Summer Placement

In

World Health Organization

Geneva, Switzerland

(April 15 – June 15, 2013)

A Report

Submitted By: Anita Dalal

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Submitted to: Dr.Santosh Kumar (Associate Professor, IIHMR)

Post Graduate Programme in Hospital Management

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CERTIFICATE

This is to certify that Dr Anita Dalal student of 17th batch of the Post Graduate Diploma in Hospital and Health Management (PGDHM) at Institute of Health Management Research , Jaipur underwent the summer internship at World Health Organization , Geneva, Switzerland from April 15th to June 15th and was assigned following projects :

- Systemic Research on Self Sufficiency in Blood and Blood Products
- Global Database on Blood Safety

The candidate successfully carried out the study assigned to her during summer training and her approach to the study was sincere, scientific and analytical.

We wish her success in all her future Endeavors.

Dr Ashok Kaushik
Dean (Academic and Student Affairs)
IIHMR ,JAIPUR

S. Kumar Jan 24, 14
Dr Santosh Kumar
Associate Professor
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Acknowledgement

I, Anita Dalal, a student of PGDHM 17 at IIHMR Jaipur, would like to sincerely express my heartfelt gratitude to:

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- Lastly, I would like to thank my college, IIHMR Jaipur, for providing me with an opportunity to learn from and work with the best personnel in the Hospital Industry, and for helping me gain an appreciation of where I currently stand as an administrator and how much work I would need in order to meet the quality specifications that the hospital industry seeks.

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1. Acronyms/Abbreviations

AFR WHO African Region

AMR WHO Region of the Americas

BCT Blood components for transfusion

BTS Blood transfusion service

CJD Creutzfeldt-Jakob disease

EMR WHO Eastern Mediterranean Region

EUR WHO European Region

GDBS Global Database on Blood Safety

HBV Hepatitis B virus

HCV Hepatitis C virus

HIV Human immunodeficiency virus

IFRC International Federation of Red Cross and Red Crescent Societies

PDMP Plasma-derived medicinal products

UN United Nations

2. Observation Learning

2A. Introduction

The summer training is an integral part of the course curriculum of PGDHM at IIHMR Jaipur. As part of the course, students at the end of their first year are required to undergo training of two months to get an in-depth exposure to the various departments in the organization, as well as take up projects as per the requirements of the organization where the students get training. What is most crucial is to build a base of knowledge about the structure and functioning of the organization, which can be used to understand and apply concepts in the subsequent study tenure at IIHMR Jaipur.

During my summer at World Health Organization, Geneva, Switzerland there were numerous learning experiences. These were enhanced due to the projects undertaken at Blood Transfusion Safety Unit, which are listed as follows:

- *A Systematic Search on Self Sufficiency in Blood and Blood Products.*
- *Global Database on Blood Safety.*

A brief report of the training of two months is presented below with the details of tasks undertaken and lessons learnt during the training.

2B. Organization Profile

WHO Headquarters in Geneva

The **World Health Organization** (**WHO**) is a specialized agency of the United Nations (UN) that is concerned with international public health. It was established on 7 April 1948, with its headquarters in Geneva, Switzerland. WHO is a member of the United Nations Development Group. Its predecessor, the Health Organization, was an agency of the League of Nations.

The constitution of the World Health Organization had been signed by all 61 countries of the United Nations by 22 July 1946, with the first meeting of the World Health Assembly finishing on 24 July 1948. It incorporated the *Office International d'Hygiène Publique* and the League of Nations Health Organization. Since its creation, it has played a leading role in the eradication of smallpox. Its current priorities include communicable diseases, in particular, HIV/AIDS, malaria and tuberculosis; the mitigation of the effects of non-communicable diseases; sexual and reproductive health, development, and aging; nutrition, food security and healthy eating; occupational health; substance abuse; and drive the development of reporting, publications, and networking. WHO is responsible for the *World Health Report*, a leading international publication on health, the worldwide World Health Survey, and World Health Day (7th-April of every Year).

Its links with the International Atomic Energy Agency and distribution of contraception have both proved controversial, as have guidelines on healthy eating and the 2009 flu pandemic.

History

Establishment

The use of the word "world", rather than "international", emphasized the truly global nature of what the organization was seeking to achieve. The constitution of the World Health Organization had been signed by all 61 countries of the United Nations by 22 July 1946. It thus became the first specialized agency of the United Nations to which every member subscribed. Its constitution formally came into force on the first World Health Day on 7 April 1948, when it was ratified by the 26th member state. The first meeting of the World Health Assembly finished on 24 July 1948, having secured a budget of US$5 million (then GBP£1,250,000) for the 1949 year. Andrija Stampar was the Assembly's first president, and G. Brock Chisholm was appointed Director-General of WHO, having served as Executive Secretary during the planning stages. Its first priorities were to control the spread of malaria,

tuberculosis and sexually transmitted infections, and to improve maternal and child health, nutrition and environmental hygiene. Its first legislative act was concerning the compilation of accurate statistics on the spread and morbidity of disease. The logo of the World Health Organization features the Rod of Asclepius as a symbol for healing.

Operational history

WHO established an epidemiological information service via telex in 1947, and by 1950 a mass tuberculosis inoculation drive (using the BCG vaccine) was under way. In 1955, the malaria eradication programme was launched, although it was later altered in objective. 1965 saw the first report on diabetes mellitus and the creation of the International Agency for Research on Cancer. WHO moved into its headquarters building in 1966. The first list of essential medicines was drawn up in 1977, and a year later the ambitious goal of "health for all" was declared. In 1986, WHO started its global programme on the growing problem of HIV/AIDS, followed two years later by additional attention on preventing discrimination against sufferers and UNAIDS was formed in 1996. The Global Polio Eradication Initiative was established in 1988.

