Research to Address Gaps in International Blood Availability and Transfusion Safety:
Challenges & Opportunities

Rockledge II 9100/9104 **April 18 & 19, 2017**

National Heart, Lung, and Blood Institute

AGENDA

Tuesday – April 18, 2017

8:30-9:00 Opening Remarks
W. Keith Hoots, MD, Director, DBDR, NHLBI
Michael Engelgau, MD, Deputy Director, CTRIS, NHLBI
Paul Sato, MD, Office of AIDS Research, NIH

Self-introduction of Participants – All

Workshop Objectives – **Brian Custer, PhD, BSRI (Chair)**

Session 1 – Translation Research and Implementation Science:
Moderator – Michael Engelgau, MD

9:00-9:20 Support to Translation Research and Implementation Science by CTRIS
Dr. Michael Engelgau; CTRIS, NHLBI

Examples of Translation Research and Technologies which may be ready for IS Research

9:20-9:40 Application of Translation Research and Implementation Science to Blood Safety and Availability (I)
Dr. Meghan Delaney

9:40-10:00 Application of Translation Research and Implementation Science to Blood Safety and Availability (II)
Dr. Magdy El Ekiaby

10:00-10:20 Application of Translation Research and Implementation Science to Blood Safety and Availability (III)
SAMBA: A Point-of-care Molecular System for Resource-limited Settings
Dr. Helen Lee

10:20-10:40 Break (20 minutes)

Session 2 – Introduction to Global Blood Safety and Availability:
Moderator – Brian Custer, PhD

10:40-11:00 Report from the Global Database for Blood Safety (GDBS)
Mr. Junping Yu
Technical officer
Blood & Transfusion Safety (BTS), World Health Organization

11:00-11:20 Report from PEPFAR
Dr. Bakary Drammeh
Centers for Disease Control and Prevention

11:20-11:35 T-REC/AfSBT – Research Priorities Overview in Sub-Saharan Africa
Prof. Imelda Bates (by conference call)

11:35-11:50 Perspectives from the East Africa Region
Dr. Julie Makani

11:50-12:05 Perspectives from the West Africa Region
Dr. Claude Tayou Tagny

12:05-12:20 Perspectives from Uganda and the Surrounding Region
Dr. Heather Hume

12:20-1:10 Lunch (50 minutes)

1:10-1:30 Perspectives from the Middle East and North Africa Region
Dr. Magdy El Ekiaby

1:30-1:50 Perspectives from the Latin America and the Caribbean Region
Dr. Ester Sabino

2:50-2:10 Perspectives from the Southeast Asia Region
Dr. Nabajyoti Choudhury

2:10-2:30 Perspectives from the Western Pacific Region
Dr. Hua Shan

2:30-2:50 Perspectives from the East Europe and Central Asia Region
Dr. Kenrad Nelson, Dr. Sheila Keating and Dr. Jed Gorlin

2:50-3:10 The joint Australia-China quality program in China
Dr. Xun Wang

3:10-3:25 Break (15 minutes)

Session 3 – Discussion on Challenges and Opportunities:
Moderator – Julie Makani, MD, PhD

3:25-3:50 Overview of Challenges and Potential Opportunities
Brian Custer, PhD

3:50-4:50 Discussion on Challenges and Opportunities

4:50-5:00 Questions for Tomorrow

Wednesday – April 19, 2017

Session 4 – Implementation Science, Burden Assessment, Emerging Topics and Methods Relevant to Transfusion

8:30-8:50 Principles and Methods for Implementation Science
Olugbenga Ogedegbe, MD, MS, MPH, FACP

8:50-9:10 Global Burden of Disease Study and Transfusion Need Assessment
Christina Fitzmaurice, MD, MPH

9:10-9:30 Insights from the REDS Program
Edward Murphy, MD, MPH

Session 5 – Key Scientific Priorities and Research Strategies:
Moderators – Drs. Custer and Makani

9:30-9:45 Summary of Challenges & Opportunities & Questions for Today

9:45-10:45 Discussion of Key Research Priorities

10:45-11:00 Break (20 minutes)

11:00-12:00 Discussion of Research Strategies

12:00-1:00 Lunch (60 minutes)

1:00-2:50 Formulation of Recommendations to NHLBI

2:50-3:00 Concluding Remarks – DBDR and CTRIS, NHLBI

The East Africa Region (Team Leader: Dr. Julie Makani)

Blood supply

1. What are the factors that influence blood donation?
2. **Can donated blood be utilized as a biomedical resource? #1**
3. Are lysine analogues a safe and effective alternative to prophylactic platelet transfusions for the support of patients with chemotherapy-associated transient thrombocytopenia.

Blood safety

4. **Does pathogen reduction (PR) of whole blood provide a major leap of blood safety in Africa? #2**
5. Can evaluation of alternative sources of blood be tested in clinical trials at scale?
6. **Can a laboratory information system (LIS) located "in the cloud" and serving hundreds of healthcare facilities be developed and sustained in Africa? #3**
7. **Can cost-effective anti-human globulin (AHG) testing be implemented in Africa? #4**
8. **Can a low-cost method for identification of transfusion recipients be developed for Africa? #5**
9. How can health facilities in Africa effectively implement appropriate use of blood and hemovigilance in recurrent blood recipients? A case study in sickle cell disease and cancer centers.
10. Will introduction of apheresis and exchange blood transfusion be feasible and effective in Africa?
11. What is the clinical epidemiology of adverse transfusion reactions (immediate and delayed) in Africa?

#1. BLOOD SUPPLY: BLOOD AS A BIOMEDICAL RESOURCE

1. ***Question***

State the scientific question in one sentence. The question should address an important issue.

Can donated blood be utilized as a biomedical resource to strengthen health, advocacy, research and training?

2. ***Rationale***

Provide an argument regarding why it is such an important question, which has not been sufficiently addressed. Also, include a sentence describing the significance of the proposed research topic.

The approach to increasing blood supply has been to encourage blood collection. There have been various strategies developed to address the different factors that contribute to the low number of voluntary, non-remunerated blood donors. These strategies have been developed and owned by blood transfusion services/blood banks or end-users. Here we propose increasing the number of stakeholders who would be interested in increasing blood collection by providing a business plan that would highlight the value of donated blood as a biomedical resource.

One potential use of donated blood is biomedical research[1]. The purpose would be for scientific groups to contribute to the establishment, maintenance and archiving of blood collected. This would mean that there would be more stakeholders that would invest resources in blood collection. In order to evaluate the feasibility of this, research would need to be conducted to 1) establish the volume of blood collected, utilized and discarded. 2) evaluate research that utilizes blood collections from blood bank 3) evaluate the ethical, social and legal issues regarding the utilization of blood collected for medical reasons being utilized for biomedical research.

Scientists have used blood from blood banks to conduct biomedical research to address fundamental basic and clinical scientific questions[2]. Here, we propose using collected blood to conduct biomedical research in Africa to initially answer 2 questions: What are the normal reference ranges of hematological parameters in African populations? 2) What is the human genome variation in Africa that influences health and disease?

3. ***Feasibility and Strategy***

Discuss the current feasibility of answering this question in the next 5 -10 years and the appropriate strategy. Although it is specifically not expected that a particular study design will be provided, it is important to know whether the tools required to answer the question are available and/or can be developed in this time frame.

It will be feasible to conduct the study within the next 5 years. The study design would be a Multi-center, cross-sectional study involving blood centers in African countries. Initial information can be collected from blood banks/centers as well as a questionnaire to be completed by scientists who could potentially utilise the platform. The ELSI aspects would also be explored in partnership with experts in boethics. There would be learning from ongoing experience from REDS and other scientists conducting biomedical research using blood banks as a platform that would be shared.

4. ***References***

1. Loureiro P, de Almeida-Neto C, Proietti AB, et al. Contribution of the Retrovirus Epidemiology Donor Study (REDS) to research on blood transfusion safety in Brazil. Revista brasileira de hematologia e hemoterapia 2014;36:152-8.

2. Soranzo N, Spector TD, Mangino M, et al. A genome-wide meta-analysis identifies 22 loci associated with eight hematological parameters in the HaemGen consortium. Nature genetics 2009;41:1182-90.

Author/Contributor
Julie Makani

#2. BLOOD SUPPLY/SAFETY: PATHOGEN REDUCTION

1. Question

State the scientific question in one sentence. The question should address an important issue.

Does pathogen reduction (PR) of whole blood provide a major leap of blood safety in Africa?

2. Rationale

Provide an argument regarding why it is such an important question, which has not been sufficiently addressed. Also, include a sentence describing the significance of the proposed research topic.

At present time, the lack of resources and high prevalence of viruses, bacteria, parasites considerably compromise blood safety in SSA. In addition, nucleated cells cannot be reduced because of high cost of filtration. Pathogen reduction with Mirasol was shown to be highly effective against transfusion-transmitted malaria (TTM) in vitro and in vivo (1-3) and effective in vitro against viruses, bacteria, babesia, trypanosome and leishmania (4-6). Mirasol technology applied to whole blood readily inactivates nucleated blood cells (7). Evidence strongly suggests that adequate blood components can be prepared from Mirasol-treated whole blood units (2, 8, 9). It is therefore legitimate to assume that in resource-poor areas such as most of SSA, implementation of Mirasol-treated whole blood might make viral NAT, bacterial contamination detection and blood filtration redundant and TTM massively reduced by a single safety step at an affordable cost.

3. Feasibility and Strategy

Discuss the current feasibility of answering this question in the next 5 -10 years and the appropriate strategy. Although it is specifically not expected that a particular study design will be provided, it is important to know whether the tools required to answer the question are available and/or can be developed in this time frame.

Mirasol whole blood technology has been approved for clinical use in Ghana and as of May 2017, will be routinely implemented in vulnerable patients (children <5y and pregnant women) in the two main teaching hospitals (Accra and Kumasi). This project supported by JICA (Japanese International Cooperation Agency) provides a platform for hemovigilance to be adopted and strengthened in all recipients and TTM monitored in children. The strategy will consist of expanding PR clinical implementation and widening the in vivo monitoring to examine the in vivo efficacy of the system for reducing or preventing less frequent safety adverse events such as bacterial contamination (presently 3-10%), HHV-8 transmission as a marker of intra-cellular viral inactivation (20% antibody positive), HBV post-transfusion infection (1:600 incidence), post-transfusion microchimerism in children <5y (25% incidence [10]). The entry of approximately 5000 patients from 3 sites in Cameroon, Ghana and Nigeria should be sufficient to provide answers to the question.

4. References

A (short) list of relevant references should be provided. One is sufficient. Please do not exceed 10.

1. El Chaar M, et al. Inactivation of Plasmodium falciparum in whole blood by riboflavin plus irradiation. Transfusion. 2013;53:3174-83. 2. Owusu-Ofori S, et al. Treatment of Whole Blood With Riboflavin and UV Light: Impact on Malaria Parasite Viability and Whole Blood Storage. Shock 2015;44 Suppl 1:33-8. 3. Allain JP, et al. Effect of Plasmodium inactivation in whole blood on the incidence of blood transfusion-transmitted malaria in endemic regions: the African Investigation of the Mirasol System (AIMS) randomised controlled trial. Lancet. 2016;387:1753-61. 4. 5. Keil SD, et al. Viral reduction of intracellular HIV using the Mirasol system for whole blood. Vox Sang 2012;103(Suppl. S1):144. 5. Tonnetti L, et al. Reduction of Leishmania donovani infectivity in whole blood using riboflavin and ultraviolet light. Transfusion 2015;55:326-9. 6. Tonnetti L, et al. Evaluating pathogen reduction of Trypanosoma cruzi with riboflavin and ultraviolet light for whole blood. Transfusion 2012;52:409-16. 7. Fast LD, Nevola M, Tavares J, Reddy HL, Goodrich RP, Marschner S. Treatment of whole blood with riboflavin plus ultraviolet light, an alternative to gamma irradiation in the prevention of transfusion-associated graft-versus-host disease? Transfusion 2013;53:373-81. 8. Pidcoke HF, et al. Primary hemostatic capacity of whole blood: a comprehensive analysis of pathogen reduction and refrigeration effects over time. Transfusion 2013;53 Suppl 1:137s-49s. 9. Schubert P, et al. Whole blood treated with riboflavin and ultraviolet light: quality assessment of all blood components produced by the buffy coat method. Transfusion 2015;55:815-23. 10. Assennato M, Owusu-Ofori S, Osei-Akoto A, Lambert N, allain JP. Microchimerism in Ghanaian children recipients of whole blood transfusion for severe anaemia. 2017; in preparation.

Author/Contributor
1. Jean-Pierre Allain 2. Shirley Owusu-Ofori

#3. MULTI-CENTRED LABORATORY INFORMATION SYSTEM FOR BLOOD TRANSFUSION

1. **Question:**

Can a laboratory information system (LIS) located “in the cloud” and serving hundreds of healthcare facilities be developed and sustained in sub-Saharan Africa (SSA)?

2. **Rationale**

Retrieval of medical information is a serious challenge to hospital-based healthcare in SSA. The inability to retrieve previously obtained laboratory results has multiple negative effects including over-looked diagnoses, fragmentation of on-going care, and repetition of testing in an environment where the cost of testing is substantial.

The development of a workable and sustainable LIS available to hundreds of healthcare facilities throughout SSA would be a substantial advance for the continent.

3. **Feasibility and Strategy**

Three key elements are needed to develop a feasible and sustainable LIS:

Cloud-based LIS software.

While numerous solutions are possible, one example of a likely workable strategy is as follows. An existing LIS vendor could make available a "basic version" of data storage and retrieval that would serve as the foundation of the system. This software could be hosted in the cloud. An individual healthcare facility in SSA would have logins to the software which would restrict access to patient records associated with their facility. In this way, each facility would have the experience of having an individualized LIS. Local facilities would need a computer with internet access (common now in SSA). Local facilities would NOT need to maintain the software which would be managed and maintained by an independent group (see below). The number of facilities which could have independent login access would be only limited by data storage capacity.

Patient identification.

