

The supply of plasma-derived medicinal products in the future of Europe

Second edition

23-24
April 2024
Rome, Italy

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Ministero della Salute

Current Situation of Plasma Fractionation in the African Continent

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Disclosure

I have nothing to declare.

African Regions according to AfSBT

54 Countries

5 Regions



1. North
2. East
3. West
4. South
5. Central

Introduction

- LMIC are suffering from lack of access to PDMPs because of high cost of importation and no local PF activities .
- Plasma produced locally is qualified to meet industrial GMP prerequisites to be candidate for further fractionation.
- Globally, plasma recovered from WBD are partly used clinically, partly manufactured to PDMPs, and mainly wasted in LMIC.
- Of the total of 311,946 L of plasma that was fractionated to plasma products in Africa, recovered plasma was 98% (305,000).



Situation in African Countries

- A large percentage of human plasma (separated from whole blood) is wasted.
- This wastage is due to **lack of**:
 - ◆ Appropriate standards and technology to ensure required freezing and cold storage conditions.
 - ◆ Functional traceability of donors.
 - ◆ Proper testing to lower the residual viral risk.
 - ◆ Regulatory control by national authorities.
 - ◆ Quality systems and good manufacturing practices (GMP).



Examples

- Rwanda wasted 95% of RP in 2021 (20500 L). 21000\$ spent on incinerating wasted plasma.
- Senegal; Massive amounts of plasma separated from whole blood but not needed clinically for transfusion are discarded as medical waste for lack of suitability for industrial fractionation.
- Namibia wasted in the past 77% of recovered plasma.
- WHO AFRO report in 2022; Scarce and critical resource of plasma is currently discarded: >1 000 000 liters of plasma.



African Countries that have activities of PF (Past, Present, & Future)

- Egypt
- Tunisia
- Morocco
- Senegal
- Namibia
- South Africa
- Rwanda, Ethiopia,
Uganda, Zambia,
Tanzania



Egypt



- Pioneer Fractionation (Past)
- Contract Fractionation (Past)
- Mini Pool Fractionation (Past, Present & Future)
- Current Fractionation Project (Future)

Egypt

Pioneer Fractionation

- In 1970s, VACSERA was instructed to produce plasma products for the use in the borders in case of war.
- Small factory was founded in the grounds of VACSERA and processed 5000 to 10000 L of plasma/Year.
- Products; Human Albumin 5 & 15%, IM IGg 16%, IV IGg 5%, and small pool coagulation factors (lyophilized).
- VACSERA continued production till late 2001, Factory was outdated and closed.
- Small scale production for crude factor VIII started in the blood bank facility, the product was popular for hemophilia cases, production ended by 2009.

N.B. slide c/o Dr. Abbadi



Egypt

Contract Fractionation

- Early 2000s, VACSERA approached several firms to process the stored recovered plasma through contract fractionation.
- 1st trial with Russ in China, 2nd trial with, Bio-Test in Germany, both failed due to incomplete plasma master file, and improperly packaged samples for testing.
- 3rd trial with SK in South Korea succeeded when PMF was completed, one shipment only was processed. A political conflict led to nonuse in Egypt, but SK purchased the products which was used abroad.
- Toll fractionation stopped after this shipment due to local conflicts.



Egypt

Mini-Pool Fractionation

- Applied in Egypt since 2013 and helped to produce more than 50 million units of FVIII at 50% reduced cost of imported products. 2 facilities are functioning.
- CE marked medical devices and chemicals. Produced and marketed by a Swiss Company for processing FFP in small pools (4 – 7 L) in one disposable kit, to produce:

○ **FVIII, VWF, Fibrinogen, FXIII, IVIG, Solvent Detergent FFP**

N.B. slide c/o Dr. M Ekiaby



Egypt

Current Fractionation Project

- Joint Project between Military and MOH.
- Plasma Collection Centers were established in several Governorates. Plasma is collected and stored according to GMP requirements.
- Fractionation Plant is planned to be constructed with Grifols.
- Contract fractionation is decided with Grifols till the completion of the plant and know how transfer.

□ GRIFOLS-EGYPT



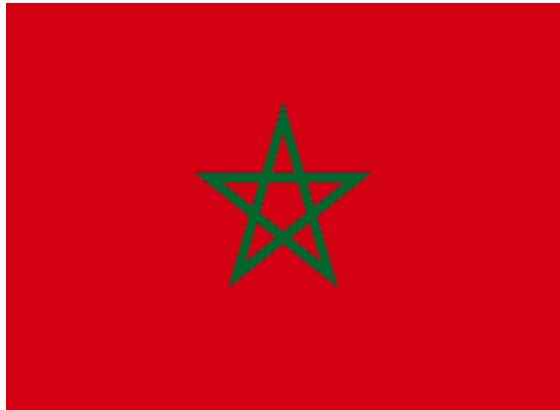
Tunisia



- Military blood services had contract fractionation with Pasteur Institute in France to produce Albumin, which stopped in 1995. They processed about 6000 L/Year (from 20000 donations).
- MOH NBTC had contract fractionation with LFB in France between 1999 to 2002. The products were limited to Albumin and IV Ig.
- This activity was licensed by NRA in Tunis.

