

Chapter 1 : Monitoring Blood Safety | Blood Safety | CDC

The national blood system should be governed by national blood policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products.

Our association believes that the time is overdue to create a new, more achievable, paradigm under which blood safety policies are adopted in the United States. AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. Our members include approximately 1, hospital and community blood centers and transfusion and transplantation services as well as 8, individuals involved in activities related to transfusion, cellular therapies and transplantation medicine. For more than 50 years, AABB has established voluntary standards for, and accredited institutions involved in, these activities. AABB is focused on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, and developing and delivering programs and services to optimize patient and donor care and safety. As we face an increasing number of potential threats to the blood supply, AABB believes there must be a careful assessment of where the largest risks are and where the greatest benefit to patient care can be gained from the implementation of new technologies or safety interventions. Prioritizing these risks is particularly important now as our country enters a new recognition that our resources, both financial and human, are not endless and must be allocated to the most urgent risks. AABB believes that we must begin to consider other than the current "zero-risk" approach to blood and transfusion safety, which in its purest form can actually hinder the introduction of important new blood safety technologies such as pathogen reduced blood components or prevent the elimination of redundant or unnecessary screening measures or tests. AABB understands that making this transition requires that we have in place a mechanism to accurately assess risks. As this committee has discussed in the past, the United States needs a robust, well-funded biovigilance program to collect data about the risks of transfusion, as well as the effectiveness of safety interventions, both proposed and existing, to reduce these risks. Adequately funded biovigilance can help us to make more evidence-based policy decisions about which transfusion risks the community should focus our limited resources on. In addition to a viable biovigilance system in the US from which prioritization of efforts would result, continued funding should also be directed to donor- and patient-oriented research from which the majority of blood safety interventions in place today have resulted. In prioritizing risks and developing new transfusion safety policies, AABB urges that we continue to focus on the non-infectious risks of transfusion. Our community has made great progress in reducing the risk of contracting infectious diseases via a transfusion. And as we continue to address potential transfusion-transmitted risks, we must also remember that today, the far greater risk is that a patient will be harmed by transfusion-associated circulatory overload TACO, the transfusion of the wrong unit of blood, transfusion-related acute lung injury TRALI or another non-infectious complication. AABB also believes that voluntary standards and guidance will continue to play an important role in transfusion safety, particularly in the absence of regulatory action. In making our policies, AABB examines the current science and aims to assist our members' blood centers as well as hospital transfusion services in establishing the best use of their resources to improve patient care. AABB understands that the adoption of a new blood safety paradigm cannot be accomplished within the blood community alone. A multi-disciplinary approach is needed. The public must be meaningfully engaged in this dialogue to determine the prevailing tolerance for risk associated with new advances and the necessary prioritization of healthcare resources. Representatives of the public and the patient community, physicians, blood centers and hospitals must all be included in these discussions. Lastly, we need to encourage the participation of industry, on which we depend to bring forward next generation technology needed to continually advance transfusion and transplant safety. Engaging in this dialogue may require the use of mechanisms not previously implemented in the blood community. Possible avenues for obtaining wide-spread public discussion need to be thoroughly explored. Town hall meetings are one possibility. For example, recently, HHS held a series of meetings across the country to garner public views about which populations should have access to limited supplies of pandemic influenza vaccines and antivirals. HHS officials have

stated that they learned a great deal from these open discussions and at times were surprised by the "ethical" choices the public was willing to make relating to that public health question. The process for establishing community consent for blood substitutes may serve as another example. HHS, at its highest levels, must explore how best to obtain broad public input into this critical public health matter. AABB understands that next spring Canada will sponsor a Consensus Conference on the topic of risk-based decision making as it relates to blood safety. In the past, Canadian consensus conferences such as this, which use the NIH consensus forum model, have proven extremely valuable in addressing critical blood safety issues and developing productive work products; the TRALI consensus conference is a prime example. The goal of the Consensus Conference is to bring together industry, regulators, blood providers, and consumers patients to work toward a common decision making process that would allow for more appropriate decisions that consider concepts such as ALARA risk as low as reasonably achievable , rather than zero-risk. The Conference aims to explore, through the consensus forum, whether a consistent process for decision making could be defined that would be both transparent and would result in building greater trust between the blood community and the public. The Canadian Consensus Conference will undoubtedly suggest a valuable process for developing public consensus around risk acceptance. Ideally, around the same time our own biovigilance program will begin providing us with critical data specific to risks in the United States. For some time there has been considerable discussion about the need to move away from the zero-risk paradigm and the time is now for widespread discussion and action in moving toward a new decision-making process. Drawing from such public discussions as well as the best available scientific information, including that gained through biovigilance, we should all work together in prioritizing risks and the most beneficial safety measures to advance patient care.

The Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) is a member federal advisory committee that provides advice to the Secretary of Health and Human Services through the Assistant Secretary for Health on a range of policy issues related to blood, blood products, and tissues.

Blood processing Blood collected in an anticoagulant can be stored and transfused to a patient in an unmodified state. However, blood can be used more effectively if it is processed into components, such as red cell concentrates, platelet concentrates, plasma and cryoprecipitate. In this way, it can meet the needs of more than one patient. The capacity to provide patients with the different blood components they require is still limited in low-income countries: It is the responsibility of individual governments to ensure sufficient and equitable supply of plasma-derived medicinal products, namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide. Only 51 of reporting countries produce plasma-derived medicinal products PDMP through the fractionation of plasma collected in the reporting country. A total of 96 countries reported that all PDMP are imported, 17 countries reported that no PDMP were used during the reporting period, and 16 countries did not respond to the question. Clinical use of blood Unnecessary transfusions and unsafe transfusion practices expose patients to the risk of serious adverse transfusion reactions and transfusion-transmissible infections. Unnecessary transfusions also reduce the availability of blood products for patients who are in need. WHO recommends the development of systems, such as hospitals transfusion committees and haemovigilance, to monitor and improve the safety of transfusion processes. Blood transfusions There are great variations between countries in terms of the age distribution of transfused patients. In high-income countries, transfusion is most commonly used for supportive care in cardiovascular surgery, transplant surgery, massive trauma, and therapy for solid and haematological malignancies. In low- and middle-income countries it is used more often to manage pregnancy-related complications and severe childhood anaemia. WHO response The risk of transmission of serious infections, including HIV and hepatitis, through unsafe blood and chronic blood shortages brought global attention to the importance of blood safety and availability. With the goal of ensuring universal access to safe blood and blood products, WHO has been at the forefront to improve blood safety and availability, and recommends the following integrated strategy for blood safety and availability: Establishment of a national blood system with well-organized and coordinated blood transfusion services, effective evidence-based and ethical national blood policies, and legislation and regulation, that can provide sufficient and timely supplies of safe blood and blood products to meet the transfusion needs of all patients. Collection of blood, plasma and other blood components from low-risk, regular, voluntary unpaid donors through the strengthening of donation systems, and effective donor management, including care and counselling. Quality-assured screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis B, hepatitis C and syphilis, confirmatory testing of the results of all donors screen-reactive for infection markers, blood grouping and compatibility testing, and systems for processing blood into blood products blood components for transfusion and plasma derived-medicinal products , as appropriate, to meet health care needs. Rational use of blood and blood products to reduce unnecessary transfusions and minimize the risks associated with transfusion, the use of alternatives to transfusion where possible, and safe and good clinical transfusion practices, including patient blood management. Step-wise implementation of effective quality systems, including quality management, standards, good manufacturing practices, documentation, training of all staff, and quality assessment. The programme provides policy guidance and technical assistance to countries for ensuring universal access to safe blood and blood products and work towards self-sufficiency in safe blood and blood products based on voluntary unpaid blood donation to achieve universal health coverage. To give a more complete overview of the global situation, data for the year have been used from 15 countries and data for the year have been used from 9 countries, where current data are not available. Overall, responses received from countries cover

Chapter 3 : Fact Sheet: Blood Safety And Availability - AboveWhispers | AboveWhispers

Introduction. Definition of the Prevention Area. Blood transfusion is an essential part of modern medical care. Inadequate and unsafe blood supply causes avoidable deaths and transmits infectious diseases, including HIV, hepatitis B and C, and syphilis.

