

African Experience in obtaining Quality Plasma for PDMP

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Unavailability of PDMPs in Africa

- Unequal access globally to PDMPs, especially scarcity in Africa.
 - WFH reported (2020) that 79% of the total FVIII IUs are used in Americas and Europe, and only 1% is used in Africa.
 - Mean FVIII usage per capita was 6.14 IU in high income countries versus 0.10 in lower income countries.
- This picture might be the same for most of the PDMPs
- Main reasons for shortage of PDMPs in Africa-
 - Limited fractionation activities in Africa due to high cost of fractionation
 - Imports of PDMPs from high income countries are too expensive
 - Shortage of plasma meeting quality for fractionation.



Status of recovered plasma wasted in Africa

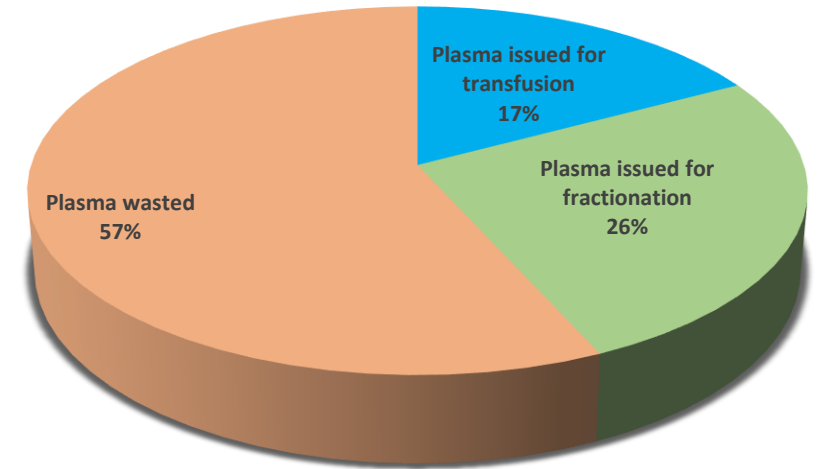
- 43 Countries in the African region provided blood collection data to WHO.
- The countries combined collected 6 million (5,981 mill) donations.
- Estimated to constitutes about 90% of whole blood collected in Africa
- 42% of whole blood collected was issued for transfusion as whole blood.
 - 44% of countries processed less than 50% of donations into components



Status of recovered plasma wasted in Africa

Proportion of plasma used and wasted in African countries

- These 43 countries had the potential to produce 1.18 million litres of plasma.
 - 202,515 litres (17%) of plasma were used for transfusion
 - 306,186 litres (26%) of plasma from two countries (South Africa and Namibia) was used for fractionation in Africa.
 - 668,000 litres (57%) was wasted/ or discarded.
- Major reasons for the waste-
 - Plasma does not meet quality requirements for fractionation.
 - A high number of donations (42%) are not processed to components



