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COLLEGE OF HEALTH SCIENCES

EVALUATION OF RAPID DIAGNOSTIC TEST METHOD FOR SCREENING BLOOD DONORS AND DETERMINING THE RISK OF TRANSFUSION TRANSMITTED VIRAL INFECTIONS IN SELECTED HEALTH FACILITIES IN CENTRAL REGION, GHANA

BY

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DECLARATION

I hereby declare that apart from specific references which have been duly acknowledged, this dissertation is my own work put together. I also declare that this work has not been presented elsewhere, either in part or in whole for another degree.

BOAH PRINCE KWESI **…….**

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DR SAMUEL OKO SACKEY **…….**

(SUPERVISOR) **DATE**

DEDICATION

This dissertation is dedicated to my parents, Mr Mathew Boah and Madam Grace Amponsah for their support and encouragement. It is dedicated to my siblings especially Mrs. Cecilia Boah Amakye and Simon Boah for their support and encouragement.

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ABSTRACT

Background: Blood transfusion is a life-saving practice in medicine but serves as a major route for spreading infections. It is therefore necessary to adopt sensitive screening technologies to guarantee the safety of blood. In Ghana, most districts and regional blood bank laboratories are limited in resources and resort to the use of rapid kits; a method less sensitive and liable to errors compared to enzyme-linked immunosorbent assay as the gold standard. This study seeks to determine the proportion of HIV and HBV infection among blood donors missed by RDT and the risk of transfusion transmitted infections when rapid diagnostic kit is solely used for screening blood donors.

Aim: The aim of the study was to detect transfusion transmissible HIV and HBV infections in donor blood screened with RDT kits and labeled as safe for transfusion.

Methods: The study was conducted in four facilities, namely Agona Swedru Municipal Hospital, Mercy Women's Catholic Hospital, Ajumako District Hospital and St. Francis Xavier Catholic Hospital in the Central Region of Ghana. Blood screened with RDT and stored in blood bank refrigerator ready for transfusion were randomly sampled and sent to the National Public Health Reference Laboratory to be retested with Enzyme-linked Immunosorbent Assay.

Results: A total of 196 donor samples were randomly selected but 194 samples with complete information were analysed. Out of 194 donor samples, 85.05% were from males and 14.95% were from females. RDT missed six (6) HIV and one (1) HBV infection but were detected with ELISA. The performance of RDT was less compared to ELISA and the calculated negative predictive value of First Response HIV 1-2, In Tec, LabAcon, Diaspot and Wondfo were 96.9%, 97.6%, 100%, 100% and 100% respectively. There was no

significant association between HIV and HBV transfusion transmitted infections and socio-demographic and RDT -related factors.

Conclusion: Rapid Diagnostic Test has limitations with regard to accuracy for screening blood donors for transfusion transmissible HIV and HBV infection and should not be the only test for guaranteeing the safety of blood for transfusion. ELISA had higher sensitivity and should be enforced as the Gold standard for blood screening in Ghana.

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LIST OF ABBREVIATIONS

AOR	-	Adjusted Odds Ratio
CLIA	-	Chemiluminescent Immunoassays
ELISA	-	Enzyme-linked Immunosorbent Assay
gp	-	glycoprotein
HBV	-	Hepatitis B
HCV	-	Hepatitis C
HIV	-	Human Immuno-deficiency Virus
HRP	-	Horseradish Peroxidase
nm	-	Nanometer
NAT	-	Nucleic Acid Testing
NBS	-	National Blood Service
NPHRL		National Public Health Reference Laboratory
NPV	-	Negative Predictive Value
RDT	-	Rapid Diagnostic Test
TTI	-	Transfusion Transmissible Infections
WHO	-	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1 Background

Blood transfusion plays an essential role in therapeutic medicine. Though it is life-saving, it may expose recipients to fatal infections like HIV, Viral Hepatitis, Syphilis and new emerging pathogens known as transfusion transmissible infections (Oluwayemisi, Olasunkanmi, Kehinde, & Oluwayemisi, 2016; World Health Organisation, 2015). Transfusion Transmissible Infection(TTI) is any infectious pathogen that is passed from person-to-person through blood transfusion or any infection detected in a potential blood donor at the pre-donation screening phase(Holy Alomatu 2016; Walana et al., 2014). Transfusion Transmissible Infections can be reduced by ensuring blood and blood products are devoid of infectious agents through stringent donor selection processes and use of improved screening methods for infections (Nahom, Naik, & Fessehaye, 2011; Oluwayemisi et al., 2016).

World Health Organization recommends that all donated blood undergo quality testing for HIV, Hepatitis B and Hepatitis C and syphilis (World Health Organisation, 2015). It is estimated that 5-10% and 12.5% HIV and hepatitis B infections in Sub-Sahara Africa are transmitted through blood transfusion respectively(Okoroiwu, Okafor, Asemota, & Okpokam, 2018).

Among the many routes for transmitting HIV (type1 &2), blood transfusion remains an effective medium (Olanrewaju et al, 2014). World Health Organization's report on Screening for TTI, recommends Enzyme-Linked Immunosorbent Assay (ELISA) as the Gold standard for screening blood donors for TTI but advanced methods like Chemiluminescent Immunoassays (CLIA), and Nucleic Acid Testing (NAT) are also

recommended for advanced countries that can afford on a larger scale. Rapid Diagnostic Test is preferred for screening blood donors in certain emergency situations (World Health Organization, 2009), despite the fact that it is liable to human errors, inherent kit defect and inability to detect infections in window period due to its low sensitivity compared to ELISA, CLIA and NAT (Mehra, Bhattar, Bhalla, & Rawat, 2014; World Health Organization, 2010).

In Ghana, the National Blood Policy for Health Sector was approved in 2006 and it mandates the National Blood Service (NBS) for its implementation. As part of its responsibilities, it shall collect, process and distribute safe blood to communities as well as coordinate and supervise the activities of the Area Blood Centres at the regional and district level. The NBS is overwhelmed because blood supply in Ghana meets 50% of the national demand (Mamaye, 2014), hence hospitals have developed strategies to keep the local blood bank functioning. Regional, district and remote hospitals, most of which have limited resources have resorted to the use of rapid kits for screening blood donors.

1.2 Problem Statement

World Health Organization's policy on screening for TTI recommends ELISA as the Gold standard method for screening donor blood(World Health Organisation, 2009) for viral infections whereas at the same time recommending RDT for emergency situations. Although RDT is cheap, has good turn-around-time and easy to perform, its sensitivity and specificity is less compared to ELISA. The testing algorithm for donors allows only RDT reactive samples to be confirmed with higher assay. There has been report of RDT giving false-negative results. A study conducted from the VCT facility of a tertiary hospital in North India revealed that RDT missed 22.5% HIV reactive samples which were detected

with ELISA (Mehra et al., 2014). According to Erhabor et. al., 12.5% Hepatitis B infection in blood donors were missed by RDT but detected with ELISA screening method.

Blood transfusion is a major route for transmitting infections from person to person. Blood donors in the early stage of viral infection may have lower viral loads but may not be detected serologically. According to Liang et al. (2009), 83 women out of 367 were infected with HIV infection via blood transfusion

In Ghana, most district and regional hospitals rely on RDT for screening due to resource limitations. World Health Organization's recommendation is not fully implemented in Ghana and there could be possible risk of spreading HIV and Hepatitis B infections through blood transfusion. Enzyme linked immunosorbent assay is expensive but infecting recipients with HIV and Hepatitis B virus is costlier and detrimental to their health in the long run.

In Ghana, there is limited information on blood linked diseases and screening of blood. This study seeks to use ELISA to determine the possibility of missing HIV and HBV infection in the screening phase of blood donation because of the wide use of RDT for screening and the study will also quantify the risk of transfusion transmissible viral infections in blood transfusion services.