Strength, Hope, Courage- We walk for a Cure An apple a day keeps the doctor away Spreading health awareness, one step at a time. The easiest way to get a healthy body is to marry one People say nothing is impossible, But I do nothing everyday Birthdays are good for your health. People who have more birthdays, live longer. Based on samples of people, the blood donation rate is An increase of Only 51 of reporting countries produce plasma-derived medicinal products PDMP through the fractionation of plasma collected in the reporting country. A total of 96 countries reported that all PDMP are imported, 17 countries reported that no PDMP were used during the reporting period, and 16 countries did not respond to the question. National blood policy and organization Blood transfusion saves lives and improves health, but many patients requiring transfusion do not have timely access to safe blood. WHO recommends that all activities related to blood collection, testing, processing, storage and distribution be coordinated at the national level through effective organization and integrated blood supply networks. The national blood system should be governed by national blood policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products. Blood supply About About 13 blood centres in countries report collecting a total of million donations. Collections at blood centres vary according to income group. The median annual donations per blood centre is in the low- and middle-income countries, as compared to 16 in the high-income countries. There is a marked difference in the level of access to blood between low- and high-income countries. The whole blood donation rate is an indicator for the general availability of blood in a country. The median blood donation rate in high-income countries is This compares with All are low- or middle-income countries. The age profile of blood donors shows that, proportionally, more young people donate blood in low- and middle-income countries than in high-income countries. Demographic information of blood donors is important for formulating and monitoring recruitment strategies. Types of blood donors There are 3 types of blood donors: An adequate and reliable supply of safe blood can be assured by a stable base of regular, voluntary, unpaid blood donors. These donors are also the safest group of donors as the prevalence of bloodborne infections is lowest among this group. Data reported to WHO shows significant increases of voluntary unpaid blood donations in low- and middle-income countries: The maximum increase in absolute numbers was reported in the South-East Asia region 5. Blood screening WHO recommends that all blood donations should be screened for infections prior to use. Blood screening should be performed according to the quality system requirements. Of reporting countries, 13 are not able to screen all donated blood for 1 or more of the above infections. Irregular supply of test kits is one of the most commonly reported barriers to screening. The prevalence of transfusion-transmissible infections in blood donations in high-income countries is considerably lower than in low- and middle-income countries Table 1. Blood processing Blood collected in an anticoagulant can be stored and transfused to a patient in an unmodified state. However, blood can be used more effectively if it is processed into components, such as red cell concentrates, platelet concentrates, plasma and cryoprecipitate. In this way, it can meet the needs of more than one patient. The capacity to provide patients with the different blood components they require is still limited in low-income countries: It is the responsibility of individual governments to ensure sufficient and equitable supply of plasma-derived medicinal products, namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide. Clinical use of blood Unnecessary transfusions and unsafe transfusion practices expose patients to the risk of serious adverse transfusion reactions and transfusion-transmissible infections. Unnecessary transfusions also reduce the availability of blood products for patients who are in need. WHO recommends the development of systems, such as hospitals transfusion committees and haemovigilance, to monitor and improve the safety of transfusion processes. Blood transfusions There are great variations between countries in terms of the age

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Chapter 4 : WHO | Blood transfusion safety

Worldwide, over million blood donations were collected during the survey, but blood availability and safety were found to vary by region and income group. For example, 47% of blood donations were collected from high income countries with 19% of the global population.

