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Syphilis screening practices in blood transfusion facilities in Ghana

Francis Sarkodie [a,b,*], Oliver Hassall [b], Ellis Owusu-Dabo [c,d], Shirley Owusu-Ofori [a], Imelda Bates [b], Ib C. Bygbjerg [e], Justina Kordai Ansah [f], Henrik Ullum [g]

[a] Komfo Anokye Teaching Hospital, Kumasi, Ghana
[b] Liverpool School of Tropical Medicine, Liverpool, UK
[c] School of Public Health, Kwame Nkrumah University of Science and Technology, Kumasi, Ghana
[d] Kumasi Centre for Collaborative Research, Kwame Nkrumah University of Science and Technology, Kumasi, Ghana
[e] Department of Public Health, University of Copenhagen, Copenhagen, Denmark
[f] National Blood Service, Accra, Ghana
[g] Department of Clinical Immunology, Copenhagen University Hospital, Copenhagen, Denmark

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SUMMARY

Objectives: The primary objective of this study was to compare laboratory practices for screening blood donors for syphilis at blood transfusion facilities in Ghana with the recommendations of the World Health Organization and the National Blood Service, Ghana (NBSG). The prevalence of syphilis antibodies in blood donors in Ghana was also estimated.

Methods: Over an 11-month period, from February 2014 to January 2015, a semi-structured questionnaire was administered to 122 laboratory technical heads out of a total of 149 transfusion facilities in Ghana. The response rate was 81.9%.

Results: A total of 58 (48%) transfusion facilities tested donors for syphilis, with an estimated 3.7% seroprevalence (95% confidence interval 3.6–3.8%). A total of 62 782 out of 91 386 (68.7%) donations were tested with assays that are not recommended. The estimated syphilis seroprevalence in voluntary donations was 2.9%, compared to 4.0% in family donations ($p = 0.001$). Only 6.9% of the health facilities were using standard operating procedures (SOPs).

Conclusions: Despite international and national recommendations, more than half of the studied health facilities that provide blood transfusions in Ghana are not screening blood donations for syphilis. These data show a considerable mismatch between recommendations and practice, with serious consequences for blood safety and public health.

1. Introduction

Early reports of the transfusion-related transmission of syphilis led to the World Health Organization (WHO) recommendations for syphilis testing of blood donors.[1] These recommendations have been questioned, since many syphilis antibodies among blood donors are the result of previous infections or even unspecific reactions. Furthermore, *Treponema pallidum* does not withstand cold storage.[2] However, as not all blood components can be assumed to be kept cold for a sufficient amount of time, if at all, and as syphilis may also serve as a potential surrogate marker for high risk behaviour in relation to HIV infection, syphilis screening continues to be a requirement in many countries.

There have been several studies conducted in many African countries indicating a high prevalence of syphilis antibodies in healthy blood donors.[3] The WHO recommends several syphilis screening tests: the enzyme immunoassay (EIA) and *T. pallidum* haemagglutination assay (TPHA) as specific tests, or the Venereal Disease Reference Laboratory (VDRL) and rapid plasma reagin (RPR) as non-specific screening tests.[4] Following a documented case of transfusion-transmitted syphilis in Ghana in 2011,[5] it was recommended that syphilis testing for blood donors be implemented so that recipients of blood transfusions would not be at risk of contracting syphilis.

* Corresponding author at: Komfo Anokye Teaching Hospital, Transfusion Medicine Unit Kumasi, Ghana. Tel.: +233244371770.
E-mail addresses: fsarkodie29@gmail.com (F. Sarkodie), ohassall@gmail.com (O. Hassall), owusudabo@yahoo.com (E. Owusu-Dabo), sowusu_ofori@hotmail.com (S. Owusu-Ofori), ibates@liverpool.ac.uk (I. Bates), iby@sund.ku.dk (I.C. Bygbjerg), kordaiansah@yahoo.com (J.K. Ansah), henrik.ullum@regionh.dk (H. Ullum).