Major reasons for poor quality plasma

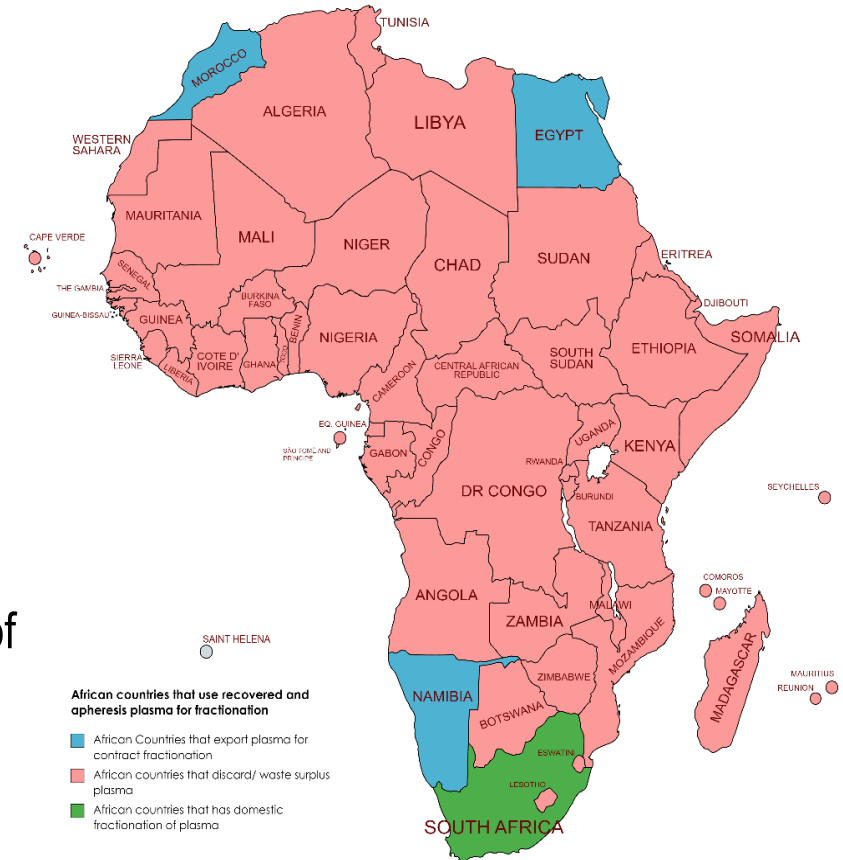
Why plasma is wasted in Africa

Internal use

- Plasma does not meet GMP requirements for fractionation due to.
 - No or poor standards and regulatory framework for national blood system in many countries.
 - Lack of appropriate equipment to produce, freeze and store plasma.
- High infectious disease rates in the donor population
 - Yet there is lack of proper testing facilities, policies and procedures, plasma may be considered unsafe.
 - NAT testing has not been implemented in many countries due to high cost.
- Inadequate financial resources.
 - Poor funding and increasing healthcare costs, huge import bill and weak currencies.
- Lack of component therapy, whole blood is directly used for therapeutic applications,
 - Whole blood cannot be separated due to lack of appropriate equipment

Plasma fractionation activities in Africa

- Africa has one fractionator (NBI) based in **South Africa**
- NBI produce PDMPs and meet domestic demand and in Namibia but not the region.
 - SA healthcare policy forbids exports if domestic demand not met
- NBI reports an increased production capacity to 1 million litres of plasma annually-
 - But less than 50% of that capacity is from S. Africa and Namibia.
 - Other African countries cannot supply due to poor quality plasma and lack of ID-NAT implementation.
- **Namibia, Egypt and Morocco** participate in contract fractionation
- Namibia export all recovered and apheresis plasma to NBI.
- **Other countries** are believed to discard all surplus recovered plasma



Namibia's experience in obtaining quality plasma for PDMPs

Overview of the operations of the Blood Service (NAMBTS)

- NAMBTS collects 47 000 donations per annum.
- Whole blood donation rate 16.5 units/ 1000 population
- 100% VNRBD - 85% from repeat donors
- Blood processing and testing are centralized
- TTI testing is by using serology and ID-NAT.
- TTI prevalence in donations is on average 1% for a year (1.14 in 2023)
- Exports all surplus recovered and apheresis plasma to be fractionated by NBI in South Africa.



How the collaboration between NAMBTS and fractionator (NBI) started

- Collaboration started in 2013 driven by mutual interest.
- Collaboration covers supply of plasma to NBI and supply of PDMPs to Namibia
- NAMBTS met all the GMP requirements and was approved by the S. African regulator as a plasma supplier in 2014.



- Needed to utilize all recovered plasma (77%) was discarded
- Required alternate avenues to generate more income to fund ID-NAT
- Required PDMP's

- **NBI** needed more plasma

What is unique about NAMBTS and NBI collaboration compared to other toll fractionation?

- NAMBTS supplies plasma to NBI for a fee.
- NBI pools NAMBTS plasma together with plasma sourced from South Africa and produce PDMPs.
- NBI supplies Namibia with PDMPs through the pharmaceutical industry.
- Both NAMBTS and NBI ensure sufficient PDMPs in Namibia through regular engagements with the distributor.
- NAMBTS supplies recovered plasma, apheresis plasma.



