UNIVERSITÀ POLITECNICA DELLE MARCHE

Master Degree in Biomedical Engineering

Safety in transfusion processes based on RFID technology

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Contents

Abstract

This paper describes the activity carried out at the company GADA S.p.A.; The activity carried out in these months has allowed to examine in depth RFID technology (physical aspects, types of system, current applications in the health and non-health field) and Identify critical elements in transfusion procedures, which could potentially be optimised by the introduction of RFID technology. Blood, blood components and blood products, because a limited resource, must be used properly. The research on RFID system applied in transfusion chain show satisfactory results, allowing the realization of a product usable in the clinical field. In particular, the project aims to the realization of a support system to the management of the blood supply chain.

The developed system guarantees:

- univocal link between the identification code of the donation and the donor;
- RFID labels for the identification of the units;
- scales used for the collection of whole blood, able to write/read data related to the collection on RFID tag;
- associates unequivocally the units selected to the transfusion request;
- safety and traceability of blood units, monitoring temperature and position during the transport;
- univocal association between the patient, the blood request and the blood sack.

The purpose is to reduce the risk of incorrect administration and, consequently, the clinical risk of adverse reaction.

Chapter 1

Introduction

Clinical risk management is a set of processes to detect, monitor and minimise the probability of adverse events related to clinical practices. The identification and risk assessment of potential adverse events, the application of appropriate corrective actions and the monitoring of trends of appropriate risk indicators as a result of actions taken, are some of the clinical risk management procedures.

Within this context, one of the thorny issues is certainly blood transfusion. The critical issues of this process, the complexity of the factors involved and the very high risk of death in the event of an incompatible transfusion, make the transfusion one of the most critical process in a hospital.

The risk associated with the management of the blood supply chain may be risk of infection (ex: HIV) and risk of immune reaction of type AB0 (AB0 incompatibility), resulting in the infusion of blood products not compatible with the recipient's blood group. The adverse reactions due to transfusion errors account for about 70% of all adverse events and, among them, about 20% are transfusion reactions from AB0 incompatibility [1]

The absence or non-application of specific procedures is an important risk factor which may lead to the occurrence of the event during one of the different stages of the transfusion process. In the entire blood transfusion-related processes, the high number of patients and other external factors will inevitably lead to human error [2]. Usually operators commit mistake during the check at the bed of the patient and consequently fail the interception of the anomaly. In fact, another important data is that 35% of errors occur at the level of direct interaction with the patient: the identification of the patient, apparently banal, is instead one of the most difficult obstacles to overcome. In 2013, preventable medical errors were estimated to cause 210,000 to 400,000 deaths each year [3].

The need to ensure traceability of all blood components is the main issues in the blood supply chain control procedures. To allow this, it's important to optimise the management of the blood supply chain through the implementation of a support system based on RFID technology.

Radio Frequency Identification (RFID) technology, based on wireless data transmission between a circuit (associated with a given entity) and a reader, has demonstrated exponential growth in recent decades, in relation to the number of applications carried out and the technological potential. RFID systems are part of the automatic radiofrequency or Auto-ID identification technology. Integrating the RFID system into the transfusion chain allow safer blood transfusion and enhance the quality of blood products [4-5]. RFID is a technology that uses radio waves to automatically detect and locate people or objects [6].

This technology has two basic features, reducing both the time and the costs of manual data entry and eliminating possible errors. RFID technology therefore uses a system that allows the automatic acquisition of data for identification and allows the automatic introduction of these identification data in computer programs.

The distinctive features of an RFID system, such as reliability, speed of data transmission and reading distance, have led to an increase of the use of this technology in the healthcare sector.

The thesis project aims to describe the research and development activity carried out in GADAMED S.R.L. The aim of the activity is to create a system capable of ensuring support for the management of the blood supply chain. In addition to the scientific research covered in the previous chapters, the work included:

- Analysis of clinical problems;
- Study and determination of project specifications;
- Finding an RFID system suitable for the project specifications;
- Conduct of the experimental tests necessary for the validation of the system;
- Analysis of the results obtained by experimental tests.

Chapter 2

RFID Technology

Radio-Frequency Identification (RFID) is a technology that allows the remote recognition of an object by means of radio communications (Figure 1). RFID systems are composed by three fundamental elements [7]:

- **Tag**: a radio frequency transponder, of various shapes and sizes, which is the main element of the system. It's a smart label that is placed on the objects to be managed, allowing the transmission of short or medium range data without physical contact;
- **Reader**: a microprocessor-controlled transceiver used to query and receive information in response from tags. They exist of various dimensions and can be static or portable;
- **Management system**: an information system that, when it exists, is connected to the network with readers. This system allows, from the identification codes of the tags, to derive all available information associated with objects and to manage this information for the purposes of the application.

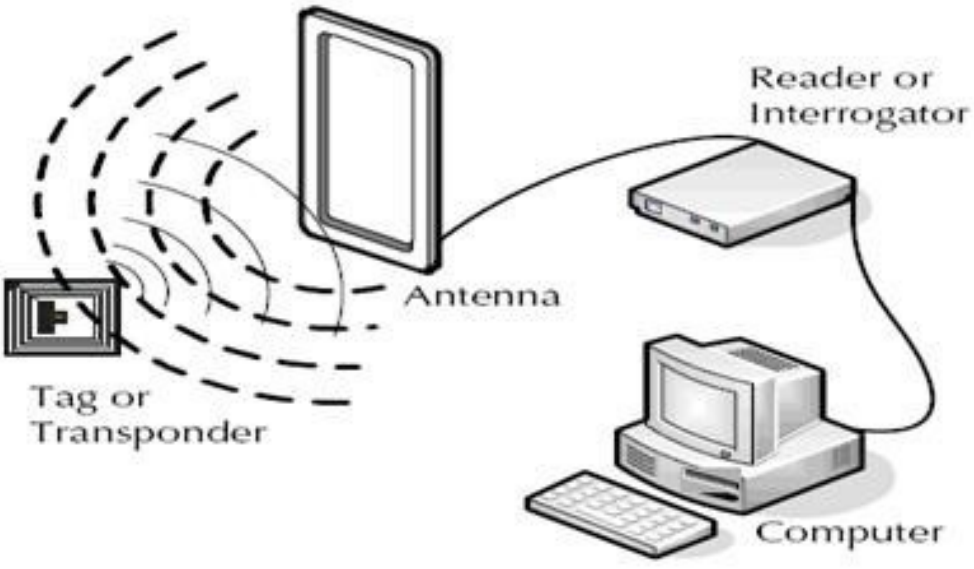

Figure 1. General scheme of an RFID system.

RFID technology is based on reading information in a tag, using readers and management systems when necessary. A reader sends a signal through an electromagnetic field generated through an antenna. This signal allows to load (in the case of a transponder called passive) the internal components that make up the power supply circuit, and this is done in a very short time of the order of a few milliseconds. The transponder, once recognized the accuracy of the query operation, sends to the reader a signal that contains its identification code as well as other data contained within its memory.

2.1 Tag or transponder

A transponder (tag) consists of some elementary components [7]:

- Integrated circuit (chip): smart electronic component with simple logic control functions that manages all the communication and identification part. It contains data including a unique identification number written on silicon (Figure 2);
- Antenna: the part that allow the chip to be powered (if it has no battery) and to receive/transmit communications with the outside world;
- Support: the component that supports or protects the system. It can be a container, otherwise tags and antennas can be embedded in a paper label, a Smart Card, a key or integrated in electronic devices (watches, mobile phones, etc.)

Figure 2. Tag RFID.

Transponders shall be classified according to the characteristic considered:

- Nature of the energy source that supply the transponders and allows it to operate and communicate.
- Type of memory possessed by the transponder, fundamental characteristic depending on the type of application you want to make of the RFID technology.
- Type of coupling existing between reader and tag that can be inductive or electromagnetic.

2.1.1 Classification based on the power supply

A first important classification of RFID tags is that based on the power supply and transmission with respect to the reader. It is possible to divide the tags into passive, semi-passive and active [7].

- **Passive tag**: low-cost, small-scale devices that allow numerous types of applications as they are implemented on almost all permitted frequency bands. Passive transponders use the field generated by the reader signal as a source of energy to power their circuits and transmit the signal. In other words, they re-radiate, modulating, the signal transferred by the reader and reflected by its own antenna. They don’t have any batteries or any other internal power source. These transponders need to receive the electromagnetic energy generated by a reader to be "switched on"; in fact the absence of energy field turns them off completely. The output from the reader signal decreases very quickly with distance. This results in low operating distances (at most a few meters). Since they consist only of an antenna (typically printed) and a generally miniaturized integrated circuit, the height of passive tags can be of few hundred microns. The transponders, therefore, can be inserted in credit cards, labels, buttons and other small plastic objects, sheets of paper, banknotes and entrance tickets.

- **Semi-passive tag**: they use, like passive tags, the field generated by the reader signal as a source of energy to transmit, but not to power their own circuits. In fact, the tag includes a battery used only to supply the chip, not to communicate with the reader. This allows the chip to perform more complex functions and to work even when the transponder does not receive power from the reader. However, the operating distance is limited, as in passive tags, due to the fact that the transponder does not have an integrated transmitter but is forced to use the reader's signal to respond. The advantage of semi-passive tags is the ability to set up rewritable memories of greater capacity, as well as, environmental sensors to measure temperature, pressure, movement, etc. Using the battery's power source, the sensors can take measurements, store them in memory with time information and return them to the reader request, providing a history of the life of the object to which they are associated. The battery with its costs, its duration and the associated pollution, is the main problem for this type of transponder.

- **Active tag**: Active tags have their own power supply system (typically a battery) and a radio frequency transmitter/receiver. Normally the memory they have is larger than that of passive tags, in addiction reading and writing operation can be done on it. Another advantage of active transponders is the much higher operating distance compared to passive and semi-passive ones, as they are equipped with a real transmitter powered by an energy source. The distance reached is limited only by the antenna and the energy available in the batteries. The reading range can be up to a few miles. Active tags, such as semi-passive tags, can also have sensors of various kinds (temperature, pressure, movement, etc.). The cost of these devices can reach tens of Euros, are generally produced for high frequencies and are dedicated to applications where the tag is reusable several times.

2.1.2 Classification based on memory

The second classification of RFID tags is based on the type of memory of the transponders. From this point of view there are three types of tags:

- **Unique bit tags**: This type of transponder is the best known and, in its simplest form, is composed of a few elements. This tag is passive, as the memory is permanent and therefore it is not necessary to have an energy source for storing data in memory. It can be realized through a high level of integration and miniaturization and then it is presented in the form of a small chip connected to an antenna. Single-bit transponders are used for Electronic Artiche Surveillance (EAS) i.e. anti-theft systems.

- **Read Only Tags**: have a read-only memory, called ROM (Read Only Memory), containing data available for consultation only. They are programmed only at the moment of realization through the laser engraving or specific preparation of the chip mask. Among the few information contained in them, there is a unique tag code according to ISO 15936. A unique identifier allows the anti-collision process, that is the simultaneous identification of more than one transponder. These memories have the advantage of occupying, with the same recorded data, the smallest area of silicon inside the chip, resulting less expensive and with a long life.