However, such measures have not been adequately implemented in low and middle income countries LMICs , especially in low resource settings. Some of the measures may also not be appropriate, practical, or validated for LMIC settings. The potential adverse events for recipients include transfusion-transmitted infections TTI including but not limited to human immunodeficiency virus HIV , hepatitis C virus HCV and hepatitis B virus HBV as well as transfusion-associated injuries due to errors, bacterial contamination, fluid overload, and transfusion reactions. The potential adverse events for donors can include incomplete or inaccurate testing leading to incorrect donor notification and an inability to follow up on donors with positive screening tests. National reports to the World Health Organization WHO Global Database for Blood Safety GDBS as well as published data further suggest that poor quality or lack of blood donation screening could be the most important gap in blood safety internationally. While the number of paid blood donations has been reduced in some settings, with successful conversion to voluntary donation, paid donation of labile blood and components may still account for a significant proportion of transfusion-transmissible infections globally due to the higher risk of infections associated with such donations. Inadequate or inconsistent supplies and acute shortages of blood for transfusion in low resources settings, often coupled with the questionable quality of the available blood supply, pose real risks to the health of patients who need blood transfusion. Such patients include those in need of transfusion secondary to malaria, sickle cell disease, thalassemia, obstetric hemorrhage, and trauma. DBDR has a major responsibility for research to assure the adequacy and safety of the blood supply and transfusion safety while CTRIS plans, fosters, and supports integrated and coordinated programs of research to understand optimal and sustainable implementation strategies for evidence-based interventions. The focus of the workshop was to identify strategies and research opportunities to foster implementation research to improve the safety and availability of blood and blood components in LMICs. Three conference calls were held prior to the workshop to discuss challenges and opportunities in international blood availability and transfusion safety, and to identify gaps as well as potential key scientific priorities and research strategies to be further discussed at the in-person meeting. In addition, seven regional working groups were formed, each including at least one expert from the local region and other experts in transfusion medicine and implementation research. The seven working groups held multiple calls and were asked to identify key scientific priorities and research strategies for their region. The findings from these working groups were presented and discussed by all participants at the workshop on April , Invited experts who were not able to attend the in-person meeting in Bethesda, MD also provided input through their active participation by teleconference, both prior to and during the workshop. These include improved government engagement, oversight and regulation, with efforts such as establishment of national blood policies, nationally coordinated transfusion services and advancing capability within hospital blood banks. Blood availability and transfusion safety is now included as government priorities in many LMICs. There has been an increase in trained personnel working on blood availability and transfusion safety, including laboratory and clinical personnel. There have been training programs for transfusion medicine at institutional, national and regional levels with local and international partnerships. The transition from more externally supported blood program operations to a system of domestically-supported operations will provide additional opportunities for implementation research on blood availability and transfusion safety. International, regional and national professional organizations as well as transfusion research networks have been developed. For example, key baseline data have been collected during the last two decades from several research studies in Africa to provide initial knowledge on the determinants of blood availability and transfusion safety. Professional organizations and networks could now be leveraged to facilitate research. Other health networks, such as those for infectious diseases like HIV, Malaria and tuberculosis as well as those for non-communicable diseases, could also now