Plasma for fractionation supply logistics

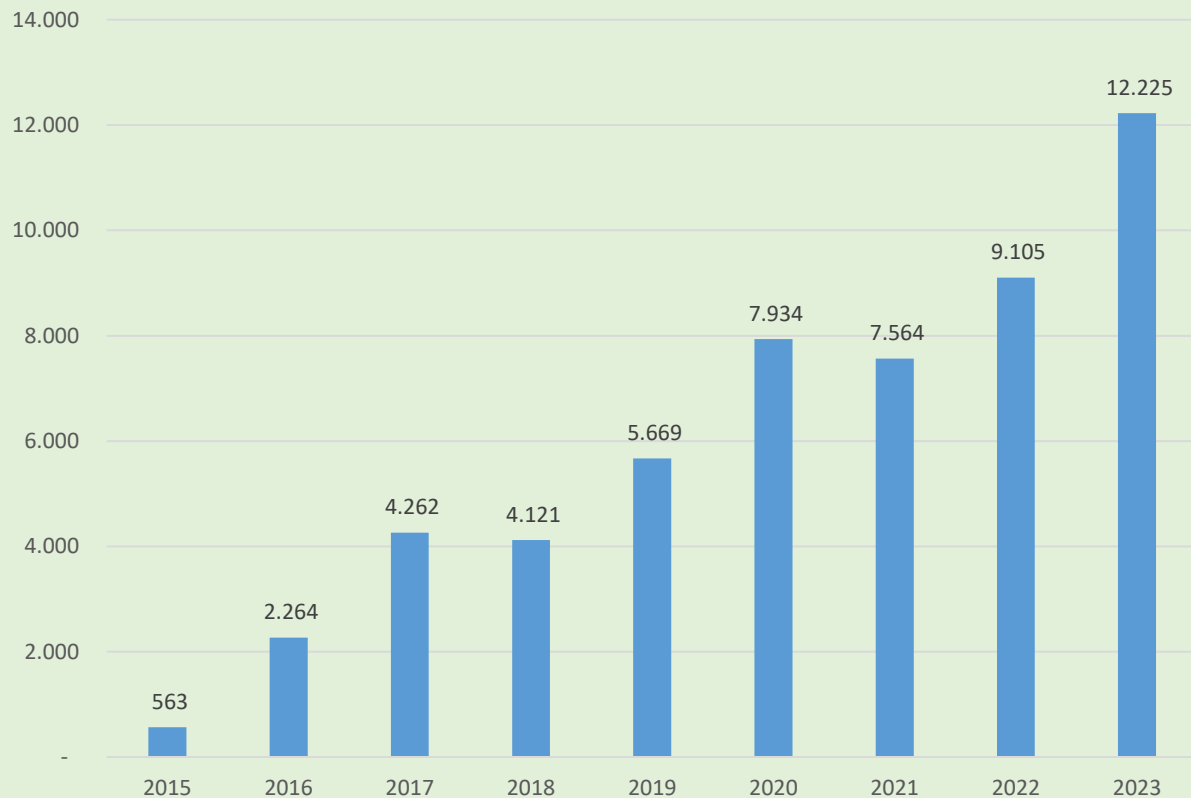
- NBI/ NAMBTS has 10 year plasma supply agreement
- Plasma supply volumes and price/ litre are reviewed annually
- NAMBTS ships twice a year by road, 2200 kms trip, takes 36 hrs.
- Use a freezer truck at -25°C, with temperature loggers on board, each pallet covered by freezer jacket.
- Plasma is packed in pallets of approx. 440 litres of plasma.
- Plasma categories include-
 - Apheresis plasma, all frozen within 6hrs of collection
 - Three categories of recovered plasma frozen within 6hrs, between 6- 24 hrs and, after 24 hrs of donation.
 - Each of these categories carries a different price per litre.



