1-1-2012

Rfid-based business process and workflow management in healthcare:design and implementation

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RFID-BASED BUSINESS PROCESS AND WORKFLOW MANAGEMENT IN HEALTHCARE: DESIGN AND IMPLEMENTATION

by

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DISSERTATION

Submitted to the Graduate School

of Wayne State University,

Detroit, Michigan

in partial fulfillment of the requirements

for the degree of

DOCTOR OF PHILOSOPHY

2012

MAJOR: INDUSTRIAL ENGINEERING

Approved by:

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Advisor Date

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DEDICATION

To my parents with love

ACKNOWLEDGMENTS

First and most important, I would like to give my utmost gratitude to my advisor, Dr. Kai Yang, for his guidance, encouragement, and confidence in me. Dr. Yang has been my inspiration as I hurdle all the obstacles in the completion of my Ph.D. research work. Over the years, I have learned a lot from the way he thinks, the way he acts, and the way he speaks as a professional engineering researcher, practitioner, and pioneer. His unique insightful definition of INNOVATION has enlightened me the way to create a new solution when dealing with complex problems. I will never forget his support and trust for me at the hardest time when I started a totally new life in the United States. Really appreciate you for all of that!

Many thanks to Ms. Susan Yu, the chief of the System Redesign Office, Veterans Affairs Medical Center, Detroit. With her continuous support, I collaborated with the logistics department, the hemodialysis clinic, the sterile processing department, and the VHA RTLS Project Management Office on multiple projects for the past three years. Her profound knowledge on system engineering issues in healthcare industry and great passion for her intensive workload inspired my research work. I really enjoyed the discussions and have learned a lot of healthcare management methodologies during our collaboration process.

I am very grateful to Dr. Shiyong Lu, for his patient guidance to answer my questions about workflow management and steadfast encouragement to complete this study. I would acknowledge Ms. Kimberly Brayley, the chief of the VHA RTLS Project

Management Office, Dr. Alper Murat, and Dr. Kyoung-Yun Kim for serving as my dissertation committee and providing profuse encouragement and productive advices on my dissertation.

I would also like to give my appreciation to the following faculty from whom I have taken the classes: Dr. Kai Yang**,** Dr. Kenneth Chelst, Dr. Leslie Monplaisir**,** Dr. Alper E. Murat, Dr. Gary Wasserman, Dr. Sara Tipton, and Dr. John Black.

It's my great pleasure and honor to work for the Veteran's Engineering Resource Center (VERC). With the continuous support from Ms. Heather Woodward-Hagg, Ms. Pamela Pau, Mr. Will Jordan, and Dr. Balmatee Bidassie, this research could be developed based on the practical problems to improve the current process management in sterile process departments.

My thanks also go to all the team members: Adel Alaeddini, Amr Alamri, Galal Abdella, Satish Tyagi, Jihan Wang, and Yanli Zhao. It was my wonderful experience to work with you.

Special thanks go to my good friends and fellows, Han Wang, Fang Gu, Zhiying Ma, Jillane McGahhey, Shelby Reynolds, Shanshan Qiu, Dingzhou Cao, Yu Sun, Andrey kashlev, Nasim Hamidian, Lizi Wu, Farshid Azadian, Mahyar Movahednejad and the list continues to my memory.

Finally, I would like to thank all my family members for their love, support, and encouragement throughout the happy and hard times in my whole life. I feel so lucky to

be born in this family. Your love creates a warm safe haven, protecting me from the storms of life.

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1.1. Research Background

Healthcare is considered one of the fastest growing business and largest service industries in the world [1]. To cope with this expansion, the healthcare industry must change its traditional operations and deploy a new information system to manage unpredictable processes and supply accurate responses in time [2]. At the same time, many hospital facilities are currently challenged by increasing patient and staff safety concerns，financial pressure, and inefficient process management.

One in every ten patients around the world have been harmed and killed by medical errors annually [3]. One major threat to patient safety among the most common adverse events in healthcare is healthcare-associated infections (HAI). Many of these healthcare-associated affections are due to unclean *reusable medical equipments* (RMEs), reprocessed from loose control of business process management in a *sterile processing department* (SPD).

