CURRENT STATUS ON BLOOD SAFETY AND AVAILABILITY IN THE WHO AFRICAN REGION

REPORT OF THE 2013 SURVEY

World Health Organization
REGIONAL OFFICE FOR Africa

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WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR AFRICA
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ABBREVIATIONS

ACCEL	Academic Consortium Combating Ebola
AfSBT	African Society of Blood Transfusion
AIDS	Acquired Immunodeficiency Syndrome
BTS	Blood Transfusion Service(s)
CAR	Central African Republic
CDC	Centers for Disease Control and Prevention
DRC	Democratic Republic of Congo
EQAS	External Quality Assessment Scheme
ESA	East & South Africa
FFP	Fresh Frozen Plasma
FRD	Family Replacement Donation
GDBS	Global Database on Blood Safety
Hb	Hemoglobin
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTC	Hospital Transfusion Committee
HTLV	Human T Lymphotropic Virus
IST/CA	Intercountry Support Team/Central Africa
IST/ESA	Intercountry Support Team/East and South Africa
IST/WA	Intercountry Support Team/West Africa
MDGs	Millennium Development Goals
MoH	Ministry of Health
NBTS	National Blood Transfusion Service
PDMP	Plasma-Derived Medicinal Products
PEPFAR	President's Emergency Plan for AIDS Relief
RCC	Red Cell Concentrate
SCI	Service Organization and Clinical Interventions
SDG	Sustainable Development Goal
SDS	Service Delivery and Safety
SOP	Standard Operating Procedure
TRALI	Transfusion Related Acute Lung Injury
TTI	Transfusion-transmissible Infection
UHC	Universal Health Coverage
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Educational Fund
UNPOP	United Nation Population Division
VNRBD	Voluntary Non-Remunerated Blood Donation

WHA	World Health Assembly
WHO	World Health Organization
WHO/AFRO	World Health Organization, Regional Office Africa
WHO/HQ	World Health Organization Head Quarters

SUMMARY

This survey was conducted to get updated data on blood safety three years since the last survey to generate relevant information from the Member States which will help to design strategies and interventions for improvement based on a sound evidence-base.

WHO prepared the Blood safety indicator tool using key elements of the questionnaire for the 2013 Global Database on Blood Safety (GDBS). All Member States received the tool online to be filled by a senior staff of the national blood transfusion service (NBTS). All Member States were requested to provide online data from 1 January to 31 December 2013 for compilation and analysis.

Questions asked included those related to administrative information, organization and management, blood donors and blood collection, screening for transfusion-transmissible infections (TTIs), blood component preparation, clinical use of blood and blood components and plasma-derived medicinal products (PDMP). This questionnaire is in Appendix 1.

Countries were divided into three categories based on the subregions that make up the three Intercountry Support Teams (ISTs) in the WHO Africa Region: Central Africa (CA), East and Southern Africa (ESA) and West Africa (WA). Regarding the attainment of the target of the regional strategy on voluntary blood donation, countries were divided into three categories: (i) at least 80%, (ii) between 50 and 79%, and (iii) under 50% of Voluntary Non-Remunerated Blood Donors (VNRBD).

We analyzed data using Microsoft Excel worksheets version 2007 and Microsoft Word version 2007.

Out of the 47 Member States that received the questionnaire, 46 (97.9%) provided a response. There were 9, 20, and 17 countries in IST/CA, IST/ESA, and IST/WA in that order. Only Equatorial Guinea that did not provide data was not considered in the analysis.

Amongst the 46 countries that sent back the data, 38 (82.6%) countries had formulated and adopted a national blood policy, 33 countries (71.7%) had developed a strategic plan for implementing their blood policy, and the transfusion legislation was drawn up in 19 countries (41.3%). Thirty-four countries (73.9%) had national guidelines on the appropriate clinical use of blood and blood products while 13 countries (28.3%) had established a national hemovigilance system.

Twenty-one countries (45.6%) had reached the level of 80-100% VNRBD. The average blood donation rate was 4.7 units/1000 inhabitants, and nine countries were collecting at least 10 units/1,000 inhabitants. The average proportion of VNRBD was 67.0%, and the overall deferral rate was 13.0%.

Forty-four countries (95.6%) were screening hundred percent for HIV, 42 (91.3%) for HBV, 41 (89.1%) for HCV and syphilis. The proportion of units of blood tested for TTIs was 99.9% for HIV, 99.2% for HBV, 98.6% for HCV and 98.3% for syphilis. The median percentage of

reactive blood units to TTIs was 1.3% for HIV, 4.2% for HBV, 1.0% for HCV and 0.8% for syphilis. In 25 countries, 79.9% of blood centres were participating in an external quality assessment scheme (EQAS) for different TTIs.

Thirty-nine countries (84.8%) out of 46 prepared blood components. The average proportion of blood units separated into blood components were 64.8% and 24.3% of blood transfusion centres were preparing blood components. Red cell concentrate (RCC) was the component most developed by countries followed by fresh frozen plasma (FFP). The overall proportion of blood and blood components discarded was 7.0% the main reason being TTIs (5.3%).

The average proportion of blood units transfused was 28.7% as whole blood, 58.7% as RCC, 7.2% as whole blood derived platelet and 7.0% as FFP. Of 4,415 hospitals 641 (14.5%) had a Hospital Transfusion Committee (HTC), 22.4% had a system for monitoring clinical transfusion practice and 13.45% had a mechanism for reporting adverse transfusion events and reactions. Eighteen point five percent of patients transfused aged under 5 years, 6.0% from 5 to 14 years, 40.6% from 15 to 44 years, 16.7% from 45 to 59 years and 18.2% for 60 years or older. Only 3 countries (6.5%) reported data on serious adverse reactions following blood transfusion.

South Africa was the only country that produced all or part of plasma-derived medicinal products (PDMP) through the fractionation of plasma collected in the country. In the remaining countries, all these products were imported from abroad, and 20 countries (43.5%) had included PDMP in their essential medicines list.

Countries in the African Region have made commendable efforts to improve the availability and accessibility of safe and quality blood and blood products in the last three years. The number of countries with national blood policies, those implementing their policies through strategic plans has also increased, but the legislation remains a matter of concern in most of the countries. The overall prevalence of TTIs among blood donors and the proportion of blood discarded due to TTIs have shown steady trends over the years.

Despite progress made by the Member States in addressing blood safety issues, significant challenges remain. These include inadequate:

(a) implementation of national blood policies and weak blood regulatory systems;
(b) insufficient number of VNRBD; less than 100% testing of transfused blood units for TTIs;
(c) poor quality management programmes with inadequate quality control of the screening tests,
(d) blood grouping and compatibility testing; inappropriate clinical use of blood, and
(e) unsustainable national funding for blood safety.

The main recommendation is to enhance technical support and advocacy for countries that have not yet achieved implementing their national blood policies, systems and structures to ensure an adequate and a safe supply of blood and blood products to meet the needs of all patients requiring transfusion regardless the subregion.

1. BACKGROUND

The WHO African Region is one of the six regions of WHO. It covers 47 countries with approximately 989 173 000 populations as of 2013. The average population life expectancy in the Region is 52.3 years, and the average maternal mortality ratio is 542 per 100 000 live births. The mortality rates are the highest in the world with an under-five mortality rate of 81.3 per 1000 live births and a neonatal mortality rate of 28 per 1000 live births. In average, there are 2.6 per 1000 uninfected population new HIV infections among adults aged 15–49 years old. Malaria incidence is 210 cases per 1000 inhabitants; Road traffic mortality rate is 20 per 100 000 inhabitants and 42% of the population has anaemia [1, 2].

Availability of safe blood and blood products has always been a key strategy for addressing such health-related challenges. While the need for blood is universal, millions of patients requiring transfusion do not have timely access to safe blood, and there is a major imbalance between developing and industrialized countries in access to safe blood. This issue is a WHO Global and Regional priority. WHO recognizes that achieving self-sufficiency, unless special circumstances prevent it, in the supply of safe blood components based on voluntary, non-remunerated blood donation, and the security of that supply are important national goals to prevent blood shortages and address health-related challenges of the population.

In May 1975, the World Health Assembly (WHA) adopted resolution WHA28.72 urging Member States to promote the development of coordinated national blood transfusion services based on voluntary and non-remunerated blood donations (VNRBD), to enact effective legislation governing the operation of these services, and to take other actions necessary to protect and promote the health of blood donors and recipients of blood and blood products [3]. As part of implementing this global resolution, the Regional Committee for Africa adopted the resolution AFR/RC44/R12 in 1994 urging Member States in the African Region to take urgent steps to enact blood safety policies, mobilize resources for blood service infrastructure development at central and district hospitals, and set goals and targets to achieve HIV-free blood transfusion in health care settings [4]. In addition, to improve the availability of safe blood products in all Member States, the fifty-first session of the Regional Committee for Africa adopted the Regional strategy for blood safety in September 2001 [5]. The objectives of the Regional Stratefy were to: (i) assist countries setting up an effective system of recruitment of low-risk donors; (ii) improve the safety of blood and blood products by implementing a quality assurance programme and mapping out effective strategies for the screening of blood for all transfusion-transmitted infections (TTIs); and (iii) promote the appropriate use of blood and blood products by clinicians. The Regional strategy defined four targets to be reached by the end of 2012: (i) a blood safety situation analysis carried out in all Member States; (ii) a national blood policy developed and adopted by 75% of the countries in the Region; (iii) a mandatory testing of all of transfused blood units for four TTIs: Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and syphilis; and (iv) that at least 80% of blood donations in all countries in the Region are VNRBD.

In order to improve the availability, safety and quality of blood and blood products, the World Health Assembly adopted in May 2010 the resolution WHA63.12 [6]. This resolution urged Member States to: (i) establish, a sustainable blood and plasma programmes; (ii) update their national regulations systems to ensure that regulatory control of quality and safety of blood products across the entire transfusion chain meets recognized standards; (iii) establish quality systems for processing whole blood and blood components and good manufacturing practices for producing plasma-derived medicinal products (PDMP) including the use of diagnostic devices to prevent TTIs; (iv) build human resource capacity through the provision of initial and continuing training of staff to ensure quality of blood services and blood products; (v) enhance the quality of evaluation and regulatory actions for blood products and associated medical devices; (vi) strengthen systems for the safe and rational use of blood products and to provide training for all staff involved in clinical transfusion; and (vii) ensure the reliability of mechanisms for reporting adverse reactions to blood and plasma donation and to the receipt of blood components and PDMP.

More recently, the Heads of State and Government and High Representatives meetings at the United Nations Headquarters in New York from 25-27 September 2015 as the Organization celebrates its seventieth anniversary, have decided on 17 new global Sustainable Development Goals (SDG) to be reached by 2030. One of the goal is to ensure healthy lives and promote well-being for all at all ages through several actions including: (i) reduction of the global maternal mortality ratio to less than 70 per 100 000 live births, (ii) reduction of neonatal mortality to at least as low as 12 per 1000 live births and under-5 mortality to at least as low as 25 per 1000 live births , (iii) end of the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases, (iv) achievement of universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all [7] . Availability of safe blood and blood products is a key strategy for achieving health-related SDGs.

Different evaluations implementing the African regional strategy for blood safety were conducted in 2004, 2006 and 2010 to measure progress using specific indicators, and to identify successes, constraints and challenges [8–10]. Regarding the availability, safety, and quality of blood products in the African Region, data showed that there had been progressing in most of the countries. Three new elements are considered in planning and implementing blood safety activities in the Region: whole blood and main blood components are essential medicines since 2013 [11]; pathogen inactivation on whole blood will be available in the next coming years, and convalescent whole blood or plasma collected from patients recovered from Ebola virus disease are used. While there is no proven treatment available for Ebola virus disease (EVD), whole blood and plasma collected from patients in the convalescent phase of infection have been used in West Africa as an empirical treatment with promising results in a small group of EVD cases [12]. Increasing awareness for a well-developed blood safety program is noted in countries affected and at risk by Ebola crisis and in international funding program. Despite these positive changes, significant challenges remain, such as: inadequate implementation of national blood policies and weak blood regulatory systems; insufficient number of voluntary non remunerated

blood donations; less than 100% testing of transfused blood units for TTIs; poor quality management programmes with inadequate quality control of the screening tests, blood grouping and compatibility testing; inappropriate clinical use of blood, and unsustainable national funding for blood safety.

2. AIMS AND OBJECTIVES

This report aims to:

1. Assess the level of implementation of resolutions from the Regional Committee for Africa and from the World Health Assembly to give an update on the blood safety situation in the WHO African Region using data from the 2013 survey;
2. Establish blood safety country profiles within the three subregions;
3. Identify successes, gaps, and constraining factors;
4. Define priority actions to be undertaken in the coming years;
5. Make recommendations to Regional Economics Communities, Member States and other stakeholders so as to merge the achievements made and to mitigate the constraining factors.

