Blood Transfusion and Patient Safety with IT
– Minimizing risk of transfusion with Point-of-Act-System -

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\textbf{Abstract}

Objectives: The purpose of this study is ensuring patient safety on blood transfusion by minimizing risk of transfusion at the point of care through IT. The targets are ensuring 5 rights of transfusion, rights process and right information by electrical identification and traceability of blood products.

Methods: We used Point-of-Act-System (POAS) as a health information system and RFID as device for auto identification and data capturing. The basic concepts of POAS for patient safety are capturing every activity in a hospital, process management to ensure right medication and product management with serialized number by single item level. As a way to secure privacy of blood donor, item management numbers on RFID were rewriting to prevent leakages of donor information.

Result: Experimental project with this system was enforced in Iwate, Japan. The system designed based on process analysis and use case of transfusion was successfully implemented in Morioka Red Cross Hospital to prevent medical errors on transfusion and ensure traceability of blood products. By reading RFID at the point of care, the system was possible to check database in blood center to look for adverse events of blood products collected from same donor through Internet within 2 seconds. The system identified all 377 blood products with RFID and acquired tracking data.

Discussion: Identification taken by this system is more comprehensive compare to previous efforts, though the time for identification is quite short and effective. The data captured by this system is significantly important for hospital management as well as patient safety and contribute to construct safer and trusted health care system.

1. Introduction

It is thought that Barcode/RFID administration systems are important technologies to improve patient safety and effectiveness of health care delivery. Auto identification and data capturing with Barcode and RFID can prevent medical error at the point of care and in addition, they promote traceability of drug and blood products. Many literatures showed improvements of medical safety with 5 rights verification at the point of care with barcode and RFID systems [1-5].

In blood transfusion setting, barcode and RFID have been introduced and gradually became widely common in hospitals as well as blood banks. According to the report published by SHOT (Serious Hazards of Transfusion) that is haemovigilance institution in UK, incorrect blood transfusion was the highest risk factor of transfusion and other researches also had shown incorrect patients or bloods are the most frequent events in transfusion settings[6]. As a result of the researches, transfusion safety has been focusing on patient and blood identification with barcode and other methods. Many hospitals have introduced barcode and RFID for patient and blood identification and they have contributed to reduce incorrect blood transfusion [1-5]. However, that isn’t all of ‘5 Rights’ for safe medication. 5 rights are right patient, right product, right dose, right root and right time. 5 Rights are essential for ensuring medication safety and Barcode and RFID are fundamental technology for the purpose. It is better strategy to keep transfusion safety that blood transfusion system should move their focus from patient identification to 5 rights identification. In addition, barcode and RFID have more capabilities to improve patient safety through managing process of activities and traceability of blood products as well as ensuring 5 rights with identification. Medication is not a single activity that is independent from other activities but process that consists of connected activities by various workers. It is quite important to make communication between medical workers and ensure rightness of medication process. This is another area of contribution to patient safety with barcode and RFID that barcode and RFID can contribute by capturing accurate data on activities by medical workers that has a capability to facilitate high quality communication. Then the accurate information can promote rightness of medications. Traceability of drug and RFID is also achieved through barcode and RFID administration of drugs and blood products. In medical setting traceability of materials is widely believed as necessary peace for enhancing patient safety. Traceability enables us to find harmful drugs and material with perfect information on their original and path ways. In addition, traceability information enables us to provide opportunity to make supply chain more efficient and construct a transparency and trust for health care system.

The discussion above can apply to blood transfusion field. Bar coding in Blood transfusion has been focusing on patient identification and blood type identification.
Other application of barcode and RFID in transfusion setting is blood management in blood bank. It has yet to be shown that barcode system designed well can contribute to ensuring patient safety with verification of 5 rights and integration of blood bank system and hospital transfusion system.

2. Objectives

The purpose of this study is ensuring patient safety on blood transfusion by minimizing risk of transfusion at the point of care with IT and constructs a system to conduct it. To minimize risk of transfusion, there are three important components achieved by auto identification and data capturing. First one is securing 5 rights of transfusion by auto identification at the point of care with right information. Right information is basic factor for right identification. Second is securing right process of transfusion. Skipping the process of transfusion including cross matching might make transfusion harmful. Third one is traceability for checking information on adverse event of products that are prepared from same blood. In terms of blood transfusion safety, window period is important concept to be considered. Window period is a term that test can’t find virus or other harmful source after infection (Figure 1). Figure 1 shows window period and window period of Hepatitis C Virus is 23 days by Nucleic acid based tests (NAT) and 82 days by Antibody test (AB test). There are risks that infected blood products passing test during window period would be distributed to hospitals.