Many individuals in low-income nations may not carry any form of national identity card or photo ID. Inconsistencies in spelling of names and uncertain dates of birth further hamper proper patient identification. In order that information retrieval of key laboratory data be associated with the correct individual, a robust form of indentification would be advantageous. Implementation research on the best technology and practice for patient identification would be an important element of a workable multinational LIS system. Numerous biometric-based systems exist and may be suitable for low-income nations. For example the "Unique Identification Authority of India" was launched in 2010 and will establish biometric patterns for 1.2 billion citizens of India in order to enable more fair acces to government benefits and healthcare services.[1]

Sustainable financial model and mangement.

An important goal of this research would be to understand and develop a sustainable financial model for a shared, multi-center LIS in the cloud. Several possible financial models exist. As one example, a condition of use could be that redacted results of all laboratory testing would be "owned" by the organization managing the program. The laboratory results could be redacted to remove patient identifiers and then the results pooled across all participating facilities thus generating large scale data at the multi-national level. A resource of big data on the incidence and severity of a wide group of illnesses from anemia, to malaria, to HIV, to cancer would then be obtained. This data could be made available *for a fee* which would be used to sustain the function of the system. Parties interested in this data are likely to include WHO, foundations (eg, Gates), governments, pharmaceutical houses, and research groups.

4. **References**

1. Rinaldi A. EMBO Rep 2016;17:22-6. doi: 10.15252/embr.201541677. Epub 2015 Dec 14.

Author/Contributor

1. Walter Dzik (Sunny)

#4. BLOOD SAFETY: PRE-TRANSFUSION TESTING

1. **Question:**

Can cost-effective anti-human globulin (AHG) testing be implemented in Africa?

2. **Rationale**

Despite the fact that sub-Saharan Africa is home to the fastest growing population in need of healthcare on Earth, diagnostic testing in SSA lags well behind world norms for transfusion medicine. Blood grouping in hospitals continues to be done on ceramic tiles. Crossmatching consists of little more than a direct agglutination check for ABO compatibility. Antibody screening for non-ABO antibodies is virtually non-existant. Transfusion reaction investigations are serologically rudimentary. Without the availability of Coombs' serum, transfusion medicine in SSA is more than 70 years behind the times.[1] Despite the complete inadequacy of pre-transfusion testing, SSA is full of serologic complexities with a high burden of transfusion care for sickle cell patients, a growing demand for transfusion support in cancer care, and one of the largest obstetrical volumes on Earth. These clinical areas require pre-transfusion testing that includes Coombs' serum.

3. **Feasibility and Strategy**

The cost of reagents is presumably the major obstacle to improved pre-transfusion diagnostics. Implementation research can uncover the major barriers preventing uptake of improved pre-transfusion testing and can determine the most cost-effective solutions to achieve a higher level of transfusion diagnostics. For example, an AHG-enhanced antibody screen is likely to be highly cost effective if selectively applied to high risk patient groups such as: recurrently transfused sickle cell patients who have previously experienced a transfusion reaction, multigravida females who have previously had an infant afflicted with

hemolytic disease of the newborn, and previously transfused RhD negative individuals. The AHG-enhanced antibody screen and antibody identification procedures could likely be made cost effective with the use of reagent red cells collected from "in country" donors and manufactured by the national blood collection agency. This relative simple procedure consists of reagent donor collection, aliquotting, using Alsevier's solution preservative, and distribution to regional hospital blood banks that would become centers for serologic investigation. Preliminary experience from Uganda underscores the feasibility of this approach. A carefully negotiated arrangement with manufacturers of Coombs' serum could be developed in a successful way similar to what has already occurred with manufacturers of far more expensive medical supplies such as HIV test kits and medications, malaria test kits, and vaccines.

4. References

Dzik WH, et al. Transfusion Medicine in Sub-Saharan Africa. Transfus Med Rev 2015;29:195-204. doi: 10.1016/j.tmrv.2015.02.003.

Author/Contributor

1. Walter Dzik (Sunny)

5. BLOOD SAFETY: BLOOD RECIPIENT IDENTIFICATION

1. **Question:**

Can a low-cost method for identification of transfusion recipients be developed for Africa?

2. **Rationale**

In the United States, proper patient identification has been a leading priority of the Joint Commission on Accreditation of Hospitals for a decade. In a landmark publication, *To err is human,* the Institute of Medicine focused national attention on errors in healthcare which often stem from poor patient identication.

Blood transfusions in SSA are most likely to involve the infusion of whole blood brought to the bedside with no recipient label attached to the unit and given to a patient with no wristband. The sample which was drawn for pre-transfusion testing is likely to have no medical record number on it.

The development and implementation of a low-cost system for proper identification of transfusion recipients would almost certainly have positive 'spill-over' effects on other healthcare diagnostics and therapeutics including laboratory and radiologic tests, medication administration, and correct surgery.

3. **Feasibility and Strategy**

Research needs to be done to identify the most successful system for recipient identification in a low HDI environment. Numerous possible system exist. As an example, a simple system, which can be made locally from basic materials, involves the use of bracelet, necklace, or wristband with multiple replicates of a peel-off sticky label. Each label displays the same number which is unique to that bracelet. Numbered labels remain on the bracelet with the patient. At the time of collection of the pre-transfusion sample, several labels (each with the same number) are removed from the bracelet and attached to the pre-transfusion specimen. In the laboratory, one of these labels from the pre-transfusion specimen is transferred to each unit assigned to the patient after crossmatching. One label may also be peeled off the pre-transfusion specimen and entered into the laboratory record (log book of crossmatches). Requests slips, if used, can include a peel off label obtained at the bedside from the bracelet. At the time of infusion, the numbered label on the unit is matched to the numbered label on the bracelet. Barriers to implementation of recipient identification are not fully known and would require testable solutions. The value of recipient identification could be assessed with a basic hemovigilance approach which would, by itself, represent an additional step forward for transfusion safety in SSA.

4. References

1. Dzik WH, et al. Transfusion Medicine in Sub-Saharan Africa. Transfus Med Rev 2015;29:195-204. doi: 10.1016/j.tmrv.2015.02.003.

Author/Contributor

1. Walter Dzik (Sunny)

The West Africa Region (Team Leader: Dr. Claude Tayou Tagny)

SCIENTIFIC PRIORITIES #1

1. Question

What are the current blood needs in Africa?

What is the best method of estimating the blood needs in an African country?

2. Rationale

Robust methods to estimate blood inventory levels are needed to plan and evaluate systems of blood provision. Existing methods for estimating national blood inventories are either not sensitive to reflect the dynamic nature of blood needs in the health care system, or are difficult to apply due to the lack of required data to use accepted estimation measures (WHO,2010). Further, availability of blood for patients depends on sufficient blood supply and appropriate clinical use of blood. Blood transfusion services rely on the availability of healthy donors to ensure a sufficient blood supply, with the majority of blood donations coming from individuals between the ages of 16 and 40. In endemic malarial regions, the needs for blood transfusion peaks in the rainy season. In addition, as the population ages, the burden of chronic and non-communicable diseases, such as diabetes and heart disease, increases. Demographic projections that account for changes in population composition and disease prevalence, will be necessary in order to estimate blood requirements. Appropriate clinical use of blood, including implementation of patient blood management principles, may reduce the demands on the available blood inventory, blood wastage and minimize individual risks to transfused patients when transfusion is not appropriate.

Many recommended approaches of estimation of blood needs are available: WHO uses an estimate of 1% of population; PAHO estimates based on number of hospital beds -- 7 units/bed. (PAHO, 2010) However, there is no validated method for reliably estimating blood needs in Africa.

3. Feasibility and Strategy

Studies may be conducted in local settings and using large administrative data sets, when available. Having estimates based on detailed as well as large data set will help to provide the most accurate measurements, given the inherent weaknesses of either approach.

1. Using auditing of blood inventories and provider prescriptions of blood in a small number of representative hospitals (countries). Data collection will include data from blood provider (donations in: received, screened, in stock; donations out: requested, issues) from blood bank (donations received, returned, issues, discarded), from patient care (requested, received, transfused, discarded).
    - Potential pitfall: Using data from a set of smaller facilities may not adequately represent the larger blood needs for areas with patchy blood availability. This study is more feasible when blood services are centralized. Decentralized will be more challenging (data collection). Participating facilities will be carefully selected to avoid missing data.
2. Using large datasets, provide estimates of optimal blood needs in regions where blood is not in shortage.
    - Potential pitfall: Large data sets are not always available and may under or overestimate regional needs and disease burden if not sufficiently detailed.
3. Evaluate and compare the current recommended approaches (WHO, PAHO) to the above estimates.
4. Develop of the “best” approach based on result of evaluation of current approaches. This step (desktop analysis) will be to identify the more accurate way of estimating by adjusting various recommended approaches and problems associated with each.
5. Validate the “best” approach in a number of representative countries in Africa: A comparative study of the real needs vs estimation of the “best” approach.
6. Enumerate the mortality and morbidity from lack of blood using the best available model. This will provide valuable information to help prioritize strengthening blood collections and maintaining adequate inventories where blood transfusion is needed.
7. Describe clinical behavior and factors associated with inappropriate and increased blood utilization. These aspects will lead to better understanding of when estimates of needed inventory may need revision based on the patterns and optimization of usage.

4. References

1. WHO experts’s consultation on estimation of blood requirements. Meeting report. 2010. World Health Organization Head Quarter. Geneva. Switzerland
2. Recommendations for estimating the needs for blood and blood components. Pan American health Organization. 2010.Washington DC. USA.
3. Greinacher A, Fendrich K, Brzenska R, Kiefel V, Hoffmann W. Implications of demographics on future blood supply: A population-based cross-sectional study. *Transfusion*. 2011;51(4):702–9.

4. Johnson LF, Chiu C, Myer L, Davies M, Dorrington RE, Bekker L, et al. Prospects for HIV control in South Africa : a model-based analysis. *Global Health Action*. 2016;9(30314):1–12.
5. Goodnough T, Shander A. Patient Blood Management. Anesthesiology, 2012; 116 (6):1367 – 1376
6. Society for the Advancement of Blood Management. SABM Administrative and Clinical Standards for Patient Blood Management Programs, 3rd Edition. Unpublished Work, 2014.
7. www.aabb.org/pbm. AABB. Building a Better Patient Blood Management Program: Identifying Tools, Solving Problems and Promoting Patient Safety, 2015. (Available online).

SCIENTIFIC PRIORITIES #2

1. **Question**

Which model for financing blood safety in Africa is sustainable for which country profile?

2. **Rationale**

Blood units are expensive for African people and national Ministries of Health. In 2006 more than 50% of people lived under the limit of poverty (with less than US$2 income per day) while a blood unit cost more than US$25 in 83% of WHO African countries. (WHO, 2010) Cost recovery models are not economically viable in resources limited settings and may contribute to destabilization of the Nationalized Blood Services. (Hensher, 2000)

Autonomy and financial sustainability of Nationalized Blood Services are a critical issue. Many National Blood Services depend on external funding. In 2013, 42% of funds of the seventeen Western Africa nations were still provided by external funding (WHO, Unpublished); these funds are not constant and many are decreasing over time. There is no evidence to guide the optimal financial model that will be economically sustainable for a particular country.

3. **Feasibility and Strategy**

Describe the current financial models that support blood transfusion systems. Analyze and model critical elements of a country's economy, demography and national health system profile that may influence sustainability of its Nationalized Blood Services program. Identify which models is appropriate for which country profile. Future studies can involve designing and testing the financial plan using simulation or implementation.

There is a need of involving an economist in this study.

4. **References**

1. Status of Blood safety in the WHO African Region. Report of the 2006 Survey. World Health Organization. Regional Office for Africa. Brazzaville. 2010
2. Hensher M, Jeffreys E. Financing blood transfusion services in sub-Saharan Africa: a role for user fees? Health Policy Plan. 2000 Sep;15(3):287-95.
3. Status of Blood safety in the WHO African Region. Report of the 2010 Survey. World Health Organization. Regional Office for Africa. Brazzaville. 2010
4. Current status on blood safety and availability in the WHO African Region. Report of the 2013 survey World Health Organization. Regional Office for Africa. Brazzaville. (Unpublished).

SCIENTIFIC PRIORITIES #3

1. Question

What are the motivations and deterrents to blood donation in Africa?

2. Rationale

Although volunteer non-remunerated blood donors (VNRBD) is the goal of the WHO and many Nationalized Blood Transfusion Services, the drivers that motivate people to donate blood in African nations is not well understood. The average proportion of VNRBD in 43 African countries in 2010 was 74.8%; ranging from 0% in Equatorial Guinea to 100% in ten countries. (WHO Afro, 2014) In fact, thirteen of the seventeen countries that report less than 50% of VNRBD in 2010 were from Western Africa. (WHO Afro, 2014) There is still a high proportion of family replacement donations as well; many nations depend on this motivation to maintain their blood inventories.

The lack of enough blood donors is one of the reasons that the inventory of available blood units is lower than desired; the average annual blood donation rate in WHO/Afro Region (46 countries) in 2010 was 4.3 units per 1000 population with a range from 0.2/1000 in Nigeria to 33.8/1000 in Mauritius. (WHO Afro, 2014) Thus, only 1/3 blood needs may be covered in Africa. (WHO, 2014) Understanding of donor motivations and subsequent implementation of an appropriate recruitment, motivation, education and collection plan will increase blood donations.

3. Feasibility and Strategy

Methodology will include

1. Describe the characteristics of blood donors in Africa. This study has already been conducted and provided the profile of a typical blood donor in Africa, however, it needs to be updated.

2. Perform a survey to measure motivations and deterrents in VNRBD and family donation. Some of the studies have already be conducted on the subjects. Motivations and deterrents have been suggested but each time in a limited and single blood service. A study in a representative number of blood donors in Africa should be conducted so it is more broadly applicable.
3. Perform observational studies linking questionnaires to data on donation behavior. This can only be done in centers with good electronic donor/donation data systems.
4. Design potential interventions at a national level using identified motivations and deterrents and Test interventions with randomized clinical trial design.