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In Sub-Saharan Africa, blood donations are collected from two main donor categories: voluntary non-remunerated donors (VNRD) and family (replacement) donors (FD). Family donors – who are individuals prompted to provide blood units to replace blood transfused to their relatives or friends[6] – remain dominant on the African continent as a response to difficulties in recruiting and attracting VNRD.[7] However in Ghana, as elsewhere, there is a higher proportion of syphilis seroreactive donations among FD possibly because they are generally older than VNRD and possibly because they are at higher sexual risk.[8]

Out of the many different categories of hospital in Ghana, a total of 149 health facilities across the country practice blood transfusion under the National Blood Service, Ghana (NBSG). Three of the facilities are teaching hospitals located in the Greater Accra, Ashanti, and Northern regions. Ghana has 10 administrative regions and each of them has a regional hospital with bed occupancy lower than the teaching hospitals. However, the 58 district hospitals are distributed unequally. The distribution of the district hospitals is based on the level of development of the region, so some regions have more transfusion centres than others. Likewise, the other health facilities such as the 36 mission hospitals, eight private hospitals, and seven clinics are distributed unequally.

In Ghana, as in many other African countries, the purchase of blood bank reagents is poorly regulated, with local blood banks purchasing whatever reagents are available and affordable. Additionally, the reagent cost per test for syphilis testing in Ghana depends mainly on the bargaining power of the facility management system in the open market. This decentralized purchasing system may lead to increased costs of reagents, as well as failures in quality and consistency. In addition to decentralized reagent purchasing, the lack of written standard operating procedures (SOPs) and effective transfusion-transmitted infection (TTI) guidelines for donor care may hamper quality and care. To ensure the safety, efficacy, and adequacy of blood and blood products for patients, the Ghana National Blood Policy, which was approved by the cabinet in 2006, states that all blood units collected must be tested prior to transfusion for TTIs including syphilis, using approved, well-controlled techniques and procedures and in accordance with WHO guidelines. Furthermore, the NBSG should be responsible for the purchasing of well-approved test kits before use.

This survey compared current syphilis screening practices in Ghana with the recommendations of the WHO and NBSG regarding the use of assays for screening blood donors and their performance. The prevalence of syphilis antibodies in blood donors was also estimated. Additionally, the survey determined whether written SOPs or guidelines were in place for syphilis screening and whether donors with positive syphilis tests were referred for clinical follow-up.

2. Materials and methods

It was intended to interview the laboratory technical heads of all 149 transfusion facilities in Ghana between January 2014 and February 2015 and to request their 2012 syphilis screening results. The survey was conducted using a semi-structured questionnaire administered by telephone call or e-mail. Contact numbers and e-mail addresses were obtained from the NBSG headquarters in Accra and other laboratory science colleagues in the various transfusion facilities in the country. Seventy-three (60%) of the technical heads responded immediately by telephone, while 24 (20%) of them were interviewed twice before providing all of the information by telephone; 25 (20%) provided information through a semi-structured questionnaire by e-mail. The total number of non-respondents was 27 (18.4%); most of these were in remote areas.

2.1. Statistical analysis

Data from the interviews were collected using Epi Info version 3.5.3 (US Centers for Disease Control and Prevention, Atlanta, GA, USA), transferred into an Excel spreadsheet, and exported into Stata version 12.0 statistical software (StataCorp LP, College Station, TX, USA) for analysis. Prevalence was estimated by calculating proportions and providing their respective confidence intervals (95% CI).

2.2. Ethics statement

Approval for this survey was obtained from the ethics committees of Kwame Nkrumah University of Science and Technology (KNUST), Kumasi, Ghana (CHRPE/AP/423/13) and the Liverpool School of Tropical Medicine, Liverpool, UK (18/02/2014). Furthermore, an introductory letter was sent to all of the respondents from the head of the NBSG, with the assurance of their anonymity in the use of their data.

3. Results

3.1. Facilities and testing

Of a total of 149 health facilities known to be undertaking blood transfusion, 122 (81.9%) responded to the inquiry. In 2012, the total number of donations collected and screened for TTIs (HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV)) other than syphilis from the 122 transfusion facilities responding to the survey was 143 787 (Table 1). From the questionnaire administered, it was found that none of the centres was using a second test to re-screen syphilis-reactive donations.

The total number of transfusion facilities not screening for syphilis was 64 (52%). When asked for the reasons, 49 facilities (77%) reported a lack of funds to purchase reagents. Fourteen facilities (21%) reported that although syphilis screening is recommended, the refrigeration of blood units for more than 5 days kills *T. pallidum*. One transfusion facility (2%) reported that screening for syphilis was not mandatory.

