



Regional Council
of Jämtland

Jegrelius 

Challenges to bring safe blood bags into healthcare

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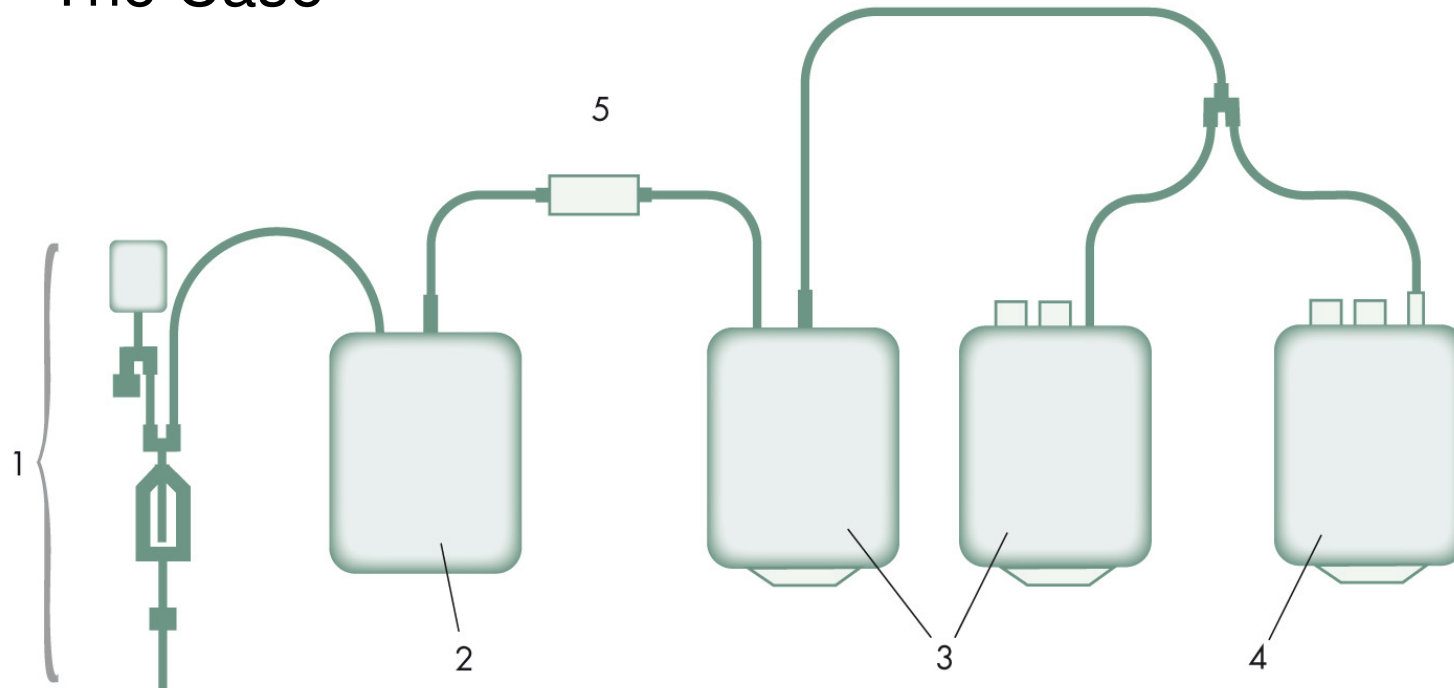
EDC in Medical devices

 PVCfreeBloodBag.eu

With financial support
from EU's Life+ programme



The Case



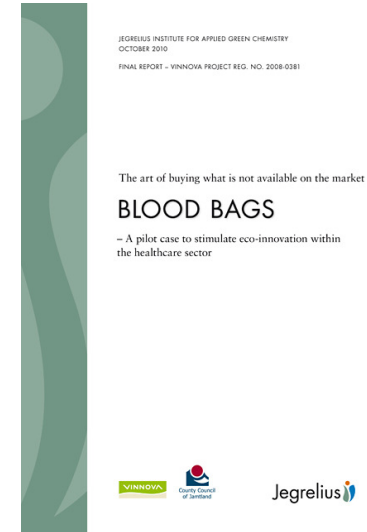
KEY

- 1. Sampling device
- 2. Collection bag

- 3. Empty transfer bag
- 4. Transfer bag with additive solution
- 5. Leucocyte filter

Before Life+

- Pre-study made
- No PVC-free blood bag on the market
- Requirement Specification
- Demand shown with petition and Letter of Intent
- It is possible in theory as shown in R&D
- Economical and technical barrier exist
- Technology procurement not possible since a market introduction is too far away!



Why PVC-free?



- PVC needs plasticizer to become soft
- DEHP is classified as a reproductive toxic
- DEHP's risks are emphasized in the directive for medical devices
- Demanding PVC-free means avoiding risks with new plasticizers. Precaution – you are not able to predict the consequences of new plasticizers
- PVC-policies within several health care organizations
- Exposure from many sources
- Waste and production problems - Globally



Why difficult to exchange PVC and DEHP ?

The challenges



We need to store blood

- The red blood cells are stabilized by DEHP causing less hemolysis
- International norms; max 0,8% hemolysis
- New studies welcome shorter shelf-life

Technical barriers

- The blood bag is a complex product
- Quality requirements on blood components
- High material properties required
 - Centrifugation
 - Sterile sealable tubings
 - Storage at low temperature up to 37 C
 - Compatibility

Economic barriers

- “Not profitable for the producers”
 - Investments and long lead times
 - Lack of life cycle perspective
 - A risk of higher initial cost
-
- Sensitive patient groups
 - Spinn off effects

Essential product

- The blood bag is a life-saving product
- Transfusion of blood is a transfer of living blood cells (or plasma) involving potentially immunological effects and effects associated with physiologically active substances. Those effects are considered to pose a significantly higher risk to the patient.

Lack of clear demand

- **How to** communicate awareness and increase demand is important as previous slide showed
- Legislation – Directive of Medical device
A stronger legislation could increase demand

SUMMARY

- Secure supply of blood components
- The blood bag is a complex product
- The blood bag is a life-saving product
- “Not profitable for the producers”
- A lack of clear demand

- Cooperation between industry and healthcare
- Non-toxic healthcare
- LIFE+ Environment

