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Improving Patient Safety and Control in Operating Room by Leveraging RFID Technology

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Abstract. Patient safety has become a growing concern in health care. The U.S. Institute of Medicine (IOM) report "To Err Is Human: Building a Safer Health System" in 1999 included estimations that medical error is the eighth leading cause of death in the United States and results in up to 100,000 deaths annually. However, many adverse events and errors occur in surgical practice. Within all kinds of surgical adverse events, wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events are the most devastating, unacceptable, and often result in litigation. Much literature claims that systems must be put in place to render it essentially impossible or at least extremely difficult for human error to cause harm to patients. Hence, this research aims to develop a prototype system based on active RFID that detects and prevents errors in the OR.
To fully comprehend the operating room (OR) process, multiple rounds of on site discussions were conducted. IDEF0 models were subsequently constructed for identifying the opportunity of improvement and performing before-after analysis. Based on the analysis, the architecture of the proposed RFID-based OR system was developed. An on-site survey conducted subsequently for better understanding the hardware requirement will then be illustrated. Finally, an RFID-enhanced system based on both the proposed architecture and test results was developed for gaining better control and improving the safety level of the surgical operations.

Keywords: Radio Frequency Identification (RFID), Patient Safety, Operating Room, IDEF0.

1. INTRODUCTION

1.1 Background and motives

Patient safety is the most important and uncompromised issue for medical institutions. It has become a growing concern in health care. As expected, many adverse events and errors occur in surgical practice. Taking the correct patient into the correct Operating Room (OR) and executing correct procedures by correct medical staff have become widely understood as the fundamental infrastructure of safe patient care to avoid adverse events in the operating room. Hence, there are four critical requirements to give the right treatment to the right patient:

(1) Correct patient
(2) Correct OR
(3) Correct medical staff
(4) Correct operations

Whether wrong patient, wrong location, wrong medical staff or wrong operation event has resulted in injury or didn't raise actual harm, those kind of events cause anxiety for patients and staff, disrupt the smooth flow of patients through the OR suite, and increase the probability of medical errors. Hence, this research aims to develop a prototype system based on RFID that detects and prevents errors in the OR. The system provides hospitals to correctly identify surgical patients and track their operations to ensure they get the correct operations at the right time.

2. LITERATURE REVIEW

Patient safety has become a growing concern in health care. Recent attention to this topic stems from several high-profile medical errors and several Institute of Medicine (IOM) reports which quantified the problem, created standardized definitions, and charged the health-care community to develop improved hospital operating systems (Kohn *et al.* 1990) (Institute of Medicine 2001).

The operating room (OR) is one of the most complex work environments in health care. Compared with other hospital settings, errors in the operating room can be particularly catastrophic and, in some cases, can result in

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high-profile consequences for a surgeon and an institution. In addition, the high rate of adverse events in surgery is incessantly demonstrated. According to a sentinel event alert issued Dec 5, 2001, by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), "fifty-eight percent of the cases occurred in either a hospital-based ambulatory surgery unit or freestanding ambulatory setting, with 29 percent occurring in the inpatient operating room and 13 percent in other inpatient sites such as the Emergency Department or ICU. Seventy-six percent involved surgery on the wrong body part or site; 13 percent involved surgery on the wrong body part or site; and 11 percent involved the wrong surgical procedure" (The Joint Commission: The Joint Commission Home Page. http://www.jointcommission.org/). After the astonishing report published by JCAHO Gawande *et al.*, in 2003, analyzed errors reported by surgeons at three teaching hospitals and found that seventy-seven percent involved injuries related to an operation or other invasive intervention (visceral injuries, bleeding, and wound infection/dehiscence were the most common subtypes), 13% involved unnecessary or inappropriate procedures, and 10% involved unnecessary advancement of disease. In addition, two thirds of the incidents involved errors during the intra-operative phase of surgical care, 27% during pre-operative management, and 22% during post-operative management (Gawande *et al.* 2003).

Within all kinds of surgical adverse events, wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events (WSPEs) are the most devastating, unacceptable, and often result in litigation. However, an estimate of 1300 to 2700 WSPEs per year based on the available databases, extensive review of the literature, and discussion with regulators in the United States seems likely. (Seiden and Barach 2006) A variety of studies have demonstrated that the rates of adverse events associated with surgery are substantial. Of course, surgery inherently carries risk, and only 17 per cent of these adverse events were judged to be preventable (Bates 2004). Nonetheless, this important proportion of surgical adverse events is preventable given what is known today. Systems must be put in place to render it essentially impossible or at least extremely difficult for human error to cause harm to patients. With the introduction of new approaches many other complications that are not associated with an obvious error may be preventable in the future.

3. REQUREMENT STUDY

As mentioned in the previous chapters, the high rate of sentinel events in surgery has been incessantly demonstrated. Among all sentinel events, performing a procedure on the wrong site or the wrong patient is mostly preventable and should never happen. Much literature claims that systems must be put in place to render it essentially impossible or at least extremely difficult for human error to cause harm to patients. Among a lot of novel technologies, RFID is an enabling technology that is generally considered to improve patient safety and savings in hospital. This technology has been applied for many fields but few applications specified to OR. Moreover, little literature analyzed from the business processes' point of view to reap the benefits of RFID but focus on an object or an individual. Therefore, we proposed using RFID from the processes' point of view to detect errors that may lead to wrong site or the wrong patient surgery.