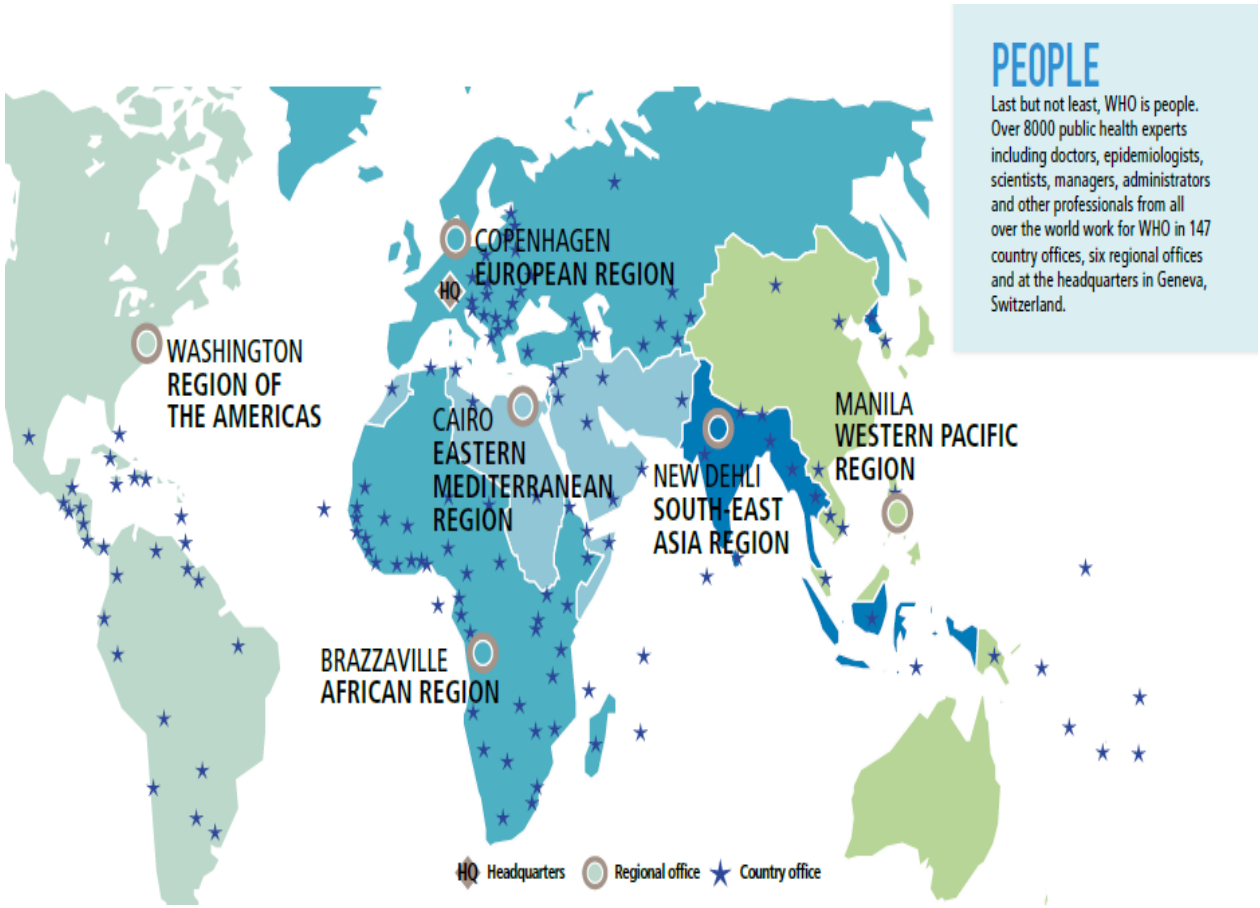
In 1958, Viktor Zhdanov, Deputy Minister of Health for the USSR, called on the World Health Assembly to undertake a global initiative to eradicate smallpox, resulting in Resolution WHA11.54. At this point, 2 million people were dying from smallpox every year. In 1967, the World Health Organization intensified the global smallpox eradication by contributing $2.4 million annually to the effort and adopted a new disease surveillance method. After over two decades of fighting smallpox, the WHO declared in 1980 that the disease had been eradicated – the first disease in history to be eliminated by human effort.

In 1998, WHO's Director General highlighted gains in child survival, reduced infant mortality, raised life expectancy and reduced rates of "scourges" such as smallpox and polio on the fiftieth anniversary of WHO's founding. He, did, however, accept that more had to be done to assist maternal health and that progress in this area had been slow. Cholera and malaria have remained problems since WHO's founding, although in decline for a large part of that period. In the twenty-first century, the Stop TB Partnership was created in 2000, along with the UN's formulation of the Millennium Development Goals. The Measles initiative was formed in 2001, and credited with reducing global deaths from the disease by 68% by 2007. In 2002, The Global Fund to Fight AIDS, Tuberculosis and Malaria was drawn up to improve

the resources available. In 2006, the organization endorsed the world's first official HIV/AIDS Toolkit for Zimbabwe, which formed the basis for a global prevention, treatment and support plan to fight the AIDS pandemic.

Structure

The World Health Organization is a member of the United Nations Development Group. WHO has its various headquarters, regional offices and country offices distributed all across the world.



Membership

As of 2013, the WHO has 194 member states: all Member States of the United Nations except Liechtenstein, as well as the Cook Islands and Niue. (A state becomes a full member of WHO

by ratifying the treaty known as the Constitution of the World Health Organization.) As of 2013, it also had two associate members, Puerto Rico and Tokelau. Several other entities have been granted observer status. Palestine is an observer as a "national liberation movement" recognised by the League of Arab States under United Nations Resolution 3118. The Holy See also attends as an observer, as does the Order of Malta. In 2010, Taiwan was invited under the name of "Chinese Taipei".

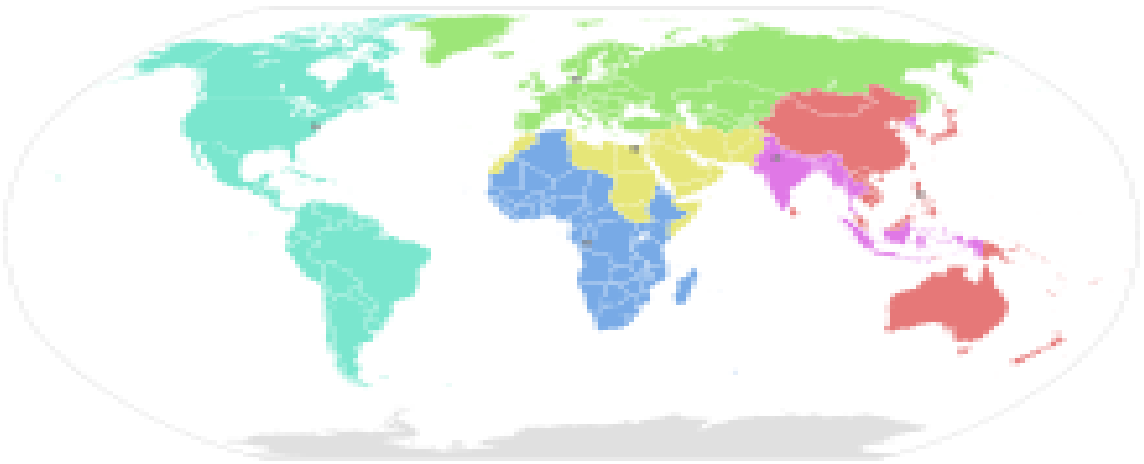
WHO Member States appoint delegations to the World Health Assembly, WHO's supreme decision-making body. All UN Member States are eligible for WHO membership, and, according to the WHO web site, "other countries may be admitted as members when their application has been approved by a simple majority vote of the World Health Assembly".