- **Read/Write Tags**: have a memory that can be read and programmed. The data contained can be modified dynamically.

2.1.3 Classification based on reader-tag connection

Another possible classification for RFID tags is based on the type of connection between transponder and reader that can be:

- **Inductive**: inductively coupled transponders are Low Frequency (LF) and High Frequency (HF) transponders. They are those that use the inductive coupling between the coil antenna of the reader and that of the tag coupled as an electric transformer. From the electrical point of view, the two antennas behave like a LC (inductor-capacitor) circuit and the energy transfer between reader and tag is maximized at the resonance frequency of the circuit which must be equal to the carrier frequency (for example, in the case of HF tags, 13.56 MHz) (Figure 3).

- **Electromagnetic**: electromagnetic coupled transponders are Ultra High Frequency (UHF) and Super High Frequency (SHF). In general, a transmitter sends an electromagnetic wave and a receiver detects the scattering generated by an object on which the wave affects. Both the reader and the tag have dipole antennas. A tag that works in inductive coupling has an antenna that consists of a closed coil on two microchip contacts and therefore has a higher production cost than a tag that works with electromagnetic coupling. In this case the antenna is basically a simple dipole composed of two wires attached to the contacts of the microchip (Figure 4).

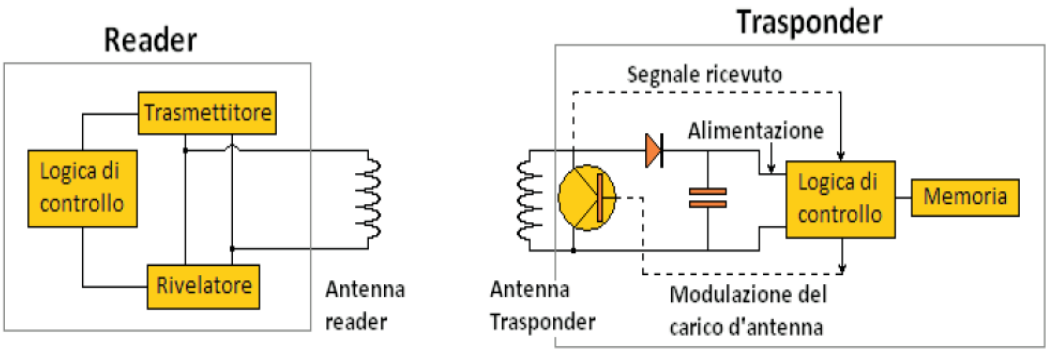

Figure 3. Operating principle of an inductively coupled passive tag.

We can try to summarize the operation of an inductively coupled RFID system in some basic steps (Figure 3):

- The request data are sent from the reader to the transmitter that generates the signal for the spire antenna;
- A magnetic field is induced by the current in the antenna of the reader and is concatenated with the spiral antenna of the transponder;
- The induced current is rectified and charges a capacitor, allowing the supply of the tag;
- Activated transponder decodes the reader's request signal;
- The data on the memory of the tag are read by the transponder. The reading of these data allows the modulation of the impedance of the tag antenna;
- As the coils of tag and reader are coupled like the coils of a transformer, the reader, through its detector, perceives the variations of impedance of the antenna and transmits the received data to its control logic.

The main problem that may arise as a result of the use of RFID systems in the near field is that if the modulated response signal has the same frequency as the reader request signal, then this signal will be masked by the request signal and therefore it will not be easily detectable due to the weak coupling between reader and tag.

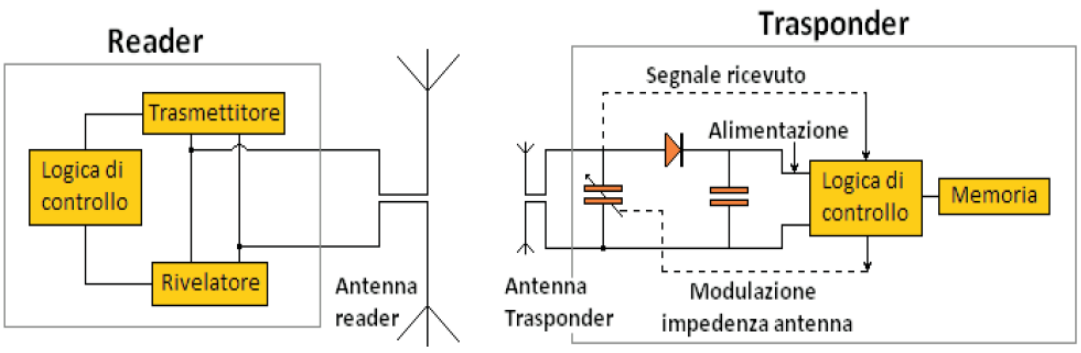

Figure 4. Operating principle of an electromagnetic coupled passive tag.

We can try to summarize the operation of an electromagnetic coupled RFID system in some basic steps (Figure 4):

- The request data are sent from the reader to the transmitter that generates the signal for the dipole antenna;
- The dipole antenna of the tag receives the signal that has spread in the far field region;
- The energy of the received signal is used to charge a capacitor, allowing the supply of the tag;
- Activated transponder control logic decodes the reader's request signal;
- The data on the memory of the tag are read by the transponder. The reading of these data allows the modulation of the impedance of the antenna (tag) and consequently modulates the backscatter;
- The reader receives the backscatter signal, decodes it via the receiver and transmits the received data to the control logic.

The main problem that may arise as a result of the use of RFID systems in the far field is that the field emitted by the reader is reflected by the antenna of the transponder but also from all other surrounding objects of a size comparable to the wavelength used. The reflected fields, overlapping the main one emitted by the reader, can cause them to be damped or cancelled.

In addition, as in the case of an inductively coupled RFID system, problems could arise if the modulated response signal is on the same frequency of the query signal of the reader.

2.2 Reader

The reader is the element that, in RFID systems, allows to take the information contained in transponders. It has the ability to analyse tags individually and send or receive data by interfacing with existing information systems. The standard reader is essentially composed of two parts [7]:

- **Control unit**: a microcomputer with a real-time operating system that allows to manage the interfaces with the antennas, to interrogate the transponders that enter in the action field of an antenna and to manage the collisions between the tag response messages.

- **Antennas**: the real physical interfaces between the control unit and the transponders. In fact, the tags to be activated must enter the magnetic field generated by an antenna that, in this way, has the ability to supply and communicate with them.

Once the tag enters the electromagnetic field generated by the antenna, the capacitor supply the tag chip; the chip, via its antenna, modulates the perturbations of the field that the antenna of the reader picks up and the reader decodes as a series of 0 and 1. In addition, readers are usually able to read different types of tags, even with different frequencies, as long as they are within the working band (LF, HF, UHF or SHF) for which they are designed. The reader is often connected to the network with computer management systems in order to obtain information from the identifier transmitted by the tags. Readers can be classified according to the reading distance from the transponder or they can be classified according to the degree of transportability (fixed or portable).

2.2.1 Classification based on reading distance

Passive and semi-passive tag readers and active tag readers are different in that the former require shorter reading distances than the latter.

- **Reader for passive and semi-passive tags**: must emit radio frequency signals that can also provide the tag with the energy needed for the response. The reading range is not very high.

- **Reader for active tags**: are controlled transceivers able to use different radio frequency techniques. Currently active tags are not covered by specific standards.

2.2.2 Classification based on transportability

A further distinction that can be made between the readers is the one that divides them into fixed and portable. Depending on the RFID technology application, you can choose one of the two types of reader.

- **Stationary reader**: fixed readers cannot be moved after mounting; infact, they are used in applications where they should not be moved. They are often mounted on warehouses access door, conveyor belts, shelves and represent (including those for smart cards), to date, more than 80% of the total worldwide. They are used where the object with the tag moves.

- **Portable reader**: are a kind of "electronic guns" aesthetically similar to those in use for barcodes. They are used where there is the need to move the reader because, for example, it is difficult to move the object containing the tag. This model of reader is often used in zootechnics.

2.2.3 Antennas in RFID systems

RFID system usually is composed of two antennas, that of the tag (Figure 5) and that of the reader; they have different dimensions, shape and characteristics depending on the application that wants to use the RFID technology. The antennas of the tag and the reader have a basic role in RFID systems, especially in passive tag.

In an RFID application an antenna is required to transmit the radio frequency signal to the tag and to receive the data from the transponder. A radio frequency signal can be effectively radiated if the linear size of the antenna is comparable with the wavelength of the operating frequency. The optimal orientation for the coils of the antennas in the tag and the reader is the parallel orientation between them, as the maximum energy transfer is obtained with the parallel direction of the two magnetic field vectors, and therefore also of the two electric field vectors. In fact, if the tag has an orthogonal orientation with respect to the field generated by the reader the probability of reading decreases. To minimize the sensitivity to the polarization of the incident signal, sometimes, UHF tags are used with an antenna with two dipoles placed in an orthogonal position.

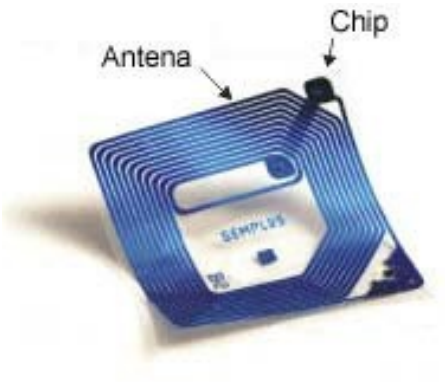

Figure 5. Antenna of the tag.

The polarization problem can be overcome by following some tricks such as placing two antennas orthogonal and out of phase with each other, like creating a 3D reader tunnel.

Portal antenna RFID systems operate with several antennas with orthogonal polarizations. The purpose of the portal is to allow the reading of different

transponders passing through it. A portal composed by three antennas allows the reading of tags according to all three planes of space (x, y, z) proving to be the best solution. The following figure (Figure 6) represents, for different configurations of the antennas, three tags arranged along orthogonal directions between them.

