

Summary in English: Description of needs

Dried blood plasma
Innovation project



BACKGROUND



The supply of dried blood plasma is limited

Dried blood plasma is currently not produced in Norway or the Nordic countries. Neither are the technology for drying blood plasma and the production of the disposables available. Norway currently buys all plasma products from abroad. There are few manufacturers in the world that produce and sell dried blood plasma. With few manufacturers, and a high demand for the product, there is a limited supply of the product which leads to reduced blood preparedness. This is also a challenge for other Nordic countries such as Sweden and Finland.

Norway needs a stable supply of dried blood plasma

Dried blood plasma is important in an emergency context. As the situation is today, Norway is vulnerable to major accidents and crises. The supply of the product is unstable, and the need is not sufficiently covered for Norway to build up an emergency stockpile. The consequence of this is that in several important situations there is a lack of access to dried blood plasma.

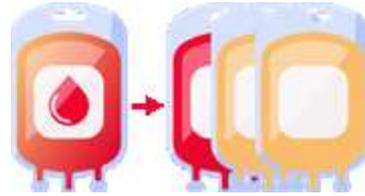
Challenging climate and terrain

Norwegian weather and terrain make patient transport challenging, and it is therefore important to be prepared also for blood transfusion outside the hospitals. Today all Norwegian air ambulances and search and rescue helicopters carry dried plasma. However, few ground ambulances and municipal health service have access to blood products, and dried blood plasma can contribute to increased patient safety in situations where it is not possible to reach the patients by helicopter or if patient transport is delayed.