In addition, the UN observer organizations International Committee of the Red Cross and International Federation of Red Cross and Red Crescent Societies have entered into "official relations" with WHO and are invited as observers. In the World Health Assembly they are seated along the other NGOs.

Assembly and Executive Board

The World Health Assembly is the legislative and supreme body of WHO. Based in Geneva, it typically meets yearly in May. It appoints the Director-General every five years, and votes on matters of policy and finance of WHO, including the proposed budget. It also reviews reports of the Executive Board and decides whether there are areas of work requiring further examination. The Assembly elects 34 members, technically qualified in the field of health, to the Executive Board for three-year terms. The main functions of the Board are to carry out the decisions and policies of the Assembly, to advise it and to facilitate its work.

Regional offices



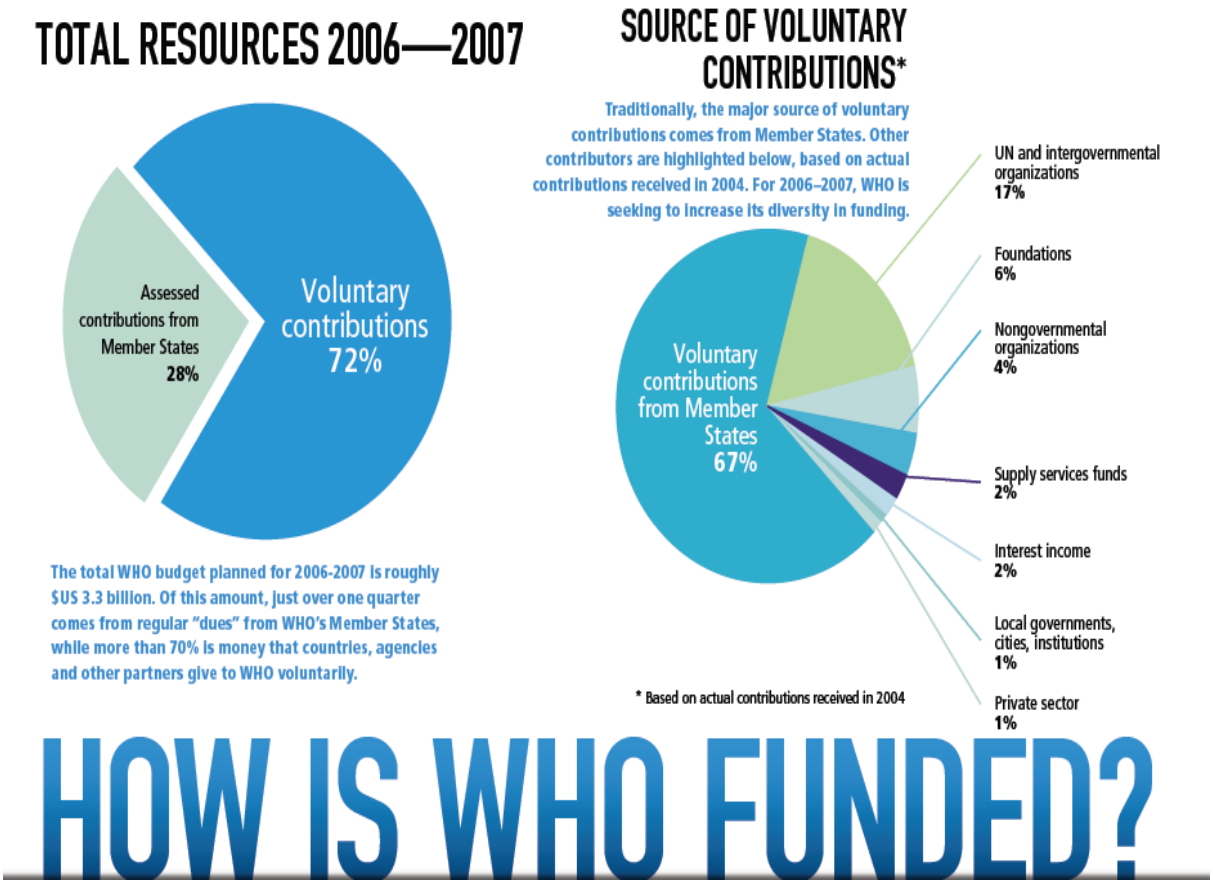
Regional Offices of WHO

Region	Headquarters	Notes	Website
Africa	Brazzaville, Republic of Congo	AFRO includes most of Africa, with the exception of Egypt, Sudan, South Sudan, Tunisia, Libya, Somalia and Morocco (all fall under EMRO).	AFRO
Europe	Copenhagen, Denmark.	EURO includes most of Europe and Israel.	EURO
South-East Asia	New Delhi, India	North Korea is served by SEARO.	SEARO
Eastern Mediterranean	Cairo, Egypt	Eastern Mediterranean Regional office includes the countries of Africa that are not included in AFRO, as well as the countries of the Middle East, except for Israel. Pakistan is served by EMRO.	EMRO
Western Pacific	Manila, Philippines.	WPRO covers all the Asian countries not served by SEARO and EMRO, and all the countries in Oceania. South Korea is served by WPRO.	WPRO
The Americas	Washington D.C., USA.	Also known as the Pan American Health Organization (PAHO), and covers the Americas. The Regional Director	AMRO

The head of the organization is the Director-General, elected by the World Health Assembly. The current Director-General is Margaret Chan, who was first appointed on 9 November 2006 and confirmed for a second term until the end of June 2017.

WHO employs 8,500 people in 147 countries. In support of the principle of a tobacco-free work environment the WHO does not recruit cigarette smokers. The organization has previously instigated the Framework Convention on Tobacco Control in 2003.

Financing and partnerships



The WHO is financed by contributions from member states and outside donors. As of 2012, the largest annual assessed contributions from member states came from the United States ($110 million), Japan ($58 million), Germany ($37 million), United Kingdom ($31 million) and France ($31 million). The combined 2012–2013 budget has proposed a total expenditure of $3,959 million, of which $944 million (24%) will come from assessed contributions. This

represented a significant fall in outlay compared to the previous 2009–2010 budget, adjusting to take account of previous underspends. Assessed contributions were kept the same. Voluntary contributions will account for $3,015 million (76%), of which $800 million is regarded as highly or moderately flexible funding, with the remainder tied to particular programmes or objectives.

In recent years, the WHO's work has involved increasing collaboration with external bodies. As of 2002, a total of 473 NGOs had some form of partnership with WHO. There were 189 partnerships with international non-governmental organization (NGO) in formal "official relations" – the rest being considered informal in character. Partners include the Bill and Melinda Gates Foundation and the Rockefeller Foundation.

