InnoBuyer

FAST TRACK TO INNOVATION PROCUREMENT

BLOODMANSYS

FUNDESALUD

BLOODMANSYS

PITCH

ADVANCED BLOOD TRANSFUSION MANAGEMENT SYSTEM aims to improve the patient's security during blood transfusion during the last stage of the process when the patients receive a blood transfusion. This stage is the highest risky part of the process and increasing the digitalization and improving the technology during this part will ensure the decrease of health burden in the health services related to blood management.

ORGANISATION DESCRIPTION

FUNDESALUD (FS) is the Public Foundation (non-profit) **ascribed to the Regional Ministry of Health and Social Services at the Government of Extremadura** that manages both research and training programs at the Regional Health (SES) and Social Care (SEPAD) system in Extremadura.
In addition, FundeSalud works in collaboration with the University of Extremadura (UEx) and other public or private research centers, providing resources, staff, and facilities to develop any biomedical research activity in the autonomous region of Extremadura (Spain).

Extremadura's Healthcare Service (SES) is the Healthcare System in Extremadura that involves 14 hospitals with around 3000 beds, 113 Community Health Centres, 420 Primary care Centres, and over 18000 professionals. For this project, JUNTAEX will provide access to clinicians, data, and healthcare infrastructure at SES.

It is important to highlight the other regional entities included in the process:

1. The Banco de Sangre de Extremadura (Regional Blood Bank of Extremadura), located in Mérida (Badajoz), coordinates the promotion, donation, processing, and analysis of human blood, which we then distribute to all the hospitals in the CCAA.

2. Área de Seguridad del Paciente de la Junta de Extremadura (Patient's Security Service) is the team responsible for the patient's security overview and management of the Extremenian Health Service. They are a team of experts in the field developing research and improvements in the public health system to decrease the number of risk cases reported yearly.
3. Hematology teams of Hospital de Badajoz. There is a team of medical, nurses, and nursing assistants.

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CHALLENGE DESCRIPTION

According to the current results of patient security figures, management of blood transfusion is not an out-of-risk process.

Human error is still being reported during the stage of transfusion between donor and receptor yearly in Spain and the region of Extremadura.

According to Service of Patient's Security, the current process is focused on two parts, initial (donor) and final (receiver). The highest risk in the process is reported between the preparation of components and the transfusion to the final patient. This stage adds storage, distribution, supply, and transfusion to the final receiver.