3. METHODS

3.1 Data collection tools

The blood safety indicators were collected using the 2013 questionnaire on the Global Database on Blood Safety (GDBS) [13]. An additional self-assessment questionnaire was developed to collected data on achieving the targets of the regional strategy at the end of 2012. Providing data on the status of the blood transfusion chain, the GDBS has the following seven sections:

1. Administrative information
2. Organization and management
3. Blood donors and blood collection
4. Screening for transfusion-transmissible infections
5. Blood component preparation
6. Clinical use of blood and blood components
7. Plasma-derived medicinal products (PDMP)

The questionnaire used to collect data on achieving targets of the regional strategy for blood safety included questions on the situational analysis, policy development, and its implementation, legislative framework, funding, voluntary blood donation, TTI screening quality management, rational use of blood and haemovigilance, strengths and weaknesses of the national transfusion system.

3.2 Collection method

For WHO Global Database on Blood Safety (GDBS) 2013, all countries of the WHO African Region were invited, from October 2015 to February 2016, to complete the questionnaire online by the relevant persons of the NBTS. Countries should provide data for the period from 1 January to 31 December 2013. The questionnaire related to achievement of targets of the regional strategy for blood safety was sent to directors of the national blood transfusion services in the Region through the WHO country offices. The data submitted from the Region were recorded, validated and analysed. Countries that had not provided information in all evaluations were excluded from the analysis. For comparison purpose, we conducted a trend analysis using data available in the previous survey reports for the years 2004, 2006, and 2010 [8-10].

3.3 Data analysis

Data entry was done using Microsoft Excel worksheet 2010. Data analysis and table preparation were done using the same Microsoft Excel and Microsoft Word 2010.

The countries were divided into three groups based on their subregions that make-up the Intercountry Support Team (IST) in the WHO Regional Office for Africa: Central Africa (CA), East & Southern Africa (ESA) and West Africa (WA). For each blood centre, country and/or subregions, variables reported or calculated were a number, rate, and percentage. The total population of the WHO African region used for estimates was that defined by UNDP in 2013 [14].

3.4 Quality

The submitted questionnaires were examined for errors, appropriateness and quality of data by the Blood Safety Unit at the WHO Regional Office in Brazzaville and WHO Head Quarters in Geneva. The compiled data of the year 2013 were cross-checked by each country through a final check table for accuracy or consistency and any clarification.

3.5 Limitations of the survey

Equatorial Guinea did not respond, and some countries data were lacking.

4. RESULTS

Out of the 47 countries of the WHO African Region, 46 (97.9%) provided data in the questionnaire. Only Equatorial Guinea did not provide any data and was excluded from the analysis.

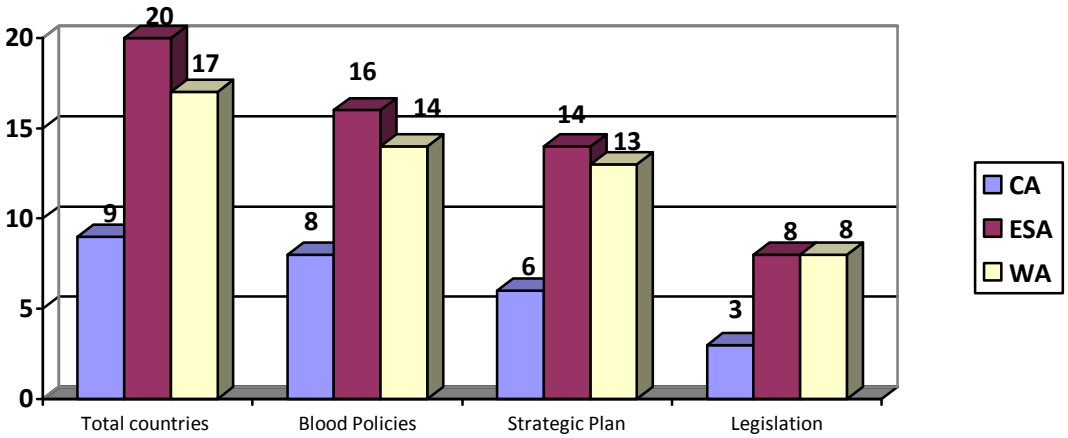
Based on countries estimates in the report, the total population of the WHO African Region in 2013 was 927 370 720 and the population of the countries that responded was 926 613 705 (99.9%).

4.1 Organization and management

Organizational and legal framework of national blood transfusion services

Out of the 46 countries that provided data, 41 countries (89.1%) had a nationally coordinated blood transfusion services (BTS). Thirty-eight (82.6%) countries had formulated and adopted a national blood policy, and 33 countries (71.7%), had developed a strategic plan for the implementation of their blood policy. The transfusion legislation was prepared in 19 countries (41.3%). The figure 1 shows the number of countries having the keys elements of blood safety organization for each subregion.

FIGURE 1: NUMBER OF COUNTRIES HAVING A BLOOD SAFETY POLICY, STRATEGIC PLAN AND LEGISLATION IN EACH SUBREGION



Facilities for blood transfusion services

All the 46 countries reported data on their number of blood centres. In total, there are 2170 blood centres and 2,045 (85.4%) provided data used for this report. Out of these, 192 (9.4%) were stand-alone while 1853 (90.6%) were hospital-based (tables 1). The questionnaire did not specify whether these facilities were under the hospital administration or were just located in the hospital premises.

TABLE 1: NUMBER AND TYPES OF BLOOD TRANSFUSION CENTRES THAT PROVIDED DATA IN THE REPORT

Subregion	Countries (n)	Stand-alone n (%)	Hospital basedn (%)	All types of centre n (%)
Central Africa	9	24 (2.1)	1106 (97.9)	1130 (100)
East & Southern Africa	20	97 (31.0)	215 (69.0)	312 (100)
West Africa	17	71 (11.8)	532 (88.2)	603 (100)
Total Region	**46**	**192 (9.4)**	**1853 (90.6)**	**2045 (100)**

Management of blood transfusion services

Out of 46 countries, 36 (78.3%) reported that there is a unit within the Ministry of Health (MOH) with responsibility for governing all activities related to provision and transfusion of blood and blood products, and 14 countries (30.4%) had a national blood transfusion committee (or similar committee) to assist the MOH in formulating policy and plans, developing standards and advising on key issues related to blood safety.

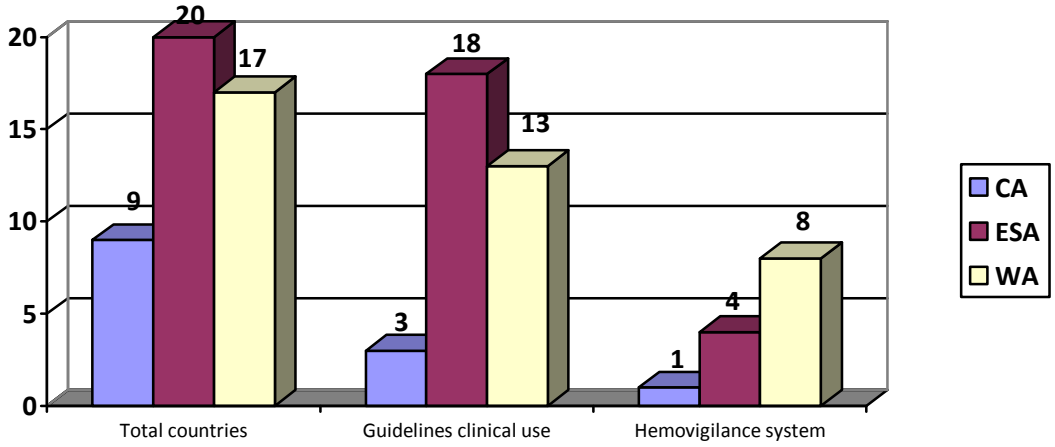
Regarding the quality management in BTS, 44 countries (95.6%) had established national standards for the collection, testing, processing, storage and distribution of blood and blood products. Data also reveals that 28 countries (60.8%) participated in a national external quality assessment scheme (EQAS) for TTIs laboratory screening and 22 countries (47.8%) for blood group serology and compatibility testing. Only four countries (8.7%) got an accreditation of their national blood transfusion services (NBTS). Details per subregion are presented in Table 2.

TABLE 2: NUMBER OF COUNTRIES HAVING BLOOD SAFETY NATIONAL STANDARDS, EXTERNAL QUALITY ASSESSMENT SCHEME ACTIVITIES FOR TTIS, BLOOD GROUP SEROLOGY AND COMPATIBILITY TESTING IN EACH SUBREGION

Subregion	Countries (n)	National standards (n)	EQAS TTIs (n)	EQAS blood grouping (n)	Accredited NBTS (n)
Central Africa	9	8	3	3	1
East & Southern Africa	20	19	18	12	3
West Africa	17	17	7	7	0
Total Region	**46**	**44**	**28**	**22**	**4**

In terms of blood use, 34 out of 46 countries (73.9%) had national guidelines on appropriate clinical use of blood and blood products while 13 countries (28.3%) had established a national hemovigilance system in order to record incidents and adverse events related to blood transfusion in both blood donors and recipients (Figure 2).

FIGURE 2: NUMBER OF COUNTRIES HAVING NATIONAL GUIDELINES ON CLINICAL USE OF BLOOD AND HEMOVIGILANCE SYSTEM IN EACH SUBREGION



Concerning the system of frequent inspection and licensing of the NBTS, 15 (32.6%) and 17 (39.6%) countries out of 46 reported had these systems in place for inspection and licensing. Moreover, ten countries (21.7%) had a training programme that offers a nationally-recognized university degree or diploma in blood transfusion medicine/science, namely Algeria, Angola, Ghana, Kenya, Madagascar, Nigeria, Rwanda, Senegal, South Africa and Zimbabwe.

Concerning the funding for NBTS, 36 (78.3%) had a national government budget and had received funding and technical supports from international agencies/institutions while 19

countries (41.3%) had a system of cost recovery. The approximate average costs in dollars US (US$) of producing a unit of whole blood was US$ 82.2 and US$ 95.0 for red cells concentrate (RCC) (ranging from US$ 16.3 in Ghana to US$ 340 in Gabon). The total estimated funding and the main sources of financing of blood transfusion are detailed in Table 3.

TABLE 3: FUNDING SOURCES OF BLOOD TRANSFUSION SERVICES PER SUBREGION

Subregion	Countries	Estimated total funding needs (USD)	Government (%)	Cost recovery (%)	External funding (%)	Total funding (%)
Central Africa	9	13,398,637	49.0	13.4	19.3	81.7
East & Southern Africa	20	257,787,510	7.0	83.8	7.0	97.8
West Africa	17	21,993,970	49.0	9.0	42.0	100
Total Region	**46**	**293,180,117**	**12.0**	**75.0**	**10.2**	**97.2**

The main international agencies/institutions that provided funding and technical supports to the NBTS be listed below (Table 4).

TABLE 4: INTERNATIONAL AGENCIES/INSTITUTIONS PROVIDING SUPPORTS TO WHO AFRICAN REGION BLOOD SERVICES

S/No	Agency/institution	Countries (n)
1.	WHO	19
2.	CDC/PEPFAR	19
3.	Global Fund	9
4.	American Association of Blood Banks	7
5.	Safe Blood for Africa Foundation	4
6.	UNFPA	3
7.	*Etablissement Français du sang*	3
8.	Swiss Red Cross	2
9.	European Union	2
10.	World Bank	1
11.	UNICEF	1
12.	UNDP	1
13.	Nordic Development Fund	1
14.	Lux Development	1
15.	Belgian Technical Cooperation	1
16.	African Society for Blood Transfusion	1
17.	Management Science for Health (MSH)	1
18.	NHS Blood and Transplant	1

In some countries, these supports were also coming from national partners such as Academic Consortium Combating Ebola (ACCEL) in Liberia, the National Health Insurance and Social Guarantee in Gabon, and the National Red Cross in Burundi and Guinea Bissau.

4.2 BLOOD DONORS AND BLOOD COLLECTION

Total number of blood donations

A total of 4 402 680 units of blood were collected in the 46 countries in 2013 ranging from 919 units in Sao Tome and Principe with a population of 192 993 to 947 890 units in South

Africa with a population of 52 776 130. The number of units of donated blood and the average annual blood donation per 1000 inhabitants in each subregion are found in Table 5.

TABLE 5: NUMBER OF BLOOD DONATIONS AND DONATION RATES PER SUBREGION.

Subregion	Countries (n)	Total blood donation reported (n)	Population (n)	Donation rate (units/1000 inhabitants)
Central Africa	9	811 060	145 155 857	5.6
East &Southern Africa	20	2 126 407	410 998 468	5.1
West Africa	17	1 465 213	370 459 380	3.9
Total Region	**46**	**4 402 680**	**926 613 705**	**4.7**

The average blood donation rate in the region was 4.7 units per 1000 inhabitants ranging from 0.7/1000 in Nigeria to 39.7/1000 in Mauritius (Table 6). Nine countries collected at least 10 units/1000 population: 2 in Central Africa (Congo, Gabon), 6 in East and Southern Africa (Botswana, Mauritius, Namibia, Seychelles, South Africa and Swaziland) and 1 in West Africa (Algeria).

