One step closer to a safe blood bag

PHOTO: ANDREAS JOHANSSON

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Life+ Environment Policy and Governance

Public healthcare and plastic makers demonstrate how to remove barriers to PVC-free blood bags in the spirit of REACH

LIFE 10/ENV/SE/037

PVCfreeBloodBag.eu

With financial support from EU's Life+ programme

We have shown that it is possible to produce a completely PVC[1]-free set of four bags with the ability to store red blood cells. The bags have fulfilled our requirement specifications, including gap analysis for CE marking, and we have increased awareness and demand for a PVC-free blood bag.

Further improvements and evaluations are necessary before market introduction, but the increased awareness and demand will facilitate the next step for suppliers who want to be at the forefront. We have removed the barriers to introducing PVC-free blood bags on the market.

Why?

Healthcare consumes a huge amount of single-use plastics that may contain hazardous substances. Many of these substances are being phased out, to reduce the impact on both health and the environment. There are many successful examples of this, but currently there are no PVC-free blood bags for red blood cells on the market.

Currently, blood bags for red blood cells are made of PVC, which requires up to 40 per cent of a plasticizer, to become soft. Plasticizer can transfer from the bag into the blood. This is problematic, because the most common plasticizer is the phthalate DEHP[2]. This substance is classified as toxic to reproduction[3] and has recently also been classified as an endocrine disrupting chemical, EDC.

We therefore decided to choose a plastic that does not need a plasticizer to become soft. There are alternative plasticizers on the market, but we cannot predict the consequences of those, so we chose PVC-free as a precaution – to avoid risks due to new plasticizers. Of course, no other substances harmful to health should be added.

There are several benefits to a new bag; most important in terms of healthcare is minimized patient exposure to potentially hazardous substances. The youngest patients are the most vulnerable ones. We are all exposed to endocrine disrupters from multiple sources, but healthcare should not be one of these. If we get rid of EDCs, in the long run we will have healthier populations and long-term healthcare costs.

1. PVC: polyvinylchloride
2. Di(2-ethylhexyl)phthalate
3. May impair fertility and may cause harm to unborn child

PHOTO: TINA STAFRÉN

Background

This Life+ demonstration project started in 2011, but was initiated a couple of years before that by the majority of healthcare organizations in Sweden. A pre-study[4] investigated methods for procure procuring a new and safer blood bag, but it became obvious that we were not able to do so. Several barriers were identified, but the main reason was that a new bag was too far from market introduction.

Instead, we focused on a new supply chain that was willing to demonstrate that it is possible to produce a new bag and the determing factor was when Karolinska University Hospital joined as responsible for the evaluation. The PVCfreeBloodBag project is based on knowledge gained during the prestudy. The challenge has been to overcome the identified barriers.

THE MAIN **OBJECTIVES** ARE:

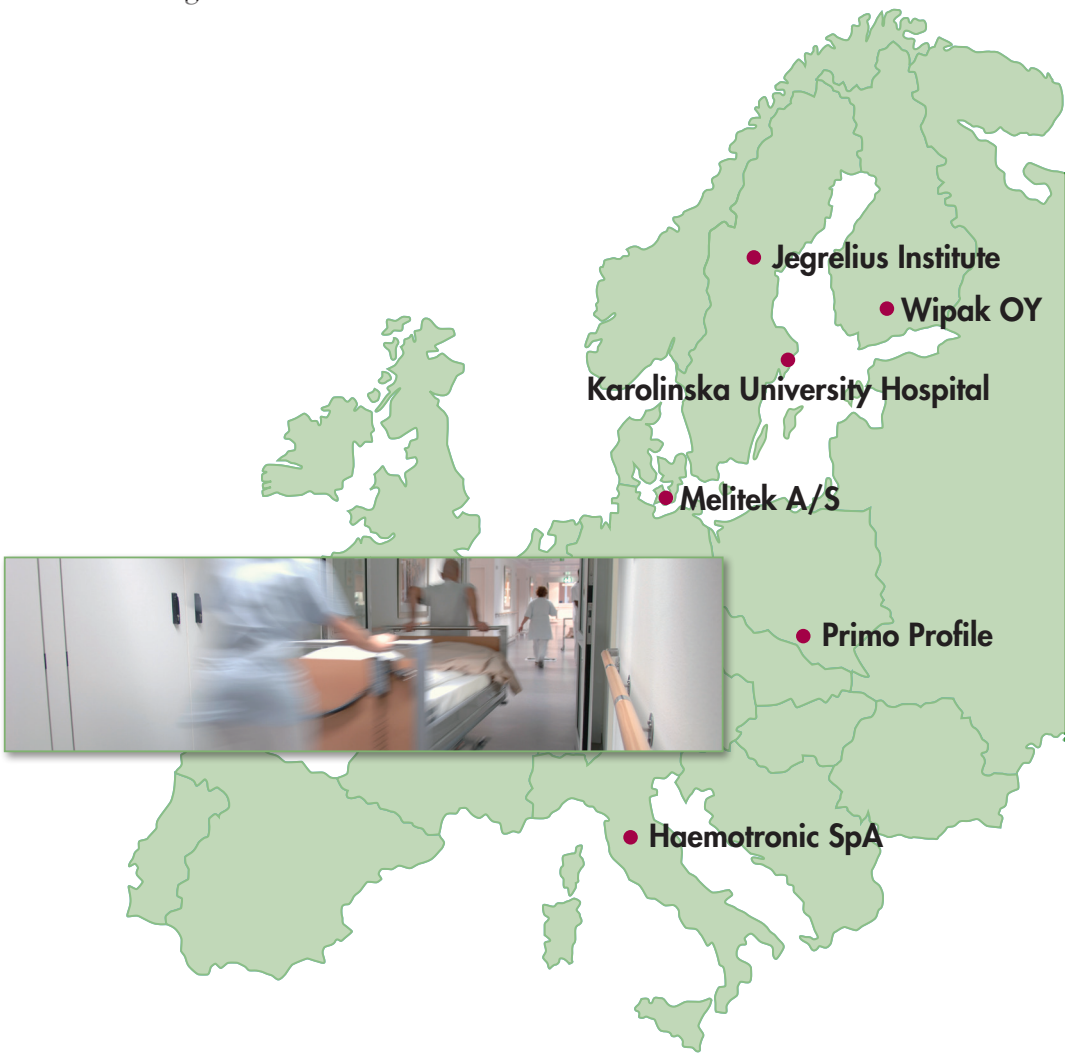
- to demonstrate that it is possible to produce a PVC-free blood bag that fulfils the requirement specifications, including CE marking, and
- to increase demand by disseminating knowledge and awareness through cooperating with European healthcare.