Escalating medical costs bring much financial pressure to governments and families. A large amount of waste recurs inevitably due to weak management and organization of medical resources in the daily operations of hospitals. Examples of waste include expired perishable medical items, lost or missing expensive equipments, and duplicated operations caused by lack of information records.

Inefficient process management often results in the low quality of patient care. For example, some crucial surgeries have to be delayed due to stock-outs or lost assets [4] , which increases the risk of patient safety if the best treatment time is missed.

Those problems almost have a similar reason: lack of efficient business process management and visibility for the real-time location and status of medical resources. This requires hospitals to deploy a new integrated system to model, automate, and monitor healthcare business processes with visualized physical objects at the right time and location.

1.2. Problem Statements

- **Lack of methodology to guide the RFID design and deployment process in hospitals**

Although RFID is considered a promising solution to improve the quality and efficiency of medical services [5-7] by collecting real-time location and identification information of medical resources automatically, the research on successfully designing and implementing an RFID-enabled system in the healthcare industry is still in its infancy. To date, many healthcare facilities have only implemented small-scale trials or installations [8-10] to avoid high upfront investment cost. Several challenges need to be addressed clearly before large-scale deployment can take place, such as how to define the resolution levels for item tracking, which technology will be the best option to achieve required tracking results, which departments are suitable for the application of RFID technology. While there have been a fair amount of academic papers [11-18] that discuss the types of the applications currently implemented with RFID technology, there have

been few academic research focusing on the system design and implementation process in the healthcare sector [19-22].

- **Lack of performance management solution for ensuring patient safety in sterile processing departments**

Patient safety has become an urgent issue for healthcare today [23-25], nearly 1.7 million healthcare-associated infections occur annually, leading to approximately 99,000 deaths. One major cause that dramatically impacts patient safety is the use of unclean reusable medical equipments [26-28], delivered from a sterile processing department (SPD). Unfortunately, current practice in the sterile processing department is mostly driven by human labor and control [29]. Many steps of a business process have to be conducted manually, and if skipped or not performed properly, errors result which will cause unclean reusable medical equipments, delayed or lost medical supplies. As a result, patient safety could be dramatically compromised, resulting in unnecessary escalated conditions, delayed discharge, or even death [30, 31]. Consequently, there is a great need for an appropriate and deliverable approach to monitor and display the real-time performance and execution status of business process management in SPDs, detect operation errors in time, and identify their causes and impacts.

- **Lack of reference architecture design for healthcare workflow systems in sterile processing departments.**

Healthcare workflow has recently become an enabling technology to facilitate well-structured business process management in the healthcare industry by automating processes, improving care quality, and enhancing patient safety [32]. Although much

research has been done on business processes [33-36] and scientific workflows [37-41], healthcare workflow poses many unique challenges as healthcare processes need to be patient-centered, policy-governed, and quality-ensured, since the consequence of errors and inefficiency is more severe and costly. Under the complex conditions of healthcare environments, there are large variations in patient conditions, even in similar medical treatments. For each process, operations must strictly satisfy the corresponding medical policy or guideline. Operation conformance management should be introduced into a healthcare workflow management system. Meanwhile, it should be flexible and adaptive to any new requirements and emergency cases. Various physical and financial resource constraints also incur the limitations of service capability. While some work has been done on healthcare workflows for some departments of a hospital [32, 42-45], none of the existing work investigated healthcare workflow system design for the automation of sterile processing procedures, preventive SOP rule conformance check, and quality management of RMEs during the whole reprocessing procedure, such as selecting the right workflow to process, checking the precondition of running a step, performing smart rerun optimization that are proposed in this research. Thus, a reference architecture design for a SPD workflow system is still lacking and needs investigation.

1.3. Contributions

- **A road map to design and implement RFID in hospitals.**

In this research, an integrated framework is proposed to implement RFID in hospitals according to the theory of Information System Design Theory, Lean

Management, and Task-Technology Fit. Performance matrixes are presented to evaluate key technologies and criteria to set the resolution level for tracking objects. Business rules are designed for extracting valuable information from collected real-time data. The findings of this research will facilitate the integration of RTLS into clinical environments to reduce cost, optimize standard operation processes, and improve dynamic medical services.