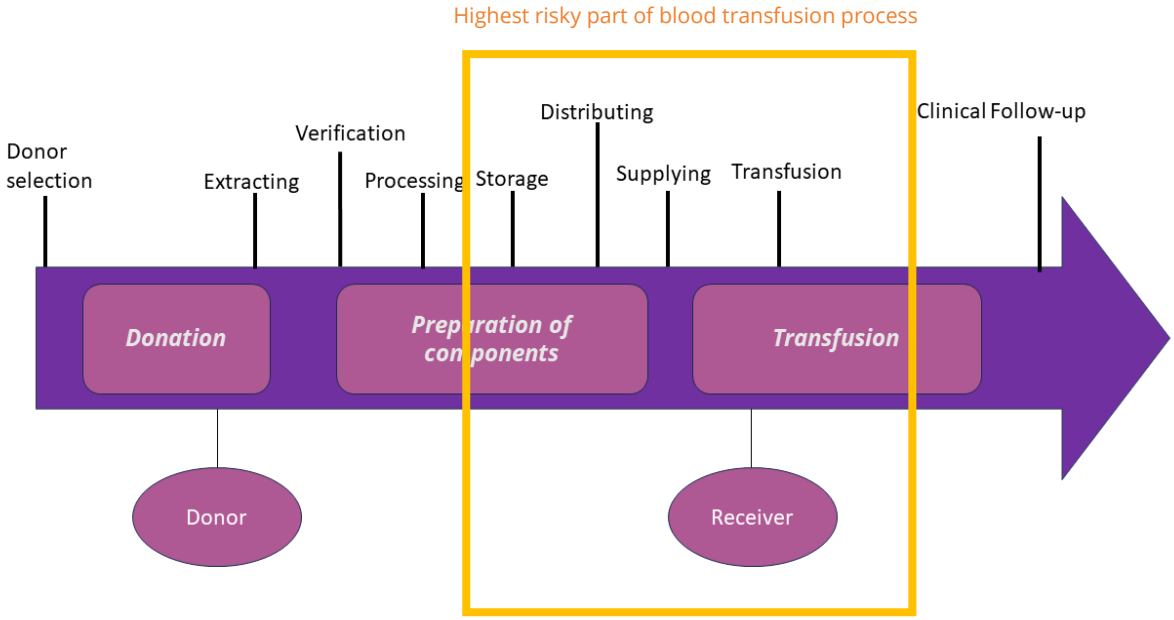

IMAGE 1: BLOOD TRANSFUSION PROCESS

Increasing the automatization and security control of blood units in health centers is key to decreasing the percentages of errors, optimizing blood component uses, increasing the research data available in the system, and reducing health burden.

Research data can contribute to having a better knowledge of the real number of transfusión, patient data, and place. This secondary information can contribute to doing much research about determined illness. Furthermore, with this information, we can go deeper and assess which variables are related to certain pathologies.

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The current number of donations is around 50,000 units/ year in Extremadura (table 1). Four components are extracted from each blood bag (a reserver sample, plasma, platelets, and RBCs) with a different useful life.

Component	Obtaining
Total Blood	49.353 units
Red blood cells	45.287 units
Platelets	9.139 therapeutic doses
Plasma	9.952 litres
Aphaeresis	238 processes

TABLE 1: NUMBER OF BLOOD DONATIONS IN EXTREMADURA (2020).

The number of incidents per year is increasing in the region dramatically compared with other regions (national system). Those incidents are registered in SINASP system (*https://sinasp.es/)*

Total Number of Incidents				
	2019	**2020**	**2021**	**2020**
Extremadura	2	6	12	11
Spain	105	115	119	157

TABLE 2: NUMBER OF INCIDENTS REPORTED RELATED TO BLOOD DONATIONS IN EXTREMADURA.

The current technological system used by the sanitary teams in all the processes in the 8 areas of health in Extremadura is **e-Delphyn** (https://bitrodiagnostico.com/e-delphyn/)

This System is a flexible tool for Blood Bank data management, enabling a complete computerization of all their activities (Donors and Patients), allowing users an easy blood component control.

All the information provided by the current system is printed to inform the sanitary team about the process to follow. The co-creation process aims to digitalize this part to reduce the use of expendable material (paper and labels) and improve the security of the information using digital devices in all the steps of the process.

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At the moment, when a donor wants to donate blood, they must complete a paper questionnaire with different information, for example, new or older illness, new tattoos, medication…

This questionnaire must be completed each time that you donate.

In this link, you can see an example of this questionnaire https://www.sanidad.gob.es/profesionales/saludPublica/medicinaTransfusional/acuerdos/docs/cuestionarioUnificado.pdf

We would like to have an alternative. For instance to digitize the questionnaire. Additionally, we would like this questionnaire to save some information about a donor when they donate again so they don't have to fill out the full questionnaire but only the new information that happened since the last donation.

CHALLENGE MAIN OBJECTIVES

The call for co-development must help to reduce the human errors detected during the last years in the region such as:

- Can Identify different Incidents (Current Incidents Table 2):
  - Patient identifying errors
  - Laboratory identification errors
  - Blood bags management errors

Other improvements to apply in the current process are:

- Be integrable with 8 different versions of the software in different health areas
- Reduction of expendable material in the different stages of the blood transfusion (2 paper-print each time)

SOLUTION FUNCTIONAL REQUIREMENTS

The proposed solution aims to have absolute certainty that there will be no errors in the blood transfusion process and that the receiver will receive only the components they need.
We seek certainty that the component that the recipient of the transfusion will receive is the one that has been chosen. Bag traceability is very important.

The development of a new functional management system will be focused on the improvement of patients' security during the last stage of blood transfusion management, connecting to current software to provide a useful layer of security.

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It will digitalize the process between the current management software and real-world patients, including the reading of bar codes (HemoCod) and including all the digitized processes.

IMAGE 2: BAR CODES INCLUDED IN TRANSFUSION PATIENTS' BRACELETS

The co-created new system will monitor the extraction process in 7 steps to decrease any possible error.

1- Extraction: including the data of the blood test studied in the laboratory
2- Verification code of the sanitary developing the action
3- Identification of the patient using CIP code (Clinic history of the patient)
4- Reading of bracelet code
5- Reading of tube code
6- Reading code in the labels attached in the report
7- Place where the transfusion is provided (Department of Hematology of the Hospital of Badajoz).