TABLE 6: DONATION RATES IN EACH COUNTRY PER SUBREGION

Central Africa		East & Southern Africa		West Africa	
Country	**Rate***	**Country**	**Rate**	**Country**	**Rate**
Angola	7.2	Botswana	10.0	Algeria	12.5
Burundi	5.5	Comoros	3.4	Benin	7.5
Cameroon	0.7	Eritrea	1.4	Burkina Faso	6.0
Central African Republic	2.5	Ethiopia	0.8	Cabo Verde	6.5
Chad	5.4	Kenya	3.6	Cote d'Ivoire	6.5
Congo	11.3	Lesotho	3.9	Gambia	5.4
Democratic Republic of Congo	6.4	Madagascar	1.0	Ghana	6.2
Equatorial Guinea	NR	Malawi	3.6	Guinea	3.6
Gabon	11.1	Mauritius	39.7	Guinea-Bissau	2.8
Sao Tome and Principe	4.8	Mozambique	4.6	Liberia	6.2
		Namibia	12.2	Mali	3.0
		Rwanda	3.7	Mauritania	2.8
		Seychelles	16.0	Niger	4.3
		South Africa	18.0	Nigeria**	0.7
		South Sudan	0.2	Senegal	4.8
		Swaziland	10.8	Sierra Leone	7.1
		Uganda	5.4	Togo	6.1
		United Republic of Tanzania	3.3		
		Zambia	7.8		
		Zimbabwe	4.0		

**Rate (units/1000 inhabitants); **the number of blood donations reported only covers around 10% of the actual collection*

Type of blood donation

All the 46 countries reported data on the percentage of voluntary non remunerated blood donations (VNRBD), family replacement donations (FRD) and paid blood donations during 2013. The average proportion of VNRBD was 67.0% ranging from 2.3% in South Sudan to 100% in 11 countries (Tables 7 and 8 and figure 3). Two countries, Guinea Bissau and Democratic Republic of Congo (DRC) reported paid donations represented 0.1% and 6.2% of their total donations respectively.

TABLE 7: NUMBER OF DONATIONS AND TYPE OF DONATION PER SUBREGION

Subregion		Type of donation			
	VNRBD n (%)	*Family replacement donation n (%)*	*Paid donation n (%)*	*Other types# n (%)*	*All types of donation n (%)*
Central Africa	279 156 (34.4)	503 889 (62.1)	27 254 (3.4)	761 (0.1)	811 060 (100)
East and Southern Africa	1 964 685 (92.4)	161 142 (7.6)	-	580 (0.02)	2 126 407 (100)
West Africa	709 142 (48.4)	755 443 (51.6)	46 (0.003)	582 (0.03)	1 465 213 (100)
Total Region	**2 952 983 (67.0)**	**1 420 474 (32.2)**	**27 300 (0.6)**	**1923 (0.04)**	**4 402 680 (100)**
#Other types: Autologous					

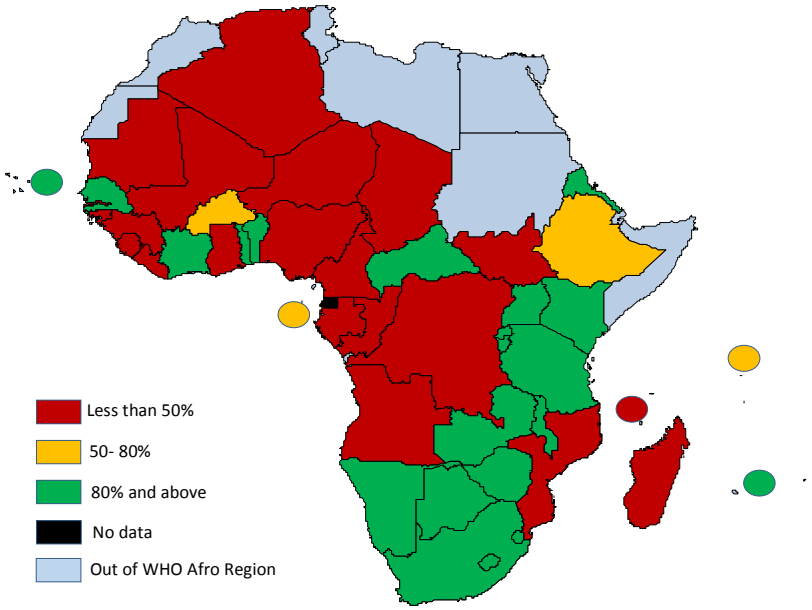
TABLE 8: PERCENTAGE OF VOLUNTARY NON REMUNERATED BLOOD DONATION IN EACH COUNTRY

Central Africa		East & Southern Africa		West Africa	
Country	**%**	**Country**	**%**	**Country**	**%**
Angola	14.8	Botswana	100	Algeria	31.3
Burundi	100	Comoros	11.5	Benin	95.5
Cameroon	25.6	Eritrea	92.5	Burkina Faso	67.5
Central African Republic	98.9	Ethiopia	67.5	Cabo Verde	85.2
Chad	6.2	Kenya	100	Cote D'Ivoire	100
Congo	38.5	Lesotho	96.6	Gambia	21.5
Democratique Republic of Congo	35.7	Madagascar	18.6	Ghana	33.0
Equatorial Guinea	NR	Malawi	82.4	Guinea	11.1
Gabon	31.1	Mauritius	84.4	Guinea-Bissau	28.8
Sao Tome and Principe	65.3	Mozambique	43.9	Liberia	26.3
		Namibia	100	Mali	30.6
		Rwanda	100	Mauritania	25.2
		Seychelles	33.2	Niger	33.9
		South Africa	100	Nigeria*	43.0
		South Sudan	2.3	Senegal	94.2
		Swaziland	100	Sierra Leone	10.0
		Uganda	100	Togo	95.3
		United Republic of Tanzania	84.6		
		Zambia	100		
		Zimbabwe	100		

**The number of blood donations reported only covers around 10% of the actual collection*

Of the 4 402 680 donations in the 46 countries, 30 651 (0.7%) were collected by aphaeresis in seven countries namely Algeria, Botswana, Lesotho, Mauritius, Namibia, South Africa and Zimbabwe). The proportion of blood donations collected using aphaeresis ranged from 0.0003% in Lesotho to 0.5% in South Africa.

FIGURE 3: PERCENTAGE OF VOLUNTARY NON-REMUNERATED BLOOD DONATION IN EACH COUNTRY OF WHO AFRO REGION IN 2013



Blood donor deferral rate and reasons

Thirty countries reported data on blood donor deferral. For a total of 2 801 442 blood donations reported, 363 443 blood donors were deferred for many reasons. The average deferral rate was 13.0% ranging from 0.02% in Togo to 68.5% in Seychelles. The summary of deferred donors per reason in each subregion is shown in Table 9.

TABLE 9: BLOOD DONOR DEFERRAL RATE AND REASONS FOR DEFERRAL IN EACH SUBREGION

		Subregion			Total Region
		Central Africa	East & Southern Africa	West Africa	
		Deferral rate (%)	Deferral rate (%)	Deferral rate %)	Deferral rate (%)
Reasons of deferral	Low weight	0.05	1.4	1.3	1.3
	Low haemoglobin	0.2	4.7	1.6	3.6
	Other medical conditions	3.7	4.4	2.1	3.7
	High-risk behaviour	0.1	1.5	2.4	1.6
	Travel	0.006	0.3	0.02	0.2
	Other reasons	1.3	3.0	1.4	2.4
	All reasons	**5.5**	**15.4**	**8.8**	**13.0**

4.3 SCREENING FOR TRANSFUSION-TRANSMISSIBLE INFECTIONS

TTIs screening

Forty-six (46) countries reported data on TTIs screening. Except Cameroon and DRC, 44 countries (95.6%) screened hundred percent of blood units for HIV, 42 (91.3%) for HBV, 41 (89.1%) for HCV and syphilis respectively (Tables 10).

TABLE 10: NUMBER OF COUNTRIES TESTING 100% OF BLOOD DONATIONS FOR THE FOUR MANDATORY TTIS

Subregion	Countries (n)	Screening of 100% of Transfusion Transmissible Infections			
		HIV	HBV	HCV	Syphilis
Central Africa	9	7	6	6	6
East & Southern Africa	20	20	20	19	19
West Africa	17	17	16	16	16
Total Region	**46**	**44**	**42**	**41**	**41**

Four countries did not screen 100% of the samples for HBV, 5 for HCV and 4 for syphilis (Table 11). In this latter case, Gambia did not provide data.

TABLE 11: PROPORTION OF UNITS TESTED IN COUNTRIES SCREENING LESS THAN 100% OF BLOOD DONATIONS FOR AT LEAST ONE TTI

Subregion	Countries	Transfusion Transmissible Infections			
		HIV (%)	*HBV (%)*	*HCV (%)*	*Syphilis (%)*
Central Africa	Cameroon	**95.35**	**95.35**	**95.35**	**95.35**
	Chad	100	**98.22**	**96.5**	**96.09**
	DRC	**99.75**	**94.07**	**88.50**	**86.16**
East & Southern Africa	Comoros	100	100	**92.0**	**95.65**
West Africa	Gambia	100	**26.8**	**17.4**	**NA**

Centres performing blood screening

All the 46 countries that provided data reported a total number of 2045 blood centres. Out of these centres, 1955 (95.6%) performed laboratory screening of blood donations for TTIs. The number of centres performing HIV, HBV, HCV, and Syphilis blood donation screening in each country is indicated in Table 12.

TABLE 12: NUMBER AND PERCENTAGE OF BLOOD CENTRES PERFORMING TTIS LABORATORY SCREENING OF BLOOD DONATIONS PER COUNTRY

Central Africa			East & Southern Africa			West Africa		
Country	**Centre in report (n)**	**Centre Performing screening n (%)**	**Country**	**Centre in report (n)**	**Centre performing screening n(%)**	**Country**	**Centre in report (n)**	**Centre performing screening n(%)**
Angola	139	139 (100)	Botswana	6	2 (33;3)	Algeria	200	200 (100)
Burundi	7	5 (71.4)	Comoros	5	5 (100)	Benin	40	40 (100)
Cameroon	15	15 (100)	Eritrea	1	1 (100)	Burkina Faso	42	42 (100)
CAR	2	1 (50.0)	Ethiopia	25	25 (100)	Cabo Verde	6	2 (33.3)
Chad	56	52 (92.8)	Kenya	54	6 (11.1)	Cote D'Ivoire	23	3 (13.0)
Congo	24	24 (100)	Lesotho	4	1 (25.0)	Gambia	11	11 (100)
DRC	890	889 (99.9)	Madagascar	47	43 (91.5)	Ghana	103	103 (100)
Equat. Guinea	NR	NR	Malawi	4	4 (100)	Guinea	33	33 (100)
Gabon	1	1 (100)	Mauritius	1	1 (100)	Guinea-Bissau	7	7 (100)
STP	1	1 (100)	Mozambique	153	153 (100)	Liberia	30	30 (100)
Total	**1130**	**1127 (99.7)**	Namibia	1	1 (100)	Mali	6	6 (100)
			Rwanda	5	1 (20.0)	Mauritania	13	13 (100)
			Seychelles	1	1 (100)	Niger	5	5 (100)
			South Africa	11	3 (27.2)	Nigeria	43	18 (41.8)
			South Sudan	2	2 (100)	Senegal	21	21 (100)
			Swaziland	1	1 (100)	Sierra Leone	30	30 (100)
			Uganda	14	7 (50.0)	Togo	2	2 (100)
			United Republic of Tanzania	7	7 (100)	**Total**	**603**	**554 (91.9)**
			Zambia	9	9 (100)			
			Zimbabwe	5	1 (20.0)			
			Total	**312**	**274 (87.8)**			

CAR: Central African Republic, Equat. Guinea: Equatorial Guinea, DRC: Democratic Republic of Congo, STP: Sao Tome and Principe

The table 13 shows the total number of units and percentage of blood tested for the major TTIs. Some countries tested 100% of their donations for malaria such as Angola Liberia, and Malawi. The prevalence of malaria was 0.4% Angola and in Malawi. Gabon reported that all their blood donations are tested for HTLV and that the prevalence of this marker is 2%.

TABLE 13: NUMBER AND PROPORTION OF UNITS OF BLOOD TESTED FOR TTIS IN EACH SUBREGION.