1.3 Justification

There is limited study on the spread of infections through blood transfusion in Ghana. This study sought to investigate the possible risk of infecting patients with HIV and hepatitis B based on the choice of screening method in blood transfusion centres. ELISA, the preferred gold standard is expensive, but comparing its cost to the cost of managing HIV and HBV infection makes it cost-effective.

The findings of this study would bring to the awareness of policymakers the threat to public health and the need to adopt and implement World Health Organization's protocol for screening donated blood for transfusion.

The study findings can be used to advocate for the need to strengthen transfusion laboratory systems in Ghana by ensuring continuous and effective monitoring of activities by supervisors and stakeholders to reduce the possible spread of HIV and Hepatitis B infection to prospective blood recipients.

1.4 Research Questions

1. What is the proportion of HIV and Hepatitis B infections in donor blood screened with Rapid Diagnostic Test?
2. What is the performance of Rapid Diagnostic Test kit for screening blood donors in transfusion laboratories?
3. What factors are associated with HIV and HBV Transfusion Transmitted Infections?

1.5 Conceptual Framework

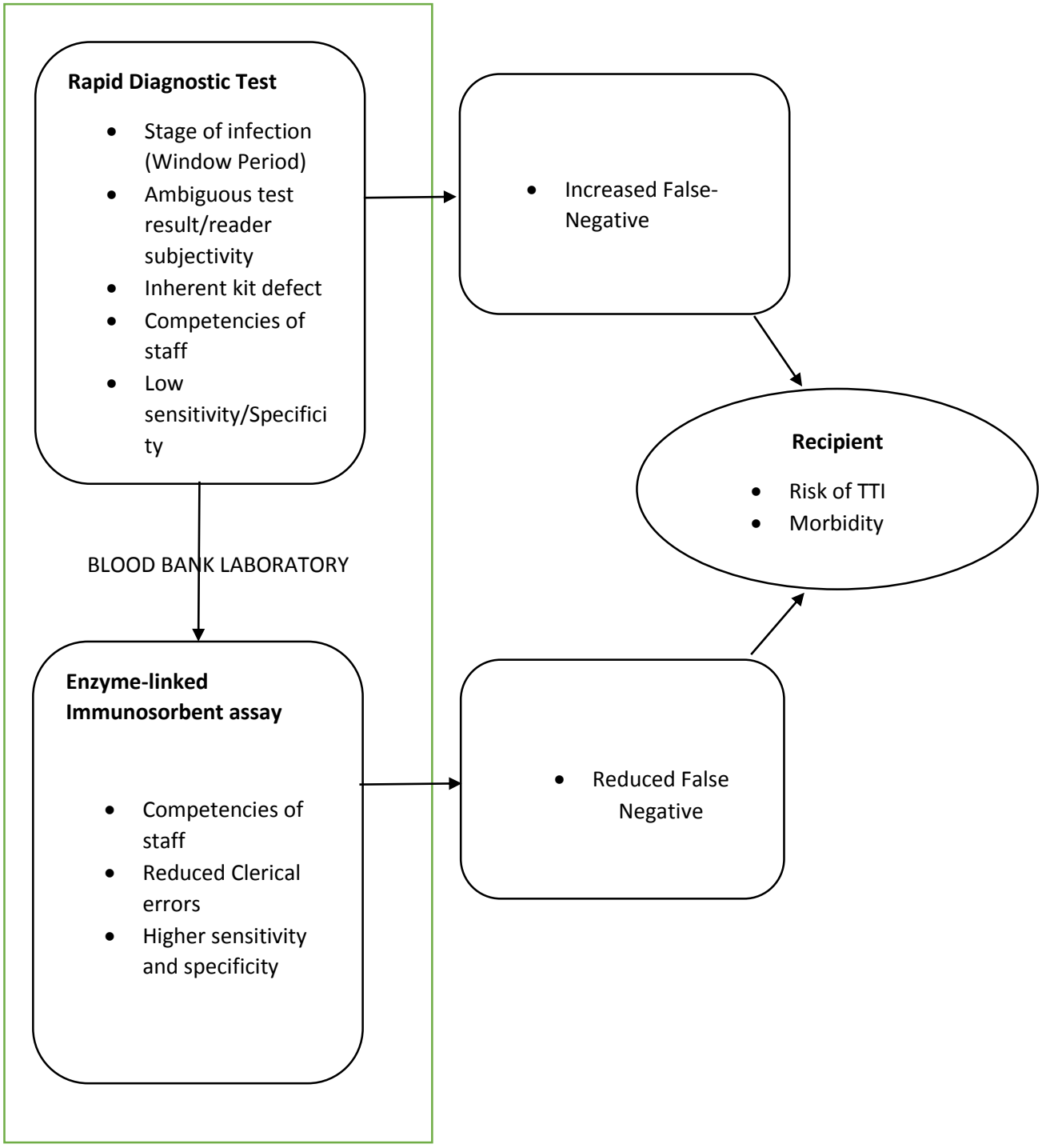

Figure 1: Conceptual framework of risk of transfusion transmissible infections (TTI) in RDT screened blood.

Figure 1 shows a conceptual framework of risk of TTI in donor blood screened with RDT.

The choice of assay for screening blood plays a vital role in achieving blood safety. Enzyme-

linked immunosorbent assay, Nucleic Acid Testing (NAT), rapid agglutination assays and rapid diagnostics are the method of choice when screening blood for infections. ELISA and NAT are the recommended screening methods (WHO, 2009).

Factors that can cause RDT to give a false negative result include poor sensitivity, early stage of infection (Olanrewaju et al., 2014), inherent kit defect, poor laboratory staff competencies, ambiguous test result (faint line on strip). False negative result indicates missing an infection and certifying blood safe for transfusion, an event that put blood recipient at risk of TTI. Eventually, this would lead to increase in morbidity in the population. Though ELISA is liable to human errors, it is sensitive and reduces window period to fewer days (Kumar Barik et al., 2018) therefore recommended for screening blood donors. For example, HIV core protein (p24 antigen) produced before seroconversion is detectable by ELISA(Kaur & Bhattacharya, 2013) and serves as an advantage to reduce window period in infectious blood donors. Selection of ELISA for screening donor blood reduces transfusion transmissible infections and hence low morbidity in a population. Initial screening with RDT and confirming with ELISA is cost-effective (Abubakar & Jamoh, 2017) and reduces the risk of spreading infections through blood transfusion.

1.6 Objective

1.6.1 General Objective

The aim of the study is to evaluate viral HIV and Hepatitis B infections in donor blood screened with Rapid Diagnostic Test method and determine the risk of transfusion transmitted infections using ELISA as the gold standard.

1.6.2 Specific Objectives

1. To determine the proportion of HIV and Hepatitis B infections in donor blood screened with Rapid Diagnostic Test.

2. To evaluate the performance of HIV and HBV RDT kits using ELISA as the gold standard.
3. To determine factors that contribute to HIV and HBV transfusion transmitted Infections in Blood Transfusion Laboratories.

CHAPTER TWO

LITERATURE REVIEW

2.1 Blood Transfusion Service

Blood transfusion is the process of collecting blood from the circulatory system of an individual and transferring it to a recipient for the purpose of clinical management (Phil, 2006). Blood transfusion is key, life-saving and plays an essential role in the area of health service delivery (Fapohunda, Atere, & Adebisi, 1937; Olanrewaju et al., 2015). In tropical countries, blood transfusion is used in managing life threatening conditions such as anaemia in children and pregnant women caused by malaria infection, malnutrition and partum and postpartum haemorrhage (Cheesbrough, 2008). Blood transfusion is indispensable, therefore safe blood and blood products are of public health importance.

Establishment of National Blood Transfusion Service to oversee, coordinate and monitor blood transfusion related activities is necessary for sustainable and timely supply of quality and safe blood in any country. Moreover, it is prudent for Regional or National Blood Centers to partner with resource-constraint and remote facilities to consolidate screening activities and work with uniform standards (World Health Organization, 2010).

