bjh review

# Moving on from voluntary non-remunerated donors: who is the best blood donor?

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## Summary

Blood transfusion safety in sub-Saharan Africa (SSA) is marred by the high prevalence of infectious agents, chronic blood shortage and lack of resources. However, considerable pressure is applied by richer countries and international transfusion bodies to establish voluntary, non-remunerated blood donors (VNRD) as the only source of blood, excluding the traditional family/replacement donors on the grounds of a higher level of safety. Such a policy increases the cost of a unit of blood by two to fivefold and exacerbates the pre-existing blood shortage. This review provides compelling evidence that first-time VNRD are no safer than family/replacement donors and that only repeat donation provides improved blood safety. In order to limit blood shortage and maintain affordability of the blood supply in SSA, both types of donors should be accepted and both should be encouraged to donate regularly.

**Keywords:** sub-Saharan Africa, blood donor, blood supply, family/replacement donor.

The best blood donor is one who contributes to ensure sufficient blood supply at an affordable cost. This review will demonstrate that the current, western-developed, World Health Organization (WHO)-supported strategy of relying exclusively on the voluntary non-remunerated donor (VNRD) in resource-poor countries is unsupported by evidence and is counterproductive. The evidence presented strongly supports a more liberal and pragmatic approach to blood collection, including family/replacement donors.

For the past 25 years, in a landscape largely obscured by the overwhelming importance given to human immunodeficiency virus (HIV) safety, despite the continuous pressure from international organisations involved in blood transfusion to collect only VNRD blood, most of the blood collected in sub-Saharan Africa (SSA) continues to be collected by small units attached to a wide range of hospitals (Bates *et al*, 2007; Tapko *et al*, 2007). These hospitals rely nearly exclusively on family/replacement donors who, when accompanying their hospitalised loved-ones, constitute a natural resource for the collection of blood to replace the units transfused to their anaemic family member or friend. This resource is not only the most readily available but also the cheapest, because it does not require a costly recruitment and collection process. However, with the imposition of schemes that are generally utilised in rich countries, the use of replacement donors was strongly discouraged on the basis of 'lower level of safety' regarding HIV infection and other transfusion-transmitted infections. The establishment of VNRD-only systems was vigorously promoted, however it was found to be unaffordable unless substantial external help was provided and sustained (Allain, 2010).

This review will examine the evidence both for and against the VNRD-only strategy drawn from the readily available sub-Saharan African literature as well as specific studies designed to consider the issues in epidemiological and economic terms. To a large extent, the conclusions reached contradict those presented in a recent review on the same subject (Erhabor & Adias, 2011).

## Definition of blood donor populations and type of donation

Blood donors in SSA are essentially of three types: volunteer, non-remunerated donors (VNRD), family/replacement donors and paid/professional donors. VNRD are benevolent individuals who give blood for the treatment of patients they do not know. They are approached through different media including radio or television advertisements as well as letters or telephone calls. In addition, talks may be given by blood centre staff in education establishments, religious congregations or community assemblies, either immediately or a few days before a blood collection session. Family/replacement donors are also voluntary and non-remunerated, however their donation is triggered by hospital or blood centre staff and is intended to replace the blood needed by a hospitalised family member or friend in a context of blood shortage. Depending on the setting and the degree of blood shortage, the transfusion

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may only be performed if a replacement blood unit is obtained. In other cases, the patient is transfused with available bloodstock, the replacement donation reducing the cost of the transfusion to the family. Alternatively, the blood is transfused and replaced without a specific advantage being given to the donor or the patient. One argument that has been used in several countries in defence of family/replacement donors is that they are volunteer donors and they are unpaid. Furthermore, they are benevolent, but their altruistic move is limited towards people they know and love instead of being directed towards unknown people. It is true, however, that they are under pressure to donate, particularly when the patient's transfusion is dependent on the replacement.

Blood shortage and the need to replace the transfused blood created a small population of individuals offering to give blood on behalf of the families who were unable to replace the unit, in exchange for substantial remuneration. These paid/professional donors are typically poor; they donate too frequently for their own health and have a high prevalence of viral infections. In all categories, blood donors in SSA are predominantly males and all paid donors are males. A generally high proportion of VNRD are secondary school students aged 16–19 years. Family/replacement donors are typically older, with a median age of 30 years, as opposed to 18 years for VNRD.

