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

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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.

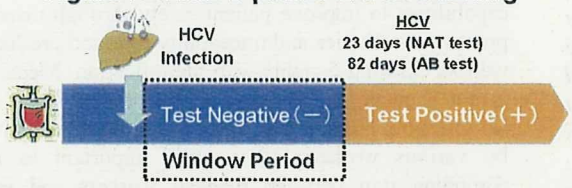
The discussion above can apply to blood transfusion field. Bar coding in Blood transfusion has been focusing on patient identification and blood type identification.

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 conduce 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.

Figure 1. Window period of blood testing



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

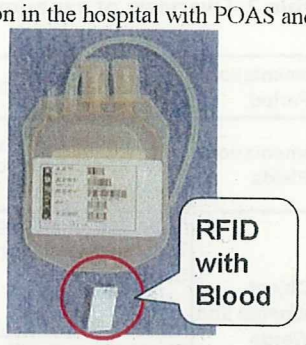
Structure of POAS data capturing is based on process management of each medical action. Process management structure requires every medical workers capture data at their point of action. Without capturing data on completion of activities, medical workers can't do next activities on the medication process. 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 that is possible to verify information of infected blood products founded just 2 minutes before in other hospitals. Table 1 shows comparison of verification component with other blood transfusion systems. Exciting systems had focused on Blood type certification and some systems had tried to integrate transfusion system with blood test laboratory system to check the results of cross matching at laboratory.

Table 1. Comparison of certification with other systems

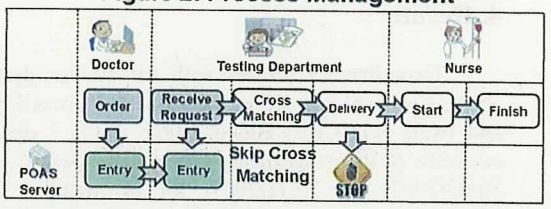
	Exiting Certification sytem	POAS system
Blood Type Certification (ABO/Rh)	○	○
Completion of Cross Matching	△	○
Checking Result of Cross Matching	×	○
Cecking virus or other harmful matters with accident information system	×	○

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 .

- Process Management/ Control

In this system, we can check completion of cross matching without fail by process management technique. In designing system, we analyzed process of medical activity and described as nonreversible process that is a series of medical activities. Figure 2 shows an example of process of transfusion inside hospital. Process of transfusion inside a hospital starts from doctor's order. And then nurse receive and request order to testing department, testing department receive order, do cross matching and deliver. And nurses start transfusion and finish it. This process is nonreversible and order cancellation starts other process of medication. Managing and controlling order of this process, we can check completion of test and prevent skipping operation of cross matching. For example, if testing department delivers blood products without cross matching, certification system 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.

Figure 2. Process Management



- 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 patters 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

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.

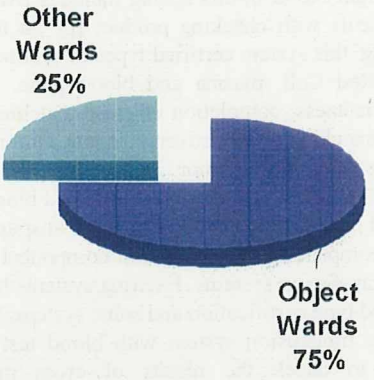
4. Result

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

Table 2. Overview of experimental project

Implementation Period	30/07/2007 - 30/11/2007
Implementation Fields	Iwate Prefecture in Japan Iwate Red Cross Blood Center Morioka Red Cross Hospital
Object Depaetments and Wards	Iwate Red Cross Blood Cente Testing, Preparation and Develivery Depatmets Morioka Red Cross Hospital Wards (Digestive Tract Internal Medicine, General Internal Medicine, Surgery), Testing Department
People who operated this experiment	Iwate Red Cross Blood Cente 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



is ready for use for transfusion and wait for requests from hospitals.

On the other side, in hospital physicians order transfusion for patients and nurses receive the order and request blood products to department of testing. This order was made junction with blood delivered from blood center and department of testing in hospital operate cross matching. If the result of cross matching shows appropriateness for transfusion, the blood deliver to the point of trasfusion. And in a ward or operating room, nurses or physicians administer the blood to patient. In this sequential process, there are movements of places and many actors engage to this process to operate transfusion.