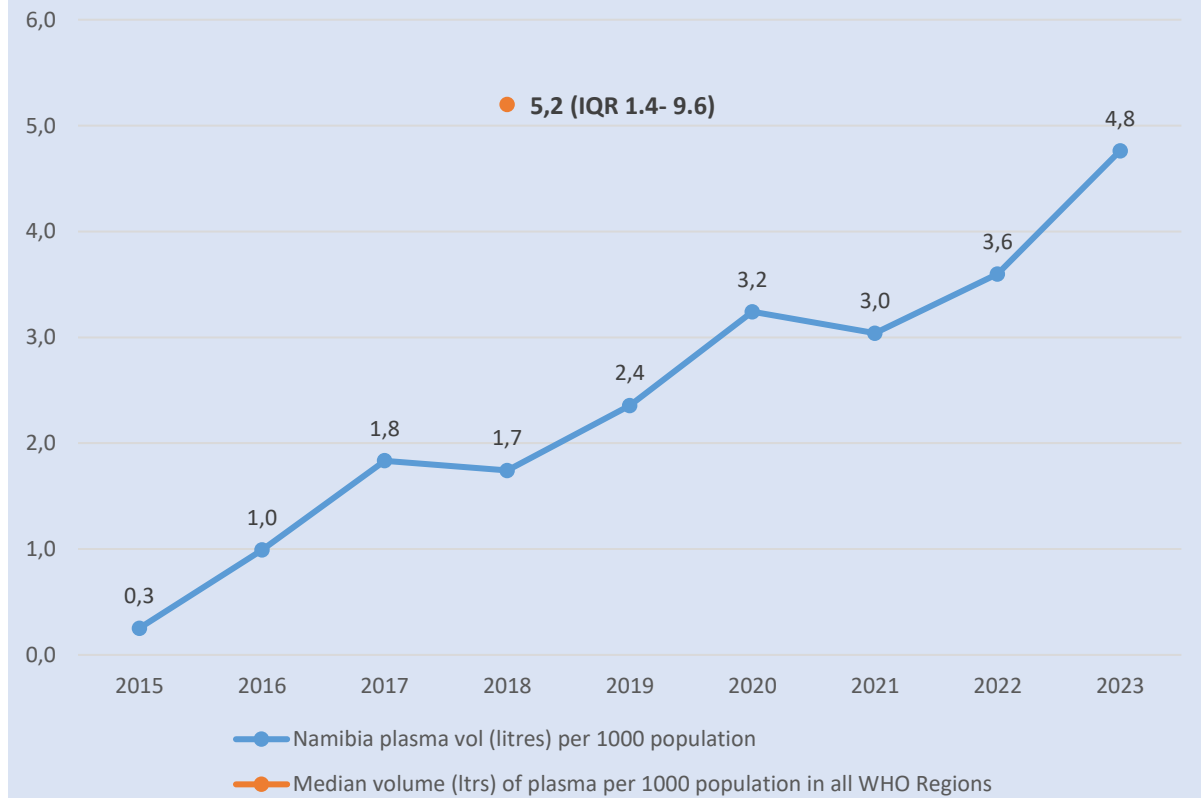
Annual volume of plasma for fractionation supplied by Namibia

Internal use

Plasma volume (ltrs) for fractionation supplied to NBI



Plasma volume (ltrs) per 1000 population



- Volume of plasma shipments to NBI increased by more than double between 2019 and 2023.
- NAMBTS introduced apheresis plasma collection from repeat donors in 2020 which increased plasma volume for fractionation by 40%.
- Volume of plasma per 1000 popn reached 4.8 ltrs in 2023 compared to the global median volume per 1000 popn of 5.2 ltrs reported in the WHO report.