- **Transforming Sterile Processing Departments by RFID-based Business Process and Workflow Management in Healthcare.**

In this research, based on an enhanced, interdisciplinary understanding of the current practice of a sterile processing department, the main factors and issues that compromise patient safety are identified. To address these issues, RFID-based business process and workflow management is proposed to transform the current operations in SPD. A business process management pattern is developed for SPD, which emphasizes the importance of execution status management under complex and dynamic healthcare situation. Service-Oriented Architecture is deployed in business process management framework for SPD to share information, integrate distributed systems, and manage heterogeneous resources among multiple stakeholders. A three-level infrastructure is designed for an RFID-based real-time SPD operation management system. A healthcare workflow system will work as one of main subsystems for the SPD floor navigator to support the design, editing, execution, monitoring, and management of reprocessing procedures in SPDs. RFID techniques are adopted to collect real-time location and

identification information of RMEs and reprocessing resources, and sensor information of reprocessing environments.

- **Service-Oriented Architecture for SPDFLOW: A healthcare workflow system for sterile processing departments.**

In this research, the key architectural requirements for a healthcare workflow system for SPDs are identified. A service-oriented reference architecture is proposed for our SPD workflow prototyping system, SPDFLOW. It aims to support the design, editing, execution, monitoring, and management of various disinfection and sterilization processes in a sterile processing department. An event-condition-action based rule engine is designed to automate the conformance check between the SPD operations and standard operation procedure (SOP) rules. Smart reasoning techniques are designed to preventively reduce errors, proactively improve workflow management, and efficiently producing high-quality ready-to-use reusable medical equipments. A case study is provided to validate this design. This research is the first effort in exploring healthcare workflow technology in the SPD domain to improve the quality of RMEs and ensure patient safety.

1.4. Organization of Dissertation

The remaining chapters are structured as follows: Chapter 2 proposes a road map to facilitate the successful integration of RFID into the clinical environment with an integrated framework. Chapter 3 provides a more detailed description of the framework and pattern to transform SPD by RFID-based business process management and

workflow technologies to improve patient safety. An SOA-enabled reference architecture for a healthcare workflow management system in SPD will be introduced in Chapter 4. Finally, Chapter 5 concludes our research results and lists some interesting topics for future research.

Chapter 2 A Road Map to Design and Implement RFID in Hospitals

Summary:

The healthcare system in the United States has been identified as one of the most "complex systems" and has suffered from ineffective logistics management, patient safety concerns and escalating costs. Real Time Location Systems (RTLS), an application based on ubiquitous computing, is recognized as a new application that will increase the visibility and operational efficiency of clinical and administrative workflows in the healthcare setting. In this section, a hybrid framework is proposed to implement RTLS in hospitals according to the theory of Information System Design Theory, Lean Management and Task-Technology Fit. Performance matrixes to evaluate key technologies and criteria to set the resolution level for tracking objects are also presented. Business rules are designed for mining the valuable information from collected real-time data. The findings of this research will facilitate the integration of RFID-based RTLS into the clinical environment to reduce cost, optimize standard operation processes and improve dynamic medical services.

2.1. Introduction:

Healthcare is considered the fastest growing business and largest service industry in the world[1]. Thus, to cope with this expansion, the healthcare industry must change its traditional operations and deploy a new information system to manage unpredictable

processes and supply accurate responses in time[2]. At the same time, many hospital facilities are currently challenged by increasing financial pressure, patient and staff safety concerns and ineffective medical supply management. Some surgeries have to be delayed due to supply shortage or lost assets[4], which can lead to increase waiting time or length of stay. Many problems are due to lack of 'visibility' among multiple medical resources. This requires hospitals to deploy a new integrated system to visualize physical objects with corresponding clinic processes at the right time and location.

