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

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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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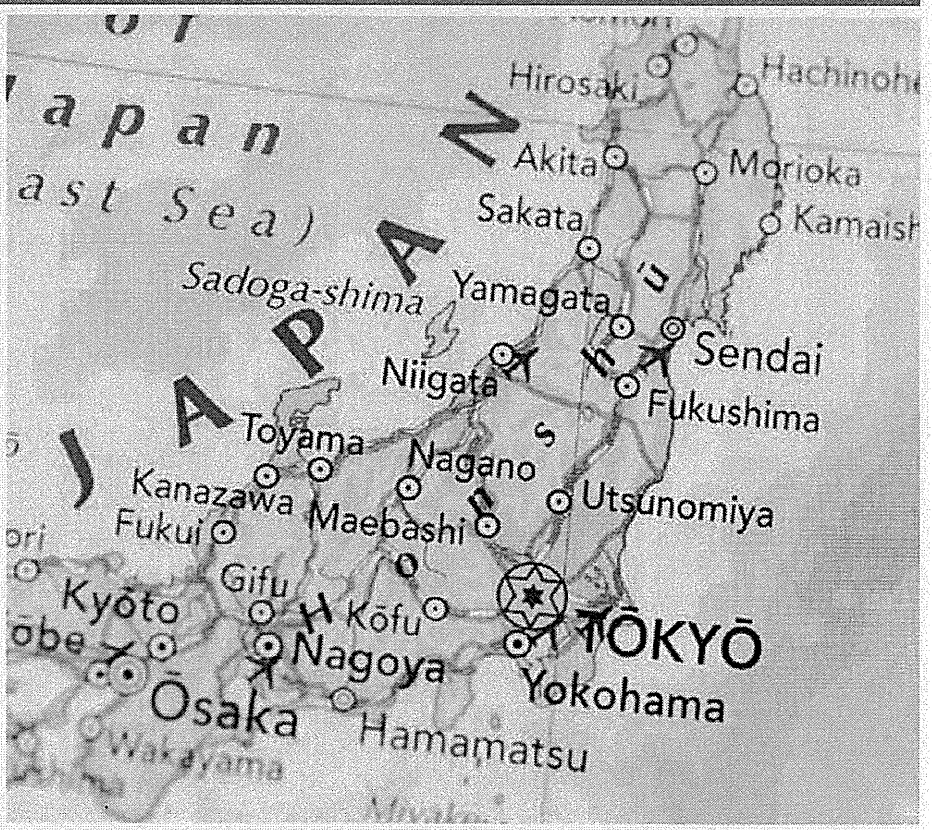

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FOREWORD

The Center for Strategic and International Studies (CSIS) in the United States and the Health and Global Policy Institute (HGPI) in Japan launched a joint project to create a dialogue on major health care policy issues and solutions in the two nations in early 2011.

In both nations, new health care policies will clearly be necessary to meet citizens' current and future demands for affordable, available, and quality health. Greater efficiencies in health care will be essential for each nation to renew and sustain economic growth over the long term.

This dialogue among national experts and senior leaders is based on the opportunities to learn from the overall similarities of the two nation's health care systems. Both the Japanese and the U.S. health care systems have multiple insurers, a fee-for-service payment system, and thousands of independent hospitals and physicians.

The project—for the first time—introduces experts and leaders from Japan and the United States to the similarities of the two nations' health care systems' problems and solutions.

The goal of the project is to generate fresh analyses and recommendations in critical areas of health care in Japan and the United States. It provides an opportunity for informed discussion of pragmatic next steps to address priority health care concerns. It aims to generate pragmatic and actionable options in each key policy area that can increase the efficiency and quality of health care.

This project's initial efforts focused on options for health care policies that addressed the development of health care information systems and the design of hospital payment reforms. The CSIS/HGPI report Information Technology in Health care: e-Health for Japanese Health Services was authored by Masanori Akiyama, MD, PhD, and Ryozo Nagai, MD, PhD. This report provides challenges and recommendations for Japan in introducing e-health.

After the Japan-U.S. Health Policy Dialogue was initiated by CSIS and HGPI in January 2011, the Tohoku earthquake, tsunami, and radiation disaster occurred on March 11. It has now been agreed by CSIS and HGPI that the next phase of the Japan-U.S. Health Policy Dialogue will shift the project's focus to collaborative U.S.-Japan efforts to the respond to the health implications of the disaster.