The total number of donations at the 58 (48%) transfusion facilities screening for syphilis was 91 386 units, of which 3371 were syphilis antibody seroreactive, resulting in an estimated seroprevalence of 3.7% (95% CI 3.6–3.8%). Of the facilities screening for syphilis, two of the three (67%) teaching hospitals screened for syphilis and contributed the highest percentage (40.4%) of the total donations. Furthermore, eight of the 10 (80%) regional hospitals screened for syphilis, but contributed only 17.7% (16 009/91 386) to the total donations, whilst 12 of the 36 (33%) mission hospitals screened for syphilis and contributed 15.4% (14 064/91 386) to the total donations, as shown in Table 1. Among the seven clinics, only three (43%) screened for syphilis and these contributed the least (1%) donations. However, the teaching hospitals reported the lowest syphilis rate of seroreactivity (3.2%), with the highest coming from the mission facilities (4.4%). Notably, almost half of the district hospitals did not test for syphilis.

3.2. Donor type and syphilis seroreactivity

The total number of donations screened for syphilis was 91 386 (63.6% of 143 787). The total number of voluntary donations screened for syphilis was 26 180 (28.6%, 95% CI 28.4–28.9%), with 757 (2.9%) testing positive. Of the total of 65 206 (71.4%) family/replacement donations, 2614 (4.0%) tested positive for syphilis

Table 1
Results of the syphilis screening survey in Ghana—January to December 2012

Health facility	Number of screening sites	Number of donations screened for TTIs other than syphilis	Centres screening for syphilis (%)	Number of donations (proportions) screened for syphilis –2012	Average number of donations screened per health facility per day	Number and proportion of donor types screened			Seroreactive and estimated prevalence (%)	
						VNRD	FD	Total	VNRD	FD
Teaching	3	56 951	2 (67)	36 951 (64.9)	51	13 390 (36.2)	23 561 (63.8)	1176 (3.2)	424 (3.2)	752 (3.2)
Regional	10	19 768	8 (80)	16 009 (81.0)	6	5241 (32.7)	10 768 (67.3)	578 (3.6)	74[a] (1.4)	504[a] (4.9)
District	58	36 650	30 (52)	20 571 (56.1)	2	4305 (20.9)	16 266 (79.1)	853 (4.1)	95[a] (2.2)	758[a] (4.7)
Clinic	7	2343	3 (43)	879 (37.5)	1	99 (11.3)	780 (88.7)	35 (4.0)	3[a] (3.0)	32[a] (4.1)
Private	8	4503	3 (38)	2913 (64.7)	3	383 (13.1)	2530 (86.9)	107 (3.7)	11[a] (2.9)	96[a] (3.8)
Mission	36	23 572	12 (33)	14 063 (59.2)	3	2762 (19.6)	11 301 (80.4)	622 (4.4)	150[a] (5.4)	472[a] (4.2)
Total/ average	122	143 787	58 (48)	91 386 (63.6)	4	26 180 (28.6)	65 206 (71.4)	3371 (3.7)	757[a] (2.9)	2614[a] (4.0)

TTIs, transfusion-transmitted infections; VNRD, voluntary non-remunerated donors; FD, family donors.
[a] Significant.

(Table 1). This indicates that the rate of syphilis seroreactivity from FD in its totality for this survey was significantly higher than the rate from VNRD ($p = 0.001$). However, there were differences in syphilis seroreactivity depending on the health facility in terms of VNRD and FD: while there was no difference between VNRD and FD in syphilis seroreactivity in the teaching facilities (Table 1), there were differences in the other health facilities, where FD seroreactivity was significantly higher than VNRD seroreactivity, except at the mission facilities, where VNRD seroreactivity was significantly higher than FD seroreactivity. However, the data received from the transfusion centres across the country did not indicate the sensitivity and specificity of the type of syphilis test used.

3.3. Recommended assays and other assays for syphilis testing, and operating them

Of the total donations screened for syphilis in this survey, 31.3% were tested using a recommended assay (TPHA; Fortress Diagnostics Limited, Antrim, UK). The non-recommended methods used were all rapid diagnostic tests (RDTs), with 60% reporting ACON as the brand name (ACON Laboratories, Inc., San Diego, USA). Of the others, 19% reported First Response (Premier Medical Corporation Limited, Kachigam, India), 12% ABON (Abon Biopharm Company Limited, Hangzhou, China), 5% Fortress (Fortress Diagnostics Limited, Antrim, UK), 3% Wondfo (Guangzhou Wondfo Biotech, Guangzhou, China), and 1% Determine (Allere Medical Company Limited, Matsuhidai, Japan).

Forty-seven percent of the transfusion facilities validated their syphilis test kits before screening, while only 7% had written SOPs (Table 2).