be leveraged to facilitate research in blood availability and transfusion safety. Various international, regional and national initiatives on blood availability and transfusion safety have been implemented in some LMICs, such as T-REC an international consortium of academics and health practitioners working to strengthen the capacity of African researchers to do research on blood transfusion and the Francophone Africa Research Network. These initiatives have in various ways laid the foundation for future research efforts. The experience and lessons learned from these initiatives can also inform the design and execution of future implementation research. New technologies such as electronic health information management systems have been deployed and mobile devices such as telephones and tablets are available and adaptable to resource-limited settings, including areas with limited or no power sources. Furthermore, the rapid growth of point of care and rapid diagnostic tests could help facilitate research on blood availability and transfusion safety in many LMICs. Different TTI testing algorithms could be explored for different settings. The diverse situations in different LMICs also provide unique opportunities. For example, countries that are in different stages of development need to implement strategies that are feasible and sustainable locally. The experience gained from countries that have gone from low to middle income status could be of value to other LMICs. Furthermore, populations in many LMICs have different genetic and environmental factors that influence health and disease, providing unique opportunities for research on blood availability and transfusion safety. This includes populations with inherited bleeding disorders such as hemophilia, sickle cell disease, and thalassemia as well as acquired disorders such as HIV patients with chronic blood transfusion needs. Finally, the diversity in transfusion resources and infrastructure within LMICs, such as urban vs rural settings, low vs. These needs could be due to: In many countries, blood transfusion services are highly fragmented with significant variation in quality and performance based on geography, urban vs. For example, in certain countries, large amounts of plasma recovered from whole-blood donations are discarded because of quality concerns or logistical, contractual, and budgetary requirements that prevent the use of this plasma in fractionation. Motivations and deterrents to optimal blood donation behaviors include social and cultural factors that may be different from those in HICs. These factors are often poorly understood in LMICs or by experts in HICs, leading to sub-optimal recruitment and retention strategies and inadequate design of the necessary research. Additionally, donor health concerns, such as donation-induced iron deficiency and anemia, have not been assessed in many LMICs. Challenges to transfusion safety include insufficient regulatory and professional oversight; lack of legislation, regulations and policies or their effective implementation; lack of quality systems and safety programs such as those for donor screening and donation testing; and lack of monitoring systems hemovigilance to track patient and donor outcomes, including both infectious and non-infectious adverse events. In some LMICs, the high rates for transmission of TTIs pose substantial challenges, and there is a high probability that these rates are currently underestimated. In some LMICs, emerging infections could also pose unique challenges. Also highlighted was the need for the routine implementation of immunohematology tests using sensitive techniques to detect antibodies and to prevent or reduce transfusion reactions. The relationship between an insufficient supply of blood for transfusion and unnecessary transfusion is not well-defined for LMICs. Inappropriate transfusion of blood products exists in many LMICs, which could be due to limited training in transfusion medicine and either a lack of clinical transfusion guidelines or their effective implementation. Social and cultural factors could also play a role in adherence to suboptimal clinical transfusion practices. In many LMICs, knowledge and financial contributions from HICs and international organizations have played a key role in developing the infrastructure and capacities for an adequate supply of safe blood for clinical transfusion. These resources are subject to the vagaries of the global economy and political shifts. Without continuing external support, how to sustain the blood supply system and services with limited resources poses a major challenge. This represents an area with tremendous risk to the sustainability of the supply, but also an opportunity for implementation research. Key Questions, Priorities and Strategies Identified The key questions, priorities and strategies identified by each of the seven regions can be grouped into the following categories: Blood availability Six of the seven regions identified blood availability as a priority. Finally, blood donor safety was also seen as not only important for blood availability but also a responsibility of governments as well as blood establishments. Anemia is often the major reason of deferral for many donors

who are then not followed up or treated appropriately. Particularly, the safety of blood donation is critically important when young donors years are targeted for recruitment. Blood and transfusion safety Questions and priorities identified by the regional working groups related to blood and transfusion safety were common to all regions, but the priority topics were variable. Several regions also highlighted the need for research on the risk of emerging and re-emerging pathogens. The neglected topic of transfusion-transmitted malaria needs to be addressed in the context of molecular testing, new preemptive anti-malarial drugs, and whole blood pathogen reduction methods. Appropriate use of blood Five of the seven regions also identified appropriate use of blood as a priority. For example, studies are needed to define appropriate clinical indications for blood transfusion that are relevant to LMIC clinical illnesses, to assess how blood transfusions are being used, and to understand whether actual use conforms to relevant best clinical practice. There is insufficient information on the extent to which blood centers and hospitals have established guidelines for transfusion indications and on the best way to implement guidelines for blood transfusions to avoid either under-transfusion or unnecessary blood transfusion. Research is needed into the role of hospital transfusion committees as well as effective implementation and sustainable uptake of clinical transfusion guidelines and hemovigilance systems. Patient blood management was also discussed. Transfusion of fresh whole blood has a prominent place in some LMICs but needs to be specifically examined with respect to definition, quality assurance and clinical indications. Quality systems The implementation of quality systems was identified as essential for blood and transfusion safety. Examples of questions that were deemed relevant for LMICs included: The cost of these proposals is paramount to their implementation and needs to be carefully assessed. Health economics and budgeting The need for incorporating health economics into implementation research for blood availability and transfusion safety was highlighted by two regions and elements of health economics were also included among the priorities identified by other regions. Relevant questions to address included: Challenging questions without clear answers were also raised, such as the cost-effectiveness of blood transfusion strategies in patient blood management of sickle cell disease SCD. Equally important is to collect comparative data on the production costs of blood products and channels and levels of reimbursement by governments, public or private insurance or patients themselves. Training and education The need for better training and education of blood center professionals in laboratory, clinical and implementation science research was reflected in many of the priorities stated above. This would establish local capacity to develop scientific evidence toward improving blood and transfusion safety as well as the recipient and donor experience. There was a specific suggestion to develop a training program for implementation research, similar in scope to an earlier fellowship program NHLBI supported for transfusion medicine. For a complete list of questions, priorities and strategies identified by all seven regions, the reader is asked to please refer to the linked workshop booklet that includes the agenda, the roster of participants, the scientific priorities and the research strategies identified by the seven regional working groups. Significant gaps remain in safe blood availability especially in low resource settings, and in implementing appropriate clinical transfusion guidelines. To address these issues and improve blood availability and transfusion safety, there is a compelling need for the systematic collection and compilation of data, and a need for epidemiological and implementation research. Implementation research addresses the acceptability, affordability, appropriateness, feasibility, fidelity, penetration and sustainability of interventions as well as their effectiveness. The need for training personnel devoted to laboratory medicine, transfusion medicine, and implementation research were also emphasized. Blood Availability At the strategic level, a coordinated multi-tiered approach to provision of blood within a country or region could be developed and assessed; for example, a centralized blood supply system s supplemented with various hospital- or organization-based supplies tailoring out to different settings in rural or austere parts of a country or region. Research needs to be conducted to identify the motivators and inhibitors or deterrents to blood donation in local settings, including the impact of socio-psychological and behavioral factors. Once motivators and deterrents are known and potential recruitment and retention strategies identified, implementation research to evaluate which strategies may best improve sustained recruitment and retention of safe blood donors in specific settings is warranted. While voluntary non-remunerated blood donation remains the goal, research into other feasible and sustainable approaches should be conducted, such as conversion of family and

