

SAFETY AND LOGISTICS PERFORMANCE EVALUATION OF A RFID SYSTEM IN A BLOOD TRANSFUSION CENTRE

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ABSTRACT

This paper aims to describe the development framework of a Transfusion Medicine RFID application, which was designed in order to enhance patient safety and in order to improve blood inventory management processes.

In the first part of the study, a reverse engineering of present processes (As-Is) was performed through two analysis tools: Flow Charts and Activity Forms. In the second part of the study, an RFID-based processes re-engineering has been designed in order to reduce criticalities and to improve Transfusion Medicine service performance. Then a Return on Safety (ROS) assessment was performed through a RFID-enabled processes FMECA and through Key Performance Indexes (KPI) design. ROS assessment showed a clinical risk reduction in every blood chain process.

Keywords: RFID, Blood supply chain, clinical risk

1 INTRODUCTION

Clinical Risk reduction, safety and quality improving of Italian Healthcare system services, is nowadays a priority and Transfusion medicine is one of the most interesting intervention areas. Due to high complexity of transfusion process, characterized by various checks, analysis and handlings of blood assets, probability of human errors is still the most dangerous. Infectious exposure and mistransfusion (mismatch between patient and assigned haemocomponent blood group) are the most serious transfusion risks.

Recent international studies reveal that pre analytical and clinical errors, which include incorrect ABO bedside testing and mistaken or missing patient identity check, represents about 80% of total adverse events [1].

Particularly "Acute Hemolytic Reaction", due to mistransfusion, has deadly consequences in about 10% of cases [2].

Statistical data of ABO-incompatible RBC transfusions incidence are relevant in different countries (rarely data are collected with standard procedures): Germany 1:36000; USA (New York) 1:38000; France 1:135207 (including autologous blood); Ireland 1:71428 [1].

Viral transmission has been reduced since the early '90, thanks to the introduction of compulsory tests based on serology and Nucleic Acid Amplification Technique (NAT) [1]. Estimates of the risk per unit of blood in the post-NAT era are approximately 1:1,900,000 for HIV and 1:1,600,000 for HCV [3].

This study aims to devise a method to enhance patient safety, by reducing error rate of mistransfusion and viral transmissions, to improve blood inventory management processes through an RFID-based process reengineering and also to estimate the potential clinical risk reduction [4] [5].

This study is the experience developed at Blood Transfusion Centre (BTC) of Brotzu Hospital (AOB) in Cagliari (Sardinia Island, Italy). Brotzu Hospital Blood Transfusion Centre operates in all standard transfusion processes: blood and platelet letting, therapeutic aphaeresis, blood-components separation, typing, analysis and assignment. About 50,000 blood units are treated every year, 60% of which are imported from other Italy regions in order to cover high Sardinian demand.

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2 REVERSE ENGINEERING

In the first part of the study, a reverse engineering of present processes was performed, in order to define information and material flows and to analyze infrastructure and technology present status. Visits in Hospital Unit wards and in the Labs during working hours were scheduled and operators answered to analyst's questions about procedures. This analysis step involved BTC and two Operative Units where transfusions are often performed: Transplant Unit and Brain Surgery Unit. In the first one, all processes are performed in a standard traditional way, while the second one was studied because it is the only Operative Unit where both paper and digital blood request forms are sent to BTC. Only ward patient bedside transfusion were considered for the study; intra-operative transfusions were disregarded.

Two main analysis tools were used: Flow Charts and Activity Forms. Flow chart is an algorithm graphical language. It allows to describe all process operations as a scheme. More than 20 Flow charts were designed, including both deep analysis charts and overall macro-process analysis charts.

A specific form, was filled for each activity in order to focus on the main pieces of information and to highlight inputs outputs and involved resources.

Due to the high number of processes to analyse and to their high level of complexity, they have been conceptually split into two sub-systems. The first one, called "Transfusion Loop", includes macro-processes from patient admission to blood component transfusion; the second one includes donation, blood components separation, validation and storage stages. Analysis and synthesis phases were independently performed for each sub-system; nevertheless they are mutually complementary [4] [5].

Patient safety depends on Blood Chain data tracing methods, so they were deeply analysed and reported on activity forms. Blood components traceability is nowadays ensured by only hand-filled paper books. One-dimensional barcode is the only employed technology and it supports at present only BTC-inside processes. Barcode technology is indispensable for automatic clinical and laboratory blood-test systems, while it is not able to achieve a complete process automation because of restricted technical potentialities.

