Models for technology transfer and technical assistance

Dr. Leni von Bonsdorff, Finland

Executive Director of IPFA, the Netherlands

Disclosures

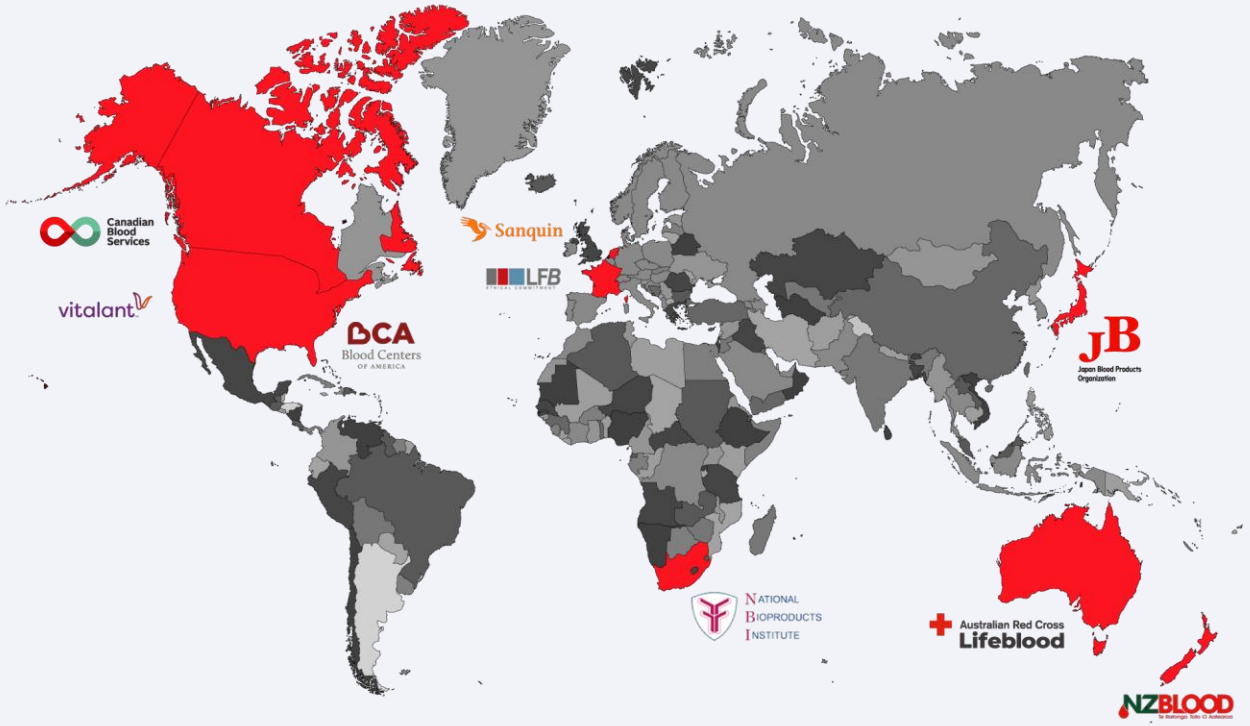
I have the following disclosures:

- Consultation company owner: *Verbenex Oy*
- Board member: *Glycorex Ab*

IPFA

IPFA supports and promotes the activities of not-for-profit organisations around the globe engaged in the collection and fractionation of plasma to enable robust, safe supply and patient access to plasma derived medicines.

Through education and collaboration with stakeholders, we advocate for public health values and donor health protection.