4. References

1. Tagny CT, Diarra A, Yahaya R, Hakizimana M, Nguessan A, Mbensa G, Nebie Y, Dahourou H, Mbanya D, Shiboski C, Murphy E, Lefrere JJ. Characteristics of blood donors and donated blood in sub-Saharan Francophone Africa. Transfusion 2009 ;49:1592-9.
2. Status of Blood safety in the WHO African Region. Report of the 2010 Survey. World Health Organization. Regional Office for Africa. Brazzaville. 2010
3. MC Carter, J Wilson, GS Redpath, P Hayes, C Mitchell. Donor recruitment in the 21st century: Challenges and lessons learned in the first decade Transfusion and Apheresis Sciences 2011; 45(1): 31-43.

SCIENTIFIC PRIORITIES #4

1. Question

Can we design a more sensitive and specific donor health questionnaire (DHQ) for use in the African setting?

2. Rationale

Effective donor selection, along with transfusion transmitted infection (TTI) testing and good quality control, is a pillar in reducing the risk of TTI's. TTIs risk factors have been studied in Africa. However, few studies followed appropriate study design and methodology for such type of research and unusual risk factors may have been missed. There is no uniform DHQ developed and validated specifically for African donors. There is an evidence of inappropriate quality donor screening in Francophone Africa (Tagny et al, 2012). There is no DHQ for an adapted and efficient donor screening in the African setting.

3. Feasibility and Strategy

Strategy will include:

1. Perform targeted studies of TTI risk factors in the African context using case-control design in several Francophone blood services.
2. To develop an adapted DHQ based upon these risk factors: A pilot phase is being conducted in Cameroon for HIV: potential risk factors were identified and a draft questionnaire has been designed. (Tagny CT & al, 2017)
3. To validate the DHQ in a number of African countries (design potential intervention and test their performance in the operational setting)

4. References

1. Tagny CT & al. Transfusion safety in Francophone African Countries: An Analysis of Strategies for the Medical Selection of Blood Donors. *Transfusion.* 2012; 52(1):134-43.
2. Tagny CT & al. Risk Factors for HIV among Blood Donors in Cameroon: Evidence for the Design of an Africa-Specific Donor History Questionnaire. *Transfusion.* DOI: 10.1111/trf.14140
3. MN Polizzotto, EM Wood, H Ingham, AJ Keller. Australian Red Cross Blood Service Donor and Product Safety Team Reducing the risk of transfusion-transmissible viral infection through blood donor selection: The Australian experience 2000 through 2006. Transfusion 2008;48(1):5563.

SCIENTIFIC PRIORITIES #5

1. Question

Is adding whole blood pathogen reduction technique in blood safety strategy in Africa affordable and sustainable?

Is whole blood pathogen reduction technique efficient and safe for African patient?

2. Rationale

Pathogen inactivated whole blood (PIWB) has been demonstrated highly efficient and safe in vitro. (Nkohkwo et al, 2016) There is an evidence of in vivo benefit of pathogen inactivation of whole blood for malaria in Ghana. (JP Allain & al, 2015) There is no evidence of in vivo safety and efficiency of PIWB to render the blood supply free from for the main TTIs.

3. Feasibility and Strategy

Strategy of the studies will intend to conduct pilot and larger prospective clinical studies in group of patients treated with PIWB across Africa. Potential interventions should be designed and tested in national implementation programs to measure affordability and sustainability.

There is a need of involving an economist in this study.

4. References

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SCIENTIFIC PRIORITIES #6

1. Question

Which blood transfusion strategy is more cost-effective in patient blood management of sickle cell disease (SCD) in resource limited African settings?

2. Rationale

An estimated 200,000 new babies are born every year in Africa with lifelong sickle-cell disease; an estimated 80% die before their 5th birthday; the remainder suffer lifelong serious morbidity and poor prognosis. At an estimated 2% prevalence, there are approximately 20 million people living with sickle-cell disease in Sub Saharan Africa (SSA), and due to the growing population in SSA, this number will increase accordingly. (WHO, 2008) The effective management of SCD in other regions suggests that 10% of a given population of sickle-cell anemic patients would require a blood transfusion episode per year, especially to prevent strokes in children, or address acute complications in other groups. (NIH 2002; NHS 2010; Sickle Cell Society 2008) Medications commonly used in other regions of the world at not widely used in SSA. There is no evidence that a therapeutic approach will be economically sustainable for a particular country profile if implemented.

3. Feasibility and Strategy

To describe the current therapeutic models and analyse critical elements of the economy, demography and health profile that may influence sustainability of its blood transfusion (and medical treatment) program that supports patients with SCD. Identify which models is appropriate for which country profile. Design and test a national implementation plan.

There is a need of involving an economist in this study.

4. References

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2. NHS. Sickle cell diseases in childhood- standards and guidelines for clinical care. London 2006 & 2010.
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SCIENTIFIC PRIORITIES #7

1. Question

What is the risk of emerging and re-emerging pathogens (ERP) to blood safety in Africa?

Which strategy is the most appropriate for blood services of resources limited settings to reduce the risk of ERP?

2. Rationale

Many agents have fulfilled the broad definition of emerging blood-transmitted infections and have the potential to cause transfusion transmitted infection, including dengue, West Nile virus (WNV) and other arboviruses, Trypanosoma cruzi, Plasmodium spp., Babesia spp., parvovirus B19 and the prions that cause variant Creutzfeld-Jacob disease (vCJD). Currently, there are no data and no control strategy of emerging and re-emerging pathogens in African blood donor population or understanding of transmission of these diseases to transfusion recipients.

3. Feasibility and Strategy

Work with colleagues in the ERP field to build multi-use biorepositories of specimens from blood donors with informed consent for future testing. Use these by repositories to measure the prevalence and time trends of the main ERP. Assess and compare strategies of reducing the risk of ERP (regular monitoring of epidemiological indicators, identification of low risk population, donor deferral, PIWB, vaccination, etc). Design and test national implementation plan.

4. References

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2. Alter HJ, Stramer SL, Dodd RY. Emerging infectious diseases that threaten the blood supply. Semin Hematol. 2007 Jan;44(1):32-41.

The Middle East and North Africa Region (Team Leader: Dr. Magdy El Ekiaby)

Mini-Pool Solvent Detergent Virus Inactivation of Plasma and Cryoprecipitate

Provision of Safer Treatement Options for Patients with Inherited Bleeding Disorders in EMR

Background:

In EMR, current estimates suggest that there are 26,524 patients with inherited bleeding disorders (IBDs) in the Region contributing to 9% of the global reported disease burden. Among these, 17,430 have Haemophilia (14,027 with Haemophilia A, 3,128 with Haemophilia B and 209 with unknown type); 3,605 with von Willebrand disease and 5,489 with other bleeding disorders. These figures underestimate the real magnitude of the problem. Accesibility to safe treatment products remains a challenge which undermines both safety and quality of life of these patients. Except for Iran and Morocco who have contract fractionation program that partially contribute to access to safe treatment products (CFCs), the majority of patients with inherited bleeding disorders still rely on domestically non-virally inactivated plasma components. Even in the region rich oil countries, only original citizens have access to safe CFCs. In these countries, the majority are foreign workers who do not have access to the privileged health systems provided to the original citizens[1].

In the meantime, blood transfusion services are relatively advanced and have the capacity to produce high quality plasma.

The introduction of new technologies for virus inactivation of plasma components such as Solvent Detergent (SD) virus inactivation of plasma and cryoprecipitate may help in better utilization of plasma components to secure safer treatment options for people with IBDs[2-4].

Mini-Pool Solvent Detergent Medical Devices to virally inactivate plasma and cryoprecipitate has been successfully developed and commercialized by a Swiss Company. The devices have been CE marked and have free sale certificate from SwissMedic. The devices are placed in the market since 2010 and used in Egypt since 2013. In Egypt more than 8000 medical device of VIPS SD Virus Inactivation of Cryoprecipitate have been used and contributed to production of about 40 million units of FVIII from domestic plasma. SD cryoprecipitate has been infused to more than 2000 patients with hemophilia A as well as to a good number of patients with VWD, FI and FXIII deficiency. The products proved to be as effective as the CFCs from fractionation industry with the same edge of safety, both virally and immunologically[4].

As well, more than 3000 medical devices of VIPS SD Plasma Virus Inactivation was used in Egypt producing 6000 units of SD plasma that was used with safety and efficacy to treat FII, FV, FVII and FX deficiency as well as in therapeutic plasma exchange for TTP and others.

Research Question:

Will the implementation of this technology, and based on the Egyptian accumulating evidence of safety and efficacy of the use of the medical devices, help to improve access of the patients with IBDs in EMR to safe plasma components in addition to know CFCs?

2. **Rationale**

In EMR there are about 26,000 patients with IBDs who have limited or no access to safe treatment products.

In the meantime, there is serpulus of domestic plasma that is currently not utilized for plasma fractionation. The use of VIPS SD medical devices technology can treat this plasma to produce virally safe products that can be used to treat patients with IBDs at affordable cost and allows for better use of this domestic resource.

3. **Feasibility and Strategy**

In view of the large amounts of available plasma while there is shortage of treatment products for patients with IBDs in EMR, the logic is to start projects to utilize this domestic resource. The known approach is to qualify the plasma for either contract fractionation or build domestic fractionation facility. These projects need typically between 5 – 10 yars from start to be fully implemented.

Mini-Pool Plasma Fractionation is a down scaling of the plasma fractionation. The validated medical device technology for virus inactivation of plasma and cryoprecipitate by SD can be implemented in few months. The needed infrastructure, human and financial resources are minimum and can be afforded by the countries of the region to respond to their patients' needs.

4. **References**

1. *Blood Safety and Availability: A Strategy for the Eastern Mediterranean Region*. 2016, Blood and Transfusion Safety

Public Health Laboratories

Department of Communicable Diseases Prevention and Control

2. M. El-Ekiaby, M.R., H. Goubran, et al, *New methods of plasma fractionation – a presentation of the 'mini-pool' fractionation procedure developed in Egypt.* ISBT Science Series 2009. **4**: p. 99–106.
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4. El-Ekiaby, M., et al., *Pharmacokinetic study of minipooled solvent/detergent-filtered cryoprecipitate factor VIII.* Haemophilia, 2011. **17**(5): p. e884-8.

Mini-Pool Intravenous Immunoglobulins (MP-IVIG)

Provision of Safer Treatement Options for Patients with Inherited & Acquired Immune Disorders

Background:

In EMR, as well as other regions in the world there is an inadequate supply of large scale fractionated Intravenous Immunoglobulins (IVIG). Indications for IVIG include replacement therapy of Primary Immunodeficiencies (PIDs), management of Autoimmune Thrombocytopenia (ITP), Acquired Immunodeficeincy such as in paediatric HIV and Chronic Lymphocytic Leukemia of B cell Type as well as many other indications as an immunomodulatory agent[1].

IVIG is typically an expensive therapy and there is an increasing demand for use in the developed world which makes access to this therapeutic agent very limited to patients in developing countries. In the meantime, in developing countries, many blood transfusion services are relatively advanced and have the capacity to produce high quality plasma that could be used locally to prepare immunoglobulin concentrates on a small scale by a novel technology.

The introduction of new technologies for virus inactivation of plasma components such as Caprylic Acid Purification and Virus Inactivation of Mini-Pools of domestic plasma to produce IVIG can be a pragmatic approach to increase access to this impotant therapeutic agent to patients living in developing countries. Moreover, the use of domestic plasma with an immunoglobulin profile that contains antibodies against the prevalent infectious agents in the community can make it selectively effective.

An MP-IVIG Medical Device to virally inactivate plasma immunoglobulins has been successfully developed and is under commercialization by a Swiss Company. The device is expected to be CE marked early 2018. The device has been validated on the laboratory scale and in animal studies[2]. A Phase 2 clinical trial was performed on a small number of recently diagnosed children with ITP*. The trial was a multi-center study from several universities in Egypt. The study was completed and the manuscript was submitted to Transfusion on 23.12.2016. MP-IVIG pharmacokinetics was also studied in a small cohort of children with PIDs[3].

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1. **Research Question:**

Can MP-IVIG be implemented in blood transfusion centers using the newly developed medical devices?

2. **Rationale**

In many developing countries, there is a serplus of quality plasma that can be used to produce safe plasma components that will provide virally inactivated and concentrated coagulation factors and IVIG.

Processing plasma from hyper immune donors can also help to produce high titer immunoglobulin for prophylaxis against hepatitis B infection. Also, it can help to produce anti-D specific immunoglobulin for prophylaxis against alloimmnization in RhD negative women.

3. **Feasibility and Strategy**

In view of the large amounts of available plasma while there is shortage of IVIG products, the logic is to start model projects to utilize this domestic resource. The known approach is to qualify the plasma for either contract fractionation or build domestic fractionation facility. However, these projects typically require between 5 – 10 years from inception to be fully implemented.

Mini-Pool Plasma Fractionation is a down scaling of the plasma fractionation. The validated medical device technology for concentration and virus inactivation of plasma immunoglobulins (MP-IVIG) can be implemented in few months. The needed infrastructure, human and financial resources are minimum and can be afforded by the countries of the region to respond to their patient's needs. Demonstration projects in selected centers should be feasible to determine effective strategies to promote implementation of this technology in areas where availability of large-scale fractionated IVIG is inadequate.

4. **References**

1. Perez, E.E., et al., *Update on the use of immunoglobulin in human disease: A review of evidence.* J Allergy Clin Immunol, 2017. **139**(3S): p. S1-S46.
2. El-Ekiaby, M., et al., *Minipool caprylic acid fractionation of plasma using disposable equipment: a practical method to enhance immunoglobulin supply in developing countries.* PLoS Negl Trop Dis, 2015. **9**(2): p. e0003501.
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*** Manuscript submitted to Transfusion and in review**

1- Research Question:

In the population of voluntary non-remunerated blood donors within the National Blood Transfusion Services in Egypt, does the demographic distribution influence the prevalence of WNV?