Before an RFID implantation, opportunity survey based on business process analysis is necessary. The survey consists of the following phases:

- **Expert interview and site survey:** Expert interview and site survey have conducted to comprehend the process in OR.
- **Existing OR Process:** Based on the result of expert interview and site survey, we described the existing OR process.
- **IDEF0 modeling:** IDEF0 modeling technique is adopted to (1) build the OR as-is model based on the result of previous step, (2) analyze the activities in the previous OR process.
- **RFID-based OR Process:** Based on the results of previous steps, we described an RFID-based state for the process.

3.1 Expert Interview and Site Survey

Before an RFID implantation, opportunity survey based on business process analysis is necessary. However, how an enterprise is typically recorded only in the heads of the experts who operate that enterprise, not in company manuals. This experience can also be applied in a hospital. Surgeons, nurses and anesthetists are the experts who know what happens behind the closed doors of the operating department. They clearly know their job functions and workflow during surgery. For this reason, we undertook several expert interviews with the medical staff worked in an operating department of a regional teaching hospital in Taoyuan to comprehend the operative process. Except expert interviews, we also perform site survey to observe the activities in OR. The activities during on-site survey include observation of nursing work, review related forms and face-to-face meeting with nurses to capture the entire workflow in OR. The results of expert interviews and on-site survey are described in the following sections.

3.2 Existing OR Process

The scope of OR process for an individual patient which we describe as follows begins with the surgical patient's arrival at the OR suite and ends when the patient leaves the OR suite. The details of the OR process is shown below:

3.2.1 Admission into operating suite

Base on operations schedule, the transporter brings scheduled surgical patient from ward to the operating suite, along with his/her medical record and related document. Upon the patient's arrival in the holding area of operating suite, the holding area nurse orally identifies patient by matching the replies from the patient about the name, ID card number, type of surgery with medical record, etc. After the confirmation, the nurse reviews the document accompanying the patient to check whether the operation related forms such as operative consent form has been completely filled in or not. The patient's national health insurance card is then received by the nurse. After a series of admission procedure, the nurse logged on to the hospital information system to change the patient's status. At the same time, the patient's status information "Waiting for surgery" is displayed in the screen located in the waiting area to reduce anxiety patient's family members.

3.2.2 Admission into operating room

The surgical patient stays in the pre-operative holding area until the OR is ready. However, before a circulating nurse takes a patient into scheduled OR, the nurse verbally identifies the patient again and changes the patient's status from "Waiting for surgery" to "In surgery."

3.2.3 Beginning of anesthesia

The anesthetist verbally confirms the patient's identification, type of surgery and part of surgery before anesthesia. If the information is correct, the anesthetist signs in the nursing records of patients' operations. Although the doctor has already determined the anesthetics and methods of delivery before surgery, the anesthetist can make the final decision depending on the patient's specific condition at that point of time. The anesthetist verbally asks the patient's information such as the history of allergy, family history in the OR to decide which kind of anesthetics he or she should use. Besides, anesthesia staff also reviews the anesthesia information and laboratory test data in medical record to assist determining the way to induce anesthesia is suitable for the patient or not.

3.2.4 Surgery

A surgeon also has to confirm the patient's identification before surgery. However, the surgical patient is usually covered with surgical drapes and has been anesthetized when a surgeon enters the OR. The surgeon can only justify the patient by medical record or pictures such as X-ray pictures. In the case that the patient was not covered with surgical drapes, the surgeon verifies patient by face. Because surgeons often meet surgical patients before surgery, the surgeons consider that they can distinguish a right patient from a wrong patient by their memory. Before performing an operation, the surgeon refers to the patient's medical record to make sure the surgical procedure and the site of operation. During surgery, surgeon can refer to medical record for the anesthesia information, patient information, results from laboratory information system if necessary.

3.2.5 Admission to recovery

After surgery the patient is takes into recovery rooms to wait for "awakening" from anesthesia. At the same time, the nurse in the recovery room changes the patient's status to" In recovery."

3.2.6 Discharge from operating suite

After a patient becomes conscious, the transporter takes the patient back to his/her ward and change patient's status information to "Return ward."

3.3 IDEF0 Modeling

After in-depth understanding of the current process in OR an IDEF0 model was developed. The IDEF0 model is used to help organizing the analysis of OR system and to promote good communication between the analyst and the medical staff. For better understanding of the sequence, we chose sequential form of breakdown which decomposes the parent activity by a sequence of sub-activities to build our system. However, the structure imposed by the IDEF0 methodology naturally creates a set of questions that must be asked and answered about each function and its sub-functions. The answers to these questions provide important information concerning how known human fallibilities which may lead to errors. Thus, we can clarify many activities during model development stage by discussing with medical staff.

In this section, first, we built the "as-is" model to define activities and functions in OR. The definition of "as-is" is a description of the current situation in terms of the work processes. With sufficient information regarding the as-is operation, analyzing current process and building a new system become easier. Second, we examined the model, found out the operations which probably threaten to patient safety or make medical staff ineffective and analyzed the opportunity for introducing RFID to solve the problem.