The way to handle these risks is traceability. If we have knowledge on when and where these bloods came from and their original, we can prevent secondary injury by recalling blood products prepared from same original. However, there is a trade off between safety and privacy in this situation. Perfect traceability of blood to ensure safety is including highly private information such as infectious information of donors. Collecting information on blood has a possibility to be a threat for donor’s privacy. Solution for this tradeoff is also required to implement traceability system and our target in this study.

3. Materials and Methods

3.1. Point of Act System

We construct auto identification and data capturing system for these objectives to achieve safe transfusion with the concept of Point-of-Act-System (POAS). POAS is a real time bar-code/RFID data capturing health information system implemented in 4 Japanese hospitals (International Medical Center of Japan, Morioka Red Cross Hospital, Kyoto Red Cross Hospital, Japanese Red Cross Kochi Hospital) [7,8]. It has a function to prevent medical errors by capturing bar cords/RFID of patients, workers and drugs and verifying correctness of each medical action for 5 rights verification. At the same time, POAS captures complete data of each medical action including 6W1H information of activities (When, Where, What, Why, for what, to whom and How) at each point of medical process. POAS was designed to capture every action in a hospital to improve quality, safety and productivity by secondary use of data. The main characteristics of data captured by this system are;

1) Complete data
   POAS data is “Complete data” that capture every action by real time and quite accurately. This means the data has full traceability of drugs and materials and can be used for analyses on healthcare management. Complete data isn’t based on any sampling methods to estimate value of indicators. That makes reliability of analyses higher. In addition, complete data is especially useful for patient safety researches, because complete survey is necessary to estimate medical error and accident rate.

2) Process Management
   Structure of POAS data capturing is based on process management of each medical action. Process management structure requires every medical workers capture data at their point of action. Without capturing data on completion of activities, medical workers can’t do next activities on the medication process. It enables POAS to acquire every result of medical action and assure capturing complete data.

3.2. Settings

We enforced our experimental project in Iwate Red Cross Blood Center and Morioka Red Cross Hospital. Iwate Red Cross Blood Center delivered 180596 units blood products as 1 unit is 200 ml in 2007. The blood center is located on same place as Morioka Red Cross Hospital. Morioka Red Cross Hospital is acute care hospital and one of the central hospitals in Iwate prefecture that is in northern part of Japan. The hospital has 444 registered beds and 900 outpatients and 340 inpatients per day in 2007. Average length of stay of inpatients is 12.5 days in 2007. The hospital has already introduced Point-of-Act-System as a hospital information system and Personal Digital Assistance (PDA) for identification and data capturing of drugs.
3.3. Methodology

We created the system for auto identification and data capturing from blood collection in the blood center to administration in the hospital with POAS and RFID.

The system put time stamp with the data to ensure rightness of information and consistency of process order in capturing data.

- Certification system for safe blood transfusion and electrical data capturing with RFID

This system was aimed to confirm 5 rights of transfusion at each point of transfusion. 5 Rights in blood transfusion is right patient, right blood, right unit, right root and right time. Right blood in this setting includes five additional components with checking product ID. At the point of checking, this system certified types of product including Blood Red Cell, plasma and blood plate, blood type appropriateness, completion of cross matching, result of cross matching and adverse event information of products from same donor. In concrete, system is especially important for traceability handle all occasions without any exception. This feature ensures their systems warn at the time of deliver. This structure doesn’t allow skipping the activity and after skipping process, medical workers can’t register information to be continuing the process. It prevents forgetting cross matching and ineffective deliver to wards and Operating Rooms.

- Use case

We described all patterns of blood transfusion process by process analysis methods. In normal transfusion process, flow of process from physician’s order to administration goes thought without hitch. However there are other patterns including emergency cancellation and rejection of blood products. Each pattern was shaped into use case with Unified Modeling Language (UML) and we decided system specification based on these use cases. By describing all patterns of use case, it is possible to construct the system can handle all occasions without any exception. This feature is especially important for traceability.

- Single item management from production to consumption with SGTIN

Serialized number was put on RFID to distinct each blood product with single item level. Serialization of blood products is essential factor to distinguish one blood from others uniquely. If a number was used for

<table>
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<th>Table 1. Comparison of certification with other systems</th>
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<td><strong>Exitng Certification</strong></td>
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<tr>
<td>Blood Type Certification (ABO/Rh)</td>
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<tr>
<td>Completion of Cross Matching</td>
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<td>Checking virus or other harmful matters with accident information system</td>
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The important thing to achieved 5 rights transfusion with IT is feasibility of the system and information. In this system all certification was operated with just one data capturing by the point of action. In verifying information, system refers original data captured or entered at the point of actions.
more than two objectives, it makes difficult to confirm a objective uniquely.