AIMS OF THE PROJECT



Establish local production of dried blood plasma

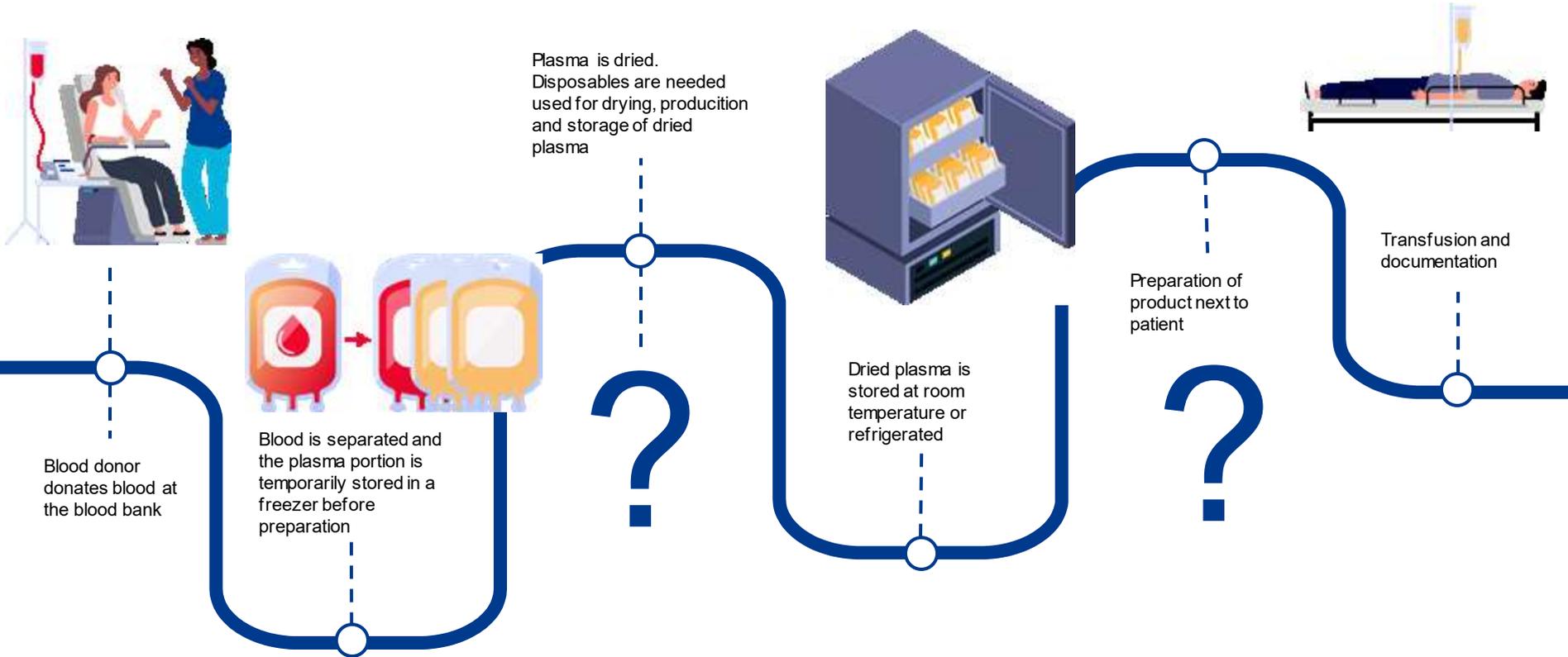


Be self-sufficient and meet national demand



Ensure preparedness and stable access to dried blood plasma

The journey of the blood from donation to transfusion



Blood donation from the blood donors perspective



“Donating blood is a good deed and helping to save lives is a motivation..”

Maria is a blood donor at the blood bank at Helse Bergen. She is a regular blood donor and her motivation is to help others in need.

It is important to her that the blood she gives is used and that everything comes in handy. She sets aside time for this and she needs the blood donation to go quickly and that it is predictable in relation to her employer. Therefore, the mobile collection unit (Blood Bus) is appreciated and allows Maria to save time.

BEFORE DRYING



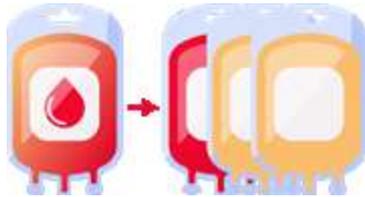
The blood donor is summoned to an appointment to donate blood at the Blood Bank or the mobile blood collection unit (Blood Bus).



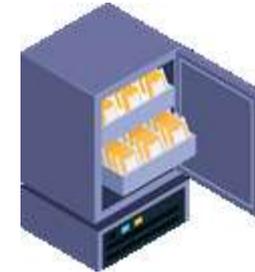
The blood donor fills out the blood donor questionnaire.



The donation is of approximately 450 ml of blood and takes approx. 10 minutes.

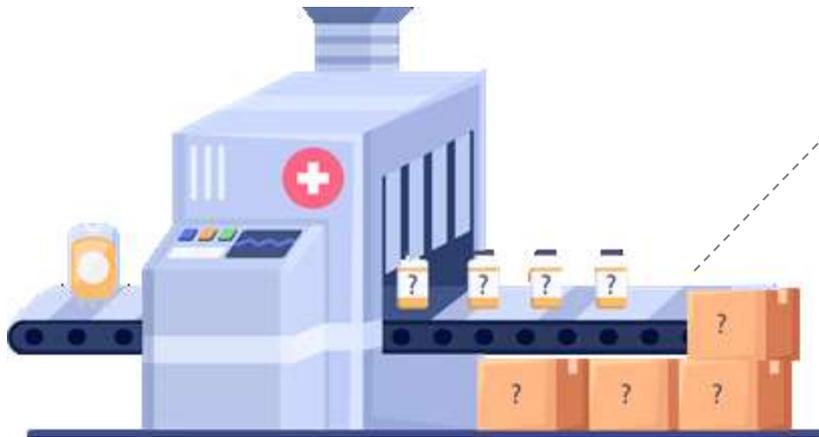


After a resting period the blood bag is centrifuged to separate the blood into three parts. The blood is separated into red blood cells, platelets and blood plasma. From a whole blood draw we get approx. 250 ml blood plasma.



Fresh blood plasma is deep-frozen and temporarily stored before production of dried blood plasma.

DRYING OF PLASMA



The blood bank needs help to develop the technology to produce dried blood plasma, as well as any disposables needed. It is important that the production meets the requirement for a sterile process and that the dried blood plasma can be approved for human use.

Dried plasma seen from the Blood Provider's perspective



"We need dried plasma because it is easy to store and has a long shelf life. This enables us to ensure availability of the product for all our users both inside and outside hospital."

Turid works as a chief physician in the blood bank at Haukeland University Hospital.

Dried blood plasma is a product that can be stored outside the blood banks and can be available where the patient is. She is concerned that blood plasma is a safe product, and that production can be performed at the blood banks premises. The blood banks need the flexibility to adapt the production to the demand. The packaging should not take up too much space because there are challenges with storage capacity in many blood banks.

Turid wants simple and user-friendly production process with a high degree of automation. It is important for the blood bank that the product is labeled according to regulations for blood products and that it is easy to track the product from donation to transfusion. She wants there to be no need to re-label during production.