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INFORMATION TECHNOLOGY IN HEALTH CARE

E-HEALTH FOR JAPANESE HEALTH SERVICES

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Introduction

As Japan faces rapid aging, a declining birthrate, widening income disparity, expanding fiscal debt, and remarkable hikes in health care costs, the sustainability of its health care system is at stake. Despite the need to allocate limited medical resources optimally, Japan lacks a common platform for sharing medical data, ideally over the Internet. The potential benefits of health information technology, or health IT, are not well known among patients, practitioners, or policymakers. Electronic patient records are not available from one hospital to another and are isolated from the Internet due to privacy concerns. Clinical practitioners have no remote access to patients' information when away from a particular hospital or clinic. Unique medical data, stored individually in each hospital or clinic, is vulnerable to accidents and natural disasters. The Tohoku disaster demonstrated the absence of a reliable backup for health data, the challenge of data management during an emergency, and the dangers of prescribing drugs with insufficient access to medical records.

It is therefore critical to move toward an improved, Internet-ready health IT system. An e-health system presents an effective and efficient means to reduce costs and improve the quality of health care services. Moving forward on a discrete set of sensible policy and operational reforms is possible and timely, as the Tohoku disaster provides a mandate to change the way the Japanese health system operates.

Why e-Health?

The ultimate measure of medical practice is the health of the patient. Failure to share data not only affects patients' health and quality of life, but also burdens the national economy with immense medical expenditures. Developing a disease registry and sharing data through a comprehensive medical information network would help identify useful trends in serious clinical events, such as stroke and heart failure.

A primary goal of electronic patient records is to collect all essential data. The input forms have required fields, and the electronic format minimizes the risk that information is subsequently

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lost. For example, the electronic records used in primary care include recording templates to ensure that key demographic, clinical, physiological, biochemical, and pharmaceutical variables are collected systematically, in a standardized manner for all patients.

Data integrated across medical centers would enable efficient detection of any adverse effects of drugs and medical devices. The construction of a comprehensive network of electronic records is essential to detect adverse effects as quickly as possible.

At present, Diagnosis-Procedure Combination (DPC) data are used to compare treatment methods and costs for the same disease across medical institutions, with the aim of improved medical decisionmaking. Until DPC data are integrated with electronic patient records, however, it will be difficult to determine the best use of limited medical resources.

Health IT is a solution to many of the challenges Japanese health care faces. In particular, e-health improves patient safety at the point of care: it facilitates better clinical decisions; it saves time for doctors; and it reduces prescription-drug-related error. Health IT makes it easier to evaluate essential data on the patient's identity and medical history, as well as medicines to be used and medical personnel required, every time a new intervention is needed.

New technologies have the capacity to extend and replace existing clinical and administrative processes in health. Technological innovation is one component of a larger process of change, which will ideally represent a new way of working, an attitude and a commitment for networked thinking to improve health care at all levels.

Issues with the current system:

1. *The current Japanese health care system presents five primary obstacles to effective e-health:* No interoperability among different systems: Each manufacturer provides electronic record systems with highly complicated specifications incompatible with other systems. In the interest of privacy, electronic patient records are disconnected from the Internet, making them inaccessible to clinical practitioners outside that particular hospital or clinic and preventing telemedicine. Moreover, storing medical data within each hospital or clinic causes severe difficulties in the case of an accident or natural disaster, in which physical records may be lost or destroyed.
2. *Insufficient privacy protections:* Because clinics and hospitals have not sufficiently invested in the security of their own electronic record systems, have not fully understood the benefit of Internet access to electronic records, and have proven unwilling to take any risks of data leakage, connecting electronic patient records to the Internet is not seen as a practical option. Japan lacks practical standards for protecting patient medical data. The government's guidelines remain vague and fail to designate the institutions responsible for ensuring compliance with national privacy law. This lack of clarity deters clinics and practitioners from connecting electronic patient records to the Internet, as they fear potential government penalties.
3. *No universal registry of hospital and clinic data:* A comprehensive disease registry is essential to provide data for future clinical studies. Japan lacks a system that would enable hospitals and clinics to share daily treatment data. Insufficient financial support has prevented the development of such a system, as has hesitance to connect patient records and electronic charts to any independent registry. Effective clinical outcomes are possible at less cost if Japan can aggregate sufficient population-based health data to develop new medicine, clinical trials, and other research to improve treatment. Furthermore, the accumulation of such data, knowledge, and

experience will raise the effectiveness of medical practice and prevent harmful side effects by incorporating feedback from clinical practitioners.