Subregion	Total donations (n)	Units tested for Transfusion Transmissible Infections			
		HIV n(%)	*HBV n(%)*	*HCV n(%)*	*Syphilis n(%)*
Central Africa	811 060	808 627 (99.7)	783 444 (96.6)	759 152 (93.6)	752 664 (92.8)
East & Southern Africa	2 126 407	2 126 407 (100)	2 126 407 (100)	2 126 194 (99.9)	2 126 194 (99.9)
West Africa	1 465 213	1 465 213 (100)	1 457 887 (99.5)	1 456 422 (99.4)	1 451 147 (99.0)
Total Region	**4 402 680**	**4 400 247 (99.9)**	**4 367 738 (99.2)**	**4 341 768 (98.6)**	**4 330 005 (98.3)**

Percentage of blood units reactive for TTIs

All the 46 countries provided data on TTIs reactivity or /positivity. The median percentage of reactive blood units to TTIs was 1.3% for HIV (ranging from 0% to 6.7%), 4.2% for HBV (ranging from 0% to 17.4%), 1.0% for HCV (ranging from 0% to 4.9%) and 0.8% for syphilis (ranging from 0% to 8.3%). Thirty-five countries were performing a confirmatory test for HIV on part or all reactive blood units, 26 for HBV and syphilis, 27 for HCV. Table 14 shows the median proportion and the range in each subregion (Table 14).

TABLE 14: MEDIAN PERCENTAGE AND RANGE OF BLOOD UNITS REACTIVE FOR TTIS

Subregion	Transfusion Transmissible Infection reactivity			
	HIV (%)	*HBV (%)*	*HCV (%)*	*Syphilis (%)*
Central Africa	2.2[1.0-4.5]	6.3 [3.4-11.4]	1.8 [0.3-4.6]	1.1 [0.0-2.0]
East & Southern Africa	0.7 [0.0-5.5]	2.08 [0.08-11.9]	0.7 [0.0-4.3]	0.3 [0.1-8.3]
West Africa	1.9 [0.08-6.7]	7.7 [0.3-17.4]	1.2 [0.0-4.9]	0.8 [0.1-4.2]
Total Region	**1.3 [0.0-6.7]**	**4.2 [0.0-17.4]**	**1.0 [0.0-4.9]**	**0.8 [0.0-8.3]**

Quality assurance in TTI testing

Out of the 46 countries, 25 reported that a proportion of their blood donations were screened in a quality assured manner. The proportion of blood donations screened in a quality assured manner for the four TTIs was 98.1% for HIV, 95.8% for HBV, 94.9% for HCV and 94.7% for syphilis. Details of proportions in each subregion are shown in Table 15.

TABLE 15: REPORTED PROPORTION OF BLOOD DONATIONS SCREENED IN A QUALITY-ASSURED MANNER IN EACH SUBREGION

Subregion	Countries (n)	Proportion of Blood donation screened in a quality assured manner for TTIs (%)			
		HIV	HBV	HCV	Syphilis
Central Africa	3	99.8	94.8	90.0	88.9
East & Southern Africa	16	97.5	97.5	97.5	97.5
West Africa	6	99.0	87.5	87.5	87.5
Total Region	**25**	**98.1**	**95.8**	**94.9**	**94.7**

In these 25 countries that reported the proportion of blood donations screened in a quality-assured manner, a total of 1050 (79.9%) centres out of 1313 participated in an EQAS for

different TTIs. The repartition of these centres per subregion was the following: 892 (86.6%) out of 1030 in CA, 87 (57.2%) out of 152 in ESA and 71 (54.2%) out of 131 in WA.

4.4 BLOOD COMPONENT PREPARATION

Countries and centres preparing blood components

A total of 39 countries (84.8%) out of 46 reported preparation of blood components. Red cell concentrate (RCC) was developed in 34 of the 39 countries while platelets concentrate, fresh frozen plasma (FPP) and cryoprecipitate were prepared only in 28, 30 and 11 countries respectively. Table 16 presents the number of countries in each subregion according to the type of blood component prepared.

TABLE 16: NUMBER OF COUNTRIES PREPARING BLOOD COMPONENTS IN EACH SUBREGION

Subregion	Country (n)	Blood components			
		Red Cells Concentrate (n)	*Platelets concentrate (n)*	*Fresh Frozen Plasma (n)*	*Cryoprecipitate (n)*
Central Africa	7	7	5	6	**1**
East & Southern Africa	18	16	13	14	**7**
West Africa	14	11	10	10	**3**
Total Region	**39**	**34**	**28**	**30**	**11**

Out of 1963 centres, 478 (24.3%) were preparing blood components. The number and percentage of blood centres in each subregion of the country that prepared blood components is reported in Table 17.

TABLE 17: NUMBER AND PERCENTAGE OF CENTRES IN THE REPORT PREPARING BLOOD COMPONENTS

Subregion	Countries (n)	Centres in the report (n)	Centres preparing blood components n (%)
Central Africa	7	1114	29 (2.6)
East & Southern Africa	18	305	218 (71.5)
West Africa	14	544	231 (42.4)
Total Region	**39**	**1963**	**478 (24.3)**

Blood components prepared

Out of 4 259 890 blood donations, 2 760 123 (64.8%) were separated into blood components. The countries separating 100% of their blood donations were Botswana, Mozambique, Rwanda, and Swaziland in East and Southern Africa; Mauritania and Nigeria (Only data from Abuja blood centre have been considered in this analysis) in West Africa. Only 7 countries namely Algeria, Botswana, Lesotho, Mauritius, Namibia, South Africa and Zimbabwe prepared blood components through aphaeresis procedures.

TABLE 18: NUMBER AND PERCENTAGE OF BLOOD COMPONENTS PREPARED IN EACH SUBREGION

Subregion	Countries (n)	Total donations (n)	Whole blood donations separated in components n (%)	Red cell preparations n (%)	Other preparations* n (%)
Central Africa	7	784, 865	430 906 (54.9)	387 739 (49.4)	43 167 (5.5)
East & Southern Africa	18	2 095 898	1 584 641 (75.6)	1 333 107 (63.6)	1 437 841 (68.6)
West Africa	14	1 379 127	744 576 (54.0)	744 076 (53.9)	355 773 (25.8)
Total Region	**39**	**4 259 890**	**2 760 123 (64.8)**	**2 464 922 (57.8)**	**1 836 781 (43.1)**

** Other preparations included Platelets, Fresh Frozen Plasma, Plasma and Cryoprecipitate*

Causes of discard of blood and blood components

Thirty-five countries reported data on causes of blood and blood components discard: 7 in Central Africa, 18 in East and Southern Africa and 10 West Africa. Out of the 4 013 814 blood donations collected in these countries, 280 164 (7.0%) were discarded. Regardless of the subregion, the main cause of discard was TTIs (Table 19).

TABLE 19: PROPORTION AND CAUSES OF DISCARDED BLOOD AND BLOOD COMPONENTS IN EACH SUBREGION

Group	Total donation (n)	Causes of discarded blood and blood components						
		Incomplete collection (%)	TTIs (%)	Expiry (%)	Storage problems (%)	Transport problems (%)	Processing problems (%)	All causes (%)
Central Africa	784 865	0.5	8.7	0.03	0.1	0.002	0.02	**9.3**
East & Southern Africa	1 979 425	1.2	3.1	1.0	0.1	0.02	0.3	**5.6**
West Africa	1 249 524	0.5	6.7	0.2	0.1	0.01	0.05	**7.6**
Total Region	**4 013 814**	0.8	5.3	0.6	0.07	0.01	0.16	**7.0**

4.5 CLINICAL USE OF BLOOD AND BLOOD COMPONENTS

Blood components issued and transfused

Out of 46 countries, 39 countries (84.8%) reported data on the clinical use of blood. Of the 4 050 190 blood units collected, in these countries, 4 151 127 were transfused as whole blood units or separated blood components units. The number of blood units transfused 1 192 904 whole blood units (28.7%), 2 438 574 RCC (58.7%), 299 198 Platelets concentrate (7.2%) and 290 946 FFP (7.0%). Sixteen countries reported that they transfused less than 25% of whole blood units.

Red cell preparations were the most transfused blood component in East & Southern Africa and West Africa. RCC transfusions represented 55.0% and 54.6% respectively, while whole blood was mainly transfused in Central Africa (52.1%) as indicated in Table 20.

TABLE 20: PROPORTION OF BLOOD TRANSFUSIONS AS COMPONENTS ACCORDING TO SUBREGION

Subregion	Countries (n)	Total donation (n)	Transfusion reported	Proportion of transfused blood components (%)						
				Whole blood (%)	*RCC (%)*	*Platelet, WBD (%)*	*Platelet aphaeresis (%)*	*FFP (%)*	*Plasma (%)*	*Cryop. (%)*
Central Africa	7	784, 865	398 529	52.1	42.9	0.4	0.0	1.6	3.0	**0.0**
East & Southern Africa	18	1 919,967	2 497 678	22.4	55.0	8.3	1.3	9.4	2.0	**1.4**
West Africa	14	1 345 358	1 254 920	33.9	54.6	7.1	0.3	3.9	0.01	**0.03**
Total Region	**39**	**4 050 190**	**4 151 127**	**28.7**	**58.7**	**7.2**	**0.8**	**7.0**	**1.5**	**0.9**

Cryop.: cryoprecipitate; FFP: Fresh frozen plasma; RCC: Red cell concentrate; WBD: Whole blood derived

Monitoring of clinical transfusion practice

Out of 46 countries, that responded, 23 provided data on the clinical use of blood. Out of a total of 5458 hospitals, 4415 hospitals reported they perform blood transfusion, 641 (14.5%) had a Hospital Transfusion Committee (HTC), 989 (22.4%) had a system for monitoring

clinical transfusion practice, and 596 (13.5%) had a mechanism for reporting adverse transfusion events and reactions. Details for each subregion are reported in Table 21.

TABLE 21: NUMBER OF HOSPITALS MONITORING CLINICAL USE OF BLOOD IN EACH SUBREGION

Subregion	Countries (n)	Total hospitals (n)	Hospitals with an HTC* n (%)	Hospitals performing clinical audits n (%)	Hospitals notifying adverse reactions n (%)
Central Africa	4	1554	148 (9.5)	875 (56.3)	151 (9.7)
East & Southern Africa	14	2128	415 (19.5)	114 (5.3)	427 (20.0)
West Africa	5	733	78 (10.6)	0 (0.0)	18 (2.4)
Total Region	**23**	**4415**	**641 (14.5)**	**989 (22.4)**	**596 (13.5)**

Of the 23 countries that monitored clinical use of blood, nine countries reported data on the number of patients transfused by age group. Out of 567 508 patients transfused, 104 902 (18.5%) were aged under 5 years, 33 577 (6.0%) from 5 to 14 years, 230 640 (40.6%) from 15 to 44 years, 94 833 (16.7%) from 45 to 59 years and 103 506 (18.2%) for 60 years or older. Details per subregion are reported in Table 22.

TABLE 22: PROPORTION OF PATIENTS TRANSFUSED ACCORDING TO SUBREGION

Subregion	Countries (n)	Patients transfused (n)	Proportion of patients transfused per age (%)				
			< 5 years (%)	*5 to 14 years (%)*	*15 to 44 years (%)*	*45 to 59 years (%)*	*60 years or older (%)*
Central Africa	3	65 955	47.5	11.0	7.5	25.3	8.5
East & Southern Africa	5	469 651	13.5	4.5	46.1	15.5	20.4
West Africa	1	31 902	31.8	16.2	28.7	16.8	6.4
Total Region	**9**	**567 508**	**18.5**	**6.0**	**40.6**	**16.7**	**18.2**

Of the nine countries that monitored clinical use of blood, only three countries (Eritrea, Namibia and South Africa) reported data on serious adverse reactions following blood transfusion. For a total of 437 579 patients transfused 967 (2.2‰) had severe incidents and reactions corresponding to 2.2 per 1000 patients transfused. These data per country were: 14 (1.7‰) out of 8170 patients in Eritrea, 44 (3.4‰) out of 12,863 patients in Namibia and 909 (2.2‰) out of 416,546 patients in South Africa.

The numbers and rates of serious adverse transfusion reactions reported in these countries were: 3 (0.3%) of immunological haemolysis due to ABO incompatibility, 5 (0.5%) of immunological haemolysis due to other alloantibody, 9 (0.9%) of non-immunological haemolysis, 23 (2.4%) of post-transfusion purpura, 377 (39%) of anaphylaxis/hypersensitivity, 1 (0.1%) of transfusion-related acute lung injury (TRALI) and 548 (56.7%) of other serious adverse transfusion reactions.

4.6 SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS

Out of 45 countries, 20 (43.5%) had included the plasma-derived medicinal products (PDMP) in their national essential medicines list. The main PDMP listed were: intravenous immunoglobulin (IVIG), Factor VIII and IX, Anti-D immunoglobulin intra muscular, Anti-Rabies IgG, Anti-Tetanus IgG, Anti-Heb B IgG and Fresh dried plasma. Only, South Africa

produced PDMP through fractionation (e.g. domestic or/and contract fractionation) of plasma collected in the country. In other countries of the region, all these products were imported from abroad.