3.3.1 Building "as-is" Model

After expert interviews and on-site survey, the OR as-is model was constructed. The purpose of this model is to find out the systemic vulnerabilities that may lead to human error and the opportunities that can improve medical staff's operations by introducing RFID technology. The model was developed from the OR medical staff's viewpoint.

Figure 1 depicts the top-level function of the IDEF0 model, "perform surgery." The activity called "performing surgery" is broadly defined as all activities during per-, intra- and post operations. In other words, all activities happened during the period which begins with a patient arriving at the holding area of an OR suite and ends up in

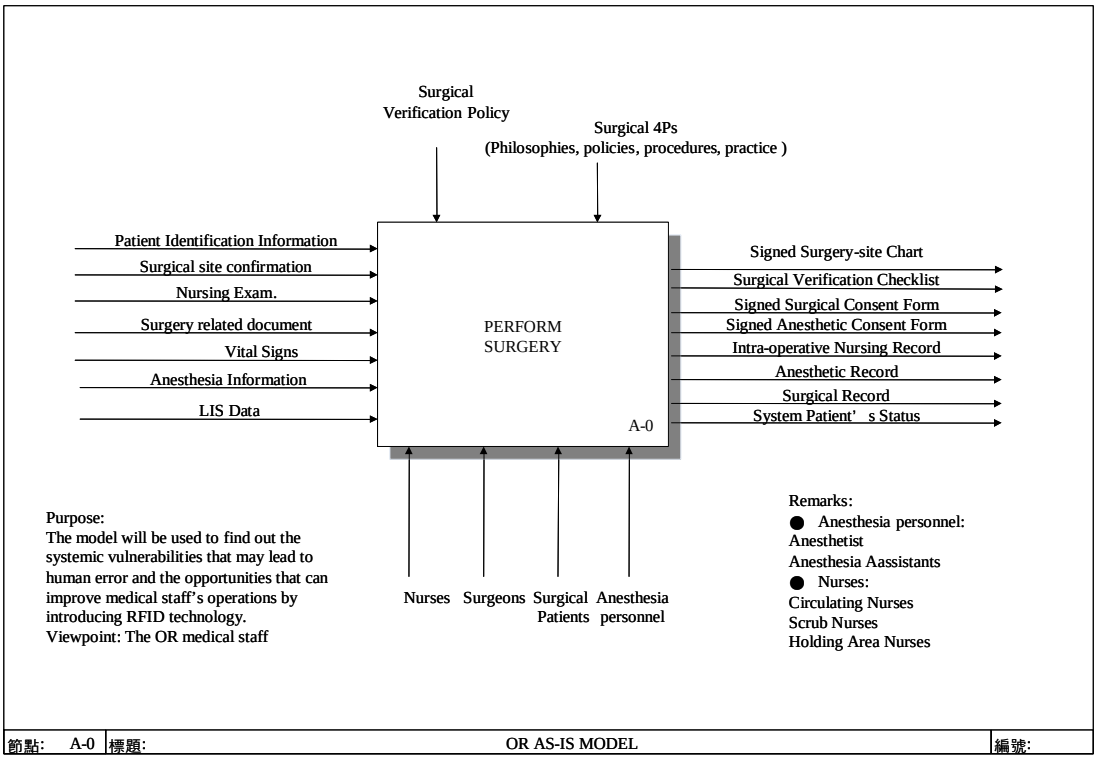

Figure 1. OR AS-IS Model.