This protocol must be interactive and managed by any digital device (mobile app, table, PDA, smart wearables, etc).

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IMAGE 3: BLOOD EXTRACTION PROCESS

The co-created new system will monitor the transfusion process in 7 steps to decrease any possible error.

1- Synchronize the device with the server and database in real-time
2- Transfusion process
3- Identification of the patient using CIP code (Clinic history of the patient)
4- Reading of bracelet code
5- Check the laboratory data results of the blood pack
6- Introduce transfusion data
7- Start the process

This protocol must be interactive and managed by any digital device (mobile app, table, PDA, smart wearables, etc).

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IMAGE 4: BLOOD TRANSFUSION PROCESS

Compulsory functional requirements

1- Real-time identification of the donor in the whole process of the transfusion by electronic devices ensuring the anonymization of the donor (complying with Law of Data Protection Regulations)
2- Stockage control in real-time informing the creation of new bags or use of bags digitally.
3- Control the stockage individually, including its position, center, date, and data to improve the efficiency of the system and decentralize the blood transfusion process, saving transport costs and time and increasing the control of the whole process.
4- Blood bag localization during the process in real-time. Currently, blood material is located with digital registries (in e-Delphyn) enough to maintain a standard (according to national law) security control of the transfusion sources and security of the patient. However, it is desirable to count with real-time digital control of the location of the blood transfusion sources to solve the needs more efficiently.
5- Automatization of the process of blood extraction using digital devices to reduce time and errors.
6- Reduce the use of expendable materials, at least, reports included in the patient's history, bars codes, or labels currently used.
7- Easy to use User Interface. The end-users of the technology are mainly sanitary teams, who are not always tech-savvy. This crew is not ready to solve technological

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issues or programming in any case, also they need a clear user interface without any possible error during the use of it because they can use the technology under high-stress situations and it will be used by different users (blood transfusions are made in any public health service of the region with 1.1. million of potential patients).

The proposed solution must be compatible with **e-Delphyn** and JARA (regional system)

Desirable functional requirements

1- Management User interface in an online platform for administrators with map and real-time information of the transfusion material.
This interface will complement the users' interfaces to control and overview the situation anytime to make decisions or develop reports related to blood bank management.

PILOT SCOPE

Pilot will be developed using real-world conditions in parallel with the "on paper" system currently active.

During this pilot, will be checked the real usability of the proposed solution as well as the resolution of connection problems or interface usability improvements.

The sanitary crew will be involved in the pilot to obtain useful feedback from the end users and patients.

Health Professionals from the Blood Bank of Extremadura, Hospitals, and the Patient Security Area will be involved in the pilot development and overview.

After the pilot, the result of the co-creation will have an approved technology for use in blood management for other regions and countries with similar legislation or needs.

At least 10 blood transfusions will be included in the process with 5 specialists, 3 blood bank users, and 5 nurses. The pilot developer will have access to **E-delphyn** system of the hospital included in the pilot.

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Type and number of targeted end-users

End-user type	Role	Number
Blood Bank of Extremadura Health Care Public System	End user of the system	3
Hematology team of Hospital in Badajoz	Specialists in the blood transfusion process. Sanitary advisors.	5
Nurses of the Regional Health Care System	End users of the system. First tier of the process.	5
Number of blood bags included in the pilot	Bags used during the pilot process	10
Number of donors and patients participating during the pilot	Name of patients included in the pilot process	5

TABLE 3: END USERS OF BLOODMANSYS PROCESS

Language

The solution must be implemented in Spanish. The users and managers of the system will only talk in that language.

Other aspects

Previous expertise in the management of health data and management of interchange of data are needed in the know-how of the solver. GDPR law must be complied with at least the data of the Pilot patients.
The final solution must be provided by the solver (approximately 10 bags). Then, if the government of Extremadura has bought the solution, they will buy the number of devices that are necessary.

PILOT SET-UP CONDITIONS

Ethical, legal, or Regulatory

Main regulation to comply during this process is:
ROYAL DECREE 1088/2005, of September 16, which establishes the technical requirements and minimum conditions for hemodonation and transfusion centers and services

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This law includes the minimum tasks to comply with. The solution must comply as a minimum, with all the requirements set in this law, and even aim for higher standards.