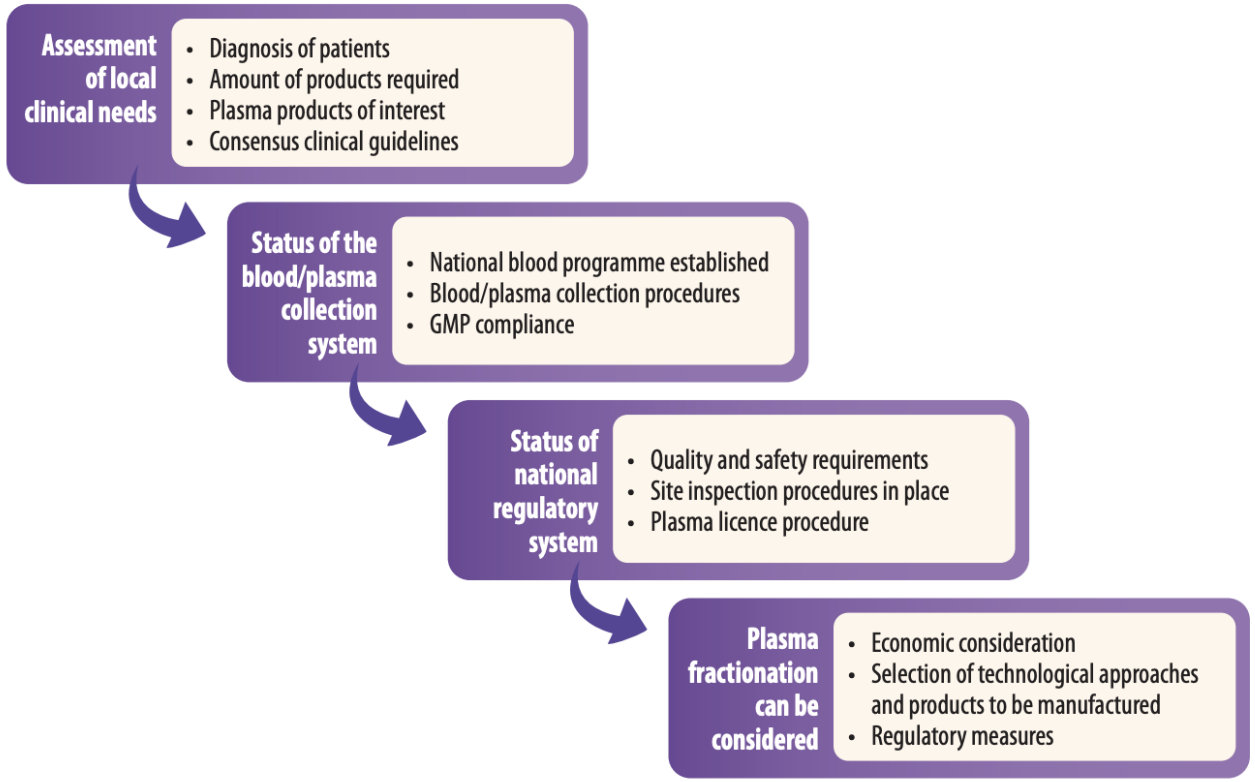


Topics

- Technology transfer and technical assistance in the plasma value chain to gain access to plasma products
- How can toll or contract manufacturing help in setting up local plasma collection?
- When is a country/region ready to start a project on fractionation and how can technology be transferred?

IPFA, embedded in community

Fig. 1. Capacity-building and decision-making steps of plasma fractionation programme to improve availability of PDMPs made from domestically produced plasma