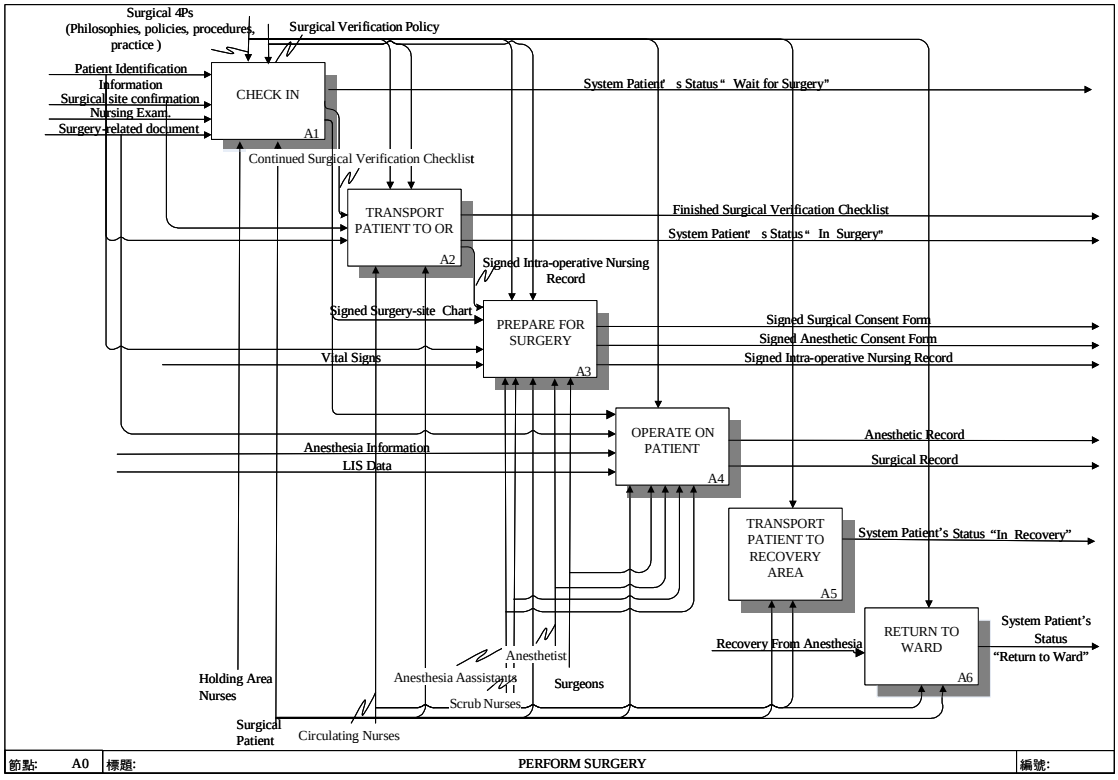

Figure 2. IDEF0 Diagram "PERFORM SURGERY".

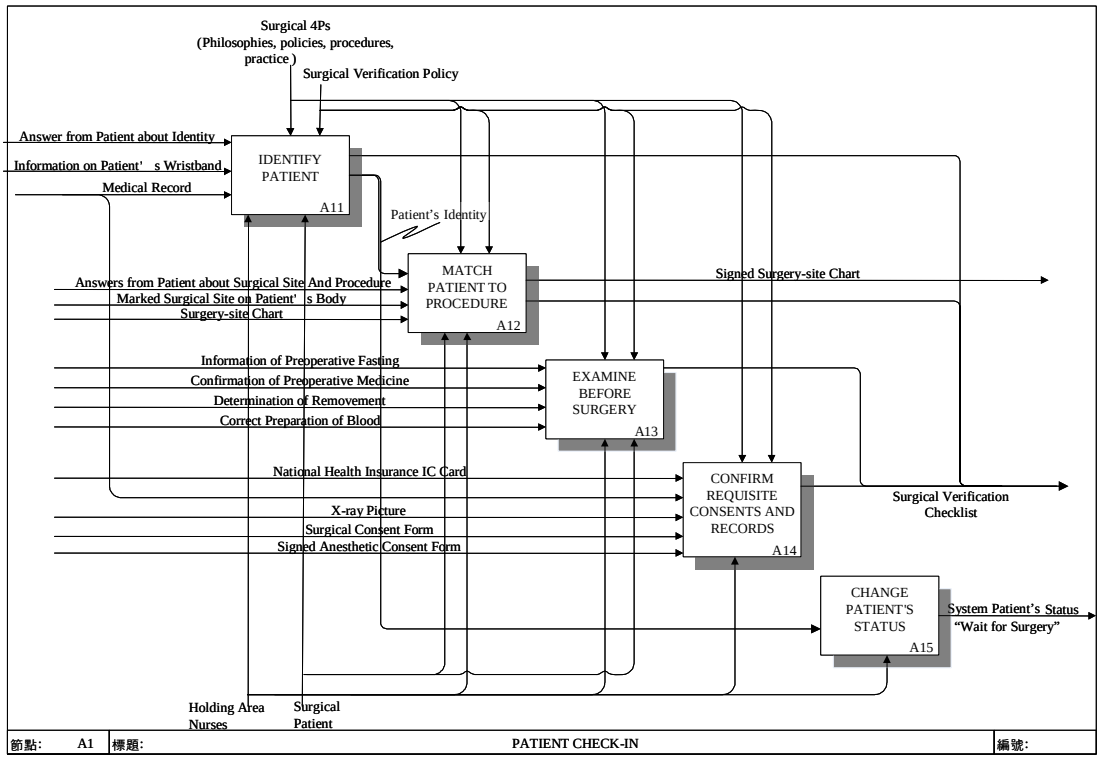

Figure 3. IDEF0 Diagram "PATIENT CHECK-IN".