replacement donors to voluntary non-remunerated blood donors for repeat blood donations. Inducing young people to become blood donors could be explored, providing donor health is safe-guarded. Donor safety in general, including research to evaluate the consequences of and how to mitigate iron depletion, as well as cost-effectiveness assessments of interventions to protect donor health, is under-studied and an area in which research needs to be strengthened. Research on blood needs, including the best method for estimating such needs, and blood utilization as well as implementation research to evaluate patient blood management strategies are needed. Further related to blood availability are the issues of appropriate balance between whole blood and blood component production and effective strategies to minimize plasma and blood wastage. Research on feasible and sustainable means, including improved inventory management and use of recovered plasma for fractionation, could not only enhance blood availability for clinical transfusion but may also provide opportunities for improving the supply of fractionated blood products which are often in short supply in LMICs. Blood and Transfusion Safety Both innovation and implementation research are needed to develop and evaluate low-cost patient identification mechanisms to decrease ABO incompatibility errors , laboratory information systems to keep track of donor and donation information , rapid tests and point of care testing with high predictive values, small pool plasma fractionation methods, transportation and delivery systems, and pathogen reduction techniques appropriate for low resource settings. Furthermore, research is required to identify and implement effective yet locally feasible and sustainable quality systems including external quality assessment systems and procedures to ensure the quality of donor selection, donation screening, processing and delivery, and transfusion to recipients. While many challenges exist in low resource settings, the availability of new technologies, such as mobile communication, offer unique opportunities throughout the transfusion chain. In view of the lack of reliable data on prevalence and incidence of major TTIs including HIV, HBV and HCV, as well as associated risk factors in many low-resource settings, epidemiologic research is also required to generate baseline data to inform local policy formulation and decision making. Solid data on transfusion-transmitted malaria and policies to prevent such transmission, particularly in vulnerable patients such as children and pregnant women, need to be generated. Health Economics Research Health economics research for sustainability, including models of blood system financing such as cost recovery, was recognized as a major gap area. Such research may help identify potential options for country-specific blood supply systems. Additionally, research that incorporates cost-effectiveness within local feasibility and sustainability assessments, by clearly demonstrating the public health benefits of such efforts, could enhance government commitment to an adequate supply of safe blood for patients.

