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Transmission of HIV Through Blood – How To Bridge the Knowledge Gap

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1. Introduction

1.1 HIV and blood transfusion – The current state of the art

Of all blood donations 65% are made in developed (very high human development index or VH-HDI) countries, home to just 25% of the world's population. In 73 countries, donation rates are still less than 1% of the population (the minimum needed to meet basic needs in a country). Of these, 71 are either developing (low HDI) or transitional (medium to high HDI) countries; 42 countries collect less than 25% of their blood supplies from the safest source: voluntary non-remunerated blood donors. However, less than 50% of these donors donates regularly, the other half just one time only. In 2007, 31 countries (19%) still reported collecting paid donations, which is more than 1 million donations in total, where 41 countries (25%) were not able to screen all blood donations for one or more of the following transfusion-transmissible infections (TTIs) - HIV, hepatitis B, hepatitis C and syphilis (WHO 2010a).

Blood transfusion as a supportive haemotherapy contributes to saving lives and improving health, but millions of patients needing transfusion do not have timely access to or can afford safe blood. In 2007, 162 countries provided data to WHO on 85.4 million blood donations (World Health Organization [WHO] 2010a). These data come from countries that account for a total of 5.9 billion people, representing 92% of the global population. The report covers around 8,000 blood centres. In developed countries, the average annual collection per blood centre was 13,600 (range 49–289,075), in transitional countries 6,000 (range 20–499,212) and in developing countries 2,800 (range 114–23,251).

1.1.1 Blood supply

While the need for blood is universal, there is still a major imbalance between developing and advanced countries in the level of access to safe blood. It is estimated that blood donation by 1% of the total population (10 per 1,000 population) is generally the minimum needed to meet a nation's most basic requirements for blood; the requirements are higher in countries with more advanced health care systems and medical interventions.

Of the 85.4 million donations in 2007, about 65 % were collected in developed countries. Blood donations per 1,000 population, which also reflect the general availability of blood in a country, vary widely and the lowest levels of availability are found in developing and transitional countries (WHO 2010a). The average donation rate in developed (VH-HDI)

countries is 38.1 donations/1,000 population (range 4.92–68.01); in transitional (H and M-HDI) countries this rate is 7.5 (range 1.07–35.18) and in developing (L-HDI) countries an average of 2.3 (range 0.40–7.46) donations per 1,000 population were collected. In 2007, 73 countries (45%) reported collecting fewer than 10 donations per 1,000 population. Among them, 71 (97%) are either developing or transitional countries. Due to relatively high TTI marker prevalence the drop out of collected blood varies between 11 and over 20%, reducing the clinical availability substantially.

1.1.2 Blood donation

There are three major types of blood donation: voluntary unpaid donations (non-remunerated/altruistic), family/replacement donations (coerced), and paid donations. Donors who give blood voluntarily, regularly and for altruistic reasons have the lowest prevalence of HIV, hepatitis viruses and other blood-borne infections, as compared to people who donate for friends and family members or because of payment. Family and replacement donations are often hidden paid and seriously coerced. Sufficient supplies of safe blood can only be assured by regular donations from voluntary unpaid and anonymous donors. The 2007 WHO data reveal some improvements in such donations worldwide, but many developing and transitional countries still rely heavily on relatively unsafe one time only family/replacement donors and paid donors (fig 1).

This means a considerable gap in public awareness and knowledge about the essentials of blood donation as an act of social solidarity and blood transfusion as an integral element of the health care system.

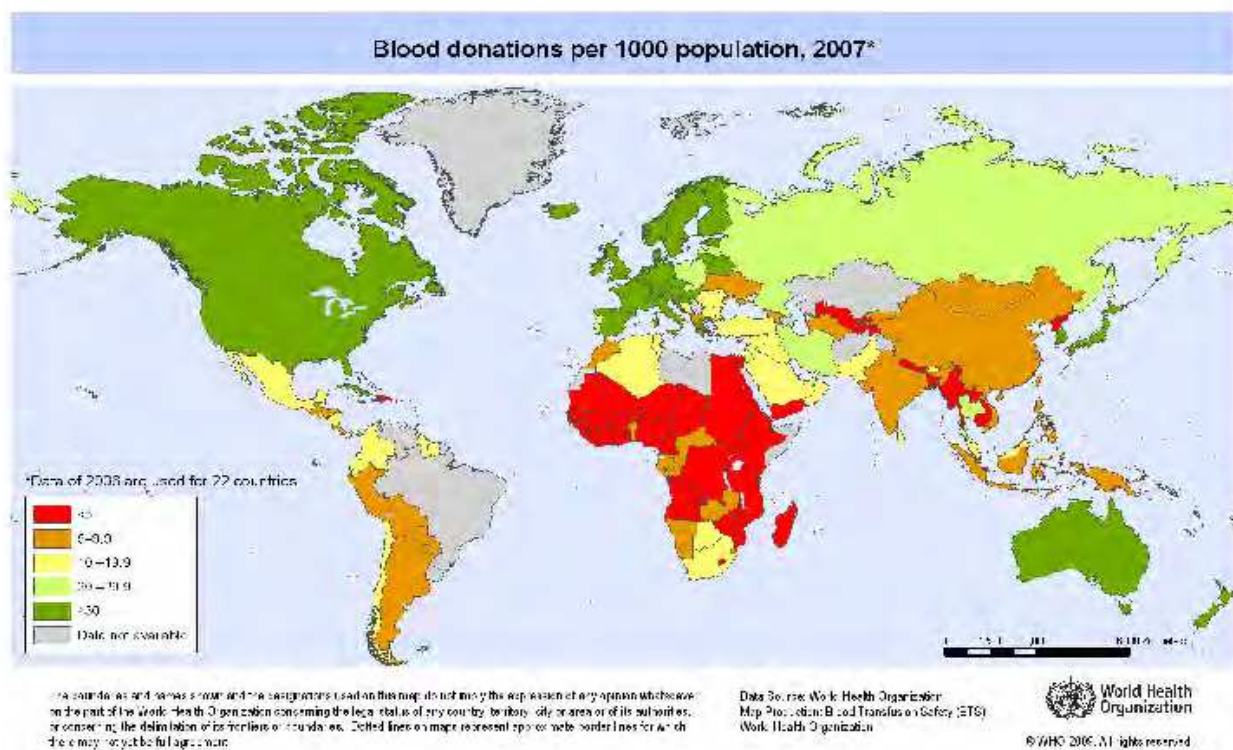


Fig. 1. Annual blood donations per 1,000 population, 2007. Source: Global Database on Blood Safety (GDBS), 2007 survey (WHO2010a)

1.1.2.1 Voluntary, unpaid donations

Of the 162 responding countries 57 (35%) report collecting 100% of their blood supplies from voluntary unpaid donors (fig. 2). Since World Blood Donor Day (14th June, birthday of Karl Landsteiner) celebration began in 2004, 111 countries (68.5%) reported an increase of the number of voluntary donations; 32 of these 111 (29%) have more than doubled the number of voluntary donations as compared to 2004 figures. All these 32 countries are developing or transitional countries. Additionally, 11 countries (Bosnia and Herzegovina, Burkina Faso, Cook Islands, Cape Verde, Kuwait, Guinea Bissau, Mauritania, Myanmar, Niue, Vanuatu and Vietnam) reported more than a 10% increase in voluntary unpaid donations in 2007, as compared to 2006 figures. However, a major problem remains the retention of voluntary non-remunerated blood donors.

1.1.2.2 Family/replacement donors and paid donors

Forty-two countries (26%) collect less than 25% of their blood supplies from voluntary unpaid blood donors. A significant amount of the blood supply in these countries is still dependent on family/replacement and paid blood donors. Thirty-one countries (18%) still report collecting paid donations in 2007, which represents more than 1 million donations in total.

The average donation rate in high-income countries is 45,400 donations per million people. This compares with 10,100 donations per million people in middle-income countries and 3,600 donations in low-income countries. If 1% to 3% of a country's population would donate blood, it would be sufficient to meet the country's needs. But in 77 countries, donation rates are still less than 1%.

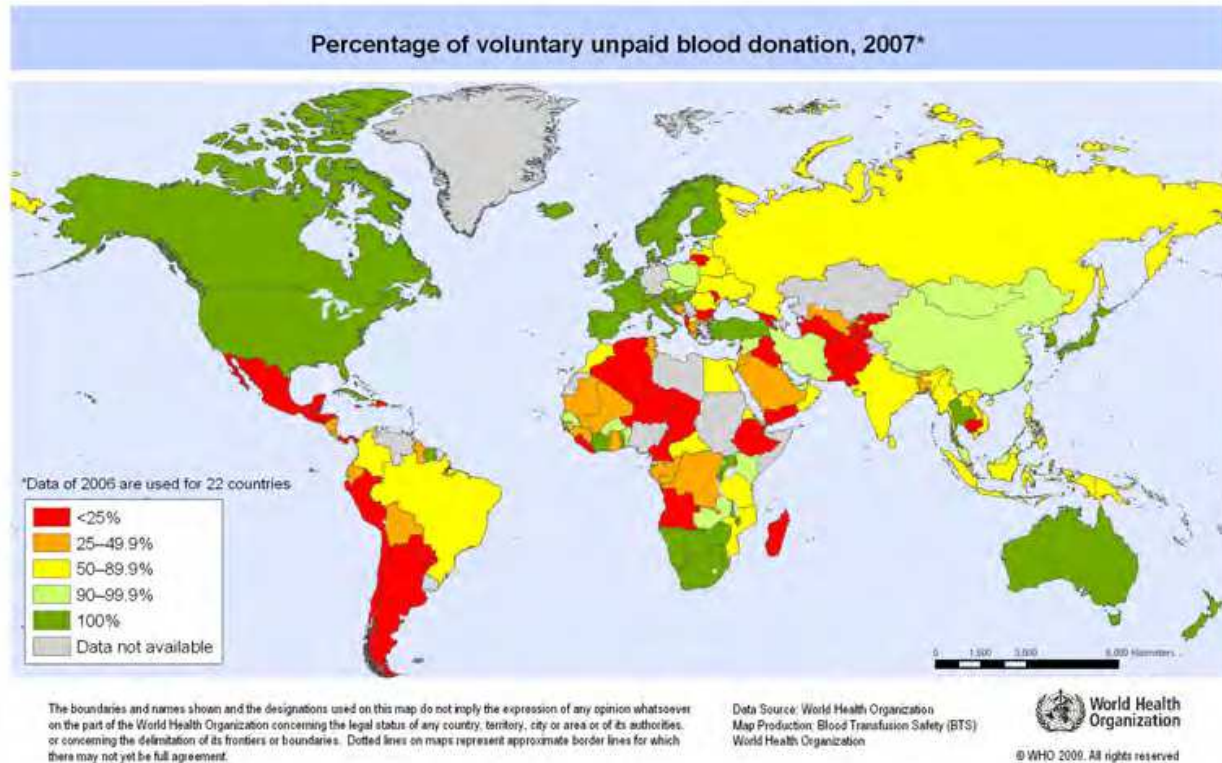


Fig. 2. Percentage voluntary non-remunerated blood donors, 2007. Source: Global Database on Blood Safety (GDBS), 2007 survey (WHO2010a)

1.1.3 Blood screening for transmissible infections

WHO recommends that all donated blood to be used for transfusion should be screened at minimum for HIV, hepatitis B, hepatitis C and syphilis (WHO 2010). Complete and accurate data on the screening of donated blood are not available from many developing countries, particularly those where blood services are not coordinated. Many countries do not have reliable testing systems because of staff shortages, lack of basic laboratory services, poor quality test kits or their irregular supply. Of the 162 countries that provided data on screening for transfusion-transmissible infections including HIV, hepatitis B, hepatitis C and syphilis, 41 (25%) are not able to screen all donated blood for one or more of these infections (fig. 3). The other 121 countries provided data on whether blood donations were screened in a quality-assured manner (use of standard operating procedures and participation in an external quality assessment scheme or EQAS). Overall, 88% of the blood collected are screened following these basic quality procedures: 89% in developed countries, 87% in transitional countries and 48% in developing countries. For the blood donations collected in the remaining 41 countries, which account for 22% of the global donations reported to WHO, the use of these basic quality assurance procedures for laboratory screening is still unknown. Additionally there is still a widespread mix of test kits used within countries, both ELISA and rapid test depending on availability and supply. Quality of performance and reliability of test results remain a problem of considerable concern.

