

# Access to plasma and plasma derived medicinal products in the region

Ravi Reddy,

South African National Blood Service (SANBS)

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# Introduction



- Key priorities for Blood Services globally are
  - Adequate blood supply to meet demand for blood products, including plasma derived medicinal products
  - High levels of Blood safety to mitigate against adverse events such as transfusion transmitted infections
- Developing Countries continue to encounter significant challenges in both adequacy of blood supply and safety



# Blood Value Chain



- Many African countries still collect less 10 units of whole blood per 1 000 population
- Not meeting Country Needs for blood products including plasma derived medicinal products (PDMP's)
- Lack sufficient regular blood donors (voluntary non remunerated repeat donors)
- Lack appropriate donation testing strategies
  - High HIV, HBV and HCV prevalence
- Quality assured processes lacking (collection, transport, production, storage)
- Inadequate Quality Systems and Audits



# Number of Blood Donations and Donation Rates per Groups of Countries in Africa

| Country Group                       | Countries (n) | Total Blood Donations (n) | Population (n) | Donation Rate (units/1000 people) |
|-------------------------------------|---------------|---------------------------|----------------|-----------------------------------|
| <b>Group A (At least 80% VNRBD)</b> | 19            | 1 980 349                 | 437 286 128    | 4.5                               |
| Group B (50 TO 79% VNRBD)           | 7             | 666 783                   | 91 255 989     | 7.3                               |
| Group C (<50% VNRBD)                | 17            | 839 060                   | 285 264 867    | 2.9                               |
| All Countries                       | 43            | 3 486 192*                | 813 806 984    | 4.3                               |

\* South Africa contributes over 950 000 donations with 52 million people

Source - WHO: Blood Safety in the Africa Region\_ 2010 survey



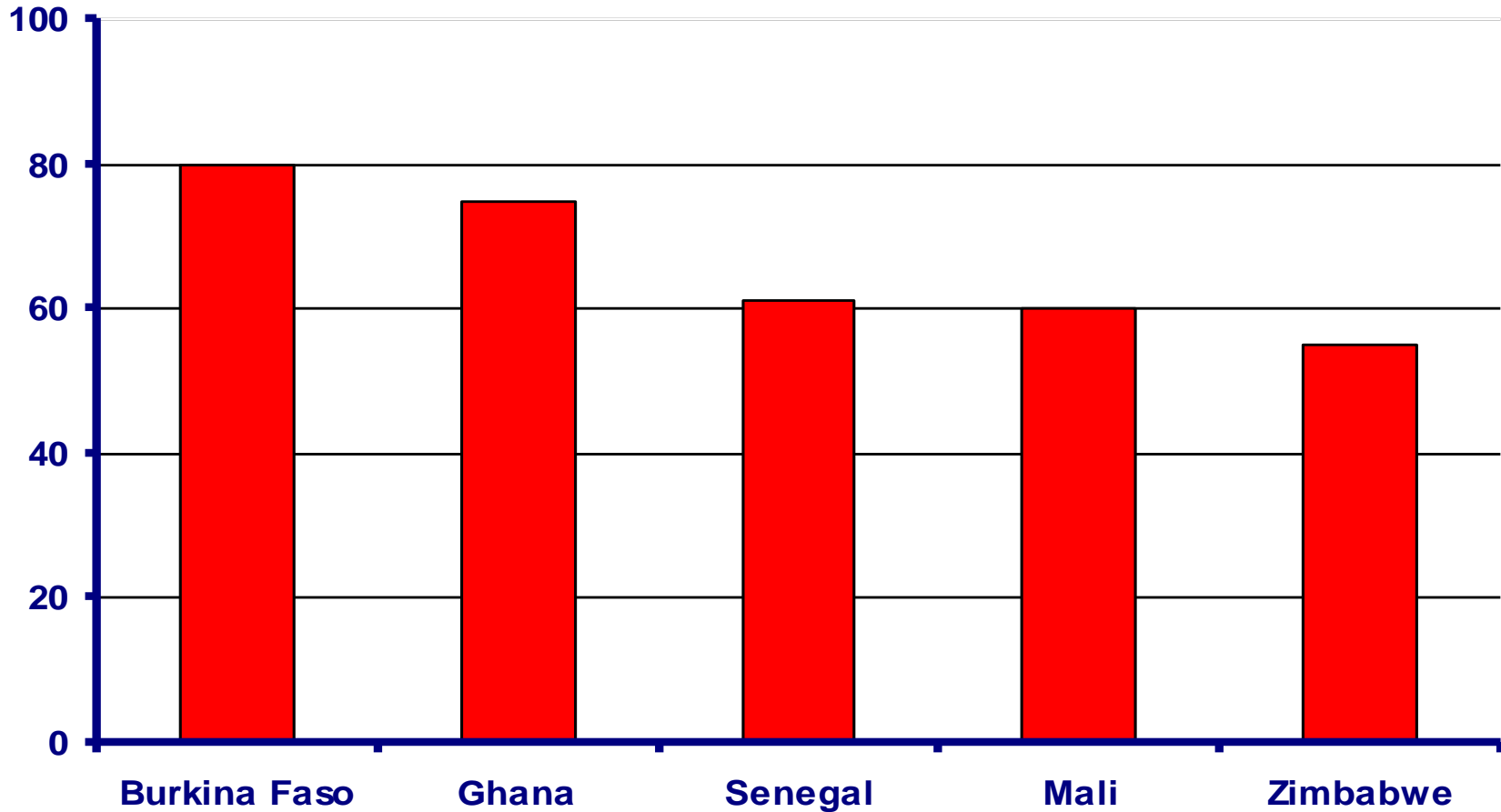
# Number of Donations and Type of Donation per Group