2.2 Blood Donation

High quantity of banked blood is essential for daily medical care. Blood Transfusion Service has the responsibility to solicit blood from low risk population. In the early stage of blood donation, rigorous processes are adopted to assess the eligibility of prospective donors to ensure the safety of donated blood and recipients of blood transfusion (World Health Organization, 2012).The process includes donor recruitment, selection and screening for TTI (World Health Organization, 2012). For selection, the steps involve donation registration, pre-donation information, completion of questionnaire on medical history and

risk factors, interview and counselling, health and risk assessment and finally the consent of the donor. Physical examination, weighing, measurement of vital signs such as blood pressure and pulse and examination of donor's veins for easy venipuncture are among the basic health checks that are carried out prior to blood donation (World Health Organization, 2012). Blood is sourced from commercial donors, voluntary donors, family replacement donors and autologous donors (Alomatu Holy, 2016). Donors who do not meet the selection criteria are deferred whereas those who meet the criteria are motivated, counselled and informed consent obtained from donors to allow legal bleeding of blood donors (World Health Organization, 2012).

2.3 Screening of Donated Blood

Screening donated blood for TTI is critical and laboratory screening determines the non-reactive status of donated blood and therefore safe for clinical use (World Health Organization, 2010). It is therefore recommended that all donated blood are screened for HIV, HBV, HCV and syphilis which represent a worldwide burden but other infections like Malaria, Chagas disease and so on can be added to the panel of screening test in settings where the infection is prevalent (Olanrewaju et al., 2015). The approach to blood screening recommends the use of highly sensitive and specific assay for detecting all infected blood donations whiles minimizing false positives that may lead to unnecessary deferrals. With reference to the testing algorithm for blood donors, a negative or non-reactive result classifies blood unit as safe and could be released for clinical use. However, a confirmatory or duplicate test is recommended for only a reactive blood unit. Reactive result upon second testing requires blood unit to be segregated and discarded (World Health Organization, 2009).

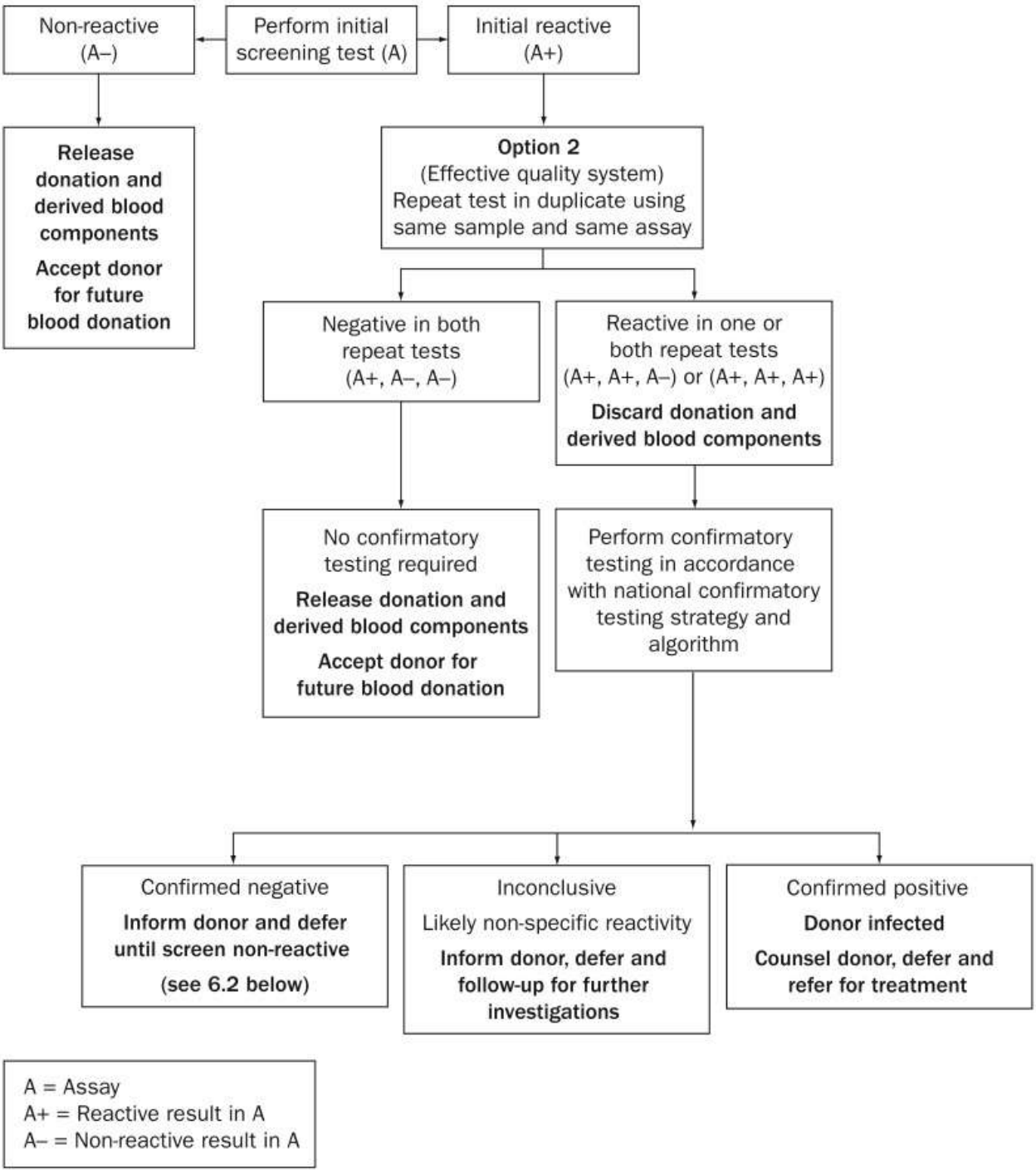

Figure 2: Algorithm for blood donor management based on screening and confirmatory testing (Source: Screening Donated Blood for TTI, WHO 2009).

2.4 Human Immuno-Deficiency Virus

Human immuno-deficiency virus is a lentivirus and infect the human white blood cells (Albrecht et al., 2007). Human Immuno-deficiency virus damages the defense system after invading the body of a person. It weakens and compromise the function of the immune

system and makes the infected person prone to a wide range of life-threatening opportunistic infections and cancers (Albrecht et al., 2007; World Health Organization, 2019). In the advanced stage of the infection referred as Acquired Immunodeficiency Syndrome, there is development of infections, cancer and severe clinical illnesses (World Health Organization, 2019).

The stage of the infection determines the symptoms of the infection. Infected individuals may show no clinical symptoms at the early stage (window period), though they are infectious and capable of transmitting the infection to another person. As infection progresses, symptoms develop and include diarrhea, swollen lymph nodes, fever, weight loss, cryptococcal meningitis, tuberculosis and other severe illnesses. HIV is transmitted through unprotected sexual intercourse with an infected person, exposure to infected blood through needle stick, blood transfusion and drug injection. Other routes of transmission include mother to child during pregnancy or delivery and breastfeeding (Alomatu, 2016;World Health Organization, 2018).

Diagnosis of the infection relies on establishing the HIV status by testing. HIV testing includes serological testing such as use of rapid diagnostic kit or enzyme immunoassays for antibody/antigen detection, western blot and polymerase chain reaction to detect viral nucleic acid (Okyere, 2017).

The absence of clinical symptoms in the early phase of the infection makes people unaware of the infection and therefore a major threat to public health. After exposure to the virus, the human body produces antibodies within 28 days and may not be detectable (World Health Organization, 2018a). Since blood donors are perceived healthy individuals, it is therefore crucial to screen blood donors with sensitive assays to avoid transmission of HIV at the early phase of the infection through transfusion.

