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Association between Blood Donor's Socio-demographic Profile and their HIV Risk Status based on the Donor History Questionnaire; A Cross-Sectional Study of 5967 Filipino Blood Donors

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Abstract

Background: Transmission of Human Immunodeficiency Virus (HIV) through blood transfusion is currently a public health issue in the Philippines. This study examined which socio-demographic characteristics of blood donors are associated with a high-risk status for transfusion transmitted infections (TTI) based on the Donor History Questionnaire (DHQ) and compared the risk status of the donor with their actual HIV status.

Methods: A total of 5967 potential blood donors were assessed for their eligibility as a donor and the risk status (high vs. low) were ascertained using the DHQ. HIV screening and confirmatory testing for all donor-respondents, regardless of risk status, was done to compare their risk status with their HIV status. Socio-demographic characteristics were collected and linked with the risk status of the donor. Multivariate logistic regression models were used to explore the associations between various socio-demographic characteristics and risk status of the blood donor.

Results: Twenty three percent (1400/5967) were categorized as high-risk group and 77% as low-risk group. Only 36% (500/1400) from the high-risk group consented while all the low-risk group donors agreed for HIV screening and confirmatory testing. Thirty from the low-risk group turned reactive during HIV screening but only three were confirmed to have HIV. Males [Odds Ratio (OR), 95% confidence interval (95%CI): 1.35 (1.06–1.75)], or who are older than 30 years old [OR (95%CI): 1.53 (1.26–1.87)], were likely to be classified as high-risk while repeat donors [OR (95% CI): 0.63 (0.53–0.77)] were less likely to be classified as high-risk based on the DHQ.

Conclusion: Males or who are older than 30 years old are more likely to being classified as high-risk donors. About 7 out of 10,000 blood donors who were classified as low risk based on the DHQ could be positive for HIV. Mandatory screening of all blood donors for HIV should be maintained in the Philippines.

Introduction

According to the World Health Organization (WHO), the Human Immunodeficiency Virus (HIV) has infected approximately seventy eight million people worldwide. In 2010, one hundred nineteen countries reported a total of 95 million people tested in 131,000 health facilities worldwide that provide HIV testing and counselling. Furthermore, by the end of 2013, about 35.0 (33.2–37.2) million people were living with HIV/AIDS and around 1.5 (1.4–1.7) million people died of AIDS-related illnesses [1].

Although previously considered as low and slow in the Philippines, transmission of HIV through blood transfusion is becoming an increasing concern in the country. Data from the National Epidemiology Center of the Department of Health (NEC-DOH) have shown more than a two thousand fold increase in documented confirmed HIV among accepted blood donors from 1998 until 2012 with an average of about 10 new cases everyday. In August 2014, there were 509 new HIV antibody sero-positive cases, which was 33% higher compared to the same period last year. About 87% of new HIV cases identified in the country have come from men having sex with men (MSM) [2]. From the HIV surveillance study conducted by Gangcuangco et al. from University of the Philippines–Philippine General Hospital (UP-PGH), ninety percent (90%) of the newly infected are single, with majority in the age group 20-34 years old. The highest are among MSMs from Metro Manila, the location site of the

study [3,4]. To ensure blood safety for patients undergoing transfusion, the Donor History Questionnaire (DHQ) has been used as a screening test to determine which blood coming from donors are free from any Transfusion Transmittable Infections (TTIs). All potential blood donors are required to answer the DHQ prior to donating their blood. It is crucial that controls are in place to protect potential blood recipients from TTIs including HIV [5-8].

Donor screening and serological testing have been extensively evaluated in developed countries like Canada, the United States of America, and other European countries [9-13]. However, only a few countries like Australia, Singapore and Thailand in Asia have started to evaluate and improve their blood donor screening procedures [14]. Data on evaluation of the high-risk blood donors as determined by the DHQ have never been studied in the Philippines.