| Country Group<br>(n = 43)           | VNRBD (n and %)  | Family Replacement<br>(n and %) | Paid (n and %) |
|-------------------------------------|------------------|---------------------------------|----------------|
| Group A (n=19) (At least 80% VNRBD) | 1 920 800 (97.0) | 18 567 (3.0)                    | 0              |
| Group B (n=7) (50 TO 79% VNRBD)     | 411 422 (61.7)   | 255 361 (38.3)                  | 0              |
| Group C (n = 17) (<50% VNRBD)       | 234 495 (27.9)   | 588 422 (70.1)                  | 16 059 (1.9)   |
| All Countries                       | 2 607 699 (74.8) | 862 350 (24.8)                  | 16 059 (0.4)   |

Source - WHO: Blood Safety in the Africa Region\_ 2010 survey



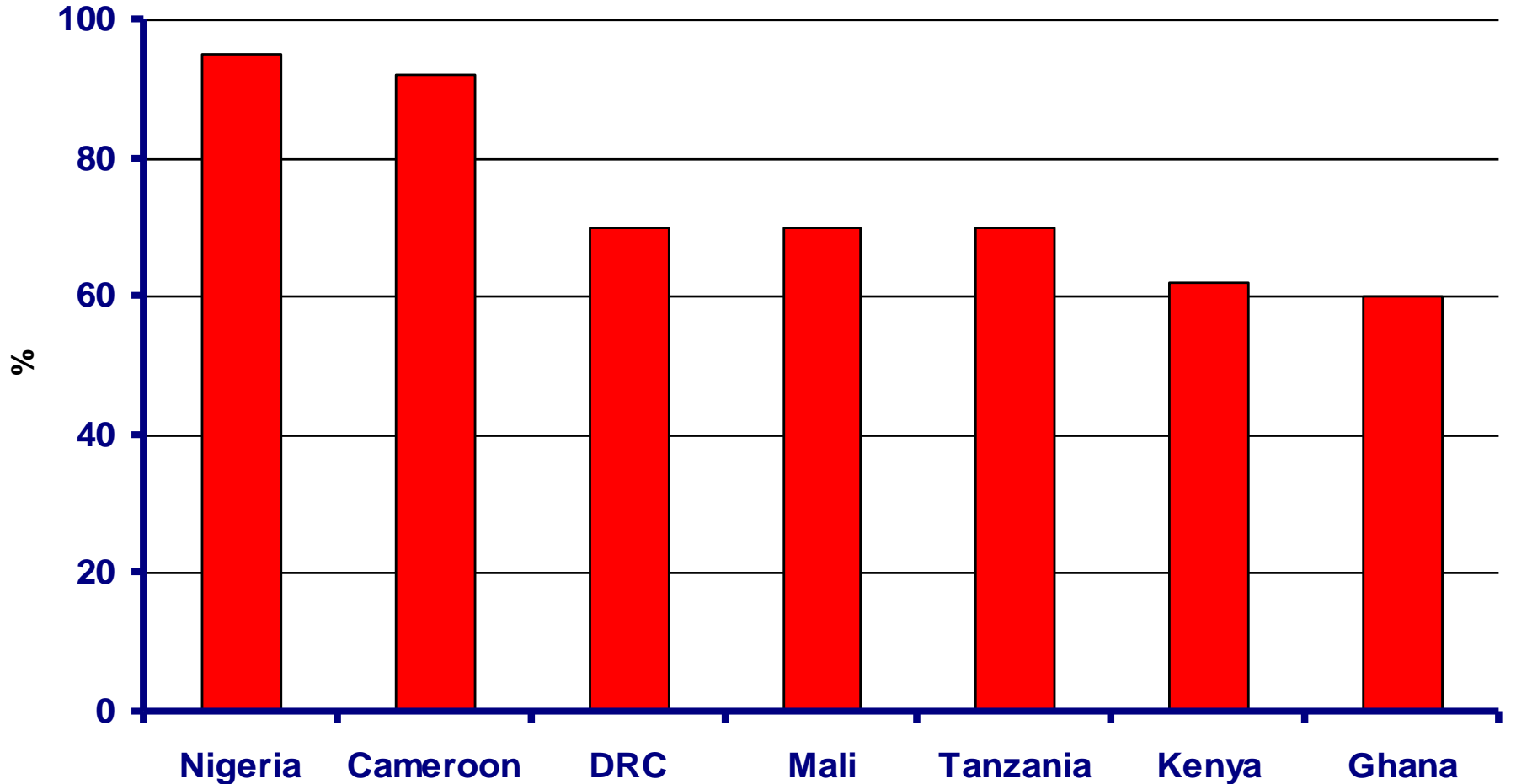
# First Time Donors in Africa



Adapted from Allain – BJH, 2011



## Replacement Donors (Africa)



Adapted from Allain – BJH, 2011

# HIV prevalence among Blood Donors



**TABLE 2. (Continued) Estimated HIV population prevalence in persons aged 15–49 years, percentage of whole blood units collected by national blood transfusion services from voluntary non-remunerated donors, and percentage of collected units reactive for HIV, by country — U.S. President’s Emergency Plan for AIDS Relief, 2003–2010**

| Country                   | % collections reactive for HIV |      |      |      |      |      |      |      |
|---------------------------|--------------------------------|------|------|------|------|------|------|------|
|                           | 2003                           | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