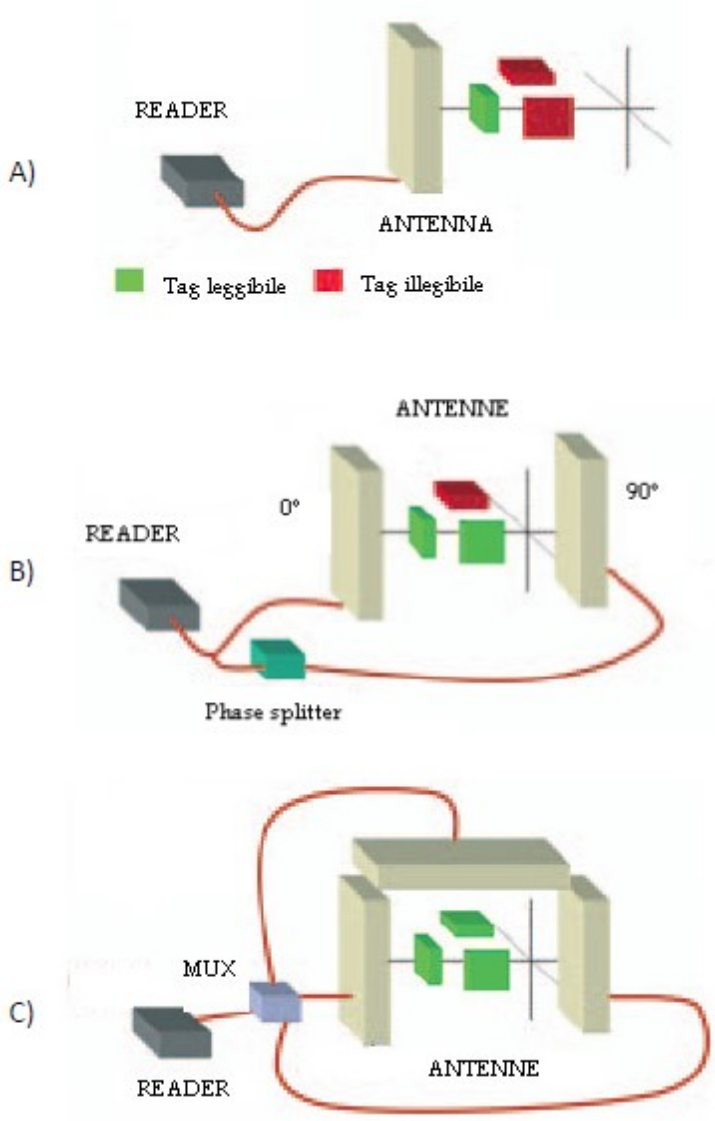

Figure 6. A) 1D Field; B) 2D Field; C) 3D Field.

The reading range, for an RFID application, is defined as the maximum distance at which readers and tags can still communicate with each other. The reading distance of a typical passive RFID application goes from a few centimeters up to about 1 meter, depending on the configuration of the RFID system.

The reading distance of a RFID device is usually influenced by the following parameters:

1. Operating frequency and performance of the spiral antenna;
2. Quality factor Q and circuit tuning;
3. Orientation of the antenna;
4. Current and excitation voltage;
5. Sensitivity of the receiving system;
6. Modulation and demodulation algorithms;
7. Number of bits and interpretation algorithms;
8. Operating conditions of the environment (metal, electrical noise, etc.).

For a given operating frequency, the first three of the previous conditions are relative to the antenna and tuning circuit. Conditions 4 and 5 are determined by the topology of the reader circuit. Condition number 6 is device communication protocol call.

Assuming the device operating under a given condition, the reading range of the device is largely influenced by the performance of the spiral antenna. It is always true that a wide reading range assumes a large antenna size. In fact, the size of the tag increases the reading distance for both proximate and far field applications.

2.3 RFID Communication Systems

The communication between an emitter system and a receiver system in an electromagnetic field depends on the relative position between the two antennas. In the case of passive RFID systems, which must be into the electromagnetic field generated by the antenna of the transceiver to work, the energy received by the transponder depends on its angular orientation and the distance to the transceiver antenna. The communication process can be divided mainly into two phases: transmission and reception. Moreover, while in transmission active transponders behave like readers, passive tags must always be powered by the electromagnetic field.

The process is conceptually simple. The transceiver antenna generates a magnetic field. A part of this energy arrives inside the antenna of the tag and induces a voltage from which is obtained a current that allows the switching-on of the internal circuits of the transponder. The energy required is minimal since the tag is a passive circuit and was designed to require a very low level of energy consumption. The voltage induced in the transponder is rectified with diodes, while a clock recovery circuit is able to detect the frequency of the signal to drive the clock of the internal system. Briefly, the behaviour of readers and tags in the communication process can be divided into two phases:

1. Data transmission: reader to tag;
2. Data transmission: tags to readers.

In phase 1, the microprocessor of the reader generates a logical signal compatible with the duration and length of the modulation. The carrier frequency is modulated through this signal to make possible the transmission of data to the tag.

In phase 2, passive and active tags mainly use the principle of backscatter radiation. This communication is usually Half Duplex because readers and transponders can transmit one at a time. It is also possible to use a Full Duplex transmission method in which the reception and transmission of data can take place simultaneously, but this application is still not widespread.

2.3.1 Tag-reader Communication Frequencies

The frequencies of communication between Reader and Tag depend both on the nature of the Tag and on the applications. They are regulated in order to limit the emission power and prevent interference. The regulation, however, is divided according to the geographical regions International Telecommunications Union (ITU) (Region 1 = Europe, Africa, Middle East up to Iraq, Soviet Union, Mongolia; Region 2 = Americas, Greenland and some Pacific islands; Region 3 = remaining part of Asia and Oceania), with different standardization from region to region (especially for higher frequencies). This can lead to incompatibility problems when RFID travel with the objects they are associated with. Anyway, some frequency bands are accepted all over the world. The choice of the working frequency and the maximum value of the power radiated by the reader affect the operating distance of the system, the interference with other radio systems, the data transfer rate and the size of the antenna.

2.3.2 The OSI model for communication between devices

The Open Systems Interconnection (OSI) model, structured on seven levels (Figure 7), has become the standard to model the communication process between two generic devices. The levels of the model are independent; they manage different functions and provide services to adjacent levels (lower or higher) through appropriate protocols. There are, therefore, different interfaces that interact between levels and that allow communication between the two stations. A message generated by one station is elaborated from level to level, until it reaches the physical level, and then follow the path backwards on the other station levels; the equal levels of two stations are, therefore, virtually linked to each other. In Table 1 they are summarised the tasks of the seven levels.

LEVEL	FUNCTION
1. PHYSICAL	Mode of real data transmission
2. DATA LINK	Data structure
3. NETWORK	Routing mode
4. TRANSPORT	Division of data into packets and the quality of the transmission
5. SESSION	Organization of data sequences
6. PRESENTATION	interpretation, encryption, decryption and compression of data
7. APPLICATION	protocols at the level of the particular application (structure and meaning of the messages that the two programs in the two stations exchange)

Table 1. Functions of the level of OSI model.

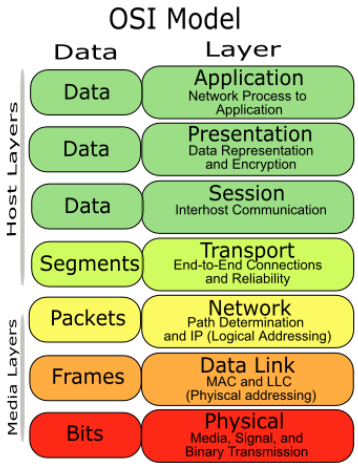

Figure 7. OSI Model.

Even RFID systems can be represented by means of the OSI model, in particular:

- *Levels 1 and 2* represent the modulation and coding of the signal;
- *Level 3* is the anti-collision management process;
- *Levels 4, 5 and 6* are the communication protocol (detection errors, correction of errors, security of access);
- *Level 7* contains the actual services of the RFID application.

Information is digital (status 1 or 0) but is transmitted in a channel which uses a modulated analog carrier.

2.3.3 The carrier modulation process

Wave has been modulated when one or more characteristics of an electromagnetic wave are modified to transmit information. This happens through a circuit called “modulator” that transforms the digital information into an analog signal determined by the carrier. The reverse operation called demodulation allows to extract digital information from a radio frequency modulated signal and is done with the help of a circuit called “demodulator”. There are several methods of modulation and demodulation that are all based on the principle of changing a fundamental characteristic of the sinusoidal alternate wave source.

2.3.4 The coding of data

Both in the tag and in the reader the data to be transmitted must be encoded in such a way as to generate a binary signal that will be used for modulation. There are numerous coding techniques with different characteristics based on the spectral employment in the base band, the complexity of co-decoding, the sensitivity to disturbances and the transferred energy. In the transmission from reader to tag the signal energy must be maximized to provide as much energy as possible to the transponder. On the contrary, in the transmission from tag to reader the signal energy must be minimized due to the low available energy but the amplitude of the signal must able to allow its detection by the reader.

2.3.5 Standards

Four areas of standardization can be identified regarding RFID technology:

- **Technology standards:** that describe the technical basis of an RFID system, defining frequencies, transmission speed, timing, coding, protocols and anti-collision systems, and aim to ensure compatibility and/or interoperability in systems produced by different suppliers;

- **Data standards**: dealing with agreements on how data are structured for compatibility and interoperability requirements. They describe different aspects of data organization and are mostly independent of technology;

- **Application standards:** that define the architecture of a technical solution for specific applications or for a sector of applications;

- **Compliance standards:** that deal with agreements and define how systems must behave in order to be considered appropriate to particular performance or operational verification tests.

There are two classes of organisms that deal with the problem of standardization and are International Organization for Standardization (ISO) and Electronic Product Code (EPC), which differ mainly on the standards of application and compliance [7].

- ISO is an international institution strongly involved in the definition of standards for RFID that deals with communication interfaces. ISO has recently developed a multi-part standard (ISO/IEC 18000) which defines the communication protocols for all applications and all frequencies commonly used in the world for the identification of objects in the distribution chain and for any other application. The ISO/IEC 18000 (RFID for item management - air interface) defines the general parameters of the radio interface and provides a description of the architecture in which these parameters are used for all possible operating frequency. It defines the physical layer, anti-collision methods, and protocol for RFID devices used to identify objects for systems operating at 13.56 KHz. At European level, the ISO standard is referred to the European Committee for Standardization (CEN) as regards hardware and communication protocols; instead the European Institute for Standardization in Telecommunications (ETSI) issues legislation regarding essentially the electromagnetic compatibility. The organization that works on ISO standards in the USA is the American National Standard Institute (ANSI).

- EPC deals with communication interfaces ensuring interoperability between readers/tags. This organization was born and operates as a private association. It has created standards on use of the RFID technology

in the logistics, making a classification of tags, size of memory for the storage of identification information in tags and a standard for radio frequency communication protocols between tags and readers. In addition to that, EPC has created standards and specifications for the interconnection of computer systems that allow access to complete information on objects identified by EPC code contained in the tag. The EPC code has contributed to the remarkable success of RFID technology in recent years. In fact, the presence of this type of code allows to improve the efficiency of the distribution chain and, at the same time, allows to reduce operating costs. The universal identification code within a tag is aimed to be used as a pointer to obtain complete and readable information contained in each information system. The innovation of the EPC code is that it does not only contain the product and manufacturer ID, as in the case of barcodes, but it includes an object serial number that makes possible to distinguish it along the distribution chain. The length of the EPC code can be 64 bits "short" or 96 bits "standard" (Figure 8). It is divided into 4 fields:

1. Header defining the length of the code and the type of EPC;
2. EPC Manager which contains the product manufacturer's identifier to which the tag is associated;
3. Object Class indicating the type of product according to the SKU (Stock Keeping Unit) that establishes its sales unit.
4. Serial Number providing a unique identifier for the individual product of a single class and a single manufacturer.