We estimated the percentage of donors with HIV for each risk status based on the DHQ and examined the relationship of socio-demographic profiles with both low and high "risk status" derived from answering the DHQ. The results of the study could hopefully provide information for policy direction of blood products collection without compromising the reliable supply of this life saving product.

Materials and Methods

Study design

This is a cross sectional study of all blood donors who consented to join the study covering the period between August 1, 2011 to January 31, 2012.

Study participants

The study population included all consecutively accepted and deferred volunteer/replacement blood donors, either male or female with ages ranging from 18 to 65 years old. Recruitment of volunteers was done at the Philippine General Hospital's Mass Blood Donation Program. Donors were either volunteer donors, and for in house may be recruitments by relatives or friends of patients in need of blood or blood components. Consent to undergo the reference standard test using Enzyme Linked Immunoabsorbent Assay (ELISA) for HIV was obtained from all participating volunteers.

Donor History Questionnaire (DHQ)

An abbreviated version of the DHQ was used for the study with 19 high-risk items from the original 48 questions released by the US Food and Drug Administration (FDA) in 2006. Most items in the DHQ pertain to risky behaviours including women and men having sex with the same gender, being paid for sexual favours and sex with a person with HIV. Other items in the DHQ included medication history, history of previous blood transfusion, accidental needle stick and ear piercing. Potential blood donors were asked to answer the truncated version of the DHQ. A trained medical technologist was available to clarify or expound on the questions. The medical technologist usually runs through the questions to inquire if the blood donors understand them and if they have any questions. The interaction between medical technologist and volunteers was usually done in a cubicle to ensure confidentiality. An affirmative reply to any item in the questionnaire had categorized the potential blood donor under the high-risk group and had disqualified or deferred the potential donor from donating blood or blood components. However, potential donors, who

answered negative to all the questions, were labelled as "low risk" and were eligible for donation. They subsequently underwent serological testing following quality standards for testing infectious disease markers and counselling [13].

Blood screening for HIV

After completion of the DHQ, potential donors classified to the low-risk group had their blood tested/screened for HIV after getting their consent. For potential donors classified to the high-risk group, consent from the donor was also obtained before blood extraction and testing/screening for HIV was done.

A total of 6104 potential blood donor volunteers answered the DHQ. One hundred thirty seven of the 6104 donor-respondents were excluded from the study due to incomplete data on their DHQ. A total of 5967 potential blood donors were further assessed for their eligibility as a donor and the risk status (high vs. low) were ascertained using the DHQ. Four thousand five hundred sixty seven (77%) of the 5,967 potential donors were classified as low-risk group based on their replies to the DHQ and the remaining 1,400 (23%) of the 5,967 potential donors were classified as high-risk group. However, only 500 of the 1,400 volunteers from the high-risk group consented to have their blood tested/screened for HIV. The remaining 900 of the 1,400 high-risk donors refused to consent for HIV testing/screening and eventually were dropped out of the study. A total of 5067 (85%) of the 5967 potential blood donor volunteers were included in the final analysis.

Donors who were repeatedly reactive to ELISA for HIV underwent confirmation for the virus using Western Blot at the Research Institute for Tropical Medicine (RITM), the National Reference Laboratory of the Philippines. Once a blood donor was confirmed positive for HIV, the patient was referred to a trained member of the HIV/AIDS Core Team (HACT) of the hospital for counselling and proper referral for treatment. This study had ethics approval from the Research Ethics Board of the University of the Philippines, Manila.

Statistical analysis

Associations between the risk status and the socio-economic factors were estimated using univariate and multivariate logistic regression models, which is a standard approach for a cross sectional study design with a binomial outcome. In the regression models, we controlled for age group (15 to 30 yrs. old, 31 to 65 yrs. old), sex, history of donation (first timer, repeater), and occupation (unemployed, white collar, student, clerk/call center, OFW/seafarer, and nurse/doctor). These covariates were chosen a priori as potentially important predictors of risk status. We considered p-values of ≤ 0.05 to be statistically significant. STATA version 11 was used in the analysis.