5. DISCUSSION

In 2010, 46 countries were members of the WHO African Region. Out of the 46 countries that received the questionnaire in 2010 survey, 43 provided required data. Angola, Liberia, and Seychelles did not submit responses to the Regional Office. In 2013, South Sudan became a member of WHO African Region. Thus 47 countries were invited to participate in the 2013 survey. Liberia that had consistently not taken part since 2004 provided data, this time, knowing the critical need of monitoring of evaluation during Ebola crisis. South Sudan took part in the survey for the first time and provided its data. This study covers 99.9% of the population and 46 out of the 47 countries of WHO African Region as only Equatorial Guinea did not send its data.

Some countries did not provide all the data required. For instance, only 23 blood centres in the report provided data on the clinical use of blood, and only nine countries reported data on the number of patients transfused by age group. Data on blood usage including haemovigilance are more difficult to collect and monitor as they are produced in clinical facilities out of the blood services, thus not under blood services control. However, they are critical data for management of adverse effects of transfused blood and traceability. Failure to provide such data reflects the low level of development of the clinical interface, the lack of functional hospital transfusion committee, the poor linkage between blood centres and hospitals, and haemovigilance system which requires much effort to improve.

As in the previous surveys, some answers did not reflect the situation on the ground in a few countries when compared with observations made during other WHO missions to these countries. For example, Cameroon has provided the number of donations of a single hospital blood bank to be considered as the total number of blood donation of the country for a year. Mechanisms for getting reliable data or missing data should minimize the risk of not finding out the true situation in some countries and, hence, in the Region. Likewise, the number of blood donations reported in Nigeria for this survey only covers around 10% of the actual collection. These countries may face challenges in data collection and reporting need to be given more attention and support to improve the situation in subsequent surveys. These limitations do not significantly change the quality of data sent by countries as they are limited to a small number of countries and few indicators.

5.1 ORGANIZATION AND MANAGEMENT

There is an increase in the number of countries that reported a developed, adopted and implemented national blood safety policy. Indeed, 29 countries in 2010 versus 38 countries in 2013 had a policy document. Similarly, 11 countries in 2010 reported to have legislation versus 19 countries in 2013. Despite this improvement, development and adoption of legislation remain the biggest issue in organization and management of blood services.

We noticed a significant increase in some blood centres in the African Region: from 1492 centres in 43 countries in 2010, the number increased to 2170 in 46 countries. Ninety percent of them are hospital-based facilities. An additional number of countries in the 2013 survey such as Seychelles, Liberia, and Angola cannot explain such significant increase in the number of blood services. The need of providing blood to population and to make it accessible to the population may explain this multiplication of centres by the government. However, recommendations should be that an efficient and quality-based organization should set appropriate centralized and coordinated facilities and not the multiplication of non-coordinated and resources-limited facilities. Behaving so hampers and contradicts huge efforts made by countries in implementing the quality system in 2013. Indeed, this report also shows that a significant number of countries had National Standards, guidelines and took part to EQAS as well. Thus, there is a need for advocacy in countries for a coherent way to a sustainable supply of safe blood through a coordinated unique national blood service that manages all blood centres in a quality manner.

For the first time in this regional report, countries provided an estimation of their needs and funding sources. Government support represented more than 40% in West and Central Africa while recovery cost through payment of blood pints by the patients or health insurance represented the largest funding source in South & East Africa. Despite a surprising 97% of funding rate compared to the need, observations in fields reveal irregular and occasional supply of financial and material needs to blood services.

5.2 BLOOD DONORS AND BLOOD COLLECTION

The total number of blood donations increased from 3,191,808 units in 2006 to 3 486 192 units in 2010 and to 4 402 680 in 2013 [9,10]. This corresponds to a population of 769 717 000 in 2006, 813 806 984 in 2010 and 926 613 705 in 2013 respectively. The donation rate then increased from 4.1 per 1000 in 2006 to 4.3 per 1000 in 2010 and 4.7 per 1000 population.

Donation rate was lower in West Africa than in East &South Africa and Central Africa. Moreover, from 2010 to 2013, it has decreased in West Africa from 4.8% to 3.9% but has increased in Central Africa from 4.6% to 5.6% and in East & South Africa from 4.9% to 5.1%. This finding could be explained by the low donation rate in Nigeria (0.7 per 1000) compared to its huge population that is increasing quickly.

The number of countries that collected at least ten units/1000 population as recommended by WHO has increased from 5 in 2010 to 9 in 2013. The four countries that recently reached the recommended donation rate in 2013 where Gabon, Namibia, Seychelles and Swaziland. Indeed, these countries were near to reach the recommended rate since 2010. However, considering the WHO standard of collecting at least ten units of blood per 1000 population as the amount of blood required for blood transfusion needs per country per year, there was a shortfall of 4 863 457 units of blood collected compared with the target for the Region in 2013.

The proportion of VNRBD dropped in WHO African Region from 2010 to 2013 -by 1.5 to 3 folds in several countries. The proportion of VNRBD had reduced from, Algeria, Burkina Faso and Nigeria from 60 to 31.3%, 100 to 67.5% and 94.5 to 43%. Since these countries are from West Africa, the total proportion of VNRBD in that subregion drops from 56 % in 2010 to 46.2% in 2013 while it has increased in East &South region. A collection of blood from VNRBR from low-risk population is a WHO recommendation. Despite the many evident reasons, challenges in keeping sustainable blood supply program from VNRBD are huge since 20-40% of blood services are usually needed for that activity. Sensitization, Education, recruitment and Motivation and mobile drives program that must be on a daily-basis is still frequently occasional in many hospital-based blood centres. Governments should increase their support to blood services for sustainable blood supply as it is the case in Malawi. Indeed, despite a continuous reduction in external funding mechanism in Malawi National Blood Services, the proportion of VNRBD had increased from 57.3% in 2010 to 82.4% in 2013.

The mean deferral (13%) increased compared to 2010 deferral rate that was 11.8%. It is the same rate found in a multicentric study in sub-Saharan Africa [14]. In 2010, high deferral rates were reported in Eritrea (64%), Equatorial Guinea (41.7%) and in Mauritania (37.6%). This reason is the need of investigation on strategy for donor medical screening implemented those countries. Low rates in some countries may be due to a more rigorous medical selection or low HIV prospective blood donors. However, since most of the questionnaires and risk factors used during medical selection of blood donors, therefore, have not yet been validated by epidemiological studies, appropriate studies need to be conducted to refine criteria for eligibility. The small number of donors deferred for low hemoglobin is questionable since anaemia is often reported in 10-30% of cases among African blood donors. Using clinical signs rather than hemoglobinometer in some facilities may underestimate anaemia [15].

5.3 TTIs SCREENING

A good proportion of blood units collected is screened for TTIs markers, and only two countries did not screen 100% of blood donors' samples for HIV. HCV and Syphilis are still less screened than HIV and HBV. East & South Africa subregion has the greater number of countries that is screening 100% of the blood units for the four mandatory infections while Central Africa has the lowest. DRC did not screen 100% of his blood units for HIV as in 2010. Some countries like Cameroon, Chad, Comores, and Gambia are also in the list of countries that issue blood without a screening of at least one TTIs. An assessment of each country is needed to understand reasons for such outcome. Irregular supply and unavailability of reagents, in blood centres, are reported as key elements that hamper systematic screening [16]. Advocacy for the supply of reagents, development of screening procedures and training of staff may increase the number of units screened for TTIs.

Despite significant decrease in TTIs seroprevalences this last decade in Africa [17], the averages proportion of blood units reactive to/positive to TTIs markers changed slightly between 2010 and 2013: from 1.2% to 1.3% for HIV, from 0.9% to 1.0% for HCV and from 1.2% to 0.8% for syphilis. However, the seroprevalence remained high in some countries

(e.g.:6.7% for HIV in Mozambique). This depends on several factors beyond the scope of this report such as the algorithms used, the test kits on the market, validation of the test kits, storage and lack of skilled human resource, among others.

In the Central Africa, the mean seroprevalence of Syphilis dropped from 5.5% to 1.1%. However, it has increased in South & East Africa for HBV (from 1.86% to 2.08%) for HCV (0.51 to 0.7%) and for Syphilis (from 0.3% to 0.87%). These data may not be too far from the reality as 94 to 98.1% of blood units screening were reported by the countries to be screened in a quality assured manner including use of documented SOPs, participation to an EQAS. Based on the observation in the field, the need of implementation of a higher level quality management system is obvious and will help in providing more reliable data. Increase in seroprevalence in some countries and subregion results from inefficient TTIs screening of blood donors at the medical selection. Recently, African Society of Blood Transfusion (AfSBT) developed a set of standards and quality document adapted to resources-limited areas as African region. Implementation of good practices using accreditation standards is a key strategy to improve blood donors and blood donation quality screening in African region [18].

5.4 BLOOD COMPONENTS PREPARATION

Thirty-four of the 46 countries (84.8%) had centres preparing blood components and paediatric units. The number of countries preparing RCC was 34 out of 39 compared with 29 out of 40 in 2004, 32 out of 42 in 2006 and 35 out of 37 in 2010. The number of countries preparing platelet concentrates was 28 out of 39 compared with 29 out of 40 in 2004 and 25 out of 42 countries in 2006 and 27 out of 43 in 2010. There was no significant increase in the number of countries preparing components over the years. All the seven countries of Central Africa that provided data reported they prepared RCC. Also, there is a slight increase in the proportion of whole blood units separated into components. It represented 60% in 2010 and 64% in 2013. Increase in proportion of VNRBD may explain this improvement in processing activities since it has been shown in the previous survey that countries whose blood programmes are organized along voluntary blood donations organize better component production programmes as their collections are not patient based, unplanned and more often not centred around emergencies. Reasons for low component production in countries should ensure improvement and appropriate clinical use of blood and to optimize the use of the converted unit implementation of this modern blood transfusion practice will be further enhanced with the production of more blood components in the Region.

Concerning the blood centres, 19.8% prepared blood components in 2010 compared to 24.3% in 2013. No details have been provided in production of paediatric preparations. However, based on data on 2010 and current observation, there is need to increase the number of prepared blood components, considering that a sizeable proportion of blood transfusions in the Region are issued for this group of patients. Countries therefore need to be supported to improve their blood component production and the preparation of paediatric packs to improve appropriate clinical use of blood and avoid wastage of a scarce resource while averting the risk of contamination associated with an open unit of blood. In this report, the leading cause of discard of blood is reactivity to markers of infections

transmitted through blood transfusion as in 2006 and 2010. According to countries that provided information on this issue, the proportion of blood units discarded for TTIs decreased from 9.3% in 2006 to 7.5% in 2010, and to 5.6% in 2013. The proportion of discarded blood units was higher in Central Africa in which countries often depend on family replacement donations unlike countries of South and East Africa. This further underscores the need to invest in collecting blood from low-risk blood donors which remains the foundation of any safe blood supply system. The 2013 survey reported also a significant decrease in proportion of expired and discarded blood units that drop from 2.9% in 2010 to 1% in 2013. Shortage of supply is another big challenge in the region that will benefit from better inventory and distribution management of blood and blood products.

5.5 Clinical use of blood and blood component

The percentage of transfused RCC has increased from 37.7% to 42.9% in Central Africa and from 46.8% to 54.6% in West Africa. In the African region, it has globally increased from 52.2% in 2010 to 58.7% in 2013. Global reduction in proportion of transfused whole blood is linked to improvement separation of whole blood into components. There was also an improvement in the proportion of hospital having set-up a transfusion committed in 2013. Indeed, 14.5% hospitals that performed blood transfusions had a HTC compared to 10.3% in 2010. However, the arrangements required to set-up a sound clinical interface were not well developed in many countries. Hemovigilance was still not implemented in many facilities since only 13.5% of blood centres had such mechanism. Thus, reporting on the outcome of a transfused unit of blood and the fate of the transfused patient is still a challenge in many countries in the Region and needs to be improved. Establishment of HTCs and other mechanisms of reporting and linkage between hospitals and blood centres should be explored and enhanced. For instance, observation during WHO missions show that some blood centres in Burkina Faso reported significant improvement in adverse reaction notification, a practice that needs to be emulated by other countries [19]. Based on reports from South Africa, Namibia and Eritrea, frequency of severe incidents/reactions is 1.7 to 3.4 per thousand. It is 10 to 20 fold higher than frequency found in developed countries [20]. This data may be underestimated since it is based on the rate of reporting from clinical units that may not registered or send all cases to the blood service. Indeed, a very few staff from African clinical units is trained for reporting adverse events and appropriate clinical use of blood [21].