1.1.4 Clinical use of blood

Data on the clinical use of donated blood is limited, but studies suggest that transfusions are often given unnecessarily when simpler, less expensive treatments can provide equal or greater benefit. Not only is this a waste of a scarce resource but it also exposes patients to the risk of serious adverse transfusion reactions or infections transmitted through the blood. Hospital transfusion committees and a system for reporting adverse transfusion reactions should be established in each hospital to implement the national policy and guidelines and to monitor the safe and rational use of blood and blood products at the local level. However, in a substantial proportion of the transition and developing countries there is still no national policy and no current guidelines or standards. In many situations haemoglobin transfusion triggers are high and surgical blood order equations and minimal blood order lists are not used (Kajja et al. 2010a, 2010b) .

In 2007, 120 countries (74%, including 46 developed, 48 transitional and 26 developing countries) identified and reported a total of 51,400 hospitals that perform blood transfusions, serving a population of around 3.6 billion. Not all countries were able to provide information on clinical practice (WHO 2010a). Data on hospitals performing transfusion provided by 96 countries (80%, including 38 developed countries, 40 transitional countries and 18 developing countries) illustrate the presence of a transfusion committee in 88% of these hospitals in developed countries, 33% in transitional and 25 % in developing countries. Mechanisms to monitor clinical transfusion practice (documentation) is present in 90% of the hospitals performing transfusion in developed countries, 52 % in transitional and 23 % in developing countries. However, a system for reporting adverse transfusion events (haemovigilance) in hospitals performing transfusion is found in 91% in developed countries, but only 46% in transitional and 23% in developing countries.

These 2007 WHO survey data illustrate a major gap in awareness and knowledge among policy makers and blood transfusion professionals, both in the procurement and the

prescribing parts of the vein-to-vein blood transfusion chain in transitional (M-HDI) and even more prominent in developing (L-HDI) countries.

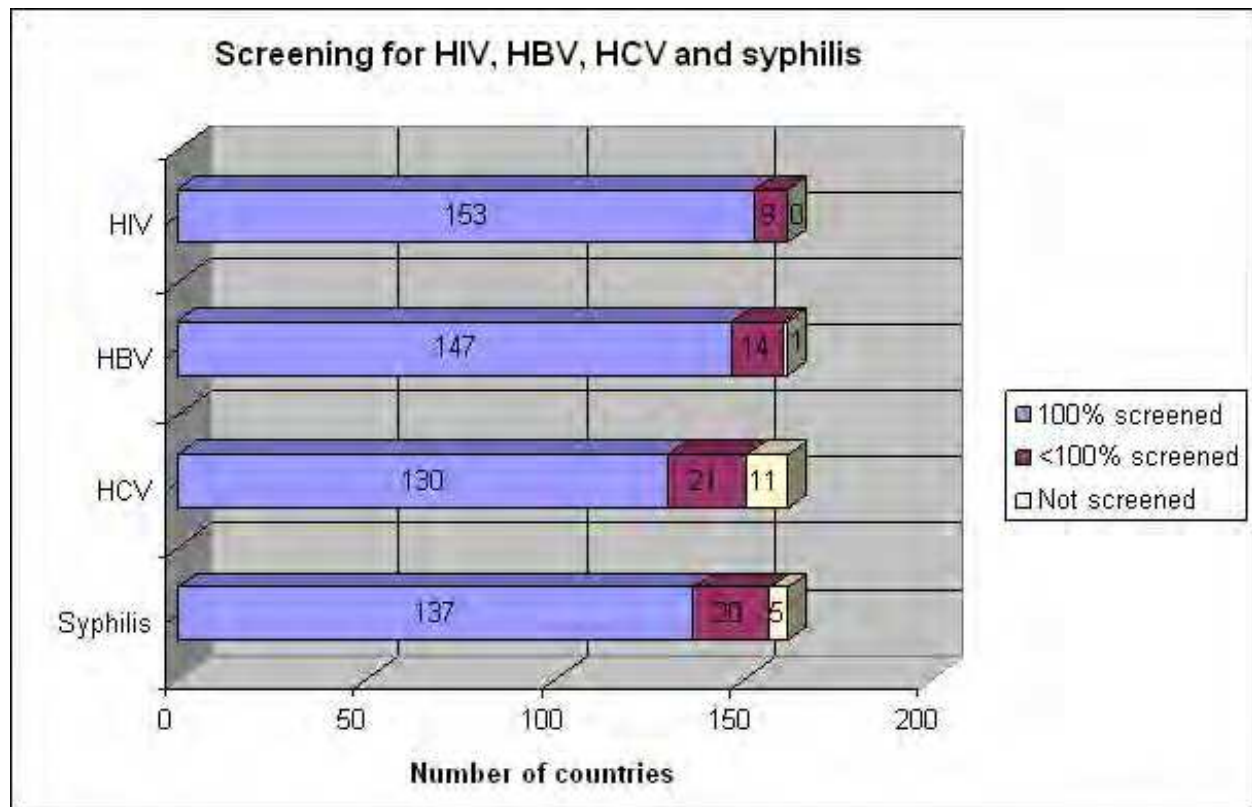


Fig. 3. Numbers of countries screening for HIV, HBV, HCV and syphilis Source: Global Database on Blood Safety (GDBS), 2007 survey (WHO 2010a)

1.2 Basics of the blood supply

Since UN together with its health organization WHO became operational in 1948, universal principles have been laid down in the UN Declaration of Universal Human Rights (UN 1948). For the health care and blood transfusion chain art. 25.1 – Right of Health through securing food, clothing, shelter and health care, and art. 26 – Right of Education, elementary and access to vocational education, are paramount.

In 1975 the WHA passed a Resolution 28.72 (Utilization and Supply of Human Blood and Blood Products), indicating that blood is a national resource, to be ‘shared’ voluntarily and altruistically and to be given as a social act of solidarity, and that human blood and tissue should never be subject to commerce (WHO 1978)

These principles have been worked out by e.g. the International Society of Blood Transfusion (ISBT) in the Code of Ethics (ISBT 2000), but also by the EU in the Directives related to blood transfusion (EU 2003, Directive 2002/98/EC).

Blood transfusion in its vein-to-vein structure should be seen as a part of a larger project to develop a safe, sustainable, high quality and efficacious blood supply and transfusion system that is fully integrated into the health care system. Ensuring the safety and availability of blood and blood products is an essential public health responsibility. Measures to ensure blood safety also play a major role in preventing the transmission of HIV, hepatitis viruses and other blood born pathogens in health care settings. The Ministry

of Health (MoH) should provide effective leadership and governance in developing a national blood system that is fully integrated into the health care system. First the foundation, then the construction of the organization and the necessary infrastructure (Quality System and Quality Management System, facilities, etc), will need to be developed. These will be followed by the development of the human capacity needed at all levels, including in the hospitals (medical and paramedical staff).

In principle, the approach for developing such an integrated nationally supported and organized country wide blood supply and transfusion system for the future, and in line with internationally accepted and advocated principles of operation, would then be as follows (fig. 4)

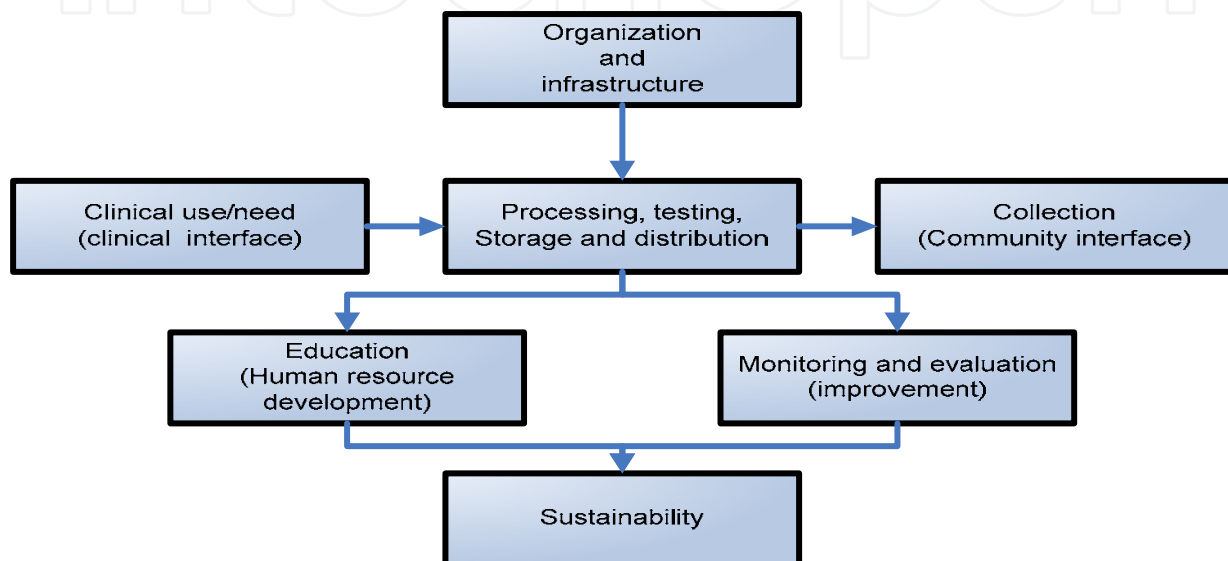


Fig. 4. Development scheme blood supply organization.

The set up should be based on a solid country specific legislative and regulatory system with sufficient authority to license operations according to international quality principles (cGMP, cGLP and cGCP)¹ supported by appropriate and standardized management principles based on ISO9001:2008. It starts with a clinical needs assessment to be followed by the logistics of the procurement and supply chain that has its roots in the community (public awareness) (Smit Sibinga 2006, WHO 2008c, Smit Sibinga et al 2009a,).

The implementation is not limited to public or private blood centres or establishments. The limitation is in the fragmentation with insufficient critical mass and economy of scale to guarantee quality and cost-effectiveness, nation wide access and affordability. National coordination and consistent and sustained governmental responsibility and support to protect citizens from unjustified and maleficent practices are the more important (Smit Sibinga 2000).

A nationally coordinated and integrated blood supply system needs competent and committed leadership and an appropriate budget to allow accessibility and affordability of haemotherapy, based on a proper and documented needs assessment. The financing system should be an integral part of a national health financing system based on cost recovery and a healthy insurance policy accessible and affordable for all citizens (WHO 2008, van Hulst et al. 2006).