All the collected data were checked and verified for accuracy prior to further analysis. About 5% of the randomly selected (computerized) data were encoded, matched, and compared with the original data using Epi Info 7. Less than 1% discrepancy or error and with >95% confidence in the proper encoding of the remaining case report forms or samples were used as the basis for assessing that the dataset was clean.

Results

Table 1 shows the baseline characteristics of both the high risk and low risk groups. Mean age of all donors was 30 years old (standard

deviation, SD=9.0). Majority of the donors in the high-risk group were males (82.4%), first time donor (58.4%) and older than 30 years compared to the low risk group who were younger, (mean age: 32.3 years old vs. 29.8 years old, p-value <0.01). All the high-risk donors were donor replacements, a type of donor who volunteers for a patient versus walk in volunteer-donors. Most of the donors in both risk groups had white-collar jobs. There were more first time donors under the high-risk group compared to the low risk group (58.4% vs. 47.3%, p-value <0.01). Thirty out of the 4567 (0.7%) low risk group tested positive for ELISA, however, only 3 out of the 4567 (0.1%) donors were confirmed positive using the Western Blot technique. Moreover, there were no cases of HIV detected under the high-risk group (Table 2).

Characteristics	High Risk (n=500)	Low Risk (n=4,567)	P values
Age (Mean ± SD)	32.3 ± 10.1	29.8 ± 8.9	<0.01
Sex (%)			
Female	17.6	22.5	0.01
Male	82.4	77.5	0.01
History of donation (%)			
First time	58.4	47.3	<0.01
Repeater	41.2	52.6	<0.01
No answer	0.4	0.1	0.15
Type of Donor (%)			
Mass Blood Donation	0.0	13.0	<0.01
Walk In	0.0	1.5	<0.01
Donor Replacement	100.0	85.4	<0.01
Pre–Deposit	0.0	0.1	0.46
Occupation (%)			
Unemployed	23.8	22.0	0.35
Student	24.2	9.7	<0.01
Clerk/ Call center	1.8	1.3	0.35
OCW/Seafarer	4.0	2.7	0.09
Nurse/Doctor	0.2	2.0	<0.01
White collar	66.0	58.8	<0.01
No answer	0.0	3.6	<0.01

Table 1: Characteristics of study participants by low-risk and high-risk groups (N=5,067).

HIV Test Result	High Risk (n=500)	Low Risk (n=4,567)	p values
ELISA[a] Method (%)			
Reactive	0.0	0.7	0.07
Non-reactive/Negative	100.0	99.3	0.07
Western Blot Method (%)			
Positive	0.0	0.1	0.57
Negative	100.0	99.9	0.57

aEnzyme Linked Immunoabsorbent Assay

Table 2: HIV test result for high-risk and low-risk groups (N = 5,067).

Figure 1 shows the risk factors for a high-risk group classification. Among the high-risk group, 20.8% were user of prohibited drugs, 18.2% had low haemoglobin or low haematocrit, 13.2% were men having sex with men, and 13.6% had sexual contact with prostitutes. In addition, <1% of the high-risk groups were either HIV reactive or Rapid Plasma Reagin (RPR) reactive, or were exposed to an endemic area with malaria, or had a sexual partner who use inappropriate needles, or were diabetics, or were aspirin takers.

Figure 1: Risk factors for a high-risk status classification (N=500).

Table 3 tabulates the characteristics of the blood donors from the low-risk group who were HIV positive. Seventy seven percent of the HIV positive donors from the ELISA method were males while all the HIV positive donors from the Western Blot test were also males. All confirmed HIV positives were engaged in white-collar jobs and were donor replacement type of donor.