- Rewriting ID on RFID to secure privacy

Blood Donors don’t want somebody to know the infection of their blood that is highly personal information. Especially HIV infection is quite sensitive information and donors don’t allow carrying information on HIV infection. However, patients who will take transfusion have much concern on infection of blood. Information to secure patient safety is highly personal information at the same time. Patients have concerns not on personal information such as name and ID to identify people but on safety of blood. It is necessity to construct methods to pick up information just related to blood safety.

To secure privacy, we rewrite product ID in RFID as a solution. After finishing preparation for blood component, staff in department of preparation changed donor ID that was putted on the blood links to donor’s information to product ID. The database includes information to link between donor ID and product ID is independent from outside and was managed quite carefully and securely in the blood center. It was impossible to acquire information on donors from outside blood center. This is one of the important features of RFID that we can rewrite and update information on it. It makes possible to put privacy secured method into practice.

4. Result

Experimental project with the system described above was implemented in Morioka Red Cross Hospital and Iwate Red Cross Blood center. Table 2 described overview of the experiment. Experimental period is from 30/07/2007 to 30/11/2007 for 4 month. Object departments in Iwate Red Cross Blood Center are department of Testing, Preparation and Delivery. Objective departments and wards in Morioka Red Cross Hospital are wards of digestive tract internal medicine, General Medicine, Surgery and Testing Department. The number of blood products used in these 3 wards is 75% of total usage in all hospital. Though the object wards are three, it is enough to investigate feasibility of the system in these three wards. We operated 377 blood products with RFID during the term.

We analyzed process of transfusion in Morioka Red Cross Hospital and Iwate Red Cross Blood Center to identification and track appropriately. Figure 3 shows result of process analysis of a transfusion in time series. Transfusion Process could be divided into two major parts, blood center and hospital, based on the place. In blood center, staffs in blood center collect blood from donors and deliver it to department of preparation. Department of preparation receive the blood and test blood for screening whether the blood is appropriate for blood products or not. Department of preparation prepare the blood passed screening for products and form products to deliver to hospitals. At this time, blood

|-----------------------|-------------------------|
| Implementation Fields | Iwate Prefecture in Japan  
Iwate Red Cross Blood Center  
Morioka Red Cross Hospital |
| Object Departments and Wards | Iwate Red Cross Blood Center  
Testing, Preparation and Delivery Departments  
Morioka Red Cross Hospital  
Wards (Digestive Tract Internal Medicine, General Internal Medicine, Surgery), Testing Department |
| People who operated this experiment | Iwate Red Cross Blood Center  
Staff member of Preparation and Delivery Department  
Morioka Red Cross Hospital  
Doctor, Nurse, Laboratory Technician |
| Number of Operation | Number of Blood Products:377  
Number of RFID:951 |

Other Wards 25%  
Object Wards 75%
Figure 3 shows normal process of transfusion in Morioka Red Cross Hospital. This is not only case to be treated by transfusion system. We analyzed transfusion process in the hospital to find every type of process to cover all case of transfusion. Each process shaped into use case with UML and there are 14 types of use case for transfusion process. Table 3 shows 14 type use case. These use cases can be classified with 4 major categories; Ordinary, Cancellation, Warning and ex post facto. In ordinary process, transfusion operation with blood stocks and without blood stocks are regarded as different use case, because interactions and movements on information and products are different in each use case. Similarly, in cancellation, the activities and information to be interchanged are different based on the timing of cancellation. Ex post facto means information was entered after injection because they are used after office hour and testing department was closed.

In Morioka Red Cross Hospital, use case 1 (Transfusion operation without stocks) is the most common use case, because the blood center is located on next to the hospital and they don’t need to have a lot of stocks. Use case 2 is usually the most common case in hospitals. In use case 1, three actors including physician, technician, nurse and staff in blood center operate the process. At first, physician makes a decision on transfusion and order transfusion. Nurse receives the order and delivers the order to testing department. Technician starts preparation for transfusion by request to blood center, because they don’t have a stock in the hospital. Technician receives blood products from blood center, operates cross matching and delivers it to ward or operation room. Nurse operates the transfusion.

Our system was created based on these analyses on process of transfusion with use cases. Every type of transfusion except use case 14 was target to ensure traceability of blood products. Figure 4 shows overview of our system. In hospital, transfusion process was managed by Transfusion management server and Hospital information/CPOE server. In blood center, transfusion process was managed by public server and donor server. At he each point of process, actors read RFID to capture data on 6W1H and auto identification with PDA and computer. Transfusion server connected to public server in hospital through internet (VPN).
connection makes possible to manage whole process from production to bedside.

