chromatography paper with colours on standard chart, varying from pink to dark red. These colours correspond to Hb levels of 4, 6, 8, 10, 12 and 14 g/dL. Intermediate shades can be identified, allowing Hb levels to be judged to 1 g/dL.

The method has been found to be useful and convenient for anaemia screening in field conditions according to many community studies, but its accuracy remains questionable. While cost, simplicity and portability add attractive propositions, the method has been found to have very low sensitivity and specificity for screening of Hb prior to blood donation. An Indian study has reported 25.2% false results with this method, whereas another study from the UK reports that only 46.08% results by this method were accurate. Given that the result interpretation by this method is subject dependent, a lot of factors may account for the inaccuracy such as reading of results in dim light and fading of standard cards. Another limitation for use in blood banks is its non-readability for intermediate value, i.e., a Hb value of 12.5 g/dl (22).

2.2.5 Non-invasive spectrophotometry (NIS)

It has been introduced with the aim of preventing pain to blood donor, which deters most blood donors from donating blood. Other than avoiding venipuncture, this method also minimizes the risk of infection for health care workers, reduces the need for trained personnel, eliminates the generation of biohazardous waste, cuts down on consumables and is sampling error proof. The device automatically and continuously performs a self-test and calibration check during measurement sessions.

Presently, t three technologies use spectrophotometry for Hb measurement, differing in the type of sensor. One is occlusion spectroscopy (NBM 200; OrSense Co., Petah-Tikya, Israel), which is a portable device operative via a ring-shaped sensor, fitted on the donor's finger. The pneumatic cuff applies pressure and temporarily stops the blood flow, creating an optical signal and yielding a high signal-to-noise ratio. Optical elements in multi-wavelength sensors perform a sensitive measurement of the light transmitted through the finger, in the wavelengths between 600 and 1500 nm. The differential light absorption, before and after blood flow obstruction in the finger, is used to determine the Hb level (21,23).

CHAPTER THREE
3.0. RESEARCH METHODOLOGY
3.1: Study Area
This study was conducted at Bugando Medical Centre Hospital (BMC) in Mwanza, Tanzania. According to the Tanzania National Blood Transfusion Service (NBTS) annual report of 2023, the selected site contributed 90.2% of blood donated in Mwanza region.

3.2: Study Design and Duration
This was a cross-sectional study conducted within a period of 3 months from May to August 2024.

3.3: Study population
The study population were healthy blood donors who were 18 years of age visiting the centre for routine blood donation. The targeted population was 236 blood donors.

3.4: Selection Criteria
3.4.1: Inclusion Criteria
The inclusion criteria were all consenting donors aged 18 years and above who provided blood samples of a minimum 2 ml volume and those who met the blood donation criteria of the NBTS
3.4.2: Exclusion Criteria
The exclusion criteria included all the samples that were seropositive, insufficient and those that did not meet the donation protocols as per NBTS.

3.5: Sample size estimation
The sample size was estimated by Taro Yamane formula.
In BMC the number of participants' capacity was estimated as;
Capacity (N) = 500
Capacity (N) =500
Taro Yamane formula
$n=N/ [1+N (e)^2]$
Since it has 95% confidence interval, the sampling error (e) =0.05
$n=500/ [1 + 500(0.05)^2]$
n=222.2 ~ 230
Therefore, the minimum sample size was 230 among blood donors attending BMC.

3.6 sampling procedure

The sampling procedure used was convenience sampling.

3.7: Data and Sample Collection.

3.7.1: Data Collection

Quantitative data was obtained from the experiments.

3.7.2: Sample Collection

The sample of choice was blood where, Capillary blood samples were collected by deep finger prick on the index or middle finger of the left hand using a dry sterile lancet (Unilet Excelite II, England) after disinfecting with ethanol and massaging the finger to facilitate blood flow. The first drop was wiped away and the second drop was used for testing by CuSo4 method and HemoCue method (HemoCue AB, Ängelholm, Sweden). Two millilitres of venous blood samples were collected into EDTA Vacutainer tubes and analysed on the automated cell counter as soon as possible.

3.8: Data Analysis and Statistical Analysis.

3.8.1: Data Analysis:

Data was entered, cleaned, and stored in Microsoft (MS) Excel version 2019, and control of data quality was conducted through the review of data collection tools. Then data was exported into STATA v15 for statistical analysis. The data set copy backup was made for any occasion that needed backup during data analysis.

3.8.2: Statistical Analysis:

The categorical variables were presented in frequency and proportions, whereas normally distributed continuous variables were presented as means with Standard deviations (SD), and those not normally distributed were presented as medians with interquartile ranges (IQR). The performance of both CuSO4.5H2O and HemoCue was estimated by calculating the sensitivity, specificity, positive and negative predictive values, and kappa agreement with results from automated haematology analyser as reference or gold-standard method.