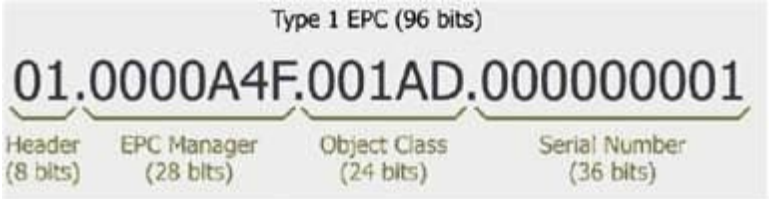

Figure 8. Example of EPC type 1 (96 bits) with hexadecimal notation.

Chapter 3

Stages of transfusion process

The use of RFID technology can make a strong contribution to the prevention of errors, in fact the major business of application is clinical risk management. Evidence of this can be found in the high number of new devices aimed at identifying the patient.
The management applications of medical equipment, especially portable, are now stifled by projects aimed at monitoring the care process of patients, because they contribute more to the justification of the investment. However, in relation to the management of portable medical equipment abroad, there is a good number of applications that support localization and traceability of a wide range of electromedical devices.

In the area of clinical risk management, one of the main critical issue is certainly that of blood transfusions. The delicate nature of this process, the complexity of the factors involved and the very high risk of death in the event of an incompatible transfusion, make this one of the most dangerous circumstance in all hospital processes.

The processes that each transfusion centre must follow, starting from donation, up to the request of the hospital ward are:

- Collection of blood from donors;
- Laboratory tests necessary for the characterization of the blood taken;
- Separation of blood components and storage under controlled conditions;
- Labelling of blood products;
- Transport of blood components;
- Request of hospital ward;
- Delivery of the blood sack to the hospital ward;
- Transfusion.

During the hospitalization, the entire procedure is based on paper requests and all checks are performed visually by operators, except the laboratory checks carried out with the help of appropriate instrumentation.

In detail, the various steps mentioned above will be described in accordance with the directives of the November 2015 Legislative Decree [8]: "Rules relating to the quality and safety of blood and blood components".

3.1 Blood sampling process

Each blood transfusion centre develops a selection procedure to ensure the suitability, once the donor's willingness to donate blood has been verified. The procedure involves:

- Unique identification of the donor;
- Compiling of the anamnestic questionnaire;
- Assessment of general health conditions;
- Assessment of the physical requirements for donation;
- Definition of suitability for donation;
- Identification of the type of donation to be submitted by the donor;
- Acquisition of informed consent to the donation;
- Acquisition of consent to the processing of personal data.

At each donation, the donor must undergo laboratory tests to exclude the positivity of infectious diseases and to identify the immuno-haematological characteristics of the donor. The transfusion centre that establishes and confirms the positive status of a marker for communicable infectious diseases must inform the interested donor, in a manner that ensures the confidentiality [8].

The periodic blood donor shall be subjected annually to laboratory tests to confirm the suitability for donation. At each donation, the donor of blood must be assessed for the following parameters and in relation to the relevant requirements:

- 18 to 65 years of age;
- Weight not less than 50 kg;

- Systolic arterial pressure (AP) not exceeding 180 mmHg;
- Diastolic AP not exceeding 100 mmHg;
- Regular heart rate, between 50 and 100 beats/minute;
- Hb ≥ 13,5 g/dl in man;
- Hb ≥ 12,5 g/dl in the woman.

Whole blood collection is the procedure by which blood is taken from the suitable donor, using sterile material and specific devices.
For whole blood a volume of 450 ml is collected, in a time of 10-15 min, excluding the anticoagulant solution used. The maximum number of whole blood donations in the year shall not exceed 4 for men and women of non-fertile age, 2 for women of child-bearing potential. The interval between two donations must not be less than 90 days. It is necessary to ensure the storage in refrigerators at 4°C [8].

The separation of the blood components takes place through the apheresis (from the Latin aphaeresis "elimination", "removal") and indicates a group of techniques to remove from the blood one or more of its components, returning to the subject the amount that is not intended to be retained [9].

In particular, the three obtainable blood components are:

- RED BLOOD CELLS: erythrocytic concentrates are obtained from whole blood decomposition and apheresis, removing buffy coat or leuco-reduction, together with removal of as much plasma as possible and resuspension in additive solution, are mandatory minimum requirements. They can be stored at +4°C (±2) for no more than 24 hours. Cryopreserved erythrocyte can be stored at temperatures of less than -60°C and their use for transfusion purposes is subjected to the current legislature and to the maintenance over time of correct storage temperature [8].
- PLASMA: if plasma is obtained from whole blood, it should be separated and frozen preferably within 6 hours of collection; The plasma may also be separated and frozen within 18 hours of collection, if the starting unit is cooled and kept below +10°C. The collection of plasma through apheresis

shall be between 600 ml and 700 ml, excluding the anticoagulant solution used, with a maximum total volume of 1,5 litres per month and 12 litres per year. The minimum time between two plasma donations and between one plasma donation and one whole blood donation is 14 days; between one whole blood donation and one plasma donation is 30 days [8].

- PLATELETS: Platelets collected by apheresis must contain an adequate volume for a minimum of 3,0 x 10^{11}. The maximum number of platelets donation is 6 per year. The minimum interval between two platelets is 14 days; the minimum interval between a whole blood donation and a platelet cell is 30 days. The platelet concentrate from single buffy coat can be prepared exclusively in closed circuit and can be stored at 22 °C in continuous agitation up to 5 days from the blood sample [8].

Whole blood and blood components collection is performed in the transfusion centre by qualified personnel, in suitable environments to ensure any emergency assistance to the donor. Blood Transfusion Services shall establish and implement specific procedures for blood collection activities.

Sampling devices and blood samples taken for the biological qualification of the collected unit and for donor controls must be labelled prior to collection. Prior to veni-puncture, the identity of the donor must be verified by the operator responsible for the collection, through the active recognition of the donor; the operator must also verify the correspondence between the donation identification code (on the labels attached to the sampling device) and blood samples.

For each individual donation must be recorded the identification data of the personnel involved, the personal data of the donor, the type of procedure adopted, the anticoagulant and other substances used, the volume and content of the blood components collected, the duration of the procedure and any pharmacological premedication.

3.2 Labelling

Devices for the collection of blood shall be labelled to identify unambiguously the donation. On each blood component, after verifying the presence of all the requirements for validation, is affixed a final label which allows to identify the type of blood component produced.

In addition, computerised procedures must be taken to check the correspondence between the sampling label and the validation label. The check must be documented electronically for the correct allocation, delivery and distribution of the blood component.

All blood components shall be labelled with the following information [8]:

- identifying name of the facility where the donation has been collected;
- donation identification code conforming to the characteristics defined by UNI 10529 and subsequent updates;
- name of the blood component conforming to the characteristics defined by UNI 10529 and subsequent updates;
- volume or net weight of blood component;
- ABO phenotype, Rh type (D), Rh phenotype, Kell antigen/phenotype, other blood group phenotypes (if determined);
- listing of the biological qualification tests with their negative result;
- type and volume of anticoagulant solution;
- type and volume of additive solution if present;
- date and time of donation and expiry;
- storage temperature;
- indication: "Not suitable for transfusion purposes if it has haemolysis or other obvious abnormalities";
- any additional treatment carried out on the blood component shall be indicated on the label.

3.3 Conservation and transport

Whole blood and blood components shall be stored in appropriate equipment to maintain optimum temperature conditions for each type of blood component and shall be equipped with temperature recording systems; visual and acoustic alarms are also present to notify as soon as possible the personnel involved.

At every stage of the transfusion chain, blood components must be transported under conditions which enable the integrity and biological characteristics of the product to be maintained, including for subsequent processing. Whole blood and blood component units shall be inspected immediately prior to packaging for transport in order to detect critical abnormalities, in this case the units must be removed.

Also in case of distribution, during the transport are applied procedures to ensure temperature conditions and the maintenance of the biological and functional characteristics of blood and blood components.

3.4 Request of the hospital ward

From the sampling process for pre-transfusion investigations, up to the time of transfusion, specific procedures must be adopted for the univocal identification and matching of the patient in order to prevent errors which may result in adverse transfusion reactions.

The recipient of the blood component transfusion and/or the administration of blood derivatives shall be informed in advance that such procedures may not be completely risk-free; in fact is required to give its consent in writing or to state explicitly its disagreement with the transfusion. When there is an imminent life-threatening situation and there is a situation of unconsciousness of the patient that does not allow the acquisition of consent, the doctor can proceed with blood transfusion even without the consent of the same. The conditions which determine this state of need shall be indicated and documented in the medical record [8].

The same doctor will have to decide the degree of urgency of the transfusion act:

- Programmed request: it must be sent to the SIMT (immune-haematology and transfusion medicine service) at least 24 hours before the transfusion, indicating the time and the day in which it will be carried out.
- Urgent request: only to be used if non-administration in a short time can lead to risks for the patient. The requested unit can be taken after a minimum time of 40-60 minutes.
- Very urgent request: to be used only in case the delay for the execution of compatibility tests could be life-threatening. If you do not know the group of the patient you must use group 0 negative erythrocyte, if the group is known you will use blood of the same group ABO/ Rh of the recipient even before the compatibility tests are completed, which will still be performed.

For the patient admitted to the hospital, a special form is supplied for the request of blood components: this is how the transfusion process begins. The application must be completed on a specific form provided by the blood transfusion service, approved by the Hospital Committee for the good use of blood and by the Hospital management.

The request for blood components shall indicate:

- patient's personal data (surname, first name, gender, date of birth);
- patient nosological data (hospital, ward, identification/nosographic code where available);
- the type and quantity/volume of blood components required;
- pathology and the reason for the request so that the justification of the transfusion is clear;
- degree of urgency;
- laboratory data for the evaluation of the appropriateness of the request and for the selection of the blood components to be assigned;

- data on immune-haematological history (pregnancies and previous transfusions);
- the date and time of the request.

In some hospital ward it is available the on-line request, through the company intranet, which allows you to forward online the request for blood components to the SIMT, without the need to fill out the paper form.

Once the need for a transfusion in the treatment process has been defined, a blood sample must be taken from the patient; the test-tube, properly labelled with the patient's identification data, is sent to the SIMT with the paper transfusion request (where no computerised request mode is present) via the pneumatic mail system or via other transport system.

3.5 ID wristband

The patient must be uniquely identified by his personal data (name, surname and date of birth) with particular attention to homonyms when taking blood samples necessary to establish immunological compatibility between blood units and recipients. The correct match between the blood samples taken, the request for transfusion and the patient must be ensured.

In this regard, strings (wristbands) containing the identification data of patients have been introduced, in order to ensure a higher level of transfusion safety, with particular reference to the prevention of ABO incompatibility reactions [9].

The minimum mandatory data to be contained on the appropriate identification wristband, are: surname, first name, date of birth, gender.

In the case of a cooperating patient, its active identification in all stages of the transfusion process is essential; for the non-cooperating patient the active identification can be made through a relative. The Health facility where transfusions are performed develop, validate and implement a unique identification procedure to safely manage cases of unidentifiable patients.