The second critical element affecting blood safety is whether the donors are giving blood for the first time (first-time donor) or if they are repeat donors (having given blood within the last year), or lapsed donors if the interval is greater. For both repeat and lapsed donors, blood testing has been performed at least once previously and presumably with negative results, because the donor was not informed that his/her previous donation was rejected for reactivity to a transmissible agent assay. Repeat or lapsed donor's period of time during which a new (incident) infection may have occurred is the time interval between donations. The risk of such infection occurring is considerably less compared to the prevalence of infection present in first-time donors. As a result, repeat/lapsed donors are a pre-selected population with a reduced risk of carrying an infectious agent marker when compared to first-time donors.

## Epidemiological studies in sub-Saharan Africa

Discussion and conclusion regarding the relative safety of a group of individuals intending to give blood depends on the accuracy of the tests and testing algorithm utilised to screen donors or donations. Based on past experience, the current position regarding the interpretation of screening immunoassays is that the positive predictive value is directly proportional to the prevalence of the marker in the population. The high prevalence of anti-HIV and hepatitis B surface antigen (HBsAg) in SSA led many investigators to consider that confirmation or confirmatory algorithms were not necessary. Anti-hepatitis C virus (HCV) prevalence has been reported in the literature to vary between 0·5% and >10% in the same regions (Hladik *et al*, 2006; Fasola *et al*, 2008). This was explained as being the result of local epidemiological factors, as demonstrated by the high prevalence observed in Egypt associated with anti-shistosomiasis treatments dispensed with incorrectly sterilised needles and syringes (Frank *et al*, 2000).

In order to re-examine this issue, a literature search was conducted according to the following selection criteria: sub-Saharan Africa, excluding South Africa, indication of the mode of testing (screening or screening plus confirmation), time period 1994–2010, and accessible through PubMed. The key words were blood donors and Africa, then selected for each sub-Saharan African country. An additional set of key words was blood donors and each sub-Saharan African country. Articles not accessible through Pubmed were not considered as readers of these articles might have considerable difficulties finding them and the standards of such journals might be at a lower level. Studies were selected if the type of donor was identified and if it was indicated whether confirmation of reactive viral marker screening assays was performed or not. Depending on the viral marker considered (anti-HIV, HBsAg, anti-HCV) 36–42 studies originating from 15 to 17 countries in SSA were examined. Individual marker rate of reactivity (non-confirmed) and prevalence (when confirmed) were tabulated and expressed as range and median (Table I). The results clearly indicate that HBsAg prevalence was not significantly different irrespective of the testing mode. Confirmation did not appear necessary, provided a test of high performance for both sensitivity and specificity was utilised (this for instance excludes rapid particle agglutination assays). The data from 27 studies across 12 countries showed that the median prevalence of confirmed anti-HIV was 2·2%. However when only screening test reactivity was used, this rose to 4·4% across 17 studies in seven countries. This result was substantiated by the studies utilising various algorithms for confirmation: the majority retested reactive samples with an alternative screening assay (different manufacturer, similar performance), whereas others used Western blot or peptide assay confirmation. In sub-Saharan African countries where the prevalence of anti-HIV reactivity ranged between 0·6% and

**Table I.** Prevalence according to mode of testing.

| | Prevalence/reactivity (%) | |
|---|---|---|
| Viral marker | Confirmed | Not confirmed |
| HBsAg | | |
| Range | 6·3–18 | 3–20·5 |
| Median | 14·3 | 13·2 |
| Anti-HIV | | |
| Range | 0·1–14·9 | 0·4–8·1 |
| Median | 2·2 | 4·4 |
| Anti-HCV | | |
| Range | 0·1–5·8 | 0·6–8·4 |
| Median | 0·6 | 2·9 |

Data compiled from 22 studies for HBsAg, 21 studies for anti-HIV and 15 studies for anti-HCV.

8·4%, depending on the donor type, only 30–40% reactive samples were confirmed.

