IPFA AWARD 2024

IPFA/PEI 30TH INTERNATIONAL WORKSHOP ON SURVEILLANCE AND SCREENING OF BLOOD-BORNE PATHOGENS

NATIONAL BIOPRODUCTS INSTITUTE NPC

Committed to providing safe, cost effective, quality medicinal products.

Presented by Jeh-han Omarjee (PhD)



Building relationships

- Joined NBI in 2007 as the Head of Quality Active Raw Materials
- Responsibilities included on-going safety and quality of plasma used within NBI
- Acquired the necessary information to operate from a solid base
- Worked jointly with NBI's plasma suppliers to improve plasma quality and supply
- Developed working relationships with plasma suppliers and improved effective communication on plasma related issues





Improving plasma quality and supply

- Improved GMP at regional zones at all plasma suppliers
- Expanded plasma categories for fractionation and reduced plasma rejection rates
- Provided guidance on improving electronic systems for issuing of plasma to NBI
- Contributed to transportation validation of plasma consignments from suppliers to NBI
- Assisted with setting up a specialized anti-rabies plasma collection programme at NAMBTS



Compliance and improving product release times



- In 2013, my job role was expanded to include the pharmaceutical microbiology discipline at NBI
- Implemented a robust site-wide environmental monitoring programme and contamination control strategy
- Designed and implemented state of the art laboratories for biological testing to address regulatory expectations
- Reduced reliance on external test service providers and improved final product release times e.g. Monocyte Activation Test (an alternate to pyrogens testing) implemented routinely at NBI





Expanding NBI's product portfolio

- Project Manager for the development of new products at NBI
- Managed the technology transfer process
- Planned and executed trial and pilot batches
- Worked with industry peers on viral validation studies, analytical test development, stability protocol designs and biochemical characterization of new products



Improving availability of Plasma and PDMPs in Africa and LMIC

- PDMPs are costly and insufficient in LMIC
- The major factors limiting the availability of PDMPs in LMIC :
  - Insufficient supply of domestic surplus plasma

  OR

  - Surplus plasma does not meet required quality standards for contract/toll fractionation



8 NATIONAL NEWS

AN ADULT WITH HAEMOPHILIA NEEDS SH22.8M FOR 3 DAYS OF TREATMENT

HAEMOPHILIA VICTIMS CRY OUT OVER COSTLY TREATMENT

By Paul Kweyuna

Specialists and parents of patients with haemophilia at Mulago Hospital have called on the Government to support the treatment of persons suffering from the illness, saying it is too costly.

The best way to treat haemophilia is to replace the missing blood clotting factor so that the blood can clot properly, Dr Phillip Kasirye, a paediatrician at Mulago Hospital's haemophilia department, said.

This is done by injecting treatment products called 'clotting factor concentrates' into a person's vein, and this is usually carried out for three consecutive days from the onset of the bleeding.

Currently, one unit of the clotting factor concentrates costs $1 (about sh3,800). Bleeding by a child with a weight of 30kg requires 3,000 units of the clotting factor concentrates for three days, which costs sh10m.

On the other hand, an adult weighing 40kg and above needs 2,000 units of the clotting factor concentrates costing sh7.6m per day, which translates into sh22.8m for the three days of treatment. However, Kasirye said the doses can vary depending on the severity of bleeding.

Currently, clotting factor concentrates are imported and funding for their purchase is done by donors through the Haemophilia Foundation Uganda (HFU).

Speaking at the commemoration of the World Haemophilia Day on Wednesday at Mulago Paramedical School, Kasirye said the rising number of patients with haemophilia requires government support to be able to access the costly clotting factor concentrates.

Data from HFU shows that over 500 Ugandans are suffering from haemophilia who seek free medical care.

Agnes Kisakye, the executive secretary HFU, said there are many more patients who are not aware that they are suffering from haemophilia.

"I call on the Government to

Assuring their partner is normal, there is a one-in-two chances of this happening," Wamwa said.

Wamwa said throughout his practice, he has never come across a female with haemophilia. "It would take a carrier marrying a haemophilia man, a very rare event. In which case, the female carrier would pass on her defective X chromosome and, the other defective chromosome from the father, resulting in a female with two defective chromosomes, causing the disease. Remember, having one normal chromosome leads to some factor production, masking the loss from the defective chromosome," he noted.

Wamwa added that it is estimated that one in 5,000 boys is born with haemophilia, with no particular ethnic group at highest risk.

"With our population as it is, we would expect to have nearly 2,000 patients with haemophilia. However, we have only 600 registered (at the Mulago haemophilia department), meaning that most of them have not been diagnosed yet," the medic said.