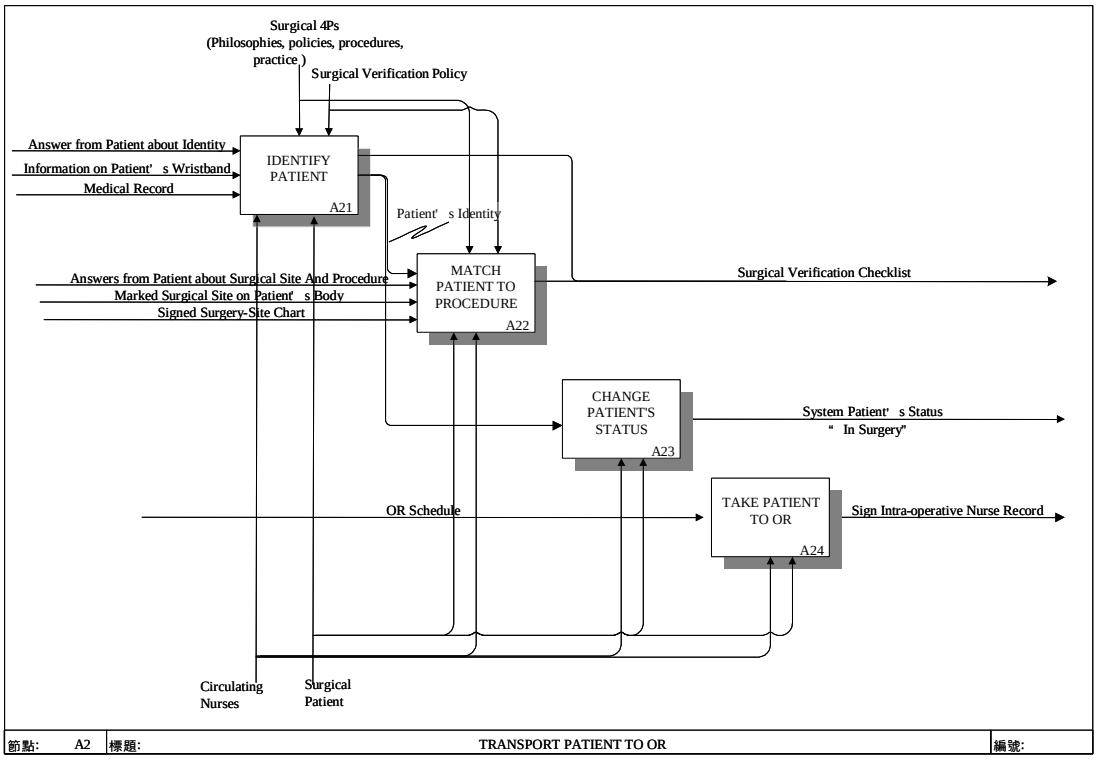

Figure 4. IDEF0 Diagram "TRANSPORT PATIENT TO OR".

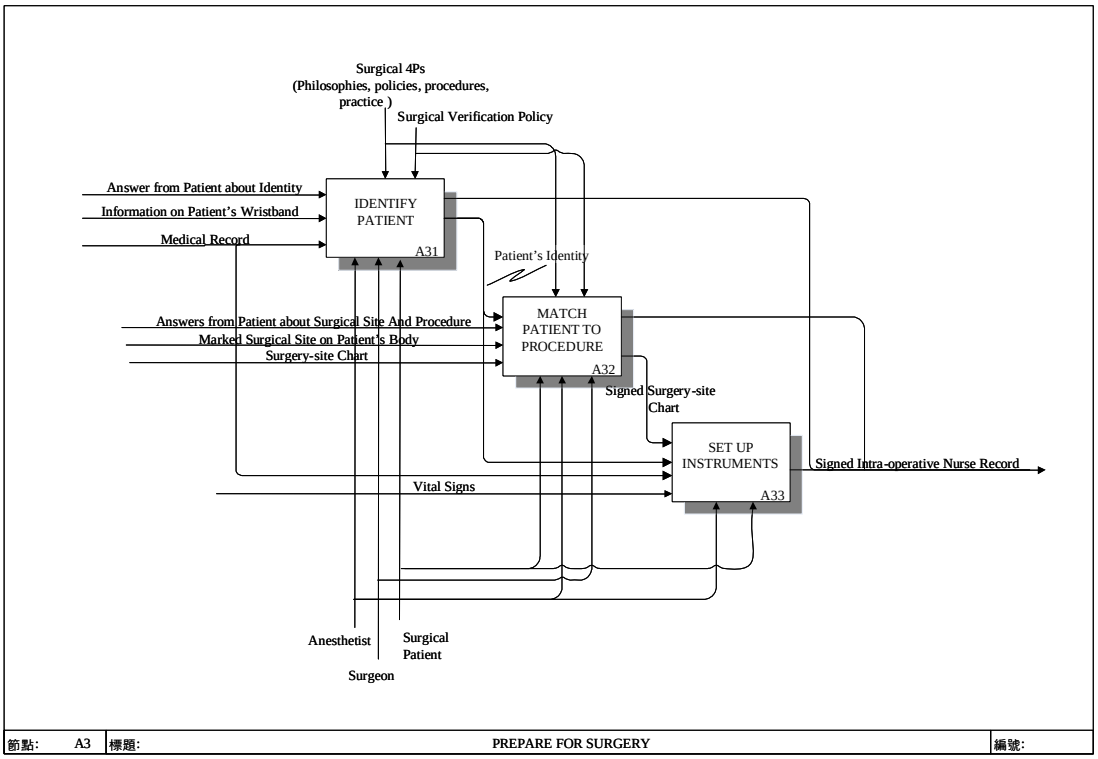

Figure 5. IDEF0 Diagram "PREPARE FOR SURGERY".

