ROAD TO 7TH ASIA CANCER FORUM

The discussions at the 6th Asia Forum identified a number of key issues that need to be tackled if a comprehensive cancer network is to be achieved. Knowledge gaps exist between the current status of cancer research and treatment in front-runner countries, such as Japan, and the perception of issues in developing and emerging countries. It was recognized that the issue of obstacles to sharing common challenges is one that requires further discussion and analysis. The Asia Cancer Forum will continue to examine means for sharing information in a meaningful and comparable manner. In particular, the role of IT in opening up cancer issues for global health consideration will be focused on in future meetings, with input being sought from policy-makers in government and from the private sector, including pharmaceutical companies. The 7th Asia Cancer Forum is scheduled to be held on 3 November 2010, with invited speakers from the Asian region and major pharmaceuticals coming together to discuss the way forward for a comprehensive cancer network in Asia. With the participation of representatives of academia, government and industry at the 7th Asia Cancer Forum, it is anticipated that the technical issues, specifically relating to knowledge and know-how gaps between front-runner and developing countries, will be further discussed, with a view to crystallizing a future path for a comprehensive cancer information network in the Asian region.

Conflict of interest statement

None declared.

Preliminary Linguistic Analysis of Large Number of Medical Incident Reports for Patient Safety

Katsuhide Fujita[1], Masanori Akiyama[2], Keunsik Park[3]
Etsuko Yamaguchi (Nakagami)[3], Hiroyuki Furukawa[4]

[1]Institute of Engineering of Innovation, The University of Tokyo
[2]Policy Alternatives Research Institute, The University of Tokyo
[3]Osaka City University, [4]Yamaguchi University Hospital

ABSTRACT

The analysis of medical incident reports is indispensable for the patient safety. Most of the incident reports include some free composition formats, therefore, the analysis of free descriptions gives new perceptions. We aimed to accumulate, to interpret information again by structured incident information, and to clarify the point that should be improved for the cause of the accident and safe medical treatment improvements in the present study.

We employ the natural language processing to the analysis of medical incident reports in this paper. The network analysis can find various relationships that are not only direct relationships but also indirect relationships. First, some important characteristic words were extracted in three categories of the accident's background, details, and solutions using TF-IDF measure. By using the TF-IDF, we can get some important characteristic words for analyzing the reports. In addition, we show the co occurrence networks using these extracted words.

1. INTRODUCTION

"In the shadow of every serious accident, there exist 29 times more minor accidents and 300 times more near misses." This principle was published in 1929 by Herbert William Heinrich, an assistant manager in the technology and research division of an American insurance company [1]. This principle, which hits home the nature of the occurrence of accidents, is taken up in various fields, such as the study of failure, safety engineering, cognitive psychology as well as the study of reliability, and the incident analysis of minor accidents associated with this is recognized as being important in preventing accidents.

Also, the use of information pertaining to medical accidents is important when implementing medical safety measures. The medical safety mechanism of WHO aims to prevent accidents by reusing incident reports through the introduction of IT technology. Harvard University is engaged in the standardization for the collection of medical accident reports and accident information in the risk management consortium. In England, the National Health Service conducts the medical accident/incident report collection project. Even in Japan, the Ministry of Health, Labour and Welfare began the project to Collect Medical Near-Miss/Adverse Event Information in 2001[2]. Through this project, the Ministry conducts analyses based on the collected incident reports.

On the other hand, regarding patient safety, guidelines for the future deployment of incident analysis are set out in WHO's International Classification of Patient Safety (ICPS) [3]. ICPS states the necessity of first investigating the adequacy of classes of incident case studies such as those mentioned above, and second, methods of expressing incidents that adequately reflect these classes, i.e., it states the necessity of ontological construction. In this research, in line with WHO guidelines, we conducted an analysis regarding the adequacy of classes in case studies collected in the Project to Collect Medical Near-Miss/Adverse Event Information and the tendencies of description that aim at ontological construction.

In the Medical Near-Miss/Adverse Event Information including the abstract, background, and solution for a single case are described using a free composition format. In this paper, we analyze the large number of medical incident repots (more than 15,000 reports) provided by Osaka City University using the natural language processing and the network analysis. By using natural language processing, an understanding of the tendencies of description as well as guidelines for future ontological construction can be acquired.

The remainder of this paper is organized as follows. First, we describe the dataset of the medical incident reports provided by Osaka City University. Next, we describe the methodology based on the Natural Language Processing and the Network analysis for analyzing the large number of medical incident reports. Then, we present the results of analysis of incident reports. Finally, we present our overall conclusions.

2. MEDICAL INCIDENT REPORTS BY OSAKA CITY UNIVERSITY

2.1 Overview of Medical Incident Reports

With increasing social demand for the prevention of medical accidents, the Health, Labour and Welfare Ministry started the Project to Collect Medical Near-Miss/Adverse Event Information from 2001 in order to collect and analyze incident case studies and to provide information conducive to medical safety, such as measures for improvements. When the project was first started, a framework was in place in which the Pharmaceuticals and Medical Devices Agency collected incident case studies from participating medical institutions and then reported these case studies to the Health, Labour and Welfare Ministry, following which a Health, Labour and Welfare Ministry study group conducted aggregate calculations and analysis. The 1st–10th collection of incident case studies were conducted following this framework, and information based on these collected incident case studies was provided by the Health, Labour and Welfare Ministry. From 2004, the Japan Council for Quality Health Care took over the collection of incident case studies, collecting case studies from the 11th collection [4].

Osaka City University also collected 18,340 incident reports from 2007 to 2010. In the incident reports provided by Osaka City University, free composition formats are taken quite seriously compared with ones provided by other Hospitals. For instance, the average number of words in the incident reports by Osaka City University is 188 words, on the other hand, the one by the Project to Collect Medical Near-Miss/Adverse Event Information is 80 words[2]. In fact, doctors and nurses in Osaka City University have to input the reports for the free descriptions at first because of the Layout of data entry screen.

2.2 Data Sets

We used free composition format written in Japanese relating to medical agents from 2007 to 2011 by Osaka City University. The number of documents is 18,340. Each case study is in a free composition format, with the abstract, background, and solution being approximately 188 words long, respectively. In addition, the two classes of medicine and accident are granted to each case study. With regard to the class of treatment, there are six classes of general drug, preparation of drugs, drowsy of drugs, contraindicated drug, chemo treatment, and other drug; with regard to the class of operation, there are the nine classes of name of drug, amount of drug, regimen, amount and regimen, flow rate, drug sensitivity, diapedesis, forget to dose, and object person. With regard to the class of treatment, as all the classes of operation do not exist, there are 32 cross classes that cross calculate the class of treatment and the negligent class of operation.

When describing accidents in a free composition format, the reporter makes every effort to include every single circumstance. We can say that extracting important information from these circumstances means creating a foothold for a bottom-up type of ontological construction. Results obtained from this and links with classes granted top-down is in accordance with the future guidelines for incident analysis sought by ICPS.

3. METHODOLOGY OF NATURAL LANGUAGE PROCESSING AND NETWORKD ANALYSIS

3.1 Methodologies for analyzing the incident reports

In this paper, natural language processing was first conducted on the incident reports. Keywords that emerge characteristically were then extracted for each category of "background/causes," "details," and "solutions," using the tfidf method. After that, the semantic tendency of the incident report was investigated in order to create a network of words by calculating the co-occurrence information of the words using the Jaccard coefficient.

Also, we show the networks among each document which are determined by the similarities between documents based on the tfidf method. As natural language processing contains a lot of noise, there is a need to conduct preprocessing in order to obtain characteristic words that can be used in determining links.

3.2 Japanese language morphological analysis

In the first stage of preprocessing, we conducted morphological analysis in order to break down reports into words. Morphological analysis is a method used to delimit each word in the text where words are not delimited by spaces, such as in languages like Japanese [5]. In this research we used MeCab, one of the most common engines for conducting morphological analysis [6].