As for patients, they are not tracked with any automatic system, nevertheless operating staff reach high level of patients direct knowledge because large unit wards have no more than 30 beds.

2 FMECA

Criticalities and process error sources were put in evidence through a process FMECA (Failure Modes Effects and Criticalities Analysis). Since 2001 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires the incorporation of prospective process analysis methods as FMEA into organizational patient safety plans.

FMEA approach is "bottom up": potential error modes were considered for each activity, causes were searched and potential consequences related to efficiency and effectiveness (patient safety) were evaluated [6]. While this step (FMEA) provided only a qualitative failure modes analysis (risk estimation), FMECA provided a criticality evaluation of each failure mode (risk evaluation). The failure modes analysis passed from qualitative to quantitative analysis through the assignment of three numerical parameters related to Detection Possibility (D), Severity (S) and error Frequency (F) and consequently by defining a Risk Priority Index (RPI):

$$RPI = D * S * F \quad (1)$$

Standard linear scales ranging from 1 to 10 were used for each parameter evaluation. Severity parameter's scale is based on the patient's injuries: S=1-2 means no injury while S= 9-10 is used when patient suffers a permanent injury. Frequency parameter's scale is based on failure modes likelihood, while detection possibility index is related to the chances of finding out the error and fixing all related problems before they lead to consequences.

Risk Priority index also allowed to classify errors. Extracted data were processed by creating a bar chart set and by performing an ABC analysis. ABC thresholds were set as different among the processes. They were calculated on the basis of the RPI data, in order to find out three zones (A, B, C) with a quite homogeneous RPI range and to focus on a "A zone" with a quite similar number of criticalities in every macro-process. Processes carried out inside BTC are characterised by an high number of checks, so they resulted safer than those carried out inside Unit wards, so, for instance A zone limit for the Request reception and blood assignation macro-process was set to RPI= 60, while for blood request macro-process was set to RPI=100.

2.1 "TRANSFUSION LOOP" FMECA

FMECA and ABC analysis put in evidence that critical Activities are carried out inside Unit Wards, confirming literature data. Particularly patient recognition and pilot test tubes labeling activities have an high RPI value (RPI=144). Brain Surgery processes were analyzed in order to point out criticalities in activities that were modified due to the digital blood-request form introduction. This study step pointed out that an high number of criticalities within the early stages of Transfusion Loop were removed. Brain surgery Unit is actually the most suitable pilot Unit for RFID project development.

2.2 FROM DONATION TO STORAGE PROCESS FMECA

FMECA pointed out that critical activities are related to patient recognition and manual operations, such as:

- Test tubes and blood bags labelling (RPI=144; RPI=135);
- Copying donation data from Paper register to management software's Data Base (RPI=84);

- Infected (or unsuitable for transfusion) blood units registration and elimination (RPI=108).

Human errors were the most dangerous, while low RPI values were measured for adverse events related to instrumentation problems because of their very low Frequency parameter value.

3 RFID APPLICATION

In the second part of the study, an RFID technology application has been designed, in order to reduce criticalities. According to As-is analysis, necessary technical integrations were studied and network infrastructure modifications were suggested in order to maximize RFID Technology impact on process efficiency and effectiveness.

Use of passive Tags integrated in barcode labels, wristbands and cards has been hypothesized. Two types of tags have been considered: HF tags emitting signals at 13.56 MHz frequency, and UHF tags emitting signals at 865-868 MHz frequency. Readers are both mobile and tunnel type. Mobile readers are based on PDA computers equipped with HF or UHF aerial. These devices enable BTC staff to perform Tag reading and writing through simple approach with the Reader. Tunnel readers broadcast an electromagnetic field allowing three dimensional Tag scanning. Thanks to the use of anti-collision protocols, up to 50 HF Tags or up to UHF 1000 tags concurrently can be read and recorded in BTC management software.

3.1 HF vs UHF

For these two types of technologies, pros and cons were analyzed, regarding unit costs, functionality and electromagnetic compatibility. Due to their unit cost, both HF and UHF Passive Tags (totally energy supply free) can be embedded into disposable RFID labels, so that To Be model was studied independently from the frequency that will be chosen for the application.