Sensitivity was defined as the percentage of donors with Hb values below the cut-off of 12.5 g/dl (failed) identified by the test out of all donors with venous Hb values below the cut-off by the gold-standard test. Specificity was calculated as the percentage of donors with Hb value above the cut-off of 12.5 g/dl (those passed) identified by the test out of all donors with venous blood Hb above the cut-off value by gold-standard test. Positive Predictive Value (PPV) was defined as the probability for a donor to have a Hb value below cut-off (failed/deferral) by both the test as well as the reference method. Negative Predictive Value (NPV) was defined as the probability of a donor to have Hb value at or above the cut-off (passed/ eligible) by both the test as well as the reference.

3.9. Quality Control:

Copper Sulphate pentahydrate (CuSO4.5H2 O) preparation was done following the World Health Organization (WHO) Standard Operating Procedures (SOPs) to ensure the quality of the CuSO4 solution. Briefly, 170 grams of crystalline CuSO4 powder was dissolved in 1000 mL of distilled water to make a stock solution of CuSO4.5H2O. Then was mixed well to ensure that the copper sulphate had dissolved. Then 51 ml stock solution was added into 49 mL distilled water to make a working solution. The specific

gravity (1.053) was checked using a hydrometer, if 1.053 gravity was not obtained, it was adjusted by either using stock solution or distilled water.

The calibration of the HemoCue was verified by a control cuvette each day before the first measurement as recommended by the manufacturer. In short, QC was performed daily as recommended by the manufacturer and the liquid QC testing was conducted prior to donor sample testing. This QC test ensured the accuracy of the HemoCue analyser. The liquid QC comes in two levels: R&D GLU/HGB Control Level 1 (low) and R&D GLU/ HGB Control Level 2 (high). In addition, the HemoCue analyser has an Internal Electronic Quality Control (EQC) that is performed automatically each time the device is turned on. This test verifies the performance of the optronic unit of the analyser. This test was performed for eight hours when the analyser remained powered on.

3.10. Data Dissemination and Utilization.

The results of this study were presented to the Dean of the Catholic University of Health and Allied Sciences (CUHAS) School of Medicine for the award of a BMLS degree, CUHAS Department of Haematology and Blood Transfusion, CUHAS library, and Bugando Medical Centre.

3.11: Ethical Consideration:

Ethical clearance was obtained from the Senate of Research and Publications Committee of the Catholic University of Health and Allied Sciences (CUHAS) with the ethical clearance certificate number 2971/2024, Managers of selected blood donation centres granted permission to conduct the study. Study participants were provided with written consent. The confidentiality of the study participants was ensured by using codes instead of their names.

3.12: Study limitations:

This study used the gold standard that is only applied to the venous sample since the Cell dyne analyser needs a larger amount of blood and therefore the cell dyne analyser could not be used to test for the finger prick samples.

CHAPTER FOUR

4.1: Social-Demographic Characteristics of Study Participants.

A total of 236 blood donors participated in this study. The median age was 30 years (IQR: 25-36). Males contributed 68.0% of the study participants. The number of deferrals was higher for the females than that of the males.

4.2: The Proportion of False Eligible and Deferred Blood Donors by CUSO4 Gravimetric Method

I compared the performance of the CuSO4 gravimetric method with an automated haematology analyser as a reference. I found that 105 (96.3%) out of 109 participants were eligible donors, whereas 10 out of 109 participants (9.8%) were deferral donors by the CuSO4 gravimetric method. Of the 99 participants eligible by the CuSO4 gravimetric method, 90 (90.9%) qualified by the automated haematology analyser, whereas the remaining 9 (9.1%) were disqualified. Thus,8.3% (9/109) of the study participants screened by the CuSO4 gravimetric method were falsely eligible.

Furthermore, I observed that 10 out of 16 (63%) of the deferral blood donors were disqualified by both the CuSO4 method and automated haematology analyser, whereas the remaining 6 out of 16 (37%) who were disqualified by the CuSO4 gravimetric method were qualified by the automated haematology

analyser. These results indicate that 5.5% (6/109) of the blood donors screened by the CuSO4 gravimetric method were false deferrals.

Table 1: Demographic Characteristics of False Eligible and Deferred Blood Donors

Variable	Deferred by CuSO4	Falsely deferred Donors	Eligible Blood Donors by CuSO4	False Eligible Donors
Sex				
	7	3	53	4
Male (55.3%)	3	2		2
			38	
Female (44.7%)				
Total	10	5	91	6

4.3: Comparison of CuSO4 and HemoCue Methods

I then compared the performance of CuSO4 and HemoCue methods with the automated haematology analyser as a reference. We observed that the sensitivity and specificity of CuSO4 gravimetric method were 94.7 % and 53.8%, respectively, and the Kappa agreement was 0.51, suggesting a moderate agreement. In contrast, the HemoCue method had higher sensitivity and specificity of 97.9% and 63.6 %, respectively, and Kappa agreement of 0.67, suggesting a substantial agreement. Furthermore, the positive predictive values (PPV) for CuSO4 and HemoCue methods were 93.8% and 96%, and the negative predictive values were 58.3% and 77.7%, respectively.