Description of needs: Blood Providers

Local production

The blood bank needs local production of dried blood plasma at the blood banks premises..

Technology

The blood bank needs technology that can be used for production of dried plasma in the blood banks premises. Preferably, the technology should also be scalable, so that production can be increased when needed.

Disposable and packaging

The blood bank also has a need for the material and disposable equipment used to be functional and to withstand harsh conditions. The packaging and disposable equipment must meet the requirement for a sterile closed system, as well as not contain substances that can cause allergic or toxic reactions. Furthermore, the blood bank wants to achieve sustainable production, potentially with the possibility of recycling.

Storage at room temperature

It must be possible to store the dried plasma at room temperature, so that it can be available for emergency preparedness outside the hospital as well. Long storage time is needed.

Labeling

There is a need for the end product to be clearly labeled from blood collection to the finished product.

Documentation and reporting

If the product should be labelled according to regulative standards. There is a requirement for documentation throughout the production process and for tracking of the product from blood donation to transfusion.

Human use

The dried plasma product must be approved for use in the treatment of patients.



Dried blood plasma from the perspective of military personnel



“I need something that can withstand tough conditions and is easy to carry”

Frank works as a paramedic and has several years of experience in the field.

His everyday life consists of a lot of movement in the terrain, high and low. In the course of a day, he moves through water, mud, and mountains in all kinds of weather.

He carries a bag with first aid equipment and needs to have dried blood plasma in the bag.

The contents of the bag are subject to harsh actions and must withstand being thrown around as it may be subject to crushing or damage. Frank experiences that he is one hand short in acute situations and he needs it to be quickly and easy to start the treatment.

Frank thinks it is important to have our own preparedness in Norway to ensure that we have access to dried blood plasma regardless of what is happening in the world.

AFTER DRYING – DRIED PLASMA IN THE FIELD



A paramedic is out on a mission and finds herself in a situation where she is moving in difficult terrain. She does not have time to find alternative routes, and it is important that she can avoid being afraid of destroying her equipment.



The paramedic finds a person who is badly injured and starts with first aid. She knows that early blood transfusion can be crucial for the patient's survival.



The paramedic prepares the product for transfusion quickly and efficiently. As the product is very easy to use, she is not afraid to make mistakes during the process, but can focus on saving lives.



While the transfusion is in progress, the paramedic gets help to transport the injured patient to further treatment.

Dried blood plasma from the perspective of air ambulance personnel



“The air ambulance is like a small intensive care unit and dried plasma helps us to treat life-threatening bleeding and save lives”

Aleksander works at the emergency medicine department and he works with a pilot and a rescuer on the air ambulance.

Everyday work is very varied and it is necessary to be ready for an emergency when the alarm goes off.

The air ambulance is dependent on having dried blood plasma and various blood products on board for patients who bleed. It is important to be able to start patient treatment quickly. Dried plasma is used as a "bridge to blood" and is given as early as possible in the course of treatment pending balanced blood transfusion.

Dried plasma can be used for various medical conditions.

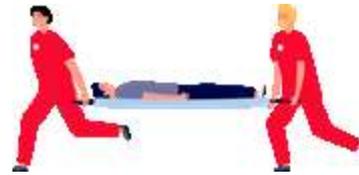
AFTER DRYING – DRIED PLASMA IN THE AIR AMBULANCE SERVICE



The air ambulance is called to the scene of the accident and moves out. On the way, they receive important information about the injured person, so that they can prepare before arrival.



On arrival, the treatment of the patient begins. Based on the severity of bleeding, they initiate blood transfusions, as they know this may be critical for survival.



As soon as possible, transport to the hospital for further treatment is started. Transfusion with plasma and other blood products is performed during transport. The air ambulance personnel document the incident and the use of blood products and report this upon arrival in hospital.

AFTER DRYING – BLOOD PREPAREDNESS



Ready-made blood plasma is packed in packages intended for transport and prepared for transport. The blood bank has established a system that allows them to scale up production in the event of an acute need.



The blood plasma is loaded into trucks for transport. Blood plasma is needed for emergency preparedness at many locations also outside the hospital, such as municipal health service, ambulance service and in the military health services.



The dried plasma is received and stored properly. It is clearly marked to make the inventory management easy. This reduces wastage and ensures that the oldest units to be used first (the first in - first out principle). This enables better utilization of the product.



End users receive practical training from the Blood Provider.