13.56 MHz HF frequency is world-wide compatibly allocated [7] and exposure tests to 13.56 MHz radio energy on RBCs and whole blood-derived platelets have recently revealed no biologic damage [8]. In addition, HF system is not affected by proximity of liquids during Tag reading phase [4]. For these reasons, use of ISO/IEC 18000-3 mode 1 13.56 MHz RFID tags has been recently accepted by the United States FDA as supplemental data carriers on blood products [9]. In HF systems, reading potentialities at medium-long range are limited, but this does not penalize the system performances.

UHF tags are the most used RFID tags for asset tracking in the world [7] because of their low unit cost. Mid UHF frequency is not homogeneously allocated in all world regions for RFID applications [7]. Nevertheless BTC imports Blood bags from Europe only, so European Standard EN 302 208 RFID could be used for project development.

As for UHF technology evaluation, two experimental results are necessary. The first one is the biological damage

absence in blood components due to UHF energy exposure. The second one is relative to the minimum system performance evaluation for single/multiple reading and writing tasks in proximity of biological liquids.

3.2 EM COMPATIBILITY ANALYSIS

Despite both system are classified as Short Range Device (SRD) in order to respect non interference principles, EM compatibility analysis to hospital instrumentation is going to be performed [7].

Experimental tests will be realized in a semi-anechoic room, in order to evaluate both read/write performances, and immunity/emission electromagnetic characteristics of the system. EM analysis will be performed on the basis of a EM noise model of hospital environment, in order to create a "electromagnetic shared test environment" similar to the real one. Reliability test of the system will be finally performed. This study step will lead to a system improvement before pilot plant installation inside Hospital Operative Units.

3.3 ECONOMIC ASSESSMENT

Due to the difference of the two technologies tag costs, the research team is nowadays developing an economic evaluation (Return on Investment, ROI) of both technologies in order to quantify the economic advantages of using UHF, instead of the classic HF Technology.

This analysis involves the two technologies and several development scenarios, for example RFID application to "Transfusion loop" only processes or to all blood chain processes, RBC tracking only or all blood components tracking, using disposable or reusable tags. In the economic analysis cash flows will be computed, considering separately plant and operating costs and all economic revenues (missing disbursements). Economic assessment for technology choice should consider the only revenues due to productivity increasing (cycle time reduction) and quality increasing (reduction of wastes) in order to compute classic evaluation financial indicators (Net Present Value NPV, Pay Back Period PBP, etc.) for every technology and applicative scenario. This kind of analysis will help to the decision between UHF and HF and it will provide information about minimum targets to be achieved on the base of project dimension. As a matter of fact by varying some parameters like number of tags, economic analysis will provide the range of waste reduction which has to be reach in order to obtain reasonable values of the main economical evaluation parameters (NPV, PBP). These values will be measured during pilot test plant experimentation stage, and they will be compared so that an economic assessment will be performed before the project extension to all Hospital Operative Units, by projecting data from pilot plant to a larger context.

Then the analysis should be implemented performing an economic conversion of non-economic benefits derived from RFID-processes using, related to safety enhancement, including for example reduction of lawsuits, image return ecc.

4 RFID-ENABLED PROCESS DESIGN

RFID technology application brings to processes re-engineering (To Be model).

According to Hammer and Champy [10] Business Process Re-engineering is the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical, contemporary measures of performance, such as cost, quality, service, and speed.

TO BE model aims to change especially critical activities according to FMECA analysis, while re-engineered processes do not vary as a function of the chosen tag frequency band (HF or UHF).

The synthesis stage was divided in two different parts, called "1st Level Step" and "2nd Level Step". Each one regarded a specific process re-engineering technique application, based on RFID technology introduction. The first one regarded "Transfusion Loop" processes [5] while the second one regarded all processes from Blood Donation to final storage [4]. The two applications were studied in order to ensure their mutual compatibility, so that their implementation would be a new system model for whole Blood Chain process management.

4.1 FIRST LEVEL APPLICATION STEP

Procedures modifications and technical integrations were studied in order to increase transfusion process efficiency and effectiveness. The most important measure suggested deals with the patient recognition through an optical reading of Healthcare ID Card.

Then processes were re-engineered, and a PDA-based RFID system was included in the study. Patients have a Tag Embedded ID wristband which stores their personal data, and all assets have an RFID tag which store personal data of patient they are assigned to. Data cross match tests would be performed between wristband and pilot test tube tags during ABO bedside test stage, and between and allocation ticket and wristband tags before blood transfusion. If test returned a negative outcome, processes would be interrupted in order to avoid errors and to prevent serious adverse events for patient health.

