Pharmaco-Economics of PDMPs Production

8 October 2021

Presentation by Executive Director Leni von Bonsdorff at

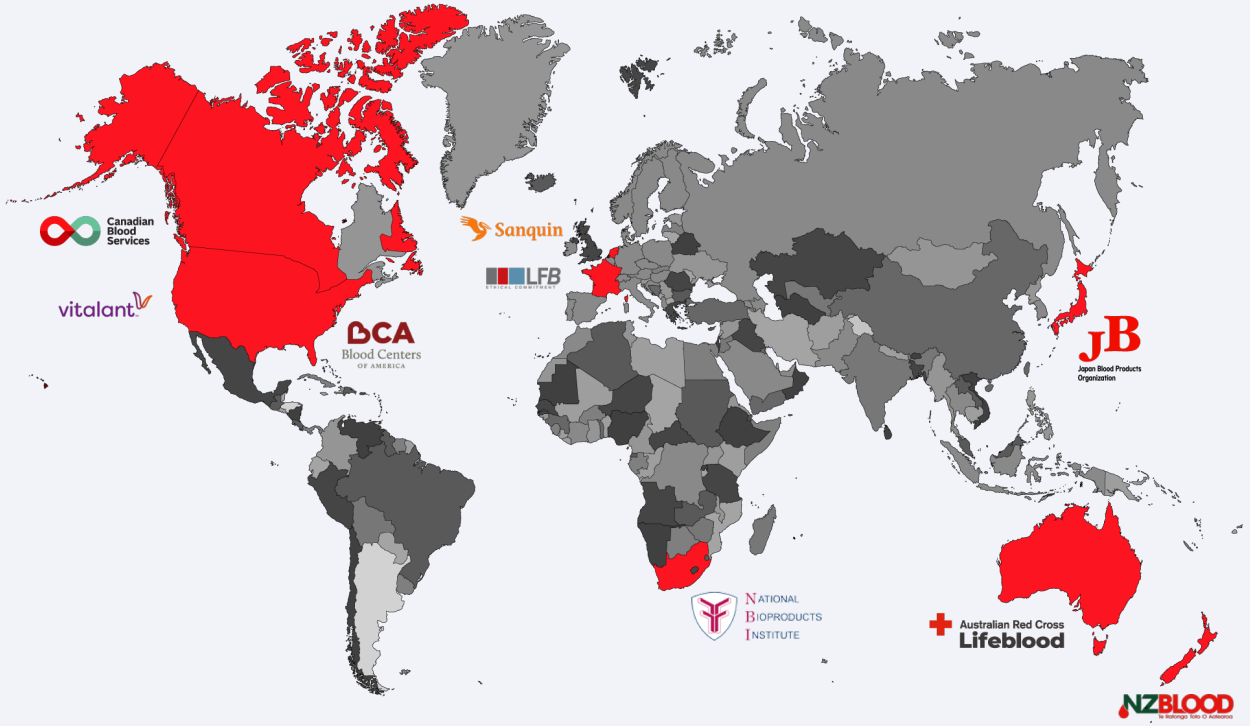
ATMF/IPFA joint webinars

international plasma and fractionation association

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.