There is the possibility that words obtained using MeCab are too finely classified to conduct the analysis of links. Therefore, we connected words using the following methods and used them as new words.

We connected words using information on the parts of speech. The above-mentioned MeCab not only breaks down words but also grants major classes and minor classes relating to parts of speech. In cases where the minor class of parts of speech of certain words was a suffix and the word before it was a noun, these two words were treated as one word.

Next, we connected words based on the number of word occurrences [7]. Let us envisage a situation in which two words -hereafter called A and B- appeared consecutively. If we designate the number of word occurrences in instances where each word is considered separately as *n (A), n (B)*, then the number of word occurrences in which they appear consecutively is expressed as *n (A∩B)*. In cases where *n (A∩B)/min (n (A), n (B))* exceeded the threshold value (*0.1* in this research) then we treated those two words as one word.

In the documents, nominalized verbs, general nouns, and proper nouns were targeted. Focusing solely on nouns is the method generally used in extracting characteristic words. Moreover, in the case of official documents in Japanese, as many of the verbs are nominalized, a lot of information can be obtained regarding action even if using only nouns.

3.3 TF-IDF Method

In this research, we calculated a value called *tf-idf* from the frequency of occurrence and conducted filtering based on this values. *Tf-idf* is one of the most widely used indices in extracting characteristic words for document classes and in cases where a certain word occurs several times in a small number of documents, it is defined so as to enlarge that value[8]. *Tf-idf* is calculated as follows:

$$tf-idf(t,d)=tf(t,d)\times idf(t) \quad (1)$$

$$tf(t,d)=n(t)/\sum_{k\in T} n(k) \quad (2)$$

$$idf(t)=\log|D|/|\{d:d\in t\}| \quad (3)$$

Here, t is a term, d is a document, $n(t)$ is the frequency of occurrence of term t, $|D|$ is the total number of documents, and is $\{d:d\backslash in\ t\}$ the number of documents in which word t occurs. T means the set of terms.

The *tfidf* of general words occurring in a large number of documents has a tendency to be of a low value, although words among even general words that have an abnormally high *tf* in some cases exceed the filter effect of *idf* and assume a high value.

3.4 Creation of Co-Occurrence Networks

The co-occurrence index is generally used as a method for finding links from the degree of similarities between words in documents. Here, the simplest co-occurrence index for finding links between the two word A and B is the number of

co-occurrence $|A \cap B|$ for two words. Here, $|A \cap B|$ is the number of characteristic words that exist in A and B. If considered with only $|A \cap B|$, there are problems such as including as many characteristic words as in long texts and links with other documents being displayed as high. Consequently, a number of co-occurrence indices that improve on these points have been proposed, with representative indices including the Jaccard coefficient [9].

$$Jaccard: |A \cap B| / |A \cup B| \quad (4)$$

A link is established between the two words in the event that these indices exceed the threshold value.

4. PRELIMINARY ANALYSIS RESULTS

Table1: Top 10 Characteristic Word in Incident Reports (*TF*; Term Frequency)

(TF)	Background	Details	Solutions
1	Patient	Report	Check
2	Check	Patient	Time
3	Drug	Check	Patient
4	Nurse	Attending Doctor	Direction
5	Direction	Monitor	Drug
6	Internal use	Duty Doctor	Explanation
7	Infusion	Doctor	Nurse
8	Pill	Direction	Thoroughness
9	Room	Nursing	Drug maker
10	Administration	Explain	Doctor

Table2: Top 10 Characteristic Word in Incident Reports (*TF-IDF*)

tf-idf	Background	Details	Solutions
1	Drug	Patient	Check
2	Patient	Report	Time
3	Check	Attending Doctor	Patient
4	Internal medicine	Check	Direction
5	Direction	Doctor	Drug
6	Nurse	Monitor	Explanation
7	Administration	Apologizing	Nurse
8	Infusion	Nursing	Thoroughness
9	Root	Duty Doctor	Before
10	Channel	Direction	After

The top ten characteristic words that appear in the incident report such as "background/causes," "details," and "solutions" with *tf* (term frequency) are shown in Table 1. The top ten characteristic words that appear in the incident report with *tf-idf* (Eq.(1)) are shown in Table 2. Under the category of "Background," the words "Patient" "Check," "Drug," "Nurse," and "Direction" rank high in Table 1. Moreover, the fact that the word "nurse" ranks high shows that there are many accidents related to nurses. Under the category of "Background," the words "Drug" "Internal medicine," "Infusion," and "Channel" rank high in Table 2. Therefore, accidents related to medicines are important for analyzing the reports. Also, the words "Check," "Direction," and "Explanation" rank high under the category of solutions. In addition, the words related to the medical process such as "before" and "after" are high rank.

One word such as "lack," "confirmation," or "drugs" alone cannot express the tendency of the accident. In this research, co-occurrence networks of words were created by connecting the words that co-occurred with each other at a high frequency. The degree of co-occurrence is calculated using the Jaccard coefficient[3] shown in Section 3.4.

Figure 1 shows the networks of characteristic words created using the accident reports related to incorrect drugs. Each node represents a word, and an edge represents the intensity of the co-occurrence between the words. First of all, in viewing the network for "background/causes" (see Figure 1 (a)) it is clear that the network is created around the word "Check," and one can see that the cause of many accidents is the fact that the "Check" on "drugs," "Patient," by "Nurse". Connecting the words that co-occur frequently allows us to understand what tends to become inadequate. In the network of "accident details" (see Figure 1 (b)) many different words appear at once, indicating the presence of diverse accident details. Viewing the network for "solutions" (see Figure 1 (c)), as with the network for "background/causes," it is created around the word "confirmation."

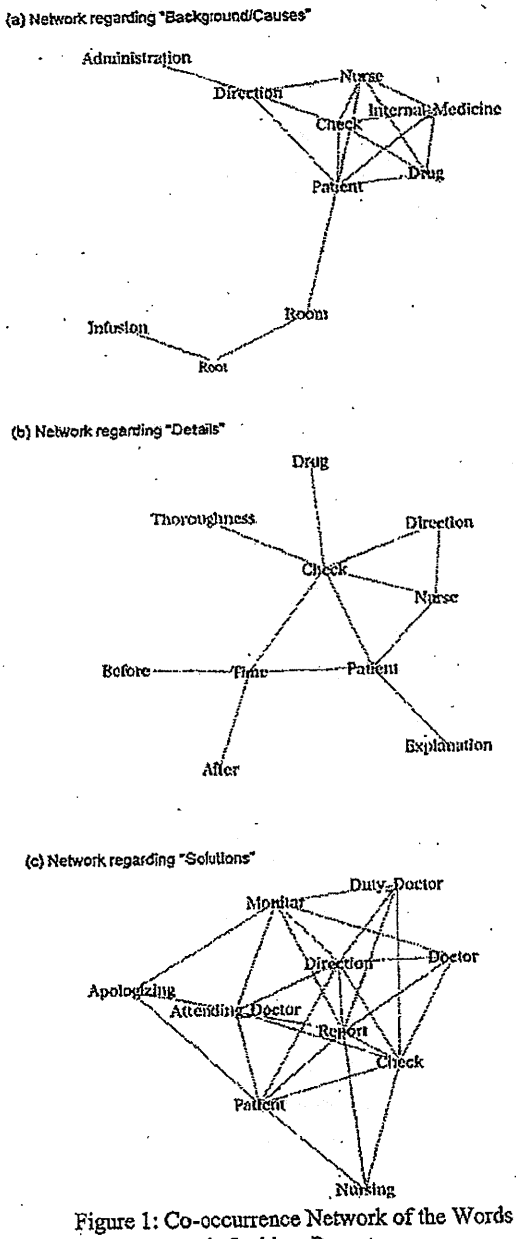

Figure 1: Co-occurrence Network of the Words in Incident Reports

5. CONCLUSION

In this paper, the characteristic words were extracted by analyzing incident reports, and the co-occurrence networks of the characteristic words were created. As a result, the language networks with the hub of the word "check," thereby revealing that inadequate confirmations on the drug labels, instructions of a physician and patient were very significant causes of accidents. These results suggest the effectiveness of introducing the network analysis method. In the future work, we would like to focus on the medical repots for improving the notational rules for the names of drugs and dosages in incident reports. Also, we would like to analyze the differences of understanding of the incident reports between positions like doctors, nurses, pharmacists.