2C. Data Collection

- With permission from the Coordinator of BTS unit Dr. Neelam Dhingra all relevant data are collected from different sources such as MEDLINE(The national library of medicines comprehensive electronic database of published articles) ,COCHRANE library that includes Cochrane database of systematic reviews were used to find relevant reports and published articles on self sufficiency in blood and blood products.
- Also already set questionnaire has been used to collect data from different countries on Global database for Blood Safety and the filled in questionnaire has been checked for internal inconsistencies.

3. I.A Self sufficiency in blood and blood products

Introduction

All countries face challenges in making sufficient supplies of blood and blood products available and sustainable, while also ensuring the quality and safety of these products in the face of known and emerging threats to public health. Since 1975, the World Health Assembly (WHA) has highlighted the global need for blood safety and availability. WHA resolutions 63.12, 58.13 and 28.72, *The Melbourne Declaration on 100% Voluntary Non- Remunerated Donation of Blood and Blood Components* and WHO Global Blood Safety Network recommendations have reaffirmed the achievement of “Self-sufficiency in blood and blood

products based on voluntary non-remunerated blood donation (VNRBD)" as the important national policy direction for ensuring a safe, secure and sufficient supply of blood and blood products, including labile blood components and plasma-derived medicinal products. Despite some successes, self-sufficiency is not yet a reality in many countries. A consultation of experts, convened by the World Health Organization (WHO) in September 2011 in Geneva, Switzerland, addressed the urgent need to establish strategies and mechanisms for achieving self-sufficiency. Information on the current situation, and country perspectives and experiences were shared. Factors influencing the global implementation of self-sufficiency, including safety, ethics, security and sustainability of supply, trade and its potential impact on public health, availability and access for patients, were analysed to define strategies and mechanisms and provide practical guidance on achieving self-sufficiency. Experts developed a consensus statement outlining the rationale and definition of self-sufficiency in safe blood and blood products based on VNRBD and made recommendations to national health authorities and WHO.

Blood Safety encompasses actions aimed at ensuring that everyone has access to blood and blood products that are as safe as possible, available at a reasonable cost , adequate to meet the needs of patients, transfused only when necessary and provided as a part of sustainable blood program within the existing health care system.

Sound, efficient health systems that provide effective disease prevention and treatment to all people, no matter who they are or where they live, are fundamental to the attainment of the highest possible level of health. Everyone should have access to the health services they need. Currently, there are wide variations in the coverage of essential health services both between and within countries. To address gaps in the coverage and delivery of essential health services, universal health coverage has become a major goal for health reforms in many countries and is also a priority objective of the World Health Organization (WHO). Universal health coverage is defined as ensuring that all people have access to needed health promotion, preventive, curative and rehabilitative health services, of sufficient quality to be effective, while also ensuring that people do not suffer financial hardship when paying for these services.

Access to sufficient, secure supplies of safe blood and blood products1 provided within a national blood system is a vital component in achieving universal health coverage. It is the

responsibility of every government to provide effective leadership and governance in developing a national blood system that is fully integrated into the health-care system, consisting of all the organizations, institutions, and financial and human resources whose primary purpose is to meet the transfusion needs of all patients within the country.

As therapeutic substances of human origin which can be obtained only from human donors, blood and blood products are a precious national resource that will remain limited by nature. Governments are accountable for the establishment of effective national blood systems that can ensure the safety, sufficiency, security and accessibility of safe blood and blood products. The management of this national resource requires a long-term perspective and systematic approach aimed at ensuring the safety, continuity, sustainability and security of the supply, and a strong foundation provided by an adequate number of regular, voluntary, non-remunerated blood donors as the most robust and safe blood systems globally are based on voluntary non-remunerated donation (VNRD). Furthermore, in their stewardship role of managing national supplies of donated blood and the blood products derived from it, governments are also responsible for protecting the health of blood donors and recipients. At the same time,

With the adoption of World Health Assembly resolution WHA63.12 “Availability, safety and quality of blood products” in 2010, working towards self-sufficiency in safe blood and blood products based on voluntary non-remunerated donation is a policy direction already agreed upon by WHO Member States. However, self-sufficiency is not yet a reality in many countries with inadequate supplies of blood and blood products from voluntary non-remunerated donors, and dependence on family/replacement donation systems and payment to blood and plasma donors to fill the gaps between supply and demand. The increasing global demands for blood and blood products, the complex nature of systems to supply these products, the inability of many national health systems to meet these urgent needs and the impact of globalization have also resulted in a rapid expansion of international commercial activities in relation to the provision of blood and blood products, as shown by increasing global markets in commercial plasma collection.

3. I.B. Data Collection

The procedure followed is enumerated below:

i. Various databases such as MEDLINE, COCHRANE and EMBASE have been used to collect data on available articles, reports and publications on Self –Sufficiency in Blood and Blood Products.
ii. Various publications, articles and reports on self sufficiency in blood and blood products have been searched in various databases.
iii. A search strategy has been formulated.
iv. Only the relevant studies were used for the synthesis of report.

3. I.C Data Analysis, Compilation and Interpretation

i. Out of the data collected on various publications, studies and reports only relevant studies were selected and a report is synthesized about the status of self sufficiency in blood and blood products.

3. I.D Conclusion and recommendations

Blood transfusion services play an essential, underpinning role in health systems. Countries throughout the world are facing serious challenges in making sufficient supplies of blood and blood products, including labile blood components and plasma-derived medicinal products, available and sustainable, while also ensuring the quality and safety of these products in the face of known and emerging threats to public health. These challenges include the risk of transfusion-transmitted infections, an inadequate number of blood donors, increasing needs for blood and blood products, inefficient blood supply systems, weak quality systems, and inappropriate and unsafe use of blood and blood products, which lead to chronic blood shortages, inequitable access, unsafe blood products and unsound clinical transfusion practices. The Oviedo Convention on Human Rights and Biomedicine of 1997 [5] explicitly prohibits any financial gain from the human body and its parts. Prevention of the commercialization of blood donation and exploitation of blood donors are important ethical principles on which a national blood system should be based. The right to equal opportunity in access to blood and blood products of uniform and high quality based on patients' needs is rooted in social justice and the social right to health care.

Payment for the donation of blood (including donations of plasma and cellular components) not only threatens blood safety, it also erodes community solidarity and social cohesion which, on the contrary, can be enhanced by the act of voluntary non- remunerated donation. By placing an onus on under-privileged populations in need of money, it also compromises

the development of a voluntary, non-remunerated blood donor programme. There are concerns that sufficient safe donations and sustainable supply, availability and access to blood and blood products based on VNRBD may be compromised through the presence of parallel systems of paid donation.