A doctor and a nurse provide identity checks and verify compatibility by comparing the data present on each unit of blood with those of the request and documents

made available by the transfusion service, such as the blood type and the certificate of compatibility of the units with the patient (Figure 9).

Identification of the recipient take place in the patient's bed by two health professionals immediately prior to the begin of the transfusion. The checks must be documented and recorded on a form, completed and signed by both operators. The identification of the recipient must always occur with the collaboration of the patient, where his clinical conditions allow it, and must always include control of the personal data reported on the wristband, compared to those reported on each unit of blood to be transferred.

3.6 Distribution of blood sack and group check

When test-tubes arrive in SIMT, if there is no paper request, the operators verify the presence of the computerized request. The paper requests instead will be recorded on the dedicated computerized system. Through this system the operators can verify if the patient has been previously transfused: it is available the history of known patients, with his/her personal data, group and other information.

If the patient has never been transfused, it is necessary to carry out a second sampling for the control of the group, as required by the national legislation of reference (Legislative Decree November 2015): the SIMT then requests a second blood sample from the hospital ward, which is essential for the release of blood sack.

The test-tube received in SIMT is then analysed: in the case of a patient already inserted it is verified that the group in the database corresponds to the blood group analysed, then it is possible to proceed with the distribution of the blood components. For the patient never previously transfused (for which therefore there were no previous data) the second sample will also be analysed in order to verify the correspondence of the group with the first sample analysed.

3.7 Delivery of blood sack

When the clinician considers it is necessary to perform the transfusion, the request for the collection of the blood sack is sent. Once the request has been received by the SIMT, the blood sack for the patient are collected and sent to the ward via pneumatic mail or other transport system.

3.8 Blood transfusion

The medical personnel that performs the transfusion to the patient, checks the correspondence of the data on the label applied on the blood sack with those in the medical record, and proceed to the transfusion (Figure 9).

The transfusion is done under the responsibility of the doctor, who must be promptly available in case of adverse reactions. The patient is kept under observation, in particular the first 15 to 20 minutes after the start of the transfusion, in order to detect any adverse reactions at an early stage. Immediately before and no later than 60 minutes after the transfusion, vital signs (temperature, heart rate, blood pressure) are detected and recorded in the chart. The transfusion information must be recorded in the medical database by the structure in which the transfusion take place: the number, type and identification code of the transfused blood components shall be recorded; date and time of the beginning of transfusion, vital signs at the start of the transfusion, date and time of the end of the transfusion, vital signs at the end of the transfusion, any adverse reactions detected and the treatment subsequently carried out must be recorded no later than 60 minutes after the end of the transfusion [8].

3.9 Traceability

The Transfusion Service organize a system for recording and storing data that allows to reconstruct the path of each unit of blood from the time of collection to its final destination, including possible removal, and vice versa.

The personal, clinical and laboratory data of the donors shall be recorded and updated as part of the IT management system in accordance with security measures.

This database shall be managed in such a way that:

- contain surname and first name, sex, place and date of birth, tax code, residence, telephone number, Voluntary Association or Federation of origin of the donor (and possibly telephone number of the workplace);
- ensuring unambiguous identification, while protecting the identity of the donor and facilitating the traceability of the donation;
- record donor adverse reactions to donation.

The blood transfusion centre shall adopt a system of safe recognition of the recipient at which the unit has been assigned.
Each unit of blood and blood components, upon delivery, must be accompanied by a transfusion form, fill in with personal and genetic data (phenotype ABO and Rh) of the recipient and the identification data of the assigned unit/s.
The qualified doctor responsible of the transfusion therapy, is forced to send to the transfusion service the documents of the transfusion with any adverse reactions related to this.

3.10 Unused blood sack

If the requested and delivered blood component unit is not used, the applicant must return it to the blood transfusion service as soon as possible after delivery. The unit returned shall be accompanied by documents that show its integrity and compliance with the instructions for its storage and transport, as defined by the Hospital Committee for the Good Use of Blood.

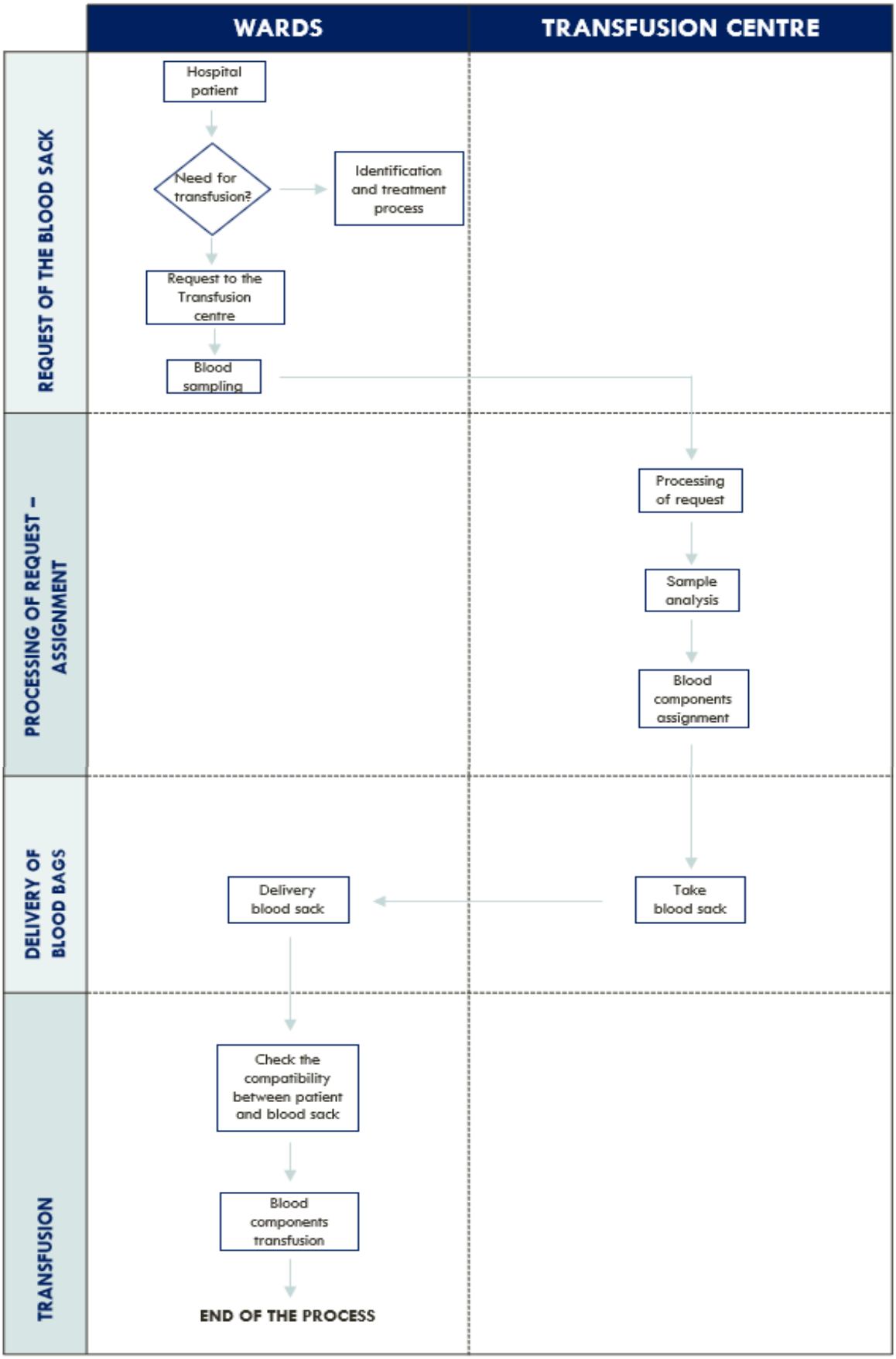

Figure 9. Stages of transfusion process.

Chapter 4

Blood supply chain support system

Today, the management of blood sack is based on the use of barcode, which involves inaccuracies and loss of time, due to the easy damage of the barcode and the impossibility of massive operations.

The risk associated with the management of the blood supply chain is double: on one hand, the infectious risk (for example, the risk of contracting the HIV virus with a transfusion, in Italy, is 1 in 500,000 blood sack) on the other hand, the risk of an AB0 immune reaction, resulting from the infusion of blood products that are not compatible with the receiving's blood group [10].

Active haemo-vigilance systems show that adverse reactions due to transfusion errors account for about 70% of all adverse events and, of these, about 20% are transfusion reactions due to AB0 incompatibility [1-11-12].

The absence or non-application of specific procedures is an important risk factor which may lead to the occurrence of the event during one of the different stages of the transfusion process. Usually an error is the sum of many errors and coincidences, unless any "filter" able to intercept one of those errors.

In many cases, it has been demonstrated that the check at the bed of the patient has failed the interception of the anomaly. In fact another important information is that 35% of errors occur at the level of direct interaction with the patient: the identification of the patient, apparently common, is instead one of the most difficult obstacles to overcome [13-14].

Another problem related to the control procedures, is the need to ensure traceability of all components.

In addition, in Table 2 are reported the high number of transfusion in the hospital "Santo Spirito" in Pescara, referred to the year 2019; those data indicates the utility of implementing, in the current processes, a system based on RFID technology that ensure safety.

BLOOD COMPONENTS	Delivered blood sack	Transfused blood sack	Returned blood sack	Rejected blood sack
RED BLOOD CELLS	15216	13356	1860	28
PLATELET	4353	4287	66	/
PLASMA (frozen)	559	539	20	20

Table 2. Data of the transfusion center "S. Spirito" of Pescara.

The Table 2 demonstrate that, besides for the internal use (i.e. Pescara), 1523 units of red blood cells and 20 units of platelets were sent to external transfusion centres (i.e. Penne and Popoli). In fact, an important factor is the monitoring of blood components during the transport.

The blood bags transported, on the basis of the November 2015 decree law, must maintain an adequate temperature and correct storage.

Blood is an indispensable and, at the same time, limited resource; the previous data show the need to implement in current processes a system that ensures traceability and safety of the transfusion (BIOTRAC) and focuses the attention on the “good use” of blood.

It is clear that there is the need to optimise the management methods of the blood supply chain; the aim of this project, in fact, is the creation of a system to support the procedures described in the previous chapter, based on RFID technology.

This system aims to support medical and nursing staff at all stages of the management of blood, ensuring that higher safety levels are achieved through radio frequency identification.

4.1 Selection of RFID system

The following system requirements must be identified:

- The electromagnetic field used must not present a risk to the patient or the healthcare professionals;
- The system must be used in accordance with the current legislation (Decree-Law November 2015);
- Ability to read tags in close contact with aqueous materials (blood component sacks);
- The tag must in no way represent a risk to the physical integrity of the blood sack;
- It must be virtually impossible to decouple the tag from the associated entity (patient, tag, blood sack);
- The reader used must be small and easy to handle by the operator;
- Readers must be configurable to ensure adequate reading distance and to avoid unwanted tag readings.