2- Rational:

West Nile Virus (WNV) is from the family of flaviviridae, genus flavivirus that was isolated in 1937 in a region close to one of the tributaries of the River Nile in Uganda. Geographical distribution includes Africa, Asia, the Middle East as well as Europe, (A, 2015) and Australia (Kunjin strain). (Dodd, 2015)

The enveloped single stranded RNA virus is transmitted to humans from birds via mosquito. (Sharifi, 2010). Other routes of transmission include blood transfusion, transplacental infection, and organ transplant in addition to reported cases of infection via breast milk. (Mekkawi, 2009)

Infected human cases are mostly 80 % asymptomatic. Severe neuroinvasive manifestations appear in only < 1% of infected cases. (A, 2015)

In Egypt, the National Blood Transfusion Center depends on voluntary non remunerated blood donors, 90 % of which are first time donors. Screening of blood donations is not mandatory for WNV.

WNV disease is expected to exist in Egypt as the geographic distribution of the virus includes the Middle East. Screening of 284 apparently healthy blood donors, of which 81 were university students while 203 were street vendors, who donated blood in the Egyptian organization for vaccines and sera production in 2007, revealed 7 MP-NAT positive cases by real time-PCR (2.5%). These were repeated individually to reveal 7 positive samples. Retesting the 7 positive MP-NAT individually revealed 7 positive samples. It was found that all positive cases were from street vendors working at different places and travelling most of the time. All samples of the 81 university students were negative for WNV. This prevalence among low income people may be due to living close to water collections and raising domestic animals creating suitable conditions for the breeding of the mosquito vector. (Mekkawi, 2009).This may reflect that an urban versus rural difference exists in the association with WNV infection.

3- Feasibility and Strategy:

A cross sectional study that aims to study the association between a predictor and outcome; (the demographic distribution; urban versus rural and the reactivity or non-reactivity of WNV). It includes the enrollment of voluntary non-remunerated blood donors from the National Blood Transfusion Center in Cairo (NBTC) and from the Regional Blood Transfusion Center (RBTC) in Tanta governorate according to the Egyptian National Donor Selection Criteria over a period of 3 months.

A major strength of the chosen study design is that there is no waiting around for the outcome to occur, which avoids the problem of loss to follow up (Hulley et al.2013).

EDTA blood samples serum or plasma (5ml) collected from the blood units according to working instructions of Blood Donor Phlebotomy (WI/NBTS/DCD/004/01) will be screened for WNV RNA using ID Nucleic Acid Testing in NBTC.EDTA blood samples collected in Tanta RBTC will be transported to NBTC according to the Standard Operating Procedure of Blood Transportation (SOP/NBTS/DCD/008/06), to be screened for WNV RNA.Screening will be done using the PROCLEIX WNV assay operated on Tigris Grifols system, which is the system in use for routine ID NAT screening for HBV, HCV and HIV in NBTC.Initially Reactive samples will be tested in three replicates from the plasma bags for WNV RNA using same assay. Any one reactive sample of the three replicates will render the donation a reactive one to WNV RNA.

3- References:

- A, R. (2015, May 21). THE CHALLENGE OF WEST NILE VIRUS IN EUROPE: KNOWLEDGE GAPS AND RESEARCH PRIORITIES. Eurosurveillance, 20(20), pii=21125.
- Dodd, R. Y. (2015). Keeping Blood Transfusion Safe FromWest Nile Virus: American Red Cross Experienc, 2003 to 2012. Transfusion Medicine Review, 29, 153-161.
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- Mekkawi, T. E. (2009, September). Detection of West Nile Virus nucleic acid in Egyptian blood donors by real time PCR. Egyptian Journal of Medical Sciences, 18(2), 45-51.
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The prevention of allo- immunization to RBCs blood group antigens in Thalassemic patients in the Mediterranean and Middle East regions.

1. **Question**

Is it possible to avoid alloimmunization to RBCs blood group antigens and minimize hemolytic transfusion reactions in Thalassemic patients who receive regular blood transfusion as long-life treatment?

2. **Rationale**

Thalassemia is a common hemoglobin disorder in the Mediterranean region and the Middle East; it is one of the major public health problems in Egypt. Although regular blood transfusion is life saving for thalassemia patients, they may be associated with alloimmunization to red blood cells, The development of alloantibodies against RBC antigens complicate pre-transfusion matching, shortens *in vivo* survival of transfused cells, delays provision of safe transfusions and may accelerate tissue iron loading and multiple organs failure. Reported alloimmunization rates ranged from 12% to 50% in thalassemia and were less in more homogenous populations, Approaches for prevention of alloimmunization are under study.They range from the provision of extended phenotyped RBCs associated with clinically significant antibodies to blood matched only. Reasons for controversy regarding following the best approach lay in the fact that some alloantibodies are not clinically significant and the costy prevention methods may therefore benefit only some patients

3. **Feasibility and Strategy**

The purpose of this research is to investigate the rate of alloimmunization and to determine the specificity of these antibodies among multiple-transfused thalassemic patients and to verify and test the contributing and risk factors. Also to develop a scientific tools, concepts and strategies to decrese mortality and morbidity due to hemolytic transfusion adverse events and to overcome this major problem.

An extended red cell phenotype must be obtained to reduce the future probability of developing alloantibodies. If a child has already started transfusions, the red cell antigen genotype can be determined by DNA testing.

Screening and identification of red cell Abs should be considered as routine pre-transfusion testings, re-evaluation of the patient`s status for development of new Abs should be done before each transfusion.

Preparation of own pheotyped RBCs to screen the patients will decrease the cost and improve the result outcome due to the use of the definitive RBCs for this population. Commercial reagents and anti-sera are already available worldwide; however expensive.

Allocation of specific phenotyped regular blood donors to match definitive patients` phenotypes could be a national protocol, to avoid alloimmunizaion to RBCs.

4. **References**

- El Danasoury AS, Eissa DG, Abdo RM, Elalfy MS. Red blood cell alloimmunization in transfusion-dependent Egyptian patients with thalassemia in a limited donor exposure program. Transfusion. 2012;52:43–7. [PubMed]
- Ameen R, Al-Shemmari S, Al-Humood S et al. RBC alloimmunization and autoimmunization among transfusion-dependent Arab thalassemia patients. Transfusion 2003;43:1604-10
- Milkins C, Berryman J, Cantwell C, et al. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. British Committee for Standards in Haematology. Transfus Med 2013;23:3-35

The Latin America and the Caribbean Region (Team Leader: Dr. Ester Sabino)

1. **Question**

What is the rate of iron depletion among Latin America blood donors?

What is the best intervention to avoid iron deficiency among repeat blood donors in Latin America?

2. **Rationale**

Blood donors are at risk of developing iron deficiency and/or iron deficiency anaemia. This affects their health and eligibility for subsequent donations. Due to dietary issues iron deficiency and anemia are more common in developing regions of the world. For example anemia is 3 times more common in Latin American than North American females (1). Data regarding iron depletion is not available for blood donors in Latin America.

Increased voluntary repeat donations in Latin America may improve blood availability and safety, but may also increase the risk of iron depletion and consequent anemia in a population already iron deficient. Screening for markers of iron depletion such as ferritin may add more costs for Latin America blood centers.

Low hematocrit/hemoglobin (Ht/Hb) is one of the most common reasons for deferral blood donors in Brazil (2). Approximately 13% of female first-time donors are deferred due to a Low Ht/Hb on a subsequent donation. Baseline Hct, Hct at the visit immediately before deferral due to Low Hct, and the intervals between donations, were associated with higher rates of development of Low Hct in repeat donors (3). Assigning longer donations intervals based on the Hct levels at the qualifying donation or supplementing iron to donors at risk may decrease deferral rates of donors with low Hct.

It is important to evaluate the most cost effective intervention to increase repeat donations and yet not cause iron deficiency and anemia among blood donors in developing regions like Latin America.

3. **Feasibility and Strategy**

Baseline levels of iron deficiency could be documented in representative populations of first time and repeat blood donors from several Latin American countries.

Different strategies and their combinations (offering iron replacement, increasing inter-donation intervals, assessment of iron stores, donor education, etc.) can be tested using deferral rates due to low Hct on subsequent donation attempts as end-points.

4. **References**

1. Stoltzfus R. Iron deficiency: Global prevalence and consequences. Food Nutr Bull. 2003 Dec;24(4 Suppl):S99-103
2. T.T. Goncalez. Analysis of donor deferral at three blood centers in Brazil. Transfusion. 2013 Mar; 53(3): 531–538.
3 Almeida FN Predictors of low haematocrit among repeat donors in São Paulo, Brazil: eleven year longitudinal analysis Transfus Apher Sci. 2013 Dec;49(3):553-9

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1. **Question**

How are blood transfusions being used in Latin America? Do blood centers and hospitals have established guidelines for transfusion indications and triggers?

How frequently are blood requests not released by blood banks and for what reasons?

What is the best way to choose and implement Guidelines for Blood Transfusions to avoid unnecessary blood transfusion?

2. **Rationale**

The use of blood transfusion therapies may vary according to medical practice traditions within and between countries and over time, particularly as blood availability, component therapy, and transfusion management practices fluctuate or change. Literature that investigates how blood is being used is especially scarce in developing countries (1-3). Collection of blood request data associated with recipient outcomes may improve the understanding of fluctuations in demand and availability and help to predict future trends. It may also allow for the detection of major blood misusage and whether or not blood centers are able to satisfy hospital requests.

Once a system is established to measure how blood is being used, we can study the best way to implement blood transfusion guidelines.

3. **Feasibility and Strategy**

A Latin American group has recently suggested a web based protocol to compile and access data in a similar way by different groups in different countries of the continent (4). The protocol basically reviews blood requests and recipient clinical data and outcomes in different regions of the continent.

After devising a system to monitor how blood is being used we can evaluate interventions to modify practices toward more evidence based policies and measure their impact.

There will be many challenges to develop a study protocol such as this one.

- the study will need to consider differing countries' jurisdictions, and/or variations in blood request procedures among diverse institutions and medical specialties throughout Latin American and Caribbean.
- a random-selection of hospitals may not be achievable because some of them may not be willing to participate, may lack computerized information systems or have only partial records, or the patient's medical records and transfusion requests may be incomplete.

4. **References**

1. Cortés A, Beltrán M, Olaya B, Hernández M. Epidemiología de la colección, proceso y uso de sangre y componentes sanguíneos en el Valle del Cauca, Colombia. Colombia Med. 1999;30:5-12.

2. Pugliese AM, Diez RS, Magaldi BG, del Pozo AE. Estimación de las necesidades de componentes de la sangre de un hospital pediátrico de alta complejidad. Rev Arg Transfusión. 2011;37(3):174. Available from: www.aahi.org.ar/wpcontent/uploads/2014/06/RAT201103.pdf Accessed on 5 May 2015.

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4. Pozo AE, Pérez-Rosales MD, Almeida-Neto Cd, Remesar MC, Cortes AD, Delgado RB, Mendrone A Jr, Sabino E. A comprehensive protocol to evaluate the use of blood and its components in Latin America and the Caribbean. Rev Panam Salud Publica. 2015 Jun;37(6):435-41.

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1. **Question**

What is the prevalence of confirmed infectious disease markers in different Latin American countries and subgroups of donors defined by demographics and donation categories?

In Brazil, voluntary donations have a higher prevalence and incidence of HIV as compared to replacement donations. Is this same observation true in other Latin American countries?

What are the most effective interventions to increase repeat voluntary donations and still maintain blood safety?

2. **Rationale**

Systematic data on prevalence and incidence of infectious disease markers are only available for the REDS sites in Brazil due to lcak of confirmation testing and data capture and analysis systems. PAHO routinely receives data from the Ministry of Health regarding number of blood collection, rates of discarded units, type of donation, etc. But these reports are sent as final tables not as raw data, hampering new analysis (1), and the infectious disease markers are not confirmed.

The REDS program has shown that Brazilian blood donors are young and that the rates of donor return vary among the sites but were higher among repeat voluntary male donors. However, voluntary and male donors had a higher prevalence and incidence of HIV than female and replacement donors, respectively. The residual risk of HIV transmission in Brazil was 10 times higher than in the USA. (2)

Two intervations to avoid donation by at risk individuals were tested at Fundação Pro-Sangue, one of the REDS sites, but none of them were effective:

1) Distribution of pamphlets explaining the window phase to the donors and asking them not to donate if they had been at risk (3);

2) HIV test was offered prior to donation (4).

There is still a need to evaluate new interventions to improve donor return rates and yet maintain the safety of the blood supply.

3. **Feasibility and Strategy**

Tools to extract data from blood centers were established during the REDS programs and could be used to compile and access data from countries in Latin America. Intervention studies could choose outcome variables that are routinely extracted from the blood center database.

4. **References**

1) Supply of Blood for Transfusion in the Caribbean and Latin American Countries 2012 and 2013. Available at (http://www.paho.org/hq/index.php?option=com_topics&view=rdmore&cid=8651&Itemid=40821&lang=en)
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4) Goncalez TT et al Does offering human immunodeficiency virus testing at the time of blood donation reduce transfusion transmission risk and increase disclosure counseling? Results of a randomized controlled trial, São Paulo, Brazil. Transfusion. 2015 Jun;55(6):1214-22.

The Southeast Asia Region (Team Leader: Dr. Nabajyoti Choudhury)

Serial: 1

1. **Question**

Knowledge attitude, prevention (KAP) study and implementation strategy to achieve total dependency on VNRBD in South Asia

2. **Rationale**

a. Majority countries in the region are dependent in family relative donors (RD). Voluntary non-remunerated blood donors (VNRBD) and RD co-exist in different ratios in all countries. It is needed to understand prevalence of VNRBD, RD (if any paid donors) in different countries.

b. Poor VNRBD is due to multiple factors country-wise including social-economic-religious reasons. It is important to understand common barriers and individual barriers for each country.

c. What were strategies already applied and why they were successful or failure?

3. **Feasibility and Strategy**

a. Few South Asian countries should be engaged in a KAP study to understand how to achieve 100% VNRBD.

b. Multiple countries could be approached through WHO-WR and through trans-national organizations like Asian Association of Transfusion Medicine (AATM) or ISBT.

c. It is recommended to include different strata of the society and different socio economic populations.

d. AATM can act like a nodal agency for this study at least in its member countries.

e. KAP study execution and analysis in 1 year and strategy for implementation of study recommendations should be another 2-3years.