Figure 3. Process of Transfusion

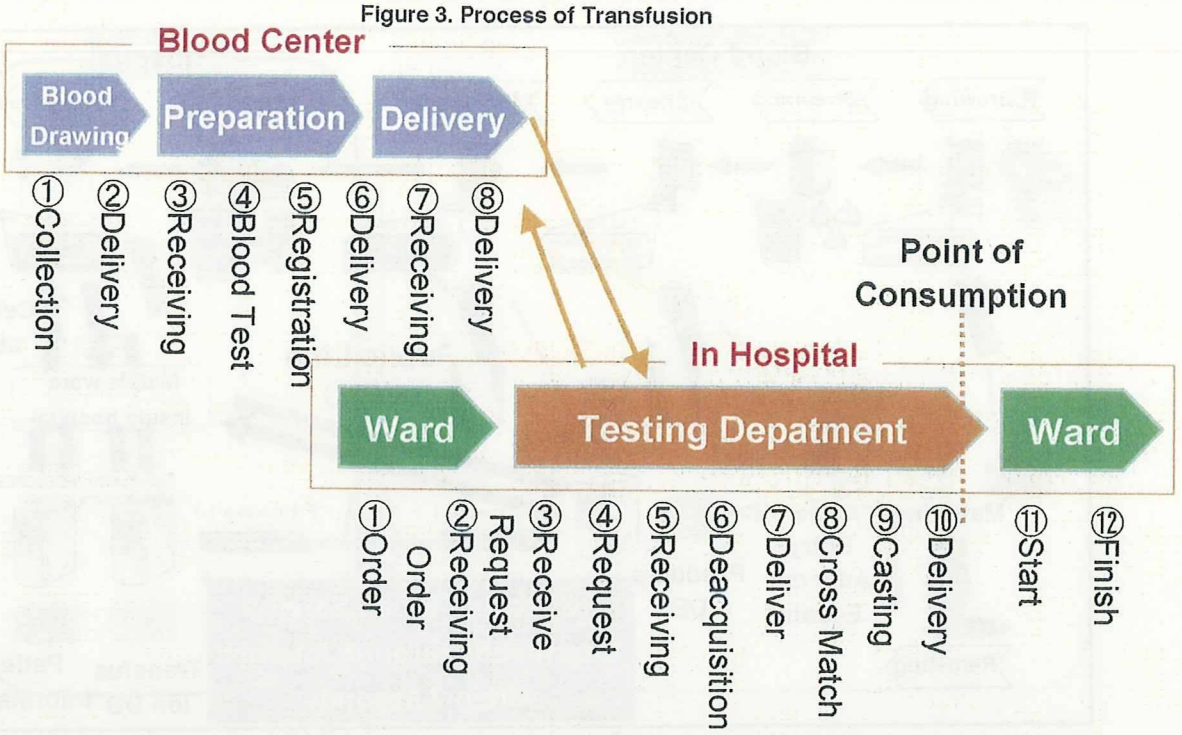


Figure 3 shows normal process of transfusion in Morioka Red Cross Hospital. This is not only case to be treated by transfusion system. We analyzed transfusion process in the hospital to find every type of process to cover all case of transfusion. Each process shaped into use case with UML and there are 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

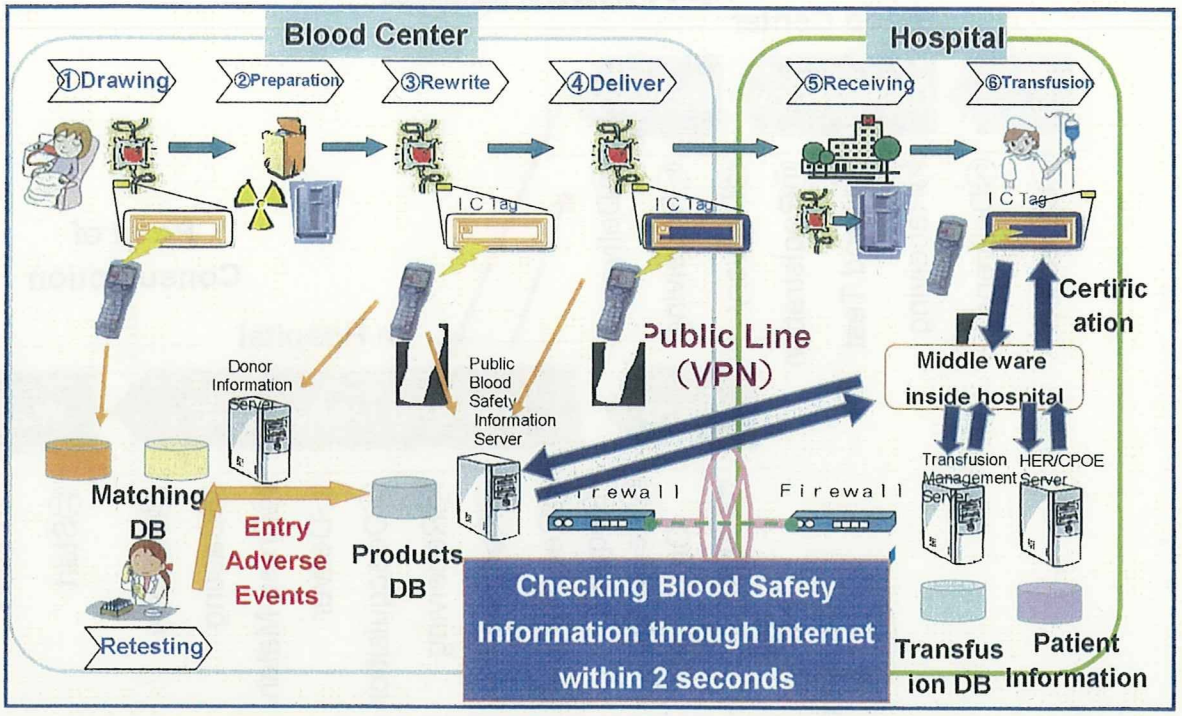
Table 3. Use Cases

Classification	Case Number	Usecase Name
Ordinarily	1	Transfusion Operation (without stocks)
	2	Transfusion Operation (with stocks)
	3	Allocated Products to Stock
	4	Cross unmatched
Cancell	5	Order cancelled
	6	Order cancelled after allocating blood
	7	Scrap blood products
	8	Request cancelled
Warning	9	Prohibition of usage in entering test results
	10	Prohibition of usage in starting transfusion
	11	Taking wrong products in deliver
	12	Wrong patient in transfusion
	13	Wrong blood products in transfusion
ex post facto	14	Usage after office hour

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). This

Figure 4. Overview of the system



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.

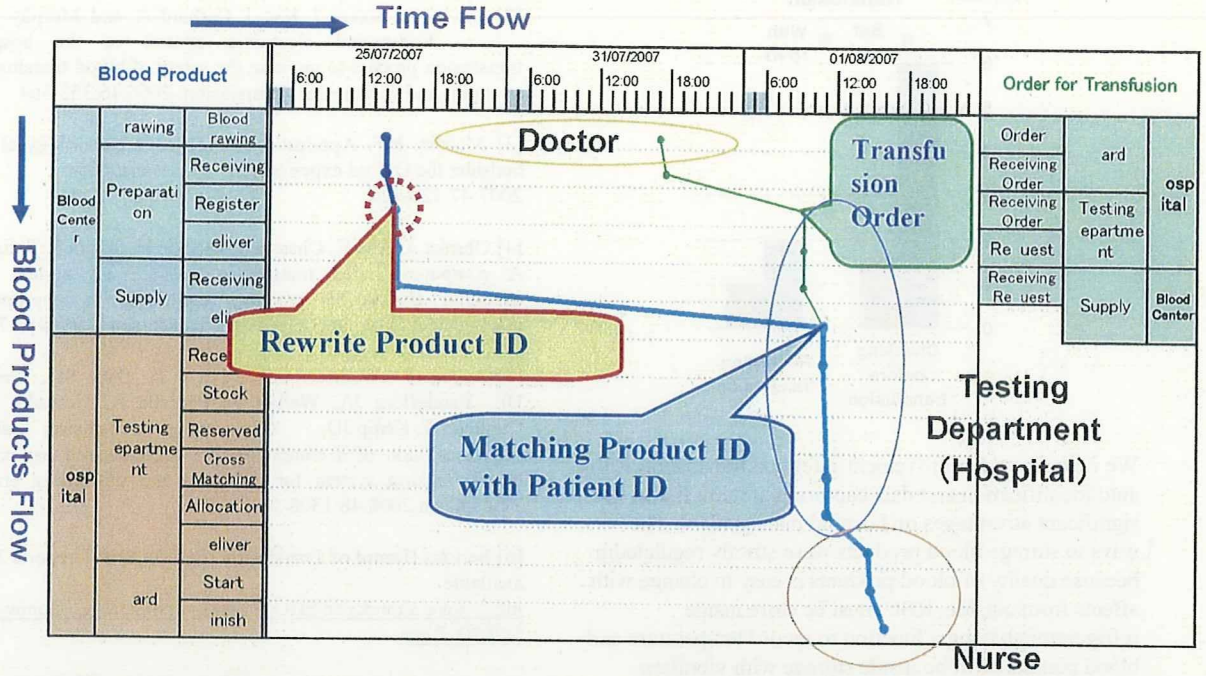
The advantage of describing traceability graph is showing result of data capturing visually and easily. If data capturing system worked correctly, data capturing point is going right with process progressions. If the line is going left, there are some problems on data capturing such as ex post data entry,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

