

# PRE-DONATION SCREENING OF BLOOD FOR TRANSFUSION TRANSMISSIBLE INFECTIONS: THE GAINS AND THE PAINS - EXPERIENCE AT A RESOURCE LIMITED BLOOD BANK.

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## SUMMARY

**Objective:** To determine whether or not pre-donation testing of blood donors affords substantial cost savings without compromise to blood transfusion safety. Pre-donation testing of blood donors for Transfusion Transmissible Infections (TTIs) is done in most developing countries because substantial cost savings are made from resources, materials and man-hours which would have been spent to procure infected blood units. Simple rapid test kits used in pre-donation testing is not as sensitive as the Enzyme Linked Immuno-sorbent Assay (ELISA) method used in post-donation screening in a quality assured manner.

**Design:** It is a retrospective study where records of pre- and post-donation tests done in donor clinic of University of Ilorin Teaching Hospital, between January and December 2010 were retrieved. All processes and inputs were evaluated and costs calculated for pre-donation testing by simple rapid techniques and post donation screening by ELISA.

**Results:** 5000 prospective donors were tested in the study period. The cost of single rapid Pre-donation testing was less than that of single ELISA Post-donation screen. The cost of double rapid Pre-donation and Post donation ELISA screen exceeded the cost of single post donation ELISA screen. Substantial cost savings were made when single rapid Pre-donation testing is relied on. More blood units were found reactive for the TTIs with the more expensive Post-donation ELISA.

**Conclusion:** Pre-donation testing of blood donors was not cost effective. Although, there is an apparent savings if pre-donation testing is not followed by post-donation ELISA testing, it is done at a compromise to blood transfusion safety.

**Key words:** pre-donation, post-donation, TTIs screening.

## INTRODUCTION

Pre-donation screening of blood donors for Transfusion Transmissible Infections (TTI) is the practice by which a prospective donor is tested for the presence of one or more of the TTI agents by a single rapid or quick method, and donation is deferred if the test is reactive for any of the TTI markers. Universally the normal procedure is to administer a standard questionnaire, measure the haemoglobin concentration and the weight of the donor<sup>1</sup>. The donor is then bled if found fit based on the selection criteria and asked to leave after a period of rest. The donor units are then separated into various components and stored. A third generation ELISA batch analyzer is used to test samples of corresponding donated units. All those non-reactive for viral markers are appropriately labeled and used for transfusion. Those reactive for any of the TTIs are appropriately discarded, including their respective components.

Hepatitis B virus (HBV), hepatitis C virus (HCV), Human immune deficiency virus (HIV) and syphilis are the most important agents causing transfusion transmitted infections (TTIs) and they constitute large health care burdens worldwide. Because of their latent nature prior to clinical presentation, their incidence rates are difficult to calculate.<sup>1</sup> Every blood transfusion therefore carries a potential risk for transmissible diseases.<sup>1,2</sup>

The blood supply and transfusion practice in the United State is one of the safest in the world because they have been based on a combination of strategies including effective donor education and donor recruitment, and collection of blood from repeat voluntary donors, donor retention, pre- and post-donation counseling, donation screening using the most sensitive and specific screening kits and recent laboratory procedures performed in a quality assured manner.

Therefore, the risks of TTIs are extremely low<sup>3</sup>. It is estimated to be about 1 in 677,000 units of blood for HIV<sup>4</sup>, 1 in 103,000 units for hepatitis C virus and 1 in 63,000 units for hepatitis B virus.<sup>3</sup>

Various integrate measures are put in place to make blood transfusion safe. These measures include the recruitment of voluntary non-remunerated donors; effective donor education and careful donor selection; and the use of sensitive laboratory screening of donated blood.<sup>5</sup> These measures together have resulted in a very low residual risk for TTIs.<sup>6</sup> Comparable results for TTIs risks are found in most developed countries. In Australia the risks are 1 in 633,000 units for HBV, 1 in 6,387,000 units for HCV and 1 in 9,242,000 units for HIV.<sup>7</sup>

The objective of pre-donation TTI testing is to save resources, materials and man-hours which would have been spent to procure donor blood which could not be used in therapy and reduce the discard rate of donated blood. By performing pre-donation testing the infected prospective donor is spared the trouble of going through the donation process unnecessarily and the discard rate of donated blood is reduced. Pre-donation TTI testing is the standard practice in many Hospital-based blood transfusion services in developing countries like Nigeria.