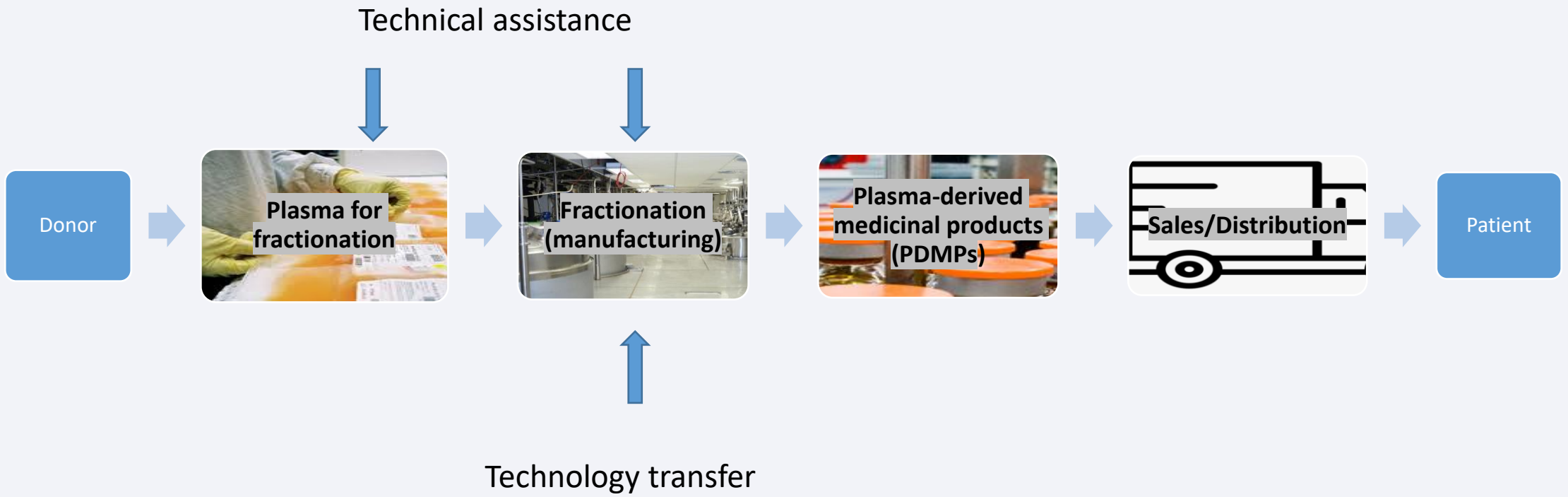


Ref: Guidance on increasing supplies of plasma-derived medicinal products in low- and middle income countries through fractionation of domestic plasma, WHO 2021

Step-wise approach:

- from local small scale
- via contract/toll manufacturing
- possibly towards full scale domestic fractionation

PDMPs: a long and complex value chain



Technical assistance

Suppliers can provide technical assistance, and it can be gained already when setting up plasma collection. It can contain following elements, as examples:

- Assistance with installation and operation of equipment, including qualification and validation
- Help on documentation of suitable standard to fulfill regulatory needs
- Support in procurement of materials/reagents/raw materials
- Training (on-site and other)
- Maintainance service

Offers from different suppliers and should include the services they may provide

Services and technical support of major importance should be included in final agreements

Toll or contract manufacturing/fractionation

- Plasma is sent abroad to a fractionator who uses it for manufacturing of PDMPs which are sent back for domestic use
- PDMPs are from the same plasma (toll agreement) and/or other plasma can be used according to contract
- Plasma has to fullfill the requirements of the fractionator/regulators
- Suitable for annual plasma volumes of about 50.0000 – 200.000 l

Toll/contract manufacturing

Pros:

- No need to build own facility, gives quicker access to PDMPs
- First step to really ensure that the local plasma fullfills all requirements needed for fractionation on quality and GMP:
  - The review process including audits and inspections from fractionator/regulatory authorities gives valuable learning on how the collection should be done
  - A good fractionator partner can give technical assistance on plasma collection

Cons:

- If need for product increases, increasing capacity maybe difficult
- Product range maybe limited
- Dependence on third party and import of products
- Can be too costly

Towards full scale domestic/regional fractionation

Can be considered:

- When there is certainty that sufficient plasma, of appropriate quality, can be collected. Preferably >200.000 l plasma per year to reach economy of scale. Regions/countries can work together to reach this goal
- There is an infrastructure supporting high tech pharmaceutical production
- If investment in a long-term enterprise (>10 years) is possible with a lead time of at least 3-4 years from planning to operation

Political environment

Public health policies

Market situation and competition

Competence and skills of management and workforce!

Environmental infrastructure

Construction of a facility for PDMPs

- Developing the whole process from scratch (lab/scaleup/implementation) is possible but needs skills and takes time and efforts, not to be recommended
- Technology is available for large scale manufacturing, willingness of fractionatiors to licence it out varies
- A good relationsship with a fractionator can start with toll/contract manufacturing and eventually later lead to licensing and technology transfer

Technology needed for PDMPs

- Basic fractionation process based on precipitation of plasma to cryopaste (for FVIII) and ethanol precipitation to split into immunoglobulin and albumin fractions
- Chromatographic techniques for further purification
- Filtration techniques for particle removal and concentration
- Dedicated virus inactivation/reduction tehniques
- Aseptical fill and finish of parenterals. For coagulation factors also freeze drying.

What is included in technology transfer?

- Should include all aspects of the production method including documentation of test methods, SOPs, etc.
- Training and possible development support
- Clinical data to support product registration is needed

A good relation with, and assistance of the technology provider, in implementation and operation!

Thank you for your attention!

info@ipfa.nl