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Healthcare IT System not Only Prevents the Medication Errors But Also Improves the Patient Safety with Evidence

Masanori Akiyama

Policy Research Alternatives Institute, the University of Tokyo, Tokyo, Japan

ABSTRACT

The purpose of this study is ensuring patient safety of blood transfusion by minimizing risk of transfusion at the point of care through Information Technology. The targets are ensuring five rights of transfusion, rights process and right information by auto identification and traceability of blood products. Auto identification and data capturing system with RFID based on the Point-of-Act-System (POAS). It provides real time right identification, process management to ensure right medication and traceability with serialized number in single item level. The system designed based on process analysis and use case of transfusion was successfully implemented in Red Cross Hospital to prevent transfusion errors and ensure traceability of blood products. By reading RFID at the point of care, we can check database to look for adverse events of blood products. We identified all 377 blood products and acquired tracking data successfully. We can improve patient safety and traceability with RFID.

1. INTRODUCTION

Many hospitals and blood centers have introduced barcode and RFID systems for patients and blood identification and they have contributed to reduce incorrect blood products and transfusion [1-6]. However, present identification of patient and blood with these technologies doesn't ensure all of '5 Rights' for safe medication. "5 rights" means right patient, right product, right dose, right root and right time administration of medication. 5 Rights are regarded as an essential factor for ensuring medication correctness and Barcode and RFID are fundamental technologies for achieving the purpose. It is better strategy to keep transfusion safety that blood transfusion system should move their focus from patient identification to comprehensive 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 identification at the point of care. Medication is not a single activity that is independent from other activities but a process that consists of connected a series of activities by various workers. It is crucially important to keep good communication among medical workers and ensure rightness of medication process without any omissions and faults. This is another area of contribution of barcode and RFID based administration system for patient safety that barcode and RFID can contribute by capturing and documenting accurate data of activities by medical workers that has a capability to facilitate high quality communication based on real-time accurate information. Good communication based on real-time information prevents miscommuni-cation and misunderstanding and can promote patient safety. Traceability of drug and other materials is also achieved with barcode and RFID administration and data capturing at the points of production, transfer and consumption. In medical setting traceability of materials has been widely recognized as necessary piece for enhancing patient safety. Traceability enables us to find harmful drugs and materials with perfect information of their original production points and path ways of transfers.

2. METHODOLOGY

The purpose of this study is ensuring patient safety on blood transfusion by minimizing risk of transfusion at the point of care with Information Technology and implementing a system to conduce it. To minimize risk of transfusion, there are three important components achieved by 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 and the information should be update in real time based upon the change of situations including clinical settings. Second is securing right processes of transfusion. Skipping process of transfusion including cross matching and incorrect processes of transfusion might make transfusion harmful. Third one is traceability that enables checking information of adverse events of products that are prepared from same bloods. 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. The 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 the risk that infected bloods would be distributed is traceability of blood products by single item level. If there is knowledge about when and where these bloods were collected and produced, we can prevent secondary infections by recalling blood products prepared from same original immediately.

However, there is an issue to achieve perfect traceability of blood products that is tradeoff between public safety and privacy data protection in this situation. In contrast to drug traceability, perfect traceability of blood products is including highly private information such as infectious information of donors and there is a possibility to like the information to a specific name. Collecting information on blood products 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.

1) *Point of Act System*: POAS captures complete data on each medical action including 6W1H information (When, Where What, Why, for What, to Whom and How) conducted in the hospital. The units of data recorded by the system are: Who—the implementer (the person who initiated the order, or the person who carried it out), to Whom—the patient, How—medical activities and changes in them, What—materials used (pharmaceuticals, medical materials and others), How much—amount of materials used and number of applications, for What—name of patient receiving medical services, When—date the order was placed, implemented and discontinued and the activities that were implemented, and Where—place of implementation (department, hospital, ward, etc.). The collection of complete data including 6W1H information is an innovative source in understanding actual situations directly without estimation or bias, and enables the investigation of solutions to prevent error [7,8].

2) *Complete data:* POAS data is "Complete data" that capture every action by real time and quite accurately. This means the data captured by the system has full traceability of drugs and materials and can be used for analyses on healthcare management. Complete data provide us great opportunity to analyze situation of healthcare management, quality and safety without any sampling methodologies to estimate original value. 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.

3) *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.

4) *Settings:* Our experimental project was enforced in Iwate Red Cross Blood Center and Morioka Red Cross Hospital as Table1. 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.

5) *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 an object uniquely.

6) *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 I 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.

Experimental project with the system described above was implemented in Morioka Red Cross Hospital and Iwate Red Cross Blood center. The 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.

Table1 Comparison of Auto Identification with Other Systems

	Exiting Administration System	POAS System
Blood Type Certification	Possible	Possible
Completion of Cross Matching	Partially Possible	Possible
Checking results of Cross Matching	Impossible (Need additional procedures)	Possible
Checking adverse event information by database located outside hospitals	Out of Focus	Possible

3. RESULTS

We analyzed process of transfusion in Morioka Red Cross Hospital and Iwate Red Cross Blood Center to identification and track appropriately. 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 is ready for use for blood 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 delivers to the point of transfusion. 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 1 shows normal process of blood transfusion in the 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.

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.

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.

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.

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. 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. 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). This 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 5 rights 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. We proved that the system with the RFID tag and SGTIN was able to manage the pharmaceutical drugs at the single item level in real time, and improve patient safety. For all 377 blood transfusions captured by this system, data was perfectly collected and there is no inconsistency on the data. For patient safety, it is very important that the response of the information processing is quick to operate the real system. We accessed the data center in Nagoya City, central Japan, away at 900km from the hospital in Morioka City in the Tohoku region, north-east Japan, through the Internet line. As a result, the processing time of the system was within 0.4 seconds, and thought to be a response enough by practical use also at each stage. Moreover, both access times were the response within one second, and it was thought enough though the access from the wholesale enterprise in Morioka City was an access to the data center in Nagoya City that used the connection of the Internet of a very narrow band up to 402 kbps by Personal Handy-phone System. To evaluate data captured by the system, we drew the data as traceability graph. An example of traceability graph is Figure 2. 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 by doctor. 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. At the level of the business load, in the entire work, each person in charge is skilled in a new system and we improved the operating effectiveness of the person in charge more than existing business. In terms of checking prescription and mixing injection drugs, we have double check system now. In near future, we can make up single check system with RFID tag system for backup.

Moreover, we proved the expectation of the effect of the medicine of the abandonment amount reduction, and contribution also improved management and the CO_2 exhaust amount reduction of the medical institution.

As a result of the operation switch verification at the failure, we confirmed the operation switch was able to be done promptly, and there was no big influence on the hospital work. We expect that applicability of the RFID tag is able to have the good effect of the batch reading in the business of confirming a large amount of medicine.

4. DISCUSSION

We constructed system with internet and RFID to manage whole processes from production to consumption of blood products to expand the capability of certification system and ensure traceability. Many previously published literatures have been tried to construct certification system at the point of care for blood transfusion or at blood center to make right documentation of blood products for blood safety and management [1-6]. Compare to these systems, this system has several advantages that other systems don't have. This system ensures 5 rights of transfusion and right process and information with real time original information. By checking original data base

through middle ware at the point of care, the correctness of information for certification is highly secured. This technique makes us possible to check the original database to certify patient information and blood products with electrical medical records and computerized order entry system directly and find adverse events information on blood products through internet.