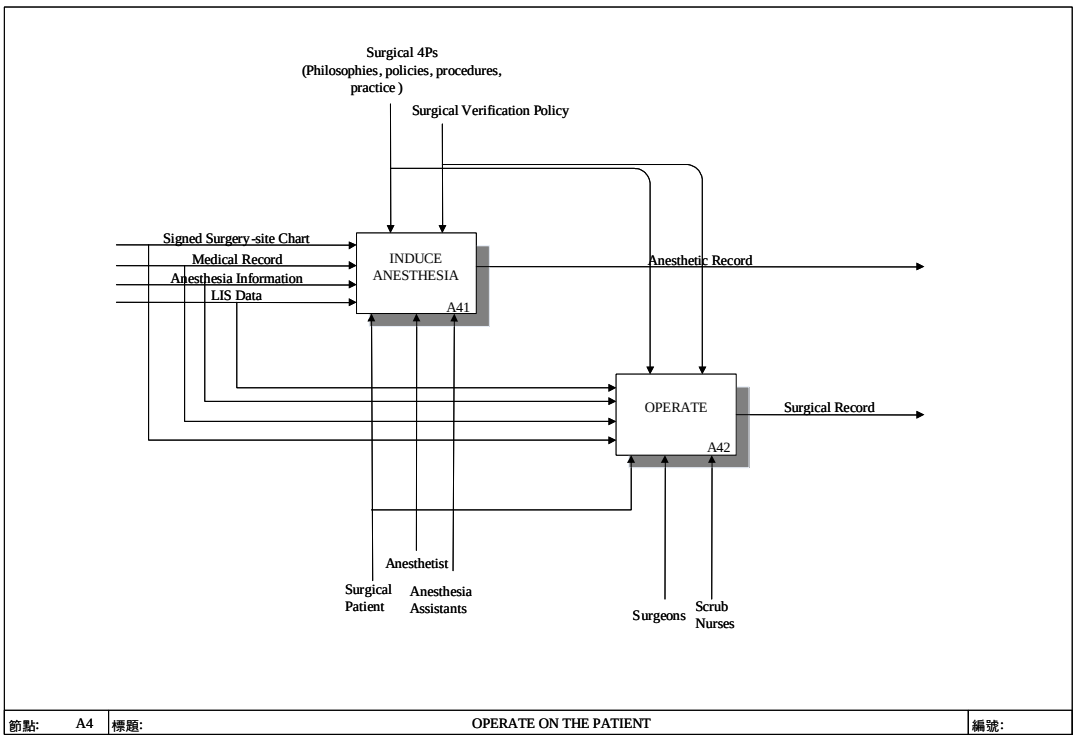

Figure 6. IDEF0 Diagram "OPER ON THE PATIENT".

the patient returning to ward are included. Figure 2 shows the top-level function decomposed into six more specific functions, representing the surgery process in more detail. Note that the general inputs, outputs, controls, and mechanisms from Figure 1 are also decomposed, illustrating the progressive exposure of detail that is a feature of the IDEF0 methodology; Figure 3 shows the decomposition of the activity "patient check-in" at an even higher level of detail. In the same way, Figure 4, 5 and 6 shows the decomposition of the other activities in detail.

3.3.2 As-is Model Analysis and RFID Solutions

After building the OR as-is model and numbers of meeting with related medical personnel, we discovered that there were a lot of systemic vulnerabilities that may lead to human error. In real situations, not every OR member completely follows the Standard Operating Procedures (SOP). If some accidental situations happen, wrong patient, wrong site/side surgery, unsuitable anesthesia or wrong OR event may occur. Based on the as-is model, the possible human errors and inefficient operations are listed as follows:

1. **Misidentification of patients:** According to the as-is model, the nurse verifies the patient's identity by asking the patient his/her full name and checks it with both the patient's identification bracelet and medical record. If frontline healthcare staff did not successfully verify a person's identity, wrong patient may be taken into OR. In other words, if an exceptional case happens, the manual process is probably permitted errors to cause wrong patient surgery. Failure to correctly identify patients constitutes one of the most serious risks to patient safety; however, in the OR, it can even cost a life.

2. **Entering the wrong OR:** In general, a teaching medical center has numbers of contiguous ORs, each performing two to three cases daily. Moreover, OR schedule varies frequently. Hence, there are many opportunities for surgeons or patients to enter the wrong ORs. If a patient or a surgeon enters a wrong OR without reconfirm, the event of wrong surgery could happen.

3. **Inducing unsuitable anesthesia:** An anesthetist has to make the final decision regarding the anesthetics and methods of delivery at the time of surgery. Therefore, providing sufficient information to the anesthetist is very important. In general, the critical information that aids an anesthetist making decision must be obtained from both ways: verbally asking the patient and reviewing some data described in the medical record. The questions now arise: first, some critical information even was not recorded in a patient's medical record. History of allergy and family history, for example, only can be received by asking patients. If the patient is not conscious or too elderly to answer the questions from medical staff, it would cause the patient to be exposed to danger. Second, looking for the unfiltered data on the paper is inefficient to anesthesia staff.

4. **Performing wrong operations:** Wrong operation mentioned here includes performing wrong procedures on a patient or perform a surgery on the wrong site/side of a patient's body. Based on the as-is model, the doctor conforms patient's operation-related information by checking the patient's medical record and surgery-site chart that describes the surgical site/side of a patient. However, because it is not convenient to find out disperse data by looking up the paper-based medical records, doctors sometimes depend on their memory for patients' condition without double-check. In addition, when a surgeon substitutes for another surgeon to perform a surgery or a surgeon operates on more than one patient at the same time, the wrong operation may be performed.

5. **Inefficiently updating patient's states:** Based on the as-is model, nurses have to manually update a patient's status information (in surgery, in recovery, etc.) in the hospital information system when the patient's status is changed. However, the essence of the OR nurses is to provide care and support to patients before, during, and after surgery. This kind of unrelated activity distracts medical staff and obstructs medical professionals providing better patient care.

As mentioned above, not every OR member completely follows the SOPs in real situations. Therefore, if some accidental situations happen, wrong patient, wrong site/side surgery, unsuitable anesthesia or wrong OR event may occur. Table1 shows potential cases that may threaten patient's safety in the as-is model.