2.5 Hepatitis B Virus

Hepatitis B is an infection of the liver, caused by hepatitis B virus. The virus, which belongs to the hepadnaviridae family is enveloped and contains a partially double-stranded DNA genome (World Health Organization, 2018). It is estimated that 2 billion people are infected worldwide, out of which 350 million have active chronic infections and about 8% chronic carriers (Mutocheluh et al., 2014). The infection is reported to be endemic in East and South Asia, South America and Sub-Sahara Africa (Mutocheluh et al., 2014).

The virus causes inflammation of the liver and long-term persistence of the virus leads to cirrhosis, liver cancer and eventually death. The infection is termed chronic when it persists in the body for more than 6 months. While some people may show symptoms such as dark urine, abdominal pain, nausea, extreme fatigue and jaundice in the acute phase, majority of the chronic infections are asymptomatic. The mode of transmission is either horizontal or vertical; horizontal transmission includes mucosal exposure to blood and body fluids (saliva, sweat, semen, blood and blood products) of an infected person whereas vertical transmission is from mother to child during pregnancy or delivery (Alomatu, 2016; World Health Organization, 2018).

On clinical examination, hepatitis B cannot be differentiated from other viral hepatitis and therefore requires laboratory confirmation. Laboratory confirmation is based on sera detection of either one or combination of hepatitis B surface antigen, hepatitis B e antigen, hepatitis B e antibody and hepatitis B core antibody. Presence of hepatitis B surface antigen and immunoglobulin M (IgM) indicate acute phase of the infection, though hepatitis B e antigen may be present at the initial phase. On the other hand, chronic infection is defined as the persistence of the surface antigen in the sera over 6 months. Moreover, HBV DNA detection has improved early diagnosis of the infection (World Health Organization, 2018b).

2.6 Screening Methods

2.6.1 Rapid Diagnostic Test

Rapid diagnostic tests are simple, qualitative and inexpensive that require minimum training of personnel to perform (Field, Brien, Daniel, & Kasha, 2014; World Health Organization, 2009). It has good turn-around time and discarded after one use. Rapid diagnostic kit is widely used in remote healthcare settings and plays a major role as the diagnostic tool for management of patients. The method employs the principle of immunochromatography, immunodot, immunofiltration and particle agglutination. Among these principles, immunochromatography is the most widely used (Okyere, 2017).

The principle is such that, the sample(whole blood, serum, or plasma) flows down the strip together with antibody-congugates (colloidal gold congugates) and react with another immobilised reagents at the stationary phase on the strip known as the test band and control band. A coloured band or dot at the test region and the control band indicate a positive result whereas a single coloured band at the control region indicate negative result. The control band validates the result independent of the test band. However, rapid diagnostic test result is qualitative and interpretation relies on the subjectivity of the reader. Currently, 4th generation RDT are constructed to detect both antigens and antibodies in sample (Okyere, 2017; World Health Organization, 2009). Though RDT is not recommended for screening large samples of blood donors, it can be used in urgent situations where blood bank is empty and blood is needed to save life (World Health Organization, 2009)

2.6.2 Enzyme-linked Immunosorbent Assay

It is an assay for detection and quantification of antigens or antibodies or both in a sample. It is widely used in biomedical research and as a clinical diagnostic tool (Gan & Patel, 2013). It was introduced by Peter Perlmann and Eva Engvall in 1971 at Stockholm University, Sweden (Pokhrel, 2016). The enhanced method, fourth generation ELISA's are powerful

and has the advantage of high sensitivity to detect antibodies at low concentrations and quantities (Gan & Patel, 2013). Thus, the fourth generation HIV-ELISA reduces detection of HIV in window period to 12 days (Okyere, 2017). In view of that, it is recommended as suitable for screening TTI in blood donors (World Health Organization, 2009).

There are 3 types of ELISA methods; indirect, sandwich and competitive. The principle of the method relies on specific antigen-antibody binding. The patient serum is incubated in wells of microplate coated with corresponding antigen or antibody for a specific time per manufacturer's instruction. After the specified time, the wells are washed with a washing buffer to remove unbound antigen or antibody. A secondary antibody conjugated to an enzyme is added to the wells for incubation following blocking of unbound antigens or antibodies. After incubation, wells are washed again with buffer and a suitable substrate is added to the wells. The enzyme reacts with the substrate to generate a colour which is directly proportional to the quantity of the antigens or antibodies in the sample. The intensity of the colour is measured at a specific wavelength using a colorimetric instrument. The test is ran alongside with positive and negative control to serve as a cut-off point (Baid, 2016; Pokhrel, 2016).

2.7 Transfusion Transmissible Infections

Globally, it is estimated that blood donations per year is 81 million, out of which 18 million of the blood are unscreened (Zameer et al., 2017). Post transfusion infections caused by HIV, HBV, HCV and syphilis are attributed to transfusion of contaminated blood (Zameer et al., 2017) . Data gathered by Joint United Nations Program on HIV/AIDS has it that, out of 75 000 HIV infections in China, 22 000 were transmitted through transfusion of contaminated blood (Song, Bian, Petzold, & Ung, 2014). Similarly, it is estimated that 104 women out of 1598 were infected with HIV via blood transfusion as a result of managing

excessive bleeding during vaginal delivery (Liang et al., 2009). Factors that lead to transfusion transmitted infections in Sub-Sahara Africa are high prevalence of infections in populations, inadequate screening facilities, and policies to ensure sustainable operations (Buseri, Muhibi, & Jeremiah, 2009).

The high demand for blood transfusion in health facilities and the short shelf-life of blood in banks determines continuous donations from voluntary donors, commercial donors and family replacement. Report reveals that 2 billion HBV, 200 million HCV, 33.4 million HIV and 12 million new infections are recorded each year. Majority of infected individuals seemingly look healthier or asymptomatic and are potentials to transmit infections in the community. However, these same people parade the blood transfusion centres as blood donors (Zameer, Shahzad, Khan, et al., 2017).

Studies have shown high prevalence of transfusion transmissible infections among blood donors in Sub-Sahara Africa. A study conducted in China estimated the prevalence of at least one transfusion transmissible infection among blood donors to be 2.67% (Song et al., 2014). However, a similar study conducted in Nigeria revealed a prevalence of 18.6%, 3.1%, 6.0% and 1.1% for HBV, HCV, HIV and syphilis respectively. Moreover, a study conducted in Ghana reported a prevalence of 9.6%, 4.9% and 4.4% for HBV, HIV and HCV respectively (Walana et al., 2014). The prevalence of HIV and HBV varies across different categories of blood donors and a shift from Family Replacement Donors (FRD) to Voluntary Donors (VD) could reduce the risk of transfusion transmitted infections. In a study conducted in Tanzania in 2017, the prevalence of HBV among first time FRD and VD was 4.8% and 4.0% respectively whereas HIV prevalence was 1.8% and 0.0% respectively for FRD and VD (Kim et al., 2019). According to a study conducted in Ghana by Alomatu in 2016, the prevalence of HBV among blood donors were 13.39%, 12.39% and 13.64% for

FRD, VD and commercial donors respectively. However, in the same study, the prevalence of HIV was 7.14%, 0.88% and 2.27% for FRD, VD and commercial donors respectively.

With high prevalence of TTI among blood donors, it is crucial that stringent criteria and sensitive technology are deployed in screening blood donors to improve detection of TTI in window period (World Health Organization, 2009). The type of test kits, competencies of laboratory scientists, clerical errors and judgment in cases of ambiguous result have influence on the outcome of the test result (Dogbe & Arthur, 2015; Okyere, 2017). It can therefore be deduced that, false-negative results emanating from these factors are most likely to lead to transmitting infections to recipients through transfusion.