Figure 5. Traceability Graph of blood product



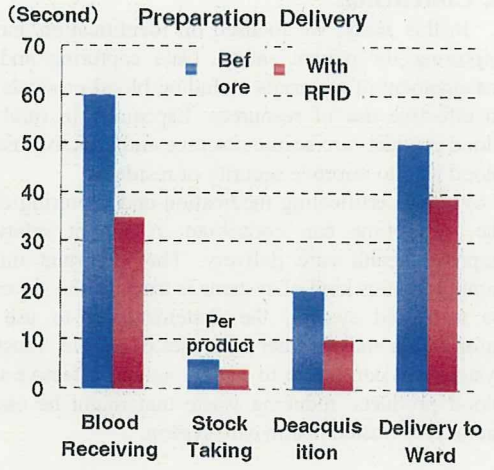
checking original data base through middle ware, the correctness of information for certification is highly secured. This technique makes possible us to check the original database to certify patient information and blood products and find any adverse event information on blood products.

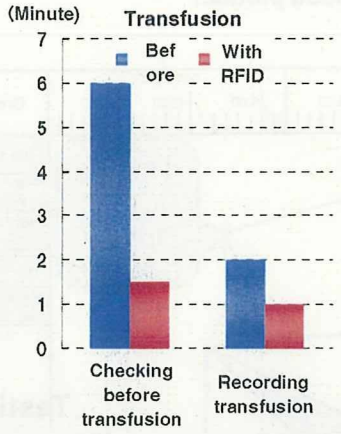
We tried to evaluate improvement on blood transfusion safety. The number of medical accidents and incidents on blood transfusion from April to June 2007 (before implementation of the system) is 0 and the number of them during experimental period is also 0. It is difficult to say there was an improvement 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 chosed blood receiving, deacqusition 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.

Figure 5. Work time comparison





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 regulatedm 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

[1] Chan JC, Chu RW, Young BW. Use of an electronic barcode system for patient identification during blood transfusion: 3-year experience in a regional hospital. Hong Kong Medical Journal.2004:10:166-171

[2] Davies A, Staves J, Kay J, Casbard A, and Murphy MF. End-to-end electronic control of the hospital transfusion process to increase the safety of blood transfusion: strengths and weaknesses. Transfusion. 2006:46:352-364

[3] Murphy MF. Application of bar code technology at the bedside: the Oxford experience. Transfusion. 2007:47:120-124

[4] Ohsaka A, Abe K, Ohsawa T, Miyake N, Sugita S, Tojima I. A computer-assisted transfusion management system and changing transfusion practices contribute to appropriate management of blood components. Transfusion.2008:48:1730

[5] Askeland RW, McGrane S, Levitt JS, Dane SK, Greene DL, VandeBerg JA, Walker K, Porcella A, Herwaldt LA, Carmen LT, Kemp JD. Improving transfusion safety: implementation of a comprehensive computerized bar code–based tracking system for detecting and preventing errors. Transfusion.2008:48:1308

[6] Serious Hazard of Transfusion (SHOT) SHOT reports 2007. available at http://www.shotuk.org/SHOT%20reports%20&%20Summaries%202007.htm

[7] Akiyama M . Risk Management and Measuring Productivity with POAS-Point of Act System-A Medical Information System as ERP (Enterprise Resource Planning) for Hospital Management. Method Inf Med. 2007:46:686-693

[8] Akiyama M, Kondo T. Risk Management and Measuring Productivity with POAS--point of act system Stud Health Technol Inform. 2007:129:208-12.

[9] Watson D, Murdock J, Doree C, Murphy M, Roberts M, Blest A, Brunskill S. Blood transfusion administration-one- or two-person checks: which is the safest method? Transfusion. 2008:48:783-789

WHO World Alliance for Patient Safety - Technology for Patient Safety

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Abstract

Information Technology has been widely thought as an important accelerator for patient safety. As "To error is human" mentioned, human can't get rid of all mistakes. Information Technology has possibility to eradicate accidents dependent on human mistakes.

Point of Act System was designed to improve patient safety and quality of care. We have implemented Point of Act System as hospital information system to prevent medical errors in 4 Japanese hospitals.

The one of the important feature of this system is its data capturing concept to prevent medication errors. Tackling patient identification error through the use of bar-coded or radiofrequency ID (RFID) chipped tags worn by the patient is increasingly advocated as an easy way to address the first of the 5 'rights' of medication safety (right patient, drug, dose, administration route and time). Implementations at the International Medical Center in Tokyo and Red Cross hospital in Morioka combine these technologies with a 'Point of Act' system that tracks both patient activity and consumable use. Every clinical contact represents a discrete event triggered – like the checking out of goods at a cashier till – by the scanning or entry of an identifier tag and captured by the system with relevant contextual information that details what was done at what time and where, to whom and why and by what means. This event-driven approach provides a robust means to explore process flows as well as inherently providing stock management capabilities.