This study report for the first time proportion of patients transfused according to their age. In Central and West Africa, patients most transfused are lower than five years old compared to East & South were they are between 15 and 44 years old. It is known that malaria morbidity is higher in Western and Central part of the continent where children are often transfused for severe anaemia because of malaria [22].

5.6 Supply of Plasma-derived medicinal products

Twenty countries (43.5%) had included the plasma-derived medicinal products (PDMP) in their essential medicines list. This is encouraging as some neurologic, hematologic and immune diseases are only treated with intravenous immunoglobulin (IVIG), Factor VIII and

IX or Anti-D immunoglobulin intra muscular. Immunization programs also need the regular provision of vaccines and sera like, Anti-Rabies IgG, Anti-Tetanus IgG, Anti-Heb B-IgG, anti-RhD, all being PDMP. However, sustainability in the provision of some products such as F-VIII and IX for haemophilia care is not guaranteed since these are highly expensive blood products ordered.

6. CONCLUSION

The status of blood safety in the WHO African Region is improving year after year in conformity with the orientations spelt out in the WHA and Regional resolutions on Blood Safety. The organization and management of blood transfusion services and the availability and safety of blood have improved tremendously in several countries independently to the subregion. Governments and Development Partners have provided tremendous support at all levels of intervention in the blood safety value chain. The year 2012 marked the end of the period for attaining the targets set in the Regional Strategy for blood safety adopted by the WHO Regional Committee for Africa in 2001. Many countries made significant progress on critical blood safety indicators since 2010 survey. Data collection was better than in the previous surveys. However, the 2013 report showed that there are still major gaps to be bridged in some countries and subregions including policy implementation rate; coordination of blood services, legislation.

The Region is still falling short of meeting its blood needs since the donation rate per 1000 population is still far from the WHO recommended rate, and proportion of blood units collected from family replacement donors is still high. Some countries are still not screening all units of blood collected for all major TTIs due to a lack of essential reagents and consumables, and the quality management systems need to be established in several blood services in the Region. Also, whole blood is still the most transfused type of blood product in many countries, and there is a need to strengthen the clinical interface of blood transfusion services in Member countries so as to promote the further appropriate clinical use of blood. The same causes frequently reported may explain the gaps: lack of policy commitment in some countries despite the development and adoption of national policies; low government funding and reliance on external funding; lack of skilled human resources with adequate career prospects for BTS staffs; lack of adequate infrastructures and equipment, absence of an adequate quality management system at each section of the blood safety chain from blood donors to recipients. Consequently, the prevention of the transmission blood borne infections is not yet entirely assured in some countries and the availability of safe blood for all transfused patients in the Region is still compromised, especially in remote areas. Furthermore, as part of health SDG and UHC, the ineffective transfusion services do not contribute to the reduction of maternal and infantile mortality as well as road traffic accidents and non-communicable diseases. The results of this survey should be used to identify gaps in each Member States and Subregion and map out strategies and specific and effective interventions that will help bridge those gaps.

7. RECOMMENDATIONS

To WHO, which should:

1. provide feedback on the findings of this survey report to the relevant authorities, partners, and implementers;
2. support Member States to adopt and implement appropriate systems and technologies for day-to-day data and information collection;
3. organize independent surveys and missions to selected countries to cross-check the accuracy of the data reported;
4. support the Member States to bridge the gaps identified at country level taking into consideration their specific needs;
5. support each subregion in solving its specific issues;
6. increase advocacy with national governments and funding agencies for allocation of more resources to national blood transfusion services; and
7. propose a discussion paper on the findings of this report at the next Regional Committee meeting.

To countries, which should:

1. increase efforts in setting-up appropriate organizational structures to ensure the provision of quality services to their population;
2. provide trusty and accurate data by improving the coordination of data collection between blood centres, hospitals and ministries of health;
3. explore the sustainability options for blood transfusion services and, where possible, minimize reliance on donor funding;
4. support blood policies with the requisite legislation and enact them into national laws;
5. implement WHO recommended strategies to increase voluntary blood donations and to reduce risk of TTIs in blood and blood components;
6. establish and/or strengthen effective a national quality management system;
7. promote the establishment of strong and well-articulated national hemovigilance systems or strengthen them where they already exist;
8. provide sufficient human, material, and financial resources to the blood transfusion services and ensure their sustainability through proved mechanisms; and
9. promote the collaboration between NBTS with complementary health care programmes and with non-health sectors which blood safety and availability issues are relevant.

To National Blood Transfusion Services, which should:

1. strive to increase the number of units collected per 1000 population to meet national demand for blood;
2. make all efforts to phase out a family replacement and other high-risk donations in order to improve the quality of blood supply;
3. ensure 100% testing of all blood units for HIV 1 and 2, HBV, HCV and syphilis and improve the quality of testing for these TTIs; and
4. identify training gaps and enhance the training of appropriate personnel while mapping out strategies to retain them in BTS.

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ANNEX 1: GLOBAL DATABASE ON BLOOD SAFETY (GDBS) 2013

BLOOD SAFETY

The World Health Organization (WHO) programme on Blood Transfusion Safety would appreciate your kind cooperation in completing this data collection tool which is designed to obtain information on blood safety indicators for the WHO Global Database on Blood Safety.

The GDBS was established by WHO to address global concerns about the availability, safety, and accessibility of blood and blood products for transfusion. It covers the four major components of the integrated strategy for blood safety advocated by WHO:

(a) The establishment of well-organized, nationally-coordinated blood transfusion services with quality systems in all areas
(b) The collection of blood from voluntary non-remunerated blood donors from low-risk populations.
(c) The screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis B and C, syphilis and other infectious agents; blood grouping and compatibility testing
(d) A reduction in unnecessary transfusions through the effective clinical use of blood and blood products.

The objective of the GDBS is to collect and analyse data from all Member States of WHO in order to enable the Organization to assess the global situation of blood safety, monitor trend and progress, and identify countries that requires support and technical assistance.

Information on the GDBS indicators provided by countries will be published on the WHO website.

DATA COLLECTION FOR THE PERIOD JANUARY 2013 — DECEMBER 2013

The GDBS data collection tool should be completed by an authorized person in the Ministry of Health or the National Blood Transfusion Service. Information for relevant sections should be collected from blood centres, hospitals, and public health and regulatory agencies, as appropriate.

The tool should be completed with data for the period January to December 2013. If calendar year information is not available, please provide information for the nearest 12-month period and indicate the period covered. At the end of each section, please provide any additional information and comments that you think may be useful for interpreting the data.

For GDBS data collection for 2013, an online tool in English, French, Russian and Spanish languages (https://extranet.who.int/surveys/admin/admin.php?sid=96169) is available and countries are encouraged to use this tool. If you prefer to use the Excel-based electronic tool, or the paper version of the questionnaire, which is available in all the WHO official languages, please download from the WHO website (http://www.who.int/bloodsafety/global_database/tools/en/).

RETURNING THE GDBS DATA COLLECTION TOOL

If you are using the Excel-based electronic or printed version, please return it to WHO via e-mail at bloodsafety@who.int. If you do not have e-mail access, please mail or fax a printed copy of the tool to the following address or fax number:

Blood Transfusion Safety Programme
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
Fax: +41 22 791 4817

SECTION 1: ADMINISTRATIVE INFORMATION

1.1	Country		
1.2	Please provide the information about the National Blood Programme Manager or equivalent:		
	1.2.1 Name		
	1.2.2 Title		
	1.2.3 Position		
	1.2.4 Organization		
	1.2.5 Address		
	1.2.6 Tel. no.		
	1.2.7 Fax no.		
	1.2.8 E-mail		
1.3	Please provide the information about the person filling out this form (if different from the national manager or equivalent):		
	1.3.1 Name		
	1.3.2 Title		
	1.3.3 Position		
	1.3.4 Organization		
	1.3.5 Address		
	1.3.6 Tel. no.		
	1.3.7 Fax no.		
	1.3.8 E-mail		
1.4	Period covered by report[1]	From to	
1.5	Number of *blood centres*[2] in the country		**Nº**
	1.5.1 Stand-alone blood centres		
	1.5.2 Hospital-based blood centres		
	1.5.3 Total		
1.6	Number of *blood centres* covered by this report		
	1.6.1 Stand-alone blood centres		
	1.6.2 Hospital-based blood centres		
	1.6.2 Total		
			PER CENT
1.7	If this report does not cover all blood donations that were actually collected in your country, please estimate the percentage of blood donations that is covered by this report.		%
COMMENTS (please insert any comments or clarifications to the data given in section 1):			

[1] Please provide data for the period **January 2013** to **December 2013**. If data for this period are not available, please provide data for the nearest 12-month period.

[2] **Blood centre:** A facility that carries out all or part of the activities for donor recruitment, blood collection (whole blood and, in some cases, apheresis), testing for transfusion-transmissible infections and blood groups, processing into blood components, storage, distribution to hospital blood banks within a defined region, and liaison with clinical services. Blood centres may be stand alone or hospital-based. The following should **NOT** be categorized as blood centres:

- Mobile or fixed blood collection sites/rooms that are operated as part of a blood centre
- Hospital blood banks that only store, check compatibility and issue screened blood.

SECTION 2: ORGANIZATION AND MANAGEMENT

		YES	NO
2.1	Is there a unit within the Ministry of Health (or other government department) with responsibility for governing all activities related to provision and transfusion of blood and blood products?	☐	☐
2.2	Is there a *national blood policy*[3]?	☐	☐
	2.2.1 If yes, please provide the URL link, or send a copy to WHO via email at: bloodsafety@who.int.		
2.3	Is there a multi-year *national strategic plan* for blood safety or equivalent (e.g., a five- or ten-year strategic plan)[4] ?	☐	☐
	2.3.1 If yes, please provide the URL link, or send a copy to WHO via email at: bloodsafety@who.int.		
2.4	Is there specific legislation or other legal instruments covering the safety and quality of blood and blood products for transfusion?	☐	☐
	2.4.1 If yes, please provide the URL link, or send a copy to WHO via email at: bloodsafety@who.int.		
2.5	Is there a *national blood committee* (or equivalent) to assist the ministry of health in formulating policy and plans, setting standards and advising on key issues?	☐	☐
2.6	Is there a National Blood Transfusion Service (NBTS)[5]?	☐	☐
	2.6.1 If yes, name of national director/chief executive officer:		
2.7	Is there a published annual report on activities of NBTS/blood transfusion services (BTS)[6]?	☐	☐
	2.7.1 If yes, please provide the URL link, or send a copy to WHO via email at: bloodsafety@who.int.		
2.8	Does the government budget include a specific line item for the NBTS/blood transfusion services within the Ministry of Health or another government entity?	☐	☐
2.9	Is there a system of cost-recovery for NBTS/ blood transfusion services? (e.g. via health insurance schemes, direct payments, such as user fees, etc.)	☐	☐
2.10	Does any international agency/organization/institution provide **financial** support to the NBTS/blood transfusion services?	☐	☐
	2.10.1 If yes, name(s):		

2.11	What is the estimated total funding (in US dollars) for operating the blood centres covered in this report (including staffing and operations)?		US$
	2.11.1	Estimated total direct funding to BTS from the national government	US$
	2.11.2	Estimated total funding from fees and cost recovery	US$
	2.11.3	Estimated total funding from external donors	US$
	Note: if only percentage of the different categories (as above or otherwise) of funding source is available, please provide it in the comment box at the end of Section 2.		

2.12	What is the approximate cost (in US dollars) of producing a unit of whole blood and/or red blood cells?			
	Whole Blood	US$	Red Cells	US$

		YES	NO
2.13	Does any international agency/organization/institution provide **technical** support to the NBTS/blood transfusion services?	☐	☐
	2.13.1 If yes, name(s):		
2.14	Are there national standards for the collection, testing, processing, storage and distribution of blood and blood components?	☐	☐
2.15	Are there national guidelines on the appropriate clinical use of blood and blood products?	☐	☐
2.16	Is there a programme of continuing education for personnel involved in blood transfusion?	☐	☐
2.17	Are there educational programmes in your country that offer a nationally-recognized university degree or diploma in blood transfusion medicine/science?	☐	☐
2.18	Is there a national *external quality assessment*[7] scheme for:		
	2.18.1 Laboratory screening for transfusion-transmissible infections	☐	☐
	2.18.2 Blood group serology and compatibility testing	☐	☐
2.19	Is there a national *haemovigilance*[8] system?	☐	☐

[3] **National blood policy**: A statement of intent by the Ministry of Health that defines the organizational, financial and legal measures that will be taken to ensure the quality, safety, availability and accessibility to blood and blood products for transfusion within the country.

[4] **National strategic plan**: A framework of action that defines the goal, objectives, strategies, targets and time scale for the implementation of the national blood policy.

[5] **National blood transfusion service (NBTS):** The organization with statutory national responsibility for the provision of blood for transfusion, and liaison with clinical services.

[6] **Blood transfusion service (BTS):** A generic term to describe an organization that is involved in the provision of blood for transfusion, regardless of whether it is nationally coordinated or not.