| Botswana                  | 7.5                            | 5.7  | 4.0  | 2.7  | 2.1  | 1.7  | 1.8  | 1.0  |
| Côte d’Ivoire             | 1.6                            | 1.4  | 1.5  | 1.4  | 1.2  | 0.9  | 0.7  | 0.5  |
| Ethiopia*                 | —                              | 3.6  | 3.4  | 2.5  | 3.0  | 2.9  | 1.8  | 1.9  |
| Guyana                    | 0.8                            | 0.6  | 1.0  | 0.6  | 0.3  | 0.5  | 0.2  | 0.2  |
| Haiti                     | 1.7                            | 1.8  | 1.6  | 1.9  | 1.4  | 1.7  | 1.4  | 1.2  |
| Kenya                     | 1.5                            | 1.7  | 1.9  | 2.5  | 1.2  | 1.5  | 1.2  | 1.0  |
| Mozambique                | 8.6                            | 6.9  | 6.4  | 8.3  | 7.2  | 6.4  | 5.3  | 6.6  |
| Namibia                   | 0.7                            | 0.6  | 0.6  | 0.5  | 0.6  | 0.5  | 0.3  | 0.4  |
| Nigeria†                  | —                              | —    | 3.8  | 3.5  | 2.5  | 1.8  | 2.2  | 2.1  |
| Rwanda                    | 1.1                            | 0.1  | 1.2  | 0.9  | 0.5  | 0.7  | 0.3  | 0.3  |
| South Africa <sup>§</sup> | <0.1                           | <0.1 | <0.1 | <0.1 | 0.1  | 0.2  | 0.2  | 0.2  |
| Tanzania†                 | —                              | —    | 4.8  | 3.2  | 2.8  | 3.3  | 2.2  | 1.2  |
| Uganda                    | 2.0                            | 1.9  | 1.6  | 1.5  | 1.3  | 1.2  | 0.8  | 1.0  |
| Zambia                    | 6.9                            | 6.4  | 9.0  | 6.4  | 3.8  | 4.2  | 3.5  | 4.8  |

Mostly repeat reactive unconfirmed – When HBV, HCV and Syphilis positives added = large percentage of discards