4. *Bureaucratic divisions:* Jurisdiction over electronic patient records overlaps among the Ministry of Health, Welfare, and Labor, the Ministry of Economy, Trade, and Industry, the Ministry of Education, and the Ministry of Internal Affairs and Communications. Ministries have no incentive for cooperative planning to promote compatibility among electronic record systems. Only after the recent Tohoku earthquake is the MyHospital Project finally underway. The project, run by the Ministry of Internal Affairs and Communications, aims to establish a communication system in which clinical practitioners can check patients' prescriptions from outside hospitals and clinics. The MyHospital Project is only a preliminary trial, however, and the Japanese government needs to promote such a compatible system vigorously and in unity.
5. *Potential for clinical error:* Even as new clinical decision support systems are introduced, significant gaps exist in the data on which new tools are based. There is a risk that the increasing sophistication of such tools makes these gaps and potential errors in design less visible.

   Furthermore, the impact of incorrect recommendations by clinical decision support systems extends beyond the risk of harm to the patient in question. If clinical decision support systems are perceived to produce unreliable reports, clinicians will be reluctant to use such systems in routine practice, negating their potential benefits. Active quality assurance—such as algorithms that check the consistency of the systems' outputs—will be necessary to assuage these concerns and mitigate the risk of covert, behind-the-screen error. An effective interface that requires active confirmation of inputs can limit user error, but interfaces that are confusing or illogical can induce errors by even the most skilled users. Successful interface design requires a detailed understanding of how a technology will be used and in what work environment to predict errors that might arise and plan for them.

Three Key Principles

What would a comprehensive e-health system look like in practice at the clinical level? Implementation of an effective health IT system would rest on three primary priorities:

1. *A shift from a financially oriented system to an integrated one:* Although hospital information systems in Japan have long been focused on the financial aspects of health care, efficiency has not been appropriately addressed. The Japanese billing system uses an "insurance disease name" to specify how the practitioner should be reimbursed and therefore pays for whatever tests and operations are performed or resources used, providing little incentive to reduce usage. Ostensibly, the primary role of health information systems is to manage patient information and to centralize ordering. The existing systems, however, have been used primarily for preparing medical payment requests.

   As a result, the existing systems cannot handle and do not receive data on clinical activities that are irrelevant to medical insurance payments. In these circumstances, when certain expenses are not covered by medical insurance, it has not been possible to make accurate cost calculations for materials and personnel based on the data in the medical financial systems. The problem is that clinical systems have served primarily as a means of supplying the appropriate billing

information to the health information services, rather than as a means of providing medical practitioners with the clinical information they need.

Therefore, it is necessary to change from a financially oriented system to an integrated architecture that supports billing and medical workflow management. Calculating medical care costs, with all of its difficulties, has become possible with the Point of Action System (POAS), a design feature of a comprehensive medical information system. POAS allows input into logs and inventories as clinical activity unfolds—at the "point of action"—creating a real-time record of which practitioner did what to which patient, when, where, using what, and for what reason. Over the last nine years, a POAS system has been in continuous operation at the International Medical Center of Japan, handling 100 transactions per second, or 360,000 per hour. Such a system improves hospital operation and encourages best medical practices, though its installation requires a complete overhaul of the system design.

2. *The introduction of e-prescriptions, as well as electronic identification and tracking of patients and drugs:* Prescription errors are among the most common medical mistakes and risk death or disability for the patient. Although most serious problems originate with the initial prescription order, errors are possible at each stage of the process:
   - Decision errors—failing to account for relevant comorbidities, the patient's use of other medications, previous reactions, and the like;
   - Calculation errors—failing to calculate the appropriate dosage;
   - Communication errors—failing to write the drug and dosage correctly and legibly, prescribing drugs for the wrong patient, providing ambiguous directions to the pharmacy, or processing prescriptions too slowly;
   - Monitoring errors—failing to track drugs for which accumulated toxicity requires time-limited or closely monitored treatment;
   - Slips or attention errors—packaging drugs under the wrong label or at the incorrect dose, or dispensing drugs to the wrong patient.