[7] **External quality assessment (EQA):** The external assessment of a laboratory's performance using samples of known, but undisclosed, content and comparison with the performance of other laboratories.

	2.19.1	Does the system include collection of data on donor-related adverse events?	☐	☐
	2.19.2	Does the system include collection of data on recipient-related adverse events?	☐	☐
2.20	Is there a system of regular inspection(s) of the NBTS/blood transfusion service(s) by the national regulatory agency or another entity?		☐	☐
2.21	Is there a system of licensing of the NBTS/blood transfusion service(s) by the national regulatory agency or another entity?		☐	☐
2.22	Are NBTS/blood transfusion service(s) accredited?		☐	☐
	2.22.1 If yes, please provide further information on the accreditation programme and number of centres accredited:			
2.23	Did stocks of any of the following consumables run out during the reporting period at the national or regional level?			
	2.23.1	Blood collection bags	☐	☐
	2.23.2	Test kits for transfusion-transmissible infections	☐	☐
	2.23.3	Reagents for routine blood grouping	☐	☐
	2.23.4	Others (please specify):	☐	☐
COMMENTS (please insert any comments or clarifications to the data given in section 1):				

[8] **Haemovigilance:** A set of surveillance procedures for the monitoring, reporting and investigation of adverse events (reactions and incidents, including near-misses) covering the entire transfusion chain, from the collection of blood from the donor to the follow-up of recipients, intended to collect and assess information related to the adverse event and to prevent their occurrence or recurrence.

SECTION 3: BLOOD DONORS AND BLOOD COLLECTION

			YES	NO
3.1	Is a specific budget provided for the blood donor programme?		☐	☐
3.2	Was World Blood Donor Day celebrated in your country during the reporting period?		☐	☐
3.3	Are there national donor selection criteria for assessing donor suitability for blood donation?		☐	☐
3.4	Is there a register/database of blood donors?		☐	☐
	If yes, at what level is the register/database of blood donors maintained?			
	3.4.1	National	☐	☐
	3.4.2	State/provincial/regional	☐	☐
	3.4.3	Individual blood centre or hospital	☐	☐
3.5	**Number of active blood donors**[9] who donated whole blood during the reporting period (excluding autologous donors)		**Nº**	
	3.5.1	Total number of voluntary non-remunerated donors		
	3.5.2	Total number of family/replacement donors		
	3.5.3	Total number of paid donors		
	3.5.4	Total number of donors who donated whole blood		
3.6	Number of **whole blood donations** collected during the reporting period (excluding autologous donations), by types of donation		**Nº**	
	3.6.1	Voluntary non-remunerated donations		
	3.6.1.1	- *Voluntary non-remunerated* donations from *first time donors*[10]		
	3.6.1.2	- *Voluntary non-remunerated* donations from *repeat donors*[11]		
	3.6.2	Family/replacement donations		
	3.6.3	Paid donations		
	3.6.4	Others (please specify):		
	3.6.5	Total number of donations		
	Note: 3.6.1.1+3.6.1.2 should be equal to 3.6.1.			

			YES	NO
3.7	Are any blood donations collected through apheresis[12] procedures?			
	If yes, Number of **apheresis donations** [13] collected during the reporting period (excluding autologous donations), by types of donation		**Nº**	
	3.7.1	Voluntary non-remunerated donations		
	3.7.1.1	- Voluntary non-remunerated donations from first time donors		
	3.7.1.2	- Voluntary non-remunerated donations from repeat donors		
	3.7.2	Family/replacement donations		
	3.7.3	Paid donations		
	3.7.4	Others (please specify):		
	3.7.5	Total number of donations		
	Note: 3.7.1.1+3.7.1.2 should be equal to 3.7.1			
3.8	Number of potential blood donors who were deferred from donating, by types of deferral		**Nº**	
	3.8.1	Permanent deferral		
	3.8.2	Temporary deferral		
3.9	Number of deferrals (potential blood donors who were deferred from donating, by reasons for deferral		**Nº**	
	3.9.1	Low weight		
	3.9.2	Low haemoglobin		
	3.9.3	Other medical conditions		
	3.9.4	High-risk behaviour		
	3.9.5	Travel history		
	3.9.6	Other reasons (please specify):		

[9] The number of individual donors who donated blood during the reporting period is required. Donors who donated on more than one occasion in the reporting period should only be counted once. For example, if one blood donor donated 3 times during the reporting period, the number of donors counted should be 1 rather than 3. Registered donors who have not donated blood during the reporting period should **NOT** be counted.

[10] **'First time' blood donor:** An individual who has never donated before and donated blood for the first time.

[11] **Repeat blood donor:** A blood donor who has donated on any previous occasion.

[12] **Apheresis:** The process by which the required component of whole blood is separated and collected using an automated blood cell separator device.

[13] When multiple blood components (such as platelets and plasma) are collected through one apheresis procedure, this should be counted as only 1 donation.

	3.9.7	Total number of deferrals		
3.10	Number of blood **donations** collected from:		**№**	
	3.10.1	Male donors		
	3.10.2	Female donors		
3.11	Number of blood **donations** collected from donors:		**№**	
	3.11.1	under 18 years		
	3.11.2	18 to 24 years		
	3.11.3	25 to 44 years		
	3.11.4	45 to 64 years		
	3.11.5	65 years or older		
	Note: if you have data by age that do not fit this framework (e.g. different age group), please provide the date that you do have in the "Comments" box at the end of section 3.			
3.12	Number of pre-deposit autologous blood **donations**			
3.13	Is there a donor notification system for:		**YES**	**NO**
	3.13.1	HIV test results	☐	☐
	3.13.2	Hepatitis B test results	☐	☐
	3.13.3	Hepatitis C test results	☐	☐
	3.13.4	Syphilis test results	☐	☐
	3.13.5	Other (please specify):	☐	☐
3.14	Is there a system of post-donation counselling and referral to care and treatment for blood donors who test positive for transfusion-transmissible infections?		☐	☐
COMMENTS (please insert any comments or clarifications to the data given in section 3):				

SECTION 4: SCREENING FOR TRANSFUSION-TRANSMISSIBLE INFECTIONS

4.1	Please specify the laboratory tests required in your country as minimum requirements for screening donated blood for the markers of transfusion-transmissible infections (TTIs):			**YES,** required for all donations	**YES,** required for selective donations[14]	**NO**
	4.1.1	HIV1+2	Ab	☐	☐	☐
			Ag	☐	☐	☐
			NAT	☐	☐	☐
	4.1.2	Hepatitis B	HBsAg	☐	☐	☐
			Anti-HBc Ab	☐	☐	☐
			NAT	☐	☐	☐
	4.1.3	Hepatitis C	Anti-HCV Ab	☐	☐	☐
			Ag	☐	☐	☐
			NAT	☐	☐	☐
	4.1.4	Syphilis	Ab	☐	☐	☐
			Others (please specify):	☐	☐	☐
	4.1.5	Chagas disease	Ab	☐	☐	☐
			Other (please specify):	☐	☐	☐
	4.1.6	Malaria	Smear microscopy	☐	☐	☐
			Ag	☐	☐	☐
			Others (please specify):	☐	☐	☐
	4.1.7	HTLV I/II	Ab	☐	☐	☐
			Other (please specify):	☐	☐	☐
	4.1.8	Other TTI marker	Please specify:	☐	☐	☐
	Please provide further information or explanations on the screening policy/strategies if only selective screening is carried out for a defined marker:					

4.2	Is confirmatory testing[15] performed on units that are reactive for :				
			YES, performed on all reactive units	**YES,** performed on part of the reactive units	**NO**
	4.2.1	HIV1+2	☐	☐	☐
	4.2.2	HBV	☐	☐	☐
	4.2.3	HCV	☐	☐	☐
	4.2.4	Syphilis	☐	☐	☐

		№
4.3	Number of blood centres that perform laboratory screening of blood donations for transfusion-transmissible infections	
4.4	Number of blood centres performing laboratory screening that participate in external quality assessment scheme for transfusion-transmissible infections?	

4.5	Number and % of donations (whole blood and apheresis) that were screened for the following transfusion-transmissible infections				
			№ SCREENED (NUMERATOR)	Total **№ OF DONATIONS** (Denominator)	**PER CENT**
	4.5.1	HIV1+2			
	4.5.2	Hepatitis B			
	4.5.3	Hepatitis C			
	4.5.4	Syphilis			
	4.5.5	Chagas disease			
	4.5.6	Malaria			
	4.5.7	HTLV I/II			
	4.5.8	Other (Please specify):			

4.6	Number and % of donations (whole blood and apheresis) that were screened for the following transfusion-transmissible infections in a quality-assured manner[16]				
			№ SCREENED IN A QUALITY-ASSURED MANNER (NUMERATOR)	Total **№ OF DONATIONS** (Denominator)	**PER CENT**

[14] For example, donations collected from first time donors, donations collected from donors who travelled to endemic areas of certain infectious disease, donations to be used by certain recipient group, etc.

[15] Confirmatory testing is carried out in samples of blood donors that give reactive results in the screening tests to confirm the infectious status of donors. Donations that are reactive may be confirmed as being of negative, inconclusive or positive status.

[16] **Quality-assured testing:** For the purpose of data collection, testing in a quality-assured manner is defined as "testing performed in a laboratory that: (1) uses documented standard operating procedures; (2) participates in an external quality assessment scheme".

	4.6.1	HIV1+2			%
	4.6.2	HBV			%
	4.6.3	HCV			%
	4.6.4	Syphilis			%

4.7	Prevalence (Number and %) of infections in blood donations for the following TTI markers				
			POSITIVE/REACTIVE Nº (NUMERATOR)	**Nº SCREENED (DENOMINATOR)**	**PER CENT**
	4.7.1	HIV1+2			%
	4.7.2	Hepatitis B			%
	4.7.3	Hepatitis C			%
	4.7.4	Syphilis			%
	4.7.5	Chagas disease			%
	4.7.6	Malaria			%
	4.7.7	HTLV I/II			%
	4.7.8	Other (Please specify):			%

		YES	**NO**
4.8	Can you disaggregate the prevalence of HIV infections in donated blood units by type of donations, such as voluntary non-remunerated blood donation and family/replacement donations?	☐	☐

If yes, please provide number (numerators and denominators) and % of HIV infections as categorized below:

		NUMERATOR	**DENOMINATOR**	**PER CENT**
4.8.1	All voluntary non-remunerated blood donations			%
4.8.1.1	- *Voluntary non-remunerated donations from first time donors*			%
4.8.1.2	- *Voluntary non-remunerated donations from repeat blood donors*			%
4.8.2	Family/replacement donations			%
4.8.3	Paid donations			%

If disaggregated data are only partially available, please enter data that you have. Do not enter anything into cells for which there is no data.

COMMENTS (please insert any comments or clarifications to the data given in section 4):

SECTION 5: BLOOD COMPONENT PREPARATION

					№
5.1	Number of blood centres that prepare blood components				
			№ (NUMERATOR)	**DENOMINATOR**	**PER CENT**
5.2	Number and % of whole blood donations separated into components				%
5.3	Number of units[17, 18] of blood components prepared from whole blood donations				**№**
	5.3.1	Red cell preparations			
	5.3.2	Platelet concentrates			
	5.3.3	Fresh frozen plasma[19]			
	5.3.4	Plasma			
	5.3.5	Cryoprecipitate			
5.4	Number of units[20] of blood components prepared through apheresis procedures				**№**
	5.4.1	Apheresis red cells			
	5.4.2	Apheresis platelets[21]			
	5.4.3	Apheresis plasma			
5.5	Number of units of whole blood /red cell components discarded, by cause				**№**
	5.5.1	Incomplete blood donation			
	5.5.2	Reactive for TTIs			
	5.5.3	Passed the expiry date			
	5.5.4	Storage problems			
	5.5.5	Transportation problems			
	5.5.6	Processing problems			
	5.5.7	Total			
COMMENTS (please insert any comments or clarifications to the data given in section 5):					

[17] The term "unit" refers to an adult-sized blood bag (approx. 450ml). Please count all satellite units (e.g., pediatric packs) derived from a single donation as "one unit."

[18] Please count pools of whole-blood-derived platelets or cryoprecipitate in terms of individual unit equivalents. For example, if 6 units of platelet concentrates were pooled into one bag, this should be counted as 6 platelet concentrates rather than 1.

[19] **Fresh Frozen Plasma (FFP):** a component prepared from whole blood or from plasma collected by apheresis frozen to a temperature that will maintain the labile coagulation factors in a functional state.

[20] `When a single apheresis procedure produces more than one types of component (e.g. plasma and platelets), all units of components should be counted.

[21] One unit of apheresis platelets usually contains 200-450 x 10^9 platelets.