¹ GMP = Good Manufacturing Practice, GLP = Good Laboratory Practice, GCP = Good Clinical Practice

The framework of such an integrated blood supply system could be based on the seven key elements (figure 4) as follows:

1. Organization and structure, including the necessary infrastructure to be strengthened and further developed. This element includes the development of an appropriate and implementable formal regulatory structure, development of a system of regional blood banks based on a sufficient economy of scale to become cost-effective. These institutions preferably should be part of a nationally coordinated blood transfusion service responsible for policy making, design of the necessary strategies, annual planning, the development of a national quality and quality management system based on internationally accepted standards and product specifications. Such quality and quality management system will have a uniform documentation system, which allows for the possibility of instituting a nation-wide ICT system for data management. The organization should have sufficient autonomy to operate its services. As the organization produces products (collection, processing and testing, storage and distribution) for clinical use, it is automatically product liable and should therefore operate independently from hospitals. Hospitals use the products for specific haemotherapy in patients and therefore have the legal obligation to protect consumer rights, which cannot be combined with product liability under the same final responsibility (conflict of interest). Another aspect of this first element is the need to develop appropriate and cGMP compliant working facilities, that guarantee a working environment that allows high quality operations to be performed by staff.
2. Clinical use needs full attention to develop evidence based transfusion practices all over the country. That means assessment of the current clinical practices and development of an in-hospital transfusion quality and quality management system. Hospitals will be supplied by regional procurement centers (blood centres) with a working stock that will be based on an inventory of actual needs per discipline – paediatrics, obstetrics, surgery and traumatology and haemato-oncology. The development of a well functioning clinical interface will lead to the change from the currently prevalent supply driven system to a demand driven system, based on mutual respect and understanding and key to the supplier-customer principle of quality operations (Kajja 2010).
3. Processing and testing of all units of blood collected will allow an efficient use of the blood collected and contribute to rational use of blood through component therapy. Testing for the key TTI markers (HIV, HBV, HCV and Syphilis) needs to be instituted with appropriate and standardized technology and methodology. Here, economies of scale are paramount to guarantee consistency of performance and cost containment. Where epidemiology indicates, additional tests can be considered such as brucellosis, Chagas or malaria. As screening tests focus on sensitivity, a system for confirmation needs to be developed at the national level – a reference laboratory that also could perform test kit and reagent validation before implementation is needed. Along with the development of component production, in-process quality control of the produced half and finished products (testing for standardized and uniform product specifications) will be part of the program.
4. Collection of source material – human blood or plasma – from voluntary non-remunerated and preferably regular blood donors, motivated and mobilized from identified low-risk groups in the community. This requires development of public awareness based on social marketing. The currently prevalent supply driven system of

the blood supply needs to be developed into a demand driven system, which means the availability of motivated potential donors willing to be mobilized to allow a balanced blood stock that is managed and the development of a contingency plan. Donor selection needs to be standardized and adjusted to internationally recommended minimum requirements for donor suitability.

5. Education (teaching and training) is the cornerstone of capacity building. A national assessment and inventory of available education (institutions, curricula) needs to be carried out to allow the development of an effective approach towards capacity building and human resource development at all levels involved. The in-country approach will focus on leadership development (senior and middle management) and development of operational competencies (professional knowledge and skills) through various education methodologies to allow larger groups of staff to benefit.
6. Monitoring and evaluation follows the implementation of a national quality and quality management system based on uniform documentation of what is being done, both at the management level (management information system) as well as at the operational level through an automated data processing system (ICT) with communication between all centres and the national Head Quarter and Ministry of Health. Use of simple statistical evaluation technology such as statistical process control (SPC) and application of Six Sigma (Gygi et al., 2005) will allow proper benchmarking focused on improvement through trend analysis. A nationwide compatible ICT system would allow proper quality management through coordinated monitoring and evaluation of uniform data collected through regional centres and hospitals (vein-to-vein).
7. Sustainability is not only dependent on financial resources, but comprehensively relates to all six elements as described above – organizational structure and infrastructure, competent and adequate human resources, a reliable and regular voluntary blood donor panel, a standardized procurement process, evidence based rational use of blood components and alternatives, and quality assurance through proper monitoring of set indicators and their evaluation through benchmarking focused on improvement. This follows the principle of the Deming cycle of improvement – **plan** (policy and strategies), **do** (implementation of managerial and operational processes), **check** (monitoring of the indicators/specifications and accurate data collection through documentation), **act** (evaluation of the collected data and the benchmarking).

1.3 Basics of the clinical use of blood

The clinical use of blood represents both the starting and the closing end of the demand and supply loop. Therefore, it does not make much sense to develop only the clinical interface if the basics of proper procurement (collection, processing and testing, storage and distribution), based on international principles (1948 UN Declaration of Universal Human Rights, 1975 WHA28/72 Utilization and Supply of Human Blood and Blood Products, International Red Cross and ISBT Code of Ethics) are not in place.

The in-hospital transfusion chain should include process analysis, process descriptions, related SOPs and operational documents such as a standard (national) blood request form, a standard compatibility test form, a transfusion outcome form, clinical guidelines and a haemovigilance report form (Kajja 2010).

The in-hospital transfusion chain consists of three distinctive processes, each containing a number of procedures, critical control points (CCPs/decisions) and documentation. (figure 5)

Each of these processes has a series of procedures and related documentation that needs to be developed:

1. The *blood ordering process* (ward/bedside) starts at the bedside with indication setting and decision making resulting in a standardized request and accompanying blood sample for compatibility testing. Traceability (documentation) is paramount to prevent adverse transfusion reactions due to clerical errors of identification (wrong blood in tube). It consists of six steps or procedures (diagnosis, indication, decision to transfuse or use alternatives, ordering, sample taking and transportation) and two operational documents (blood request form and sample label);
2. The *blood selection process* (laboratory) of blood components as requested and compatibility testing. It should be noted that compatibility testing is a laboratory diagnostic procedure. The blood selection process consists of four steps or procedures (reception and registration of request and sample, selection of blood, compatibility testing and transportation) and two operational documents (logbook and cross match form);
3. The *bedside transfusion process* (ward/bedside) of the selected units at the bedside, which needs careful identification of units and recipient (match), and the technical handling and observation of the transfusion, carried out by nursing staff and based on proper and uniform standard operating procedures with appropriate documentation to allow evaluation necessary to develop evidence based practice. It consists of two sub-processes:
 - a. The preparation of the patient and the unit of blood before the transfusion – three steps or procedures (reception at the ward, patient and unit identification, vital signs);
 - b. Transfusion and observation of the patient – four steps or procedures (connection to the patient, immediate observation, transfusion or discontinuation, observation of outcome).

These processes are closely interrelated, though distinctly different. The following steps are involved in the process:

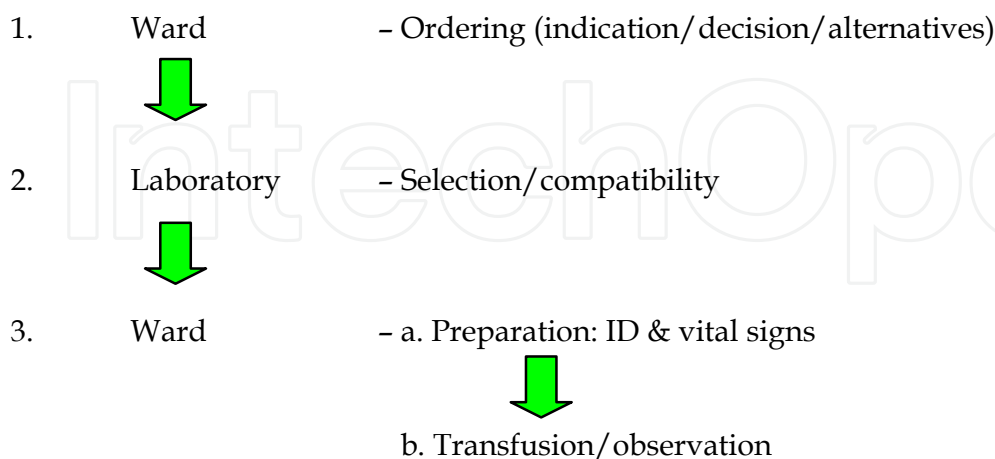


Fig. 5. In-hospital transfusion flow of steps.

Clinicians and nursing staff need to be trained in these steps and the related quality assurance and documentation to develop a proper and standardized monitoring and evaluation evidence based transfusion practice. To create ownership among the prescribing

clinicians and nursing staff education should focus on consensus on items such as a uniform blood request form, terms of reference of a Hospital Transfusion Committee (HTC) and the outline of clinical guidelines (general and per prescribing discipline).

1.4 Gaps in the blood supply and clinical use

In many developing countries blood transfusion in the vein-to-vein concept is still in its first or second generation stage. This means that blood is most often collected and transfused in the absence of a formal policy environment and without adequate regulatory controls or standards. In such systems, blood collection and utilization are fragmented, often dependent on independent factors limited to specific hospitals, such as the availability of trained and competent staff, funds for procurement, and a population of blood donors willing to come on a voluntary and regular basis.

Following the vein-to-vein transfusion chain, major gaps exist in the following areas:

1. Organization and infrastructure -
 - a. Legal and regulatory frameworks are often outdated or do not exist.
 - b. Commitment of health authorities is lacking or isolated in fragmented centres.
 - c. Management capacity to sustain blood collection, storage, testing and transfusion services differs from routine hospital or laboratory management.
 - d. Organization and infrastructure for blood services requires national and facility-specific assessments and inputs.
 - e. Chain of command and clear job descriptions contribute to quality control, stock management, and career development.
 - f. Quality culture and professional discipline are dependent on successful pre-service and on-going in-service training opportunities.
 - g. Poor hygiene and waste management may contribute to broader infection control problems within a facility and the local community.
2. Clinical use -
 - a. Clinical awareness and accountability among clinicians is essential to avoid unnecessary transfusions and preserve limited blood stocks.
 - b. Improper indication setting and decision making may increase transfusion recipients' risk.
 - c. Informed consent of patients can create additional ethical and legal challenges for a facility when not obtained properly (Kajja et al. 2011)
 - d. Poor documentation and traceability contribute to wastage; may facilitate fraud, and; create barriers to appropriate epidemiological follow-up and tracing in the event of an adverse transfusion event.
 - e. Communication and understanding between suppliers and users is essential to ensure that suppliers (i.e., blood donors) contribute based on a humanitarian impulse, not one based on personal gain, and that users (patients and clinicians) recognize and consent to the risks related to transfusion.
3. Processing and testing -
 - a. Standards of processing and quality control are a crucial line of defense in patient safety and preventing unnecessary wastage.
 - b. Inconsistent supply logistics can interrupt quality-associated work routines, contribute to unnecessary wastage (out-dating and cold chain spoilage) and promote unequal service between regions or facilities (Kajja et al. 2010a, 2010b)

4. Collection of source material (community interface) –
 - a. Community awareness about the need for blood and the risks of disease transmission via transfusion are essential to mobilize a safe donor pool.
 - b. Types of blood donors must be actively motivated, selected and screened for safety.
5. Education –
 - a. Education and staff competency: The basis for a quality assured and sustained system. (Smit Sibinga, 2009a)
6. Monitoring and evaluation –
 - a. Applied research in the field of transfusion medicine through proper monitoring and evaluation (M&E) and continued statistical process control (SPC) can contribute to improved operations as well as global understanding of risks, barriers and best practices (Smit Sibinga, 2009b).