A major consumable for blood collection is the imported blood bag hence pre-donation testing and deferral of unsuitable prospective donor/s is assumed to produce substantial cost savings on procurement of blood bags. It appears however that the basis for such assumption has not been clearly established. All related financial costs and the implications for blood safety must be factored in to justify routine Pre-donation testing of blood donors. This study was carried out to establish whether or not Pre-donation testing affords substantial cost savings without compromise to blood safety.

## MATERIALS AND METHODS

In the University of Ilorin Teaching Hospital, pre-donation TTI testing is done after the prospective donor has passed the haemoglobin check. Two rapid test systems are used to test for HIV, namely Determine and Unigold. The single rapid kit used for testing HBsAg is the ACON while Diaspot is used for testing HCV. Donation is deferred when the blood sample of a prospective donor is reactive for any of the TTI markers. Blood donated by donors found non-reactive on pre-donation TTI testing is later subjected in batches to routine Post-donation ELISA testing for the three TTI markers.

All records of Pre and Post-donation tests carried out in the donor clinic of University of Ilorin Teaching Hospital between January and December 2010 were reviewed. All processes and inputs were evaluated. Costs were calculated for Pre-donation testing by simple rapid techniques and Post-donation testing by ELISA for blood samples from all prospective donors.

The compared costs were also computed for both Pre-donation testing of all prospective donors and Post-donation testing of blood samples of donors who eventually donated blood. All costs were compared.

We also compared the number of samples that were reactive with rapid testing and the number that were reactive with ELISA.

### RAPID TEST KITS

DETERMINE (Inverness Medical Japan Co. Ltd) is an immunochromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2.

UNIGOLD (by Trinity Biotech Plc, Ireland) is a single reagent assay for the detection of antibodies to HIV-1 and 2 in serum, plasma or whole blood.

ACON (ACON Laboratories, Inc, San Diego, USA) is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in whole blood, serum or plasma.

DIASPOT (Reagent by USA) is also a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum or plasma.

### ELISA TEST KITS

GENSCREEN PLUS HIV Ag-Ab (Bio-Rad, Raymond Poincare 92430, Marnes Coquettes and France) is an enzyme immunoassay for the detection of HIV infection, based on the detection of antibodies to HIV 1 and 2 and the HIV 1 Ag in human serum or plasma.

MONOLISA HBsAg ULTRA (Bio-Rad, Raymond Poincare 92430, Marnes Coquette, France) is a one-step enzyme immunoassay based on the principle of the sandwich type using monoclonal antibodies and polyclonal antibodies selected for their ability to bind themselves to the various subtypes of HBsAg now recognized by WHO and the most part of variant HBV strains.

## RESULTS

Approximately 5000 prospective donors presented at UITH donor clinic between January and December 2010 and were tested. Eight hundred (800) of these prospective donors were deferred after simple rapid testing.

Table 1 shows the unit costs of various inputs required for different testing methods for TTIs in Nigeria Naira (N) and in US Dollar (\$).

**Table 1** Unit cost of various inputs required for simple rapid testing and ELISA screening at UITH.

Cost of HIV simple rapid screen/unit by Determine	N100 (\$0.62)
Cost of HIV simple rapid screen/unit by Uni-gold	N250 (\$1.5)
Cost of HBsAg simple rapid screen/unit	N80 (\$0.5)
Cost of HCV simple rapid screen/unit	N70 (\$0.4)
Cost of HIV ELISA/unit	N945 (\$5.7)
Cost of HBsAg ELISA/unit	N600 (\$3.6)
Cost of HCV ELISA/unit	N600 (\$3.6)
Cost of Blood bag/unit	N200 (\$1.2)
Cost of consumable/unit	N100 (\$0.6)

Three million eight hundred and forty thousand naira (N3,840,000 (\$23,040)) was the cost of pre-donation

screening by rapid method for 5000 prospective donors, Table 2.