Human error is inevitable and unavoidable. However, most preventable adverse events are not simply the result of human error but are due to defective systems that allow errors to occur or go undetected. Therefore, we propose an RFID-based OR system that can reinforce SOP and prevent potential errors for achieving the ultimate objective of improving patient safety in OR. The proposed RFID-based OR system is expected to complement current human-based operations in the following ways:

1. **Patient Identification:** Improving the accuracy of patient identification is one of JCAHO 2006-2007 patient safety goals which suggest using active communication technique to conduct final verification process and using at least two patient identifiers. However, either suggestion was not adopted in the "as-is" process. The problem can be solved

Table 1. Defects in the as-is Model.

Events That May Threaten Patient's Safety	Node Number	Accidental Case (Do not follow the SOP)
Wrong Patient	A11, A21, A31	• A surgeon directly brought a patient to an OR without reconfirmation. • Just call the first name of a patient with Mr. or Ms. to verify the patient. (A21) • A nurse misidentifies a patient because of fragmented communication between the nurse and the patient.
Wrong OR	A24	• Mistakenly bring a patient into a wrong OR.
Wrong Procedure	A42	• Passive and inconvenient confirmation processes do not encourage medical staff to reconfirm patient's information. • A substitute surgeon is not familiar with the surgical patient. • A surgeon operates on more than one patient simultaneously.
Wrong Anesthesia	A41	• A patient who is not conscious or too elderly to answer the questions from medical staff causes that some critical information can not be obtained. • It is inconvenient to look for dispersed and unfiltered information.
Inefficient Operations	A15, A23, A5, A6	• Wasting time to update patients' status information in the computer obstructs medical professionals providing better patient care.

by introducing RFID that can automatically identify patients to complement current human-based verification.

2. **Surgical site verification:** To decrease the incidence of wrong site/side surgery, we have developed a digital chart of surgery site marking which can be displayed on the LCD monitor of OR. By integrating RFID with hospital information system (HIS), the digital chart and some critical information of the patient are automatically shown on the monitor when the patient is brought to the scheduled OR. The adverse events of wrong site in surgery can be significantly reduced.

3. **OR verification:** If a patient is brought to an unscheduled OR, the system will create a warning on the monitor. Thus, the RFID-based system checks the wrong-location event to prevent the potential wrong surgery.

4. **Patient status update:** The activity of updating patient's status distracts medical staff from surgery related tasks. In the developed RFID-based system, the status will be updated automatically by integrating RFID with the back-end HIS.

3.4 RFID-enabled OR Process

After analyzing as-is model, we have developed an RFID-based prototyping system that detects and prevents errors in the OR. The system provides hospitals to 1) correctly identify surgical patients, 2) track the ORs in which patients and medical staff enter, and 3) furnish critical information to ensure patients get the correct operations at the right time and place. The "to-be" RFID-based OR process derived from analyzing the "as-is" model is illustrated as follows:

3.4.1 Admission into the operating suite

When a surgical patient is scheduled to be operated upon, the nurse in the ward assigns the patient an RFID-embedded wristband encoded with a unique ID. When the surgical patient is brought to the holding area in the OR suite, an RFID reader automatically verifies the identity of the patient. If the details of the patient and operation schedule match, the monitor in the holding area displays some brief information about the patient. Simultaneously, the system automatically changes the patient's status information to "waiting for surgery" in the database. Then, the patient's status information can be displayed on the screen located in the waiting area; this helps in reducing the anxiety of his/her family members.

3.4.2 Admission into operating room

The RFID readers in the OR automatically capture the information on the patient's tag to identify him/her upon entering the OR. If the details of the patient and the OR into which he/she has entered match, the screen in the OR displays the patient's information, including his/her name, age, gender, laboratory test data, digital surgery-site chart, and scheduled procedure, by associating the tag's ID number with the patient records stored in the hospital information system. However, if an unscheduled patient enters the OR, the system can alert the medical staff to take the necessary measures in the OR. Thus, unfamiliar faces can be checked with assurance, thereby decreasing the probability of performing the procedure on

a wrong patient. Subsequently, the system automatically changes the patient's status information to "in surgery" after confirming that the correct patient has entered the correct OR. In addition, because the time is automatically recorded, the medical staff does not have to record the time manually.

3.4.3 Initiation of anesthesia

When a tagged anesthetist or nurse enters the room, the system will also ensure that the person has entered the right room, thus preventing medical staff from rushing into the wrong OR and administering inappropriate medical treatment. In addition, information such as the history of allergy, family history, and laboratory test data, which aids the anesthetic team in determining the appropriate anesthetics and method of administration, is displayed on the monitor when the anesthetic team enters the OR. The anesthetist can then refer to this information without having to ask the patient or check through the patient reports. Furthermore, any abnormal values will be marked in red to bring them to the medical staff's attention.