2. Principles and ethical aspects of blood donation and transfusion - How do these elements promote blood safety?

Like other medical specializations, the practice of transfusion medicine is bound by the ancient Greek Hippocratic mandate *Primum est non nocere* (first, do no harm). However, for transfusion specialists, this principle is not limited to the transfusion itself or to the recipient of the transfusion. Rather, it applies to a long chain of ethical decisions that stretches from the motivation of potential donors whose blood is used for transfusions to post-transfusion follow-up. This section will describe and explain how each link in this chain contributes to a safe blood supply and to safe transfusion practice.

2.1 Ethical aspects of blood donation

A brief history of blood donation and transfusion ethics

The ethical principles that govern the modern vein-to-vein transfusion system were developed relatively recently, that is to say, largely within the second half of the 20th century, when the science of transfusion medicine became an accepted and routine part of medical practice. (American College of Physicians [ACP], 1984) Indeed, from the 17th century, when physicians began experimenting with transfusing animal blood into humans, through the late 19th and early 20th century when blood groups were discovered and coagulation factors described, the field of transfusion medicine was marked by experimentation, trial and error, and few human subjects protections. (Feldschuh, 1990; McCullough, 1998; Kendrick, n.d.) The 1948 Nuremberg Code established a global framework for medical ethics following the atrocities committed by Nazi doctors during the Second World War. In Europe and North America, laws covering ethical concepts such as the requirement that patients give informed consent prior to medical procedures began to emerge in the 1950s and 1960s. (ACP, 1984) In the mid-1930s, the founding of the International Society of Blood Transfusion (ISBT), created a global forum for the development of specific ethical guidelines for the practice of blood transfusion. Two decades later, in 1955, the International Federation of Blood Donor Organizations (FIODS) was established to focus attention on ethical guidelines for the donation of blood and plasma. Both entities, as well as authors such as Richard Titmuss (*The Gift Relationship: From Human Blood to Social Policy*, 1971) (Titmuss, 1971), contributed to a body of ethical work that led to the 1975 World Health Assembly resolution containing global recommendations

for ethical blood donations and transfusions (WHA 28.72). Those recommendations included the following key elements of transfusion ethics:

1. Blood donations should be voluntary and unpaid.
2. Countries should collect an adequate supply of blood to be self-sufficient.
3. Countries should develop legislation and supporting regulations to monitor and control the quality of blood collections, blood service laboratory operations (infectious disease screening, compatibility testing, production of blood products), and transfusion practice.

These recommendations seem especially prescient following the emergence of the HIV/AIDS epidemic in the 1980s, and the identification of blood transfusion as a significant route of HIV infection (US CDC, 1982). Between 1980 and 2000, the ISBT and WHO refined and adapted these original principles into a global code of ethics whose purpose was “to define the ethical principles and rules to be observed in the field of Transfusion Medicine.” The ISBT code of ethics is discussed in detail below. Most countries worldwide have blood policies based on these fundamental principles (WHO, 2011a). Since 2000, these principles have guided numerous global resolutions related to HIV prevention and the emerging donor-supported field of ‘blood safety’. (PEPFAR, 2005-2010; WHO, 2011b)

‘Safe blood starts with me’. This commonly used blood donor motivation slogan captures one of the principal ethical issues in blood donation, namely that donors share an equal burden of responsibility with blood services to ensure the safety of the blood supply (Grainger et al., 1997). As the sole source of blood for transfusion, donors are indispensable. Yet, donors also have rights that must be respected and are, more critically, the principal vector for transfusion-transmissible infections. Ensuring the safety of donated blood, therefore, requires a balanced, combination approach, including active, education-based and non-coercive social mobilization practices by transfusion services and donation centres, and the *active and honest* participation of donors in the pre-donation screening process.

The ISBT Code of Ethics (2000, 2006 revision) contains 11 principles that expand on these concepts, especially as they relate to donor health and safety, donors’ right to anonymity or confidentiality during and after donation, and donors’ *ethical responsibility* not to donate if they believe their blood may be infected with HIV or another blood-borne pathogen.

The ISBT code can be collapsed into a chain with four basic links. This pre-donation chain describes the individual links that protect donors and the recipients of donated blood. As noted above, each of these links contributes to blood safety in a different way.

Link 1: Mobilizing blood donors without coercion

Identifying, mobilizing, educating, motivating and retaining an adequate pool of eligible and willing blood donors is the primary challenge faced by blood transfusion services worldwide. The problem is especially serious in the developing world, where public awareness of blood transfusion is low (Elhence, 2006), traditional or cultural beliefs about blood may serve as powerful disincentives to blood donation (Umeora et al., 2005), and high population prevalence rates for HIV and other TTIs may be a barrier to blood donor appeals to the general public (McFarland et al., 1998). In countries with serious blood shortages, the impulse to pay or coerce blood donors can be powerful (Parry, 1984). But since the 1980s, prompted largely by concerns about transfusion-transmitted hepatitis and HIV, blood services in the developed world have largely adopted policies promoting voluntary and anonymous blood donation and prohibiting or limiting the payment of donors (ISBT,

2006b).² In the developing world, national blood policies developed since 2000 increasingly reflect World Health Organization recommendations that call for blood donors to act on an altruistic impulse, not in exchange for money or other kinds of compensation, and for blood services to mobilize *voluntary, non-remunerated* donors. The WHO Aide-Mémoire on establishing national blood transfusion services considers this practice '*the foundation of a safe and adequate blood supply.*' (WHO, 2011c)

The ISBT Code of Ethics (2006 revision)

Blood Centers: Donors and Donation

(International Society for Blood Transfusion [ISBT], 2006a)

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonable needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation. The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.
2. A profit motive should not be the basis for the establishment and running of a blood service.
3. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.
4. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.
5. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.

² Exceptions exist to this general trend, most notably in paid plasma donations in the United States. Other developed countries provide financial or material compensation to donors, or have laws granting blood donors time off from work in exchange for donations. (European Commission, 2003, as cited in Farrugia et al., 2010; U.S. Food and Drug Administration, 2002) While the push for 100% voluntary, non-remunerated blood donations in developing countries has been shown to effectively screen out donors at high risk of infection with HIV or other transfusion-transmissible infections (Sarkodie et al., 2001), an emerging body of evidence suggests that some donors who act for reasons other than personal altruism – for instance, family members or others who donate in emergencies or to replace blood units – may present no greater risk to the blood supply than first-time volunteer donors (Allain et al., 2009; Diarra et al., 2009). Indeed, WHO and others stress the importance of motivating and retaining repeat donors '*who give blood regularly*', as the best way to screen out potential donors with a high behavioural risk profile. Yet, despite regular reinforcement of this global guidance, many services continue to provide or experiment with some forms of remuneration for blood donors, e.g., cholesterol screening (Glynn et al., 2003), distribution of lottery ticket (Stutzer & Goette, 2010), or transportation to and from the donation clinic (ISBT, 2006). These divergent findings pose a substantial ethical challenge for blood service managers faced with a limited pool of willing blood donors and unmet demand for blood.

6. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.
7. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
8. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.
9. Donors and recipients should be informed if they have been harmed.
10. Blood is a public resource and access should not be restricted.
11. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

Link 2: Education is key

Worldwide, the public must be educated to understand that blood donation supports the collective good – that a unit donated today could save the life of a neighbour, a friend, a loved one, a stranger, or even the donor himself, tomorrow (*'today me, tomorrow you'*). But donors must also be educated about the risks associated with donation, both for the donor and for the recipient of donated blood. Education materials and programs should emphasize two main areas of risk and consent.

Risks to the donor and consent required prior to donation:

- The potential for syncope (fainting), hyperventilation, bruising or damage to veins during the veinipuncture process.
- Since most countries test or strive to test 100% of donated blood for pathogens such as HIV, hepatitis B and C, and syphilis, donors must be informed of these tests and given an opportunity to receive their results with appropriate counselling. In South Africa, the South African National Blood Service (SANBS) includes a clear statement about testing and the potential emotional impact on donors: *'Every blood donation is tested for HIV/AIDS. Persons testing positive must be aware that this may have a psychological impact and profoundly influence their lifestyle.'* (South African National Blood Service [SANBS], 2006)

Risks to recipients of donated blood:

- Transmission of infectious pathogens, including HIV.
- Other adverse transfusion events, e.g. circulatory overload, TRALI, mis-matched blood group, allogenic reactions.

Social mobilization and donor education campaigns will differ depending on the target audience. In many developing countries, youth, especially high-school students, contribute a substantial proportion of the national blood supply (Jacobs et al., 1994). However, it should be noted that donation camps at schools usually are based on coercion through the school authorities. (Los et al., 2009) In addition to confirming the voluntary nature of school-based donations, blood services must also study the epidemiology of HIV and other transfusion-transmissible infections among school-aged donors to ensure that this group actually carries a lower risk of infection compared to the general population. Over the last 10 years, several successful models to promote blood donation among youth have been established worldwide. These include the Club 25 model created by the International Federation of Red Cross and Red Crescent Societies (See: <http://www.ifrc.org/en/what-we-do/health/blood-services/international-club-25-new-blood-for-the-world/>) and the annual WHO-sponsored World Blood Donor Day on June 14, the birthday of Karl Landsteiner.

Link 3: Pre-donation counselling and behavioural risk screening

Pre-donation screening occurs after a donor has decided to make a donation, but before the blood is collected. The use of behavioural screening – also often referred to as self-exclusion screening – allows donors a confidential space in which to reflect on their behavioural risk profile and to weigh the consequences of a contaminated donation, especially donations that carry a high risk of infection with HIV. Behavioural questionnaires provide the blood service with information about lifestyle practices that could increase the donor's risk of carrying a TTI, and work-related information (e.g. do you operate heavy equipment?) that could create a safety hazard for the donor immediately after a donation. Questionnaires also provide information on medicines the donor is taking or other health conditions that could cause adverse reactions in the transfusion recipient or an adverse reaction for the donor (e.g. dizziness or fainting).

In most countries, pre-donation screening includes a written questionnaire and a face-to-face interview with a trained nurse or a donor counsellor. Questionnaires should ask donors simple, yet direct, questions about their general health and lifestyle, especially risky sexual practices. The following questions, drawn from the South African National Blood Service (SANBS) pre-donation questionnaire, are representative of the kinds of behavioural questions donors should be asked in confidence prior to a donation:

- Have you ever been refused as a blood donor, or told not to donate?
- In the past six months have you had sexual activity with or without a condom: With more than one sex partner? With a regular sex partner excluding your spouse? With someone whose sexual background you do not know?
- In the past six months have you: Had sexual activity with a prostitute or anyone else who takes money or drugs or other favours for sex? Received money, drugs or other payment for sex? Been a victim of a sexual assault?
- Male donors: In the past 6 months have you had oral or anal sex with another man with or without a condom?
- In the past 12 months: Have you had a sexually transmitted disease (STD) e.g. syphilis, gonorrhoea, genital ulcers, VD or 'drop'?
- Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor or a nurse?
- Do you think your blood is safe for transfusion to a patient?
- To your knowledge does your sex partner have other sex partners?

While the safety rationale justifies this kind of intrusive personal questioning, some automatic exclusion criteria, notably YES answers to questions about homosexual sex, have sparked ethical debates about the fairness of excluding donors on the basis of sexual orientation (Martucci, 2010).