We tried to evaluate improvement on blood transfusion safety and traceability with this system. The number of medical accidents and incidents on blood transfusion from April to June 2007 (before implementation of the system) is zero and the number of them during experimental period is also zero. This information didn't provide us evidence of improvement on safety based on number of accidents. These data about number of accidents were based on voluntary reports by medical workers. Therefore, it is impossible to find any accidents if they don't report medical accidents. However, administration systems have possibility to provide new opportunity to evaluate and measure level of safety. Warning logs by reading wrong patients and blood products RFID means that there is a possibility that the administration for the patient would be accident or incident without administration system. The data captured by the administration system has a potential to measure the level of safety and comparison of the data between before and after implementing interventions for patient safety is our next target for researches.

Costs including work burdens of medical workers are sometimes the highest obstacle to introduce health IT system [9-10]. It is useful to investigate feasibility of the system by evaluating change of time to finish each activity [11-18]. We investigated time to finish each activity by collecting data observationally and computed average length of time from around 10 observationally data of each activity. We compared length of time to finish each activity between using this RFID based administration system and using paper based communication and documentation. We chose six activities for comparison and six activities are blood receiving, decussation testing 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 paper based system. Works of nurses and technicians would be also effective as well as safer 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.

Another way for identification and data capturing used widely is barcode technology. RFID is superior to traditional barcode technology in numerous ways [15,16]. RFID does not require line-of-sight, allows simultaneous read of multiple tags, is able to store more information on the chip, cab include sensors for condition monitoring such as time and temperature, and enables automatic identification and data capture [15]. In addition to these operative advantages, RFID enable rewriting information and it is significantly important to construct a solution for privacy data protection and future extensions.

We investigated and focused improvement of transfusion safety with auto identification and data capturing system. In addition to these advantages, it also has possibility to provide significant advantages on hospital management and regional health system management. The ways to storage blood products were strictly regulated, because quality of blood products is easy to change with affects from outside. Red blood cell products must be stored 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 are scarce and valuable resource from human blood, and waste of blood products might cause safety and management problems in hospitals and regional healthcare system. 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 hospitals to blood center and among hospitals.

5. CONCLUSION

In this study, we focused on identification and data capturing for patient safety. Capturing data and alibi management of materials including blood products leads to effective use of resources as well as improve patient safety as mentioned above. We can certificate each medication and capture those data at the same time, contribute to patient safety and improve health care delivery. 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.

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SERIES 医療機器をめぐる現状と展望 (21)

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医療機器に関わる規制の方向性について

大西 昭郎*1, 佐藤 智晶*2

A Direction of Regulations for Medical Devices

Akio ONISHI*1 and Chiaki SATO*2

1. はじめに

1980年代以降，エレクトロニクスや情報技術，材料技術，そしてバイオテクノロジーなどの分野における技術革新の進展に伴って，さまざまな機器や技術が，医療現場に導入されてきた．CTやMRIの画像を用いた診断や，内視鏡やカテーテルを用いて実施する侵襲度の低い手術，更には，植込み型の機器や材料による治療や疾病管理などが実現してきている．古くから医療用具として扱われてきた医療機器は，その要素技術の技術革新が加速化したことにより，医療そのもののイノベーションにも大きく貢献してきたと考えられる．より広く医療分野では，医療機器に加えて，再生医療や個別化医療などの革新的な技術の開発が進んできており，医療のイノベーションを更に推し進めることが期待されている．

一方，こうした新しい技術の発展は，当然のことながら，医療に関連する制度にも影響を及ぼしてきている．古くから医療に使用される製品として扱われてきた「医薬品」については，その「規制」についての理念や方法論は，長い歴史を通じて，大きな方向性がほぼ確立されていると考えてよいように思われる．しかしながら，新たに登場してきた「医薬品と性質が異なる製品や技術」については，その規制の体系は，必ずしも医薬品での規制の考え方を当てはめることができない．

ここでは，医療機器を例にとって，欧米でのその規制の様子，とりわけ医薬品と医療機器の性質の違いに由来する規制の考え方に主眼を置いて眺めるとともに，わが国における規制の方向性などについても考えみたい．

2. 欧米の医療機器規制の主眼

欧米では1970年代から，医療機器に関する規制を確立してきた．欧米では，医薬品と医療機器の性質の違いを踏まえて，医薬品と異なる制度体系を整備してきている．

以下では，イノベーションの促進を図りつつ，医療上の便益を適切に確保すること，そして医療上の安全性を確保することについて，欧米でどのような取り組みがなされているかを概観する．

2.1 欧州

欧州では，次の2つの点で，医薬品とは決定的に異なる規制が医療機器に導入されている[1]．1つは，各国政府が販売承認をするわけではなく，認証機関（notified bodies）によって各機器の安全性が審査されるという点であり，もう1つは市販前の審査を認証機関に，市販後調査・規制を各国政府に委ねるという形で，規制の役割分担が行われている点である．すなわち，ある医療機器について法律上の重要な要件（legal essential requirements）を満たしていることを確認し，その旨を宣言し

*1 日本メドトロニック株式会社 東京都港区東新橋2-14-1 コモディオ汐留5階（〒105-0021）
Medtronic Japan Co. Ltd., Comodio Shiodome 5F, 2-14-11 Higashi Shinbashi, Minato-ku, Tokyo 105-0021, Japan
*2 東京大学政策ビジョン研究センター 東京都文京区本郷7-3-1（〒113-0033）
Policy Alternatives Research Institute, University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan

て販売する義務が医療機器メーカーに課せられているものの，多くの場合には認証機関の審査を経て医療機器が販売され，その後，各国政府の市販後調査に基づくリコールが控えているというのが，欧州の規制である．

また，欧州では，規制のために工業標準が広く利用されていることも特筆すべき点である．これは，医療機器が医薬品ではなく，あくまで工業製品の1つとして扱われていることを認識させるものといえる．法律上の重要な要件を満たしていることを確認する手続き（conformity assessment）は，原則として工業標準に準拠していなければならない（ISO 9000 or European harmonized Standard, EN 46000）．医療機器メーカーは，販売しようとする医療機器のリスク分類に基づいて，確認手続きを自ら選択することができるものの，それは工業標準に準拠している必要がある．その手続きでは，添付文書を含めて医療機器の安全性が確認されることになり，より具体的にいえば，主に「科学的な知見」（必ずしも臨床試験のデータを意味しない）と「技術的な性能」から安全性が評価されている．そのため，有効性は審査の基準ではない，といわれる．この点が，医薬品との大きな違いである．医療上の有効性の議論は規制の枠組みではなく，医療保険制度や保険償還の観点から，それらを運営している各国や地域，保険機関などによって検討が進められる．

法律上の重要な要件を満たした医療機器には，"CE"というマークが付記される．CEマークが付記されれば，医療機器メーカーは欧州経済地域（European Economic Area, EEA）内でその機器を販売することができる．もちろん，医療機器メーカーは，単に当該域内で販売できる自由を獲得するだけではなく，欧州委員会と各国政府のもとで市販後調査とリコールの義務を果たさなければならない．

以上のような欧州規制の背景には，新しい手法で欧州域内の市場を拡大しようという基本的な考え方があり（いわゆる，New Approach）[2]，欧州評議会レベルでの医療機器規制の導入が進んだ．医薬品と区別する形できめ細かい規制を行い，イノベーションの促進と患者安全の向上が図られることになったのである．たとえば，医療機器規制に関するEC指令は，3つも存在している[3]．欧州では，単に医療機器を医薬品と区別するだけでなく，医療機器のなかでも駆動式植込み機器，診断機器，それ以外の機器を分けて，それらの製品ごとにより適切な，より個別で具体的な規制を行うことにより，イノベーションの促進に加えて，患者を不合理な危険から守ろうとしているのである．