# TTI Testing Strategy

- 17/43 (39.5%) Countries performed confirmatory testing for TTI's
  - Algorithms lacking for repeat testing in many countries
  - No confirmatory testing in 26 Countries
- Significant percentage of blood donations with false positive results discarded
  - Contributes further to the shortages
- Donor deferral and counselling challenges
  - Loss of donors

# Plasma Quality and Availability in Africa



- Few countries (South Africa, Namibia and some North African countries) have systems in place for production of frozen plasma that meets requirements for fractionation
- Plasma not of suitable quality for fractionation in most countries
  - Whole blood is used for transfusion
  - Number of countries make components from whole blood
    - Excess plasma is discarded



# Potential Sources of Recovered Plasma from some African Countries

| Country     | Total Annual Blood Collections | Potential litres of Plasma available (large percent currently discarded) |
|-------------|--------------------------------|--|
| Kenya       | 230,000                        | 57,500   |
| Malawi      | 60,000                         | 15,000   |
| Tanzania    | 230,000                        | 57,500   |
| Uganda      | 220,000                        | 55,000   |
| Zambia      | 120,000                        | 30,000   |
| Zimbabwe    | 80,000                         | 20,000   |
| Ethiopia    | 125 000                        | 31 000   |
| Ivory Coast | 130 000                        | 32 000   |

Potential for almost 300 000 litres plasma from 8 countries

Source: AfSBT survey and personal communication



# Access to PDMP's (South Africa)



- South Africa – National Bioproducts Institute (NBI) and WPBTS have Fractionation plants
  - South African National Blood Service (SANBS) supplies 165 000 litres of excess plasma to NBI annually
  - NBI and WPBTS supply most of South Africa's PDMP requirements
  - NBI imports some plasma to meet shortfalls of specific products (e.g. anti-D immunoglobulin and factor VIII)



# SA National Blood Service



**Whole Blood Donation** from  
voluntary, non-paid blood  
donors

**Hyperimmune FFP donation**  
from voluntary, non-paid  
plasmapheresis donors

**Blood Products:**  
Cellular Products

**Blood Products:**  
Fresh Frozen Plasma (FFP) and  
Hyperimmune FFP

- Whole Blood
- Red Cell Concentrate
- Platelet Concentrate

- Cryofibrinogen
- Cryo-poor FFP
- FFP – Therapeutic

**Excess Plasma to  
National Bioproducts  
Institute (Fractionator in  
South Africa)**  
**(165 000 litres per  
annum from SANBS)**

# Access to PDMP's (Rest of Region)



- Some North African countries (e.g Morocco/LFB France) have contract fractionation agreements and PDMP's are available
- NBI has products registered for SADC countries and supplies some products
  - Challenge of not having sufficient products to export
- Other regions – import from international companies
  - Challenges are cost, consistency of supply, reliance on funding agencies
- WHO recognised need for improvement/support



# WHA63.12: "Blood Products" definition



"Any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products"



# Resolution WHA63.12

## Availability, safety and quality of blood products



- Points out the need to support improvements in the availability, safety and quality of blood products
- In particular, the Resolution draws attention to the large volumes of human plasma, that have been separated from whole blood, and currently go to waste
- Yet, the plasma wasted could be used as a starting material for the manufacture of essential plasma-derived medicinal products unavailable today for treatment of local populations





# Resolution WHA63.12 on availability, safety and quality of blood products



- The resolution recognized that “stringent regulatory control is vital in assuring the quality and safety of blood products...”
- and urged Member States to “update their national regulations ... 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.”