Link 4: Laboratory screening

The WHO Aide Mémoire for National Blood Programmes encourages '*testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing.*' However, this WHO recommendation must not be viewed in isolation. Indeed, the Aide Mémoire and other WHO guidance stresses that laboratory screening must be part of an '*integrated strategy*' that includes the mobilization of low behavioural risk voluntary, non-remunerated donors, a quality assurance system within the laboratory, and the reduction of unnecessary transfusions (WHO, 2011a). Research from high HIV prevalence countries in

Africa has shown this integrated approach can have a positive impact on reducing the number of donations with incident or 'window period' HIV infections that the antigen/antibody assays used in most developing countries might not detect (Basavaraju, 2010).

The 2010 WHO Guidelines on Screening Donated Blood for Transfusion-Transmissible Infections recognize that operational limitations (*lack of coordination ... inadequate infrastructure ... shortages of trained staff ... poor quality systems*) may prohibit some blood services from screening all donated units, or create barriers to the implementation of a coordinated, integrated laboratory screening program. The guidelines identify the following negative outcomes that may occur when laboratory screening systems do not exist or fail:

- Inefficient screening systems and wastage of resources owing to differing levels of operation at multiple sites
- Lack of quality assurance and quality management systems
- Use of poor quality test kits and reagents
- Unreliable, inconsistent supplies and transport conditions of test kits and reagents due to poor logistics
- Equipment failure
- Variations in laboratory procedures and practices
- Double standards due to a mix of technologies and methodologies
- Incorrect storage or inappropriate use of test kits and reagents
- Inadequate procedures for identification, leading to the misidentification of patient or donor blood samples, donations or processed units of blood and blood components
- Technical failure in testing
- Misinterpretation of test results
- Inaccuracies in the recording or transcription of test results.
- Higher error rates in test results
- Increased risk of failure to detect TTIs
- Unnecessary hold time due to poor access to confirmatory tests
- Unnecessary discard of non-reactive blood
- Blood shortages and use of unscreened blood in urgent situations
- Incorrect donor notification and stigmatization. (WHO, 2009)

2.2 Ethical aspects of blood transfusion

As noted in section 1.2, Article 25 of the 1948 UN Declaration of Universal Human Rights (DUHR) makes reference to individuals' *'right to security in the event of ... sickness, disability ... or other lack of livelihood in circumstances beyond his control.'* The principle of obtaining patient consent prior to performing a blood transfusion or other medical procedure is derived from the broad concepts of *health and security ... in the event of sickness* described in the DUHR. Subsequent codes of medical ethics, including the Council of Europe's 2007 revision of its Guide to the Preparation, Use and Quality Assurance of Blood Components; these codes expanded on this basic definition of 'security' to cover all of the decisions preceding, during, and following a transfusion: From confirming the appropriate diagnosis and prescription order, to correct patient identification and adverse event monitoring during the transfusion itself. (Council of Europe, 2007) Occasionally, prescribers of blood will encounter patients who refuse a recommended transfusion on religious grounds. Clinicians may also face difficult decisions with patients who are minors and patients for whom a transfusion may extend life but not necessarily improve the quality of the patient's life; the creation of

institutional ethics committees within hospitals and transfusion centres is recommended to educate staff about ethical issues; support ethical decision-making; develop ethics codes and policies, and; counsel staff and conduct ethical reviews (Perlin, 2001; Kajja et al. 2011).

Ethical considerations continue even after a successful transfusion, most notably in cases where recipients become infected with a transfusion-transmissible infection, or are deemed at risk of infection because new information about the donor of the transfused unit comes to light (e.g. HIV sero-conversion in the donor).

The ISBT code of ethics for hospitals and patients contains seven key principles related to the transfusion of blood and blood products.

ISBT Code of Ethics for Hospitals and Patients

(International Society for Blood Transfusion [ISBT], 2006a)

1. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.
2. In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.
3. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.
4. Genuine clinical need should be the only basis for transfusion therapy.
5. There should be no financial incentive to prescribe a blood transfusion.
6. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.
7. Blood transfusion practices established by national or international health bodies and other agencies competent and authorised to do so should be in compliance with this code of ethics.

It should be noted that these seven principles are predicated on an assumption that the ethical principles related to blood donors and the screening of blood for transfusion-transmissible infections have been respected. As with the ethical framework for blood donations, these principles can contribute to reduced risks of transfusion-transmissible infections by reducing or minimizing the number of inappropriate transfusions.

3. Assessment techniques and methodologies: Identifying and addressing gaps and needs in blood safety programs and blood transfusion services

Understanding the roles and responsibilities associated with the various departments and job descriptions within a blood transfusion service is a complex task, involving layers of policy, science, human behaviour, risk, ethics, finances, and, ultimately, medical practice. Further identifying gaps, risks and needs within each (or all) of these layers, is an additional step that blood transfusion services must take in order to address weaknesses, strengthen services, recruit and/or retain staff, improve quality and evaluate the impact of services and products provided to transfusion centres or hospitals and patients. The ultimate goal of these objectives is to improve the safety of blood and blood products used for transfusion. The U.S. Food and Drug Administration cites the '*safety, purity, and potency*' of blood products as the main rationale for conducting blood service quality audits and assessments (Food and Drug Administration, 2010).

To accomplish assessment and evaluation objectives, blood services may use a number of assessment and evaluation tools, many of which are drawn from business practices (e.g. Six Sigma, Total Quality Management, SWOT analyses) or the field of risk analysis. International organizations (WHO, ISBT, the IFRCRCS), national blood transfusion services, regulatory agencies, and Red Cross/Red Crescent Societies, as well as multilateral and bilateral donors (e.g. the European Union, the U.S. President's Emergency Plan for AIDS Relief, the Japan International Cooperation Agency) have also developed assessment tools and indicators to assist with the development, implementation and monitoring of blood safety projects and programs.

The field of evaluation has evolved and expanded substantially in the last 20 years. A recent PubMed literature search found nearly 250,000 papers dedicated to public health evaluations or assessments within the last decade. Beyond the scientific literature, thousands of programme reports, guides and other documents in the 'gray literature' are published each year. This massive diversity of material includes many different methodologies, some of which have been used by blood transfusion services to monitor, evaluate, assess or audit (Chevrolle et al., 2000) human resource needs (Ferrera et al., 2001), blood banking, stock management, laboratory and transfusion practices (Fretz, 2003; Dosunmu & Dada, 2005), training curricula (Wehrli, 2011), epidemiological surveillance (Roussel et al; Linden & Bianco, 2001), and quality systems (Berte, 1997; Mintz, 1995; Smit Sibinga, 2001).

This chapter will review the basic elements these tools are designed off to assess, monitor and evaluate. Examples derived from specific tools and indicators, such as the WHO Global Database on Blood Safety, will be presented to highlight the utility of assessment and evaluation in the development of strong blood transfusion services, especially in areas with high burdens of HIV and other transfusion-transmissible infections.

As mentioned above in section 1.2, blood services worldwide are built around a framework with seven basic components, each of which can be evaluated through techniques such as SWOT analyses (Strengths-Weaknesses-Opportunities-Threats), and addressed with the principles of the Deming cycle of improvement (Plan-Do-Check-Act):

1. Structure and organization
2. Clinical use of blood
3. Processing and testing
4. Blood collections
5. Education and Training
6. Monitoring and Evaluation
7. Sustainability

Within each of these elements, WHO and other blood safety technical assistance programs have developed assessment indicators to help blood services identify needs, gaps and risks.

3.1 The WHO global database on blood safety

A good place to begin to make sense of the diversity of available materials is the WHO Global Database on Blood Safety (GDBS). The GDBS was developed by WHO with expert input through the Global Collaboration on Blood Safety (GCBS) and launched in 1998. WHO member countries are asked to submit data to the GDBS every two years. The indicators collected by the GDBS are periodically revised and increasingly reflect collaborative work between WHO and development partners supporting blood safety programmes in countries.

The GDBS questionnaire contains 253 process, outcome and output indicators clustered around eight operational and technical areas (WHO, 2011d) :

1. Administrative Information
2. Organization and Management
3. Blood Donors and Blood Collection
4. Screening for Transfusion-Transmissible Infections
5. Blood Group Serology Testing of Blood Donations
6. Blood Component Preparation, Storage and Transportation
7. Hospital Transfusion Process and Clinical Use of Blood & Blood Components
8. Fractionated Plasma Products

Since its launch, WHO has received and compiled three reports (1998-1999; 2001-2002; 2004-2005); data collection for a fourth report was begun in 2008.

3.1.1 Mind the gaps – Recent GDBS findings

The identification of blood transfusion as a significant vector for HIV transmission in Africa in the 1990s (Colbunders, 1991) led to increasing attention and financing for blood safety programmes via global health programmes focused on HIV prevention.³ As noted above, the epidemiology of transfusion-transmitted HIV also drove the passage of World Health Assembly (WHA) resolutions on the blood safety, and the development, over the last decade, of WHO's catalogue of blood safety guidelines and recommendations. In many countries this increased attention to blood safety as part of a comprehensive HIV prevention strategy has strengthened the whole national blood service – from vein-to-vein – in addition to reducing the transmission of HIV through transfusion. Still, despite progress, transfusion systems remain weak in many countries, especially those in the lower income strata. The most recent GDBS report (2004-2005) highlighted a number of these weaknesses, including:

- Less than 50% of countries report collecting blood exclusively from voluntary, non-remunerated blood donors.
- 40% of the 172 countries surveyed, reported having national haemovigilance systems.
- 53% reported having national regulatory bodies for blood transfusion.
- 80% of the world's population live in countries that collect only 45% of the global blood supply.

3.1.2 Addressing gaps – Achieving change

Experience and evidence from the field over the last decade has shown that blood services in countries with high prevalence HIV have been able to systematically reduce the prevalence of HIV in donated blood units by identifying and addressing gaps and weaknesses in their operations and structures. In 2008, the U.S. Centers for Disease Control and Prevention (CDC) presented data from the PEPFAR blood safety program that showed substantial gaps in the legislative and policy frameworks in 14 countries in sub-Saharan Africa and the Caribbean (US CDC, 2008).