For a better design must be also taken into account some features of RFID:

- Low frequency (LF) operating Tags have lower operating distances and reading speed; High frequency (HF) operating Tags have higher operating distances and reading speed (this means that higher memory or security features are reserved for high frequency Tags);
- The signal is able to pass through many materials, with the exception of metals; there are also important attenuations with liquids (water, alcohol);
- There is the possibility of simultaneous reading several Tags;
- Tags usually have a flat format (label, badge);
- In the current state of the art, the design of the Tags is relatively easy and their production is quite cheap.

Once the decision to use RFID technology has been made and once the purposes to be achieved is known, the choice of the system to be used can be made.
A set of parameters should be evaluated:

- transmission standard adopted (variable with frequency and use of RFID system):
    - 125/134 kHz (ISO11784/85) LF;
    - 13,56 MHz (ISO15693, ISO14443) HF;
    - 868/915 MHz (EPC) UHF;
- type of system:
    - passive (able to obtain energy from the incident magnetic field, this means that its Tags are very small and cheap);
    - semi-active;
    - active;
- power consumption:
    - Tag query periodicity;
    - Tag battery life (if active or semi-active);
- operating distance (depends on the transmission standard adopted and the passivity or not of the Tags);
    - proximity (<10 cm);
    - vicinity (<1 m);
    - long distance (>1 m);
- size:
    - maximum size of the reader;
    - maximum antenna size (optional);
    - maximum tag size;
- materials:
    - affect antenna performance;
    - some materials (ex: water) interfere more with increasing frequency;
    - metal structures are sources of reflections and interference;

- type of casing:
    - glass, paper label, plastic card, other;
    - possibility of overprinting;
    - water resistance;
    - protection against chemical agents;
- memory of the Tags:
    - size [including UID (serial number)];
    - rewriting of tags [R/W (Read/Write)];
    - rewriting of the Tag program [OTP (One Time Programmable) or other];
    - multipage (independent pages);
    - segmentation/file structure;
    - duration (retention time of stored data, which, even for active tags, can be disconnected from battery life);
- integrated functionality and programmability:
    - type and quantity of operational functions already integrated in the reader management system;
    - ability to program new operational features.
- security functions (security):
    - unprotected communication;
    - reading or writing operation protected by password;
    - mutual authentication;
    - encrypted communication;
    - mutual authentication with encrypted communication and reading/writing protected by password;
- scale of the system:
    - quantity/cost of Readers
    - Tag quantity/cost
- other requirements:
    - strength of the tags;
    - anti-collision detection mode;

- temperature range for operation;
- use of the Reader casing normally provided by the manufacturer or development of a casing with an appropriate shape.

It was considered appropriate to discard a priori the LF and SHF working frequencies, characterized respectively, by a limited reading distance (a few centimetres, therefore not sufficient, in relation to the design specifications) and a high sensitivity to the presence of metals (therefore not compatible with the proximity to the metal casings of electromedical equipment).
The possibility of choice is therefore passed onto the HF and UHF bands.
The transmission standard adopted is 13,56 MHz (ISO15693, ISO14443) high frequency; the system choose is passive, in fact it is able to obtain energy from the incident magnetic field and this means that its Tags are very small and cheap; the choice is in agreement with the working frequency used allowing an adequate operating distance; the electromagnetic field used must not present a risk to the patient or the operator. The memory of the tag is “read/write”.

4.2 Transfusion process based on RFID technology

It is possible to note what are the aspects that modify the current processes, through a system that allows the identification and traceability of blood components, correct conservation during transport, adequate storage and finally the verification of the correspondence between the blood sack and patient; this system take advantage of RFID technology and provides:

- Devices for writing RFID tags;
- Wristbands with RFID tags;
- RFID labels for blood sack;
- Smartprobe for the monitoring of temperature;
- GPS tracking device;
- Palmtop device for reading tags.

By following the transfusion chain described in the previous chapter, it is possible to understand the control procedures adopted by the experimental system created; these measures ensure greater safety in all processes, from donation to transfusion (Figure 21).
Starting from the donation process, once the donor is considered suitable, an RFID tag will be applied on the blood sack before the collection of blood.
The tag aims to a faster identification and give the possibility of being tracked during transport.

During collection, the blood sack is placed on a scale that monitors the volume of whole blood or blood component collected; here the project developed in collaboration with Gadamed SRL provides a dual option: if the scale is able to read and write on the memory of the RFID tag (see Hemomix 3 Delcon scale, Figure 10) then the tag previously applied on the blood sack will be directly encoded with the necessary information; otherwise once the donation process is completed, using an A4 Plate (Figure 11), it will be possible to communicate and update the information contained in the memory of the tag.

In any case, the information written on the RFID tag are: univocal tag code (all transponder chips have a factory-programmed Unique Tag Identification Number (UID)), donor ID and donation ID, etc (Table 3).

FIELD 1	*FIELD 2*	*FIELD 3*	*FIELD 4*	*FIELD 5*	*FIELD 6*	*FIELD 7*
ID HEALTHCARE OPERATORS	*ID DONOR*	*ID DONATION*	*TEST-TUBE*	*DATE AND TIME*	*REAL WEIGHT*	*UID CODE OF THE TAG*
ID OPERATOR 1	*ID DONOR 1*	170120110164	I170120110164	01/12/2020 09:53	528	E0040108220D2545
ID OPERATOR 2	*ID DONOR 2*	170120110165	I170120110165	04/12/2020 12:12	613	E0040108220D253A
ID OPERATOR 3	*ID DONOR 3*	170120110166	I170120110166	08/12/2020 14:30	450	E0040108220D252D

Table 3. Test export file RFID scale - Hemomix 3.

Figure 10. Hemomix 3 - RFID scale (Delcon) used to monitor blood collection during donation and to write/read RFID tags applied on the monitored blood sack.

Figure 11. A4 Plate, device able to support in writing/reading mode more RFID tags present in its working area. The device can also integrate a Barcode reader to perform reading, writing, control and comparison operations using data derived from both technologies.

The blood collected will be assessed as suitable according to the criteria defined by the November 2nd 2015 Legislative Decree focused on "Instruction relating to the quality and safety of blood and blood components".
After passing all blood validity tests, it is possible to separate the various components:

- Packed red blood cells;
- Plasma;
- Platelets.

Once the individual blood components are obtained by centrifugation of whole blood, a thermal printer (Zebra) will produce labels, integrated with RFID tags, that contain information about blood components.

At this point, if the blood sack was collected in a main blood collection centre (i.e. Pescara), it will be enough to wait for the results of the blood tests, allowing the validation of the unit. Instead, in the case that the blood sack is not collected in a main centre (i.e. Penne o Popoli), the BIOTRAC programme comes into play.

4.2.1 BIOTRAC

BIOTRAC is the innovative solution for identification and traceability in transfusion. Today the management of blood sack is based on the use of barcode, modality that imply inaccuracies and loss of time, due to the easy damage of the barcodes and the impossibility of massive operations.
BIOTRAC devices allow a complete, safe and effective monitoring from the donation to the transfusion; these devices guarantee unique identification of the sample and a control of the temperature during the displacements of the blood sack.
BIOTRAC uses RFID technology, this means that through radio frequency and the support of a "reader" can read, communicate and update the information contained in the memory "tag" of the object in question.
This technology allows not only a more secure identification (as univocal) and

more accurate traceability, but also the management of many blood sack at the same time.

We indicate below the devices used during the process to ensure proper identification and traceability.
The FREEBOX (Figure 12) and A4 PLATE (Figure 11) allow:

- blood sack labelling at the acceptance/donation stages;
- management of different operations during the process using the TAG and monitoring of movements.

Figure 12. Freebox, a device that can support simultaneously in writing/reading mode multiple tags.

The SMARTPROBE (Figure 13) allows a complete, safe and effective monitoring of the temperature of the blood bag during the transport phase.

Figure 13. Smartprobe, a device capable of detecting temperatures during transport and recording any anomalies when the thresholds set are not respected.

The 3D Tunnel is an RFID 13,56 MHz reader that allows traceability of multiple units of blood simultaneously (also positioned inside appropriate containers), in the various phases of the process (Figure 14). It is placed on a special carriage to facilitate its movement inside the health facilities. 3D Tunnel can optionally be equipped with:

- monitors to highlight operations and support interaction;
- weight management system;
- internal and/or external roller conveyor to facilitate the passage of containers used for massive transport of blood units equipped with RFID tags.

Two tests carried out with this devices are shown below; in Figure 15 is represented an example of an empty RFID tag reading test; in Figure 16, instead, the reading test of an RFID tag containing information previously written by Hemomix 3 RFID scale (Delcon) or A4 Plate.

Figure 14. 3D Tunnel, a device designed to solve problems related to the logistics/transport of blood components.

Figure 15. Empty RFID tag reading test.

Figure 16. Previously overwritten RFID tag reading test.

Optionally it is possible to insert antennas or identification devices that can be used both in the hospital ward (to confirm the admission or the exit of blood sack) and in the transfusion centre for the monitoring in the storage room (Figure 17).

Figure 17. Antenna, device that can be used to integrate the monitoring flow.

Through these devices that take advantage of RFID technology and an application management software, it is possible to guarantee the traceability and identification of blood (Figure 18-19).

Below is reported one of carried out test; it consists in the simulation of the transport of a blood bag (with its test tubes) inserted in a container together with the smartprobe and the GPS.

As described above, the smartprobe is a device that monitors the temperature during transport. In figure 18 it is possible to observe, in fact, that every 30 seconds the temperature is recorded; this provides the safety and correct transport of the blood units, maintaining the temperature within the established range described in the above cited law Decree 2015.

The GPS terminal instead assess the position of the blood component. In figure 19 the position of the container, transported by the blood drive truck, and the route taken are monitored until the arrival at the hospital.

This system is essential because it is possible to discriminate a bag (or test-tube) which has been subjected to inadequate condition during the transport.