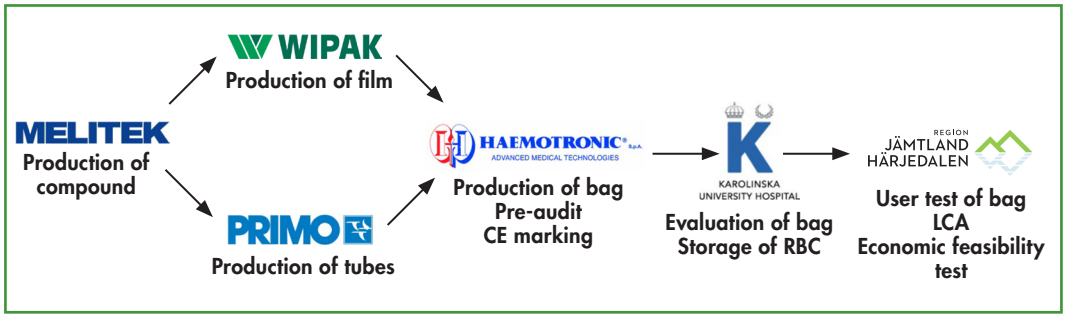
4. The prestudy is available at www.pvcfreebloodbag.eu

How?

The bag's supply chain starts at Melitek in Denmark. Melitek makes the compound and sends it to Wipak in Finland and Primo Profile in Poland. Wipak makes the film and Primo makes the tubing. Both Wipak and Primo then send the material to Haemotronic in Italy, where the bags are produced. A PVC-free filter and a needle have been provided by an external source.

Karolinska University Hospital has been responsible for evaluating the bags' ability to store red blood cells. The evaluation was an in-vitro study in which two different storage solutions were used.





The next step was user testing, for which Region Jämtland Härjedalen was responsible. We simulated the handling of the bags using water that was coloured green, making it easier to detect any leakage. Four hospitals in Sweden performed tests: Östersund, Trollhättan, Jönköping and Uppsala. There is a 2-minute film about this on the projects website.

As well as the storage tests and the user tests, a CE marking pre-audit and a life cycle assessment have been performed to verify the bags' quality.

We have worked with healthcare, other projects, decision-makers, and organisations to increase awareness and demand. Meetings, seminars, webinars, a YouTube clip, hand out and newsletters have been used to communicate and all this information is easily accessible via the project's website.

Have we overcome the challenges?

We have shown that it is possible to produce a completely PVC-free set of four bags, which can store red blood cells and fulfil the requirement specifications, including gap analysis for CE marking.

PHOTO: LENA STIG

Storing red blood cells

In the in-vitro study, which was to verify the bag's ability to store red blood cells, two different additive solutions were compared over 42 days of storage. Haemolysis, the decomposition of red blood cells, was one of the processes measured.

PHOTO: ANDREAS JOHANSSON

Hans Gulliksson and Alice Ravizza.

This study was promising and showed that the quality of the red blood cells during storage depends on the storage solution. Other additive solutions may improve the quality of red blood cells stored in the new blood bags, to prolong the storage time past 21 days. Further evaluations are needed.

The study is published in Vox Sanguinis (2017) 112, 33–39[5]. Presentations by Hans Gulliksson and Stephan Meinke are also available on the project's website.