   Electronic systems offer not only to process prescriptions more efficiently but also to inform and enhance the safety of clinical decisions. Like other decision support systems, e-prescriptions record and display relevant details in real time, making essential information more accessible to practitioners and reducing their propensity for mistakes. Increasingly sophisticated tools can integrate relevant history—such as recent laboratory results—with risks and contraindications specific to each medicine. Designed correctly, e-prescription software interprets data, flags potential mistakes, presents prescription information unambiguously, and transmits it electronically to those who need it.

   POAS functionality and e-prescriptions go hand in hand with more efficient electronic identification and tracking of patients and drugs. Identification and tracking technologies—typically using bar codes—are pervasive in commercial settings but have yet to realize their potential in health care. The implementation of such a system—labeling prescription drugs with bar codes and asking patients to wear tags with bar codes or radio frequency identification (RFID) chips—makes it easier to provide the right drugs to the right patient and, as part of a broader clinical decision support system, lowers the risk of doctor error.

An integrated identification and tracking system also provides extensive data on hospital processes, the flow of practitioners, tests, procedures, and the use of drugs and other resources—creating a natural resource for studies on clinical practice and a forensic tool to reconstruct the journey leading to any clinical incident. Similarly, bar code and RFID provides real-time stock management capabilities, as a central computer system tracks hospital resources.

A potential concern is the current lack of regulatory oversight and consistency among systems. For example, prescribing systems are exempt from federal oversight in the United States and the United Kingdom. While empirical benefits—including a reduction in preventable adverse events—have been shown with in-patient care, these studies have generally been carried out in centers of excellence with home-grown software. A 2000 Cochrane review suggested that dosage advice can decrease adverse drug reactions and can improve performance with drugs that pose a toxicity risk. The efficacy of systems that flag drug interactions and allergies is also unclear. Clinical decision support systems that include drug management appear to improve clinical performance, but have not shown concomitant benefits in terms of patient outcomes. When flagging systems are optional, they appear to be used infrequently, while routine flagging may come to be viewed as an unwelcome distraction. In a 2002 survey of UK general practitioners, 28 percent admitted to frequently or very frequently dismissing electronic alerts without reading them. These concerns suggest the need for a comprehensive system that supports decisionmaking in redundant fashion, looking for mistakes at each level of the clinical and drug-dispensing process.

Adverse Clinical Events

Worryingly, clinical events that risk harm to patients appear to be extremely common. With increasing social demand for the prevention of medical accidents, the Ministry of Health, Labor, and Welfare in Japan began collecting data in 2001 on "medical near-misses and adverse events" in order to analyze case studies and identify measures to improve medical safety. In 2004, the Japan Council for Quality Health Care took over the collection of incident case studies.

Most events have a mixture of latent and active contributory causes, which complicates their analysis and makes it difficult to identify strategies for prevention. Each "fix" has a cost-benefit profile, and changes to established processes present their own safety implications.

Although high rates of reporting have reduced adverse events in other industries, there is significant underreporting in health care, as the process is voluntary. The reasons for this are complex and include fear of blame, organizational culture, lack of reminders, and other demands on time.

Automated post-hoc identification of adverse events holds significant promise to address underreporting issues. Data-mining technology can help identify threats to patient safety, particularly clusters of adverse events or deaths following health care interventions.

3. *Careful management of the transition to new technology:* The effects of dramatic changes to current practices and familiar tools can be difficult to predict and must be managed carefully. The introduction of new technology can change the behavior of users, who may resist new systems, use them incorrectly, or miscalculate how much time and attention various tasks now require. Introducing new systems too quickly or failing to address these possible effects carries the risk of patient harm. By designing user-friendly systems and making the case to clinicians for the utility of new tools, however, policymakers and leaders in the health care industry can facilitate adoption of e-health technology.

There are a number of methodologies for evaluating new health IT tools. The critical gap between the benefits anticipated from theoretical work and those realized in clinical practice can only be addressed through well-designed evaluation programs. Successful evaluation programs involve systematic planning and oversight throughout the life span of each technology, as the challenge shifts from implementing new tools to maintaining them—training, sustainability, and service-level issues. A robust strategy must also identify and address the unpredicted consequences of new technologies, a task that may extend beyond the implementation phase. Measuring the impact on patient safety should be a recurring and explicit program of work throughout the life cycle of every relevant IT tool.