The difference was even greater for anti-HCV. Data from 20 confirmed testing studies and 23 reactivity studies from 12 countries demonstrated the percentage of reactive samples was five times higher than confirmed in various donor groups. This issue was specifically addressed in several studies (Candotti *et al*, 2003; Vardas *et al*, 1999, Ampofo *et al*, 2002). As a result, it appears that the true prevalence of anti-HCV across SSA is well below 1%.

## Comparing first-time volunteers and replacement donor epidemiology

The literature examined for the purpose of this article identified several reports comparing screening data from volunteer, replacement and occasionally commercial blood donors in SSA. It has been previously reported that comparing data from VNRD and replacement blood donors was illegitimate because first-time and repeat volunteer donors were not differentiated and repeat donors excluded from analysis. Repeat donors, having been previously tested negative, thus created a biassed low prevalence subpopulation (Allain, 2010). Appropriate comparison is therefore limited to first-time VNRD who represent the majority of volunteer donors in SSA (50–80%) (Fig 1). The comparison between types of donors through the available literature is presented in Tables II and III, which shows the distribution of donor type and test results in the 42 articles examined. Ten articles report on VNRD only, five on replacement donors only and 16 on a mixture of both in various ratios. This distribution does not necessarily reflect the situation in a given country but that of the populations the authors chose to examine.

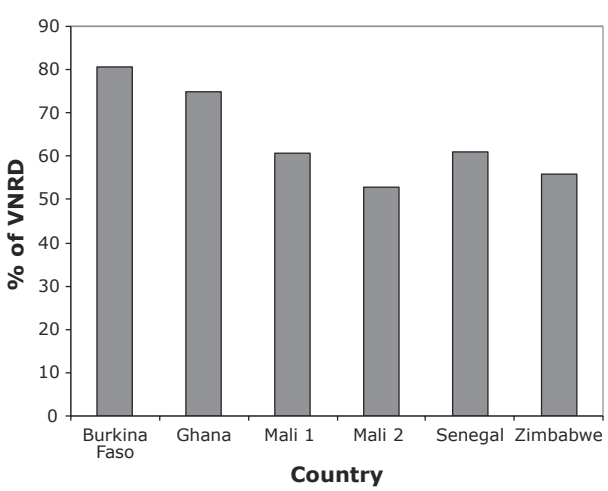


**Fig 1.** Percentage of first-time volunteer non-remunerated donors in various countries of sub-Saharan Africa. The percentage of first-time donors amongst VNRD ranges between 53 and 80%. (Dahourou *et al*, 2010; Allain *et al*, 2010; Tounkara *et al*, 2009b; Diarra *et al*, 2009; Toure-Fall *et al*, 2009; http://www.bloodbank.co.zw/index.php?option=com_content&task=blogcategory&id=19&Itemid=27).

**Table II.** Type of donors and country of 42 selected articles (References in foot note).

| VNRD* | Replacement | Commercial | Mixture† | Unknown |
|---|---|---|---|---|
| Burkina Faso | Cameroon | Nigeria | Cameroon 8V 92R | Benin |
| Djibouti | Ghana | Nigeria | Cameroon 30V 70R | DRC |
| DRC | Mozambique | | Cameroon 12V 88R | Ethiopia |
| Ethiopia | Nigeria | | DRC‡ 30V 70R | Ghana |
| Guinea | Somalia | | Ghana 40V 60R | Ghana |
| Namibia | | | Ghana 60V 40R | Malawi |
| Senegal | | | Ghana 40V 60R | Nigeria |
| Senegal | | | Ghana 50V 50R | Nigeria |
| Sudan | | | Guinea 18V 82R | Nigeria |
| Uganda | | | Kenya 38V62R | Nigeria |
| | | | Kenya 63V 37R | |
| | | | Mali 30V 70R | |
| | | | Mali 34V 66R | |
| | | | Nigeria 30V 70C | |
| | | | Nigeria 5V 25R 70C | |
| | | | Nigeria 5V 95R | |
| | | | Tanzania 30V 70R | |

*Volunteer non-remunerated donors.

†Type of donor indicated as a percentage of the total followed by donor type: V, volunteer; R, replacement; C, commercial.

‡Democratic Republic of Congo.