'Ubiquitous computing' was developed by Weiser [46] to compose a vision where computing power becomes invisibly integrated into the world around us and accessed through intelligent interfaces, which is also called the 'Internet of Things,' from its original linking and sharing of computers and documents to currently connecting with personnel. With the exploitation and exploration of technology innovation, it is possible to create a context-aware environment where hardware and software components can seamlessly and spontaneously interoperate to supply services regardless of the unique requirements of the environment [47]. Many fields within businesses and institutions have deployed the ubiquitous computing technologies to develop context-aware services, varying from small intelligent spaces to large virtual enterprises [48]. Radio-frequency Identification (RFID) is one of the key enabling technologies behind the vision of the 'Internet of Things' and has been identified as 'the next evolutionary step in Automatic Identification Data Capture (AIDC) technology'[49] . Since RFID tags use radio waves to identify, track, and trace individual objects accurately and automatically in real time, the capability of capturing data triggers the enormous attention and expectation that RFID

technology can improve supply chain visibility, operation efficiency, and asset management[50].

An RFID system can be represented as a multi-layer system composed by RFID tags that capture encoded data onto an integrated circuit and an antenna, readers that use radio signals to communicate with the tags and a middleware that interprets and manages the real-time information [51]. Healthcare is believed to be 'the next home for RFID' [52] after its successfully improvement in supply chain visibility, operation efficiency, and asset management[50]. As Fisher and Monahan stated, RFID is an emerging technology that is quickly becoming the standard for hospitals to track valuable assets, identify and locate patients, and manage medical personnel[53]. There is a great potential for improving the quality of medical services and increasing the productivity of value-added operations [54]. Vilamovska et al. summarized preliminary classification of healthcare RFID applications, which are patient safety / quality of care, pharmaceutical application, management of devices, supplies and biological material, and patient and healthcare personnel support/management [55]. Turcu demonstrated a successful RFID deployment example in emergency room. Effective treatment time is saved by reading the accurate medical history of unconscious, incoherent and unaccompanied patients from an RFID wristband [56]. Koh et al. designed the application of RFID to detect and control counterfeit drugs in pharmaceutical logistic management[57]. Because of the unpredictable service demand and the complex infrastructure of hospitals, quickly locating the critical items with high utilization numbers has been one of the perpetual problems in the healthcare service industry [58]. Bendavis et al. proposed a framework to

redesign the replenishment process of medical supplies with RFID and approved a 2-bin 'e-kanban' replenishment system [51]. Consequently, the integrated information system 'Real-time Locating System (RTLS)' is selected as an extremely promising system to improve safety, quality, and the overall value of healthcare to address a wide array of issues in the medical industry.

However, implementing RTLS in a healthcare setting is considered to be challenging and complex, which has the potential for considerable costs. To date, many healthcare facilities have only implemented small-scale trials or installations. While there have been a fair amount of academic papers that discuss the types of the applications currently implemented with RTLS technology, there have been few academic publications focusing on the system design and implementation process in the healthcare sector.

In the chapter, a strategy for an RTLS-based Healthcare Management System (RHMS) design and implementation is proposed. It aims to facilitate the integration of RTLS into different clinical environments for cost reduction, process optimization and clinical service improvement. The rest of this chapter is organized as follows: a) a brief overview of previous RFID (RTLS) designs and implementations in healthcare; b) an analysis of the challenges in deploying RTLS in a hospital, c) a description of the proposed methodology to design and develop a RHMS, d) an implementation of an RTLS-based system in a hospital and e) concluding remarks on the study and future research.

2.2. Previous Study in RTLS Implementation

With the exploding growth of RTLS applications in asset management and patient tracking, the need to define a methodology for the prototype of RTLS-based healthcare management system (RHMS), and guide a road map for the implementation, has aroused academic attention. However, there are few published articles related to the development of an information system design theory for an RTLS-based healthcare management system. A brief review of literature is presented below.