3.4.4 Surgery

In the same manner, when a surgeon enters the room, the system will also check whether the person has been assigned to the room, in order to prevent doctors from entering the wrong OR and performing surgery on the wrong person. If the patient has not yet been covered with surgical drapes, the surgeon can reconfirm the patient's identity by matching the patient with a photograph displayed on the screen. In addition, the surgeon is also provided with the patient's critical information on the digital display, rather than having to search for the pertinent information in the documented reports. Thus, bringing all this information together not only saves time but also increases patient safety. The surgeons are encouraged to confirm the patient records through the centralized data displayed on the monitor because of this increased accessibility. In the absence of such a system, doctors would generally depend on their memory, without performing any reconfirmation due to the inconvenience involved. However, with this system, the OR team can easily see a snapshot of a patient, thereby simplifying the process.

3.4.5 Transfer to recovery

After surgery, patients are transferred to the recovery area. Here, the RFID readers detect the patient's RFID tags and the system automatically changes the patient's status to "in recovery."

3.4.6 Discharge from operating suite

After a patient recovers from anesthesia, the transporter brought the surgical patient leaving recovery room and returning to ward. At this time, the system automatically updates the patient's status information to "returned to ward."

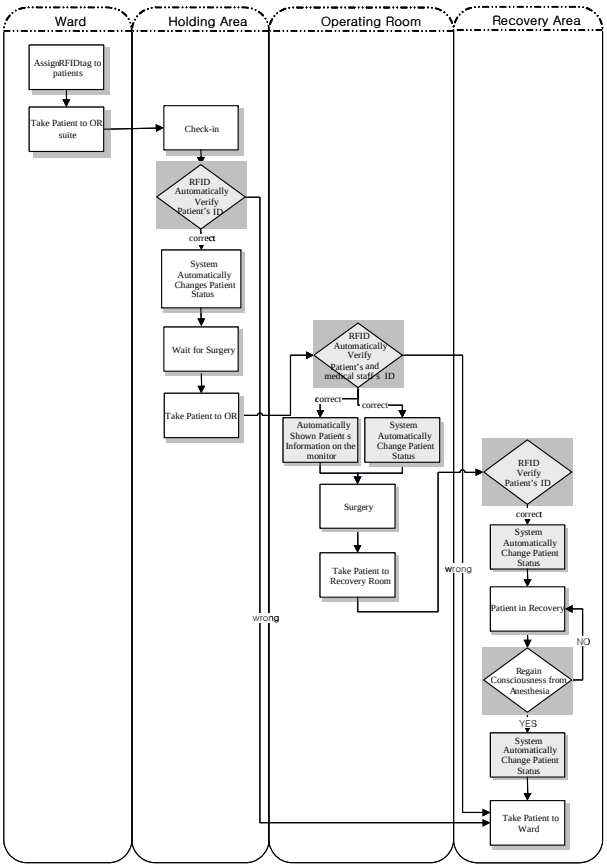

Figure 7. RFID-based OR Cross-functional Flowchart.

Figure 7 is a cross-functional flowchart constructed to describe the RFID-based process.

4. THE ARCHITECTURE OF RFID-BASED OR SYSTEM

Based on the RFID-enabled OR process depicted in the section 3.4, we developed an architecture for the practical implementation of such a system. The architecture of the RFID-based OR system consists of physically distributed RFID readers, tags, an RFID server that processes the data from the readers, several client PCs that run different hospital applications, and the hospital information system (HIS) that plays the same role as that of an ERP system in enterprise-level architectures. The architecture developed is illustrated in Figure 8. The RFID server contains a backend database and software called the concentrator that receives the data from the RFID readers when the tags are detected, checks this data for errors, and then stores it on an operational database. In our architecture, the concentrator also communicates with other software that implement the application's business logic on client PCs. In addition, the RFID server is connected to the HIS to extract hospital data through an intranet. With the developed architecture, a practical RFID-based system can

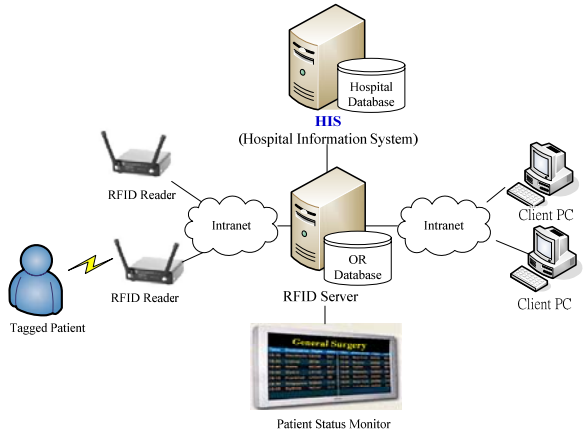

Figure 8. The Architecture of RFID-based OR System.

be built to faithfully execute the improved OR process and consequently provide higher level of safety for patients.

5. CONCLUSION

Patient safety is the most important and uncompromised issue for medical institutions. In this research, we analyzed the existing OR process based on the as-is model and developed the RFID-based OR process. This RFID-based process can improve surgical patient safety and make medical staff efficient. From the surgical patient safety point of views, the RFID-based OR system (1) correctly identifies surgical patients, (2) automatically compares the OR which patients enter with the OR schedule, and (3) actively provides patients' information to ensure that patients get correct procedures. The proposed system decreases the probability of medical errors such as wrong patients, wrong locations, wrong medical staff and wrong procedures. From the medical staff point of views, the system replaces some time-wasted manual input processes. Therefore, it will improve operational efficiency in the OR and consequently help medical professionals better manage patient care.

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