The hospital management of 52 (89.7%) transfusion facilities purchased syphilis screening reagents on the open market (Table 2). The variation in cost per test strip for syphilis screening varied 10-fold, from US$ 0.2 to US$ 2.0.

3.4. Follow-up of syphilis seroreactive donors

Only 33 (56.9%) facilities referred syphilis-reactive blood donors for clinical advice (Table 2).

4. Discussion

This survey aimed to describe syphilis screening practices and seroprevalence for blood donors in transfusion facilities in Ghana. The estimated national syphilis seroprevalence of 3.7% in this survey is similar to that found among healthy blood donors elsewhere in the region.[9–11] The high occurrence of syphilis has provoked a greatly heightened emphasis on safety, with significant implications in relation to complexity and cost. The study found that about half of the studied facilities in Ghana were not screening blood donations for syphilis, which could lead to syphilis transmission through blood transfusion. Of those facilities that were found to screen donated blood for syphilis, only a third used a recommended test. Among those facilities that were screening, half were not validating the kits, and of donors found to be syphilis-seropositive, more than a third were not referred for further clinical management.

Many parts of the world have reported syphilis seroreactivity rates among FDs similar to that found in the present study.[8,12,13] One reason for the high rates is that FDs are older and therefore have had a longer time to acquire syphilis antibodies. However, FDs may be under pressure to donate blood when their relatives are admitted to hospital and in need of a blood transfusion, even when they know that they are potentially at risk of sexually transmitted diseases as a result of high-risk behaviours. They may

Table 2
Results of the syphilis screening survey in Ghana – 2012

Health facilities	Number of centres that validated test kits[a] *n* = 58, (%)	Number of centres with written SOPs *n* = 58, (%)	Number of centres that referred for clinical advice *n* = 58, (%)	Proportion of reagents purchased by hospital management *n* = 58, (%)	Donations screened with recommended assays (TPHA) *n* = 91 386, (%)	Non-recommended assays (RDTs) used at the screening sites
Teaching	2 (3.4)	1 (1.7)	2 (3.4)	2 (3.4)	25 726 (69.6)	Fortress
Regional	7 (12.1)	1 (1.7)	7 (12.1)	8 (13.8)	0	ACON, First Response, and Determine
District	12 (20.7)	1 (1.7)	16 (31.0)	28 (48.3)	612 (3.8)	ACON, ABON, First Response, and Wondfo
Clinic	0	0	1 (1.7)	1 (1.7)	165 (18.8)	ABON
Private	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)	2062 (67.7)	Syphilis ultra-rapid test
Mission	5 (8.6)	0	8 (13.8)	12 (20.7)	0	ACON and First Response
Total	27 (46.5)	4 (6.9)	33 (56.9)	52 (89.7)	28 565 (31.3)	

SOPs, standard operating procedures; TPHA, *Treponema pallidum* haemagglutination assay; RDTs, rapid diagnostic tests.
[a] Validate: prove the efficiency of a test kit.

be more likely to conceal a relevant medical history and the risky sexual behaviours that predispose them to infections and thus pose a threat to the safety of the blood supply. Despite this, family donations remain dominant in the African continent because family and community ties are often considerably stronger than in other types of society; making the gift of blood is a natural contribution to relieve sufferers in hospitals.[7] Additionally, potential donors may be less willing to donate to someone not known to them. The WHO states that blood from VNRDs who give blood out of altruism is the safest source of blood.[1]

The survey demonstrated that only 6.9% of the facilities followed written SOPs, indicating poor quality systems where these should play a vital role in blood safety. Written and followed SOPs are an integral part of a quality system, as they facilitate consistency in the performance of procedures in accordance with standards. There have been several recommendations from the WHO that each transfusion service should develop written SOPs as guidelines covering all procedures in the testing of donated blood.[14] The WHO has specified that consistency and reliability of performance in conformity with specified standards raises the quality of systems in promoting blood safety. Unfortunately, an earlier exercise carried out by the Ministry of Health (which was reported in the Ghana National Blood Policy) to determine the status of the blood services in regional and district health facilities in 2006, revealed that the quality assurance programme including SOPs that had been written and followed was under-developed and that the equipment at all sites was generally inadequate. The present survey confirmed the existence of major problems within quality assurance systems and the supply of logistics services.

Previously the NBSG had an external quality assessment (EQA) programme only at its headquarters. However the NBSG checks internal quality assessment (IQA) processes at other blood banks elsewhere in the country. As indicated earlier, because the NBSG does not have absolute control over the purchasing of reagents at individual health facilities, it becomes challenging to make recommendations on IQA.