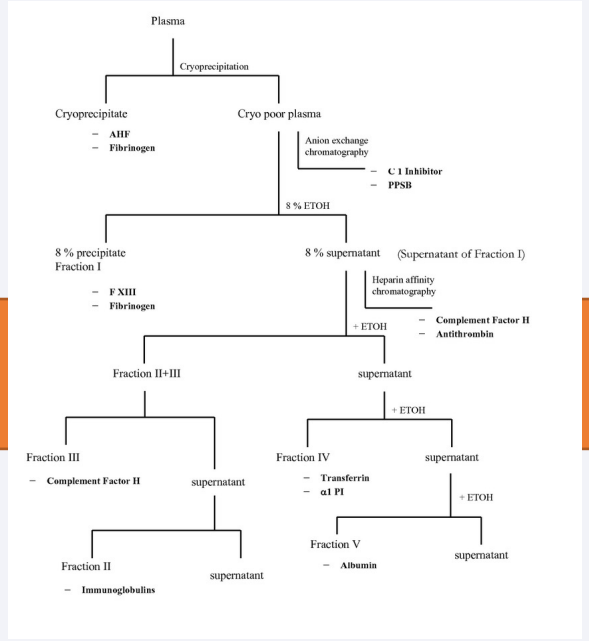


Topics covered

- What is good to understand about the economy of the plasma value chain when dealing with plasma collection intended for manufacturing of PDMPs (and as support when setting up local blood/plasma collection strategies)
- What is the cost structure of the plasma manufacturing process
- Some points on health economic/technology assessments (HTA) for PDMPs and value-based health care

Large scale manufacturing of PDMPs = fractionation







Plasma for fractionation

- Unique raw material!
- Many units of individual donations will be combined

Production = fractionation

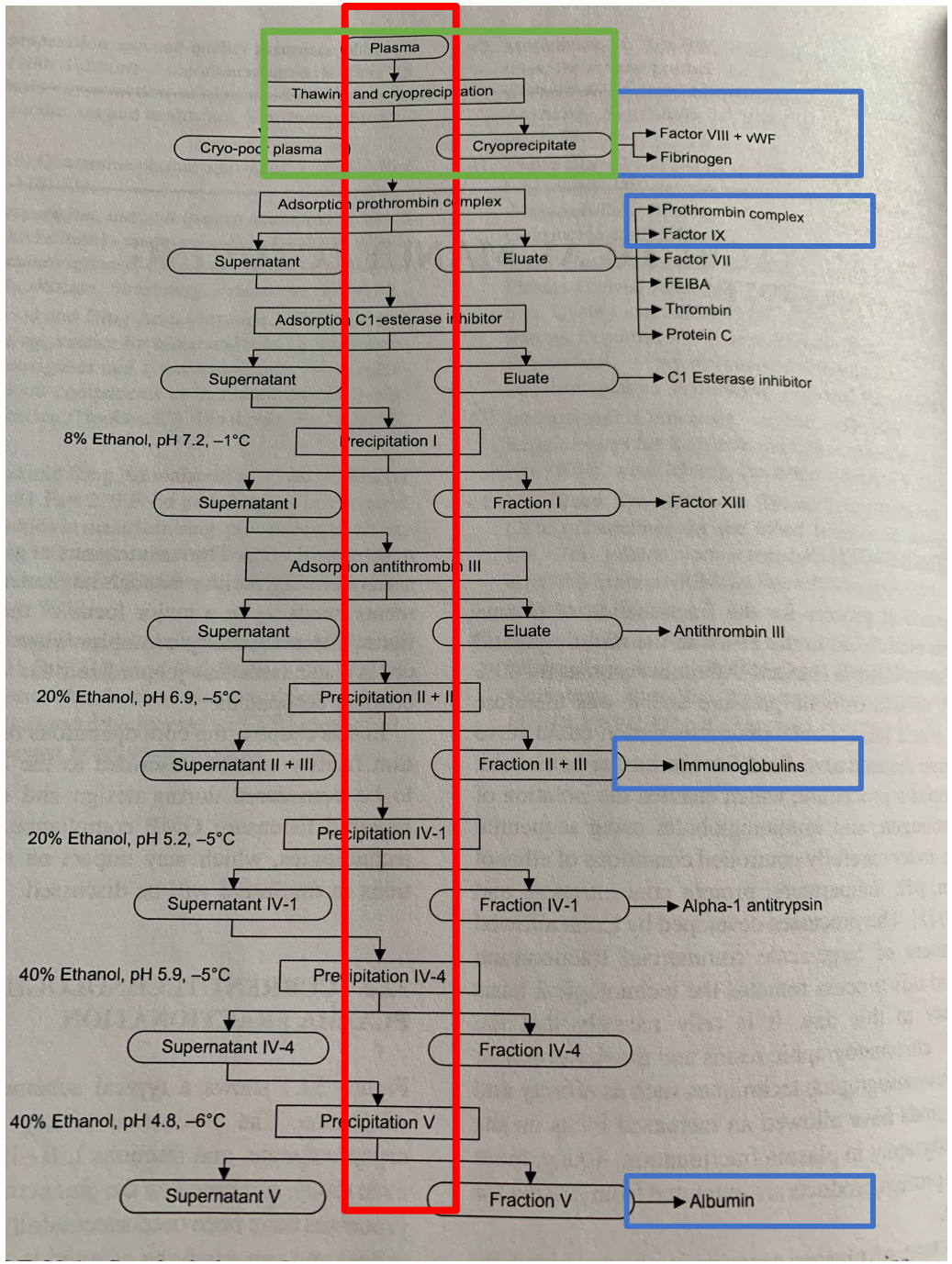
- Complex manufacturing process
- Stringent hygiene and GMP requirements