References: Collenberg *et al*, 2006; Dray *et al*, 2005; Mulanga-Kabeya *et al*, 1998; Tessema *et al*, 2010; Loua *et al*, 2004; Vardas *et al*, 1999; Toure-Fall *et al*, 2009; Dieye *et al*, 2006; Abou *et al*, 2009; Hladik *et al*, 2006; Mbanya *et al*, 2003; Ampofo *et al*, 2002; Cunha *et al*, 2007; Salawu & Murainah, 2006; Nur *et al*, 2000; Mutimer *et al*, 1994; Oronsaye & Oronsaye, 2004; Mbanya *et al*, 2010; Mbanya & Tayou, 2005; Mbanya *et al*, 2001; Batina *et al*, 2007; Allain *et al*, 2009; Sarkodie *et al*, 2001; Candotti *et al*, 2001; Owusu-Ofori *et al*, 2005; Loua & Nze Nkoure, 2010; Moore *et al*, 2001; Kimani *et al*, 2010; Diarra *et al*, 2009; Tounkara *et al*, 2009b; Koate *et al*, 2005; Ahmed *et al*, 2007; Salawu & Murainah, 2006; Matee *et al*, 2006; Jeannel *et al*, 1998; Mbendi Nlombi *et al*, 2001; Rahlenbeck *et al*, 1997; Candotti *et al*, 2003; Allain *et al*, 2003; Candotti *et al*, 2001; Ejele *et al*, 2005; Erhabor *et al*, 2006; Buseri *et al*, 2009; Jeremiah *et al*, 2008.

Table III shows the prevalence of viral markers from published confirmed and unconfirmed testing results stratified between family/replacement donors, first-time and repeat donors. Firstly, the considerably lower prevalence of viral markers in repeat donors is clearly apparent, justifying the exclusion of this group from population comparisons. Secondly, the differences between the confirmed and unconfirmed data presented in Table I remain apparent for anti-HIV and anti-HCV but not for HBsAg in all categories of donors. Thirdly, in the confirmed data set, the prevalence of HBsAg is higher in VNRD than in replacement donors, the reverse being true for both anti-HIV and anti-HCV although the differences are small for all three markers. Numbers of samples involved in each study are widely variable, making statistical analyses irrelevant.

**Table III.** Comparison of prevalence/reactivity of viral markers according to type of donors and testing mode.

| Viral marker | Donor type | Studies (*N*) | Mean prevalence | |
|---|---|---|---|---|
| | | | Confirmed | Not confirmed |
| HBsAg | Replacement | 8 | 12·0 | 11·6 |
| | First-time VNRD | 8 | 15·1 | 11·4 |
| | Repeat VNRD | 6 | NA | 2·6 |
| Anti-HIV | Replacement | 9 | 3·6 | 5·2 |
| | First-time VNRD | 7 | 2·1 | 3·4 |
| | Repeat VNRD | 5 | 0·03 | 1·3 |
| Anti-HCV | Replacement | 6 | 0·7 | 3·3 |
| | First-time VNRD | 6 | 0·4 | 2·3 |
| | Repeat VNRD | 3 | 0·1 | 0·7 |

NA, not available.

## Studies designed to compare viral epidemiology between first-time VNRD and family/replacement donors

In 2010, three articles reported comparisons of prevalence of HBsAg and anti-HIV in Ghana (Allain *et al*, 2010), Guinea (Loua & Nze Nkoure, 2010) and Cameroon (Mbanya *et al*, 2010). A summary of the data is presented in Table IV. In these three countries, no significant difference in the prevalence of anti-HIV was observed except for Guinea. In two of the countries, the prevalence of HBsAg was significantly higher in first-time VNRD than in replacement donors. As previously described (Allain, 2010), the younger age of volunteers often recruited in secondary schools biassed this population towards lower anti-HIV prevalence but did not affect HBsAg prevalence as hepatitis B virus (HBV) infection is mostly acquired during childhood in West Africa. The same epidemiological comparison was repeated at the Kumasi Blood Centre, Ghana on 5162 first-time volunteer and 6511 replacement donors tested in 2010. Confirmed anti-HIV prevalence was 0·8% and 1·2% and HBsAg 16·4% and 12·6% for VNRD and replacement donors respectively, reinforcing the conclusions reached in 2008 (Allain, 2010; S. Owusu-Ofori, Komfo Anokye Teaching Hospital, Kumasi, Ghana, personal communication).