Safer care is anticipated from the constraints that are placed on patient and medication selection (the universal use of barcodes should guarantee the identity of both), the traceable provenance of the latter (managing the risk of counterfeiting and batch quality issues). In addition, the automatic capture of care data – and the unambiguous nature of the associated contextual information – makes this a useful resource that can be mined prospectively for unreported adverse events as well as a forensic tool to reconstruct the care journey prior to any incident.

In addition to this feature to prevent errors at point of care, the data captured by the system is also quite helpful to investigate hypothesis on methods to improve patient safety. It captures complete data of medical activities and ensures traceability of every drug and material.

We presented this system at Technology for Patient Safety, World Alliance for Patient Safety, World Health Organization. This alliance consists of 4 programs as follows.

1. Information Technology.

To consider interventions like electronic records, CPOE, decision support, and bar coding. The importance of IT for data collection systems to facilitate reporting and learning is also emphasized. Some of the barriers to the wider implementation of IT, workarounds, cost and institutional resistance are considered.

2. Introducing New Technology Safely.

To consider the role of regulation, health technology assessment, clinical engineering and training and surveillance in the introduction of new technologies. Particular consideration is given to the needs and challenges in developing world settings.

3. Making Existing Technologies Safer.

To consider reporting systems, human factors, home care, hospital care, primary care and quality assurance. Particular consideration is given to the needs and challenges in developing world settings.

4. Simulation and Training.

To consider the potential of simulation to improve patient safety through education and training, moving the learning curve from patient to simulator. The use of both low and high-tech simulation will be considered, as well as the potential for using simulation in research, design and testing.

This initiative has been trying to collect best practices and literature on patient safety and facilitate collaborations among the world to figure global standards on technology and create better technologies and systems for patient safety. As a Japanese government representative, I had worked with Information Technology and Making existing safer. We presented Point of Act System as complete health care system for patient safety without any human mistakes.

The initiative might make a difference to attack patient safety and gain in popularity of information technology and other technology related to patient safety.

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Open Source Software in Medicine and its Implementation in Japan

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ABSTRACT

Despite the recognised benefits of electronic medical records and electronic healthcare data, many organisations have still to implement them. This is not due to doubts about their benefits but mainly for commercial reasons. The cost of licensing proprietary systems and customising them to meet their needs is a major barrier to many organisations. Another problem is the difficulty of choosing a system with the confidence that it is and will remain the best system and will be able to integrate with their existing and future IT systems. Many of these problems can be addressed through the use of open source software (OSS). OSS is computer software for which the human-readable source code is made available. There are no licence fees for OSS and the software can be freely modified by an organisation to its specific needs. At present there are over 150 health-related OSS projects and some of these have been very successful worldwide. Japan also has the same problem of high costs, inflexibility and restrictions associated with implementing proprietary software systems. To address this problem the Japan Medical Association has provided an information and communication infrastructure based on OSS in a project known as ORCA (Open Receipt Computer Advanced). Today, nearly 14,000 medical providers in Japan are using products of the ORCA project. In this paper we discuss the challenges of healthcare information systems and of OSS development in healthcare, illustrating this with the experience in Japan.

INTRODUCTION

The benefits of electronic medical records (EMRs) and electronic healthcare data are increasingly apparent, but many healthcare organisations have yet to implement them. This is not due to scepticism about their benefits but mainly due to commercial reasons. Licence fees and the costs of customising software to their needs are

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significant barriers to many organisations. Further barriers are difficulty committing to a particular vendor and concerns about compatibility of the chosen vendor's system with existing and future systems.

This global problem also affects Japan. It is estimated that to implement an EMR system in a Japanese hospital will cost approximately $10,000 per hospital bed. If this was scaled up to full EMR implementation for all medical providers in Japan (about 150,000), the Japanese Medical Association (JMA) has estimated a cost of US $180 billion over a 10 year period. Given that the size of the Japanese medical market is about $300 billion per year, this technology is not readily affordable in Japan without a significant reduction in costs.

One approach to reducing the high cost of clinical information systems is to integrate various existing clinical systems. A major barrier to this solution is there is no established standardised data communication protocol and consequently communication among different systems is problematic. Another potential solution to reducing the high costs of implementing IT systems in healthcare is the use of Open Source Software (OSS)[1].

OPEN SOURCE SOFTWARE (OSS)

Open Source Software can be defined as computer software for which the human-readable source code is made available under a copyright license (or arrangement such as the public domain) that meets the Open Source Definition[1]. This includes free distribution of the software, the inclusion of the source code in the program, and permitted modifications and derived works which can be distributed under the same terms as the license of the original software. In addition the licence itself should not be specific to a product, must not restrict other software and must be technology neutral. In essence this permits users to use, change, and improve the software, and to redistribute it in modified or unmodified form. This in turn has considerable commercial and technical benefits.

The availability of OSS source codes allows engineers to avoid reinventing the wheel and to concentrate instead on developmental efficiency. Proactive use of OSS promotes a low cost and short delivery time of software development and this has for example been beneficial in the development of internet software.

A particularly attractive appeal of OSS is that an organisation (user) gains confidence for future availability and full ownership of its data and customisability of its software by avoiding 'vendor lock-in'. Organisations can freely adapt OSS to their personal needs performing any necessary customisation themselves or by employing a third party. If in the future for any reason the organisation decides to use a different company to perform their customisation, they are free to do so. This is in marked contrast to proprietary software where the organisation is dependent on the vendor's willingness to perform any customisation, usually has little control over how quickly they perform the customisation and will inevitably pay a substantial

fee for it. The organisation would also not have any control over a vendor's decision to change data format or even structure.

OSS IN MEDICINE

A wide range of OSS solutions are already in use in healthcare. Many of these are technical tools and business applications, e.g. Linux, Apache, Open Office, and MySQL (Table 1), but a large number of healthcare specific OSS (Table 2) also exists. At the beginning of 2009 there were over 150 health-related OSS available to download from Source Forge, a website devoted to OSS[2].