During the implementation of the InnoBuyer activities and for five years after the end of the activities, the parties must keep confidential any data, documents, or other material (in any form) that is identified as confidential at the sub-grant agreement signing time ('confidential information').

If a selected applicant requests, the Commission and the InnoBuyer Consortium may agree to keep such information confidential for an additional period beyond the initial five years. This will be explicitly stated in the sub-grant agreement. If the information has been identified as confidential during the InnoBuyer program or only orally, it will be confidential only if this is accepted by the InnoBuyer coordinator and confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the sub-grant agreement. The selected applicants may disclose confidential information to the InnoBuyer consortium and to the selected reviewers, whom a specific Non-Disclosure Agreement will bind.

All participants in the study, regardless of whether they are health professionals or patients, must sign a prior informed consent, where they consent to the processing of their data.

Technological

JARA is the current digital system in the Extremadura regional health system to which all health professionals have access. E-Delphy is already compatible with JARA for that reason, the technological solution proposed must be compatible with the E-Delphy software.
Currently, each of the 8 health areas of Extremadura has an independent method for managing blood transfusions.
The general blood bank, located in Mérida, uses the E-dephy software to manage the process.

During the pilot, one person from Blood Bank will help to connect the new technology with the current registries. The integration will be studied during the pilot and can be used as an API, exportation of the registries, or connection with user credentials.

In any case, the Public Health System team will help to connect the new technology to the current one.

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Data access

As explained before, data access is integrated into a unique system called JARA. Data access is currently accessed by user and password. The team integrated into the development of the technology will provide accessibility to the needed data. The Blood Bank crew will be in charge of this part of the development with the help of FUNDESALUD to control all the processes and provide the support needed.

Integration in E-delphy must be included in the protocol developed in the pilot to ensure the total interoperation of the system with the current databases and software.

This software allows the exchange of information with other software and using bar code labels allows the control of the same information in duplicated databases.

Other

The Pilot will be developed in 2 places. First, the Blood Bank of the region will be involved in checking and correcting the technology according to their needs and also A hospital in Badajoz will participate as end-users of the technology during the pilot time. Specifically in the hematology department.

They will be in charge of generating daily plasma demands and verifying donor and recipient suitability.

EXPECTED IMPACTS AND KPIS

Those incidents are registered in SINASP system (*https://sinasp.es)*

- *The number of incidents reported regionally related to blood transfusion error.*
    - *Reducing 20% of current figures.*
- *Reduce the percentage of human error in the process of blood transfusion.*
    - *Reducing 80% of current figures.*
- *Time to manage the blood transfusion process.*
    - *Reduction 25% from the current time (around 6 min per patient to collect and manage data)*
- *Decrease the number of expendable materials*
    - *Reduction of at least 2 paper prints per transfusion step (extraction/transfusion)*

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BUSINESS OPPORTUNITY

Market size

The new solution provided by this innovation process will help in any of the 14 hospitals of the region of Extremadura as well as 420 primary centers.

Mainly this system will be implemented in each of the 14 hospitals of the 8 health areas of the region with around 1.1 million patients.

Nowadays Extremadura has around 46 donations per 1000 inhabitants (Spain has around 35 donations per 1000 inhabitants). Per year around 50,000 blood units will be managed by the new system in the region.

Extremadura represents 2.5% of the total population of Spain However, it is 8% of the total blood transfusion error in the country.

Finally, after the development of the technology, this solution can be implemented in other regions and countries with similar laws because it will comply with the regulations of Spain and Europe in this field.

Adoption plans

The solution will be procured in the 8 health areas of Extremadura with 1.1 million patients if the pilot is successful.

The current plan is to, improve the transfusion process with the newer technology applicable. Nowadays new technologies have been tested in the area of Cáceres with new Personal Digital Assistants (PDAs) and the plan is to use the process provided by InnoBuyer to co-create a final technology to be integrated into the system of the 8 areas of health in Extremadura.

We have volunteered to participate and implement the technological solution on-site.
We have the help of health professionals from the Extremadura blood bank, for the management and traceability of blood components. The hematology department of the Badajoz Hospital will be in charge of requesting and supplying the components and choosing the recipients.

The budget reserved by year to cover the costs can be increased if the improvements demonstrated by the InnoBuyer process are cost-effective. The results of the pilot and co-creation process are key to making a final decision to implement or continue with the current system.

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The main interested party in finding a solution to the problem is the patient safety service. They have shown their commitment to the project and their intention to collaborate.

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