2.8 Recommended Screening Method

Prevalence of transfusion transmissible infections among blood donors is high in Sub-Sahara Africa. One of the major risks of transfusing infected blood stems from donations done in the window period where serological test is negative (Agrawal, Chandraker, & Agrawal, 2017). In the pursuit to avoid this, highly sensitive testing methods that have been evaluated are required for screening donor blood (World Health Organization, 2009). In a study conducted in Burkina Faso to compare the performance of ELISA and RDT, rapid diagnostic test (Determine HIV ½ test kit) missed 30 HIV positive cases. Out of these 30 cases, 4 were confirmed to be missed in the window period after blood donors were retested with same rapid kit after 2 months (Sanou et al., 2018).

Residual risk of transfusion may be caused by the insensitivity of the test kit. Factors contributing to the low sensitivity of rapid diagnostic kits include inadequate/low concentration coating of antigens or antibodies, the nature of the antigen used by manufacturers and the heterogeneity of the virus (Torane & Shastri, 2008). Similarly, a study reveal that out of 100 samples from blood donors confirmed negative for HBV by

RDT, 9 were detected as positive by ELISA (Erhabor, Kwaifa, & Bayawa, 2014). Likewise, a study by Mehra et al, revealed RDT missed 22.5% HIV reactive samples but were detected with ELISA (Mehra et al., 2014) upon secondary testing.

False negative screening test result may not necessarily be caused by the insensitivity of the screening kit but may emanate from the competencies of the laboratory staff, clerical errors and the brand of kit (Dogbe & Arthur, 2015; Okyere, 2017). A study conducted in Ghana reported one false negative result for HBV out of 300 blood donors initially screened with RDT and confirmed with ELISA. However in the same study, the performance of HIV RDT was comparable to ELISA (Dogbe & Arthur, 2015). Currently, 4th generation ELISA is known to be more sensitive to antibodies and antigens and therefore increases detection in window period (Sanou et al., 2018)

Hence, it can be concluded that rapid diagnostic test is liable to diverse errors or factors that could lead to false negative result as compared to ELISA. False negative result blindly leads to residual risk of transfusion transmitted infections in future patients. This calls for immediate screening strategies for both regional and local blood banks to guarantee the safety of blood transfusion in Ghana.

2.9 Performance of a Screening Test

Ideally, a diagnostic test should correctly determine the presence of disease in a person, and at the same time identify those without the disease. Thus, for the validity of the test result, gold standard tests are preferred to establish the health status of a population. However, it is expensive and requires trained professional to perform, therefore cheap and easy to operate tests are selected over gold standard tests (Stojanovi et al., 2014). In the absence of a gold standard test, the performance or validity of a newly opted clinical test must be evaluated and compared to the gold standard (Stojanovi et al., 2014). To evaluate a clinical

test, sensitivity and specificity are used irrespective of the health status of the population being tested (Ghaaliq & Mccluskey, 2008). Sensitivity is defined as the ability of test to correctly identify the disease if present. It is the proportion of diseased persons who test positive by the clinical test. On the other hand, specificity of a test is the ability to correctly classify those without the disease (Ghaaliq & Mccluskey, 2008; Stojanovi et al., 2014).

Thus, for a screening test to correctly discriminate between those with or without the disease, both sensitivity and specificity should be high. Sensitivity and specificity depend on the cut-off values for quantitative test; the limit between positive and negative result (Stojanovi et al., 2014). For diagnosis of viral infections using RDT, the cut-off value for detection depends on the concentration of antigens or antibodies in the serum of a person. Low viral antigens and antibodies concentration in pre-seroconverted blood donors may lead to false negative result (Pruett et al., 2015). Serum viral antigens or antibodies concentration below RDT detection limit may lead to false negative result. Whereas sensitivity and specificity have limited usefulness in the likelihood of the disease in the individual, predictive value is of utmost significance for measuring diagnostic accuracy in a population (Ghaaliq & Mccluskey, 2008; Stojanovi et al., 2014). To prevent and reduce transfusion transmitted infections, negative RDT result is required to represent the true absence of a disease. Thus, a screening tool for blood donors must have a high Negative Predictive Value (NPV) to guarantee the diagnostic accuracy of the test in a characteristic population. Negative Predictive Value is the proportion of people with negative test result who do not have the disease (Ghaaliq & Mccluskey, 2008; Okyere, 2017).

2.10 Factors Affecting the Performance of RDT

To correctly classify blood as safe for transfusion, screening assays must have optimum performance. WHO's document for screening TTIs in 2010 recommends that assays for

screening blood donors should have sensitivity and specificity level of not less than 99.5%. However, comparative studies have reported sensitivity and specificity lesser than WHO standards; a factor that increases the risk of false negatives (Marie et al., 2019). In a study conducted by Marie et al. in 2019, HIV and HBV RDT for screening blood donors showed false negative result after evaluation. Low sensitivity of the kits was attributed to blood donors who may have donated blood in the window period, influence of HIV variants and low antigen levels in blood donors. Different brands of testing kits have shown different sensitivity and specificity. In an evaluation study conducted in the northern part of Ghana, 5 different HBV rapid kit for screening blood donors showed less sensitivity as reported by the Manufacturer (Mutocheluh et al., 2014). Rapid Diagnostic test relies on immunochromatography principle to form a band. Interpretation of RDT result is dependent on subjective evaluation and therefore faint or weak bands could be interpreted as negative result (Okyere, 2017; World Health Organization, 2009).

Also, differences in RDT performance could be influence by the study population (Mba et al., 2019). Studies have shown that prevalence of HIV and HBV is higher among Family Replacement Donors compared to Voluntary and Commercial blood donors (Alomatu Holy, 2016; Kim et al., 2019). Indirectly, predictive value of RDT may be influenced by prevalence of HIV and HBV among different categories of donor population.

CHAPTER THREE

METHODS

3.1 Type of Study

The study was a quantitative cross-sectional study that involved stored donor blood screened with RDT and certified as wholesome for transfusion at Agona Swedru Municipal Hospital (ASMH), Mercy Women's Catholic Hospital(MWCH) at Mankessim, Ajumako District Hospital(ADH) and St. Francis Xavier Catholic Hospital(SFXH) at Assin Fosu, all in the Central Region from April 2019 to June 2019. Sampled donated blood were sent to National Public Health Reference Laboratory for HIV and HBV screening using ELISA test. The gold standard method, ELISA was used to evaluate the performance of HIV and HBV rapid test kit for screening blood donors and to determine the risk of transfusion transmitted infections.

3.2 Study Location

The study was conducted at Agona Swedru Municipal Hospital, Mercy Women's Catholic Hospital, Ajumako District Hospital and St. Francis Xavier Catholic Hospital, all located in the Central Region of Ghana. Samples were collected from RDT screened stored blood in the blood bank of the hospitals and sent to National Public Health Reference Laboratory, located at Korle Bu in the Ga South Municipal of Accra, Ghana.

Mercy Women's Catholic Hospital, Agona Swedru Municipal Hospital, Ajumako District Hospital and St. Francis Xavier Catholic Hospitals are primary healthcare facilities located in the Mfantseman Municipal District, Agona West Municipal District, Ajumako-Enyan-Esiam and Assin North District respectively and provide primary healthcare to the indigenes of the community and nearby communities. The facilities were selected because they were

resource constrained in the area of blood banking and adopt the use of RDT for screening blood donors.