The finding that 56.9% of facilities referred syphilis-reactive blood donors for clinical advice suggests that, at the other 43.1% of facilities, syphilis reactive donors remained untreated and potentially infectious and could be transmitting the disease to others. This represents a substantial public health failure.

The variation in costs for syphilis screening has significant cost implications, particularly in resource-poor settings in Sub-Saharan Africa. There is little published information on the variation in costs per test for syphilis, but reported costs range from US$ 0.3 to US$ 4.5.[15] In Ghana, the cost variation in syphilis test kits exists due to a lack of guidelines to indicate the effective and accepted test kits and their costs. As a result, many test kit types are available on the open market without proper validation and at different costs. For quality and consistency, the NBSG should be responsible for purchasing approved test kits before use in order to provide safe blood. The present survey did not indicate whether centralized purchasing would necessarily lead to lower prices, but it may help to reduce the cost variations and more importantly, would ensure proper validation.

The techniques used for syphilis screening are different from one country to another: the VDRL or RPR alone for some, and the VDRL and TPHA for others.[1] Tests and algorithms should be selected so that they correspond with the prevalence of the disease and match the technical expertise of the personnel and the availability of reagents and equipment.[16] The selection criteria for a screening strategy must include simple techniques, reliability, sustainability, and cost-effectiveness. Although they are not recommended for blood banks in Africa, rapid test techniques may be preferred because of their affordability, user-friendliness, the availability of test materials, and good sensitivity and specificity; furthermore they do not require sophisticated laboratory materials.[16]

The WHO recommends that each country should decide on the TTIs to be screened for as part of the blood screening programme and develop a screening strategy appropriate to its specific situation, influenced by the incidence and prevalence of infection, the capacity and infrastructure of the blood service, and the costs of screening.[17] The critical factor is the effective implementation of the strategy selected and the consistency of implementation within a well-managed quality system. The NBSG does recommend standardized syphilis screening of all donated blood, but this survey revealed that the guidelines were not generally being followed and serves as an example of the consequences when national guidelines are made without structures to enforce them and without the resources needed to implement them locally.

This survey was not able to reach all of the transfusion facilities in Ghana, but since the facilities that were omitted represented a very small proportion of the total number of donations screened for syphilis it is likely that the results provide a true reflection of the national situation. The study relied on information provided by telephone and e-mail. Resource constraints meant that it was not possible to substantiate the findings first-hand. Nevertheless, this was considered the best methodology with the resources available because some transfusion facilities are located in remote areas with challenging roads. The estimated prevalence may not be a perfect reflection of the epidemiological situation in Ghana. This is because the donor population that was not screened could have had a higher or lower prevalence of syphilis than the screened population. For the population that was actually screened, variation in screening practices may have led to both under-reporting due to a lack of

sensitivity or over-reporting due to poor specificity of the screening tests used.

From the questionnaire administered it was found that none of the centres was using a second test to re-test syphilis-reactive donations, for example a non-treponemal test to detect active infection. Therefore it is difficult to estimate how many donations may have been infective, and how many patients receiving a blood transfusion are potentially at risk. It is planned to examine this in a further study.

In conclusion, there is a relatively high prevalence of syphilis reactivity in the blood donor populations in Ghana, as elsewhere in Sub-Saharan Africa. However, there is a low syphilis testing rate and a relatively high use of non-approved, non-validated test kits (RDTs) for syphilis screening, obtained at different costs, in Ghana. If these rapid tests are effectively validated and managed, they could be incorporated into the existing guidelines to enhance blood safety. However the considerable mismatch between recommendations and actual practice for syphilis screening may compromise blood safety. Further studies on syphilis RDTs for blood donors are suggested, in order to improve their application in resource-poor settings.

In terms of recommendations, as shown in Table 1, screening with the TPHA or a *T. pallidum* IgG-specific ELISA would be more appropriate for the workload in teaching hospitals compared with the other health facilities. It is recommended that teaching hospitals perform syphilis screening using current generation equipment for testing (e.g., TPHA or *T. pallidum* IgG-specific EIA), and that the smaller facilities use validated RDTs for testing. The challenge might be the cost implications, but we must also think of cost-effectiveness as a public health issue. It is also recommended that the NBSG ensure that written SOPs are developed and incorporated into the laboratory guidelines for screening as part of strong quality systems in the health facilities across the country, and that all syphilis-reactive donors are referred for clinical advice.

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