4. **References**

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b. Towards 100% voluntary blood donation: a global framework for action. World Health Organization. II. International Federation of Red Cross and Red Crescent Societies. ISBN 978 92 4 159969 6 (NLM classification: WH 460)

c. http://www.ifrc.org/en/what-we-do/health/blood-services/

Serial No: 2

SCIENTIFIC PRIORITIES TEMPLATE (BLOOD AVAILABILITY)

1. Question: Recruitment of future donors by interventions with high school teachers and introducing chapters in course curriculum for students

2. Rationale

a. Blood donation age usually starts after attaining usually 18 years of age. These youngsters usually are not aware of blood donation. Blood donation is not a part of study course curriculum in most of South Asian countries.

b. There is no structured training program for high school teachers so that they can motivate their students to donate blood after attaining recommended age.

c. Blood donation camps may be organized with parents and relatives of students regularly which will also inspire future blood donors.

3. **Feasibility and Strategy**

a. One knowledge attitude prevention (KAP) study is needed to know the percentage of blood donation by new blood donors in each country after attaining eligible age. The same study may also be employed to understand elements of blood donations in the course curriculum of high school students. As per the results obtained, intervention shall be planned to prepare high school students for voluntary donation by introducing VNRBD chapters in course curriculum.

b. Another KAP study is needed to understand the knowledge level of high school teachers on blood donations. Short term modular training program on VNRBD for high school teachers shall be designed in motivate future young donors.

4. **References**

a. Zito E, Alfieri S, Marconi M et al. Adolescents and blood donation: motivations, hurdles and possible recruitment stretegies. Blood Transfun. 2012; 10: 45-58

b. Finck R, Ziman A, Hoffman M et al. Motivating factors deterrents to blood donation in high school aged blood donors. J Blood Donation. 2016; 8.

c. Eligibility of blood donation: Recommendations for education and selection of prospective blood donors. PAHO; Regional office of World Health Organization, 2009

Serial No: 3

SCIENTIFIC PRIORITIES TEMPLATE (BLOOD SAFETY)

1. **Question**

To improve bed side transfusion safety by planning training courses for transfusion nurses.

2. **Rationale**

a. Once blood/ component units are issued to the patient from the Blood Bank, safety is dependant on nursing staff.

b. There is a need to enhance safety in transportation, temporary storage at ward, proper identification of patient, monitoring and documentation of the episode

c. Introducing special courses of 'Transfusion Nurse' which include blood collection, apheresis procedures, followup of transfusion and hemovigilance.

3. **Feasibility and Strategy**

a. One KAP study may be designed to understand involvement of nursing staff and prevailing practices in blood transfusion services in South Asian countries.

b. Three types of training courses may be planned for nursing: a). one day regular sensitization/ refresher course; b). three days refresher course for training of trainers; c) six months certificate couse for 'Transfusion Nurse'

c. Course implementation may be planned in few selected countries depending on low-medium-high income countries.

4. **References**

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c. Training module for Blood Bank Nurses. National Blood Transfusion Council. Ministray of Health & Family Welfare, Govt. of India. http://naco.gov.in/sites/default/files/3

Serial No: 4

SCIENTIFIC PRIORITIES TEMPLATE (BLOOD SAFETY)

3. **Question**: To audit transfusion practices in South Asian countries and to develop guidelines for rational use of blood.

2. **Rationale**

a. Most of the countries in South Asia usually practice transfusion of whole blood. Majority of clinicians still would like to transfuse fresh whole blood.

b. Real time baseline data is not available about transfusion practices.

c. One guideline for rational use of blood may be prepared keeping in view of blood/ component availability and disease burden

3. **Feasibility and Strategy**

a.Three countries, each from low, medium and high HDI countries from South Asia may be included in the project to study transfusion practices and availability of blood components in the region.

b. Availability of blood/ components in member countries and disease burden for transfusion shall be collected.

b. Guidelines for rational use of blood/ components shall be developed on the basis of information gathered from above two points depending on countries requirements.

4. **References**

a. Blood safety and availability. Fact sheet. July, 2016. World Health Organization. http://www.who.int/mediacentre/factsheets/fs279/en/

b. Bray TJ, Prabhakar K. Blood policy and transfusion practices-India. Trop Med Int Healt. 7 (6); 2002: 477-478

c. Safe and rational use of blood. World Health Organization. http://www.who.int/bloodsafety/clinical_use/en/

Serial No: 5

SCIENTIFIC PRIORITIES TEMPLATE (BLOOD SAFETY)

4. Question: To study status of temperature monitored and controlled transportation of blood and components in South Asian countries and planning of intervention whenever applicable.

5. Rationale

a. Ambient temperatures in South Asian countries range from -20^{o}C to +47^{o}C. There is always requirement of temperature controlled transportation of blood and components in outdoor settings (blood donation camps, Blood Banks to hospitals etc.). There is also requirement of transportation for short distances like the Blood Bank to wards. There is scanty data available on status of blood/ component transportation temperature maintenance in this region. A study is needed to understand existing practices in different countries and scope for improve of transfusion safety

b. One guideline is required at national or regional levels for transportation of blood/ components in temperature controlled and monitored conditions in these countries.

3. **Feasibility and Strategy**

a. One knowledge attitude prevention (KAP) study will be planned to gather information on existing practices in selected countries at capital, regional and district levels. Intervention will be planned to achieve required temperature in consistent manner.

b. One guideline shall be framed for blood/ component transportation for South Asia keeping in mind the resource constraints and existing difficult terrain/ bad road conditions.

4. **References**

a. Transportation of blood components. Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee. http://www.transfusionguidelines.org/red-book/chapter-6

b. Blood cold chain. World Health Organization. http://www.who.int/bloodsafety/processing/cold_chain/en/

c. Hardwick J. Blood storage and transportation. May-2008; ISBT Science Series.

The Western Pacific Region (Team Leader: Dr. Diana TEO)

1. **Question**

What are the major motivational and inhibitory factors for VNRBD, and the measures to take to overcome these inhibitory factors in various countries in the WPR? What are the major enabling factors for the successful transforming from family/replacement/paid donations to voluntary non-remunerated blood donations in the countries in the WPR?

2. **Rationale**

Over the past two decades, countries in the Western Pacific Region (WPR) have experienced significant economic and social evolution. Although blood supply and transfusion safety has improved significantly, many low- and middle-income countries are faced with challenges of collecting sufficient blood to meet the rapidly increasing clinical need. Voluntary non-remunerated blood donor (VNRBD) recruitment is a shared challenge. Although 97% of the estimated 25.3 million whole blood donations collected in 2013 were from VNRBD, there are still 5 countries in the Region collecting more than 50% of blood from paid or replacement donors (World Health Organization, 2016)). In larger countries such as China, the proportion of VNRBD varies in different cities. The proportion of whole blood donations by repeat VNRBD ranges from 1 to 89%. Several low- and middle-income countries in the region had successfully shifted from family/replacement/paid donations to a system fully or mainly based on voluntary non-remunerated blood donations, but for other countries, this process is slow and blood supplies still mainly rely on family/replacement/paid donations.

An understanding of major motivational and inhibitory factors for voluntary blood donation in the WPR will be very valuable to guide the design of more effective donor recruitment strategies. Although studies have identified a number of common motivators and barriers to blood donation, values and beliefs specific to different cultural groups may influence blood donation behaviour. By gaining a better understanding of differences in attitudes towards blood donation, the interventions developed in predominantly western countries may be adapted more effectively to other cultures. Given the lack of resources that developing countries often experience in this area, it would also be worthwhile taking a broader regional view of this issue to determine whether there are a set of standard materials and messages that could be utilised across countries to address community attitudes and beliefs about blood donation and promote the recruitment and retention of voluntary blood donors.

3. **Feasibility and Strategy**

Many studies, conducted primarily in prospective donors in North America and Australia, have identified a number of common barriers and motivators which can be used as the basis for further research (Bednall & Bove, 2011; Masser et al, 2008; Charbonneau & Tran, 2013). Various interventional strategies have also been developed and introduced to directly address these barriers and motivators (Ferguson et al, 2007; Godin et al, 2012). A handful of studies conducted in the Western Pacific Region report similarities as well as differences in motivators and demotivators for blood donation compared to western societies (Ngoma et al, 2013; O'Brien et al, 2013; Tison et al, 2007; Lownik et al, 2012). Studies based on similar design should be extended to the different countries in the regions, and culturally-specific information collected to determine the differences if any, to be followed by development of the appropriate interventions. The significance of this work is the ability to address context-specific motivators and demotivators through recruitment strategies, and in doing so enhance recruitment of targeted donor populations in both developing as well as developed countries.

4. **References**

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1. **Question**

   What systems can we develop to encourage young donors to donate blood and assure ourselves of the safety of blood donation, and how can we communicate with and transmit information to them to address their barriers?

2. **Rationale**

   Because an adequate and stable blood supply requires the active participation of new donors, it is crucial to develop and implement strategies that successfully address perceived barriers among prospective young donors to promote their recruitment. At the same time, because young donors are disproportionately affected by donation-related reactions and injuries and may be vulnerable to iron deficiency with frequent donation (Bloch et al., 2017), it is equally imperative that recruitment efforts are combined with equivalent efforts to maximize young donor health and safety.

   Studies around the world have identified a number of common barriers to blood donation, including fear of needles, pain, blood, infection, and fainting (Bednall & Bove, 2011). Educational materials that were developed to directly address common barriers reported by prospective donors in North America and Australia have decreased anxiety and increased confidence, intention, and donation behavior (France et al, 2010; Masser et al, 2016). This psychoeducational approach, which can be applied to a range of perceived barriers and delivered in a variety of formats (e.g., brochure, web, text message), can be adapted to meet local needs in an effort to enhance recruitment of targeted donor populations.

   The experience of vasovagal reactions is the most common adverse event among young blood donors, and is reliably associated with reduced retention (Eder et al, 2008). Pre-donation hydration and applied muscle tension have been shown to reduce reports of vasovagal symptoms among high-risk donors in several small clinical trials (Ditto et al, 2003; France et al, 2010; Morand et al, 2016). In addition, two large-scale observational cohort studies provide suggestive evidence of benefit (Eder et al, 2011; Tomasulo et al, 2011), but these studies have lacked adequate measures to ensure donor adherence. Given that hydration and applied muscle tension have demonstrated feasibility, safety, and preliminary efficacy in North American and European trials, further study of their ability to reduce vasovagal reactions and increase donor safety, satisfaction, and retention is warranted in other parts of the world. In addition, given the relationship between frequent donation and risk for iron depletion, particular efforts are needed to investigate and mitigate this risk among young donors.

3. **Feasibility and Strategy**

   Both of the recruitment and retention strategies described above have demonstrated feasibility in published trials; hence, they can be readily implemented pending adaptation to local needs and circumstances. Specifically, effective psychoeducational coping materials for prospective young donors have been developed and applied among diverse donor populations. Following appropriate efforts to identify prevailing donation-related concerns and to generate relevant coping strategies, this approach can be adapted to meet local needs and available modes of delivery. Similarly, pre-donation hydration and applied muscle tensing interventions have demonstrated feasibility in diverse geographic settings and therefore there are existing strategies for implementation that can be readily modified for implementation in future trials. Finally, prior efforts to mitigate the risk of iron depletion through donor monitoring, donation frequency management, and interventions to support iron levels are available to guide future practice.

4. **References**

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Question

How do we measure and assess residual risk for major TTI, and develop the capacity to evaluate and select the appropriate safety measures for implementation?

2. **Rationale**

Reducing TTI risk is and will continue to be an important task to improve blood safety. Even though there has been a general gradual decrease of the residual risk level for major TTIs through the improvement of the donors screening (including testing) procedures, the rate of the progress is not evenly distributed throughout the entire Western Pacific Region. For example, not all countries have implemented Nucleic Acid Testing (NAT) for all blood donations and the quality system for the donor screening (testing and non-testing) process is still a work in progress for some countries.

Updated methodologies have been developed for determining the incidence and residual risks for major TTIs using data from serological plus NAT donor screening. Implementing these methodologies and conducting research in developing countries in the region will yield previously unavailable epidemiological information from these countries on major TTI. Such epidemiological data such as prevalence and incidence rate and residual risk level, will provide an assessment for the current state of blood safety in terms of TTI risks, as well as providing a system for measuring the effectiveness of new safety improvement measures.

3. **Feasibility and Strategy**

Proven research models have already been developed for studying prevalence, incidence and residual risk levels for major TTIs (reference), and which have been applied in several countries with established donor testing systems. Since more and more countries in the regions have adopted standardized donor testing procedures, donor routine testing data can be used to derive these epidemiological data using the established methodologies. In settings where the current donor testing procedures are not yet standardized (e.g. no routine confirmatory testing for serological tests and or no routine NAT), research resources should be provided to gather necessary data by incorporating serological confirmatory testing and NAT in order to obtain data for prevalence/incidence and residual risk level investigations. These can be used to assess the effectiveness of existing as well as evaluating potential new strategies in reducing risk within the country.

4. **References**

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1. **Question**

What are the success factors and strategies adopted by successful blood systems in ensuring blood availability and transfusion safety, including the allocation of resources and effecting governance?

2. **Rationale**

The success of a blood service can be attributed to many different factors, which when functioning together, ensure a safe and sufficient blood supply (WHO Aide Memoire, 2011). Generally speaking, strong blood systems are supported by a strong governance model, good resourcing, and secure financial support through national government due to a healthy economic environment (Custer et al, 2009). It has been well documented that a combination of both insufficiency in these key areas, as well as other factors affecting blood collection and blood use in developing countries limits the capacity to operate at this level (Ala et al, 2012; Field et al, 2007; Roberts et al, 2016). To date, the focus of this research has been based in the sub-saharan African region, which demonstrates that simply applying a gold standard approach to blood systems in countries with low GDP indexes offers minimal impact in improving the blood system without the required supporting factors (Gallaher et al, 2017; Mbanya et al, 2001). Through a stronger understanding of the specific success factors and strategies adopted by high functioning blood systems, and subsequent analysis of limiting factors outlined in the available papers, a similar contextually-adapted model may be implemented with more tangible results, with the opportunity to enhance blood availability and transfusion safety in these areas (Chevalier et al, 2016; Busch et al, 2009).