Using indicators adapted from the WHO GDBS, CDC asked countries if a national blood policy was in place or if the national blood transfusion service (NBTS) was supported by a 'legislative framework' (e.g. laws and regulations). In 2003, only six of the 14 countries

³ Half of the 101 countries that responded to a GDBS question about external support for their blood services indicated that they were receiving some kind of international assistance in 2004-2005.

reported having a national blood policy; the same year only four of the 14 countries reported having a 'legislative framework' to support NBTS activities. By 2007, all 14 countries had national blood policies in place or in development, and 10 of 14 countries had established or were developing 'legislative frameworks' based on WHO blood safety guidelines. (Table 1)

Country	Established national policy		Enacted legislative framework		No. of whole blood units collected					No. of whole blood units collected per 1,000 population†				
	2003	2007	2003	2007	2003	2004	2005	2006	2007	2003	2004	2005	2006	2007
Botswana	Yes	Yes	No	No	11,583	13,210	20,643	21,061	22,230	6.4	7.3	11.2	11.2	11.6
Côte d'Ivoire	Yes	Yes	Yes	Yes	67,780	77,972	86,321	86,082	92,009	3.8	4.3	4.6	4.5	4.8
Ethiopia‡	No	Yes	No	No	17,208	17,941	19,203	21,019	22,220	0.2	0.2	0.2	0.3	0.3
Guyana	Yes	Yes	No	In development	4,008	4,896	4,531	5,192	5,475	5.4	6.6	6.1	7.1	7.5
Haiti	No	Yes	No	In development	8,711	9,513	10,823	13,622	17,094	1.0	1.0	1.2	1.4	1.8
Kenya	Yes	Yes	Yes	Yes	40,857	47,661	80,762	113,080	123,787	1.2	1.4	2.3	3.1	3.3
Mozambique	No	In development	No	In development	67,105	69,648	76,667	72,170	79,925	3.4	3.5	3.8	3.5	3.8
Namibia	No	Yes	No	In development	17,860	19,154	19,133	18,422	18,309	9.1	9.6	9.5	9.0	8.9
Nigeria¶	No	Yes	No	Yes	—	—	1,266	5,519	16,987	—	—	<0.1	<0.1	0.1
Rwanda	No	Yes	No	No	30,786	28,777	37,893	38,539	32,543	3.5	3.2	4.1	4.1	3.3
South Africa**	Yes	Yes	Yes	Yes	809,322	813,239	805,923	822,950	821,258	17.3	17.2	16.9	17.2	17.0
Tanzania¶	No	Yes	No	In development	—	—	12,597	63,411	109,471	—	—	0.3	1.6	2.7
Uganda	Yes	Yes	Yes	Yes	102,703	106,996	115,988	122,442	133,585	3.8	3.8	4.0	4.1	4.3
Zambia	No	In development	No	In development	40,616	38,477	61,982	54,308	68,056	3.7	3.4	5.4	4.6	5.7

* As described in: World Health Organization. Aide-memoire for national blood programmes. Geneva, Switzerland: World Health Organization; 2002. Available at http://www.who.int/bloodsafety/transfusion_services/en/Blood_Safety_Eng.pdf.

† Based on United Nations Population Division census estimates for 2003–2007.

‡ Ethiopia Red Cross Society is the designated national blood transfusion service.

¶ Nigeria and Tanzania established their national blood transfusion services in 2004. The first year with 12 complete months of data available was 2005.

** Includes data from South Africa National Blood Service and Western Province Blood Service.

Table 1. Standards of national blood transfusion policies and legislative frameworks, number of whole blood units collected, and number collected per 1,000 population – U.S. President's Emergency Plan for AIDS Relief, 14 countries, 2003–2007

Country	% of persons with HIV infection*		% of blood collections reactive for HIV					% of blood collections received from voluntary, non-remunerated donors				
	2001	2007	2003	2004	2005	2006	2007	2003	2004	2005	2006	2007
Botswana	26.5	23.9	7.5	5.7	4.0	2.7	2.1	100	100	100	100	100
Côte d'Ivoire	6.0	3.9	1.6	1.4	1.5	1.4	1.2	100	100	100	100	100
Ethiopia†	2.4	2.1	—	3.6	3.4	2.5	3.0	38.8	27.5	23.2	28.1	28.4
Guyana	2.5	2.5	0.8	0.6	1.0	0.6	0.3	21.7	18.9	26.1	31.2	61.1
Haiti	2.2	2.2	1.7	1.8	1.6	1.9	1.4	5.2	5.4	14.9	27.4	51.9
Kenya	8.1	7.8§	1.5	1.7	1.9	2.5	1.2	99.0	95.3	97.6	98.9	99.5
Mozambique	10.3	12.5	8.6	6.9	6.4	8.3	7.2	58.0	58.3	59.6	52.0	72.3
Namibia	14.6	15.3	0.7	0.6	0.6	0.5	0.6	100	100	100	100	100
Nigeria¶	3.2	3.1	—	—	3.8	3.5	2.5	—	—	100	100	92.3
Rwanda	4.3	2.8	1.1	0.1	1.2	0.9	0.5	100	100	100	100	100
South Africa**	16.9	18.1	<0.1	<0.1	<0.1	<0.1	0.1	100	100	100	100	100
Tanzania¶	7.0	6.2	—	—	4.8	3.2	2.8	—	—	66.5	80.0	89.2
Uganda	7.9	5.4	2.0	1.9	1.6	1.5	1.3	95.5	96.3	99.0	99.9	100
Zambia	15.4	15.2	6.9	6.4	9.0	6.4	3.8	72.7	71.2	90.6	97.9	99.6

* Estimates from the Joint United Nations Programme on HIV/AIDS (UNAIDS), available at http://data.unaids.org/pub/globalreport/2008/jc1510_2008_global_report_pp211_234_en.pdf. Because UNAIDS methodology used to estimate 2003 prevalence was different from the methodology used for 2007, data are presented for 2001, the most recent pre-program year for which the same methodology was used as for 2007.

† Ethiopia Red Cross Society is the designated national blood transfusion service.

§ Preliminary estimate.

¶ Nigeria and Tanzania established their national blood transfusion services in 2004. The first year with 12 complete months of data available was 2005.

** Includes data from South Africa National Blood Service and Western Province Blood Service. Autologous donations and collections from designated donors are reported as donations from voluntary, non-remunerated donors.

Table 2. Estimated percentage of persons aged 15–49 years with human immunodeficiency virus (HIV) infection, percentage of blood collections reactive for HIV, and percentage of collections from voluntary, non-remunerated donors – U.S. President's Emergency Plan for AIDS Relief, 14 countries, 2003–2007

During the same four year period, all 14 countries reported lower or stable rates of HIV prevalence in donated units (Table 2).

Although a strict causal association cannot be derived (Noumsi et al., 2008) from these data, this report suggests a positive relationship between progress toward addressing policy and other operational gaps and improvements in the safety of donated blood for supportive haemotherapy.

4. Evidence based strategies to move from a supply-driven to a demand-driven blood transfusion system

4.1 Community specifics for tailor made solutions

In the majority of economically restricted countries the transfusion chain from vein-to-vein is determined by what happens to be available. The supply drives the system. When a clinical need occurs, either the scarce hospital or blood bank stock is being used and exhausted or family is urged to search for blood donors, whether family related, friends or what the market offers. Often that results in under-treatment of patients, unjustified use or no treatment at all. The data available for mother and infant death due to shortages illustrate this situation (WHO et al. 2010).

Most of these donors are seriously coerced, time pressure stimulates poor handling and the serious and realistic effect of transmission of infections such as HIV, HBV and HCV. Besides, it has been observed and documented that hidden stocks are being kept or just grow due to shortage in organization and poor logistics of the supply (Kajja I et al., 2010a). The chain quite often is interrupted at the clinical interface side, with a serious paucity of communication between producer/supplier and prescriber/consumer of blood and blood components. The root cause of this paucity is in limited and focused knowledge and related practices on either side of the chain. When regular need assessments are being done a better idea would grow about the epidemiology of blood transfusion in the hospitals, which then could lead to balanced and evidence based logistics of supply of human blood in anticipation of the needs.

As a consequence the blood supply and clinical use should be firmly embedded in the health care system with major involvement of the community to allow such anticipatory strategies. Community involvement means community education to understand why a continuous and not an incidental and *ad hoc* support is needed (Los & Smit Sibinga, 2001). It is the principle of 'today me, tomorrow you' as a social act of solidarity. When the blood supply becomes a community issue, awareness and responsibility to support with healthy blood on a sharing principle, rather than being dragged into blood donation because of urgent needs of family and relatives who might die if you would not donate immediately (Los & Smit Sibinga, 2001). Questionnaires and testing, whether rapid or ELISA then move towards the edge of becoming a farce, seriously jeopardizing the safety of blood transfusion. To find out what the knowledge, attitudes and practices of a community are in relation to blood donation and transfusion, a KAP (knowledge, attitudes, practices) study could certainly be beneficial. KAP studies can be done broad, focused on the community by and large or target specific groups, such as presumed low risk categories, known or registered blood donors, and non-donors. Each such KAP study will need a careful analysis to unravel the underlying anthropological and psychological information needed to understand how the mind is set of those who participated and how that relates to community feelings and behaviour as a whole. KAP studies should not be incidental, but be part of a mechanism to

follow up and study the changes in mind set and behaviour of the community. Only then will it provide a useful tool for benchmarking progress in attitude and related practices (Los & Smit Sibinga, 2009; Los et al. 2009).

4.2 Prerequisites – Leadership, awareness, willingness, environment/climate, access

Unsafe blood transfusions have contributed to the enormous burden of HIV infections in various developing parts of the world, in particular in sub-Saharan Africa and the Central Asian region (World Bank et al., 2008), and still continue to add to this burden. The risk of HIV, HCV and HBV infection through unsafe blood and blood products is exceptionally high (95–100%) compared to other common routes of exposure: For example, 11–32% for mother-to-child transmission of HIV and HBV and 0.1%–10% for sexual contact. Sub-Saharan Africa has a particularly high level of transfusion-associated HIV compared with other developing regions due to a higher risk of infected blood being transfused. This results from a combination of factors: High rates of transfusion in some groups of patients (particularly women during labour, and children in the malaria Season), a higher incidence and prevalence of HIV infection, dependence on unsafe blood donors and inadequate or even absence of testing of blood for HIV in some countries (WHO 2008a, 2010a, 2010b). However, also the poor education level and poverty among larger groups in the community play an important role. Women and children account for a disproportionate number of HIV, HBV and HCV infections through unsafe blood because they are the main groups of patients receiving blood transfusion. In developing countries around 50% of the blood is transfused to women and 25% to children, largely under the age of 5 years. Up to 20% of maternal mortality and 15% of child deaths have been attributed to severe anaemia due to malaria. Timely access to safe blood transfusion is a life-saving measure in many of these clinical conditions and can also prevent serious illness in these patients.

Besides the need for identified, competent and designated leadership (Smit Sibinga 2009a, 2009b), there is the holistic need for awareness – politicians and policy makers, community in all its diversity, health professionals and related stakeholders such as hospital managers, religious leaders and educators. The government is final responsible for the well being of the community and should create the environment and climate for education and professional infrastructure to allow awareness and willingness to grow and sustain. The organization of the health care should guarantee access and affordability to all in need, and the blood supply and clinical prescribers should use and optimize the professional and social climate and environment to allow proper, safe and justified practices of procurement and clinical use of blood and blood components to be developed and implemented.

It has been demonstrated that a well organized and structured nationally supported blood supply and transfusion system yields a better and safer transfusion practice with a minimum residual risk for transmission of blood born infections, in particular HIV/AIDS, as compared to a non-cohesive and fragmented blood supply. Any structure should find its anchor in an appropriate legal framework – documented principles of blood donation and transfusion, adequate regulations and an operational system for audit and inspection of compliance with the principles and related operational standards and technical requirements (Hollan et al., 1990)

4.3 Role of education and vocational institutes

As mentioned in section 2.1 the key factor is competent human capacity at all levels, which means education of the community to create public awareness, the professionals to create professional awareness and politicians to create political awareness. The awareness to be

raised relates to the risks for contracting infectious diseases such as HIV/AIDS, hepatitis, malaria and tuberculosis. Additionally these infectious diseases may be spread through a variety of contacts, e.g. the blood supply. Education provides knowledge through information, which is stored in the brains. A major question and related process is how to convert the acquired knowledge into appropriate action. The process depends highly on how the information is presented and how the knowledge is perceived. The perception ultimately triggers the action needed (WI Thomas & Thomas DS, 1928).