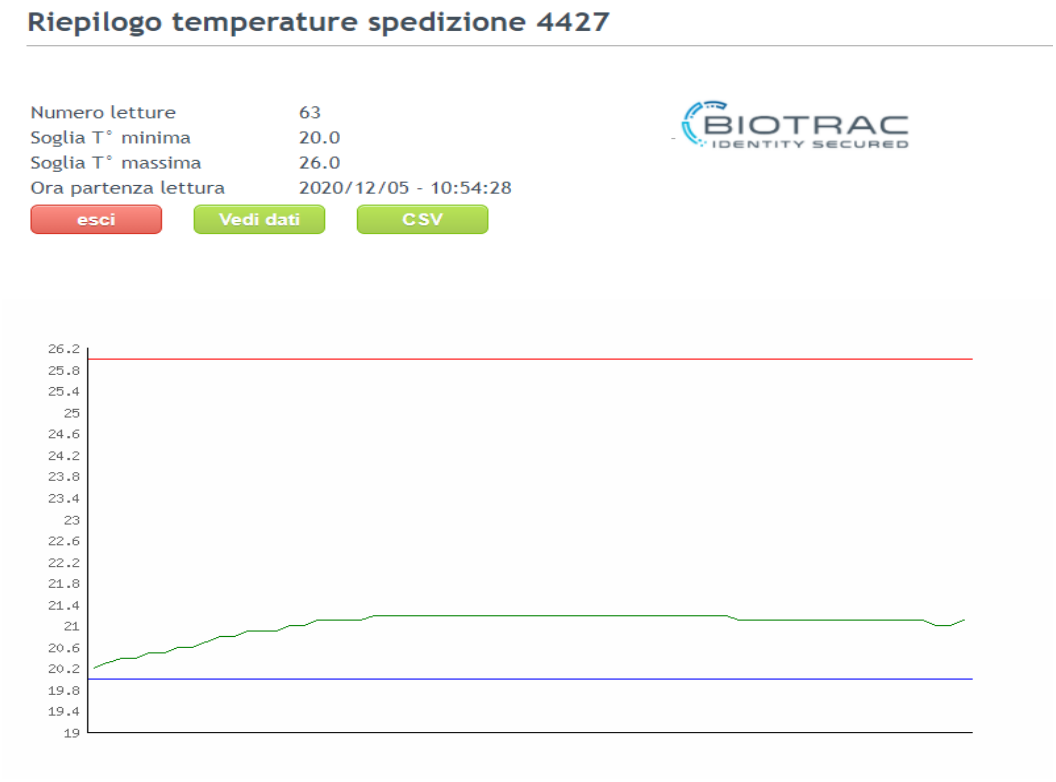

Figure 18. Temperature monitoring by the smartprobe device.

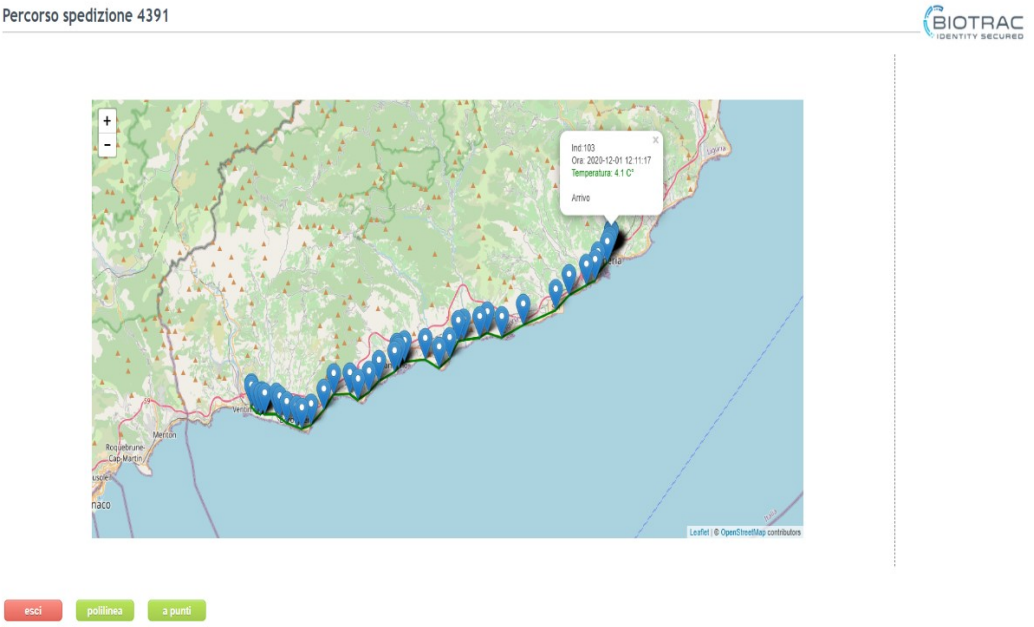

Figure 19. Monitoring of the position of the blood unit during transport.

Finally, the storage of blood components depends on their intended use.

In fact, blood units intended for clinical use are stored in blood bank refrigerators, instead blood components used by the industry are stored in freezers (ex: plasma units).

4.2.2 RFID wristband for the identification of patient

An innovation introduced is a wristband with RFID tags; it is possible to associate a passive RFID tag with a patient by means of a wristband (Figure 20). The record number contained in the Tag allows the identification of the patient, the storage of his data and its localization within the health facility.

The non-manual identification of the patient by means of non-transferable wristbands allows several benefits:

- improve the efficiency of the system (improves communication and reduces data collection and input errors);
- increase patient safety;
- the technology allows fast access to the patient's data and medical record stored within the information system (for read/write and transfer operations);

- reading operation is faster than reading a barcode;
- unlike barcodes, reading can be done through and around the human body, clothes, bed covers and non-metallic materials, without disturbing the patient;
- RFID tags provide greater security with respect to barcodes, which are easy to copy and duplicate;

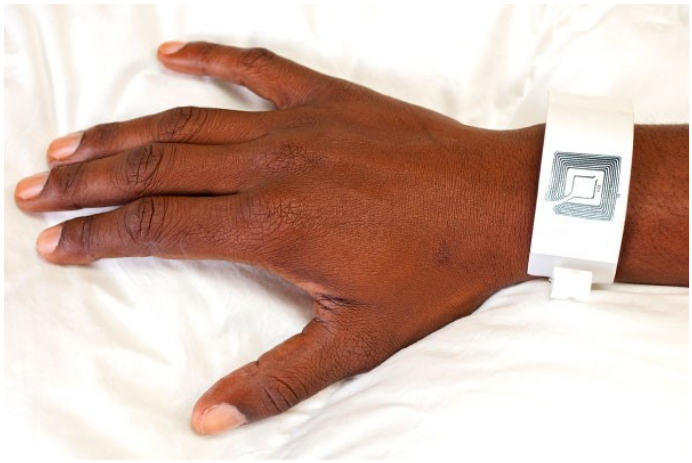

Figure 20. RFID wristband.

It will be now discussed how the transfusion process, described in the previous chapter, is partially modified by the RFID technology. The process will be splitted into stages to facilitate the understanding of changes and improvements due to the use of RFID technology.

4.2.3 Hospital ward application

Distinctive characteristics of the system is to realize a direct match between the blood transfusion request and the patient to be transfused. If the clinician predicts the need to intervene with a transfusion in the treatment process, a specific form of the SIMT is complete in order to request blood components for the patient: the transfusion process begins.

An optional solution is the use of a software that, through the company intranet, allows to forward online the request of blood components to the SIMT. The detailed use of this mechanism will be explained below.

Once the possible need for a transfusion in the treatment process is defined, a blood sample must be taken from the patient. The test-tube, appropriately labelled with the patient's identification data, is then sent to the SIMT with the paper transfusion request through the pneumatic mail system.
The healthcare professional take one of the applications prepared by the SIMT, then fill the request form with the patient's personal and clinical data and does the patient wear the RFID wristband. The RFID tag in the wristband will be encoded by a terminal (Zebra MC3330) able to read/write on this type of tag; then the information regarding the request and the patient's data will be forwarded into a database and taken by the transfusion management centre.
A fundamental step to perform, before sending the request, is the control of the correspondence between RFID tags of the wristband and clinical/identification data.

4.2.4 Distribution of blood component and group check

Paper requests received in SIMT are recorded on the dedicated computer system. Through this system the operators can verify if the patient has already been transfused previously. In this case, in fact, it is available the history of known patients, complete with personal data, group and other information.
If the patient has never been transfused, it is necessary that a second blood sample is taken for the control of the group, as provided for the national legislation of reference (Legislative Decree 11/02/2015). The SIMT then sends to the hospital ward an application expressing the need to make a second blood sample, for the correct release of blood sack.
The test received in SIMT is then analysed. In the case of a patient already inserted in the transfusion system, it is verified that the group in the database corresponds to the blood group analysed, then they proceed with the distribution of the blood sack.

For the patient who has never been transfused, the ward analyses the sample and verifies the correspondence of the group with the first sample analysed. The blood request is then passed to the operator that is dedicated to the management of the system in SIMT.

At this moment the operator activates the preparation procedure, inserts the patient data previously written on the request, and finally identifies the request for blood components through a specific barcode applied on all copies sent by the hospital ward. Once the blood component suitable for the patient has been selected, the unit assigned is taken by the blood bank. At this point the UID code of the blood bag(s) must be associated with the patient's information (UID code of RFID wristband and Barcode of the blood request) in order to ensure a unique match between the blood component and the patient.

In the case of an urgent request, the intra-hospital transport to the wards must take place as soon as possible and normally must not exceed 15 minutes (the time of delivery is marked) to allow the beginning of the transfusion within 30 minutes of delivery.

The transport of blood components should be carried out by means of a system which ensures the integrity of the product and the procedures for the transport should be validated periodically.

For this reason, BIOTRAC devices, can also be used in this step of the transfusion process since they are able to monitor the temperature and position of the blood sack even inside the hospital.

4.2.5 Transfusion in the hospital ward

During the transfusion in the hospital ward, it is first necessary to verify the compatibility between the identification code (UID code) of the blood sack and the RFID wristband of the patient through the RFID device supplied to healthcare professionals. The operator must be identified in each step as responsible for checks (as specified in Legislative Decree 2 November 2015).

Therefore, will be made the recognition of the patient for the safety of the process. Only if a match is established between the RFID wristband and the blood sack, the RFID device confirms the beginning of the transfusion and the starting time will be recorded. At the end of the transfusion it is necessary to record the end time of the transfusion process.

All transfusion information, including any adverse reactions, must be sent to the SIMT.

It is possible to integrate special antennas that, upon the arrival of blood sack in the hospital ward, are able to identify:

- UID code of the blood sack to be transfused;
- Time of entry of the blood sack;
- Exit time, if the blood component is not transfused.

4.2.6 Transfusion management online

The transfusion management service, once acquired the blood requests from the department, associates the UID code of the RFID wristband to the barcode applied on the request of blood.

Once the blood bag suitable for the patient's transfusion has been selected, the delivery must be made via A4 Plate to ensure that the Transfusion Management acquires the UID code of the RFID tag of the assigned blood unit. Useful information to verify the compatibility in the hospital ward between the patient and the blood unit will be:

- assigned blood sack UID code;
- blood sack donation code;
- product code of the blood sack (ex: red blood cells or plasma);
- description of blood component;
- group;
- RH factor;
- CDM code (optional - merge between DONOR code + DONATION code).

The UID code of the selected units must be associated with the patient's information (RFID wristband UID code and barcode of the application) in order to ensure an univocal match between the blood component and the patient; the barcode of the blood unit together with the UID code of the bag will be added to the record previously created to associate RFID wristband and blood request.

In this way a unique association between the elements will be established and, through an interchange folder, all the information will be stored in the portal. This will allow in the hospital ward a check between the elements and will ensure, in case of verified check, that the patient receives the right blood sack avoiding fatal errors.

At the end of the transfusion, all the information (starting date/time, end date/time, operator identification code and any adverse reactions) will be transferred electronically to the Transfusion Management Service.

