Increasing the supply of plasma-derived medicinal products to Namibia through the fractionation of local plasma – A NBI-NAMBTS success story

Benefits for the Namibian Health Sector

Israel Chipare
Windhoek
Namibia

and

Jeh-han Omarjee (PhD)
Durban
South Africa

NAMBTS donate life

NATIONAL BIOPRODUCTS INSTITUTE NPC

Plasma Derived Medicinal products (PDMPS)

- A number of PDMP's play a major role in health care
- WHO Model List of Essential Medicines

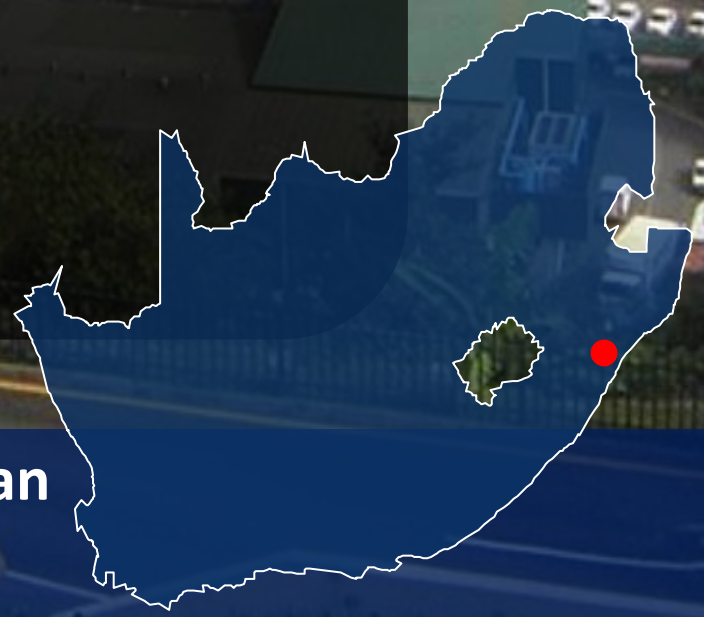
But

- Unequal access globally to PDMP's, especially Low-Middle-Income Countries (LMIC)
- A major factor limiting the global availability of PDMP's is inadequate supply of plasma meeting the requirements for fractionation

NATIONAL BIOPRODUCTS INSTITUTE NPC

- Manufacturer of PDMP's
- Not-Profit Company (NPC)
- Registered with the South African Health Products Regulatory Authority (SAHPRA)
- 90% products are listed on WHO Essential Medicines List





Based in Pinetown, approximately 20 km from Durban
Situated at **10 Eden Road** in **Paradise Valley**

Overview of NBI's Product Range

- **Coagulation Factors** used in the management and treatment of Haemophilia as well as other bleeding disorders.
- **Albumin solutions** - for fluid resuscitation and protein replacement.
- **Immunoglobulins** - for the management of Immunodeficiencies, autoimmune diseases or for infectious disease post-exposure prophylaxis .
- **Fresh dried plasma** to treat coagulation defects.
- **Diagnostic products** comprise a near-patient test kits for determining the Rho status of patients; monoclonal antibodies used in the manufacture of near-patient malaria and hepatitis B detection kits and ELISA kits for in-house use.

NBI's Mission:

NBI strives to meet the needs of patients and improve their quality of life by providing protein therapies and services within the South and Sub-Saharan African region and diagnostic products globally.



NBI's Purpose:

We provide products for patients to alleviate pain and suffering and improve their quality of life



The NBI-NAMBTS Collaboration

NBI

- **NBI** needed more plasma



- **NAMBTS** needed to utilize all recovered plasma (77%) was discarded
- **NAMBTS** required alternate avenues to generate more income to fund ID-NAT
- **NAMBTS** required PDMP's

NAMBTS donate life

Overview

- NAMBTS collects approximately 38 000 donations a year
- For 2021 financial year (ended 31 March 2021)
  - Total donations was 38 109
  - 34773 whole blood
  - 2644 apheresis plasma
  - 692 apheresis platelets
- 15 units/ 1000 population
- 100% VNRBD - 85% from repeat donors
- All whole blood processed into components

NBI and NAMBTS collaboration
improved availability of PDMPs in Namibia

- Before the collaboration there was shortage of PDMPs in Namibia
- Specifically between 2009- 2012 there was a serious shortage of PDMPs in Namibia
  - NBI could only supply local market in SA and no surplus to export to Namibia and SA region.
  - Had to look for alternative suppliers e.g. Kedrion, Pharmaplan
  - PDMPs became more expensive
- Collaboration between NAMBTS and NBI since 2013 led to an adequate supply of all PDMPs including Fresh Dried Plasma (Bioplasma FDP) from NBI.
  - Bioplasma FDP is supplied by NAMBTS to all remote areas while other PDMPs are sourced from NBI and supplied through pharmaceutical industry

Prior collaboration with NBI, plasma collected was discarded

- A total of **33373** litres of recovered plasma was produced during the 5 years before collaboration with NBI and only a small fraction (15%) was transfused to patients.
- 25798 (77%) litres of this quality plasma was discarded as surplus to clinical requirements
  - On average 77% of surplus plasma that met quality for fractionation was discarded.
  - The costs of disposal of this medical waste were staggering.
  - Ethical dilemma to discard such precious blood component donated by selfless blood donors who trust that the product will be used to benefit patients.
- There was a desperate need to collaborate with NBI and ensure surplus plasma is exported for fractionated.