Two widely used OSS for supporting patient and clinical management, are OpenEMR and VistA[3,4]. OpenEMR supports medical practice management, electronic medical records, prescription writing, and medical billing. It is used in the United States, Puerto Rico, Australia, Sweden, Holland, Israel, India, Malaysia, Nepal, and Kenya. VistA is an integrated comprehensive clinical information system supporting clinical, administrative, financial, and infrastructure functions. It was developed by the Departments of Veterans Affairs to serve the more than 4 million veterans cared for in its 150 hospitals and 700 clinics. VistA has been adopted for use by several other health institutions in America as well as hospitals in other countries, e.g. Egypt, Germany and Mexico.

Table 1. *Representative OSS projects*

Name	Description	URL
Linux kernel	OS kernel	http://www.kernel.org/
FreeBSD	OS environment	http://www.FreeBSD.org/
BIND	Berkley Internet Name Daemon	http://www.isc.org/
Sendmail	SMTP server	http://www.sendmail.org/
Apache	Web server and its peripherals	http://www.apache.org/
GCC	GNU Compiler Collection	http://gcc.gnu.org/
Perl	Script language	http://www.perl.org/
Ruby	Object-oriented script language	http://www.ruby-lang.org/
Vim	Text editor	http://www.vim.org/
Emacs	Extensible, customisable text editor	http://www.gnu.org/software/emacs/
PostgreSQL	Relational database management system	http://www.postgresql.org/
MySQL	Relational database management	http://www.mysql.com/
JBoss	Java enterprise edition container	http://www.jboss.com/
X Window System	Graphical engine and Windows environment	http://www.X.org/
OpenOffice.org	Business software suite	http://www.openoffice.org/

Table 2. *Some medical OSS projects*

Project Name	Description	URL
VistA	Veterans Affairs hospital information system, electronic health record.	http://worldvista.org/
OpenEMR	User friendly electronic medical record system.	Http://www.openemr.net/
FreeMED	Electronic Medical Record	http://www.freemed.org/
OpenMRS	Infectious disease management	http://www.openmrs.org/
ORCA	Information infrastructure for clinics/hospitals in Japan	http://orca.med.or.jp/
openEHR	Specification standards for interoperability of clinical information	http://www.openehr.org/
ImageJ	Image processing software for biomedical research	http://rsb.info.nih.gov/ij/
XMedCon	Medical image conversion toolkit	http://xmedcon.sourceforge.net/
NetEpi	Epidemiology studies	http://sourceforge.net/projects/netepi

More specialised OSS for various medical fields also exists. For example, Radiology Imaging and Visualisation has MicroDicom an application for primary processing and preservation of medical images in DICOM (Digital Imaging and Communications in Medicine) format. Public Health and Biosurveillance benefits from RODS (Real-time Outbreak and Disease Surveillance) a system to collect and analyse disease surveillance data in real time, and NetEPi a data collection and data management tool for use in communicable disease outbreaks and other epidemiological investigations and studies[5,6]. Medical research is supported by OpenClinica[7] a web-based platform for managing clinical studies and for telemedicine an open source telemedicine platform (iPath) is available[8].

MEDICAL OSS IN JAPAN

Japanese medical practice is generally subsidised by public health insurance programs. To receive reimbursement, doctors need to submit details of medications prescribed and treatments administered to their patients. To meet the government's accounting rules a health insurance computing system called '*Receipt Computer*' was developed during the 1970's and released in the 1980's. This software was expensive to deploy, costing as much as US$ 50,000 even in very small clinics or hospitals. Nevertheless, it was installed in 90% of clinics/hospitals in the country as it could meet the complex bureaucratic accounting procedures. The high cost of the software inevitably placed a financial strain on clinics. In addition all the data entered into the receipt computer was locked into the vendor's proprietary software and could not be

utilised for any other purpose or with any other systems without paying the vendor additional fees for integrating it.

To address the high costs of commercial software and to avoid any dependency on a specific vendor or technology the JMA decided to provide its members with an OSS-based information and communication infrastructure. In 2000 it presented an OSS project known as ORCA (Online Receipt Computer Advanced) with two major goals[9]. The first was to provide a networked system with software for submitting claims for government reimbursement (named as 'JMA standard receipt computer') at low or no cost to JMA members. The second was to use the knowledge and experience from the project to inform healthcare policymakers about the potential of OSS for other aspects of medical management in Japan and particularly electronic medical records.

All the components of the JMA standard receipt computer are OSS. Today, nearly 14,000 medical providers in Japan are using products of the ORCA project, and the number of participants is increasing. According to the ORCA website in May 2008 more than 6,300 clinics and hospitals have adopted the ORCA accounting system. The software is free and can be installed by individuals themselves or by JMA authorised vendors in which case a fee is payable.

Inevitably OSS has many other potential applications in the medical field and to investigate possible uses of OSS in the medical field in Japan, The Medical Open Source Software Council was established in 2004. One of the key areas where OSS may play a role is standardisation of medical data transaction protocols. In Japan there are few vendors of medical information systems and this inevitably limits competition and drives up the cost of information systems. The limited number of vendors also creates other problems such as a 'data lock-in' state, in which the hospital cannot use information entered within its system in intuitive ways as it is limited by the functionality and features provided by the vendor. In addition there may be a 'vendor lock-in' state, in which an organisation cannot change vendors because their present vendor will not provide them with the necessary information about their system to allow data migration to take place. These problems do not occur with OSS and users consequently avoid any 'lock-in state'.

As OSS resources become more commonly used in the medical field, barriers to new vendors should be reduced, and more vendors will be attracted to the medical field. The increased competition should break the oligopoly of vendors in Japan and lead to greater diversity and lower costs of medical IT systems. At present each organisation may operate slightly differently from other organisations, and clinical information systems usually have to be customised for individual organisations which increases the initial cost. With greater uses of OSS systems the diversity of available clinical information systems will increase and therefore be easier to adapt to the needs of a new organisation without the need for extensive customisation.

DISCUSSION

OSS offers great promise for realising the vision of ubiquitous low-cost, electronic medical record systems to improve healthcare. The absence of licence fees and the removal of dependency on a single vendor remove some of the most significant barriers to the implementation of EMRs. Another, absence of common data standards which makes it difficult to integrate systems or change from one EMR system to another, may also be addressed by OSS.