Twelve million eight hundred and forty nine thousand Naira (N12,849,000 (77,094)) was the total cost for pre-donation screen of the 5000 prospective donors in addition to post-donation ELISA testing of 4200 blood samples from respective donors who were found suitable to donate, Table 2.

Twelve million two hundred and twenty five thousand Naira (N12, 225,000 (\$73,350)) was the total cost for ELISA testing without pre-donation screen of all the 5000 prospective donors, Table 2.

In UITH, approximately 75% of all donated blood is used on emergencies. Three million two hundred and sixty five thousand two hundred and fifty Naira (N3, 265,250 (\$19,592)) was the total cost for post-donation ELISA screening of samples of donated units remaining after emergency use, Table 3

**Table 2** Total cost expended with simple rapid pre-donation testing only, simple rapid pre-donation testing plus ELISA and ELISA screening only.

Simple rapid pre-donation testing of blood donors only		Simple rapid pre-donation testing of blood donors plus ELISA screen of donated blood units		Pos-donation ELISA screen of donated blood units	
Procedure	Amount N(\$)	Procedure	Amount N(\$)	Procedure	Amount N(\$)
Pre-donation screen of 5000@ N500 (\$3)	N2,500,000 (\$15,000)	Pre-donation screen of 5000 @ N500 (\$3)	N2,500,000 (\$15,000)	ELISA for 5000 @ N2,145 (\$13)	N10,725,000 (\$64,350)
Blood bags for 4200@ N200 (\$1.2)	N840,000 (\$5,040)	Post-donation ELISA testing of 4,200 @ N2,145 (\$13)	N9,009,000 (\$54,054)	Blood bags for 5000 @ N200 (\$1.2)	N1,000,000 (\$6,000)
Consumables for 5000 @ N100. (\$0.6)	N500,000 (\$3,000)	Blood bags for 4,200 @ N200 (\$)	N840,000 (\$5,040)	Consumables for 5000 @ N100 (\$0.6)	N500,000 (\$3,000)
TOTAL	N3,840,000 (\$23,040)	Consumables for 5000 @ N100 (\$0.6)	N500,000 (\$3,000)	TOTAL	N12,225,000 (\$73,350)
		TOTAL	N12,849,000 (\$77,094)		

**Table 3** Cost expended on post-donation ELISA screening of 800 donated units found reactive to pre-donation simple rapid testing and ELISA screening of units remaining after emergency use.

Post-donation ELISA screening of 800 units found reactive to simple rapid testing		Post-donation ELISA screen of donated units remaining after emergency use	
Procedure	Amount N(\$)	Procedure	Amount N(\$)
ELISA for 800 @ N2,145 (\$13)	N1,716,000 (\$10,296)	ELISA for 1250 units @ N2,145 (\$13)	N2,681,250 (\$16,088)
Blood bags for 800 @ N200 (\$1.2)	N160,000 (\$960)	Blood bags for 4200 units @ N200 (\$1.2)	N84,000 (\$504)
Consumables for 800 @ N100 (\$0.6)	N80,000 (\$480)	Consumables for 5000@ N100 (\$0.6)	N500,000 (\$3,000)
<b>TOTAL</b>	<b>N1,956,000 (\$11,736)</b>	<b>TOTAL</b>	<b>N3,265,250 (\$19,592)</b>

From Table 2 it is obvious that an excess cost of six hundred and twenty four thousand Naira (N624,000(\$3,744)) was made when post-donation ELISA screen of all donated blood followed pre-donation testing of all donors as compared with post-donation screen of all donated blood only. Also an apparent saving of nine million five hundred and eighty three thousand, seven hundred and fifty naira (N9,583,750 (\$57,503)) was shown when approximately 75% of all the donated blood were used as emergency without further ELISA screen on them.