Table 4 shows the estimated crude odds ratio (OR) and multivariate adjusted OR for the effect of each predictor on the risk status of the blood donor. Univariate logistic regression analysis revealed that being older than 30 years old or being male were significant risk factors for high-risk status [crude odds ratio (OR): 1.56, 95% confidence interval (CI): 1.30–1.88; and crude OR: 1.36, 95% CI: 1.07–1.74, respectively]. In addition, several occupation although not statistically significant were associated with increased risk of being in the high-risk group including call center agents/clerks (crude OR: 1.29, 95% CI: 0.58–2.53), OCW/seafarers (crude OR: 1.38, 95% CI: 0.81–2.25), and white-collar workers (crude OR: 1.04, 95% CI: 0.83–1.30). After adjusting for confounding factors, donors who are older than 30 years old and

males remained risk factors for being in the high-risk status, adjusted OR: 1.53, 95% CI: 1.26–1.87 and adjusted OR: 1.35, 95% CI: 1.06–1.75, respectively.

Discussion

The rationale of administering the DHQ is to defer blood donors who admit to high-risk behaviour. A study in 2012 by Salamat investigated the positive predictive value for the history of jaundice, which is one of the 7 items for hepatitis risk, directed questions using a case control design. Deferral rate for all seven questions was 20% [15]. In this cross-sectional study, we had 1400/5967 or 23% deferrals based on the DHQ. We evaluated the potential socio-demographic factors that contributed to the high-risk status of blood donors. We found that the adjusted odds of being in the high-risk group for males were 35% higher than the odds for females and the adjusted odds for donors who are older than 30 years old were 53% higher than the odds for donors who are 30 years old or younger. Furthermore, the adjusted odds for OCW/seafarers, and call center agents/clerks were 16% and 37%

higher than the odds for the unemployed. Type of donor was not included in the multivariate analysis since almost all were donor replacements. Nonetheless, more studies are needed to verify the results of our study and to develop recommendations for effective blood donation deferral criteria in the Philippines.

Characteristics	ELISA Method	Western Blot Method
Sex (%)		
Female	23.3	0.0
Male	76.7	100.0
Age Group (%)		
15–30 y/o	70.0	66.7
31–65 y/o	30.0	33.3
Type of Donor (%)		
Mass Blood Donation	0.0	0.0
Walk In	0.0	0.0
Donor Replacement	100.0	100.0
Pre–Deposit	0.0	0.0
Occupation (%)		
Unemployed	30.0	0.0
Student	6.7	0.0
Clerk/Call center	0.0	0.0
OCW/Seafarer	3.3	0.0
Nurse/Doctor	0.0	0.0
White collar	60.0	100.0

Table 3: Characteristics of HIV positive blood donors by ELISA method (N=30) and Western Blot method (N=3).

Characteristics	Crude OR [95% CI]	Adjusted OR [95% CI]
Age Group		
15–30 y/o	1.00	1.00
31–65 y/o	1.56 [1.30, 1.88]	1.53 [1.26, 1.87]
Sex		
Female	1.00	1.00
Male	1.36 [1.07, 1.74]	1.35 [1.06, 1.75]
History of Donation		
First-timer	1.00	1.00
Repeater	0.63 [0.53, 0.77]	0.58 [0.48, 0.71]
Occupation		
Unemployed	1.00	1.00
Student	0.40 [0.24, 0.63]	0.49 [0.29, 0.71]
Clerk/Call center	1.29 [0.58, 2.53]	1.37 [0.62, 2.71]

OCW/Seafarer	1.38 [0.81, 2.25]	1.16 [0.67, 1.91]
Nurse/Doctor	0.09 [0.01, 0.42]	0.12 [0.01, 0.55]
White collar	1.04 [0.83, 1.30]	0.98 [0.78, 1.25]

Table 4: Crude and adjusted odds ratio (OR) and 95% confidence interval (CI) of having a high-risk status and the socio-demographic characteristics of the donor (N=5,067).