Quality of bags

The pre-study identified potential problems regarding welding, the connection between tube and bag, and the choice of sterility method. These problems have been solved, but the user tests revealed that improvements are still necessary.

Blood bags are medical devices, which means that they are subject to special legislation, the EU Directive for Medical devices. To verify the quality of the bags we commissioned a notified body CE marking pre-audit.

Stephan Meinke.

5. A link to the publication is available on www.pvcfreebloodbag.eu

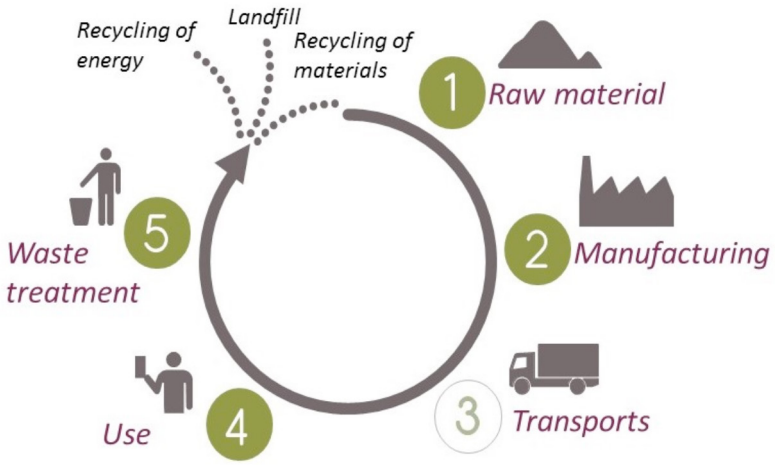
Alice Ravizza, who represented Haemotronic, created a technical file for the notified body Italcert which performed the pre-audit.

The pre-audit gave us a gap analysis for CE marking, showing the status of the product and what remains to be done: scaling up production and validating the sterilization cycle for commercial lots.

Alice Ravizza at CleanMed.

Environmental impact

To compare the new bag's impact on the environment with that of the existing PVC bag, we commissioned an external company, Miljögiraff, to perform a life cycle assessment.



The LCA shows that the biggest difference between the two bags is due to whether the plasticiser, DEHP, is used or not. The LCA also indicates that there are ways to reduce environmental impact. The report and the critical review are published on the website.

Demand

We have increased awareness and demand in partnership with projects and organisations related to healthcare or the phasing out of harmful chemicals.

SUPSPORT: www.subsport.eu
HCWH – Health Care Without Harm: https://noharm-europe.org
NCSH – Nordic Center for Sustainable Healthcare: www.sustainablehealthcare.se
EBA – European Blood Alliance: www.europeanbloodalliance.eu
UNDP – United Nations Development Programme: www.undp.org
C2DS – Comité pour le développement durable en santé: www.c2ds.eu
Life EDESIA: www.iss.it/life/index.php?lang=2
Life ChildProtect: childprotectfromchemicals.eu
The National Substitution Group on chemicals in articles

The project has, together with HCWH Europe, among others, pushed for stronger legislation on medical devices. In March 2013, project manager Lena Stig visited the European Parliament for a lunch debate arranged by HCWH on how to move towards a non-toxic European healthcare. She also participated in a policy strategy meeting on how to phase out EDCs in medical devices. A subsequent process, in which the PVCfreeBloodBag project participated, resulted in a proposal and, in plenary session 22 of October 2013, the European Parliament (EP) voted in favour of the European Commission's proposal on Medical Devices that among other issues, stipulates a ban on hazardous chemicals in medical devices.

In April 2015, the EC announced that new rules to enhance patient safety and modernize public health are on the way. The implementation of the new rules will be important for the introduction of new bags.

Success factors

One success factor is that we did this together: healthcare demanded and evaluated the bag, while the companies produced the bag. The knowledge and commitment from the members and all the participating organisations were also vital.

After Life

The answer spells together.

We still need higher demand. Without buyers, a market introduction would be very slow. One way is to strengthen legislation, and another way is to collaborate regarding requirements specifications, or on joint procurement.
How will the new directive be applied?

Because it is a life-saving and a complex product, it is essential that the bag is of high quality. We know that further improvements are needed, and thus so we need the supply side too.

Our hope is that the demand and supply sides will continue work together in the future, as that is what made this project a success.

WANT TO LEARN MORE?

More information is available at www.pvcfreebloodbag.eu

Documents	First LCA 2012 Second LCA April 2017 Monitoring of blood transfusions operation in EU-countries October 2015 Vox Sanguinis (2017) 112, 33–39 Gap analysis of CE marking Economic feasibility study Layman report 2017 in several languages
Moving pictures	YouTube PVCfreeBloodBag, January 2016 Presentations at seminar Östersund, September 2016 User tests
Webinar	Together with HCWH, October 2015 Jesper Laursen Melitek, November 2016 Final webinar, May 2017

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