Table 2: Comparison of CuSO4 and HemoCue Methods Using Automated Haematology Analyzer as the Gold Standard

Method	Sensitivity	Specificity	PPV[1](%)	NPV[2](%)	Cohen's Kappa (K)
Copper Sulphate	94.7%	53.8%	93.8	58.3	0.45
HemoCue	97.9%	63.6%	96	77.7	0.67

Remember: 1) Positive predictive value, 2) Negative predictive value.

CHAPTER FIVE

5.1: Discussion

In this study I evaluated the comparison of copper II sulphate to hemocque in estimation of haemoglobin among voluntary and replacement blood donors at Bugando medical centre and revealed that 5.5% of blood donors screened by the CuSO4 gravimetric method, were falsely eligible. This proportion is lower than that reported in other studies that used the CuSO4 gravimetric method, such as the study by *Dorina Kamori* et-al Dar-Es-Salaam Tanzania 2023 that reported a higher proportion of 19.6% false eligible donors(1); and that by Guracha et al. in Ethiopia at 9.2% of falsely eligible blood donors. and another study by Chaudhary et al found that 6.9% of blood donors were falsely eligible(2–4). Such difference could be due to variations of practice in preparations, quality control measures in the use of CuSO4

gravimetric methods as previously reported to affect the performance and also due to a small number of study participants that have been included in the comparison of the methods of Hb estimation. The high proportion of falsely eligible donors in my study setting increases the risks for donation-induced anaemia among donors and inadequate blood transfusions to recipients.

I observed that 5.5% of blood donors screened by the CuSO4 gravimetric method and failed were false deferrals. This proportion was higher when compared to the study done by Gupta et al. in India, where the proportion of deferred blood donors was only 1.4%. The high proportion of false deferred donors in our study may also be due to inadequate quality control checks, as shown previously, to influence the performance of the CuSO4 gravimetric method. The finding suggests that to improve the performance of the CuSO4 gravimetric method to estimate haemoglobin among potential blood donors, one needs to improve the frequency and efficiency of the quality control checks.

With regard to CuSO4 gravimetric method sensitivity and specificity, the study showed that the CuSO4 method had high sensitivity. The findings are in line with the sensitivity reported in other previous studies conducted by Sobhy et al, Pistorious et al, Wilkinson et al, Gupta et al., Guracha et al., and Agnihotri et al. that reported a sensitivity of 97%, 94%, 95.7%, 98.4%, 94.4%, and 96.55%, respectively(3). In contrast, the specificity of the CuSO4 gravimetric method in our study was low compared to that reported by Gupta et al (98.8%) and Agnihotri et al (74.42%).20, 25 Furthermore, our study revealed low PPV and NPV for the CuSO4 gravimetric method compared to PPV of 97.8%, 92.3%, and 80% and NPV of 81.0%, 90.7% and 99% reported in previous studies(1). The difference in PPV between the present study and the previous studies might be due to the non-conformity of the Standard Operating procedure (SOP).

The implication of low PPV and NPV may result in donation-induced iron deficiency (DIID) anaemia, and lead to an increased risk of adverse events reporting from the blood donors.

In this study, it was observed that the HemoCue method performance was superior to that of CuSO4 gravimetric method. This observation is similar to what has been reported elsewhere (5,6).Therefore, these findings suggest HemoCue method may be a reasonable substitute for the CuSO4 gravimetric method in our setting.

5.2: CONCLUSION

This study shows that the CuSO4 method performed poorly compared to the reference method in estimating haemoglobin among blood donors, leading to high levels of false eligibility for donation. On the other hand, the HemoCue method performed better in the same settings.

5.3 RECOMMENDATIONS

As CuSO4 pentahydrate is still the most affordable method, these findings call for healthcare providers and stakeholders to formulate strategies to improve the screening of blood donors to enhance the quality of donated blood in our setting and other resource-limited settings. More studies are needed for quality improvement of this method as it is still the most widely available and most appropriate technique considering the different environments which blood donation is done. Assessment of the frequency of quality control checks and how that affects the accuracy of the haemoglobin estimation could help to find the optimal frequency and points at which quality checks should be done to increase the effectiveness of this method. Investigating the accuracy of the technique with different concentrations of copper sulphate solution is an alternative method that may improve the quality of the technique. In addition, I suggest that

in order to save inappropriate deferrals, when CuSO4 method be used for massive screening, and subsequent testing should be done with HemoCue in situations where there is high demand for blood.

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