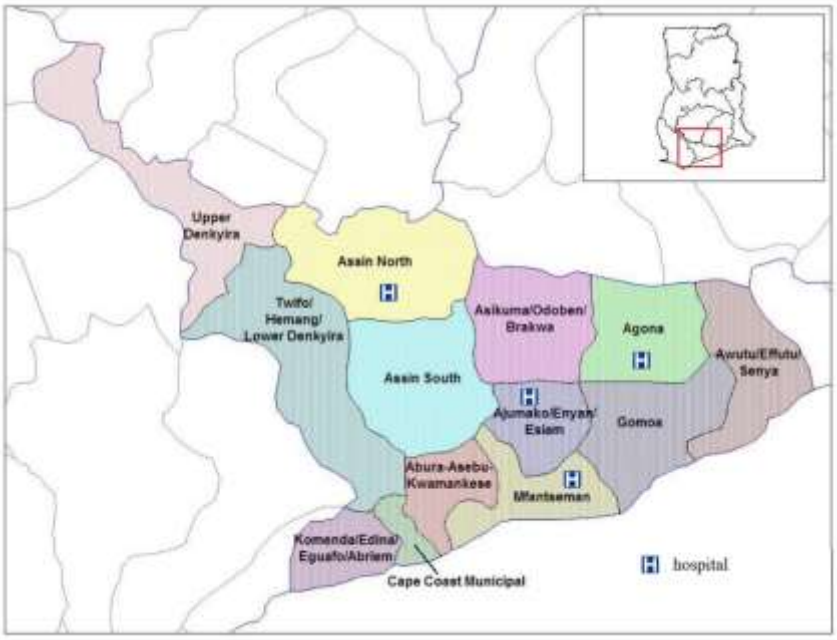

Figure 3: Map of Central Region of Ghana showing district and hospitals selected for the study. (Source: https://www.google.com)

The National Public Health Reference Laboratory serves as a reference laboratory for investigation and confirmation of infectious agents involved in disease outbreaks and for sentinel purposes in Ghana. Similarly, in collaboration with National Blood Service, it is responsible for validation and assisting in determination of kits for microbiological testing of donated blood(National Blood Policy for the Health Sector, 2006). The facility was selected because it is well resourced, had the capacity to perform ELISA test and conforms to WHO standards for testing donor blood.

3.3 Study Population

The study involved donated blood screened with RDT, certified as wholesome and stored in blood bank refrigerator ready for transfusion between April 2019 and June 2019 at St

Francis Xavier Hospital, Ajumako District Hospital, Agona Swedru Municipal Hospital and Mercy Women's Catholic Hospital.

3.4 Variables

Dependent variable: HIV and HBV

Independent Variables:

I. Stage of infection
II. Brand of RDT Kit
III. Type of blood donor
IV. Competencies of laboratory staff

3.5 Sampling

3.5.1 Sample Size

The sample size (n) was calculated using the formula

$$n = \frac{Z^2_{1-\frac{\alpha}{2}} P(1-P)}{e^2}$$

Where n is the minimum sample size

Z is the standard normal deviation set at 1.96 corresponding to 95% confidence interval

p is the prevalence set at 14.6% and 4.0% for Hepatitis B(Mutocheluh et al., 2014) and HIV(Dadzie, Muniru, Adu, & Cudjoe, 2018) respectively

e is the margin of error or degree of accuracy is 5%

$$n = \frac{1.96^2 \; 0.146(1-0.146)}{0.05^2}$$

n = 191.59

The sample size for the study was 200 samples after correcting for insufficient samples and spillage that may occur during the transportation or analysis of the samples.

3.5.2 Sampling Method

Proportionate sampling method was employed in the sampling process at the study facilities. Based on the average donations done in 3 months for each facility, the respective sampling proportion was calculated. After calculation, 55, 32, 55, 44 donated blood were sampled from MWCH, ADH, SFXH and SMH respectively. Donated blood declared wholesome after RDT screening and kept in refrigerator were conveniently sampled and recruited into the study. Samples were recruited into the study as at when blood is donated and available in storage.

3.6 Inclusion Criteria

All stored blood screened with RDT in the facilities and certified as safe for transfusion were included in the study.

3.7 Exclusion Criteria

Donor blood that were borrowed or transferred from other facilities were excluded from the study. This is because the screening method was unknown and lack of socio-demographic information on blood donors.

3.8 Specimen Collection

The objective, inclusion and exclusion criteria were communicated to focal persons selected to aid in the collection of specimens at each facility. Three milliliter (3ml) of blood from blood bag was aseptically transferred into a 4ml EDTA tube. Each sample was labeled same as it was on the donated blood bag.

3.9 Specimen Storage

All samples were spun, and plasma separated into well-labeled microtubes for storage at -70^{0}C to maintain the integrity of the samples until ready for laboratory analysis.

3.10 Specimen Transportation

All samples were transported to the testing site, National Public Health Reference Laboratory in a triple package system, at the same time maintaining the storage temperature with icepacks.

3.11 Laboratory Testing

Samples were sent to National Public Health Reference Laboratory for ELISA test. The test was carried out according to their protocols for confirmation HIV and HBV using ELISA. The Fortress 4th Generation HIV(Ag/Ab) (Fortress Diagnostics Limited, United Kingdom) and Hepatitis B (Surface Antigen) 4th Generation ELISA (Fortress Diagnostics, United Kingdom) were used at the NPHRL as the Gold standard. The 4th Generation Enzyme-linked Immunosorbent Assay is an advanced test for detecting antibodies and antigens in serum or plasma. The Fortress kit used in this study was for qualitative determination of serum or plasma HIV antigen and antibodies and HBV surface antigen. It was recommended kit for screening blood donors and for diagnosis of clinical condition related to HIV and HBV infections.

3.12 Principle of Fortress HIV ELISA Test

Fortress HIV (1&2) ELISA kit employs a two-step incubation, a sandwich enzyme immunoassay which involves the precoating of polystyrene microwells with recombinant HIV antigens (HIV-1 gp41/gp120 and HIV-2 gp36) and HIV-p24 antibodies. During first incubation, biotinylated anti-HIV(p24) antibodies and sample (donor's plasma) are added to the wells. HIV 1&2 antibodies present in the sample bind to coated antigens in the wells whereas HIV p24 antigen is captured in a sandwich between the coated p24 antibodies and biotinylated anti-HIV p24. The microwells are washed with a washing buffer to remove unbound serum proteins.

At the stage of incubation, Horseradish Peroxidase (HRP) enzyme conjugated to HIV 1+2 recombinant antigens and to avidin is added to the microwells. For detection of p24 antigens, avidin react with biotin to attach HRP to the Ab-p24-Ab complex. On the other hand, HRP-antigen conjugate reacts with captured antibodies to form Ag-Ab-Ag (HRP). The wells are washed, and chromogens added to the wells. Chromogens in wells containing immunocomplex are hydrolysed by HRP to a blue colour complex. Sulphuric acid is added to stop the reaction and the intensity of the colour is proportional to the concentration of the antibodies or antigens in the sample at a wavelength of 450nm.

3.13 Principle of Fortress HBsAg ELISA test

Fortress HBsAg Elisa test is based on sandwich enzyme immunoassay. In the first phase of the reaction, serum or plasma specimen and peroxidase conjugated Anti-HBsAg antibody are added to polystyrene wells coated with antibodies specific to HBsAg. Hepatitis B surface antigen present in the sample binds to both antibodies coated on the microtiter wells and peroxidase Anti-HBsAg antibody to form a complex. After washing with buffer to remove unbound materials, TMB substrate solution is added to the wells and incubated for specific period and this is followed by addition of suphuric acid to stop the peroxidase-TMB reaction. The intensity of the developed colour measured at 450nm using a photometer is proportional to the amount of HBsAg bound to the coated antibodies in the microtiter well.

3.14 Laboratory Quality Control

Positive and negative In-House control samples were analysed together with the study samples to ensure the validity of the test results and proper functioning of the reagents and instrument. The integrity of the frozen samples was monitored by storing HBV and HIV positive specimen together with the samples after which both samples were subjected to

same ELISA testing at the blind sight of the Laboratory Scientist. Expiry date of reagents were checked to avoid use of expired reagents.

Laboratory professionals selected as research assistant were trained to carry out accurate sampling procedures as well as the use of the study tool before the start of the study. Also, pre-testing was carried out at the National Public Health Reference Laboratory before commencement of the study.