Kisakye (left) interacting with participants during World Haemophilia Day at Mulago in Kampala, on Wednesday

PHOTO BY GODFREY KAKAI

PARENT SPEAKS OUT

Leonard Ssengooba, a father of a 14-year-old

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Improving availability of Plasma and PDMPs in Africa and LMIC

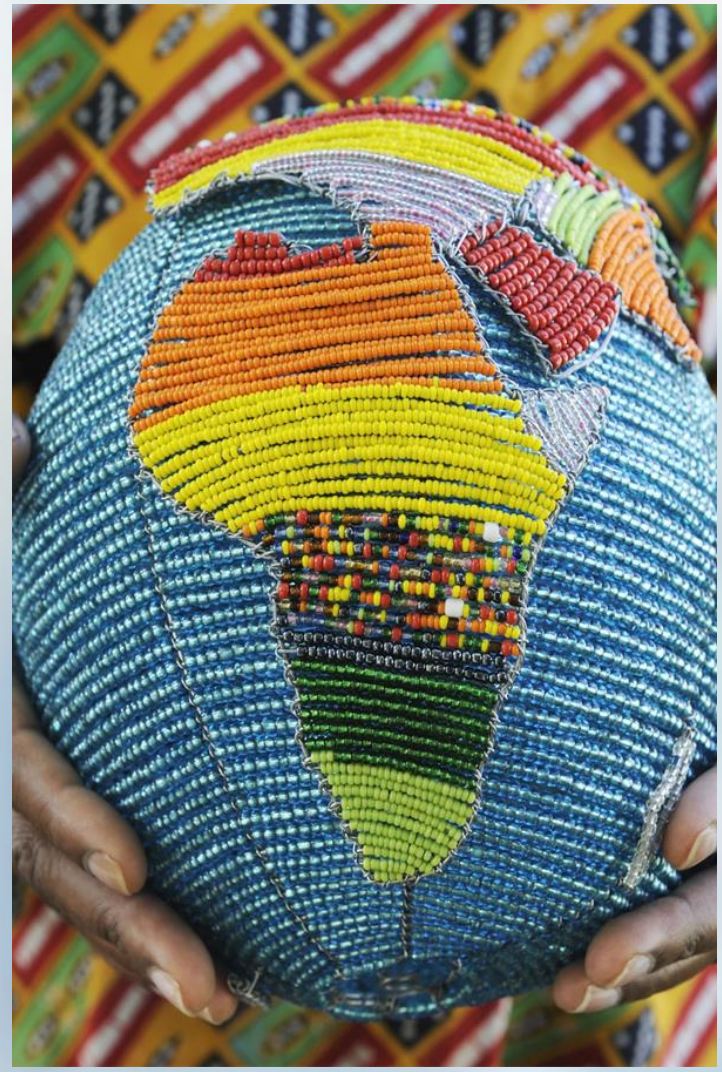
- NBI launched the "**Plasma from Africa for Africans**" programme
- Objective of the programme is to partner with blood establishments across Africa and assist with improving plasma quality and supply for the manufacture of PDMPs to address the needs of patients in Africa
- Improved awareness of the programme
- Currently working with blood establishments in Rwanda, Uganda, Ethiopia, Zambia, Tanzania and Kenya



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Collaboration with key organisations

- To overcome challenges to improve plasma quality and allow for the export plasma for contract fractionation collaborations were initiated with:
  - AfSBT
  - WHO/International Coalition of Safe Plasma Proteins (ICSPP)
  - Paul Ehrlich Institute (PEI)
  - African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD)



World Health Organization
REGIONAL OFFICE FOR Africa

ISBT
ICSPP
LAUNCH OF THE INTERNATIONAL COALITION FOR SAFE PLASMA PROTEINS (ICSPP)
To advance access to safe plasma proteins in Low- and Middle- Income countries

Paul-Ehrlich-Institut

THE NEW PARTNERSHIP FOR AFRICA'S DEVELOPMENT
NEPAD

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Conclusion

- Fulfilment in personal values
- Making a positive contribution
- Building relationships as they are a key to achieve goals

"*Every adversity, every failure, every heartache carries with it the seed of an equal or greater benefit*," Napolean Hill

What next?

- Advance on our approach by working with key organisations to overcome challenges related to export of plasma from Africa and other LMIC
- Continue to build relationships with blood establishments in low resource settings and work together to improve plasma quality and availability of PDMPs



Thank you

- IPFA
- NBI Executive Team
- Microbiological Sciences and Q-ARM Team
- NBI team










Thank You for Your Attention

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