Education and vocational institutes do play a paramount role in the presentation of information and the way the acquired knowledge is perceived individually and collectively, leading to individual behaviour and collective or group behaviour – the moral and ethics of a community. To bridge the existing knowledge gap, analysis is needed of both the way, the environment and the contents of the information offered, and the intellectual mechanisms of the perception of the knowledge necessary for the triggering of appropriate action (Los & Smit Sibinga, 2009; Kajja, 2010).

Potential teachers and parents therefore need to be educated on how to pack and present the information and how to monitor and evaluate the perception of the knowledge. This continuum should have a high rank on the priority list of any nation, filling in one of the key universal human rights – the right of education. Competence is the intimate twinning through matching of acquiring knowledge and developing skills to act appropriately, whatever is concerned. When the community or public understands the need for a healthy life style, for sharing regularly a bit of healthy blood with those in need, by donating blood on an altruistic and regular basis, when the professionals in the health care understand the need to appropriately deal with the collection, processing, testing, storage and distribution of human blood as a transplant and at the clinical side with the in-hospital processes of prescription and ordering, selection and compatibility testing, and the ultimate transfusion and its monitoring and evaluation, the gap will be substantially narrowed and shallowed. However, without a proper understanding of the policy makers, the gap will not be bridged completely.

Evidence-based strategies for blood safety and availability have been successfully implemented in most developed countries and some transitional and developing nations. However, despite the proven effectiveness of these strategies, many countries are making slow progress towards their implementation. There is ample evidence that a nationally supported blood supply and clinical use of human blood, well regulated and professionally implemented on an adequate economy of scale, leads to a significant reduction in risk of transmission of infectious diseases.

Such nationally supported approach covers the entire nation and is based on education of all parties involved, understanding the importance and relevance of the necessary and ongoing provision of information and related actions.

Such systems recognize and address the potential weaknesses and gaps as listed above in the 6 major areas of transfusion medicine - 1. Organization and structure; 2. Clinical use (clinical interface); 3. Processing and testing; 4. Collection of source material (community interface); 5. Education; 6. Monitoring and evaluation (research and development).

Such systems are based on the needs of the community to be met by the supply through anticipation, proper planning and adequate logistics (Smit Sibinga, 2000). The demand then will drive the supply and no longer the other way around.

5. Directions for improvement – Values and realities

Over the past few decades, since the outbreak of the HIV/AIDS epidemic, much work has been done to provide a better understanding of the routing of transmission of the virus. There

are prominent differences in the various cultures in the perception of the risks related to behaviour, personal and collective. That relates to different standards of moral and ethics, of values of life and realities of human attitudes and behaviour. Education remains a key factor in the provision of knowledge and related perception needed for action to prevent transmission, both vertical and horizontal. Blood transfusion in the vein-to-vein concept lacks behind in its development despite the continuum of initiatives developed by organizations such as the World Health Organization (WHO), the International Federation of Red Cross and Red Crescent Societies (IRC), the International Society of Blood Transfusion (ISBT) and the World Federation of Hemophilia (WFH) (Smit Sibinga, 2002). The WHO Blood Transfusion Safety Programme at WHO-HQ, Geneva, evolved from the WHO Global Programme on AIDS and the Global Blood Safety Initiative (GBSI) of the late 1980s. The leadership role of WHO has become visible through the development of a number of tools for education, collecting data, and providing guiding documents such as the series of *Aide Mémoires* to support and advise Governments in their attempts to structure national blood supply systems on a cost-effective, safe and sustainable basis. The Global Blood Safety Initiative started to map the situation of the blood supply and clinical use in the world and provide a series of expert advises, including two documents on education in transfusion medicine (WHO 1992a, 1992b).

5.1 WHA resolutions

With the goal of ensuring universal access to safe blood, WHO has been at the forefront of the movement to improve blood safety as mandated by successive World Health Assembly resolutions. In 2007 an important global meeting took place in Ottawa, Canada, addressing in a global consultation crucial aspects of a universal access to safe blood all part of the identified gaps (WHO, 2008a). More than 30 years after the first World Health Assembly resolution (WHA28.72) addressed the issue of blood safety, equitable access to safe blood and blood products and their safe and rational use still remain major challenges throughout the world. While the demand for blood is growing in the advanced world with longevity of life and increasingly sophisticated clinical procedures, national blood supplies are rarely sufficient to meet existing requirements in the restricted economy part of the world with some 80% of the global population.

Since that first World Health Assembly Resolution, a series of Resolutions has been created, endorsed and signed by the Member State representatives in an attempt to stimulate implementation at national level (Table 3). A recent one, WHA63.12 on Availability, Safety and Quality of Blood Products, was endorsed in May 2010 and urges Member States -

1. to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency, unless special circumstances preclude it;
2. to take all the necessary steps to update their national regulations on donor assessment and deferral, the collection, testing, processing, storage, transportation and use of blood products, and operation of regulatory authorities in order to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards;
3. to establish quality systems, for the processing of whole blood and blood components, good manufacturing practices for the production of plasma-derived medicinal products and appropriate regulatory control, including the use of diagnostic devices to prevent transfusion transmissible diseases with highest sensitivity and specificity;

4. to build human resource capacity through the provision of initial and continuing education (teaching and training) of staff to ensure quality of blood services and blood products;
5. to enhance the quality of evaluation and regulatory actions in the area of blood products and associated medical devices, including in vitro diagnostic devices;
6. to establish or strengthen systems for the safe and rational use of blood products and to provide education (teaching and training) for all staff involved in clinical transfusion, to implement potential solutions in order to minimize transfusion errors and promote patient safety, to promote the availability of transfusion alternatives including, where appropriate, autologous transfusion and patient blood management;
7. to ensure the reliability of mechanisms for reporting serious or unexpected adverse reactions to blood and plasma donation and to the receipt of blood components and plasma derived medicinal products, including transmissions of pathogens (haemovigilance);

The red thread through all these resolutions is the prevention of further spread of HIV/AIDS through contaminated blood transfusions and improving patient care, addressing the major knowledge gaps.

The global need for blood safety and availability has been highlighted in the following WHA and Executive Board (EB) resolutions and regional resolutions (PAHO and AFRO) that provide specific direction on strategies and activities within individual regions:	
1975:	WHA Resolution WHA28.72: Utilization and Supply of Human Blood and Blood Products
1987:	EB Resolution EB79.R1: Blood and Blood Products
1995:	WHA Resolution WHA48.27: Paris AIDS Summit
1999:	DC-PAHO/AMRO Resolution CD41.R15: Strengthening Blood Banks in the Region of the Americas
2000:	WHA Resolution WHA53.14: HIV/AIDS: Confronting the Epidemic
2001:	RC-AFRO Resolution AFR/RC51/R2: Blood Safety Strategy for the African Region
2002:	WHA Resolution WHA55.18: Quality of Care: Patient Safety
2003:	WHA Resolution WHA56.30: Global Health Sector Strategy for HIV/AIDS
2005:	WHA Resolution WHA58.13: Blood Safety: Proposal to Establish World Blood Donor Day
2007:	WHA Resolution WHA60.24: Health Promotion in a Globalized World
	WHA Resolution WHA60.29: Health Technologies
2010:	WHA Resolution WHA63.10: Partnerships
	WHA Resolution WHA63.12: Availability, Safety and Quality of Blood Products
	WHA Resolution WHA63.18: Viral Hepatitis
	WHA Resolution WHA63.19: WHO HIV/AIDS strategy for 2011–2015
	WHA Resolution WHA63.20: Chagas Disease: Control and Elimination

Table 3. WHA Resolutions related to blood safety.

5.2 Millennium development goals

The United Nations Millennium Development Goals (MDG) are eight goals that in 2000 all 191 UN Member States have agreed to try to achieve by the year 2015 (UN, 2000). The United Nations Millennium Declaration, signed in September 2000 commits world leaders to combat poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women, all essential parts of the original 1948 UN Declaration of Universal Human Rights.

The eight MDGs are derived from this UN Millennium Declaration.

1. to eradicate extreme poverty and hunger;
2. to achieve universal primary education;
3. to promote gender equality and empower women;
4. to reduce child mortality;
5. to improve maternal health;
6. to combat HIV/AIDS, malaria, and other diseases;
7. to ensure environmental sustainability;
8. to develop a global partnership for development.

All eight goals have specific targets and indicators. Of these eight goals, the numbers 4, 5 and 6, and eight of the 18 targets relate directly to health and safe blood transfusion. The number 2 relates to education and the number 8 to the role of partnership for development, equally important to the development of safe and efficacious blood transfusion practices.

Some developing countries have made impressive progress in achieving the health-related Millennium Development Goals, targets and indicators. However, many more are still falling behind. Progress is particularly slow in sub-Saharan Africa but also in other developing and transition countries such as a number of the Newly Independent States (NIS), where knowledge gaps remain a major issue to address.

5.3 Success stories

There is a steadily growing number of success stories on bridging the knowledge gap and improving on the safety of the blood supply. We present just a few recent examples, largely from the African continent.

Eritrea (Baraki et al., 2010) - In 2006, despite the production of blood components in the National Blood Transfusion Centre (NBTC), about 90% of blood requests were for whole blood, an evidence of inappropriate use of blood and blood components in Eritrea. This could be the result of absence of proper and up to date guidelines and lack of training in appropriate use of blood and blood components, and alternatives. To change, the NBTC adapted clinical guidelines from the WHO document on appropriate use of blood (WHO, 2001). Copies of this document were distributed to all hospital staff in the country followed by training to the guidelines.

Objective of this Swiss Red Cross and Academic Institute IDTM (Groningen, NL) supported project was to assess the impact of distributing clinical guidelines and training (interventions) on knowledge, attitude and practice (KAP) of clinical prescribers in blood transfusion before and after the interventions. Correctly responded knowledge, attitude and practice (KAP) questions were collectively considered. Baseline: 3.8 percent of respondents correctly answered all KAP questions, which increased to 6.1 percent after the intervention. Of the total KAP questions, the average correct responses were 15.86 in the baseline and 17.45 in the follow-up assessment. The difference was positive and statistically significant ($p < 0.000$) demonstrating the intervention had a major impact in changing the overall

knowledge, attitude and practice of these health workers. When certain tools were audited, the compliance was found to be 38.1 percent among the assessed hospitals, though the auditing was limited to seven (7) major hospitals. This shows the intervention has made an impact when compared with the pre-intervention status.

When blood and blood components utilization comparison was made before (2006) and after the intervention (2008), demand for whole blood had decreased whereas the demands for all blood components had increased significantly (except FFP which remained unchanged).

This shows the progress made in Eritrea through focused education in addressing safe transfusion practice, and the measurable improvements in that practice.

Malawi (courtesy Dr. Jean C. Emmanuel) – Malawi (population of ± 11 million) is a Low Human Development Index (L-HDI) country. The European Union EC EDF VIII Project document set out to develop an independent and sustainable National Malawi Blood Transfusion Service (MBTS) following the recommendations and guidelines of the World Health Organisation (WHO), International Federation of Red Cross and Red Crescent Societies (IFRCRCS) and the International Society of Blood Transfusion (ISBT). The MBTS project plan was based on sustainable and effectively managed and organised independent National Blood Services. The platform for development was the establishment of a Finance and Administration department, with an experienced chartered cost accountant (CPA) as Director; with facilities and trained staff. Effective collaborative networks have been established with Ministry of Health (MoH) and Ministry of Finance (MoF), ensuring incorporation of a sustainable budget into the national annual fiscal budget, negotiated 'fee for service' from the private health insurance schemes for the private sector, and an equitable career structure for all staff with social benefits to ensure continuous capacity building and retention of staff. MBTS Trust Board appointed an experienced CEO; Finance & Administration Director and Medical Director.