3.15 Data Collection Tool

Demographic data (age and sex) of donors and brand of kits used for the screening were extracted from the facility database and recorded into a notebook designed purposely for the study. ELISA screening outcome was recorded for each sample. The data were inputted into Microsoft Spreadsheet and later imported into Stata/IC 15.0.

3.16 Data Analysis

Data was entered in MS Excel software and imported into Stata/IC (version 15.0) and analyzed. Categorical data such as sex, type of donor, blood group, brand of kit and test results for HIV and HBV were expressed in proportions whereas continuous variables such as age was categorized into age groups and presented as percentages. Rapid Diagnostic Test was evaluated by determining the number of False Negative results expressed as a percentage. False negative result was defined as any discordant result whereby RDT was negative and ELISA was positive result for HIV and HBV. Negative Predictive Value (NPV) was calculated as described below;

$$NPV = \frac{True\ negative}{True\ negative + false\ negative} \times 100$$

Negative Predictive Value is defined as the probability that a disease is absent when the screening test is negative.

Bivariate analysis was done to determine the association between outcome variable and demographic factors which were age, sex, category of donor, facility and blood group using Pearson's Chi-Square test. Univariate logistic regression analysis was done to obtain the association between outcome variable and each demographic factor. Multivariate analysis was done using multiple logistic regression to determine association between the outcome variable and the demographic factors such as age, sex, type of donor and facility. All statistical analyses were performed with 95% confidence interval and 5% level of significance and their respective p-value reported.

3.17 Ethical Clearance

Ethical approval was sought from Ethics Review Committee of Ghana Health Service. The approval number was GHS-ERC026/02/19.

Permission was sought from the Management of Ajumako District Hospital, St. Francis Xavier Catholic Hospital, Mercy Women's Catholic Hospital and Agona Swedru Municipal Hospital before commencement of the study.

3.18 Confidentiality

Data collected were kept on computer and protected by passwords to ensure confidentiality. Hardcopies were locked up in cupboard accessible to only the Principal Investigator

CHAPTER FOUR

RESULT

4.1 Socio-demographic Characteristics of Study Participants

A total of 196 samples were tested into the study, out of which 41, 58, 65 and 38 samples were obtained from Swedru Municipal Hospital, Mercy Women's Catholic Hospital, St Francis Xavier Catholic Hospital and Ajumako District Hospital, respectively.

Two samples had indeterminate result hence were not included in the analysis. One hundred and ninety-four (194) samples with complete information were analysed for the study. The median age of donors was 29 years with a minimum of 18 years and maximum of 50 years. The age group that dominated was 20-29 years (50%). The number of males who donated blood was higher (85.05%) than females (14.95%). Majority of the donors (64.45%) were Family Replacement Donors followed by Voluntary Donors (25.26%), and Commercial Donors (9.28%). Table 1 describes the socio-demographic characteristics of the study participants whose donated blood samples were recruited into the study.

Table 1: Socio-demographic characteristics of blood donors in the study.

Variable	Frequency (N=194)	%	HIV Positive (N=194)	HBV Positive (N=194)
Age group(years)				
< 20	9	4.6	0	0
20 – 29	97	50.0	2	0
30 - 39	70	36.08	4	1
40 – 49	16	8.25	0	0
≥ 50	2	1.03	0	0
Sex				
Male	165	85.05	6	1
Female	29	14.95	0	0
Category of Donor				
Family	127	65.46	3	1
Replacement				
Voluntary	49	25.26	3	0
Commercial	18	9.28	0	0
Facility				
ASMH	41	21.13	1	1
MWCH	58	29.90	1	0
ADH	32	16.49	3	0
SFXH	63	32.47	1	0
Blood Group				
A Positive	27	13.92	3	0
A Negative	2	1.03	0	0
B Positive	37	19.07	0	0
B Negative	3	1.55	0	0
AB Positive	4	2.06	0	0
AB Negative	1	0.52	0	0
O Positive	112	57.73	3	1
O Negative	8	4.12	0	0

ASMH-Agona Swedru Municipal Hospital MWCH-Mercy Women's Catholic Hospital ADH-Ajumako District Hospital SFXH-St. Francis Xavier Catholic Hospital

4.2 Proportion of HIV and HBV Infected Donor Blood

Table 2 indicates proportion of donated blood infected with HIV and HBV. From the study, the proportion of samples reactive for HIV was 3.1% (95% CI=1.14 - 6.61) using ELISA test as a confirmatory gold standard. For HBV, 0.5% (95% CI= 0.01 – 2.8) was reactive after ELISA test.

Table 2: Results of RDT kit compared to ELISA results

VARIABLE		GOLD STANDARD (ELISA)		
		NEGATIVE	POSITIVE	TOTAL
RDT				
	HIV	188	6(3.1%)	
NEGATIVE				194
	HBV	193	1(0.5%)	

4.3 Performance of RDT using ELISA as the Gold Standard

Rapid kits used for screening donated blood were evaluated by comparing their results to a gold standard (ELISA). In total, 5 RDT kits were used for screening donated blood samples in all the facilities. First Response was used for screening blood donors for HIV in all the facilities recruited into the study whereas 4 kits, namely; In-Tec, Diaspot, Acon, and Wondfo were used for screening HBV. Overall, the false negativity of First Response kit was six (6) and that of HBV kits was one (1).

Negative Predictive Value (NPV) of the kits were determined. The NPV of the test kits in this study answers the question how likely that when a test is negative, the blood sample does not have any HBV antigen or HIV antibody or antigen. First Response, Intec, Acon, Diaspot and Wondfo that were assessed in this study had NPV of 96.9%, 97.6%, 100%, 100% and 100% respectively. Table 3 illustrates the performance of the rapid test kits used in the study.

Table 3: False-Negative Results and Negative Predictive Value of Rapid test Kits

Rapid Kit	True Negative	False Negative	NPV (%)
HIV			
First Response HIV 1-2	188	6	96.9
HBV			
In Tec	40	1	97.6
Diaspot	96	0	100
LabAcon	45	0	100
Wondfo	12	0	100

4.4 Socio-demographic Factors and HIV/HBV Transfusion Transmitted Infection

In univariate logistic regression analysis in Table 4, there was no significant association between HIV transmitted infection and identified factors: age group, sex, site/hospital facility and category of blood donor. Again, univariate analysis showed no significant association between HBV infection and predicted factors: age group, sex, site/hospital facility, brand of kit, category of blood donors.

In multivariate analysis using multiple logistic regression in Table 4, there was no significant association between HIV and HBV transmitted infection and identified factors: age group, sex, site/hospital facility, brand of kit, category of blood donors. However, from the study the odds of RDT missing HIV infection in Ajumako District Hospital was 2.03 times higher compared to RDT missing HIV infection in Swedru Municipal Hospital [AOR=2.03; (95%CI=0.14 - 29.11)]. Also, the odds of RDT missing HIV infection in St. Francis Xavier Catholic Hospital was 68% lower compared to RDT missing HIV infection in Agona Swedru Municipal Hospital [AOR=0.32; (0.01-8.58)]. The odds of RDT missing HIV infection among voluntary blood donors reduces by 26% compared to family replacement donors [AOR=0.74 (0.04-12.86)].