Benefits of NBI and NAMBTS collaboration

supply of plasma for fractionation and availability of PDMPs

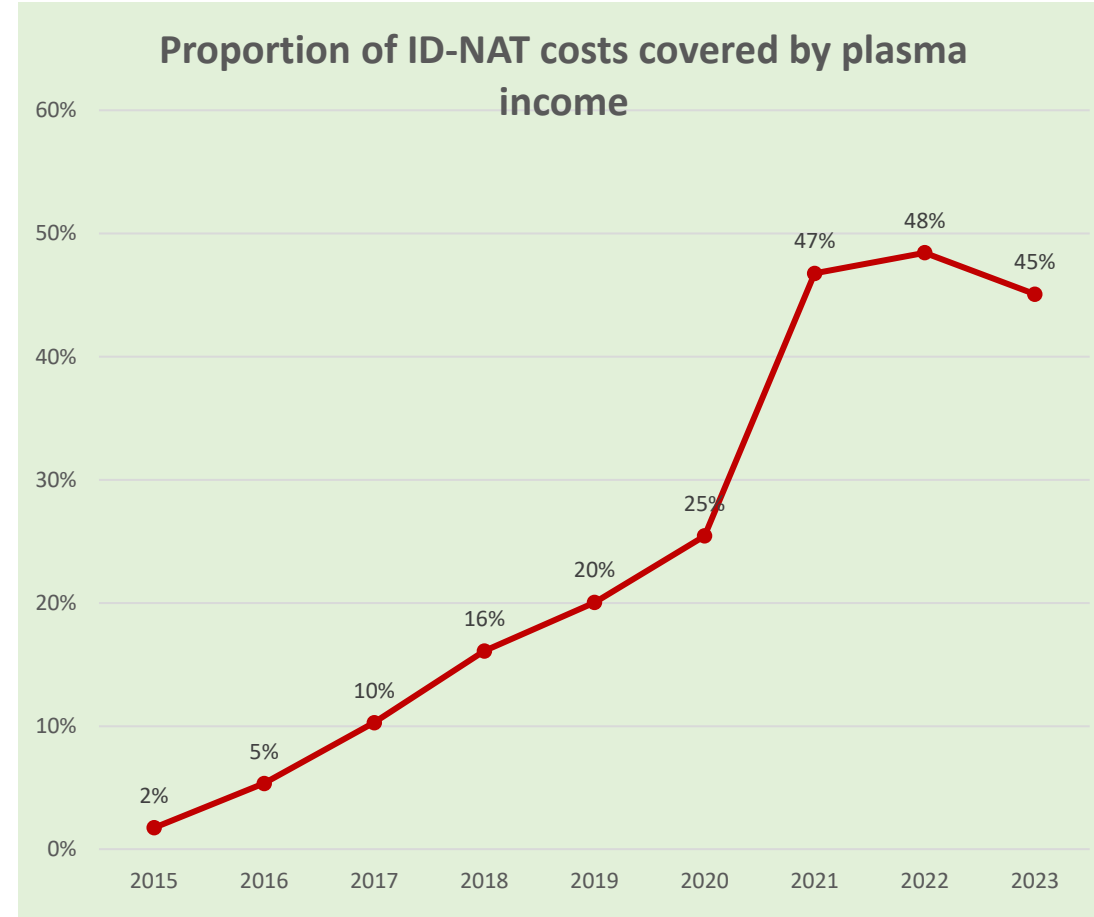


- Collaboration improved availability of PDMPs in Namibia
 - No known shortage of PDMPs in Namibia
 - Contributes to availability of hyperimmune globulins for rabies and hepatitis B in Namibia.
- Namibia contributes to availability of PDMPs in the region
 - Namibia cannot absorb all PDMPs made from Namibian plasma
- The collaboration has made freeze dried plasma (FDP) became available to Namibia as well.
 - Patients in remote areas have improved access to plasma.
- NAMBTS generates more income from plasma exports, subsidize cost of ID-NAT
- Save costs from plasma waste disposal.
- Maximize use of blood donations

Contribution of income from surplus plasma

How has income from plasma exports benefited NAMBTS

- NAMBTS received PEPFAR funding during the period 2005 to 2015, cessation of funding left a huge deficit
- Surplus plasma exports to NBI helped to cover this deficit.
 - During the past 5 years plasma exports to NBI contributed between 3%- 8% to total operating income
- Surplus plasma exports subsidise cost of ID-NAT
 - Overall goal of NAMBTS is for income from plasma exports to cover at least 50% of the cost of ID-NAT
 - For the past 3 years, more than 45% of ID-NAT costs were covered by income from surplus plasma exports as shown in the graph.



How did Namibia overcome challenges faced by other countries

- Blood system in Namibia are supported by a sound legal and regulatory framework
- Implementation of QMS and accreditation at level 3 by AfSBT since 2013
- Introduced of ID-NAT since 2005, initially contracted to SANBS and moved to Namibia in 2014
- 100% component therapy implemented since 2006
- Blood service invested a lot in equipment and automation during PEPFAR grant
- Adequately funded through cost recovery system supported by a sound financial management system.
- Adequate trained and competent staff.

Challenges that Namibia experience with the plasma programme

- High cost of operating the plasmapheresis programme
 - Cost of testing and collection sets, these are imported at high exchange rates
 - The programme barely breaks even
 - We had put a maximum ceiling on the volume we can supply.
- Only one plasma pheresis centre at head office due to high cost
- High prevalence of HIV (>13%) and hep B (>10%) in the population, rigorous screening process excludes many potential donors.

Conclusion

- NBI needs to work closely with AfSBT's SWAP and African countries and assist them technically to improve plasma quality.
 - The 'Plasma from Africa for Africans' programme introduced recently by NBI may offer this solution if implemented effectively
- The supply of plasma for fractionation through collaboration with NBI provided significant benefits to NAMBTS and Namibian healthcare system by:
 - Ensuring sufficient PDMPs in Namibia as well as FDPs for remote hospitals in the country
 - Reduced plasma wastage
 - Generated more income to fund ID-NAT testing for the blood supply.
- A success story in line with WHO framework - increasing supplies of PDMP's to LMIC countries through fractionation of domestic plasma

Thank you for your attention