2.2 米国

米国でも欧州とは異なる形ではあるが，医療機器向けの規制が医薬品とは区別して行われている．米国では，連邦健康保健省のもとにある食品医薬品局（U.S. Food and Drug Administration, FDA）が医療機器の審査・販売承認だけでなく，市販後調査とリコールを行っている．医薬品については医薬品評価研究センター（Center of Drug Evaluation Research, CDER）が規制を担当するのに対し，医療機器については各部門に医師を重点配置した医療機器・放射線保健センター（Center of Devices and Radiology Health, CDRH）が，審査などの規制を担当している．

米国では，医薬品等の医療関連製品の規制に関する法律を修正する形で，1978年に医療機器規制が導入された[4]．「修正」というと，法改正前から医療機器規制が存在していたかのような印象を受けるが，当時医療機器には実質的な規制がなく，医薬品規制が代用された時期さえある（食品医薬品局は，医療機器については虚偽の表示による販売を取り締まる権限しか持っていなかった）．いきなり新しい規制，とりわけ医薬品向けの規制を導入すれば，すでに販売されている医療機器は市場から追放されかねず，より新しく優れた機器の上市は著しく妨げられてしまう可能性さえあった．他方，十分な規制なしにこれまでどおりに医療機器を流通させてしまえば，患者の安全を確保することができなくなる．このようなジレンマこそ，米国における医療機器向けの規制を生み出すきっかけになった．

米国の承認申請は，大きく分けて2つある[5]．1つは，通常の販売承認手続き（Pre-Market Approval, PMA）である．原則としてクラス3の医療機器は，食品医薬品局のもとで安全性と有効性を確認されない限り，販売が許されない[6]．もう1つは，1976年当時に販売されていた医療機器の流通及び，当該機器の改良・改善を妨げないために導入された手続きである（Pre-Market Notification, 510k review）．関連法令によれば，クラス2の医療機器に加えて，1976年以前に販売されていた医療機器と後の製品が実質的に同等（substantial equivalence）である場合，その後発医療機器は，通常の承認手続きを免除される[7]．この2つの手続きが相まって，米国では医療と医療機器産業の発展が支えられてきたのである．

興味深いことに，プロダクトサイクルが比較的短く，改良・改善が繰り返される医療機器分野においては，申請全体の約7.4パーセント（2008年度）のみが，通常の販売承認手続きを利用していたとされる[8]．もっとも，2つめの簡易な手続きに依存することについては，最近激しい論争が繰り広げられている．とりわけ，全米科学アカデミー・医学部会は，イノベーションへの寄与が十分に証明されておらず，患者安全の確保からも問題がある，という報告書を2011年8月に公表した[9]．その後も，著名な医学系ジャーナルにおいて論争が続いている[10]．

米国で特筆すべきは，やはり医療機器のリスクに応じた，きめ細やかな臨床試験の規制である[11]．医療機器の安全性と有効性を審査するときに，臨床試験データが重要であるとしても，必ずしも提出が求められないという点では，米国と欧州の間に違いはない．しかしながら，臨床試験の実施について，米国ではより柔軟かつ適切な規制を模索している．たとえば，重大なリスクがある医療機器とない機器で区別が設けられていて，後者については倫理委員会の審査手続きなどの一定の要件を満たせば，食品医薬品局への申請なしに臨床試験を実施できるのが米国である[12]．その試験で得られたデータは審査の際にエビデンスとして提出することができる．また，重大なリスクの有無を判断するためのフィージビリティ・スタディについては，柔軟に申請を認める旨のガイダンスが公表されている[13]．更に，非侵襲的な診断機器の一部については，研究のみの，又は臨床試験のみのための利用とラベリングして販売することも許されている[14]．このような米国の規制は，医薬品と医療機器の性質の違いを踏まえて，医薬品とは異なる形ではあるが，イノベーションの端緒となる臨床試験を阻害することなく，合理的に利用可能なあらゆる手段で患者を実効的に保護しようとする試みであるといえる．

3. わが国の規制制度における検討課題

わが国では，医療機器に関する規制は，薬事法が基本となっている．過去に何度か改正が行われてきているが，2003年の法改正に際して，「医療機器」が法律の中で初めて記述された．この際に，政省令を含め，医療機器に関する規制が大きく見直され，改めて整備されたが，規制の基本的な考え方は，医薬品での規制の考え方がその基盤になっているといえるだろう．

2005年に法が施行されてから6年が経過しているが，この間に，医療機器の規制に関する議論がさまざまになされてきた．いわゆる「デバイスラグ」や「デバイスギャップ」はその象徴的なものである．ここではその詳細は取り上げないが，こうした議論に呼応して，政府が進めている「アクションプログラム」などにおいて，規制や制度の体制の強化や運用上の改善などの施策が実施されてきている．あわせて，これらの議論や施策の検討を通じて，医療機器をめぐる規制についての基本的な考え方が，次第に明確になりつつあるようにも思われる．

ここでは，先に述べた欧米の事例を参照しつつ，わが国の制度における論点を検討課題として提示してみたい．

3.1 法の理念や目的に関して

医療機器に関する規制の本質は，より安全で優れた医療機器を医療現場でより早く使えるようにすること，それによって国民の健康を守ることはもちろん，技術水準の向上や国民経済の健全な発展を実現することにあると思われる．医療機器規制については，欧米でも試行錯誤が続けられており，必ずしも全てが成功しているわけではない．たとえば，欧州では認証機関への規制が，米国では簡易な審査手続き（510k）がまさに見直されようとしている．そこでは，現在利用可能な最善の科学的データと方法を用いて製品の安全性を確保しつつ，イノベーションを促進するような規制が模索されているのである[15]．わが国でも，より透明性が高く，予見可能性のある規制によって，公衆衛生の向上と国民経済の発展を実現するための規制が欠かせない．

3.2 医療機器の定義

医療機器の特性に鑑みた規制を実現する見地からは，医療機器の定義などを含めて，医薬品等の他の製品とは異なる規制の可能性を検討する必要がある．まず，医療機器は医療従事者などを介して，化学反応や代謝によらない物理的な作用を及ぼすことではじめて診断や治療上の効果を発揮する．医薬品とは決定的に異なるこの特性については，欧米の例にならって医療機器の定義などに反映する可能性があるだろう[16]．

医療機器の安全性や有効性の考え方についても，医薬品とは異なるものと考える余地が大きい．医療機器における有効性とは，設計上意図された使用条件で，医療従事者が適切に使用し，設計上意図された機器の性能が十分に発揮される場合にはじめて実現されるものである．他方，医療機器における安全性とは，いわゆる機械としての通常の安全性に加えて，医療現場での使用者の安全性が確保され，かつ想定される危害が意図されている医療上の便益を損なわない範囲にあること，が求められると考えるべきであろう．医療機器は，それらが使用される環境や条件によって医療上に果たす役割に影響が生じると考えられるからである．臨床上の環境や条件を相当程度的確に設定したうえで使用（投与）され，それ自体が効能や効果を発揮する医薬品の場合との違いである．

欧米の間では，安全性と有効性の扱いについて若干の違いがあるものの[17]，少なくとも設計上意図された目的，機能や性能（パフォーマンス），対象患者，そして使用条件（環境）のもとで限定的に評価され，必ずしも臨床