4.2 SECOND LEVEL APPLICATION STEP

Processes were re-engineered, and a PDA/Tunnel reader based RFID system was included in the study. Blood donors are recognized by healthcare ID card optical reading and they have a Tag-embedded ID wristband or a RFID Donation card which stores their personal data. All assets (blood bags, pilot test tubes) have an RFID tag which stores donor's personal data. Data cross match tests would be performed between wristband (or Donation card) and pilot test tube and empty blood bag tags before blood donation stage. If test returned a negative outcome, processes would be interrupted in order to avoid errors and serious adverse events for patient health. To Be model also includes a simultaneous asset reading through a Tunnel Reader during "Whole-Blood Check in" macro-process, and blood components disposal and storage PDA-aided processes.

4.3 TIMING AND METHODS ANALYSIS

Blood Transfusion Centre (BTC) productivity has been analyzed, focusing on both blood inventory management and Transfusion Loop processes.

A time and methods analysis has been performed for each activity, global and unit cycle times were measured, differentiating each kind of involved operator.

4.4 EXPECTED RESULTS

Process reengineering and RFID technology application expected results are very important:

- Patient and blood assets identification errors impact reduction.
- "Transfusion Loop" Blood Asset full tracking
- Process traceability and checking during each activity: PDA downloaded data (timetables, logins etc.) would be available to BTC and Operative Units authorized personnel.
- Interdepartmental communication enhancement.
- Post-transfusion viral transmission due to reduction of blood bags handling human errors impact.
- Blood supply inventory data base real time up-to-date development.
- Paper register use reduction or disposal.
- Personnel safety enhancement, thanks to PDA-aided procedures.
- Cycle times reduction. Personnel have more time to take care of patients, and this leads to a service quality enhancement.

The two study steps implementation would allow complete asset tracking and the whole blood chain processes checking. RFID system is not invasive for patients and no additional skill is required to BTC personnel. The studied RFID-based solution is also a flexible ICT system and could be an optimal solution to other health logistic processes.

5 REENGINEERED PROCESS FMECA

A blood chain reengineered processes FMECA was necessary in order to assess Return on Safety (ROS) obtained through the use of RFID-enabled procedures. This analysis aimed to evaluate process effectiveness before the experimentation step (ex-ante).

The following are the main critical activities for each macro process, and their major failure modes.

"Clinical data typing into digital request form" and "Paper request form labeling" are "Blood components request" Macro-process activities with the highest RPI value (RPI=36).

"Whole Blood Check in" macro-process have two different critical activities. The first one, is related to listing of suitable units by physician personnel during "Validation" process: Physician personnel must enjoy clinical decision-making wide power, while Computing infrastructures may only have a control and directing role within physician decisional steps, and they may point out unconventional

and suspected choices through warning messages. Nevertheless physician's clinical experience nowadays is not replaceable by any computer algorithm, so human error is not completely erasable. This is the most critical stage (RPI=54), it has an high severity factor (S=9) while a low detection factor (R=3) due to warning message introduction possibility. The second one is related to "Blood Components Separation" process. The main failure mode is the non sterile-air inlet into blood bags. This even could be given by the operator during whole blood separation, and it becomes a dangerous event if it is not properly reported. This event increases the likelihood of severe adverse events for patient,[13] e.g. septic shock (RPI=48).

"Blood transfusion" is the most critical activity and transfusion of a not properly kept blood component is the main failure mode (RPI=72). Guidelines impose strict temperature limits during handling and analysis stages and this parameter is nowadays verified through a blood bag stamp that changes colour in case of prolonged exposure to high temperature, and through a visual quality check. Moreover operators eventually report that blood units could have exceeded time limits outside of blood banks through paper documents filling. Transfusion of a damaged blood component could have serious effects on patients, so a blood temperature monitoring system project is a clear need.

The accidental non-sterile air inlet inside whole-blood bag was pointed out also within "blood donation" process (RPI=48) [13] so several quality control need was confirmed.

"Final blood unit Allocation Confirmation or Revocation" and "Automatic Clinical Testing" are the "Blood request check-in & Blood component Allocation" macro-process critical activities. The first one is a computer-enabled activity, nevertheless human error, due to physician personnel essential decision task (RPI=54), is not erasable. As for the second one (RPI=50), preventive maintenance and supply level periodical check is strictly recommended. Automatic Clinical Test system reliability is a significant item for patient safety. FMECA also confirmed current procedures requirements regarding AB0 clinical tests: it must be performed both manually (by O.U. personnel) and automatically (through Automatic Test systems), so that outcomes can be compared.