3. Feasibility and Strategy

A number of recent observational reviews of previous blood-system specific implementation experiences are available, identifying a number of factors and strategies that ensure blood availability and transfusion safety, and the allocation of resources and how best to effect good governance. However, there appears to be a general absence of systematic scientific trials over extended periods within this topic. The existing strategies and other successful health-care related interventions tools can be readily modified and combined for implementation in future trials (Lee, Case Study IHI).

4. References

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1. Question

What needs to be done to improve, strengthen, correct or implement quality systems for blood safety? And how can blood quality be improved with appropriate tools including external quality assessment scheme (EQAS) and quality control (QC) in developing countries?

2. Rationale

Blood transfusion is a multi-step process with risk of error in each process from selecting donors, collecting and processing donations, testing of donor and patient samples, issue of compatible blood, to transfusing the patient. An effective quality system provides a framework within which activities are established, performed in a quality-focused way and

continuously monitored to improve outcomes. The risk associated with blood transfusion can be significantly reduced by the introduction of quality systems, external quality assessment and education and training for staff.

Based on an investigation performed in 2014 by the WHO Regional Office for the Western Pacific and the National Reference Laboratory (NRL), Australia, none of the 7 investigated countries had complete quality systems in place, and not all laboratories participating in EQAS, and some laboratories could select any testing assays on the market regardless of its performance. In addition, some laboratories did not perform QC when testing.

Even for the countries with basic quality systems, the systems also need to be appropriate reviewed and improved. In many developing countries, the only form of external audit, if it is existing, is the (internal) supervisorial visit to the network of blood services/blood banks organized by the national blood centre. The obstacle factors for implementing and/or improving quality systems should be identified, and practical strategies to overcome these factors should be studied. Since testing assays and testing strategies in the developing countries are often quite different to that of the western countries, appropriate EQAS and QC strategies should be studied and applied.

3. Feasibility and Strategy

Quality systems, as well as EQAS and QC, are not new concepts in blood transfusion. Many studies have already been published on how to implement quality systems, how to organize EQAS, and how to establish QC algorithms in developed countries. WHO has also issued guidelines on good manufacturing practices for blood establishments and EQAS. Most developing countries have already been implemented quality systems; however, the systems need to be reviewed for their integrality, effectiveness and efficiency. The obstacle factors could be figured out by investigation and comparative analysis between different countries and regions. The existing strategies could help towards implementing and improving quality systems, and establishing feasible EQAS and QC strategies for developing countries.

4. References

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The East Europe and Central Asia Region (Team Leader: Dr. Kenrad Nelson)

Research question: What are effective donor recruitment strategies for increasing blood collections in resource limited settings

Proposer: Jeffrey McCullough, MD

Rationale There is a tendency to believe that issues surrounding recruitment are different in different settings. A review of eighteen knowledge attitudes and practices (KAP) studies conducted in seventeen developing countries noted several common themes: misinformation about blood donation, fear of blood donation, willingness to donate for family and friends, concern about selling blood, and a failure to transfer positive attitudes into actual blood donation (1). Thus despite considerable differences in the culture and demographics, common themes emerge suggesting that recruitment strategies may have broad utilization.

Donor recruitment programs are complex (2). However, there have been few structured studies to compare and determine the value of various aspects of a comprehensive donor recruitment program. Understanding the most effective recruitment strategies could have a valuable impact in improving donor recruitment and thus increasing blood availability.

Students are a common donor source especially in resource limited areas, but this leads to blood shortages when school is not in session. Programs to convert the school students into donors once they leave school are important in strengthening the overall blood supply. One such program has been called club 25 but evaluation of different strategies such as those used in Zimbabwe are important. Another example of donor recruitment opportunities is that in Afghanistan blood typing is required to obtain a drivers license. A program to convert these new drivers to blood donors after blood typing could improve the blood supply.

Finally the WHO policy and general belief that voluntary non-remunerated donors (VNRD) are preferable to replacement donors should be studies further. Some data indicate that the main effect on donor safety is first time compared to repeat donors. It should be determined whether replacement donors have similar risk rates to first time VNRD.

Feasibility

Donor recruitment research activities are feasible since national blood programs have people with appropriate expertise in developing the different aspects of a donor recruitment program. It may be necessary to strengthen social sciences research capacity for effective research into donor recruitment strategies.

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2. Lee, S MPH, Mwenda, R MBA, Nkya, E. MD, Espejo, N MPH, de Coning, D, BA, Juma, A MD, McCullough, J MD A Comprehensive Approach to Increasing Blood Collection in a Developing Country (awaiting clearance from CDC for submission to Transfusion)

SCIENTIFIC PRIORITIES TEMPLATE Central Asia: Kazakhstan, Kyrgyzstan

Proposer: Jed B. Gorlin MD, MBA jed@mbc.org

1. **Question**

   Variable quality blood donor screening may contribute to missed transfusion-transmitted infections. “Would establishing a local centralized proficiency testing reference lab in Central Asia contribute to assessing and improving the quality of blood donor screening in Central Asian republics?”

2. **Rationale**

   Anecdotal observations and historic “crises” raise concerns about uniform quality of blood donor screening. Establishing a high quality reference lab in central Asia might be a sustainable strategy to providing real time feedback on quality of donor screening.

   Current observed positive screening rates in Kyrgyzstan in 2015: HIV 0.37%, HBV (HBsAg) 4.7%, HCV 2.26%

3. **Feasibility and Strategy**

Setting up a centralized reference lab in Almaty, Kazakhstan (as one of the countries with more advanced laboratory facilities) and providing incentive for blood collection agencies/hospitals in the region to pour off and freeze residual samples for centralized testing. This would require a truly objective method of saving a statistically representative sample in an unselected fashion (not just repeat donors!) and having a way of comparing local results to results obtained in a centralized reference lab. (Note: much record keeping in Krygyzstan if manual not computerized). This has been done successfully by multiple groups for donor sites in Ghana, South America etc.

4. **References**

Diagnostic accuracy of blood centers in the screening of blood donors for viral markers

Pan Afr Med J. 2015; 20: 119. Elliot Eli Dogbe, Fareed Arthur

Residual risk of blood transfusion in Ghana British Journal of Hematology D. Candotti, F. Sarkosie, Allain, JP (2001) 113(1): 37-9

http://www.who.int/biologicals/expert_committee/Residual_Risk_Guidelines_final.pdf

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SCIENTIFIC PRIORITIES TEMPLATE: Central Asia: Kazakhstan & Kyrgyzstan

Proposer: Jed B. Gorlin MD, MBA jed@mbc.org

1. **Question**

Both Kazakhstan and Kyrgyzstan defer donors via ALT testing. Kazakhstan screens for HIV, HCV and HBV using both EIA and NAT, so by analogy to North America and Europe, there is unknown additional yield by doing ALT. Krygyzstan uses only EIA screening (and then not 100% of the time), so there may be additional yield.
"Does ALT testing provide any additional recipient safety?"

2. **Rationale**

Both Kazakhstan and Kyrgyzstan cite insufficient supply, especially from volunteer donors as a #1 priority for improving blood safety and availability (see ECO survey below). Up to 5-10% of donor units are lost due to ALT testing exceeding a specified cutoff. (Awaiting confirmation of most recent rates). (of note this is also true in China!)

3. **Feasibility and Strategy**

Units with positive ALT testing but negative for other markers would have samples frozen for subsequent batch "proficiency testing" (See parallel proficiency testing proposal). They would be screened by a designated state of the art assay, including single donor NAT testing. Given the higher prevalence of Hepatitis B as opposed to Hepatitis C or HIV, a very sensitive method for HBV detection might take priority. Any changes in blood donor management and screening require Central government approval, but having local data to support this change would be an important tool in not discarding useful donations.

4. **References**

"The status of blood safety in ECO member states" F. Seighali, NS Hosseini Divkolaye, E Koohi, AA OPourfathollah, AM Rahmani Blood Transfus. (2015) 13: 583-7

Priorities identified for Georgia – Proposer: Sheila M. Keating

1) **SCIENTIFIC PRIORITIES: Project 1**

a. **Question**

Are methods used by blood banks sufficient in identifying TTI? If not, what is the true prevalence of TTI in blood donations? Could implementation of auditing procedures reduce transfusion transmission?

b. Rationale

Current prevalence of transfusion transmission: Blood donations HIV 0.1%, HBV 0.8% and HCV 2.6%
In a 2015 survey national estimates indicated that approximately 5.4% of the population [150,300 people in absolute number] was chronically infected with HCV (Georgia Ministry of Labor, Health and Social Affairs, unpublished data, 2016).

In April 2015, the Georgian government with partnership and technical assistance from CDC and commitment from Gilead Sciences to donate direct acting antiviral (DAA) medications, Georgia established the first **HCV elimination program**. The integrated approach to achieve this goals included a fully scaled-up plan for testing, prevention and treatment with goals of 90% diagnosed, 95% treated and 95% cured.

Since 1997, a State Safe Blood Program operates in Georgia which aims at preventing the spread of transfusion transmissible infections, involves 12 blood establishments and requires screening of blood donors for HIV, Hepatitis B and C by means of EIA and Syphilis by TPHA, as well as blood group and rhesus determination. There is currently no mechanism required for confirmation of results. For some testing laboratories, the ELISA assays that are used for screening are not CE marked or FDA approved, these assays have not been validated and may not be sensitive for identifying TTI in donations. A quality assurance program has been established by State Safe Blood where all participating blood banks provide samples from 5% of all donations to a national reference laboratory for confirmation of results for all TTI infections using FDA-approved tests; NAT is not being performed for testing in blood banking. There is no oversight in specimen selection for retesting; the retest specimen set is selectively curated by the blood banks. There are currently no regulations for specimen collection, processing, storage or tracking; this leads to poor sample quality and insufficient volume in the QAQC retesting. There is no mechanism for reporting discrepant results back to the blood banks or for identifying recipients of infectious units.

The current (2016) prevalence of HCV in blood donations is 2.6%, a decline from 3.9% in 2006. This prevalence number is based on the reported infectious donation results provided from the blood banks. If inadequate testing is missing TTI or if testing is not done, these prevalence numbers are underreported. There is Government support and political will to eliminate HCV infection from the country and a source of residual infection could happen through transfusion transmission. More research needs to be done to determine if the current system for blood screening is sufficient for identifying infectious units and if not, give guidance on implementation of regulations on reducing TTI.

c. Feasibility and Strategy

1) Are all blood donations being screened?
    a. Documentation of test records are held on site at the blood banks. An audit of these records would determine if testing is being performed on all donations the National Blood Program donation database.
2) Are assays that are used locally for screening TTI missing infections?
    a. Provide oversight in specimen process and banking.
    b. Guidance on specimen database and selection of specimens that will be used for QAQC program.
    c. More extensive testing of negative donations including FDA-approved, Ag, and NAT.
3) Implementation of QAQC program at the testing laboratories.

e) References

See Below

SCIENTIFIC PRIORITIES: Project 2

a. Question

Can we identify TTI transmission by prospectively following transfusion recipients? Can patients that require therapeutic transfusions for thallesemia or other diseases be monitored for TTI? Can transfusion recipients return for follow up testing 6 months after transfusion?

b. Rationale

Overall, Blood Banks are not regulated or audited by any organization in Georgia. Although all blood banks claim to be testing every blood donation, there has been no audit of the data to prove this. The screening assays are inexpensive to maximize on profits and may not be sensitive to identify TTI or may have a longer window period for detection. Only 5% of donations are being confirmed by a reference laboratory. The vast majority of donations do not have adequate screening or confirmatory testing. A prospective study to determine if TTI were acquired through blood transfusion would be important in identifying laboratory missed identification of TTI.

3. **Feasibility and Strategy**

In a country where the donors are paid and the prevalence of HCV infection is 5-7% with PWID as the main risk, there is high potential for transfusion transmission. Current methods of screening is ELISA and the assays could be inadequate or transfusions could be window phase. Implement a testing scheme that regularly tests all blood transfusion recipients or recalls donors 3 - 6 months after transfusion.

4. **References**

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HCV Elimination Technical Advisory Group 2016 Recommendations.

3) SCIENTIFIC PRIORITIES: Project 3

a. Question

A study of blood use in Georgia would be important to determine if privately owned hospitals and blood banks are not over prescribing blood transfusions. Assessment of blood usage is required.

b. Rationale

The National Health Service in Georgia funds the majority of health care in the country. Hospitals and blood banks are privately owned any would gain financially by using transfusion in a unnecessary clinical intervention. Focused studies on the appropriate use and quantity of transfusion is needed.

c. Feasibility and strategy

Quantitative and qualitative data collection methods including focus group discussions could be considered to assess the effectiveness of blood donor selection. Training and guidance on blood transfusion policies can be updated.

d. References

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4) SCIENTIFIC PRIORITIES: Project 4

a. Question

Are the donor interview procedures adequate in excluding high risk donors to prevent TTI or other transfusion transmitted adverse events? Can the blood donor system in Georgia change over from a paid to a voucher or other incentive program?

b. Rationale

The National Health Service in Georgia funds the majority of health care in the country. Blood banks are privately owned for profit entity that would gain financially for selling blood to healthcare settings. On visiting blood banks in Georgia, there is little evidence of vigorous interview process and even display completed questionnaires to show prospective donors how to fill them out correctly.