In many countries, systems based on family/replacement donation are currently in use for providing blood for patients. These systems, however, often lead to coercion and place undue burden on patients' families and friends to give blood, also leading to systems of hidden payment. Such systems are unreliable, putting the onus for the provision of blood on the patients' families rather than on the health system. In the long term, family/replacement donation systems will be unable to provide safe, sufficient and sustainable national blood supplies, employing both component preparation and apheresis donations, to ensure equitable access for all patients. Such systems will inevitably act as a barrier to enabling national blood systems to develop appropriately alongside countries' overall health systems

WHO strategy for blood safety and availability

The risk of transmission of serious infections, including HIV and hepatitis, through unsafe blood and chronic blood shortages brought global attention to the importance of blood safety and availability. With the goal of ensuring universal access to safe blood and blood products, WHO has been at the forefront of the movement to improve blood safety and availability, and recommends the following integrated strategy for blood safety and availability to its Member States.

1.Establishment of a national blood system with well-organized and coordinated blood transfusion services, effective evidence-based and ethical national blood policies with the goal of achieving self-sufficiency, and legislation and regulation, that can provide sufficient and timely supplies of safe blood and blood products to meet the transfusion needs of all patients.

2.Collection of blood, plasma and other blood components from low-risk, regular, voluntary-non-remunerated donors through the strengthening of systems for VNRD, the phasing out of family/replacement donation, the elimination of paid donation, and effective donor management, including care and counselling.

3.Quality-assuredscreeningofalldonatedbloodfortransfusion-transmissibleinfections (TTI), including HIV, hepatitis B, hepatitis C and syphilis, confirmatory testing of the results of all donors screen-reactive for infection markers, blood grouping and compatibility testing, and systems for processing blood into blood products (blood components for transfusion and plasma derived-medicinal products), as appropriate, to meet health care needs.

4.Rational use of blood and blood products to reduce unnecessary transfusions and minimize the risks associated with transfusion, the use of alternatives to transfusion, where possible, and safe and good clinical transfusion practices, including patient blood management.

5. Step-wise implementation of effective quality systems, including quality management, standards, good manufacturing practices, documentation, training of all staff and quality assessment.

This strategy for blood safety and availability has evolved out of successive resolutions adopted by the World Health Assembly, WHO Executive Board and WHO Regional Committees, as supreme decision-making bodies for WHO. In 2010, the Sixty-Third World Health Assembly adopted resolution WHA63.12 “Availability, safety and quality of blood products” (3) which recognizes that achieving self-sufficiency in the supply of safe blood and blood products based on voluntary, non-remunerated blood donation and the security of that supply are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population.

Recommendations to National Health Authorities

Incorporate the goal of achieving self-sufficiency in safe blood and blood products based on VNRBD into the national health policy, and strengthen the national blood system accordingly, by:

1. Clearly positioning self-sufficiency, based on VNRBD, in blood components for transfusion and human plasma-derived medicinal products in the national blood policy and its legislative framework, implementing strategies and mechanisms to achieve self-sufficiency based on VNRBD in blood components for transfusion as well as plasma-derived medicinal products, providing appropriate and sufficient financial, technical and human resources.

2. Introduce legislation with specific implementation timelines for the achievement of self-sufficiency based on VNRBD, by:

- identifying VNRBD as the sole source of blood, plasma and cellular components for the production of the six driver blood products (blood components for transfusion as well as plasma-derived medicinal products) for the treatment of patients;
- instituting the preferential use of plasma-derived medicinal products sourced from VNRBD, as a transitional measure;
- prohibiting payment in cash or in kind for the donation of blood, plasma and cellular components, thus ensuring alignment with similar legislations and WHO recommendations on the donation of other substances of human origin such as organs, tissues and cells.

3.Introduce specific measures, consistent with relevant international trade agreements, to protect the health of the public by ensuring the provision of safe and sufficient blood components for transfusion and plasma-derived medicinal products in the national health system through nationally, or where needed, regionally (such as from neighbouring countries) sourced VNRBD.

4. Establish mechanisms of cooperation between countries to secure regional self- sufficiency in blood and blood products based on VNRBD.

5. Introduce strategies and measures to establish appropriate quality systems and standardized procedures in the national blood system for the collection, testing and preparation, storage, distribution, transportation and use of blood components for transfusion and plasma (either recovered from whole blood or by apheresis).

6. Put in place mechanisms for the fractionation of surplus recovered plasma from VNRBD for national or regional self-sufficiency to avoid the discard of recovered plasma donated by VNRBD. This may require:

- formal agreements between the blood system and the fractionator(s) to support contract fractionation and for the procurement or exchange of plasma and plasma-derived medicinal products, with oversight of the ministry of health or an appropriate authority accountable to the ministry of health; and
- Negotiations with (contract) fractionators to provide an appropriate part of the resources and technological knowledge needed.

3. II. GLOBAL DATABASE FOR BLOOD SAFETY

3. II.A Introduction

The WHO Global Database on Blood Safety was established in 1998 to provide data about the availability, safety and accessibility of blood for transfusion. The main objective of the survey is to collect and analyse data on national blood systems from all countries as the basis for effective action to improve access to safe blood and blood products and transfusion practices globally. The WHO Blood Transfusion Safety programme has undertaken surveys on the safety and availability of blood in Member States since 1998. GDBS data are collected using a standardized tool which is sent to national health authorities for completion. Web-based tools were used for 2011 data collection.

A questionnaire, which has been developed as a standardized tool for the collection of data, is sent to national health authorities for completion. The questionnaire is based on the WHO Aide-Mémoire for National Health Programmes: Blood Safety, which covers the four major components of the integrated strategy for blood safety advocated by WHO. Data obtained through the questionnaire are supplemented by information collected by experts during on-site visits to ministries of health and blood transfusion services. Based on earlier responses, the questionnaire has been refined in order to enhance the reliability of the information received. It has been translated into the six official languages of WHO and contains additional background information to facilitate its completion.

The data collected through the GDBS questionnaire are analysed and reports are published on the WHO website. This is updated with the availability of the latest global data. The focus of the analysis is to provide information on the current status of blood transfusion services, assess country needs in improving blood safety, formulate strategic recommendations to countries, plan and implement activities and evaluate progress.

Data submitted by national health authorities have not been independently verified. While many countries report comprehensive national data on blood availability and safety, others provide limited information on the activities of a subset of blood centres. Efforts have been made to validate GDBS data by comparing them with data available from other published sources. Where GDBS data are available from a relatively small number of countries only and

no similar data are available in other published literature, caution is needed to generalize the findings to other countries.

3. II.B. Data Collection

Data was collected with the help of a pre formed standardised questionnaire consisting of seven sections.