"Blood Unit delivery to an incorrect O.U. auxiliary staff member" is the main failure mode within "Blood Component Check-out" stage; however this error is detected by RFID system before blood transfusion, so it could only bring to a process time delay (RPI=20).

Reengineered-processes FMECA RPI data, were classified through ABC charts, which pointed out 14 critical activities.

These activities are potentially affected by several kinds of error. Human errors in manual operations are still the most important (n=7). Particularly clinical activities (including patient treatment, manual testing etc.) are fewer (n=2), than other general activities (writing, material handling etc.)

(n=5). Some criticalities regarded activities for which blood component quality check could fail (n=4). Other error modes concern blood bags selection stages in "Blood Validation" and "Blood Component Allocation" processes due to the physician essential decision task (n=2), and automatic clinical analysis system reliability (n=1).

Within reengineered processes FMECA, main error modes were considered for each analyzed activity. In addition to human errors, any communication difficult, any missing or misplaced supplies chance and any equipment problem were considered [12]. Particularly data reading, writing, matching, automatically performed by RFID system, were considered as equipment problems potentially affected activities, although they are carried out individually and in ideal conditions.

Nonetheless bar-charts and ABC-charts data graphical analysis clearly pointed out a critical failure modes number reduction and an important RPI value decrease.

5 KEY PERFORMANCE INDICATORS

Key Performance Indicators (KPI) were designed in order to improve results analysis and to point out quantitatively process performance variation within As Is – To Be transition. KPI design is a very important study step and it is based on the company management goals. Most important process parameters are chosen and constantly measured, then they are processed in order to obtain KPI. They are usually used for online performance monitoring and their trend analysis allows to evaluate or to forecast economic and productivity status, and to study strategic changes in order to maintain or to achieve goals.

Within this study KPI are used in order to evaluate "ex ante" clinical risk reduction in Blood Transfusion Chain. Processes and activities cycle times, their amount, their failure modes amount, and their RPI values were the measured parameters of each macro-process. Three indicator types were designed:

Average RPI: Nonzero RPI Arithmetic Average calculated within the n activities of each macro-process.

$$\text{AverageRPI} = \frac{\sum_{i=1}^n \text{RPI}_i}{n} \quad (2)$$

Number of Activities: number of activities which form a macro-process.

Peak RPI: Maximum RPI value within the macro-process.

Cycle Times: Sum of activity Cycle Times calculated for each macro-process.

As-Is cycle time were derived from time and methods analysis, while To-Be cycle times were estimated by analysing To-Be model flow charts and activity forms.

Key Performance Indicators values of both "As Is" and "To Be" models were computed, and their increase or decrease were expresses in percentage.

5.1 OUTCOMES DISCUSSION

Study results are displayed in Table 1.

Most important result was pointed out for “Blood Component Request” Macro-process. RFID-enabled process, allowed two goals achievement: average (-73.2%) and peak (-75%) RPI severe reduction, supported by activity number reduction (-31.2%) and an appreciable cycle time expected reduction (-13.3%). Operative procedures have been made both safer and more streamlined, so that a cycle time reduction is predictable.

As for “Whole Blood Check-in” macro-process, average and peak RPI severe reduction (respectively -77.3% and -62.5%) was obtained while no appreciable activities count variations were observed (+4.3%). Thanks to the RFID Tunnel Reader multiple reading possibility, a severe cycle time reduction is expected within this process step (-66.7%).

On the contrary, severe clinical risk reduction within Donation critical activity was obtained through the activity number doubling. This result cannot be considered disappointing because the analysis step [4] pointed out the procedure integrations and additional automatic checks needs. The activity amount goes from 8 to 16, remaining at a medium level, and expected cycle time variation is held down (+9.1%) so this 100% increase is largely justified.

As for “Blood Transfusion” critical macro-process, results were quite satisfactory: RPI reduction (-67.4% average RPI and -55.6% peak RPI) was obtained through a necessary activity weak integration (activity amount goes from 10 to 13) and cycle time expected variation is +0.8%.