Chapter 5 : The global status report on blood safety and availability

The Advisory Committee on Blood Safety and Availability (ACBSA) recommended at its August meeting that the Department coordinate Federal actions and programs to support and facilitate biovigilance in partnership with private sector initiatives.

Bood bags hangs to isolate white blood cells. Based on samples of people, the blood donation rate is An increase of Only 51 of reporting countries produce plasma-derived medicinal products PDMP through the fractionation of plasma collected in the reporting country. A total of 96 countries reported that all PDMP are imported, 17 countries reported that no PDMP were used during the reporting period, and 16 countries did not respond to the question. National blood policy and organization Blood transfusion saves lives and improves health, but many patients requiring transfusion do not have timely access to safe blood. WHO recommends that all activities related to blood collection, testing, processing, storage and distribution be coordinated at the national level through effective organization and integrated blood supply networks. The national blood system should be governed by national blood policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products. Blood supply About About 13 blood centres in countries report collecting a total of million donations. Collections at blood centres vary according to income group. The median annual donations per blood centre is in the low- and middle-income countries, as compared to 16 in the high-income countries. There is a marked difference in the level of access to blood between low- and high-income countries. The whole blood donation rate is an indicator for the general availability of blood in a country. The median blood donation rate in high-income countries is This compares with All are low- or middle-income countries. The age profile of blood donors shows that, proportionally, more young people donate blood in low- and middle-income countries than in high-income countries. Demographic information of blood donors is important for formulating and monitoring recruitment strategies. Types of blood donors There are 3 types of blood donors: An adequate and reliable supply of safe blood can be assured by a stable base of regular, voluntary, unpaid blood donors. These donors are also the safest group of donors as the prevalence of bloodborne infections is lowest among this group. Data reported to WHO shows significant increases of voluntary unpaid blood donations in low- and middle-income countries: The maximum increase in absolute numbers was reported in the South-East Asia region 5. Blood screening WHO recommends that all blood donations should be screened for infections prior to use. Blood screening should be performed according to the quality system requirements. Of reporting countries, 13 are not able to screen all donated blood for 1 or more of the above infections. Irregular supply of test kits is one of the most commonly reported barriers to screening. The prevalence of transfusion-transmissible infections in blood donations in high-income countries is considerably lower than in low- and middle-income countries Table 1. Prevalence of transfusion-transmissible infections in blood donations Median, Interquartile range IQR , by income groups These differences reflects the variation in prevalence among population who are eligible to donate blood, the type of donors such as voluntary unpaid blood donors from lower risk populations and the effectiveness of the system of educating and selecting donors. Blood processing Blood collected in an anticoagulant can be stored and transfused to a patient in an unmodified state. However, blood can be used more effectively if it is processed into components, such as red cell concentrates, platelet concentrates, plasma and cryoprecipitate. In this way, it can meet the needs of more than one patient. The capacity to provide patients with the different blood components they require is still limited in low-income countries: It is the responsibility of individual governments to ensure sufficient and equitable supply of plasma-derived medicinal products, namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide. Clinical use of blood Unnecessary transfusions and unsafe transfusion practices expose patients to the risk of serious adverse transfusion reactions and transfusion-transmissible infections. Unnecessary transfusions also reduce the availability of blood products for patients who are in need. WHO recommends the development of systems, such as hospitals transfusion committees and haemovigilance, to monitor and improve the safety of transfusion processes. Blood

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Chapter 6 : Africircle: Blood safety and availability

Quality-assured screening of all donated blood for transfusion-transmissible infections (TTI), as appropriate, and recommends the following integrated strategy for blood safety and availability: 1. through unsafe blood and chronic blood shortages brought global attention to the importance of blood safety and availability. massive trauma.