Eight hundred (800) out of 5000 samples (16%) were reactive with simple rapid testing for the TTIs [259(5.2%) for HIV 1 and 2, 537(10.7%) for HBsAg and 4(0.08%) for HCV] while 850 (17%) [267(5.3%) for HIV1 and 2, 574(11.5%) for HBsAg and 9(0.2%) for HCV] eventually came out reactive with ELISA,

## DISCUSSION

The result of this study shows that pre-donation testing of blood donors is not cost effective. For example, in order to save N160,000 (\$960) on blood bags for the 800 deferred donors, N2,520,000 (\$15,120) was spent to screen, perhaps unnecessarily, the 4200 accepted donors. The alternative to pre-donation testing of blood donors is the post-donation screening of all donated blood by standard ELISA. The cost of ELISA testing for 5000 post donation samples is N12,225,000 (\$73,350), compared to N3,840,000 (\$23,040) for pre-donation rapid testing of 5000 prospective donors.

Thus, a huge sum of N9,583,750 (\$57,503) is apparently saved if pre-donation simple rapid testing is not followed by post donation ELISA testing of donated samples. When the cost of post-donation ELISA testing of blood samples of the 4200 accepted donors (N9,009,000 (\$54,054)) is added to the cost of pre-donation rapid testing of 5000 prospective donors (N3,840,000 (\$23,040)), the total cost is N12,849,000 (\$77,094). The cost of double rapid testing of donors and ELISA testing of donated samples exceeds the cost of single post-donation ELISA by N624,000 (\$3,744), while only N160,000 (960) is saved on blood bags, giving a deficit of N464,000 (\$2,784).

It is therefore apparent that if any saving is to be made, it is done at an incalculable cost of compromise to blood safety when reliance is placed only on pre-donation rapid TTI testing of blood donors. Our study further revealed that approximately 75% of donated blood is used for emergency transfusion before undergoing ELISA testing in our environment. This is what creates the false impression of savings by pre-donation testing of blood donors.

This is not the best practice of blood transfusion, in which reliance is placed on only rapid screening of prospective donors.

Literature comparing the total cost expended in pre- and post-donation testing for TTIs is very sparse, but several studies carried out have been for and against pre-donation TTI testing.<sup>8,9</sup> Pre-donation testing has been found to be highly recommended in eliminating many potential risks for the donors, laboratory staff, blood recipients and their families and the overall society in Pakistan.<sup>8</sup> Another study in Ghana recognized the importance of post donation screening when up to 3% of Hepatitis infected blood were tested positive with post donation sophisticated methods. In this study, they still recommended pre-donation testing of donors but with more sensitive and effective methods, donor screening with questionnaire before donation, donor information and counseling in high prevalence areas because the more sophisticated methods cannot be routinely available to all, in resource poor countries.<sup>9</sup>

Consensus on blood transfusion practice is the same despite varying statistics from various researches all over the world. That is donors are the vital links in the chain of transmission of TTIs via blood transfusion. Therefore careful selection using designed questionnaire, proper screening of the blood (pre- or post-donation) is the priority of all donations and overall transfusion services. With this, professionals in the field will be able to deliver safe end products.

## RECOMMENDATION

It is therefore recommended that pre-donation TTI testing be abolished, and all donated blood be tested by routine ELISA method. However, in order to accommodate emergency use of blood, simple rapid testing of donors for TTIs may be done pre-donation in addition to ELISA testing of donated blood which should still be carried out post-donation. Patients who may have been transfused with blood showing discordant results must then be followed up and managed accordingly.

Apart from the financial loss incurred, pre-donation testing of blood donors is a form of inconvenience and time wasting to the prospective donor and can lead to discouragement of true voluntary donors. It should be mandatory to carry out the usual pre-donation selection using standard questionnaire and post donation screening of donated blood in all our blood banks.

Family replacement donation, which is the main form of donation in resource poor countries like ours and which contributed to the high prevalence of TTIs, should also be discouraged.

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