This filled in questionnaire is collected from all the member states and checked for internal inconsistencies

3. II.C Data Analysis, Compilation and Interpretation

The filled in questionnaires were checked for internal inconsistencies and in case of presence of internal inconsistencies the health authority of that nation is asked to provide information about that.

Once this review of the questionnaire is done and are found consistent then they are analysed with the help of statics software and results are disseminated online and are also used for various other reports and help the various governments in policy making regarding safe and sufficient supply of blood and blood products.

3. II.D Conclusion

In 2011, 68% of countries had a national blood policy, compared with 60% of countries in 2004. Overall, 62% of countries have specific legislation covering the safety and quality of blood transfusion:

- 81% of high-income countries
- 60% of middle-income countries
- 44% of low-income countries.

Blood supply

About 107 million blood donations are collected worldwide. Almost half of these are collected in high-income countries, home to 15% of the world's population.

About 10 000 blood centres in 168 countries report collecting a total of 83 million donations. Collections at blood centres vary according to income group. The median annual donations per blood centre is 3100 in the low- and middle-income countries, as compared to 15 000 in the high-income countries.

There is a marked difference in the level of access to safe blood between low- and high-income countries. The whole blood donation rate is an indicator for the general availability of blood in a country. The median blood donation rate in high-income countries is 39.2 donations per 1000 population. This compares with 12.6 donations in middle-income countries and 4.0 donations in low-income countries .

75 countries report collecting fewer than 10 donations per 1 000 population. Of these, 38 countries are in WHO's African Region, 6 in the Americas, 8 in the Eastern Mediterranean Region, 6 in Europe, 7 in South-Eastern Asian and 10 in the Western Pacific. All are low- or middle-income countries.

Blood donors

Age and gender of blood donors

Data about the gender profile of blood donors show that globally, 30% of blood donations are given by women, although this ranges widely. In 18 of the 104 reporting countries, less than 10% donations are given by female donors. The age profile of blood donors shows that overall 6% of donors come from the under-18 age group, 27% from people aged 18–24, 38% from the 25–44 group, 26% from 45–64 group and 3% from those over 65.

In low- and middle-income countries, proportionally more young people donate blood than in high-income countries. Demographic information of blood donors is important for formulating and monitoring recruitment strategies.

Types of blood donors

Data reported to WHO shows significant increases of voluntary unpaid blood donations in low- and middle-income countries:

- An increase of 7.70 million blood donations from voluntary unpaid donors from 2004 to 2011 has been reported by 156 countries. The highest increase of voluntary unpaid blood donations was observed in the South-East Asia (65%) and African (48%) Regions. The maximum increase in absolute numbers was reported in the Western Pacific Region.
- 71 countries collect more than 90% of their blood supply from voluntary unpaid blood donations, including 60 countries with 100% (or more than 99%) of their blood supply from voluntary unpaid blood donors (38 are high-income countries, 22 middle-income countries and 11 low-income countries) .
    - 15 countries of these 60 countries have achieved 100% (or more than 99%) voluntary unpaid donation in 2011 from a lower percentage reported in 2004; six of these 15 countries have achieved this target from a percentage lower than 75% reported in 2004:
- In 73 countries, more than 50% of the blood supply is still dependent on family/replacement and paid blood donors (8 are high-income countries, 45 are middle-income countries and 20 are low-income countries).
- 22 countries still report collecting paid donations in 2011, around 800 000 donations in total. 58% of paid donations reported are apheresis donations.

Blood screening

WHO recommends that all blood donations should be screened for infection prior to use. Screening should be mandatory for HIV, hepatitis B, hepatitis C and syphilis.

- 25 countries are not able to screen all donated blood for one or more of the above infections.

- Irregular supply of test kits is one of the most commonly reported barriers to screening.
- 24% blood donations in low-income countries are not screened following basic quality procedures which include documented standard operating procedures and participation in an external quality assurance scheme.
- The prevalence of transfusion-transmissible infections (TTIs) in blood donations in high-income countries is considerably lower than in low- and middle-income countries. The prevalence of HIV in blood donations in high-income countries is 0.003% (median), in comparison with 0.1% and 0.6% in middle- and low-income countries respectively. This difference reflects the variable prevalence amongst members of the population who are eligible to donate blood, the type of donors (such as voluntary unpaid blood donors from population at lower risk) and the effectiveness of the system of educating and selecting donors.

Blood processing

Blood collected in an anticoagulant can be stored and transfused to a patient in an unmodified state. This is known as 'whole blood' transfusion. However, blood can be used more effectively if it is separated into components, such as red cell concentrates, plasma, and cryoprecipitate and platelet concentrates. In this way, it can meet the needs of more than one patient.

The capacity to provide patients with the different blood components they require is still limited in low-income countries: 40% of the blood collected in low-income countries is separated into components, 78% in middle-income countries and 97% in high-income countries.

Supply of plasma-derived medicinal products (PDMPs)

41 countries (20 high-income, 19 middle-income, 2 low-income) of the 151 reporting countries, reported producing all or part of the PDMPs through the fractionation (e.g. domestic or/and contract fractionation) of plasma collected in the country.

- 32 of the 41 countries report plasma fractionation carried out within the country.
- 9 of the 41 countries report plasma sent for contract fractionation in another country.

Clinical use of blood

Unnecessary transfusions and unsafe transfusion practices expose patients to the risk of serious adverse transfusion reactions and TTIs. Unnecessary transfusions also reduce the availability of blood products for patients who are in need.

WHO recommends that all countries have transfusion committees to implement national policy and guidelines on rational use of blood in hospitals and a national haemovigilance system to monitor and improve the safety of the transfusion process.

- 109 countries have national guidelines on the appropriate clinical use of blood.
- 86% high-income countries have a national haemovigilance system, compared to only 34% of low- and middle-income countries.
- Transfusion committees are present in 79% of the hospitals performing transfusions in high-income countries and in about half of the hospitals in low- and middle-income countries.
- Clinical audit are conducted in 91% of hospitals performing transfusion in the high-income countries and in 58% of hospitals in the low- and middle-income countries
- Systems for reporting adverse transfusion events are present in 93% of hospitals performing transfusion in high-income countries and 76% in low- and middle-income countries.

Blood transfusions

There are great variations between countries in the age distribution of transfused patients. For example, in the high-income countries, the most frequently transfused patient group is over 65 years, which accounts for up to 76% of all transfusions. In the low-income countries, up to 65% of transfusions are for children under the age of five years.

In high-income countries, transfusion is most commonly used for supportive care in cardiovascular surgery, transplant surgery, massive trauma, and therapy for solid and haematological malignancies. In low- and middle-income countries it is used more often to manage pregnancy-related complications and severe childhood anaemia.