In Georgia, 53% are paid donations and 17% are family replacement donors.

c. Feasibility and strategy

Quantitative and qualitative data collection methods including focus group discussions could be considered to assess the effectiveness of blood donor selection.

d. References

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Members of Working Groups

East Africa Working Group:
Julie Makani, MD, PhD, FRCP, FTAAS
Professor Imelda Bates
Walter Dzik, MD
Heather Hume, MD
Gbenga Ogedegbe, MD

West Africa Working Group:
Dr. Claude Tayou Tagny, MD
Edward L. Murphy, MD, MPH
Meghan Delaney, DO, MPH

Middle East and North Africa Working Group:
Dr. Magdy EI Ekiaby
Jay Epstein, MD
Dr. Yetmgeta Eyayou
Brian S. Mittman, PhD

Latin America and Caribbean Working Group:
Ester Sabino, MD, PhD
Louis M. Katz. MD
María Dolores Pérez-Rosales, MD, MPH
Gbenga Ogedegbe, MD

Southeast Asia Working Group:
Dr. Nabajyoti Choudhury
Roger Y. Dodd, PhD
Sharon E. Straus, MD

Western Pacific Working Group:
Dr. Diana Teo
Christopher France, PhD
Paul Ness, MD
Linda Nicole
Hua Shan, MD
Dr. Sally Thomas
Emily Tonks
Xun Wang, PhD
Junping Yu

East Europe and Central Asia Working Group:
Kenrad Nelson, MD
Jed Gorlin, MD
Sheila Keating, PhD
Jeffrey McCullough, MD
Sheila O'Brien, PhD

PARTICIPANTS

Chair
Brian Custer, PhD
Associate Director
Blood Systems Research Institute (BSRI)
Senior Investigator
Epidemiology and Health Outcomes Research, BSRI
Adjunct Professor, UCSF
270 Masonic Avenue
San Francisco, CA 94118
Phone: 415- 901-0756
bcuster@bloodsystems.org

Co-chair
Julie Makani, MD, PhD, FRCP, FTAAS,
Hematology & Blood Transfusion Medicine
Muhimbili University of Health and Allied Sciences
P.O Box 65001
United Nations Road, Upanga
Dar-es-salaam
Tanzania
Phone: +255-754-381-551
jmakani@blood.ac.tz
jmakani@muhas.ac.tz

Dr. George Alemnji
Senior Technical Advisor for Laboratory Services
Office of the Global AIDS Coordinator and Health Diplomacy
1800 G Street NW, Room 10300
Washington D.C. 20006
Phone: 202-663-1160
ikv3@cdc.gov

Prof Jean-Pierre Allain
Suite 11, Science Village
Chesterton Research Park
Little Chesterton CB10 1XL, UK
Phone: +44 1223 785351
Phone: home +44 1223 351506 2
jpa1000@cam.ac.uk

Robert D. Allison, MD, MPH
Deputy Chief, Clinical Studies
Infectious Diseases Section
Department of Transfusion Medicine
Clinical Center, National Institutes of Health
Bldg 10, Rm 1N226
Bethesda, MD 20892-1184
Office: 301.451.4967
Phone: 240.762.8159
robert.allison@nih.gov

Timothy Amukele, MD PhD
Assistant Professor of Pathology
Director of the Clinical Laboratories
Johns Hopkins Bayview Medical Center
4940 Eastern Avenue
Baltimore, MD 21224
Phone: 410-955-9790
tamukele@jhmi.edu

Kudbidinov Azmidin, PhD
Republican Research Center of Blood
Dushanbe
Tajikistan
Phone: +992 939 350525
Azmidd.87@mail.ru

Christine Bales, BS, MT (ASCP) I, CQA (ASQ)
Vice President, Consulting and Global Services
AABB Division of Global Services
Phone: 1.301.215.6494 (office)
Phone: 1.314.378.5145 (mobile)
cbales@aabb.org

Geetha Bansal, PhD
Program Officer
HIV Research Training and AIDS-TB
Division of International Training & Research
Fogarty International Center, NIH
Building 31 Room B2 C39, 31 Center Dr. MSC 2220
Bethesda MD 20892-2220 USA
Phone: 301 496-1492
geetha.bansal@nih.gov

Professor Imelda Bates, PhD
Chair in Clinical Tropical Haematology
Liverpool School of Tropical Medicine
Liverpool, L3 5QA UK
Phone: +44 (0)151 705 3115
imelda.bates@lstmed.ac.uk

Celso Bianco, MD
Past President
International Society of Blood Transfusion
6524 Elgin Ln
Bethesda, MD 20817-5400
Phone: 202- 352-5089
celso@txmedicine.com
cbiancomd@gmail.com

Evan Martin Bloch, MD, MS
Assistant Professor of Pathology
Associate Director, Transfusion Medicine
Johns Hopkins University School of Medicine
600 N. Wolfe Street/Carnegie 446 D1
Baltimore, MD 21287
Phone: 410-614-4246
ebloch2@jhmi.edu

Zhandos Burkitbayev , PhD
Director of the Center of Transfusiology
MOH
Astana, Kazakhstan
Phone: +7 (7172) 54 33 00 (office)
Phone: +7 701 777 96 13 (cell)
burkitzhan@gmail.com

Michael P. Busch, MD, PhD
Senior Vice President
Research and Scientific Affairs
Blood Systems Inc.
Co-Director
Blood Systems Research Institute (BSRI)
Professor of Laboratory Medicine
University of California, San Francisco
270 Masonic Ave.
San Francisco, CA 94118
Phone: (415) 749-6615

mbusch@bloodsystems.org

Marcia Cardoso, PhD
Global Sr. Scientific Marketing Manager Blood Center Segment 4
Terumo BCT
Ikaroslaan 41, 1930 Zaventem
Belgium
Phone: +32 473 42 97 80
marcia.cardoso@TERUMOBCT.com

Ashley Cecere, MS, PMP
Interdisciplinary Scientist
Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
U.S. Depart. of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201
Phone: 202-691-2056
Ashley.Cecere@hhs.gov

Michelle Chevalier, MD, MPH
LCDR, U.S. Public Health Service
Medical Officer
Division of Global HIV/TB
U.S. Centers for Disease Control and Prevention
1600 Clifton Rd, Mail Stop E-04
Atlanta, Georgia 30333
Phone: 404-639-6056
Mchevalier@cdc.gov

Nabajyoti Choudhury, PhD
Additional Director & HOD
Department of Transfusion Medicine
Fortis Memorial Research Institute
Sector: 44, Gurgoan-122002 (National Capital region-DELHI)
Haryana
INDIA
Phone: +91-124-4386666
nabajyoti_2000@yahoo.com
nabajyoti.choudhury@fortishealthcare.com

Christine Cserti-Gazdewich, MD
Assistant Professor
Blood Transfusion Laboratory
Toronto General Hospital
200 Elizabeth St. Rm 3EC-306
Toronto, Ontario, M5G 2C4 Canada
Phone: 416-340-5390
christine.cserti@uhn.ca

Meghan Delaney, DO, MPH
Bloodworks Northwest
Center for Global Impact
921 Terry Avenue
Seattle, WA 98104
Main line: 206-292-6500
Direct line: 206-233-3330
Apheresis: 206-292-4174
MeghanD@BloodWorksNW.org

Roger Y. Dodd, PhD
Secretary General
International Society of Blood Transfusion
Executive Scientific Officer
American Red Cross Holland Laboratory
15601 Crabbs Branch Way
Rockville MD 20855
Phone: 240)-447-4547 (mobile)
roger.dodd@redcross.org
rydodd@icloud.com

John J. Donnelly, PhD
President Global Healing
2140 Shattuck Ave. Suite 203
Berkeley, CA 94704
Phone: 510-898-1859
Cell: 925-325-3935
john@globalhealing.org

Bakary Drammeh, DrPH, MT (ASCP)
Medical Transmission Team
HIV Prevention Branch, Division of Global AIDS
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS E-04
Atlanta, GA 30333
Phone: 404-718-8604
bdrammeh@cdc.gov

Andrew Dunham, PhD
New Health Sciences
Phone: 2242232012
andrew.dunham@newhealthsciences.com

Walter Dzik, MD
Associate Pathologist
Massachusetts General Hospital
Associate Professor of Pathology
Harvard Medical School
Phone: 617-726-3715
SDZIK@mgh.harvard.edu

Quentin Eichbaum, MD, PhD
Vanderbilt University Medical Center
1211 Medical Center Drive
Nashville, TN 37232
Phone: 615-936-5124
qeichbaum@gmail.com

Magdy El Ekiaby, PhD
Head of Blood Transfusion and Hematology
Shabrawishi Hospital
Finni Square, Dokki, Giza
Egypt
Office phone: +20233384684
Phone: +201002109671
magdyelekiaby@gmail.com

Jay Epstein, MD
Director, Office of Blood Research & Review
CBER, FDA, WO 71-4230
10903 New Hampshire Avenue
Silver Spring, Maryland 20993
Phone: 240-402-8360

Jay.Epstein@fda.hhs.gov

Christina Fitzmaurice, MD, MPH
Assistant Professor
Department of Medicine
Division of Hematology
Institute for Health Metrics and Evaluation
University of Washington
2301 5th Avenue, Suite 600
Seattle, WA 98121
Phone: +1-206-897-3701 | +1-443-980-1202
cf11@uw.edu

Christopher France, PhD
Distinguished Professor
251 Porter Hall
Ohio University
Athens, OH 45701
Phone: 740-593-1079
france@ohio.edu

Russell Glasgow, PhD
Visiting Professor
Department of Family Medicine
School of Medicine
University of Colorado
Mail Stop F496, Academic Office 1
12631 East 17th Avenue
Aurora, CO 80045
Phone: 303-724-7374
Russell.Glasgow@ucdenver.edu

Jed B. Gorlin MD, MBA
VP Medical and Quality
Innovative Blood Resources/Memorial Blood Centers
Medical director, transfusion service
HCMC and Children's hospitals and clinics Minnesota
737 Pelham Blvd. St. Paul, MN 55114
Phone: 612-810-6937 (cell)
Phone: 651-332-7284 (office)
jed@mbc.org

Salim Haddad, MD
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-9313
salim.haddad@fda.hhs.gov

Jong-on Hahm, PhD
Division of International Training and Research
Fogarty International Center
National Institutes of Health
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220
Phone: 301-827-5337
jong-on.hahm@nih.gov

Indira K Hewlett, PhD
Chief, Laboratory of Molecular Virology
Division of Emerging and Transfusion Transmitted Diseases
CBER/FDA
Bldg 52/72, Rm 4308
White Oak Campus,
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 240-402-9587
Indira.hewlett@fda.hhs.gov

Jerry Holmberg, PhD
Grifols
jerry.holmberg@grifols.com

Heather Hume, MD
Professeure titulaire de Clinique
Département de Pédiatrie
Université de Montréal Service d'Hématologie/Oncologie
CHU Sainte-Justine 3175, Côte-Sainte-Catherine
Montréal, QC
Canada, H3T 1C5
Phone: 514-345-4639
heather.hume@umontreal.ca

Orieji Illoh, MD
Director, Division of Blood Components and Devices
Office of Blood Research and Review
CBER, FDA
10903 New Hampshire Avenue
Silver Spring, Maryland 20993
Orieji.illoh@fda.hhs.gov

Bakyt Karabaev, PhD
Director General
Republican Blood Center of the MOH
Bishkek
Kyrgyzstan
Phone: +996 772 760 005
kbakyt@bk.ru

Louis M. Katz. MD
Chief Medical Officer
America's Blood Centers (ABC)
725 15th St. NW, suite 700
Washington DC, 20005
Phone: 202-393-5725 DC Office
Phone: 563-349-5401 Direct and cell
lkatz@americasblood.org

Sheila M. Keating, PhD
Scientist II
Head, Core Immunology Laboratory
Blood Systems Research Institute
270 Masonic Avenue
San Francisco, CA 94118
Phone: 415-749-6606 x499 9
skeating@bloodsystems.org

Barbara Konkle, MD
Director, Hemostasis, Platelet Immunology, and Genomics
Director, Platelet Immunology and Genomics Laboratory
Associate Chief Scientific Officer
Bloodworks Northwest
Professor of Medicine/Hematology,
University of Washington
921 Terry Avenue
Seattle, WA 98104
Phone: 206-689-6191

barbarak@bloodworksnw.org

Laurence Landow, MD
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-8318
laurence.landow@fda.hhs.gov

Helen Lee, PhD
Director of Research
Diagnostics Development Unit, University of Cambridge
Cambridge UK
President & CEO
Diagnostics for the Real World, Ltd
San Jose, California
Phone: +1 4086872314 (US)
Phone: + 44 795816759
hl207@cam.ac.uk

Jeffrey McCullough, MD
Transfusion medicine advisor
Emeritus professor of laboratory medicine and pathology
University of Minnesota
7400 Shannon Dr.
Minneapolis MN 55439
Phone: 612-432-3272
mccul001@umn.edu

Fatima Donia Mili, MD, PhD
Medical Prevention Team, HIV Prevention Branch
Division of Global HIV & TB
CDC/Center for Global Health
1600 Clifton Rd NE / Mail Stop E-04
Atlanta, GA 30329
Phone: +1 (404) 718-5743
FMili@cdc.gov

Brian S. Mittman, PhD
Research Scientist
Health Services Research and Implementation Science
Kaiser Permanente Southern California
Department of Research & Evaluation
100 S. Los Robles Ave., 3rd Floor
Pasadena, CA 91101
Phone: 626-564-3450
Brian.S.Mittman@kp.org

Edward L. Murphy, MD, MPH
Professor in Residence
Laboratory Medicine, UCSF and
Senior Investigator,
Blood Systems Research Institute
Phone: 415 -749-6668
Ed.Murphy@ucsf.edu

Kenrad Nelson, MD
Johns Hopkins University
615 N. Wolfe Street
Room E7638
Baltimore, MD 21205
Phone: 410-955-1296
knelson3@jhu.edu

Paul Ness, MD
Director, Division of Transfusion Medicine
Professor of Pathology
Johns Hopkins Medicine
Phone: 410-955-6583
pness@jhmi.edu

Carina Newton, B.S.
Phone: 240-678-8847
cncnewton37@gmail.com

Linda Nicolo
Humanitarian Project Scientist
International Services
Australian Red Cross Blood Service 8
1/69 Walter Drive
Osborne Park, WA 6017
Phone: +61 8 6213 5929
lnicolo@redcrossblood.org.au

Philip J. Norris, MD
Co-Director, BSRI
Vice President, Research and Scientific Affairs,
Blood Systems Inc., Scottsdale, Arizona
Adjunct Professor, UCSF Department of Laboratory Medicine
Clinical Professor, UCSF Department of Medicine
Associate Director, UCSF / Gladstone Institute of Virology and Immunology Center
270 Masonic Ave.
San Francisco, CA 94118
Phone: 415- 923-5769
pnorris@bloodsystems.org