Final PDMPs

- Several products can be made out the same plasma

Fractionation of plasma

Small scale manufacturing for virus safe plasma and/or cryoprecipitate
An alternative to large scale manufacturing where only one or few plasma units are processed



The large scale manufacturing, the basic process
This is commonly used for all the plasma and forms a basic cost per unit of product.

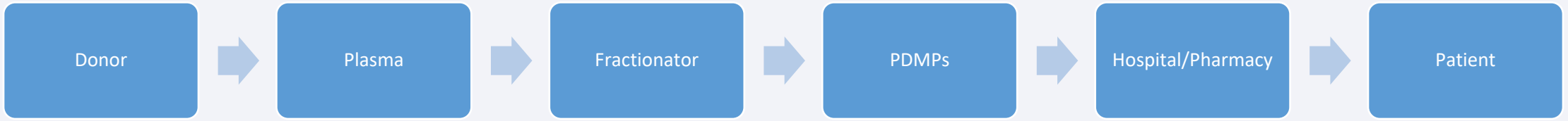
Specific PDMPs in separate side processes. Each have a certain capacity and not all plasma from the basic process is necessrily used for these. Different manufacturing and virus safety steps are inlcuded depending on product.

Plasma value chain

Income/Revenue, potential ones

Sales of plasma for fractionation

Sales of PDMPs



Costs

All costs related to plasma collection:
Donor recruitment, donation, processing into plasma, testing, storage, quality system etc

All costs related to plasma manufacturing into PDMPs:
Transport, manufacturing process and all its steps, QA, QC etc

All costs related to PDMPs:
Registration, distribution, reimbursement, marketing, sales

Cost structure 1.
Small scale manufacturing of virus safe plasma and/or cryoprecipitate

- An alternative to PDMPs and a step towards access before large scale manufacturing is/can be considered
- Builds on medical devices, with certain quality control provided
- Main costs items:
  - the medical devices, single use equipment
  - labour intensive, training
- Suitable for blood processing enivornment, not so high investement in facility or utilities and environment

Cost structure 2.
Large scale manufacturing of PDMPs

- Manufacturing unit capable of processing large volumes (thousands to million liters) of plasma to final approved PDMPs
- Needs substantial capital investment (>100 M €)
- Apart from plasma raw material, main costs are:
  - Operation and maintenance
  - Materials and reagents
  - Labour costs
  - Quality assurance control
  - Utilities

PDMP vs traditional pharmaceutical manufacturing

- Long production lead times:
  - from about 7 months to over 12 months from donation to delivery to patients vs with around 2-3 months for traditional pharmaceuticals
- Plasma raw material costs:
  - typically comprise over 50% of expenditure of products compared with less than 15% for other pharmaceuticals

Cost structure, the traditional way to present it with many PDMPs giving higher value