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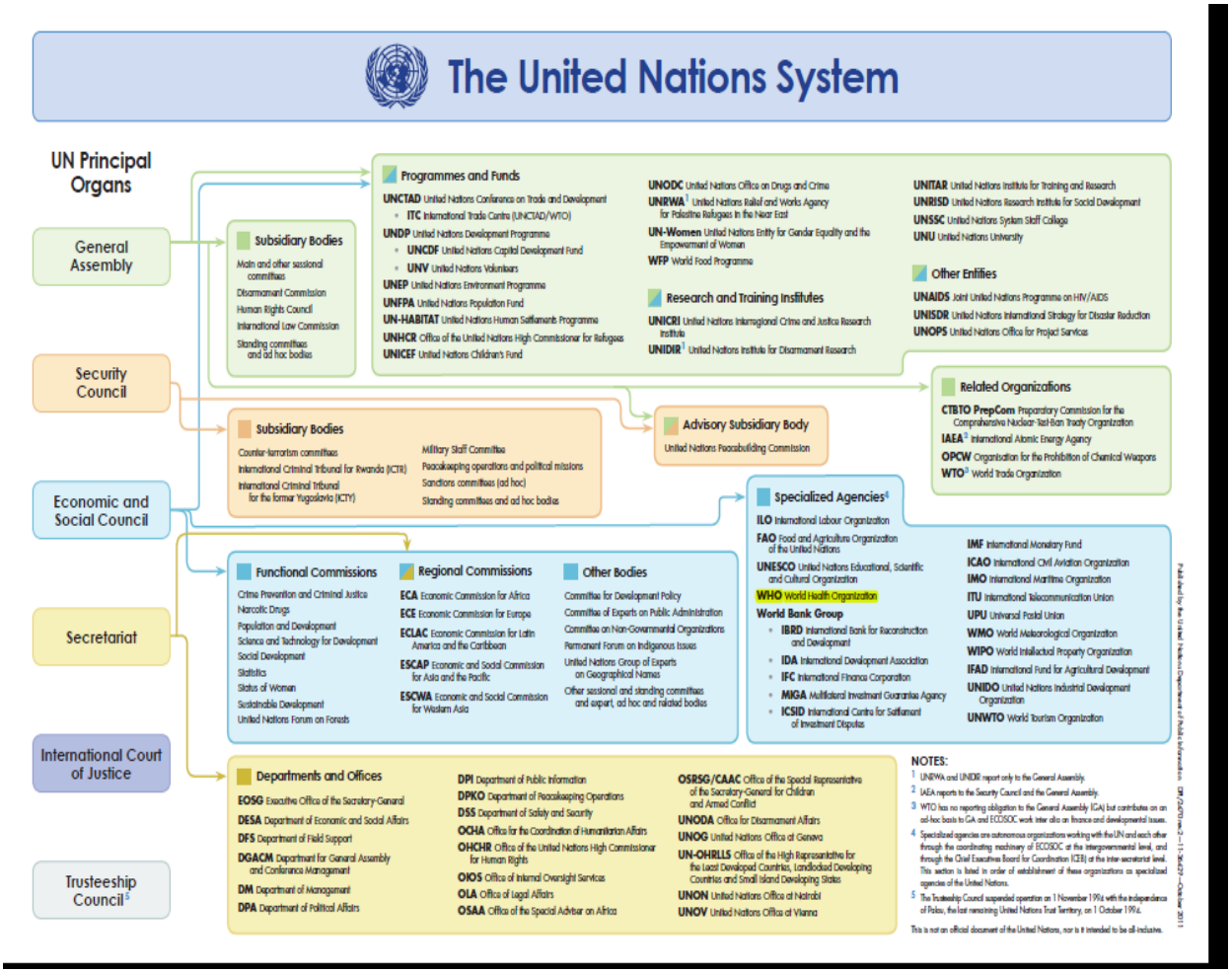
5. Annexure

Annexure 1.

Organ gram of UN and WHO location.


The United Nations System
UN Principal Organs
General Assembly
Security Council
Economic and Social Council
Secretariat
International Court of Justice
Trusteeship Council[5]
Subsidiary Bodies
Main and other sessional committees
Disarmament Commission
Human Rights Council
International Law Commission
Standing committees and ad hoc bodies
Programmes and Funds
UNCTAD United Nations Conference on Trade and Development
ITC International Trade Centre (UNCTAD/WTO)
UNDP United Nations Development Programme
UNCDF United Nations Capital Development Fund
UNV United Nations Volunteers
UNEP United Nations Environment Programme
UNFPA United Nations Population Fund
UN-HABITAT United Nations Human Settlements Programme
UNHCR Office of the United Nations High Commissioner for Refugees
UNICEF United Nations Children's Fund
UNODC United Nations Office on Drugs and Crime
UNRWA[1] United Nations Relief and Works Agency for Palestine Refugees in the Near East
UN-Women United Nations Entity for Gender Equality and the Empowerment of Women
WFP World Food Programme
Research and Training Institutes
UNICRI United Nations Interregional Crime and Justice Research Institute
UNIDIR[1] United Nations Institute for Disarmament Research
UNITAR United Nations Institute for Training and Research
UNRISD United Nations Research Institute for Social Development
UNSSC United Nations System Staff College
UNU United Nations University
Other Entities
UNAIDS Joint United Nations Programme on HIV/AIDS
UNISDR United Nations International Strategy for Disaster Reduction
UNOPS United Nations Office for Project Services
Related Organizations
CTBTO PrepCom Preparatory Commission for the Comprehensive Nuclear-Test-Ban Treaty Organization
IAEA[2] International Atomic Energy Agency
OPCW Organization for the Prohibition of Chemical Weapons
WTO[3] World Trade Organization
Subsidiary Bodies
Counter-terrorism committees
International Criminal Tribunal for Rwanda (ICTR)
International Criminal Tribunal for the former Yugoslavia (ICTY)
Military Staff Committee
Peacekeeping operations and political missions
Sanctions committees (ad hoc)
Standing committees and ad hoc bodies
Advisory Subsidiary Body
United Nations Peacebuilding Commission
Specialized Agencies[4]
ILO International Labour Organization
FAO Food and Agriculture Organization of the United Nations
UNESCO United Nations Educational, Scientific and Cultural Organization
WHO World Health Organization
World Bank Group
IBRD International Bank for Reconstruction and Development
IDA International Development Association
IFC International Finance Corporation
MIGA Multilateral Investment Guarantee Agency
ICSID International Centre for Settlement of Investment Disputes
IMF International Monetary Fund
ICAO International Civil Aviation Organization
IMO International Maritime Organization
ITU International Telecommunication Union
UPU Universal Postal Union
WMO World Meteorological Organization
WIPO World Intellectual Property Organization
IFAD International Fund for Agricultural Development
UNIDO United Nations Industrial Development Organization
UNWTO World Tourism Organization
Functional Commissions
Crime Prevention and Criminal Justice
Narcotic Drugs
Population and Development
Science and Technology for Development
Social Development
Statistics
Status of Women
Sustainable Development
United Nations Forum on Forests
Regional Commissions
ECA Economic Commission for Africa
ECE Economic Commission for Europe
ECLAC Economic Commission for Latin America and the Caribbean
ESCAP Economic and Social Commission for Asia and the Pacific
ESCWA Economic and Social Commission for Western Asia
Other Bodies
Committee for Development Policy
Committee of Experts on Public Administration
Committee on Non-Governmental Organizations
Permanent Forum on Indigenous Issues
United Nations Group of Experts on Geographical Names
Other sessional and standing committees and expert, ad hoc and related bodies
Departments and Offices
EOSG Executive Office of the Secretary-General
DESA Department of Economic and Social Affairs
DFS Department of Field Support
DGACM Department for General Assembly and Conference Management
DM Department of Management
DPA Department of Political Affairs
DPI Department of Public Information
DPKO Department of Peacekeeping Operations
DSS Department of Safety and Security
OCHA Office for the Coordination of Humanitarian Affairs
OHCHR Office of the United Nations High Commissioner for Human Rights
OIOS Office of Internal Oversight Services
OLA Office of Legal Affairs
OSAA Office of the Special Adviser on Africa
OSRSG/CAAC Office of the Special Representative of the Secretary-General for Children and Armed Conflict
UNODA Office for Disarmament Affairs
UNOG United Nations Office at Geneva
UN-OHRLLS Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States
UNON United Nations Office at Nairobi
UNOV United Nations Office at Vienna
NOTES:
1 UNRWA and UNIDIR report only to the General Assembly.
2 IAEA reports to the Security Council and the General Assembly.
3 WTO has no reporting obligation to the General Assembly (GA) but contributes on an ad-hoc basis to GA and ECOSOC work inter alia on finance and developmental issues.
4 Specialized agencies are autonomous organizations working with the UN and each other through the coordinating machinery of ECOSOC at the intergovernmental level, and through the Chief Executives Board for Coordination (CEB) at the inter-secretariat level. This section is listed in order of establishment of these organizations as specialized agencies of the United Nations.
5 The Trusteeship Council suspended operation on 1 November 1994 with the independence of Palau, the last remaining United Nations Trust Territory, on 1 October 1994.
This is not an official document of the United Nations, nor is it intended to be all-inclusive.