Blood donation rate in high-income countries is An increase of 7. Only 41 of countries produce plasma-derived medicinal products PDMPs through the fractionation of plasma collected in the country, whereas the other countries import PDMPs from abroad. National blood policy and organization Blood transfusion saves lives and improves health, but many patients requiring transfusion do not have timely access to safe blood. WHO recommends that all activities related to blood collection, testing, processing, storage and distribution be coordinated at the national level through effective organization and a national blood policy. This should be supported by appropriate legislation to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products. Blood supply About million blood donations are collected worldwide. About 10 blood centres in countries report collecting a total of 83 million donations. Collections at blood centres vary according to income group. The median annual donations per blood centre is in the low- and middle-income countries, as compared to 15 in the high-income countries. There is a marked difference in the level of access to safe blood between low- and high-income countries. The whole blood donation rate is an indicator for the general availability of blood in a country. The median blood donation rate in high-income countries is This compares with All are low- or middle-income countries. In low- and middle-income countries, proportionally more young people donate blood than in high-income countries see Figure 2. Demographic information of blood donors is important for formulating and monitoring recruitment strategies. Types of blood donors There are three types of blood donors: An adequate and reliable supply of safe blood can be assured by a stable base of regular, voluntary, unpaid blood donors. These donors are also the safest group of donors as the prevalence of bloodborne infections is lowest among this group. Data reported to WHO shows significant increases of voluntary unpaid blood donations in low- and middle-income countries: The maximum increase in absolute numbers was reported in the Western Pacific Region. Percentage of voluntary unpaid blood donations Enlarge image Blood screening WHO recommends that all blood donations should be screened for infection prior to use. Irregular supply of test kits is one of the most commonly reported barriers to screening. The prevalence of transfusion-transmissible infections TTIs in blood donations in high-income countries is considerably lower than in low- and middle-income countries. The prevalence of HIV in blood donations in high-income countries is 0. This difference reflects the variable prevalence amongst members of the population who are eligible to donate blood, the type of donors such as voluntary unpaid blood donors from population at lower risk and the effectiveness of the system of educating and selecting donors. Blood processing Blood collected in an anticoagulant can be stored and transfused to a patient in an unmodified state. However, blood can be used more effectively if it is separated into components, such as red cell concentrates, plasma, and cryoprecipitate and platelet concentrates. In this way, it can meet the needs of more than one patient. The capacity to provide patients with the different blood components they require is still limited in low-income countries: It is the responsibility of individual governments to ensure sufficient and equitable supply of plasma-derived medicinal products namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide. The other countries report that all PDMPs are imported. Around 10 million litres plasma from 33 reporting countries including 17 high-income countries, 15 middle-income countries and 1 low-income countries, covering a population of 2. Clinical use of blood Unnecessary transfusions and unsafe transfusion practices expose patients to the risk of serious adverse transfusion reactions and TTIs. Unnecessary transfusions also reduce the availability of blood products for patients who are in need. WHO recommends that all countries have transfusion committees to implement national policy and guidelines on rational use of blood in hospitals and a national haemovigilance system to monitor and improve the safety of the transfusion process. Blood transfusions There are great variations between countries in the age distribution of transfused

patients. In high-income countries, transfusion is most commonly used for supportive care in cardiovascular surgery, transplant surgery, massive trauma, and therapy for solid and haematological malignancies. In low- and middle-income countries it is used more often to manage pregnancy-related complications and severe childhood anaemia. The programme provides policy guidance and technical assistance to countries for ensuring universal access to safe blood and blood products and work towards self-sufficiency in safe blood and blood products based on voluntary unpaid blood donation to achieve universal health coverage. To give a more complete overview of the global situation, data for the year have been used from 14 countries, where data are not available. For more information please contact: World Health Organization 4th Fl.

Chapter 7 : ISBT: Global Blood Safety

This webpage was developed to provide the public with important information about the safety and availability of biological products. Safety communications older than 2 years are available on FDA.

Chapter 8 : AABB Statement before the Advisory Committee on Blood Safety and Availability

As a current student on this bumpy collegiate pathway, I stumbled upon Course Hero, where I can find study resources for nearly all my courses, get online help from tutors 24/7, and even share my old projects, papers, and lecture notes with other students.

Chapter 9 : Global Variations in Blood Safety and Availability Based on WHO Report

HHS Advisory Committee on Blood Safety and Availability. On June , , the HHS Advisory Committee on Blood Safety and Availability (ACBSA) met to discuss the current Food and Drug Administration (FDA) policy on men.