Table 4: Socio-demographic Factors Associated with HIV

Variable	OR (95%CI)	p-value	AOR (95%CI)	p-value
Age group(years)		**0.65**		
< 20	1.0		1.0	
20 – 29	0.35(0.06 - 1.98)	**0.24**	0.35 (0.05-	**0.28**
30 - 39	1.0		2.32)	
40 – 49	1.0		1.0	
≥ 50	1.0		1.0	
			1.0	
Sex				
Female	1.0		1.0	
Male	1.0		1.0	
Type of Donor		**0.83**		
FRD	1.0		1.0	
Voluntary	2.72(0.53 -	**0.23**	0.74 (0.04-	**0.84**
	13.95)		12.86)	
Commercial	1.0		1.0	
Facility		**0.18**		
ASMH	1.0		1.0	
MWCH	0.70 (0.04 -	**0.80**	0.16 (0.01-	**0.31**
ADH	11.56)	**0.23**	5.61)	**0.60**
SFXH	4.13 (0.41 -	**0.74**	2.03 (0.14-	**0.49**
	41.82)		29.11)	
	0.63 (0.04 -		0.32 (0.01-	
	10.23)		8.58)	

CHAPTER FIVE

DISCUSSION

In this study, the facility that had the highest donation was St. Francis Xavier Catholic Hospital followed by Mercy Women's Catholic Hospital. This is because of the presence of Medical Specialist, diverse services provided and the high demand for blood and blood products for therapeutic purposes. Majority of the blood donors in this study were males and this is not different from what has been reported in similar studies (Alomatu Holy, 2016; Mutocheluh et al., 2014). Males are often the preferred blood donors due to masculinity characteristics of high hemoglobin levels and energetic appearances as opposed to female donors (Alomatu Holy, 2016). Also, majority of the blood donors were within the age group 20-29 years which is similar to findings from a study conducted by Alomatu Holy (2016) on blood donors. This could be attributed to the fact that it is the young adult group and society fall on them for blood donation when the need arises because of the belief that they are young and have fresh and 'more' blood in their body. In addition, persons that society fall on for blood donation are relatives, hence the domination of Family Replacement Donors (65.46%) as reported in this study.

The study also found out that First Response Kit was the only test kit for screening blood donors in transfusion laboratories in the facilities. National AIDS/STI Control Program endorses First Response Kit for screening all client in health centres for HIV as part of its strategies to control HIV in the country and this explains the universal usage in screening blood donors in this study. However, different types of kits were used for screening HBV depending on what is available on the market.

5.1 Risk of Transfusion Transmitted Infection

The study confirmed the wide use of RDT for screening blood donors in Ghana, especially in resource limited settings. Detection of HIV and HBV in supposed 'safe blood' found in this study means that considerable number of blood donors are being misdiagnosed and the possibility of passing HIV and HBV infection from blood recruited into this study to future blood recipients.

The study revealed that 3.1% of donated blood were false negative for HIV after screening with RDT whereas those declared negative by RDT, one (1) out 194 samples was positive for HBV after ELISA testing. The outcome of this study is consistent with other studies (Dadzie et al., 2018; Dogbe & Arthur, 2015; Erhabor et al., 2014). Thus, 3.1% and 0.5% of future patients who would be transfused with the donated blood recruited into this study may be at risk of HIV and HBV infection respectively. This finding indicates that the safety of blood and blood products cannot be guaranteed when donated blood is solely screened with RDT. Similar study by Dogbe et.al concluded that rapid immunochromatography assay is not adequate to reduce transmission of viral agents through transfusion. False negative result of RDT observed in this study can be explained in the light of low performance of rapid kits on the market which is inconsistent with the 100% sensitivity and specificity quoted by manufacturers (First Response and In Tec). Also the false negative result may be attributed to the fact that donation may have occurred during the window period of the infection as reported by some studies (Erhabor et al., 2014; Kim et al., 2019; Mutocheluh et al., 2014). Moreover, low levels of antigens and antibodies in blood samples of donors and failure to follow testing protocols or reading result earlier than indicated by the manufacturer may account for the false negative result of RDT.

5.2 Performance of RDT Kit

New testing techniques are invented on regular basis with enhanced detection limit and performance. This study evaluated the performance of RDT by confirming negative result of rapid test with ELISA. The study found that the performance of Wondfo, Acon and Diaspot was comparable to ELISA test for screening blood donors. On the contrary, the performances of First Response HIV 1-2 and In Tec were relatively poor compared to ELISA. According to the manufacturer, the reported sensitivity of First Response kit was 100%, meaning that the test can detect antibody to HIV 1 and 2 in all infected HIV samples if present. A plausible reason for the kit missing HIV infection could be that the actual sensitivity of the kit was lower than what was reported by manufacturers or antibody titre below detection limit. Another reason is reading result earlier than the designated time for RDT. Also, the study found NPV of First Response and In-Tec HBV kit to be 96.9% and 97.6% respectively. Thus, NPV reported by this study for First Response and In-Tec imply that the probability of a negative result being accurate is 96.9% and 97.6% respectively depending on the prevalence of the disease in the population. From the perspective of blood transfusion safety, rapid kits are not suitable as the only and final test for screening blood donors. Although RDT are less effective for screening blood donors, it remains the only available test for screening in resource limited settings.

5.3 Factors Associated with Transfusion Transmitted HIV and HBV Infections.

The study found no significant association between transfusions transmitted HIV and HBV infection and identified factors. However, majority of donors who tested reactive were between the ages of 30-39years. This finding disagrees with other studies that detected HBV and HIV in 17-29 age category (Dadzie et al., 2018; Mutocheluh et al., 2014). Moreover, donors infected with HIV and HBV but were missed by RDT were skewed towards males. A probable reason accounting for this is that males in their youthful age hardly undertake

regular health screening from health service providers and this study brought to light HIV and HBV infections detected in the acute phase of asymptomatic donors.

The study further assessed the safety of blood transfusion in different health facilities. Here, the study showed that at least HIV or HBV infections was being transmitted through blood transfusions in all the study sites. Testing inefficiency in health facilities could probably be the factor as similar study conducted by Dogbe et al in 2015 reported false negative results for HBV and HCV among blood donors in Komfo Anokye Teaching Hospital and Bekwai Government Hospital after initial testing with RDT. Weaker health systems and low level of knowledge and skills of laboratory professional in resource constraint facilities indirectly may account for this phenomenon as compared well-resourced laboratories.

On the contrary, the study found commercial donors to be negative for HIV and HBV after testing with ELISA. Due to economic benefit attached to blood donation, commercial donors may be concerned about their health and may refrain from risky behaviors to remain eligible for blood donation.

5.4 Limitations

The study variables were stored samples and therefore blood donors were not around to collect detailed lifestyle information or risk factors.

Findings of this study is limited to the samples selected for the study, hence generalization cannot be made on all RDT screenings in Ghana.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The study found 3.1% and 0.5% of donated blood screened with RDT and labelled safe for transfusion to be positive for HIV and HBV respectively after second testing with ELISA. Evaluation of RDT kits showed that the NPV of First Response Kit was 96.9% whereas In-Tec gave NPV of 97.6%. Although there was no significant association between identified factors and TTI, the false negativity rate of RDT for screening blood donors vary from facility to facility.

It is extrapolated that 3.1% and 0.5% prospective blood recipient exposed to donated blood recruited in this study are at risk of HIV and HBV infection respectively.

The study has shown that RDT is not efficient for screening blood donors for transfusion transmitted HIV and HBV infection and continuous use of RDT for screening blood donors could put prospective blood recipient at risk of HIV and HBV infection.

ELISA has higher sensitivity compared to RDT for screening blood donors and therefore, necessitate for its adoption as the Gold standard for screening blood donors in Ghana.

6.2 Recommendation

To the National Blood Transfusion Ghana

The study showed that ELISA has higher sensitivity compared to RDT for screening blood donors and therefore

1. ELISA should be enforced as the first line of test for screening blood donors.

2. In resource limited settings, RDT-negative results should be confirmed with ELISA in a serial testing algorithm for screening blood donors.

To National AIDS Control Program and Public Health Reference Laboratory

1. There should be continuous assessment of rapid kits for screening blood donors.
2. There should be a strengthened surveillance system to ensure blood transfusions in the country are safe.
3. The sampling method employed in this study could be incorporated into the HIV Sentinel Survey as part of surveillance to ensure blood transfusions are safe in the country.

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