In February 2000 a financing agreement, MAI/7001/002, was signed between the Republic of Malawi and the European Commission (EC) for € 7.8m in order to support the Malawi MoH to establish an independent National MBTS under a formally constituted and independent Malawi Blood Transfusion Service Trust. Project funding was increased with a further € 1.3m following a successful mid-term review (MTR). The Project Manager was appointed in March 2003 and development commenced. The Board of Trustees is responsible for the effective operation of MBTS and drafted appropriate legal frameworks, comprising the Constitution for the Board of Trustees and Legislation of the Service. MBTS is an officially registered Non Government Organisation (NGO) with a legal seal. MBTS is managed and organised by a competent Chief Executive Officer (CEO) who has internationally recognised qualifications, a Finance and Administrative Director and Medical Director with a Deputy; together form the Senior Management Team reporting directly to the Board. Developing collaborative working partnerships with the relevant NGOs, stakeholders and bodies in the private and public sector in Malawi is an important and ongoing strategy.

The overall objective of MBTS is to provide safe blood and blood products, reduce the incidence of HIV, and other diseases transmissible by blood, ensuring equitable access and availability of blood and promoting appropriate clinical use of blood. The goal was achieved within the planned project timeframe a sustainable, national blood transfusion service providing a safe, adequate and accessible supply for all those in need in recognised health care establishments from 100% voluntary non-remunerated safe blood donors, which

meets the needs of all hospitals in Malawi through the three centres specifically designed and built within the project framework.

The five-year project ended 2007. An independent Mid Term Review (MTR) Team contracted by European Commission (EC), concluded that the project had been successfully implemented. As a result EC agreed to an extension to the funding of € 1.3m through EDF IX, for the construction of 3 Blood Centres.

Key achievements of the project:

- Establishment of an approved and effective Board of Trustees, CEO and Executive Team, with effective leadership, organisation and management, personnel (110 staff) all trained to international standards in all areas of work, with job descriptions, SOPs and implementing quality systems;
- MBTS policy, plan and legal framework approved as official legal instruments;
- Construction of 3 blood transfusion centres (completed 2008);
- Equipment and vehicles for 8 mobile collection teams including a blood donor bus;
- Recurrent expenditure secured in fiscal budget by 'subvention' from fiscal year beginning July 2006 to present;
- Project Manager/Technical Assistance funded by EC responsible for development and training ended 31 March 2007;
- All objectives, and planned outputs, were achieved on time;
- All donated blood is tested for HIV I/ II, p24 antigen; Hepatitis B & C; Syphilis and malaria with the introduction of a quality management system, and good laboratory practices. Trained senior staff have become trainers of district hospital blood bank staff and future MBTS staff;
- Blood Cold Chain (BCC) system in place for the transport of blood specimens for centralized testing and distribution of blood and blood products to all hospitals; provision of targeted hospitals with appropriate resources for the storage of blood and blood products for blood transfusion;
- District Hospital laboratory staff have been trained using WHO Distance Learning Materials (every technician has a personal copy);
- Training workshops, seminars and lectures on appropriate clinical use of blood facilitated by respective senior staff;
- Research ongoing on knowledge, attitudes and practices (KAP) on blood donation issues; evaluating prevalence of Hepatitis C (HCV); on evidence based rationale for individual patient identification arm bands; research paper co-authored on Clinical Paediatric Transfusion Guidelines;
- MBTS provides blood and products from 100% voluntary non-remunerated donors to all public and private hospitals;
- MBTS is a sustainable and effective Service with an approved fiscal budget and a "fee for service" through private medical insurance.

Sudan (Hassan Ali et al., 2010) - In Sudan blood transfusion services were fragmented - hospital based with 85% of blood collected from family and replacement donors. More than 300 hospital blood banks practice blood collection and transfusion; 40% are rural hospitals with transfusion rate of 5-100 units of blood per month besides large central and specialized urban hospitals with transfusion rate of 100-300 units of blood per month. About 300,000 units of blood are collected annually; 56% is screened using rapid tests and 44% by ELISA technique, with a TTI marker prevalence of HIV - 2%, HBV - 6%, HCV - 2% and syphilis - 5%. Apart from a few solitary guidelines and SOP-like instructions no quality system was in

place. Almost exclusively whole blood is being transfused and adverse events are poorly observed. In 2009, in close collaboration with World Health Organization and the Academic Institute IDTM (Groningen, NL), a project to improve quality in blood transfusion through an appropriate quality management system was established, focused on the creation of a solid national blood supply and transfusion framework. Objectives were to review existing quality management programme and identify gaps, assist in the development of a draft national quality policy and develop a plan for quality improvement including capacity building. Through a series of field visits to main blood transfusion centres in three main States, the establishment of a National Steering Committee to create full ownership, capacity building through basic education in quality management and clinical transfusion medicine (quality culture) and enhancement of a voluntary blood donation programme strategy, the following goals were reached –

1. Endorsed National Blood Transfusion Policy (Ministry of Health);
2. Voluntary Blood Donor Association established and registered;
3. 50 senior blood bank quality managers from 10 States educated in the basics of quality management. Committees from these trainers have worked on developing a draft national quality manual;
4. 6 seminars for prescribers conducted in 3 States, to improve clinical blood transfusion knowledge and practice (in-hospital transfusion chain).

This demonstrates that international collaboration (WHO/IDTM) can generate major achievements in establishing a national framework and improving quality blood transfusion services in developing countries to achieve the goals of safe and adequate blood supplies and clinical awareness and knowledge at national level.

Uganda (Kyeyune et al., 2010) - In 1957, a centralized transfusion service - the Uganda Blood Transfusion Service (UBTS), was started at Nakasero. This supplied blood to the entire country for the following 20 years. The period from 1977 to 1987 saw political unrest disrupt national infrastructures and aggravated the human resource crisis in the health sector. This resulted into reversion to the original unregulated hospital based transfusion service nationwide. Like any other low HDI country, Uganda is still challenged by a low availability of voluntary non-remunerated blood donors (VNRBD); insufficient transport and storage facilities; low capacities in testing of donated blood and quality assurance in testing laboratories. Through a step-by-step approach these problems are being reversed using locally and internationally sourced technical and financial support. In May 1987, Uganda with the assistance of the Global Programme on AIDS (GPA) of the World Health Organization (WHO) held a financial donor conference in Kampala. As a result, the Uganda AIDS Control Programme (UACP) was formed. The European Commission (EC) through its AIDS Task Force (ATF) made a pledge of 1.5 million Euros to rehabilitate the central blood bank at Nakasero and the collection, processing and distribution of 10,000 units of whole blood to be supplied to hospitals within 100 kms from Nakasero Blood Bank. In the period 1989-2004, further funding from EC together with adequate technical advice and support enabled the UBTS to improve its infrastructure by opening four regional blood banks in Mbarara, Fort-Portal, Gulu, Mbale and two satellites in Arua and Kitovu. This was accompanied by development and adoption of a National Blood Transfusion Policy, and organization and coordination of a national safe blood transfusion service based on voluntary non-remunerated blood donors. This period saw significant reduction of HIV and hepatitis B sero-prevalence among donors. A quality assurance programme was instituted in the UBTS establishment, and opportunities for human resource development in-service

training were initiated. The EC fund was phased out in 2004 amidst increasing demands for safe blood for an increasing population. From 2004 to date UBTS has enjoyed technical (TA provision) and financial support from the US PEPFAR project, focused on strengthening of the national blood transfusion service. This has been followed by renovation of existing and establishment of new facilities, increased blood collection from 107,000 units in 2004 to 165,500 units in 2009. Blood testing for hepatitis C was started in 2005 in addition to HIV, Hepatitis B and syphilis testing. Hospital transfusion committees to oversee clinical use of blood are being created, and a major emphasis is on quality system essentials and capacity building in the regional blood banks.

Uzbekistan (Makhmudova & Smit Sibinga, 2008) - Project focus: development of a Republican Blood Supply and Transfusion System based on international standards – safe, efficacious, sustainable and affordable.

The Government of Uzbekistan initiated measures to reform the Health Care System. Government and Asian Development Bank (ADB) signed a Loan Agreement (2004) for a major project: Woman and Child Health Development (WCHD); part is used to improve blood services. The blood services situation requires radical improvement: Donated blood is not safe, majority is collected from paid donors with serious risk of HIV, HCV and HBV transmission. The country lacks a national blood safety policy, strategic plan, appropriate legislative and regulatory framework. The Blood Safety Program (component 3) of WCHD comprises a nationwide blood supply system, initiated in 2004 and substantiated in 2006, based on WHO and Red Cross principles. The programme is public health oriented, addressing the need for a nationally supported system, cost-effective, motivation and mobilization of the community to convert the current paid and replacement system into a truly voluntary and regular blood donor system, upgrading procurement operations (regional and economy-of-scale). It addresses the need for equitable access of safe blood to all citizens, appropriate clinical practices, and a national budget system to allow sustained and continuous operations. Using public education and social marketing campaigns with the support of NGOs, a voluntary and regular donor programme will be implemented stepwise. Another major point is in establishing appropriate clinical transfusion practices. With support of international expertise, MoH has created a Republican reform plan to reduce the number of inadequate hospital based blood transfusion units. The plan focuses on consolidation of core activities - blood collection, processing and testing, storage and distribution in 6 regional centres, strategically spread over the country to be able to handle logistics of demand and supply, and provide cost-effective operations. Implementation is in phases to allow proper adaptation and guarantee of continued supply of blood over the transition period. The WCHD conducts training needs assessments, develops training modules based on WHO guidelines and provides education for clinicians and transfusion medicine specialists (capacity building). Another example of how to bridge the knowledge gap.

This demonstrates that donor funding when appropriately utilized and supported by adequate provision of guidance and technical advice can improve blood transfusion programmes in the low human development index countries.

5.4 Lessons learned

To reduce the burden of morbidity and mortality through HIV infected blood transfusions of particularly the poor and marginalized populations, the focus should be on an increasing access to clinical and diagnostic technology, safe blood, blood components and medical devices. This could be achieved through reducing the leading risk factors to human health

in which lack of education (knowledge) plays a major role. When a safe and professional environment for the vein-to-vein use of blood and blood components is created, the risk for transmissible and transfusion related diseases will be reduced. At the same time there should be developed a sustainable and integrated health care system by building competent leadership, management and operational capacity in the methodologies and technologies involved in the procurement and clinical use of blood and blood components as fundamental elements of a sustainable health care system.

That could only be achieved sustainably when enabling policies and an institutional environment are developed through appropriate national drug and blood policies (legal and regulatory framework), with all partners involved in the health technologies and within the framework of national health policies (integrated), which generate a common vision and a realistic and feasible plan for action.

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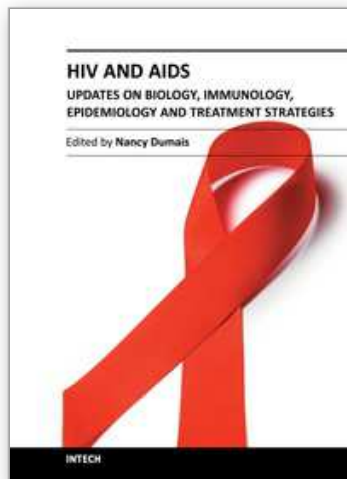
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