試験データで証明する必要がない，という点で変わりはない．そして安全性に関しては，機器の品質情報の収集や解析がより重要な要素となっている．

臨床現場で絶え間なく改良改善が行われるという点も，医療機器の特性としては見逃すことができない．さまざまな部材を組み立てて生み出されることが多い医療機器では，エレクトロニクス，材料技術，バイオテクノロジーなどの技術の進展に伴い，製品の改良や改善が頻繁に実施されうる．そのような改良改善は，臨床現場におけるニーズに基づいて，開発者が医師などと協力して研究，設計，製造されることではじめて可能となる．そうすると，適切な条件の下で患者の安全を十分に確保しつつ，医師と開発者が協力して，医療機器の改良改善を進められる環境の整備が重要になるだろう．

3.3 業規制・品質保証

加工組み立てという過程を経て製品化されることも，医薬品にはない医療機器の特性である．多くの医療機器は，複数の部材から構成される．化学構造式によって特定されてしまう医薬品とは根本的に異なり，医療機器には設計と製造において代替的な可能性が残されていることから，品質管理の仕方にも配慮が必要になる[18]．具体的にいえば，次の3つの点が問題になると思われる．

第1に，業規制の対象である．本来，医療機器の製造販売について規制を受け，責任を負うのは最終製品の設計，品質管理，購買管理に責任を負う者であり，部材を供給する者や関連サービスを提供する者ではない．他の多くの加工組立産業の製造物と同じように，医療機器の場合にも，部品や材料の供給者や加工などのサービスの提供者は，最終的に製品を製造して販売する者とは異なる義務を負っている．すなわち，部材の供給者や加工サービスの提供者は，いわゆる部材や加工サービスの具体的な危険性について，最終製品の製造者や販売者に適切に警告して部材やサービスを提供すればよく，医療機器の危険性については，最終製品の製造者や販売者が責任を負うのが原則，ということである．医薬品の場合には，部材の供給者や関連サービスを提供する者の規制について検討する余地はほとんどないが，医療機器の場合には十分な検討を要する．なお米国では，医療機器規制とは別の観点ではあるが，医療機器，なかでも植込み型の医療機器のための部材供給を安定的に確保する目的から，1998年に医療機器に生体材料を提供する者が負う製造物責任について，特別に法律（Biomaterials Access Assurance Act）を制定し，原則として部材供給者が最終製品の製造物責任を負わないこととしている[19]．医療機器の特徴に由来する医薬品とは異なる法制度という意味で注目に値する．

第2に，改良改善を妨げないような品質保証のあり方についてである．医療機器の場合，設計上の改善や改良はもちろん，製造工程や検査工程の改善や改良の可能性がある．これらを促しながら，品質の確保が実現できるようにするためには，他の加工組立産業と同じような品質マネジメントシステム（QMS）の思想が欠かせないのではないか．

第3に，国際的な整合と実情の反映である．製造業の許可については，国際的な整合性を更に高めることが1つで，もう1つは品質保証に関する具体的な規制内容のあり方として，国際標準化機構の工業標準などを利用する可能性がある．また，医療機器には製造業のほか，医薬品にはない修理業などの業態が存在している．より安全な製品を臨床現場にいち早く届ける見地からは，医療機器の業態として修理まで含めて，適切な業態規制のあり方を議論する必要があるだろう．

3.4 市販前と後の規制のバランス

医療機器の規制にあたっては，市販前と市販後の規制のバランスを図ることが極めて重要である．先に説明したとおり，欧州では，市販前と市販後で規制主体を分け，限りある優れた人材や予算をより効果的に活用している．わが国でも，医療機器の審査や調査について医薬品医療機器総合機構の役割を強化するだけでなく，医療機器の特性に十分照らして，十分な能力がある第三者機関の利用可能性を検討する余地がある．すなわち，市販前と市販後の規制のバランスをどう取るのか，新しい技術を用いたリスクの高い製品とそれ以外を区別するかどうか，品質保証をどうやって図るべきかを十分に検討し，臨床現場において改良改善される医療機器の導入や利用を妨げないような規制のあり方を模索してはどうか．

4. 結びに代えて

医療機器の規制に関する法においては，規制の透明性と予見可能性を高めるために，基本的な考え方を明確にすることが重要である．運用や解釈に多くを委ねることは，制度の透明性が確保しにくいばかりでなく，産業界からの投資や参入の阻害，イノベーティブな技術や製品の医療現場への導入の遅れなどを招き，社会全体のコストを増大させる結果につながるおそれがある．欧米の例は，そのことを如実に物語っている．

われわれは，医療機器のイノベーションを促進するために，最低限どのような規制をすべきなのかについて，今後，さらなる議論が必要である．その際には，欧米の方向性を十分に参考にすべきであろう．医療機器の規制については，欧米でも歴史的な背景を踏まえつつ，今なお試行錯誤を繰り返している最中であるともいえるが，規制の考え方や理念に関しては一定の方向性を見いだせるからである．また，こうした方向性についての見識を深めることは，医療機器だけに留まらず，医療分野でのイノベーションを牽引すると考えられるさまざまな技術についても，その規制の考え方を検討するうえで大いに参考になることと思われる．

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解説特集：看護を測るME

タイムスタディによる看護業務プロセスの可視化

清水佐知子[*,**]・大野ゆう子[*]・岩佐　真也[*]・尾島　裕子[*]・林　剣 煌[*]
冨澤　理恵[*,***]・大西喜一郎[*]・本杉ふじゑ[†]・岡田　千鶴[††]

Visualizing Nursing Work Process using Time and Motion Study

Sachiko SHIMIZU,[*,**] Yuko OHNO,[*] Maya IWASA,[*] Hiroko OJIMA,[*] Jianhuang LIN,[*]
Rie TOMIZAWA,[*,***] Kiichiroh OHNISHI,[*] Fujie MOTOSUGI,[†] Chizuru OKADA[††]

1. 緒　　言

看護師は，目的や環境，患者や他スタッフの行動や状態を認識して自分の行動を自律的に決定する自律分散型業務である．換言すれば看護師は不確実性の下で柔軟に意志決定し行動している．この性質ゆえに看護業務は個別状況的であり，そのプロセスは論理的把握が困難であると言われている．

看護師の業務分析に関して，これまでのところ業務量（業務所要時間）に関する研究が先行しており，業務の構造化，即ち業務プロセスの定義や視覚化，他生産領域で蓄積されてきたような業務プロセスをめぐる学術的研究の蓄積は乏しい．しかしながら，業務プロセスの改善を行う上で，業務を論理的に関連した活動の連鎖として捉え，明示化することは必須である．

そこで本研究は，作業測定法の一種であるタイムスタディ調査結果を基に，看護師の患者移送業務の構造を明らかにし，その可視化を試みるものである．表現手法として，オブジェクト指向による業務モデリングを行う．

* 大阪大学大学院医学系研究科
Osaka University School of Medicine
** 神戸大学大学院国際協力研究科
Kobe University Graduate School of International Cooperation Studies
*** 千里金蘭大学看護学部
Senri Kinran Universty Faculty of Nursing
† 国立循環器病研究センター
National Cerecral and Cardiovascular Center
†† 独立行政法人国立病院機構奈良医療センター
National Hospital Organization Nara Medical Center

2. タイムスタディからタイムプロセススタディへ

タイムスタディとは特定の人間の行動を実際に測定する手法であり，その結果は看護業務量の測定[1-3]やワークフロー分析[4]，動線解析[5]のみならず，業務スケジューリング[6]，効率的人員配置[7,8]の基礎資料として，また電子カルテシステムの導入といった病院内システムの変更の評価指標として用いられており[9]，国内外問わず多くの研究蓄積がある．

具体的には，タイムスタディは連続的観察により作業の生起毎に計時記録するものと定義される．タイムスタディと同じく作業測定手法の一種に，測定条件として計測間隔を予め決めサンプリング的に作業を把握するワークサンプリングがある．ワークサンプリングは，作業を全的に把握することはできないが，測定者負担は軽く作業者自身が計時記録することも可能である．これに対しタイムスタディは作業を全的に把握することができるが測定者負担は大きい．特に生起の少ない作業について，両手法の結果は大きく異なることが指摘されており[10]，現時点ではタイムスタディによる連続観察による作業測定による結果がゴールドスタンダードであると言える．