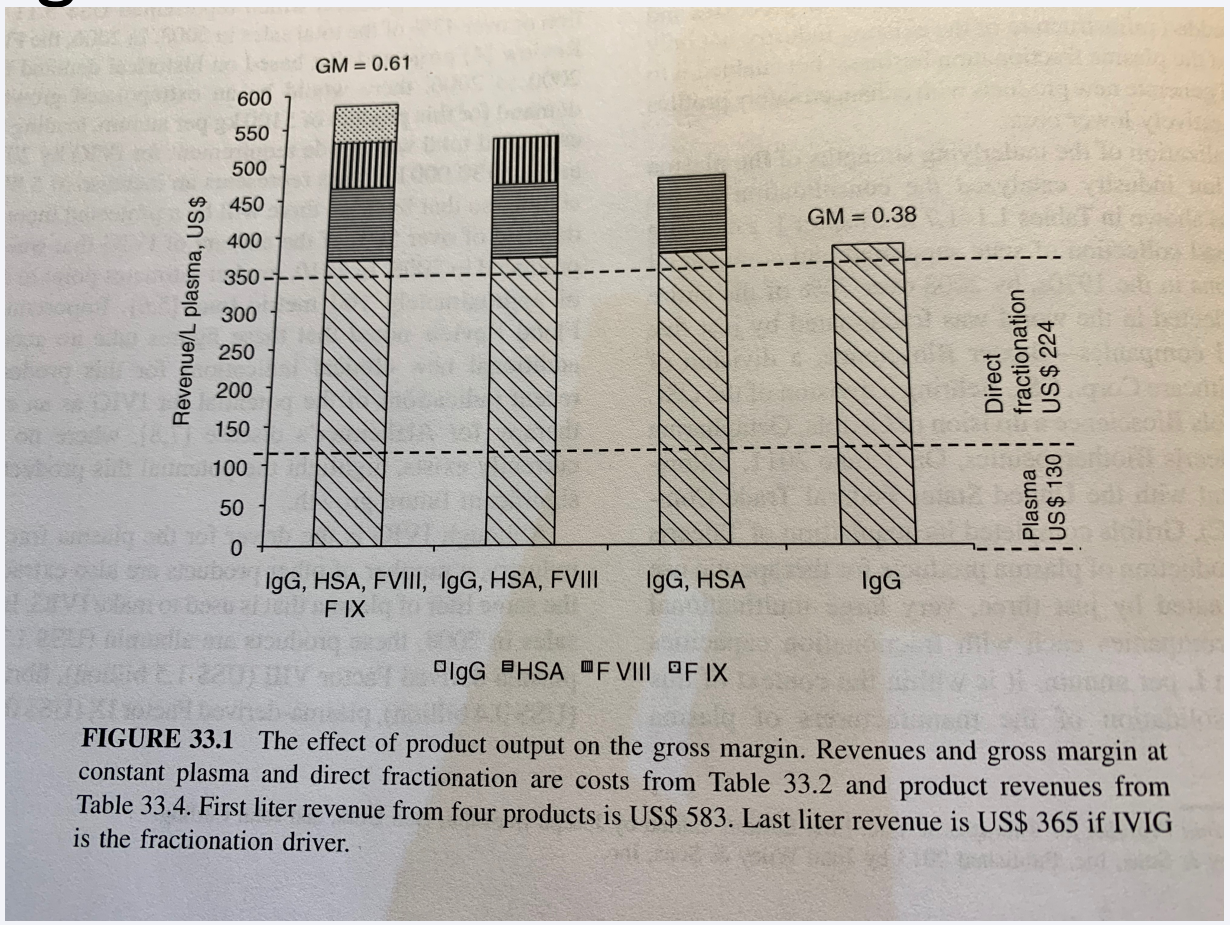


FIGURE 33.1 The effect of product output on the gross margin. Revenues and gross margin at constant plasma and direct fractionation are costs from Table 33.2 and product revenues from Table 33.4. First liter revenue from four products is US$ 583. Last liter revenue is US$ 365 if IVIG is the fractionation driver.

Ref Book on "Production of plasma proteins for therapeutic use, Wiley, 2013"

Health technology assessments and PDMPs

- The classic method to assess whether a medicine is cost effective and its price justified for a certain treatment or disease. Important tool for e.g. reimbursment bodies
- PDMPs have existed long before this method became common practice
- Always has to be adopted to local situations and circumstancies
- Does not usually look at the value chain beyond the product and the direct costs related to the treatment

Value based health care

One definition:**“Value-based healthcare is the equitable, sustainable and transparent use of the available resources to achieve better outcomes and experiences for every person.”***