Although OSS clearly has many attractions, potential drawbacks must also be considered. As OSS development depends mainly on volunteers and usually provides its products *'as is'*, some people are sceptical about its security and availability. However comparisons of OSS with proprietary software have been favourable[10]. For example, the analysis of source codes for the Linux kernel has been reported to have fewer bugs[11], and be more reliable than proprietary software[12,13]. OSS has also been shown to respond more quickly than proprietary software in releasing patches to identified vulnerabilities. Clinical information systems must inevitably have a high level of security to maintain patient privacy. OSS can theoretically be made more secure than proprietary software because it can receive input from many developers[10–13].

As described earlier, the potential of OSS has been recognised in the medical field, and many healthcare related OSS projects have achieved success[3,4,14]. However, many problems remain to be solved. The development of OSS requires many developers with numerous skills and ideas in order to produce a good product, and as a consequence OSS projects recruit developers worldwide. Unfortunately, worldwide projects are rare in medicine, because each country has its own unique medical system and thus software cannot readily be shared without specific adaptations and a literal translation of the language. When language is not a barrier and the practice is exactly the same throughout the world, e.g. viewing Radiology images, OSS can be readily used with minimal or no adaptation[15–17]. Furthermore, despite differences in medical systems, the workflow at hospitals does not differ markedly among countries, making it possible to produce a unified worldwide medical application. To accomplish this, a worldwide medical project should separate common and local components (e.g. accounting, insurance claims, etc.) and standardise their interoperability.

With respect to the implementation of standards, Health Level 7 or HL7-compliant OSS is abundant throughout the world. The openEHR Project has standardised these programs according to their unique modelling method and has released them as the ISO/CEN 13606 standard[14]. OSS and open standard products have improved the interoperability of the Internet, and can similarly improve the interoperability of medical systems.

OSS is sometimes used for purposes other than those intended by the developers. Although most OSS has not been developed specifically for clinical use, some OSS

has been adapted for the clinical situation. Similarly, OSS that has been developed for medical applications may also be used in other fields as OpenCOBOL[18] or CGI.pm[19]. OSS should be enriched not only for clinical use but also for use by the entire OSS community, as human intellectual property.

In summary OSS has the potential to improve both clinical operations and the interoperability of medical systems. A number of promising OSS projects in the medical field may benefit both medicine and human intellectual property.

REFERENCES

1 Open Source Initiative. http://www.opensource.org/.
2 SourceForge. http://www.sourceforge.net/.
3 The OpenEMR Project. OpenEMR. http://www.openemr.net/.
4 Veterans Health Administration. Veterans Health Information Systems and Technology Architecture (VISTA). http://www.va.gov/vista_monograph/.
5 The RODS Open Source Project -Open Source Outbreak and Disease Surveillance Software. http://openrods.sourceforge.net/.
6. The NetEpi Project, NetEpi. http://sourceforge.net/projects/netepi.
7 Clinical Trial Software. http://www.openclinica.org/.
8 iPath. http://telemed.ipath.ch/ipath/.
9 Japan Medical Association. ORCA Project; 2000. http://www.orca.med.or.jp/.
10 Raymond E. The Cathedral and the Bazaar; 1997. http://www.catb.org/~esr/writings/cathedral-bazaar/.
11 Coverity, Inc. Analysis of Linux kernel; 2004. http://linuxbugs.coverity.com/linuxbugs.htm.
12 Miller B, Fredriksen L, So B. An empirical study of the reliability of UNIX utilities. *Communications of the Association for Computing Machinery* 1990; 33: 32–44. Available from: http://citeseer.ist.psu.edu/miller90empirical.html.
13 Miller B, Koski D, Lee CP, Maganty V, Murthy R, Natarajan A, *et al. Fuzz Revisited: A Re-examination of the Reliability of UNIX Utilities and Services*, 1995.
14 The openEHR Project. OpenEHR. http://www.openehr.org/.
15 Rosset A, Spadola L, Ratib O. OsiriX: an open-source software for navigating in multidimensional DICOM images. *J Digit Imaging* 2004; 17: 205–16.
16 NIH. ImageJ. http://rsb.info.nih.gov/ij/.
17 Nolf E. XMedCon: An open-source medical image conversion toolkit. *European Journal of Nuclear Medicine* 2003; 30(suppl. 2): S246.
18 The OpenCOBOL Project. OpenCOBOL. http://www.OpenCOBOL.org/.
19 Stein L. *How Perl Saved the Human Genome Project*, 1996. http://www.bioperl.org/GetStarted/tpj_ls_bio.html.

解　説

診療録関連の法規、特に職種との関連についての文献的考察

Bibliographical consideration for medical chart related regurations and medical qualifications

八　幡　勝　也

要旨：診療関連の情報に関連する法規の現状をまとめ、資格との関係の重要性とその考え方について、医療側、法規上の解釈の意見を調査した。
行政的な考え方と法的な考え方により「診療録」、「診療情報」、「その他の診療に関わる諸記録」、「診療に関するその他一切の書類」という形で整理した。さらに医療関連資格との関係についても整理した。これらの情報と資格の関係について考察し、その中で、同じ情報でも司法や行政など視点が異なるとその取り扱いが大きく異なることから、診療情報を考えるためのキーワードとして、「行政」、「司法」、「学術」、「医療」の４つについて考察した。

キーワード：診療録、法規、司法、学術、医療

1．背景

診療録の利用について検討する際に避けられないのが、コンピュータシステムに関連した記載や参照についての法規との関係である。

また、医療法規について検討する際には、さらに資格や判例の関係を整理しなければならない。本論文は、主に既存の見解をまとめると共に現場での診療録を取り巻く多様性について法規と職種を中心に検討する。