The ID on RFID was rewritten after preparation. Information to link donor ID to product ID was securely managed inside blood center and blocked physically and nobody could refer to this server from outside. The process of rewriting was also under process management and the process can’t be processing without rewriting.

By connecting hospital system to public server in blood center through internet, it is possible to certify availability of blood products by original product database including adverse event information in real time. When nurse identified blood product at the point of care, PDA checked adverse event information in blood center database trough middle ware as well as patient information and product information. All transaction for identification to ensure 5rights and right process was completed within 2 seconds. If some infected blood were found at other hospital and the information was putted in public server, right after the time PDA warn usage of the blood products prepared from same source. By this system, nurses can check safety of transfusion from the various points of view by just one reading RFID with PDA within 2 seconds. It is effective to improve patient safety and operation of nursing works.

We evaluated the system based on data captured by this system. For all 377 blood transfusions captured by this system, data was perfectly collected and there is no inconsistency on the data. To evaluate data captured by the system, we drew the data as traceability graph. An example of traceability graph is Figure 5. Horizontal axis shows time flow and vertical axis shows flow of blood products from production to consumption. There are two lines before delivery. Left line shows blood product flow in blood center. Before delivery, blood products don’t timed with any special patients. Right line shows flow of transfusion order. Followed by the order, a blood product was matched with a transfusion order at the point of delivery. From the point, Product ID is associated with Patient ID.

The advantage of describing traceability graph is showing result of data capturing visually and easily. If data capturing system worked correctly, data capturing point is going right with process progressions. If the line is going left, there are some problems on data capturing such as ex post data entry, delay of the system and time lag among systems.

The result of describing 377 traceability shows the system ensures traceability for all blood products from production to consumption. Certification at each process was successfully done. During the experimental period, there is no accident and medical mistakes on blood transfusion.

5. Discussion

We construct system with internet and RFID to manage whole process from production to consumption to expand the capability of certification system and ensure traceability. Many literatures have been tried to construct certification system at the point of care for blood transfusion [1-5]. Compare to these systems, this system has several significances that other systems don’t have. This system ensures 5rights of transfusion and right process and information with original information. By
checking original database through middleware, the correctness of information for certification is highly secured. This technique makes possible to check the original database to certify patient information and blood products and find any adverse event information on blood products.

We tried to evaluate improvement on blood transfusion safety. The number of medical accidents and incidents on blood transfusion from April to June 2007 (before implementation of the system) is 0 and the number of them during experimental period is also 0. It is difficult to say there was an improvement on safety based on number of accidents. These data on accidents were based on voluntary reports by medical workers. However, administration systems have possibility to provide new opportunity to evaluate safety. Warning log sometimes shows there is a possibility that the administration would be accident or incident without administration system. The comparison based on warning data is our next target for researches.

Sometimes cost including work burden of medical workers is the highest obstacle to introduce health IT system [9]. It is useful to investigate feasibility of the system by evaluating change of time to finish each activity. We investigated time to finish each activity by collecting data observationally and computed average from about 10 observationally data. We compared time to finish each activity between this system and before system using paper communication. We chose blood receiving, deacquisition and stock taking in the blood center and delivering to wards, certification before administration and recording administration in the hospital.

For all 6 activities, the time to finish each work with RFID is shorter than with before system. Work of nurses and technicians would be effective by introducing RFID based traceability system. Especially time for administration of transfusion is decreasing. This system has a possibility to improve productivity of transfusion process as well as transfusion safety.
We investigated improvement safety on transfusion with auto identification and data capturing system. It also has significant advantages on hospital management. The ways to storage blood products were strictly regulated because quality of blood products is easy to change with affects from outside. RBC must be store inside refrigerators having a function to record temperature and blood platelet must be inside storage with vibration system. They require strict methods to store and blood products delivered once were regarded as consumption and sometimes wasted. Blood products is scarce and valuable resource from human blood, and waste of blood products might cause safety and management problems. Traceability data can contribute to solve these issues by visualizing data of distributed blood products. That would enhance effective use of blood products by connecting a hospitals to blood center and hospitals.

6. Conclusion

In this study, we focused on identification and data capturing for patient safety. Data capturing and alibi management of materials including blood products leads to effective use of resources. Especially in rural area, blood products are scarce resource and effective usage of blood lead to improve security of residents.

Systems certificating medication and capturing data at the same time can contribute to patient safety and improve health care delivery. The important thing to familiarize this kind of systems is trust for the system. To be a trusted system, the systems have to use right information and consider securities of people. Trusted IT system can contribute to patient safety, effective use of blood products, reducing waste that might be essential factors for trusted health care system.

References