しかし一方でタイムスタディによる測定結果を用いた研究の多くは全看護業務を対象とし，清潔ケア，食事ケア，排泄ケアといったケア単位で業務量を検討するのみにとどまっている．特に特定の業務に注目し，業務プロセスを明らかにした上で業務量を評価した研究は少なく，看護業務とは異なるが，Shiki et al. によるがん患者登録業務のプロセス可視化と業務量把握のみである[11]．Shiki et al. は「タイムプロセススタディ（プロセスに時間情報を付加した業務可視化手法）」を提案しているが，プロセス，業務

量ともにインタビューによる見積測定であり，その客観性に乏しいと言える．そこで本研究では実測作業測定法であるタイムスタディ調査を行い，患者移送業務に注目し，そのプロセスを明らかにするものである．明示化されたプロセスと時間情報により業務プロセス可視化手法の可能性について検討する．

患者移送業務は病棟外での業務実施が多く，看護師の身体的精神的疲労を伴うものであり，患者安全の視点からは患者移送で看護師が病棟外へ出ることにより，病棟内スタッフの人数が少なくなる点からも注目すべき業務である．

3. 対象と方法

循環器専門治療施設4病棟を対象とし患者移送に関する看護業務のタイムスタディ調査を行った．対象者は患者移送に関わる看護師，看護助手，医療クラークとし，作業発生時点から終了時点まで作業者に測定者が追尾し，業務行動を記録した．記録した業務行動とは対象看護師の行動内容，開始時間，終了時間，対象者，場所であった．また，4病棟の内訳は心臓血管内科心不全病棟，心臓血管内科不整脈病棟，心不全・心筋症・肺高血圧症病棟，脳血管代謝内科病棟であった．なお，移送先としては，CT，X線撮影，MR，心エコー，呼吸機能検査，心臓リハビリ，脳リハビリ，心臓カテーテル検査，透析等の各検査室が挙げられた．

得られたタイムスタディ記録より，ユースケース図，アクティビティ図を作成した．ユースケース図，アクティビティ図とは統一モデリング言語（Unified Modeling Language：UML）の表記法によるダイアグラムの1種である．UMLはオブジェクト指向に基づく表記法のデファクトスタンダードであり，ソフトウェア開発分野で発展してきた言語であるが，近年UMLによるビジネスモデリングが提案されている[12]．この理由として，業務の構造が資源や利用者といったオブジェクト間のメッセージ交換として捉えることができ，オブジェクト指向の考え方と同じである点，UMLによる表記法が直感的に理解可能である点が挙げられる．本研究ではUMLユースケース図により患者移送業務の機能的側面を明示化した．また，アクティビティ図により患者移送業務プロセスを可視化し，最後にアクティビティ図に時間情報を加え業務負担と時間効率について議論した．なお本研究は対象病院の倫理審査委員会の承認を得て行った．

4. 結　　果

タイムスタディ調査により記録した患者移送業務は213件であった．業務記録レコード数は3,775件であり，内387件は患者移送業務ではない業務記録であったため分析から除外した．

タイムスタディ結果より抽出したユースケースを図1に図示する．患者移送に関与するアクターは看護師，リーダー看護師，医療クラーク，看護助手，中央診療部門，オーダーエントリシステム，病院情報システムの7種類であった．看護師は勤務帯のリーダーの役割を担うリーダー看護師と患者を受持ち，ケアを提供するスタッフ看護師に区分される．リーダー看護師と医療クラークは，患者移送の連絡を受付けし，予め決められている移送ケア方法を確認していた．リーダー看護師はこれに加え，移送実施者の変更や適任者の探索といった調整を行っていた．また，看護師，看護助手は移送ケアのうち患者に直接関わる業務を担っていた．対象病院では酸素療法中の患者や心電図装着者，輸液中の患者は看護助手ではなく看護師が担当していた．

患者移送業務の動的側面をアクティビティ図に示す(図2)．病棟連絡担当者であるリーダー看護師や医療クラークは中央診療部門からの患者呼出しを受け，患者カルテから安静度を確認する．患者1人で病棟外までの歩行が可能であれば（独歩），連絡担当者はカルテ，診察券，検査室までの地図を準備し，患者を探して検査呼出しを伝え，必要物品を渡す．一方，安静度が護送（車椅子移送）または担送（ストレッチャー移送）であれば，連絡担当者は移送担当者を探し，検査呼出しを申し送る．移送担当者はカルテ，診察券を準備し，車椅子やストレッチャーといった移送ケア用具を準備し患者の元へ搬入する．その後患者に検査情報を伝え，患者の状態をアセスメントし移送可能か否か判断する．移送可能と判断すれば，酸素や輸液を移送可能なよう準備し，排泄のケアや更衣の介助を行う．その後，患者をベッドから移送ケア用具へと移乗し，検査室まで移送する．検査室に到着後，検査受付で患者到着を知らせ，患者を受け渡しし，カルテや診察券といった持参物品を引き渡す．X線検査のように検査が短時間で終了する場合，移送担当者は検査室で待機し，患者の検査準備を介助し，