なお、本論文では仮に医療機関内で取り扱われる情報全体を「診療情報」、それが記録されたものを「診療記録」と呼ぶ。

1．診療録の法的な規定

診療録に関しては、従来から医師法24条、同施行規則23条の記載事項及び、いわゆる療担則８条および22条の規定が基本となっている。以下それらを列挙する（表１）。

「医師法第二十四条　医師は、診療をしたときは、遅滞なく診療に関する事項を診療録に記載しなければならない。」

「医師法施行規則第二十三条　診療録の記載事項は、次の通りである。

一　診療を受けた者の住所、氏名、性別及び年齢
二　病名及び主要症状
三　治療方法（処方及び処置）
四　診療の年月日」

保険医療機関及び保険医療養担当規則

「第八条　保険医療機関は、第二十二条の規定による診療録に療養の給付の担当に関し必要な事項を記載し、これを他の診療録と区別して整備しなければならない。

第二十二条　保険医は、患者の診療を行った場合には、遅滞なく、様式第一号又はこれに準ずる様式の診療録に、当該診療に関し必要な事項を記載しなければならない。」

また、「様式１の１の２」において、既往症欄の記載事項として既往歴、原因、主要症状、経過等が示され、同じく処置欄の記載事項として処方、手術、処置等が示されている。

これらへの注意事項として[1]、「既往歴、原因、主要症状、経過欄には特に現象に関連があると思われる既往症および原因について、その時期、経過等必要な事項を記載すること。主要症状・経過については、患者の主訴及び自他覚所見等、診断の根拠及び

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表1　医療・介護関係法令において医療・介護関係事業者に作成・保存が義務づけられている記録例（医療・介護関係事業者における個人情報の適切な取扱いのためのガイドラインより）

病院・診療所
- 診療録【医師法第24条、歯科医師法第23条】
- 処方せん【医師法第22条、歯科医師法第21条、医療法第21条】
- 助産録【保健師助産師看護師法第42条】
- 照射録【診療放射線技師法第28条】
- 手術記録、検査所見記録、エックス線写真【医療法第21条】
- 歯科衛生士業務記録【歯科衛生士法施行規則第18条】
- 歯科技工指示書【歯科技工士法第18条、第19条】

助産所
- 助産録【保健師助産師看護師法第42条】

薬局
- 処方せん（調剤した旨等の記入）【薬剤師法第26条、第27条】
- 調剤録【薬剤師法第28条】

指定訪問看護事業者
- 訪問看護計画書【指定訪問看護及び指定老人訪問看護の事業の人員及び運営に関する基準第17条第1項】
- 訪問看護報告書【指定訪問看護及び指定老人訪問看護の事業の人員及び運営に関する基準第17条第3項】

治療の裏付けとなるべき必要事項（検査成績、画像診断等の所見を含む）を診療のつど記載すること。処方、手術、処置欄には、診療のつど処方、手術及び処置の内容、診療上の指導内容等を記載すること。」とされている。

2．助産師、保健師、看護師記録

診療録以外にも助産師のみ「助産録」の記載が義務づけられている。（保健師助産師看護師法第42条保健婦助産婦看護婦法施行規則第三十四条）

保健師助産師看護師法施行規則

「第三十四条　助産録には、次の事項を記載しなければならない。

一　妊産婦の住所、氏名、年令及び職業

以下略」

看護記録については厚生労働省の省令「指定訪問看護及び指定老人訪問看護の事業の人員及び運営に関する基準」第三十条2項には、「指定訪問看護事業者は、利用者に対する指定訪問看護の提供に関する諸記録を整備し、その完結の日から二年間保存しなければならない。」とあり、分野は限られているものの看護記録が明示されている。

3．診療録以外の情報

医療機関では診療録以外にも数多くの診療関連記録がある。それらは医療法の中で「診療に関する諸記録」としてまとめられている。

「医療法施行規則第二十条十項　診療に関する諸記録は、過去二年間の病院日誌、各科診療日誌、処方せん、手術記録、看護記録、検査所見記録、エックス線写真、入院患者及び外来患者の数を明らかにする帳簿並びに入院診療計画書とする。」

しかし、これら以外にもレセプトなど重要な書類が数多くあり、それらを総称して「診療に関するその他一切の書類」という分類の考え方もある[2)]。

Ⅱ．診療関連情報の定義

以上、法令で触れている診療録関連法規について述べたが、診療関連情報についても以下のように区分されている。

旧厚生省による「カルテ等の診療情報の活用に関する検討会」（1998年）の報告書では、「一般的に診療情報とは、医療の提供の必要性を判断し、又は医療の提供を行うために、診療等を通じて得た患者の健康状態や、それらに対する評価及び医療の提供の経過に関する情報であり、これらが紙等の媒体に患者ごとに記録されたものが診療記録であると考えられる。診療情報・診療記録には、これら以外にも、もっぱら医療機関の管理に資する目的で収集、作成されるもの、検診、行政機関の調査、医学研究に際して収集、作成されるものがある。」、と診療情報と診療記録の関係を定義し、その範囲が医療機関内に留まらないことを示した。

日本医師会による「診療情報の適切な提供を実践するための指針第2版」（2002年）では以下のように

定義されている。

(1) 診療情報……診療の過程で、患者の身体状況、疾病、治療等について、医師またはその指揮・監督下にあたる医療従事者が知り得た情報。

(2) 診療録……医師法第24条所定の文書。

(3) 診療記録等……診療録、手術記録、麻酔記録、各種検査記録、検査成績表、エックス線写真、助産録、看護記録、その他、診療の過程で患者の身体状況、病状等について作成、記録された書面、画像等の一切。

厚生労働省による「診療に関する情報提供等の在り方に関する検討会」報告書およびそれに基づく「診療情報の提供等に関するガイドライン」(2003年)においては診療関連の各種の情報について次のように定義されている。

(1) 「診療情報」とは、診療の過程で、患者の身体状況、病状、治療等について、医師、歯科医師、薬剤師、看護師等医療従事者が知り得た情報をいう。

(2) 「診療記録」とは、診療録、処方せん、手術記録、看護記録、検査所見記録、エックス線写真、紹介状、退院した患者に係る入院期間中の診療経過の要約その他の診療の過程で患者の身体状況、病状、治療等について作成、記録又は保存された書類、画像等の記録をいう。

以上より、長谷川[3]が述べたように、診療情報⊇診療記録⊇診療録という関係が用語の共通認識とされている。しかし、これらの診療情報はあくまでも医療職による情報という前提がある。よって、レセプトなどの事務的な書類の扱いが課題となる。米田[2]によると医療刑事事件捜査では、「診療に関するその他一切の書類」という包括的扱いで考えられている。