“Blood components allocation” macro-processes outcomes were less appreciable due to the weak changes imposed by RFID-enabled processes. Nevertheless fair improvements were pointed out (about -25% average and peak RPI reduction, -33% number of activities reduction).

RFID technology introduction and RFID-enabled process design was positively evaluated. The whole Blood Chain activity amount do not varies considerably from As-is to To-be models (-3.8%): procedures integration and streamlining are balanced, so that expected global cycle times variation is slightly favourable (-0.8%). Clinical risk reduction is appreciable in every Blood chain process. Total Average RPI reduction is 67.6% while total peak RPI reduction is 60.2%. Achievement of the Healthcare Facility strategic goal through the RFID system project is expected. Considering FMECA-derived RPI as a random variable, both AS-IS and TO-BE RPI Normal distribution curves were plotted. The mean and variance values, and the variation range reduction were graphically pointed out (Figure 1).

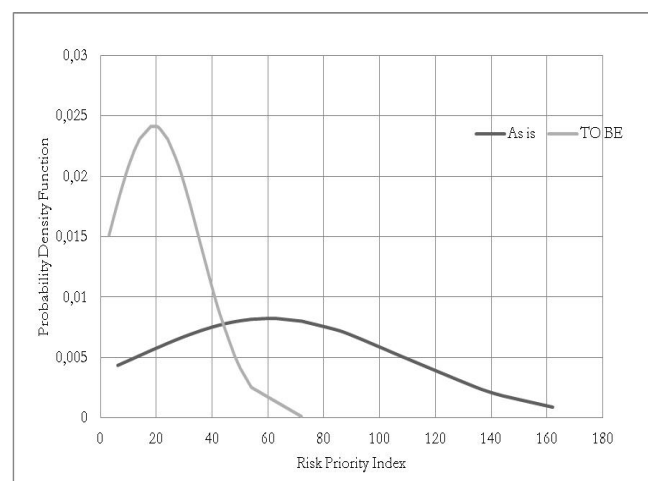


Figure 1 Probability density function of As-is and To-be models.

Table I - KPI variation within AS-IS and TO-BE models

Macro Process	Average RPI [%]	Number of activities [%]	Peak RPI [%]	Cycle Time [%]
Blood Component Request	-73.2	-31.2	-75.0	-13.3
Blood Transfusion	-67.4	+30.0	-55.6	+0.8
Blood Donation	-81.8	+100.0	-70.4	+9.1
Whole Blood check-in	-77.3	+4.3	-62.5	-66.7
Blood Component assignation	-26.4	-33.3	-25.0	-2.3
Blood components check-out	-63.7	+50.0	-33.3	+6.3
Total	-67.6	-3.8	-60.2	-0.8

CONCLUSIONS

A process reverse engineering was performed in order to identify and map the whole Blood Chain.

Through a FMECA, potentially error affected activities were founded and failure modes were classified by a risk priority index (RPI) which included detection possibility, severity and frequency factors.

Criticalities were processed through a new operative procedures definition based on the use of RFID system.

UHF and HF technology (passive tags, PDA and Tunnel readers) pros and cons were evaluated, and a cost- benefits analysis, nowadays in progress, resulted necessary in order to perform a final technology choice.

The TO-BE model, was validated through a reengineered-process FMECA and through Key Performance Indicators (KPI) evaluation, which confirmed a clinical risk reduction within Blood Transfusion Chain. Most important results regarded Blood components request macro-processes, particularly the main benefits were caused by PDA-aided cross match tests.

RFID-enabled processes FMECA also pointed out several important criticalities which have to be processed by the management staff. The most important one, is related to cold chain failure: biological damaged, due to high temperature, blood component transfusion. This issue opens up to a study improvement i.e. RFID semi active tags using to improve the performance of the cold chain. Manual-performed quality checks within several Blood Chain tasks are very important; they are by-passable only by using an appropriate system for blood temperature history measurement and storage during pre-transfusion handling stages. RFID semi-active tags could be integrated with temperature sensors in order to allow both periodic temperature measurement and data storage for a long time range, so that blood component storage and handling conditions always would be checked.

Due to the RFID platform flexibility, it can be used in order to control other logistic processes, for instance to improve processes characterized by activities and error modes comparable to transfusion processes (for instance drugs management, bone marrow transplant, chemotherapy drugs management), in order to achieve economic and safety improvements. The RFID platform use extension would also contribute to a global Pay Back Period decrease for AOB hospital.

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