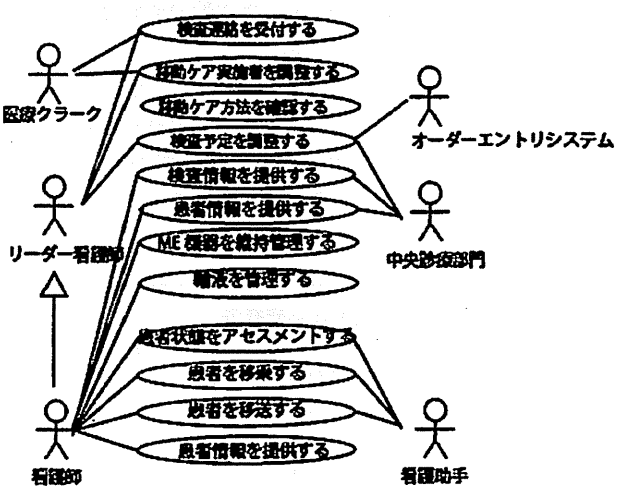

図1　患者移送業務のユースケース

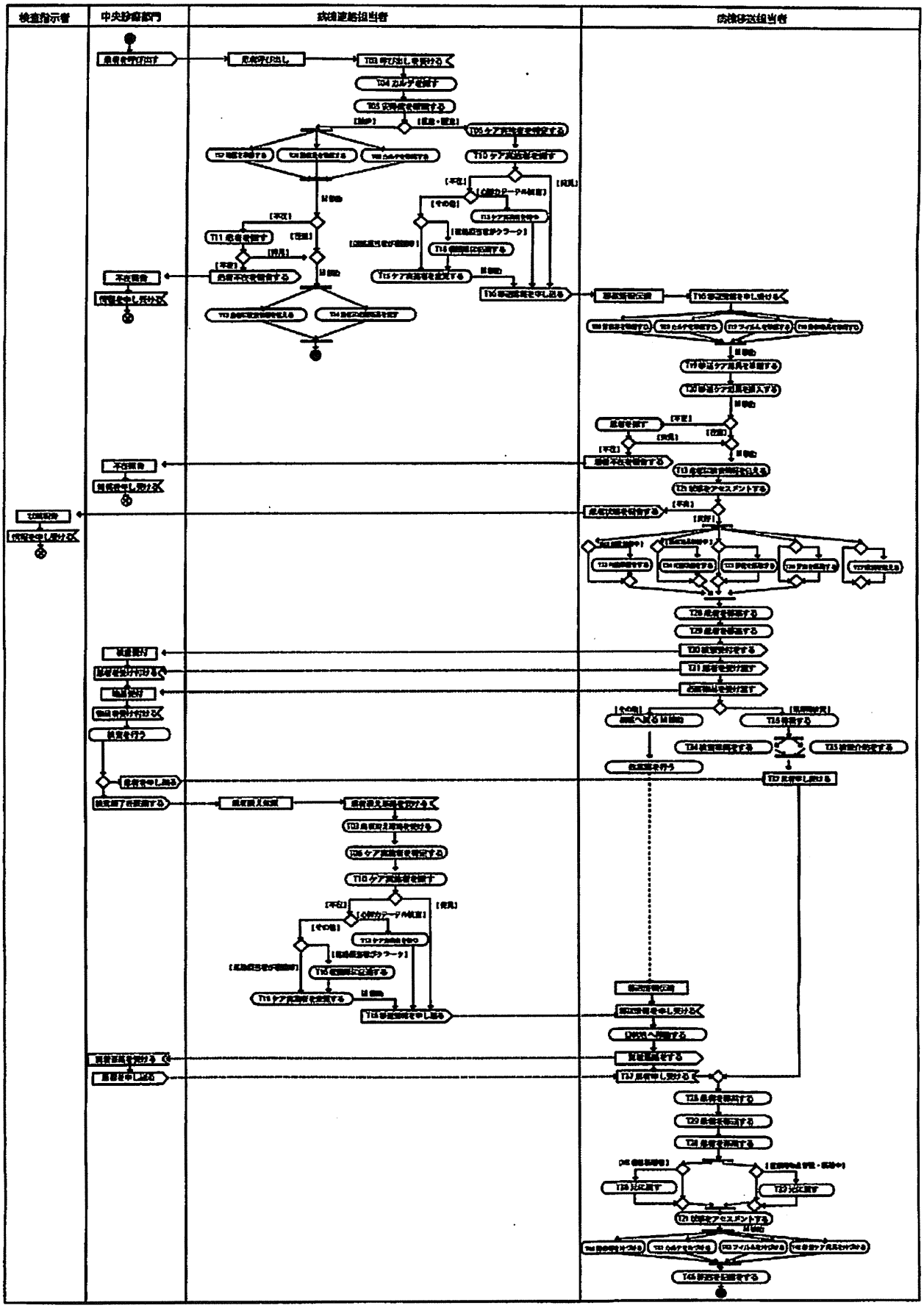

図2　患者移送アクティビティ図

検査介助をする．検査が短時間で終了しない場合，移送担当者は病棟へ戻り別業務を行い，検査室からの迎え連絡を受けて検査室へ移動する．検査終了後は検査室から患者を申し受け，移送ケア用具へ移乗し，病棟まで移送し，病室のベッドへ再び移乗する．ME機器や装着中の医療物品をベッド上生活可能なよう整え，患者の状態をアセスメントした後，診察券，カルテといった持参物品を片づけ，移送記録を行う．アクティビティ図により患者移送業務プロセスが47のタスクより構成されることが明らかとなった．

アクティビティ図で示した47のタスク別に4病棟各1日間の所要時間合計，発生件数，平均値，中央値，標準偏差，範囲を示す（表1）．合計所要時間量が最も多いものは，「T29 患者を移送する」（9：15：49）であり，1件あたり平均5分患者移送を行っている．記録された患者移送213件中109件が実際の患者の移送を伴うものであった．患者移送を伴わない患者移送業務とは，独歩患者への対応や検査予定時間調整のみの業務であった．次いで所要時間量が多いものは「T36 目的地で待機する」（1：57：19）であり，さらに「T28 患者を移乗する」（1：46：59）であった．一方，「T06 ケア実施者を特定する」「T12 ケア実施者を待つ」「T15 ケア実施者を変更する」といった移送担当者の探索や変更に関するタスクは発生件数が少なかった．変動係数を比較すると，「T41 カルテを片づける」「T16 看護師に検査情報を伝える」「T36 目的地で待機する」「T21 状態をアセスメントする」で変動係数が高く，「T29 患者を移送する」や「T43 移送ケア用具を片づける」では変動係数は相対的に低かった．

業務分類別所要時間を表2に示す．直接業務とは直接的に患者に対して行う業務であり，間接業務とは直接業務のための準備や片づけを含む，患者に直接接することなく行う業務である．患者移送の約60%を直接業務が占め，間接業務は14%程度であった．

5. 考　　察

タイムスタディデータを利用しオブジェクト指向に基づく業務プロセス可視化により第一に，業務責任者の所在と役割が明らかとなった．機能的側面から患者移送業務の主たる担い手は看護師であるが，連絡調整に医療クラーク，ME機器や輸液の留置・装着を伴わない患者の移送に看護助手が関与することが示された．医療クラークは検査の連絡を受けカルテにて移送ケア方法を確認するものの，実施者の変更や業務委任の権限は無く，リーダー看護師に委ねられている点が明らかとなった．さらに病棟連絡担当者は独歩患者については，連絡担当者が医療クラークか看護師であるかに関わらず患者への検査情報の伝達まで責任を負うことが示された．また，護送，担送患者の場合連絡を受けてから担当者に検査情報を申し送るまでの責任を負い，連絡担当者がクラークの場合，ケア実施者の変更権限がないため，リーダー看護師へ業務を委ねることが示された．このプロセスで最も時間を要するタスクは「患者への検査情報の伝達」であり，次いで「カルテの準備」「診察券の準備」であった．診察券の利用は入院患者の外来受診，検査受診時に限られており，収納場所も固定されているのに対し，カルテは医師，看護師，医療クラーク，その他医療従事者の複数が様々な用途で利用するためカルテ探しが発生しており，カルテ準備の所要時間が長くなっていた．連絡担当者から移送担当者へ情報伝達がなされた後，移送記録まで移送担当者が全ての責任を持つことが分かった．

第二に広く臨床で用いられている業務手順書と実際の業務プロセスの乖離が示された．対象病院の業務手順書では，「患者を探す」「移送担当者を探す」「移送担当者を変更する」「（検査室で）検査準備をする」「検査介助をする」といったタスクは明示されていない．この理由として業務手順書が標準的手順について書かれており，業務プロセスで注目すべきイレギュラーな事象や重複作業を念頭に置いていない点が考えられる．また，業務手順書は個人の看護師の業務手順として書かれており，先述したような業務責任者の所在と役割が明確ではない．本研究で実際の業務記録に基づく業務プロセス描画により，

第三にプロセスに時間情報を付加することで，業務の稼働効率が示された．稼働効率は業務プロセス改善で最も注目すべき点である．タスク別に所要時間及び時間のばらつきが示されたことにより，患者移送ケアを構成する時間要素が明らかとなった．今後制約条件により所要時間がどのように変化するか詳細に検討していくことが求められる．

第四にリスク分析が可能となった点が挙げられる．本研究により最終的に患者移送を構成する業務タスクとして47タスクが抽出され，タイムスタディ記録によりその順序関係が明らかとなった．これにより，各タスクの入力と出力が明確化され，またイレギュラー例の頻度も明らかとなった．「患者を探す」「看護師を探す」といったイレギュラー事象は今回の調査で記録された業務の目標達成を阻害するリスクと言えよう．今後タスクひとつひとつに注目し，それぞれの出力を阻害する因子を明らかとすることで，患者移送業務の抱えるリスクをタスク毎に抽出することが可能であり，安全やケアの質向上といった議論が可能になると考える．

6. 今後の展望

本研究により患者移送業務構造が可視化された．患者移送業務は患者の状態や検査の種類，業務発生時間により扱うオブジェクト，プロセス，時間効率が大きく異なることが示唆された．また，業務発生が不定期であることが多く，かつ迅速な対応を要するため，看護師は他業務との調整を図りつつ患者移送業務を遂行しなければならないことが明らかとなった．