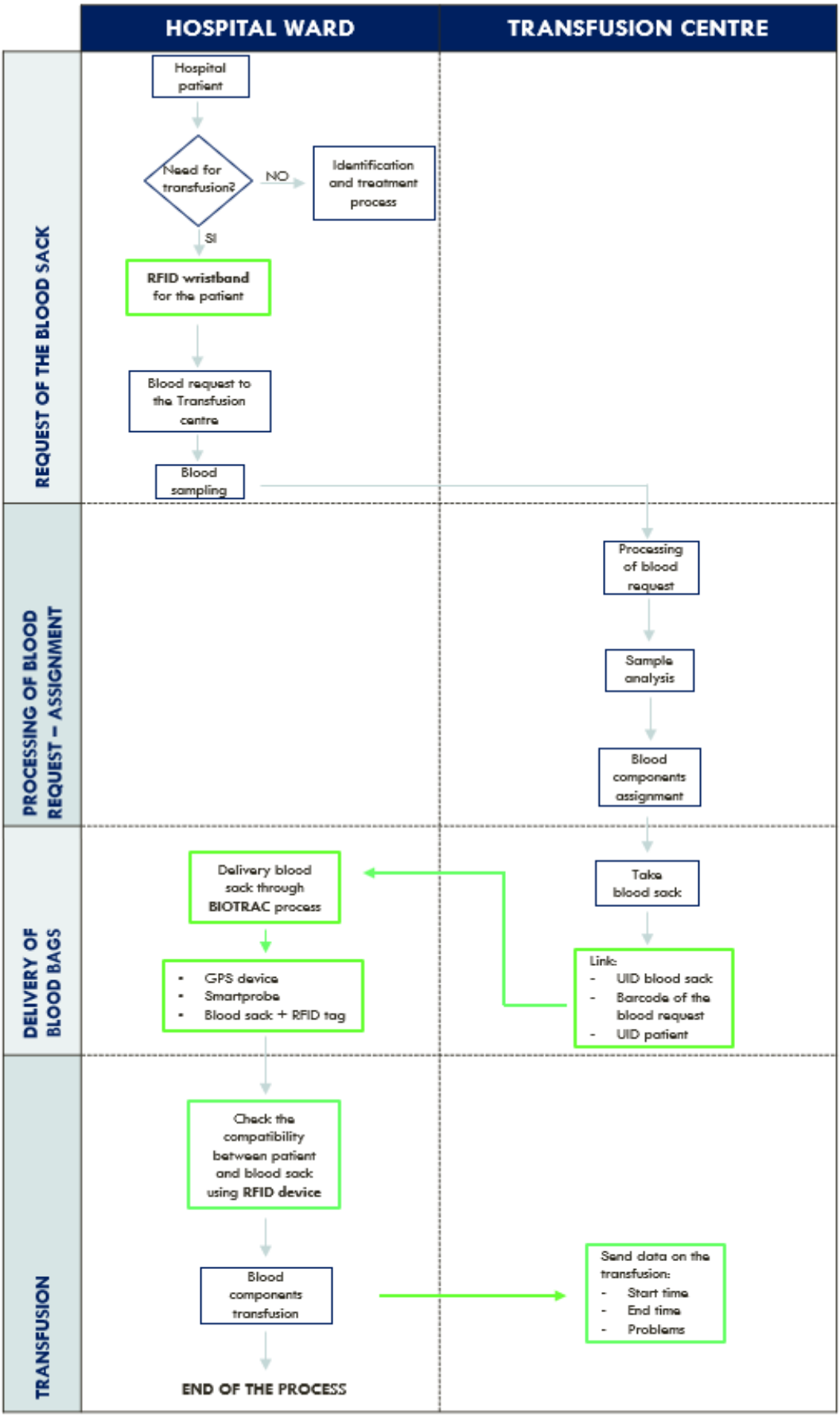

Figure 21. RFID-based transfusion process block diagram.

Chapter 5

Discussion and conclusion

Human blood, collected by voluntary donors, is a precious, irreplaceable and indispensable asset for the treatment of numerous pathological, surgical and medical conditions. Blood, blood components and blood products, due to a limited resource, must be used properly.

The activity carried out in these months has allowed to:

- Examine in depth RFID technology, with reference to the physical aspects, types of system, current applications in the health and non-health field;
- Identify critical elements in certain clinical and care procedures, which could potentially be optimised by the introduction of RFID technology, with improvements in safety, efficiency and cost-effectiveness.

The developed system guarantees fundamental characteristic in terms of safety and traceability.

In fact, for each donation, the system ensures the traceability of the following information:

- Collection Place;
- Donor;
- Donation type;
- Volume of the unit(s);
- Date and time of the start/end of the procedure;
- Lot of devices used for whole blood collection procedures;
- Healthcare professional(s) that carried out collection activities;
- Healthcare professional(s) that have taken whole blood units or blood.

The developed system guarantees:

- Acquisition of personal information about the donors (with its medical record) and ensures univocal link between the identification code of the donation and the donor.
- Generation of labels with specific code for the identification of the units to be collected and biological samples. The system allows to print (Zebra) labels containing data reported in clear and recorded also in RFID tag.
- Scales used for the collection of whole blood, able to acquire and record the data related to the collection.

After the assignment of blood units, the system associates the units selected to the transfusion request, allowing to couple the delivery of the units to a specific patient.

In relation to the transport of blood, the system guarantees the traceability of:

- Delivery date and time;
- data present in the transfusion request;
- healthcare professional(s) that ordered the delivery of the unit;
- type and quantity/volume of blood components delivered.

During the transfusion process the system provides:

- the registration of the transfusion data;
- the return or elimination of units;
- the recording of any unwanted reactions.
- the recording and traceability of the re-entry of units delivered and unused, as well as the reason for non-use.
- the elimination of blood units expired or otherwise not usable and the recording of their reasons;

As the experimental system is pending approval, it was not possible to verify tangibly the positive effects that this system would have on transfusion processes.

Despite this, some of the studies found in the literature state that health facilities, after the introduction of RFID technology in hospital supply chain, operate more efficiently, improve the quality of the organization processes and reduce possible errors.

In 2013, preventable medical errors were estimated to cause 210,000 to 400,000 deaths each year [3].

In the entire blood transfusion-related processes, the high number of patients and other external factors will inevitably lead to human error [2].

The three main functions in the management of blood products are identification, screening and labelling [15]. The causes of blood transfusion errors occur in the following processes:

- identifying the blood drawn during the donation process;
- identifying the correct patient at the bedside;
- laboratory testing and screening;
- labelling the blood sample.

These errors have been caused by human error and indicates that electronic technologies such as RFID can reduce transfusion errors [15].

Integrating the RFID system into the blood transfusion supply chain can provide safer blood transfusions [4]. Through the RFID system, medical product data input can be performed quickly, automatically and without contact through radio waves [16]. As a result, goods can be transported faster and cheaper, while tracking in a more accurate and timely manner [17].

One of the most significant advantages of using RFID in blood transfusion services is to have an impact on positive patient identification by helping to eliminate human error.

Using RFID to identify the recipient, the risk in the match between the patients and the related blood unit can be greatly reduced.

The implementation of RFID technology in the hospital supply chain enables healthcare organizations to operate more efficiently and improve patient-level accessibility [18].

Lou et al. (2011) reported that passive RFID can reduce fatal transfusion reactions enhancing a correct identification of the patient [19].

Porcella and Walker (2005) pointed out that a preliminary study conducted in a hospital system in Iowa reduced the error in the identification of the patient by 3-10% during the transfusion process. In addition, RFID technology allow a complete elimination of blood bag transport errors and reduces the blood unit losses by 87% [20].

RFID utilization in transfusion will be able to improve transfusion medicine workflow processes [4]. The use of RFID technology in the hospital supply chain can bring multiple benefits to the healthcare organizations. RFID technology can improve patient safety, speed up critical treatments, reduce supply chain costs, and better track patient compliance with medications, thereby leading to better follow-up treatments. But the most important benefit of this technology is certainly the possibility of saving lives or improving patient outcomes [21].

RFID technology is not considered a new technology, but the integration of this technology into health-related practices is new.

Actually barcode technology is used in healthcare processes and in particular in transfusion.

In the following table (Table 4) are reported all the advantages and disadvantages of RFID and barcode technology.

	RFID TECHNOLOGY	BARCODE
ADVANTAGES	- Does not require a line of sight - Depending on the characteristic; of the tag, RFID technology allow different data storage, forms and functions; - On Read/Write tags information are modifiable; - Possibility to read simultaneously different tags; - Signal can go through opaque materials; - RFID tags can be reused;	- Low cost - High capacity for 2D barcodes - Widespread utilization
DISADVANTAGES	- High cost of the hardware - In health care you must take in account electromagnetic interference with other devices.	- Water and other aqueous substances can affect the reading capacity; - Possibility to read only one barcode at time; - It is required a clear line to sight because the data transmission is done optically; - Limited amount of data transmissible; - It is not possible to write or modify barcode information;

Table 4. Advantages and disadvantages of RFID and barcode technology.

The two main negative effects of RFID systems in healthcare organizations are the management of patient's sensible data and system implementation. In fact, ensuring that patient privacy is maintained at the highest level is the main RFID-related-problem of medical institutions. Passwords and access codes can be used to protect encrypted data of RFID tags.

Although there are no reports of patient injuries due to the low level of radiation emitted by the RFID devices, these devices may have adverse effects on patients with pacemakers or implantable cardiac defibrillators [22].

With the introduction of these technologies, errors have been corrected, but a new category of errors has also been introduced. This new category of errors is called "technology-induced errors" to emphasize the close link that exists between their occurrence and the triggering causes.

The possible sources of such risks can be identified in:

- inadequate requirements;
- design errors (designed for the designer or the buyer and not for the end user);
- training errors or deficiencies;
- inefficiencies of the systems themselves;
- cognitive errors (misidentification, difficult storage, etc.) that often lead to bias;
- errors in communication.

RFID systems have been proven to play a role in multiple areas of healthcare delivery systems. However, there is a lack of research on the management and standardization of RFID use. Future research in these fields will be beneficial to the healthcare. A deeper understanding of the connectivity and interoperability of RFID systems with the health information systems and medical service providers is essential for the continued implementation of RFID systems in the medical environment.

RFID technology has risks related to the privacy and security of patient information. The use of lower quality tags enhances the possibility that unauthorized sources can access patient information because they do not have the possibility to ensure that the reader has the permission to access the selected information.

I would like to conclude my thesis with the thought of the major American transfusion safety expert, Walter H. Dzik, whose sentence is particularly suggestive: “Blood transfusion to the wrong patient is the most common and serious danger of the transfusion. By administering blood without protection against AB0 error, any incorrect transfusion subjects the patient to a level of care typical of a 19th century health system. In this sense, the wrong transfusion is equal to surgery without anesthesia, a diagnosis without radiology or infectious treatment without antibiotic. Thus the pre-transfusion control at the patient’s bed, practiced by a human person, in a manner little varied over 50 years and without the aid of any new technology, represents everything that separates the patient of the 21st century from the consequences of a transfusion practiced as in the 19th century [23]”.

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