A recent study from Kenya indicated that volunteer donors had a significantly lower prevalence of confirmed anti-HIV than family donors (Kimani *et al*, 2010). However, this conclusion was based on data from a general population survey, which included questions asking whether 'they had donated blood in the course of 1 year prior to the survey' and 'to state the source of blood donation request: family or friends (FRD), NBTS (voluntary) or others'. The voluntary donor group is highly likely to include many repeat blood donors. Donors rejected at the first donation (first-time donors) were likely to be reluctant to consider themselves as having donated blood. This very indirect study cannot be considered reliable due to the substantial risk of bias.

When compiling data from epidemiological studies in the literature and the specific studies addressing the issue, viral safety is not significantly different between first-time VNRD and family/replacement donors (Allain, 2010). The reason is that both groups are mostly representative of the general population, whether they are students attending secondary schools or families of hospitalised patients. In fact, they reflect the same population taken at different times of their lives and under different circumstances (Allain *et al*, 2010). Differences are not related to the population in question but rather age, as previously mentioned, or gender. Blood collection mobile sessions in male and female schools are equal in population and productivity, explaining the relatively high percentage of female voluntary donors. In contrast, where populations are of mixed gender, such as when collecting in places of worship, public sites or within families, male donors are largely predominant (Sarkodie *et al*, 2001; Matee *et al*, 2006; Cunha *et al*, 2007; Allain *et al*, 2009; Tounkara *et al*, 2009a; Tessema *et al*, 2010), except in Namibia where 58% of donors are female (Vardas *et al*, 1999).

## Eliminating commercial donors and promoting repeat donation

A further factor that misled transfusion organisations to downgrade the safety of replacement blood donors was the inclusion of paid donors. It was therefore difficult to separate the data for the two groups. In the past few years, most countries of SSA have banned commercial donors by law or exclusion has been operated by individual blood centres (Allain, 2010). Very little data is available in the literature regarding viral marker prevalence in commercial donors compared to other types of donors. Such a comparison was

**Table IV.** Comparison of prevalence of viral markers between first-time VNRD and replacement donors in three Sub-Saharan African countries.

| Country (reference) | Viral marker | First-time VNRD (%) | Replacement donors (%) | *P* value |
|---|---|---|---|---|
| Ghana (Allain *et al*, 2010) | Anti-HIV | 69/6640 (1·0) | 50/4360 (1·1) | 0·87 |
| | HBsAg | 919/6640 (13·8) | 649/4360 (14·9) | 0·13 |
| Guinea (Loua & Nze Nkoure, 2010) | Anti-HIV | 26/1784 (1·5) | 42/8956 (0·5) | <0·001 |
| | HBsAg | 259/1784 (14·5) | 1142/8956 (12·8) | 0·047 |
| Cameroon (Mbanya *et al*, 2010) | Anti-HIV | 11/272 (4·0) | 114/3053 (3·7) | 0·9 |
| | HBsAg | 49/272 (18·00) | 233/3053 (7·6) | <0·001 |

**Table V.** Viral marker prevalence in repeat donors from sub-Saharan Africa.

| | | Anti-HIV (% prevalence) | | HBsAg | | Anti-HCV | |
|---|---|---|---|---|---|---|---|
| Country | Number tested | Confirmed | Not confirmed | Confirmed | Not confirmed | Confirmed | Not confirmed |
| Ethiopia | 1989 | | 1·4 | | 3·4 | | 0·6 |
| Guinea | 529 | 0·06 | | | 0·7 | | |
| Mali | 3183 | | 0·4 | | 6·4 | | 0·8 |
| Senegal | 1200 | 0·01 | | 0·2 | | 0·1 | |
| Tanzania | 474 | | 2·0 | | | | |

made in one study from Nigeria (Ahmed *et al*, 2007), though unfortunately test reactivity confirmation was not included. However, the results are informative and show a similar prevalence of reactivity between volunteer and replacement donors (anti-HIV 4·1% and 4·6%, HBsAg 13·5% and 14·1%, 1·4% and 1·8% for anti-HCV respectively) but significantly higher prevalence of all markers in commercial donors (8·1%, 20·5%, 2·8% for anti-HIV, HBsAg and anti-HCV respectively) (Ahmed *et al*, 2007). The ban of paid donors is therefore justified.