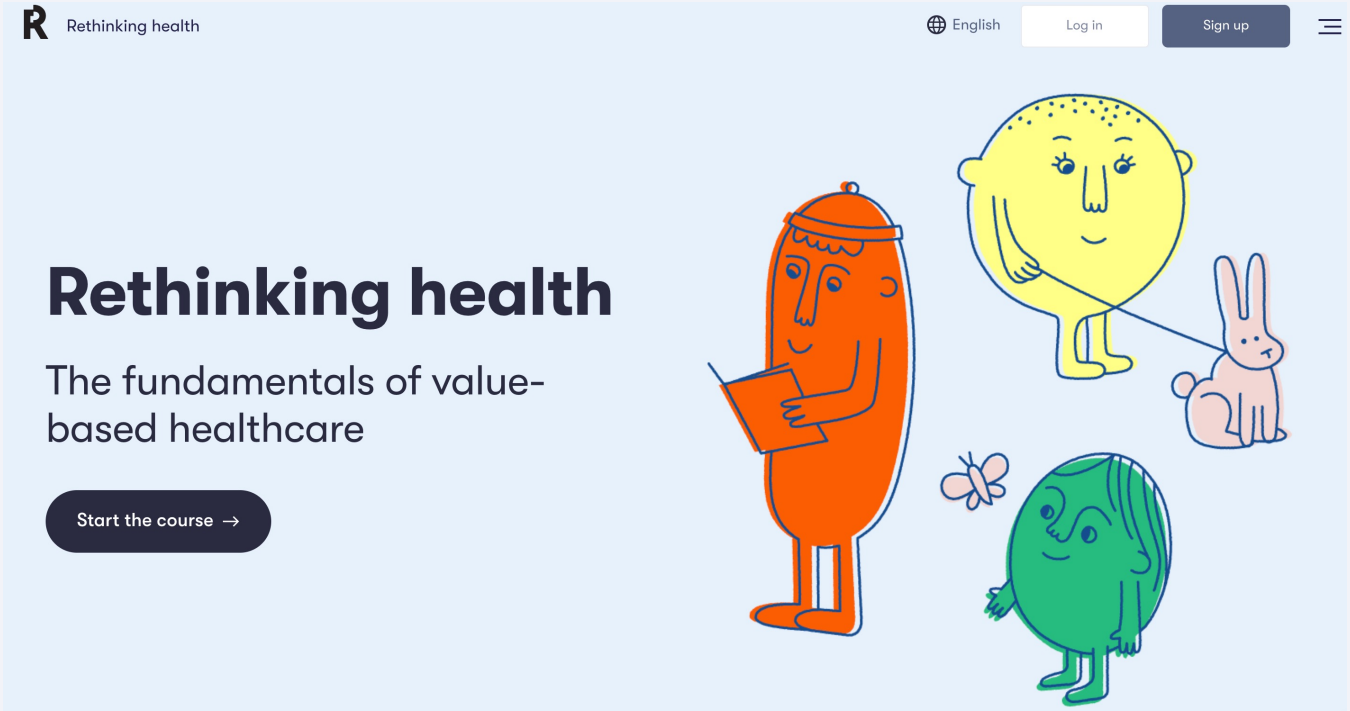
In the field of blood/plasma collection this could be seen a higher focus on IMPACT of the total plasma value chain, and its societal value than focusing on the profit of the product.

This fits well with the public health mission of blood establishments and goes beyond just the labile blood components to include also PDMPs to explain why plasma collection and medicines are important and should be invested in.

*Hurst L, Mahtani K, Pluddemann A, Lewis S, Harvey K, Briggs A, Boyle A, Bajwa R, Haire K, Entwistle A, Handa A and Heneghan C. Defining Value-based Healthcare in the NHS: CEBM report. https://www.cebm.net

Where to learn more about the concept

- https://reaktoreducation.com/en/courses/rethinkinghealth/



Conclusions

- Large scale plasma manufacturing differs from other pharmaceutical manufacturing due to its unique raw material which has high impact on the cost structure of PDMPs
- It is important for policy and decision makers to understand the full impact of the plasma value chain and it value for public health and patients

Thank you for your attention!

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