以上を総括すると、中心に「診療録」があり、これは医師法第24条で示す文書で、医師が記述することが前提であるが、事務職による代行が可能で、最終的に医師が承認する。次いで「診療記録」があり、これは診療録を含むとともにいわゆる「診療に関する諸記録」が加わり、医療職が記述する。そして、記録を含む形で、医療従事者が知り得た情報を「診療情報」とする、という構造である。しかし、さらにレセプトなどの事務的な書類は、「診療に関するその他一切の書類」と呼ばれる。これからすると医療機関にとって扱うこれらの情報をまとめて「診療関連情報」として総括する事が適当と考えられる(図1)。

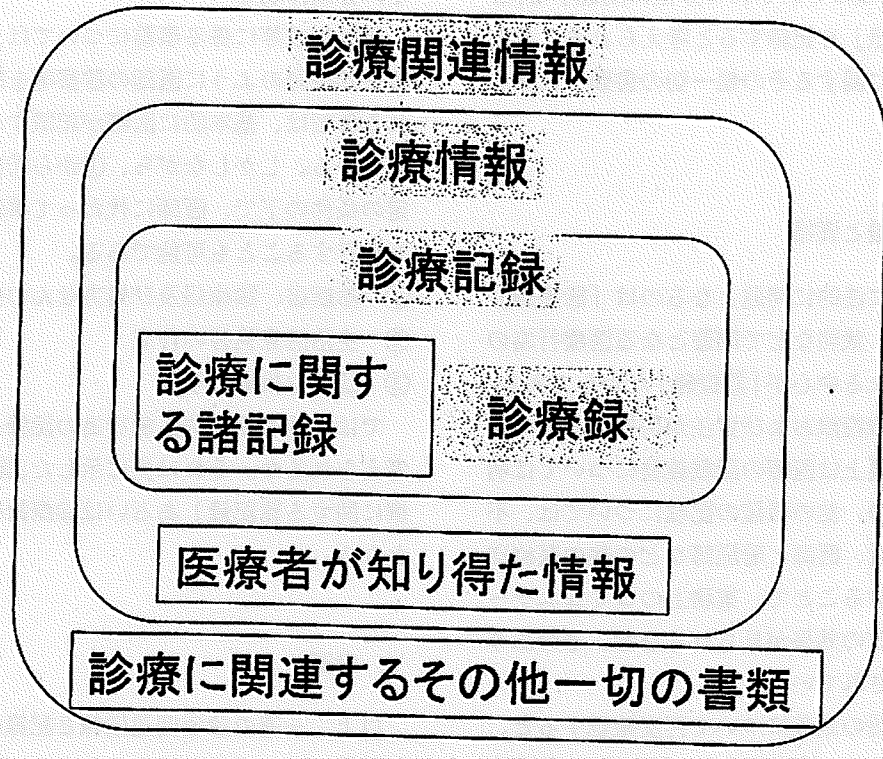

図1 診療関連情報の概念図

Ⅲ. 医療に関連する職種

医療に関連する医療業務者は以下のように分類されている[4,5]。

1．医師

医師及び歯科医師をいう。医師は医療及び保健指導を掌る者であって、医師国家試験に合格し厚生労働大臣の免許を受けた者である。

2．医療補助業務者

医療補助業務者とは医師の医療行為を補助する者をいう。医療補助業務者は国家試験による厚生労働大臣の免許を要する者、都道府県知事の免許を要する者に分かれる。

3．医療類似業務者

医業類似業務者とは、はり師、柔道整復師など医業類似行為を行うものを言う。

4．医療関与者[6]

いわゆる事務担当者である。

医療補助業務者という用語は一般的でないので、ここでは「医療職」と呼ぶ。また、医療類似業務者は医療機関に従事することは少ない。医療機関内には、さらにいわゆる事務職があり、「医療関与者」という呼び方がある。しかし、一般的ではないので「事務職」をここでは用いる。

以上から、医療職はそれぞれの分担に関連する「診療に関する諸記録」を記録すると考えられる。また事務職は「診療に関するその他一切の書類」に関わると考えられる。

Ⅳ. 診療録の記載と資格

この中で、特に法的に問題となるのは「診療録」である。それは、裁判などで問題となる医療行為の記録として扱われる中心が「診療録」だからである。

診療録への記載権限および責任が何処にあるのかについては、法規上は医師の記載義務については明示してあるものの、他の職種の記載については、不明であった。最近、医師と看護師などの他の医療職が診療録に記載することで、業務上のコミュニケーションの向上などの効果が見られるなど、そのあり方について検討されている。

ここで、診療録の定義について再度確認すると、医師法二十四条には、診療録とは、「医師は、診療をしたときは、遅滞なく診療に関する事項を診療録に記載しなければならない。」とあり、医師がその診療行為を何らかの形で記録したものといえる。その診療行為は、「絶対的医行為」と「相対的医行為」に分かれる。

「絶対的医行為」と「相対的医行為」のうち医師（又は歯科医師）が常に自ら行わなければならないほど高度に危険な行為を「絶対的医行為」といい、それ以外の行為を「相対的医行為」という。「相対的医行為」を医師以外の医療従事者に行わせるか否かは、医療従事者の資格と能力を勘案した医師の判断による[7]。となると、医師は少なくとも「絶対的医行為」については診療録に必ず記載しなければならないこととなる。

診療録の記載に関しては、条文上、医師しか規定がないため、記載義務については「医師」資格に限定したものと考えられている。しかし、平成19年12月28日に厚生労働省から出された通達「医師及び医療関係職と事務職員等との間等での役割分担の推進について」（医政発第1228001号）において、最終的な医師の承認を前提に一定の条件下ではあるが、医師以外による代行記載が認められた。

(1) 医師、看護師等の医療関係職と事務職員等との役割分担

1）書類作成等

書類作成等に係る事務については、例えば、診断書や診療録のように医師の診察等を経た上で作成される書類は、基本的に医師が記載することが想定されている。しかしながら、①から③に示す通り、一定の条件の下で、医師に代わって事務職員が記載等を代行することも可能である。

① 診断書、診療録及び処方せんの作成
② 主治医意見書の作成
③ 診察や検査の予約

では、他の相対的医療行為の記録とはどのように考えられるか。それは先に示した、診療録以外の「診療に関する諸記録」あるいは診療録に追加することとなる。

Ⅴ. 考察

以上、一連の診療関連情報と記録に関連する法規と資格についてまとめた。しかし、現実には、さら