At the other end of the spectrum, first-time VNRD who had been tested once and found non-reactive or negative for viral markers are unlikely to be infected in the short period of time elapsed between their first and second or subsequent donations. It is recommended that volunteer donors become regular or repeat donors, donating 2–3 times per year. As a result of having passed previous screening, the prevalence of viral markers in repeat VNRD is considerably decreased compared to first-time VNRD. Tables I and V show the data extracted from the 42 studies examined. In studies where confirmation was performed, the prevalence is very low, less so when only reactivity is provided, reflecting a substantial background of false reactivity.

This analysis clearly shows that, contrary to first-time VNRD and replacement donors, repeat donation is the key to improving blood safety. Unfortunately, in SSA, the majority of volunteer donors are first-time donors (Fig 1), however various strategies have been utilised to promote regular donations, such as Club 25 or organising blood collection sessions in radio stations (Mvere, 2002; Allain *et al*, 2009; Owusu-Ofori *et al*, 2010). The real challenge would be to design strategies aimed at attracting replacement donors to become repeat donors.

## Why should sub-Saharan African countries maintain collecting blood from replacement donors?

Two critical issues overshadow transfusion in SSA: supply and cost. Many reports from individual blood centres or, at a more general level, from the WHO, have emphasised that SSA is experiencing a chronic shortage of blood which becomes more critical during school recesses for Christmas, Easter and summer holidays because of the reliance on secondary school students as VNRD. It is generally accepted that in countries where emergency transfusion for severe anaemia is the main demand, 10 units/1000 inhabitants is required (Tapko *et al*, 2005, 2007; Allain *et al*, 2008; Basavaraju *et al*, 2010; Dahourou *et al*, 2010). Only South Africa and, more recently, Namibia and Botswana meet such criteria. In all other countries, whether they received substantial external help through PEPFAR (President's Emergency Plan for AIDS Relief) or not they failed to reach these targets (Allain, 2010). Blood shortage was shown to be the cause of peri- and post-partum mortality in 26% of women experiencing severe bleeding (Bates *et al*, 2008). In acute paediatric malaria, it is not so much lack of blood but rather the delay between prescribing and transfusing blood that affects mortality (Idro & Aloyo, 2004; Meremikwu & Smith, 2010). As a result, preventing an area that is experiencing blood shortage from collecting all available donors is causing harm to patients and is ethically disputable, particularly when the basis for discrimination between first-time VNRD and family/replacement donors is to assume safety risks that are unsupported by evidence (Dahourou *et al*, 2010).

This policy is further questionable when, as previously pointed out, the cost of replacement donor blood ranges between $12 and $18 per unit but VNRD blood costs $26–$60 per unit (Allain *et al*, 2004, 2010; Bates *et al*, 2007; Bates & Hassall, 2010). The reasons for such a difference include advertising for volunteers, recruiting staff to organise mobile blood collection sessions in schools or public places, obtaining vehicle(s) and driver(s), purchasing small gifts for donors and organising a reward system. While these extra costs can remain moderate and only double the cost of blood when practiced by small blood centres that are usually attached to hospitals, the costs increase substantially when transfusion services are organised in a stand-alone, centralised, automated system, such as those established with substantial external funding in the capitals or large cities of several sub-Saharan African countries. When including facilities, amortisation of equipment, specialised staff and huge overheads, the costs increase by three to fourfold. Being funded by external, affluent sources, Western-developed features of a blood service are often imposed, such as VNRD only, systematic preparation of blood components, automation of testing and IT infrastructure. With

the possible exception of the Zimbabwe blood service in Harare, no centralised, VNRD-only blood system has ever been established in SSA without substantial external funding. That is to say that such a system and the consequent cost of blood is essentially unaffordable with local resources.

## Conclusions

On the basis of the evidence presented above, there is no justification for excluding the well-established and culturally adapted family/replacement blood donation system. In a situation of chronic blood shortage, such an exclusion policy leads to the worsening of blood shortages and might cause harm to patients. Instead of creating or deepening the blood shortage, combining replacement and volunteer blood collection is a legitimate and pragmatic approach to ensure a sufficient blood supply in SSA. Safety improvement relies on repeat donation of either type of donor.

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