Sheila O'Brien, PhD
Associate Director, Epidemiology & Surveillance
Canadian Blood Services
Ottawa, ON, Canada
Phone: 1-613-739-2144
sheila.obrien@blood.ca

Gbenga Ogedegbe, MD
Professor
Director, Division of Health & Behavior
Director, Center for Healthful Behavior Change
Vice Dean and Chief Medical Officer
Global Institute of Public Health
Center for Healthful Behavior Change
NYU Langone Medical Center
550 First Avenue
New York, NY 10016
Phone: 212-263-4183
olugbenga.ogedegbe@nyumc.org

Larisa Ozeryansky, MPH
ASPPH/CDC Alan Rosenfield Global Health
Medical Transmission Team
HIV Prevention Branch, Division of Global AIDS
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS E-04
Atlanta, GA 30333
Phone: 618-521-8399

wmw5@cdc.gov

María Dolores Pérez-Rosales, MD, MPH
Asesora Regional Servicios de Sangre y Trasplantes
Medicamentos y Tecnologías Sanitarias, Sistemas y Servicios de Salud (MT/HSS)
Regional Advisor Blood Services and Organ
Medicines and Health Technologies Pan American Health Organization (PAHO)
525 Twenty-Third Street, N.W.
Washington, D.C. 20037
Phone: +1 202 974-3230
perezmd@paho.org

Heather Pidcoke, MD, PhD
TerumoBCT
Phone: 720-539-1677
heather.pidcoke@terumobct.com

Brendan Quinn, PhD
UCLA
Phone: 929-500-5336
brendan.quinn@burnet.edu.au

Harvey Rubin, MD, PhD
Professor of Medicine, Microbiology and Computer Science
University of
Pennsylvania 502C Johnson Pavilion 36th Street and Hamilton Walk
Philadelphia PA 19104
Phone: 215-746 4234
www.energizethechain.org

Martin Ruta, PhD
Regulatory Counsel in the Office of the Director
Office of Blood Research and Review
CBER, FDA
Martin.Ruta@fda.hhs.gov

Ester Sabino, MD, PhD
Faculty of Medicine
University of Sao Paulo
Av Dr Eneas de Carvalho Aguiar 470
São Paulo. SP 05403-000
Brazil
Phone: (11) 3061-8702
sabinoec@usp.br
sabinoec@gmail.com

Alonur Saidov, PhD
Director
Research Center of Hematology and Blood Transfusion of the MOH
Tashkent
Uzbekistan,
Phone: +998 94 683 3818
salonur@mail.ru

Paul A. Sato, MD, MPH
CDR, USPHS
Scientific Lead for Funding Programs and Alignment Assessment
Office of AIDS Research
U.S. National Institutes of Health
5601 Fishers Lane, Room 2E62
Bethesda, MD 20892-9840
(for courier deliveries: Rockville, MD 20852)
Phone: +1 301-480-2330
paul.sato@nih.gov

Dejana Selenic, MD, MPH
Senior Medical Epidemiologist
Medical Transmission Team
Division of Global HIV/AIDS
HIV Prevention Branch
Centers for Disease Control and Prevention
1600 Clifton Road, NE MS E-04
Atlanta, GA 30333
Phone: 404 639 8012
dselenic@cdc.gov

Hua Shan, MD
Professor of Pathology
Stanford University
Phone: 650-736-4250
hshan@stanford.edu

Leah Mendelsohn Stone, JD
Director, Public Policy and Advocacy
AABB
8101 Glenbrook Road
Bethesda, Maryland 20814
Phone: 301-215-6554
lmstone@aabb.org

Susan Stramer, PhD
Vice President, Scientific Affairs
American Red Cross (ARC)
9315 Gaither Rd.
Gaithersburg, MD 20877-1417
Phone: 301- 795-4736
Susan.Stramer@Redcross.org

Sharon E. Straus, MD
St. Michael's Hospital
University of Toronto
30 Bond Street, Shuter 2-026
Toronto, ON M5B 1W8
Canada
Phone: 416-864-3068
sharon.straus@utoronto.ca

Malika Taalbi
International Reduce Portfolio Manager
Office of Global Material Security/Office of Radiological Security (NA-212)
National Nuclear Security Administration
Phone: 1-202-586-1130
Cell: 1-240-654-2489 14

malika.taalbi@NNSA.Doe.Gov

David R. Tabatadze, PhD
ZATA Pharmaceuticals, Inc.
60 Prescott St. Worcester, MA 01605
Phone: 508-615-6328
dtabatadze@zatapharmaceuticlas.com

Claude Tayou Tagny, MD
Hematology Unit
Department of Microbiology, Parasitology, Hematology and Infectious Diseases
Faculty of Medicine and Biomedical Sciences
University of Yaounde I
PoBox: 5739
Yaounde
Cameroon
Phone: +237 242 72 15 15
Cell: +237 693 06 00 83
tayouclaude@yahoo.fr
tayouclaude@gmail.com

Diana Teo, PhD
Chairman | HSA Professional Board
Senior Consultant | Blood Services Group
Singapore
Phone: (65) 6213 0600
Diana_TEO@hsa.gov.sg

Sally Thomas, PhD
Australian Red Cross Blood Service
Level 1
69 Walters Drive
Osborne Park WA 6017
Australia
Phone: +61 8 6213 5904
SThomas@redcrossblood.org.au

Emily Tonks
Technical Program Manager – International Humanitarian Blood Projects
International Services
Australian Red Cross Blood Service
Level 1, 69 Walters Drive
Osborne Park
Perth WA 6017
Phone: +61 8 6213 5906
Phone: +61 410 659 409 (cell)
ETonks@redcrossblood.org.au

Aaron Tobian, MD, PhD
Representative of AABB
Associate Professor of Pathology, Medicine and Epidemiology
Associate Director, Transfusion Medicine
School of Medicine
Bloomberg School of Public Health
The Johns Hopkins University
1800 Orleans St.
Sheikh Zayed Tower
Baltimore, MD 21287
Phone: 410-955-9790
atobian1@jhmi.edu

Sheikh Zayed Tower
Baltimore, MD 21287
Phone: 410-955-9790
atobian1@jhmi.edu

Jeroen Van den Bossche, PhD
Global Product Manager - Blood Safety
Terumo BCT
Ikaroslaan 41
B-1930 Zaventem, Belgium
Phone: +32 2 710 58 11
Mobile: +32 470 89 36 26
jeroen.vandenbossche@terumobct.com

Jaro Vostal, MD
FDA
Phone: 2404028222
jaroslav.vostal@fda.hhs.gov

Shiyong Wang
Senior Health Specialist
GHN07
World Bank Group
1776 G Street, NW
Washington, DC, 20433
Phone: 202- 473-4532
swang1@worldbank.org

Xun Wang, PhD
Vice President
Shanghai Institute for Blood Transfusion
Shanghai Blood Center
1191 Hong Qiao Road
Shanghai, 200051
China
Phone: +86-1381 6348589
wangxun_11@hotmail.com

Bryan J. Weiner, PhD
Professor
Department of Global Health
Department of Health Services
Box 357965
University of Washington
Seattle, WA 98195-7965
Phone: 206-221-7882
bjweiner@uw.edu

Season Wong, PhD
Co-Founder and President
AI Biosciences, Inc.
1902 Pinon Dr., Suite C
College Station, TX 77845-5816
Phone: 979-450-3602 (Direct)
Phone: 979-268-1091 (Company)
season.wong@aibiosciences.com

Karina Yazdanbakhsh, PhD
New York Blood Center
310 East 67 Street
New York, NY 10065-6275
Phone: 212-570-3383

KYazdanbakhsh@nybc.org

Mr. Junping Yu
Technical Officer
Blood & Transfusion Safety (BTS)
Service Delivery and Safety (SDS)
World Health Organization
Avenue Appia 20, CH-1211
Geneva 27
Switzerland
phone: +41 22 791 26 07
yuj@who.int

NHLBI Participants:

David Abram
Center for Translation Research and Implementation Science
Health Inequities and Global Health Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Phone: 301- 827-8177
david.abram@nih.gov

Deshirée Belis, MPH
Scientific Program Analyst
Health Inequities and Global Health Branch
Center for Translation Research and Implementation Science (CTRIS)
National Heart, Lung, and Blood Institute
6705 Rockledge Drive, Suite 6185A
Bethesda, MD, 20892
Phone: 301-827-8156
deshiree.belis@nih.gov

Della E. Claiborne
Program Specialist
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge, Drive, Room 9038D
Bethesda, MD 20892-7950
Della.claiborne@nih.gov

Naomi Clarke
Extramural Support Assistant
National Heart, Lung, & Blood Institute
6701 Rockledge Dr., #9038B
Rockledge II, MSC 7950
Bethesda, MD 20892
Phone: 301-827-8265
clarkenv@mail.nih.gov

Tony Creazzo, PhD
National Heart, Lung, & Blood Institute
Division of Extramural Research Activities
6701 Rockledge Dr., #9038B
Rockledge II, MSC 7950
Bethesda, MD 20892
Phone: 301-435-0260
Tony.creazzo@nih.gov

Allison M. Cristman
National Heart, Lung, & Blood Institute
Division of Extramural Research Activities
6701 Rockledge Dr., #9038B
Rockledge II, MSC 7950
Bethesda, MD 20892
Phone: 301-435-0260
Allison.Cristman@nih.gov

Pablo Cure, MD, MPH
Program Officer
Blood Epidemiology and Clinical Therapeutics Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute,
6701 Rockledge Drive, Room 9163
Bethesda, MD 20892-7950
Tel: 301-435-0065
pablo.cure@nih.gov

Alex Dillon
Program Specialist
National Institute of Health (NIH)
National Heart, Lung and Blood Institute
Blood Diseases and Resources Division
6701 Rockledge Drive, Building 2
Bethesda, MD 20892
Phone: 301-435-0080
Alexander.dillon@nih.gov

Donna Dimichele, MD
Deputy Director
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive
Bethesda, MD 20892-7950
Phone: 301-435-0080
donna.dimichele@nih.gov

Michael Engelgau, MD
Deputy Director
Center for Translation Research and Implementation Science
National Heart, Lung, and Blood Institute
National Institutes of Health
RKL1 BG RM 6188
6705 Rockledge Drive
Bethesda, MD 20718
Phone: 301-496-1051
michael.engelgau@nih.gov

Simone Glynn MD, MSc, MPH
Branch Chief

Blood Epidemiology and Clinical Therapeutics Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Phone: 301-435-0065
glynnsa@nhlbi.nih.gov

Melissa Green Parker
Center for Translation Research and Implementation Science
National Heart, Lung, and Blood Institute
National Institutes of Health
6705 Rockledge Drive
Bethesda, MD 20718
Melissa.greenparker@nih.gov

W. Keith Hoots, MD
Director
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive, Room 9136
Bethesda, MD 20892-7950
Phone: 301-435-0080
hootswk@nhlbi.nih.gov

Norma Lerner, **MD, MPH**
Senior Advisor to the Director
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive
Bethesda, MD 20892-7950
Phone: 301-435-0080
norma.lerner@nih.gov

Catherine Levy, RN
Clinical Trials Specialist
Blood Epidemiology and Clinical Therapeutics Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 9143
Bethesda, Maryland 20892
Phone: 301-435-0065
levyc@nhlbi.nih.gov

Phyllis Mitchell, M.Sc.
Program Director
DBDR SBIR/STTR Coordinator
Translational Blood Science and Resources Branch
Division of Blood Diseases and Resources (DBDR)
National Heart, Lung and Blood Institute
301-827-8282 (phone)
mitchelp@nhlbi.nih.gov

Brad Newsome, PhD
Center for Translation Research and Implementation Science
National Heart, Lung, and Blood Institute
National Institutes of Health
RKL1 BG RM 6184
6705 Rockledge Drive
Bethesda, MD 20817
Phone: 301-827=8170
brad.newsome@nih.gov

Emmanuel Peprah, PhD
Chief of Staff
Center for Translation Research and Implementation Science
National Heart, Lung, and Blood Institute
National Institutes of Health
RKL1 BG RM 6184
6705 Rockledge Drive
Bethesda, MD 20817
Phone: 301-496-3620
peprahek@nhlbi.nih.gov

Marlene Peters Lawrence, BSN, RN, RRT
Clinical Trial Specialist
Blood Epidemiology and Clinical Therapeutics Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
6701 Rockledge Dr. Rm 9141 MSC 7950
Bethesda, MD 20892
Phone: 301-827-8284
mpeters@nhlbi.nih.gov

LeShawndra N. Price, Ph.D.
Chief
Health Inequities and Global Health Branch
Center for Translation Research and Implementation Science
National Heart, Lung, and Blood Institute
6705 Rockledge Drive, Suite 6070, MSC 7960
Bethesda, MD 20892-7960
Phone: 301-827-8166
leshawndra.price@nih.gov

Rebecca Roper
Health Inequities and Global Health Branch
Center for Translation Research and Implementation Science
National Heart, Lung, and Blood Institute
6705 Rockledge Drive, MSC 7960
Bethesda, MD 20892-7960
Phone: 301-496-1051
Rebecca.roper@nih.gov

James F. Troendle, PhD
Mathematical Statistician
Office of Biostatistics Research
Division of Cardiovascular Sciences
NHLBI/NIH/DHHS
Bld. RKL2, Room 9196
Bethesda, MD 20892
301-435-0421
jt3t@nih.gov

PARTICIPANTS

Ronald Warren, PhD
Program Officer
Ronald Warren, PhD
Health Scientist Administrator
Molecular, Cellular & Systems Blood Science Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive
Bethesda, MD
Phone: 301- 827-8288
ronald.warren@nih.gov

Shimian Zou, PhD
Blood Epidemiology and Clinical Therapeutics Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute,
6701 Rockledge Drive, Room 9144
Bethesda, MD 20892-7950
Phone: 301-827-8301
shimian.zou@nih.gov

PARTICIPANTS

PARTICIPANTS