SECTION 6: CLINICAL USE OF BLOOD & BLOOD COMPONENTS

			№	
6.1	Number of hospitals in the country that perform blood transfusions			
6.2	Number and % of hospitals performing blood transfusion that have, or participate in:		№	PER CENT
	6.2.1	Hospital transfusion committee		%
	6.2.2	Clinical audit[22]		%
	6.2.3	System for reporting adverse transfusion incidents and reactions		%
6.3	Number of units of each of the following blood components issued / transfused (excluding autologous blood units) in the country			
			№	
	6.3.1	Whole blood		
	6.3.2	Red cells		
	6.3.3	Platelets, whole blood-derived		
	6.3.4	Platelets, apheresis		
	6.3.5	Fresh frozen plasma		
	6.3.6	Plasma		
	6.3.7	Cryoprecipitate		
			№	
6.4	Number of patients transfused in the country			
	If the number is estimated, please provide information on how the estimation is made:			
6.5	Number of patients transfused, by age		№	
	6.5.1	under 5 years		
	6.5.2	5 to 14 years		
	6.5.3	15 to 44 years		
	6.5.4	45 to 59 years		
	6.5.5	60 years or older		
	Note: if you have data by age that do not fit this framework (e.g. different age group), please provide the date that you do have in the "Comments" box at the end of section 6.			
			№	
6.6	Number of *serious adverse transfusion reactions*[23] reported in the country			
	6.6.1	Immunological haemolysis due to ABO incompatibility		
	6.6.2	Immunological haemolysis due to other allo-antibody		
	6.6.3	Non-immunological haemolysis		

[22] **Clinical audit:** A quality improvement process that seeks to improve patient care and outcomes through systematic review of the use of transfused blood or blood products and compare with transfusion guidelines. The aim of this process is to create a culture of delivering a quality service to patients as well as to improve medical care on a continuous basis.

[23] **Serious adverse transfusion reaction**: An undesirable response or effect in a patient associated with the administration of blood or blood components that is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalization or morbidity.

	6.6.4	Post-transfusion purpura	
	6.6.5	Anaphylaxis/hypersensitivity	
	6.6.6	Transfusion-related acute lung injury (TRALI)	
	6.6.7	Graft versus host disease	
	6.6.8	Transfusion-associated HIV-1/2 infection	
	6.6.9	Transfusion-associated HBV infection	
	6.6.10	Transfusion-associated HCV infection	
	6.6.11	Other transfusion-associated viral infection	
	6.6.12	Sepsis due to bacterial contamination of the donor unit	
	6.6.13	Transfusion-associated malaria infection	
	6.6.14	Other transfusion-associated parasitical infection	
	6.6.15	Transfusion-associated circulatory overload	
	6.6.16	Other serious adverse transfusion reaction	
COMMENTS (please insert any comments or clarifications to the data given in section 6):			

SECTION 7: PLASMA-DERIVED MEDICINAL PRODUCTS (PDMD)

			YES	NO
7.1	Does the Essential Medicines List[24] in your country include the following plasma-derived medicinal products (PDMP)[25]?			
	7.1.1	Albumin	☐	☐
	7.1.2	Intravenous immunoglobulin (IVIG)	☐	☐
	7.1.3	Factor VIII	☐	☐
	7.1.4	Factor IX	☐	☐
	7.1.5	Others (please specify):	☐	☐
7.2	How are PDMP provided to meet the health care needs in the country**?**			
	7.2.1	All or part of the products are produced through the fractionation (e.g. domestic or/and contract fractionation) of plasma collected in the country	☐	☐
	7.2.2	Plasma collected in the country was sold to the manufacturers of plasma-derived medicinal products and products purchased from PMDP suppliers in the market	☐	☐
	7.2.3	No plasma collected in the country are used for fractionation. All products are imported from abroad	☐	☐
	7.2.4	No PDMP is provided /transfused in the country	☐	☐
Answer the following question 7.3 - 7.10 only when the answer to question 7.2.1 or 7.2.2 is "yes".				
7.3	Is plasma fractionation carried out within the country through the public/not-for-profit sector?		☐	☐
7.4	Is plasma fractionation carried out within the country through the for-profit sector?		☐	☐
7.5	Is plasma sent for contract fractionation in another country?		☐	☐
7.6	Volume of plasma used for domestic or contract fractionation, or sold to the manufacturers of PMDP for fractionation[26]			
	7.6.1	Recovered plasma		litres
	7.6.2	Apheresis plasma		litres
7.7	Number of plasmapheresis/source plasma[27] donors who donated plasma during the reporting year		**Nº**	
	7.7.1	Voluntary non-remunerated plasma donors		
	7.7.2	Paid plasma donors		
	7.7.3	Other plasma donors (please specify):		
7.8	Which products are manufactured by fractionation within the country or through contract fractionation?			
			YES	**NO**
	7.8.1	Albumin	☐	☐
	7.8.2	Intravenous immunoglobulin (IVIG)	☐	☐
	7.8.3	Factor VIII	☐	☐
	7.8.4	Factor IX	☐	☐
	7.8.5	Others (please specify):	☐	☐
7.9	Of the following products supplied in the country, what percentage is supplied through the products provided by fractionation (e.g. domestic or/and contract fractionation) of plasma collected in the country?			
				PER CENT
	7.9.1	Albumin		%
	7.9.2	Intravenous immunoglobulin (IVIG)		%
	7.9.3	Factor VIII (excluding recombinant products)		%
7.10	Is there a surplus of plasma-derived medicinal products in excess of national needs?			
	Is yes, how are these products utilized		**YES**	**NO**
	7.10.1	Donated to another country/organization		
	7.11.2	Sold to the manufacturer		
	7.10.2	Sold to another country/organization		
	7.10.3	Discarded		
	7.10.4	Other (please specify):		
COMMENTS (please insert any comments or clarifications to the data given in section 7):				

[24] **Essential medicines List (EML):** Essential medicines are those that satisfy the priority health care needs of the population. National-level EMLs include medicines that governments or other institutions deem vital for the most common health conditions facing their populations. Medicines on an EML are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness and merit special efforts to ensure availability and correct use. The EML supports the systematic delivery of medicines in the health care system and is an important strategy in improving access to and use of medicines.

[25] **Plasma-derived medicinal products (PDMP):** Human plasma protein products prepared under pharmaceutical manufacturing conditions. Plasma products include albumin, immunoglobulin and coagulation factors VIII and IX.

[26] This figure should include all plasma used for fraction within the country and /or sent for contract fractionation. If plasma was imported for fractionation during the reporting period, it should also be included here.

[27] **Source plasma:** Plasma obtained by plasmaphereis for further fractionation into plasma-derived medicinal products.

DEFINITIONS

For the purposes of this tool indicated in sections 1-7 above, the following definitions should be used in answering the questions.

Apheresis: Procedure that involves withdrawal of blood, ex vivo separation and collection of a desired component (e.g. red cells, plasma or platelets) and reinfusion of the other components.

Blood centre: A facility that carries out all or part of the activities for donor recruitment, blood collection (whole blood and, in some cases, apheresis), testing for transfusion-transmissible infections and blood groups, processing into blood components, storage, distribution to hospital blood banks within a defined region, and liaison with clinical services. Blood centres may be stand alone or hospital-based. The following should NOT be categorized as blood centres:

- Mobile or fixed blood collection sites/rooms that are operated as part of a blood centre
- Hospital blood banks that only store, check compatibility and issue screened blood.

Blood donors

- **Voluntary non-remunerated blood donor**: A person who donates blood (and plasma or cellular components) of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money.
- **Family/replacement blood donor**: A person who gives a replacement unit of blood only when a family member or friend requires transfusion.
- **Paid blood "donor"**: A "donor" who gives blood for money or other form of payment.
- **Autologous blood donor**: A patient who donates his/her blood to be stored and re-infused, if needed, during surgery.
- '**First time' blood donor**: An individual who has never donated before and donated blood for the first time.
- **Repeat blood donor:** A blood donor who has donated on any previous occasion.

Blood transfusion service (BTS): A generic term to describe an organization that is involved in the provision of blood for transfusion, regardless of whether it is nationally coordinated or not.

Clinical audit: A quality improvement process that seeks to improve patient care and outcomes through systematic review of the use of transfused blood and blood products against transfusion guidelines. The aim of this process is to create a culture of delivering a quality service to patients as well as to improve medical care on a continuous basis.

Essential medicines List (EML): Essential medicines are those that satisfy the priority health care needs of the population. National-level EMLs include medicines that governments or other institutions deem vital for the most common health conditions facing their populations. Medicines on an EML are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness and merit special efforts to ensure availability and correct use. The EML supports the systematic delivery of medicines in the health care system and is an important strategy in improving access to and use of medicines.

External quality assessment (EQA): The external assessment of a laboratory's performance using samples of known, but undisclosed, content and comparison with the performance of other laboratories.

Plasma-derived medicinal products (PDMP): Human plasma protein products prepared under pharmaceutical manufacturing conditions. Plasma products include albumin, immunoglobulin and coagulation factors VIII and IX.

Fresh Frozen Plasma (FFP): a component prepared from whole blood or from plasma collected by apheresis frozen to a temperature that will maintain the labile coagulation factors in a functional state.

Haemovigilance: A set of surveillance procedures for the monitoring, reporting and investigation of adverse events (reactions and incidents, including near-misses) covering the whole transfusion chain, from the collection of blood and its components to the follow-up of recipients, intended to collect and assess information and to prevent their occurrence or recurrence.

National blood policy: A statement of intent by the Ministry of Health that defines the organizational, financial and legal measures that will be taken to ensure the quality, safety, availability and accessibility to blood and blood products for transfusion within the country.

National blood transfusion service (NBTS): The organization with statutory national responsibility for the provision of blood for transfusion, and liaison with clinical services.

National strategic plan: A framework of action that defines the goal, objectives, strategies, targets and time scale for the implementation of the national blood policy.

Quality-assured testing: For the purpose of data collection, testing in a quality-assured manner is defined as "testing performed in a laboratory that: (1) Uses documented standard operating procedures; (2) Participates in an external quality assessment scheme".

Serious adverse transfusion reaction: An undesirable response or effect in a patient associated with the administration of blood or blood components that is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalization or morbidity.

Source plasma: Plasma obtained by plasmaphere is for further fractionation into plasma-derived medicinal products.

ANNEX: QUESTIONNAIRE ON ACHIEVING TARGETS OF BLOOD SAFETY

Regional strategy for blood safety achievement of targets by Member States for the period January - December 2012			
Date :			
Country :			
Population:	Source:		
❒ National Blood Transfusion Service	❑ National Blood Transfusion Programme ❑ None		
Name of Director/Manager :			
Contact : Tel.:	email:		
N⁰	**Regional Strategy Target**	**Response**	**Comments**
01	Situation analysis done (**YES or NO**)		
02	National Blood Policy formulated (**YES or NO**)		
03	National Blood Policy adopted (**YES or NO**)		
04	If **YES** date of adoption		
05	National Blood Policy is being implemented (**YES or NO**)		
06	Legislation formulated (**YES or NO**)		
07	Legislation adopted (**YES or NO**)		
08	If **YES** date of adoption		
09	Legislation is being implemented (**YES or NO**)		
10	Annual budget allocated by MOH to Blood Transfusion Service	USD	
		%	
11	Total Number of blood donations		
12	Number of voluntary non remunerated blood donors in the country (VNRBD)		
13	Percentage of voluntary non remunerated blood donors in the country (VNRBD)	%	
14	Number of units of blood collected and screened for various TTIs	HIV	
		HBV	
		HCV	
		SYPHILIS	
15	Percentage of units of blood collected and screened for various TTIs	% HIV	
		% HBV	
		% HCV	
		% SYPHILIS	
16	Prevalence (number and percentage) of TTIs in blood donations	VIH :	
		VHB :	
		VHC :	
		SYPHILIS :	
17	Is blood tested in a quality-assured manner[28] (**YES or NO**)		
18	If **YES** what is percentage of blood units tested in quality-assured manner?	%	
19	Quality management programme in place in BTS (**YES or NO**)		
20	If **YES** which elements of quality system are in place?		
21	Participation in external quality assessment scheme for TTIs (**YES or NO**)		
22	Participation in external quality assessment scheme for blood group serology		

[28] Testing in a quality-assured manner is defined as testing performed in a laboratory that uses documented standard operating procedures and participates in an external quality assessment scheme.

	and compatibility testing (**YES or NO**)		
23	Number and percentage of whole blood donations separated into components		
24	National Guidelines for appropriate clinical use of blood available (**YES or NO**)		
25	National Hemovigilance system in place (**YES or NO**)		
26	Number and percentage of hospital with Hospital Transfusion Committee (HTC)		
27	Cost recovery system in place **(YES or NO)**		
28	If **YES**, what is the cost of a blood unity	USD	
29	General comments on progress made during the last 10 years with special emphasis on the main achievements and challenges		NB: Add additional page if necessary