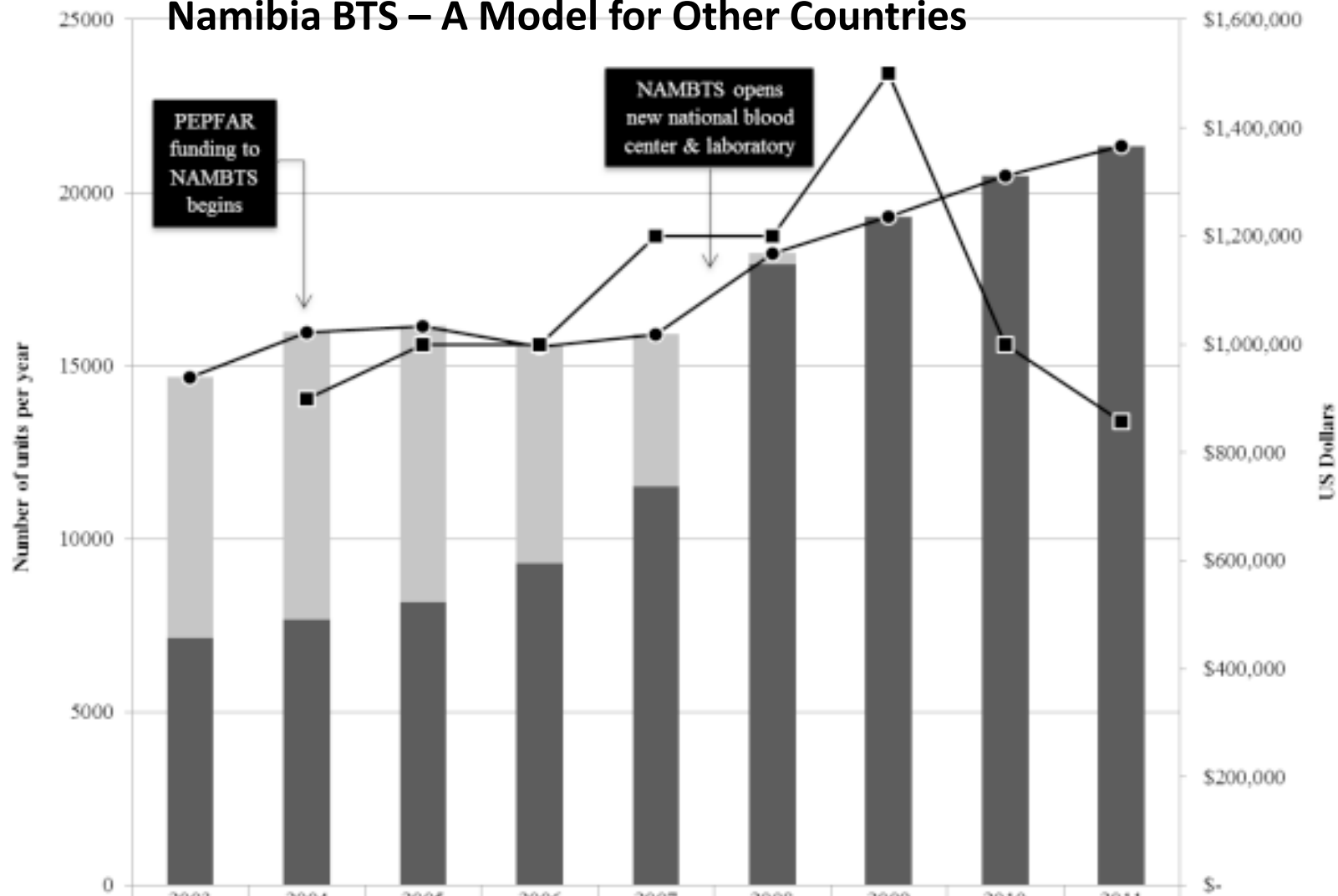
# The WHO Achilles Project



- Aim is to assist Countries to use the recovered plasma otherwise discarded to generate essential blood derived medicines
  - By raising quality standards and quality assurance systems in blood establishments for the production of blood components, including plasma for fractionation
- Improve access to safe essential blood derived medicines
- Being piloted in Indonesia



# Namibia BTS – A Model for Other Countries



|                | 2003  | 2004   | 2005    | 2006    | 2007    | 2008    | 2009    | 2010    | 2011   |
|----------------|-------|--------|---------|---------|---------|---------|---------|---------|--------|
| Whole Blood    | 7529  | 8306   | 7990    | 6253    | 4404    | 318     | 9       | 10      | 20     |
| RCC            | 7146  | 7665   | 8167    | 9312    | 11513   | 17931   | 19293   | 20471   | 21331  |
| Total          | 14675 | 15971  | 16157   | 15565   | 15917   | 18249   | 19302   | 20481   | 21351  |
| PEPFAR funding | 0     | 899440 | 1000000 | 1000000 | 1200000 | 1200000 | 1500000 | 1000000 | 857458 |



# Road Map



- National Policy and Strategy
- Effective Quality Management system
- Sustainable donor base and increase blood supply
  - Voluntary, low risk, repeat donors
  - Increase collections (e.g Uganda, Ethiopia)
- Effective donation screening strategy (NAT testing in high prevalence countries)
- Validated systems for the transport, processing and storage of blood in place
- Systems for Monitoring and Evaluation



Thank You