Policy Recommendations

The implementation of a comprehensive health IT system throughout Japanese health care will necessitate support and e-health–friendly policies at a national level. If Japan is to see cost savings and improved clinical outcomes through health IT, the Japanese government should:

1. *Adopt a long-term goal and strategy:* Japan needs to establish a long-term vision for e-health. The long-term goal is to achieve a sustainable health system with optimal utilization of limited medical and financial resources by making e-health the foundation of Japanese health care. Japan needs a common platform for sharing medical data over the Internet. Designing a standardized system calls for national leadership, perhaps including a National Council for Health IT, established under a cabinet office and chaired by the prime minister.
2. *Create incentives for participation:* To make e-health sustainable, Japan needs to create incentives for hospitals and clinics to contribute health and treatment data within the existing insurance structure. It is important to start with a voluntary or opt-in/opt-out mechanism. Eventually, making insurance repayment conditional on participation in a national registry could provide an incentive to keep the database robust and sustainable.

   The Japanese government should also look to eliminate the disincentives that deter participation in a national e-health system. Ambiguity about government privacy regulations and concerns about the security of electronic patient records, as discussed above, are sources of concern that can be addressed with policy clarity and well-designed technology.
3. *Adopt a national health ID:* The current discussion of national ID—led primarily by the Ministry of Finance—focuses on the introduction of a social security ID for social welfare and taxation purposes. The introduction of a health ID is less controversial, however, and should be discussed separately. The first phase of a health ID system should not be mandatory but should instead offer opt-in or opt-out options. The voluntary contribution of health data tied to personal IDs could establish the basis of a more comprehensive e-health system.
4. *Standardize electronic patient records:* The standardization of electronic patient records has been discussed, but these discussions have so far focused on the convenience of the individual patient and not on using medical information to evaluate the present state and effectiveness of medical practice. Consistent medical records, available electronically and comparable to each other, would allow epidemiological analysis and cost-effectiveness studies in real time, providing data for medical policymaking and guiding medical innovation.

5. *Regulate e-health software:* A recurring theme in health IT is the lack of regulation for medical software. Japanese regulatory authorities have significant scope to exact the same demands for reliability as in other industries in which software tools are mission critical. The complexity of medical systems is often cited as a barrier to regulation; however, simple parameters like system upload time are easily measurable.

   Standards in health informatics focus on two main areas: data capture and data exchange. Regulations in both categories hold the potential to address a number of issues. Ensuring that data inputs are comprehensive is essential for many tools with potential clinical benefits, such as e-prescriptions and clinical decision support systems. Facilitating data exchange likewise has direct safety implications: systematic transfer reduces the likelihood of transcription errors and physical loss of data. When patients are receiving care from many different providers, particularly in emergencies, the easy and reliable electronic transfer of their clinical records has clear benefits. Furthermore, disease and intervention taxonomies and terminologies also need to be considered in a process of standardization.

Conclusion

A key lesson from the countries that have successfully implemented health IT is that a commitment from the funders of health care (governments, national insurance schemes, or third parties) to meet the costs of IT solutions is essential to ensuring their rapid and effective adoption. Countries where this is not the case, such as the United States, have had a much lower uptake of essential technologies, such as electronic patient records, than countries—such as many in the European Union—where funders have shown greater commitment.

Although IT solutions have considerable potential to heighten the efficacy of medical practice and improve patient safety, there is currently a gap between the theoretical benefits and those that have been empirically demonstrated. Future e-health applications should be evaluated against a comprehensive and rigorous set of measures at all stages of the application life cycle. Attention must also be paid to professional dynamics and ease of use—the human factors—to maximize the likelihood of successful adoption. It is necessary to make the case for new technologies to clinicians and other professionals and to provide adequate training to allow them to use health IT solutions appropriately.

It is also important that methods for effective data exchange among IT systems are in place, both to realize the full benefits of health IT and to limit the workload and errors that can arise from duplicative and unnecessary data entry. DPC data, electronic patient records, health insurance claims, and a national disease registry for clinical study should be combined into one database system—e-health.

Finally, the implementation of IT solutions in health care should be linked to an effective research, development, and evaluation agenda to ensure that the Japanese health care system adopts only those technologies that have a real impact on the safety, quality, and efficiency of medical care.

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