According to the Philippine HIV/AIDS registry, from January 2014 to September 2014 333 blood units were confirmed positive for HIV by the Research Institute of Tropical Medicine. However, there was no concurrent data on the total number of blood units donated for the same duration. This number can't be translated to the number of donors positive for HIV since one donor can donate more than one unit of blood. Furthermore, HIV positive blood donors may not be in the HIV & AIDS Registry unless they had undergone voluntary counselling and testing as individuals [16]. The Philippines is still a low-HIV prevalence country, with less than 0.1 percent of the adult population estimated to be HIV-positive. The Department of Health (DOH) AIDS Registry in the Philippines reported 22,527 people living with HIV/AIDS in 2014 [17]. In our study, we observed 0.1% (3 out of 4567) of the low-risk donors to be positive for HIV. However, no one in high-risk donor group tested positive for HIV. We hypothesize that if the 900 (64%) of the 1,400 high-risk donors agreed to be tested for HIV, we would have had a higher rate of HIV positive donors in the high-risk group (>0.1%). Testing for residual risks for HIV among the high-risk group, using nucleic acid testing may be warranted however was not done due to budgetary constraints.

In the absence of other cost effective screening tools for HIV in a developing country, the DHQ seems to be a practical alternative to outright blood testing for HIV. In our study, donors who were more likely to be categorized under the high-risk group were those who were too honest not to answer the DHQ truthfully, such as first timer donors and donors who are older than 30 years old. Moreover, in the Philippines, men will likely deny having sex with men but will likely boast having had sexual encounters with female prostitutes. It is also difficult to pursue a study investigating the reliability of the DHQ in a country where HIV remains a stigmatizing disease and consent for testing HIV will be difficult to obtain. Treatment should also be offered to those who eventually turn out positive on blood testing. In the August 2014 report of the Philippine HIV and AIDS registry, only 7,380 people living with HIV are on anti-retroviral therapy distributed at 19 treatment hubs in the country [17]. There was a high rate of refusal to undergo HIV testing from the high-risk group in our study indicating that Filipinos are disinclined to get tested for HIV even if they have been told that they are at a high-risk for the disease. From the results of our study, screening of all blood donors for HIV may be a better alternative to the DHQ.

The cost and adequacy of blood supply remains a major concern in the Philippines, there is a need to determine if deferrals are correctly identified in blood banks. Approximately 35% of blood donors are deferred at UP-PGH, which is similar in other tertiary hospital blood banks and a great number of donors have high-risk behaviours linked to HIV infection (personal communication based from blood bank statistics). Data on evaluation of the high-risk blood donors as determined by the DHQ have never been studied in the local setting. To our knowledge, our study is the first study to assess the socio-demographic profile and risk status based on DHQ of donors in the Philippines.

There are several limitations of our study. First, we were not able to screen and test 900 high-risk donors for HIV, which could affect the number of positive HIV status from the high-risk donors and bias our odds ratio estimates. There were circumstances the donor elected not to complete the questionnaire, some of the donors could have realized that he/she was not eligible to donate, or some simply wish to leave prior to completing the questionnaire. Second, bias due to unmeasured or residual confounding and predictor factors cannot be ruled out. This could bias the effect estimates in either direction. Lastly, since the study population consists of blood donors from one tertiary hospital; the results may not be generalizable to age groups ineligible to donate blood (paediatric), or other ethnic and racial groups, or other blood bank health facilities. The effect of socio-demographic factors on risk status on these other populations should be addressed in future studies. Moreover, nucleic acid testing as an evaluation for residual disease for HIV should also be evaluated in these further studies.

Conclusion

In conclusion, this study documented the associations between socio-demographic factors and risk status based on the donor history questionnaire, an outcome that has the capacity to affect the efficiency of blood donation. Screening of all blood donors for HIV must be a requirement before they can be considered for blood donation.

Acknowledgement

Conflict of Interest

There are no conflicts of interest to disclose. The views expressed in this paper are those of the authors and not to be construed as the official position of the local government. The research proposal was approved by the University of the Philippines-National Institutes of Health, Research Ethics Board in 2011 and given the Identifier NIH-2011-042.

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