Annexure 2 –Search Strategy

Medline, Cochrane and Embase are used to find out various publications, reports and papers on self sufficiency in blood and blood products.

Following are the MeSH and key words for the literature search on self-sufficiency for last

Blood supply
Self-sufficiency
Sufficiency
Blood donation
Blood procurement
Plasma procurement
Plasma fractionation
Fractionation
Fractionated products
National blood system
Plasma derivatives
Blood products
Blood economics
19,000 searches were found, among which only the relevant searches were chosen.

In order to search the grey literature i.e. the unpublished articles, reports and papers Google Advanced Search was used and the search strategy used was “on in blood and blood products "self sufficiency" filetype:pdf”

Number of results found out was 20,000.Now in this also only the relevant studies were used for consideration

Annexure 3 Questionnaire prepared by World Health Organization, BTS Unit and used for data collection.

It had seven sections.

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		N°
	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] Please provide data for the period **January 2011** to **December 2011**. If data for this period are not available, please provide data for the nearest 12-month period (e.g., April 2011 to March 2012).

[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$	

[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.

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 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?			

[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.

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	☐	☐	☐
			Combined Ag + Ab	☐	☐	☐
			NAT	☐	☐	☐
	4.1.2	Hepatitis B	HBsAg	☐	☐	☐
			Anti-HBc Ab	☐	☐	☐
			NAT	☐	☐	☐
	4.1.3	Hepatitis C	Anti-HCV Ab	☐	☐	☐
			Combined Ag + Ab	☐	☐	☐
			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	☐	☐	☐

	N°

[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.

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		Nº	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]		Nº	PER CENT
	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			
			Nº	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		☐	☐

[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".

Section 5: Blood component preparation

				Nº
5.1	Number of blood centres that prepare blood components			
			Nº	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			Nº
	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			Nº
	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			Nº
	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):				

Section 6: Clinical use of blood & blood components

			Nº	
6.1	Number of hospitals in the country that perform blood transfusions			
6.2	Number and % of hospitals performing blood transfusion that organized training or educational programme for appropriate use of blood and blood products for the following category of hospital staff during the reporting period		Nº	PER CENT
	6.2.1	Doctors		%
	6.2.2	Nurses		%
	6.2.4	Midwives		%
	6.2.5	Others(please specify):		%
6.3	Number and % of hospitals performing blood transfusion that have, or participate in:		Nº	PER CENT
	6.3.1	Hospital transfusion committee		%
	6.3.2	Clinical audit[22]		%
	6.3.3	System for reporting adverse transfusion incidents and reactions		%
6.4	Number of units of each of the following blood components issued / transfused (excluding autologous blood units) in the country			
			Nº	
	6.4.1	Whole blood		
	6.4.2	Red cells		
	6.4.3	Platelets, whole blood-derived		
	6.4.4	Platelets, apheresis		
	6.4.5	Fresh frozen plasma		
	6.4.6	Plasma		
	6.4.7	Cryoprecipitate		
			Nº	
6.5	Number of patients transfused in the country			
	If the number is estimated, please provide information on how the estimation is made:			
6.6	Number of patients transfused, by age		Nº	
	6.6.1	under 5 years		
	6.6.2	5 to 14 years		
	6.6.3	15 to 44 years		
	6.6.4	45 to 59 years		
	6.6.5	60 years or older		

[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.

Section 7: Plasma-derived medicinal products (PDMDs)

7.1	Does the Essential Medicines List[24] in your country include the following plasma-derived medicinal products (PDMP)[25]?		YES	NO
	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 PDMPs 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	All products are imported from abroad	☐	☐
Answer the following question 7.3 - 7.11 only when the answer to question 7.2.1 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	Is plasma sold to manufacturers of plasma-derived medicinal products and products purchased from the manufacturer or other suppliers?		☐	☐
7.7	Volume of plasma used for domestic or contract fractionation, or sold abroad for fractionation[26]			
	7.7.1	Recovered plasma		litres
	7.7.2	Apheresis plasma		litres
7.8	Number of plasmapheresis/source plasma[27] donors		Nº	
	7.8.1	Voluntary non-remunerated plasma donors		
	7.8.2	Paid plasma donors		
	7.8.3	Other plasma donors (please specify):		
7.9	Which products are manufactured by fractionation within the country or through contract fractionation?			
			YES	NO

[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.