N.B. slide c/o Prof. Bukef

Morocco



- Contract fractionation with LFB in France was signed in 1999 and renewed in 2012.
- Commitment of full quality system covering vein to vein.
- 2 centers were accredited by LFB, followed by 2 more in 2012.
- Moroccan regulatory framework is compatible with EU regulatory framework.
- Regular assessment and external audits by LFB to the Moroccan TCs.

Morocco

- Only recovered plasma from VNRBD is exported to LFB.
- Average 6100 to 6500 liters yearly.
- All testing kits are CE marked.
- Cold chain is very strict.
- Yearly around 30000 packages of PDMPs are exported back to Morocco.
- This number of packages saves more than 50% of the local need.

N.B. slide c/o Dr. Lahjouji



Morocco

- **The PDMPs that are exported back are;**
 - Human Albumin 20% and 4%,
 - Human coagulation Factor VIII,
 - Human coagulation factor IX,
 - Normal immunoglobulin intravenous 5g and 10g



Senegal



- 2022, ISBT approached WHO with a request to host a collaborative effort to conduct pilot projects for local plasma protein factors production (revived Achilles project).
- NBTC, Dakar was approached to establish local preparation of pathogen-reduced cryoprecipitate through education and onsite support. Recovered plasma is targeted.
- Pilot project is currently supported by the Swiss company (mini pool technology), to explore its feasibility in Sub-Saharan Africa under supervision of ISBT & WHO.
- 2023, Capacity building of regulatory authority, training in Egypt, and strengthening of blood establishment.
- Joint funding under supervision of ICSP.

N.B. Slide c/o Prof. S. Diop

South Africa



- SANBS collects approximately 950 000 units of whole blood (WB) annually.
- Excess plasma is sold to National Bio-products Institute (NBI) for the manufacture of plasma derived medicinal products (PDMP's).
- SANBS implemented a source plasma (SP) programme from voluntary, non-remunerated donors.
- Blood groups A and AB donors were targeted since they have an excess supply of WB.

N.B. slide c/o Dr. Jey Han Omarji

NBI, SA

- Established in 1994 and is the largest Biotechnology Pharmaceutical Company in South Africa.
- Registered as a Non-Profit Company. Self funded non-government entity.
- Manufactures bio-pharmaceutical products from human plasma into plasma derived medicinal products.
- NBI develops and manufactures diagnostic kits and monoclonal antibodies for the SA and international diagnostic market.



NBI, SA

- Products registered with South African Health Products Regulatory Authority (SAHPRA).
- NBI sells PDMPs in several SSA countries and m AB's sold in India, China, USA, France and Australia
- Based in Pinetown, South Africa, approximately 20 km from Durban.



NBI Products

Products of NBI

- **Fresh dried plasma**
- **Immunoglobulins**
- **Albumin solutions**
- **Coagulation Factors**
- **Diagnostic products**

NBI HQ



Namibia



- Collaboration with NBI since 2013.
- Recovered plasma was stored for 5 years and shipped in 2022.
- Supply of surplus plasma (77% previously discarded) to NBI.
- 100%VNRBD, 84% repeat donors
- Centralized testing for the whole country.
- Need for more income to fund NAT ID testing
- Need for PDMPs to treat local patients.

Namibia

- 33373 L of recovered plasma was accumulated during 5 years before the cooperation (toll manufacture) started.
- High cost of discarding unused plasma was part of this decision.
- Strategy to reduce TTIs, donor program, then NAT testing were required by NBI.
- 2020, introduced plasma apheresis to regular donors as a trial to increase the plasma to be sold to NBI.
- This activity is a perfect example of win-win situation.
- This model was very inspiring to other countries.

N.B. Info c/o Mr. Israel Chipare



Rwanda



- In 2022 Feb, NBI assessed BTD for potential processing of their RP.
- Following requests by NBI to move further;
 - ✓ Blast freezers
 - ✓ NAT testing
 - ✓ Update software
 - ✓ Enhance cold chain and blood processing
 - ✓ Update AfSBT accreditation
- MOH agreed to go ahead for the toll fractionation project.

N.B. Info c/o Dr. Thomas Myobo

Other Countries

- NBI assessed the Blood donation to transfusion chain as preparation of outsourcing plasma from more African countries. All prerequisite steps were done. These countries are; Uganda, Ethiopia, Zambia, Tanzania, Senegal. This is part of the project; **plasma from Africa to Africans.**
- Mini pool fractionation (revived Achilles project) is negotiated in the present with Uganda and Ethiopia.



Recommendations to African Countries

- ◆ Establishing Systems to ensure quality and safe blood products.
- ◆ Maximising component preparation and usage (according to the infrastructure of the BTS and needs of the specific country).
- ◆ Standardizing collection, transport, production, testing and storage.
- ◆ Staffing infrastructure required to prepare quality blood components.
- ◆ Supporting the local production of quality plasma collected locally from voluntary non-remunerated whole blood & source plasma donors.
Namibia model is successful.
- ◆ Improving access to essential medicines and to safer blood products as well as ensuring self sufficiency.



Thank You



AfSBT
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para Transfusão Sanguínea