Volume (Ltrs) of plasma produced and wasted
2010-2014

Year	2010	2011	2012	2013	2014	Total
TOTAL recovered plasma produced	6224	6236	6652	6738	7523	33373
FFP issued for clinical use	801	876	921	986	1221	4805
Wasted surplus plasma that meets quality for fractionation	4825	4861	5199	5213	5700	25798
% of quality plasma wasted	78%	78%	78%	77%	76%	77%

NBI audit of NAMBTS QMS
and approval as a supplier

On Condition SANBS Testing only

- Pre-assessment of QMS by NBI
- Physical Audit by NBI-May 2013
- Second Audit by NBI- successful in Dec 2013
- SAHPRA approval
- NAMBTS implemented ID-NAT testing in Feb 2014
- Re-audit by NBI Feb 2014- submitted to SAHPRA for approval
- SAHPRA Approval in October 2015
- Resumed plasma consignment shipments to NBI

Volume of plasma supplied to NBI
2018 - 2021



NATIONAL BIOPRODUCTS INSTITUTE NPC

NAMBTS
donate life
www.bts.com.na

Contribution of income
from surplus plasma to annual operational income

- NAMBTS received PEPFAR funding during the period 2005 to 2015 which contributed 6-44% of total operating income while the rest was derived from cost-recovery.
- PEPFAR grants ceased completely in 2015.
- Full operational budget is now fully funded through cost recovery.
- The deficit left by PEPFAR had to be covered by blood product increases.
- Surplus plasma exports to NBI helped to cover this deficit.
  - During the period 2016- 2021 plasma exports to NBI contributed between 1%- 5% to total operating income

Surplus plasma exports to subsidize cost of ID-NAT

- ID-NAT testing is one of our major cost drivers constituting on average 18% of annual total expense.
- Overall goal of NAMBTS is for income from plasma exports to cover at least 50% of the cost of ID-NAT
- By 2021 34% of ID-NAT costs were covered by income from surplus plasma exports as shown in the table below.

	2016	2017	2018	2019	2020	2021
% of ID-NAT testing covered by NBI plasma	5%	13%	11%	20%	21%	34%

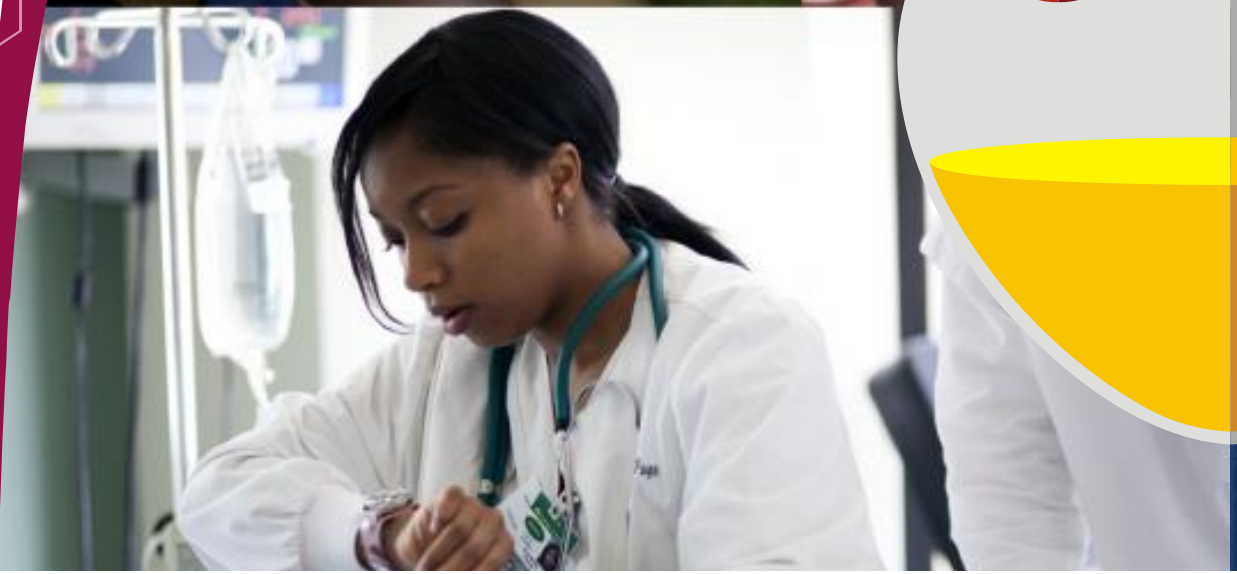
Conclusion

- The collaboration between NBI and NAMBTS resulted in:
  - Increased plasma supply to NBI thereby building capacity for production of PDMP's to Namibia and other countries
  - Reduced plasma wastage at NAMBTS
  - Generated income for ID-NAT testing at NAMBTS

A success story in line with WHO framework - increasing supplies of PDMP's to LMIC countries





Thank You for Your Attention

NATIONAL BIOPRODUCTS INSTITUTE NPC

NAMBTS
donate life
www.bts.com.na