'Action research' is an iterative process, with researchers and practitioners acting together, diagnosing problems, actively intervening to achieve enhancement and reflective learning[59]. Unnithan et al. [4] investigated an action research framework for a pilot implementation of RFID in a large hospital, involving the cycles of situation diagnosis, action planning, action taking, evaluating and specifying learning. Kuo et al[21] identified important issues during the RIFD implementation in Hospitals. Wu [60] et al. discussed a number of challenges that have hampered the adoption of RFID in organizations, including technical settings, standard settings, lack of infrastructure, high costs, and migration problems. Curtin et al.[61] explored a research agenda to address a series of broad research questions related to how RFID technology (1) was developed, adopted, and implemented by organizations; (2) was used, supported, and evolved within organizations and alliances; and (3) has impacted individuals, business processes, organizations, and markets. The difficulty and cost to control the real-time data from tagging and tracking was also noted. Based on participant observation and interviews with hospital staff members and industry consultants, Fisher et al. [53] found that

organizational factors contributed to the success or failure of the RFID systems in hospitals and suggested taking into account privacy concerns and the increased workload for hospital staff, especially during the implementation process. In the research by Ngai et al.[62] , a prototype of the RFID-based healthcare management system was built and implemented in a quasi-real world setting. By describing four components of Information System Design Theory (Kernel theories, meta-requirements, meta-design, and design method), several RFID-enabled processes, such as patient identification, location tracking, and drug inventory management, were analyzed and designed. Ting [19] et al. composed 11 steps in the preparation, implementation, and maintenance stages of constructing a RFID project in a medical organization. Ting conducted a case study to illustrate the 23 critical success factors that should be taken into consideration in the development framework.

2.3. The Challenges in Deploying RTLS in a Hospital

Although researchers and practitioners have provided useful insights for successful deployment, the research on designing and implementing an RTLS-enabled system in the healthcare industry is still in its infancy. Some studies (such as Ting et al.[19]) suggest that the first step for implementation is to visually represent the current state processes via a set of prevailing process mapping methods. However, few papers pointed out the necessity of eliminating non-value-added activities based on the methodology of lean management. Duplicated or unnecessary work flows should be discarded or simplified in order to optimize the standard operation process and reduce tracking complexity before system implementation. Meanwhile, the design proposed by

Ngai et al. [62] has not covered all of the flows running in the daily operational management in a hospital and the potential adoption field, such as process engineering flow (reusable equipment cleaning in Sterile Processing Department). In addition, business rules should be composed to analyze the real-time data and mine the significant information from corresponding tracking objects. Furthermore, preliminary steps of implementation, such as technology evaluation, tracking objects selection, and resolution level setting, have not been discussed deeply in previous studies. Finally, few researchers have demonstrated the importance of engrossing RTLS in the facilities' culture for the successful deployment of a new technology in the traditional working place.

2.4. Hybrid Design and Implementation Framework for RTLS Adoption in a Hospital

Information Systems Design Theories (ISDTs) were defined by Walls et al.[63] to be a prescriptive theory to integrate normative and descriptive aspects into design paths for designing information systems with more effective approaches. Based on designing principles and managing the effective development practice, ISDTs are considered as the guideline for adopters since they increase development reliability and the likelihood of success [64]. Ngai et al.[62] demonstrated the product design and process design for RFID-based healthcare system according to ISDTs. This research continues to explore the design and implementation methodology by combining ISDT with lean management and the concept of Task-Technology Fit for defining a comprehensive action plan.

Before implementation, project managers should consider the following questions:

- What is the compatibility of the solution with the existing environment and healthcare informatics system?
- What are the risk factors associated with using new or newer technology?
- Can the existing IT capability handle the data storm retrieved from RTLS?
- How accurate are tracking results?
- Compared to other technical solutions, how applicable is the RTLS approach to implement in hospitals?
- Is the potential ROI in an acceptable range?

The answer to these questions should clarify four basic concepts, which are 'why, where, when and how' to implement RTLS. The questions in detail could be described as follows: 1) Why should we choose an RTLS system? 2) Which applications and process are best improved or automated via an RTLS system? 3) When is a suitable time to implement it in practice? and 4) How can a facility best adopt the technology into their culture and daily practice? [65].

ISDTs define a design process in two aspects: 'Design Product' and 'Design Process', which includes the components 'Kernel Theories', 'Meta-Requirements', 'Meta-Design', 'Design Method', and 'Testable Design Hypotheses' [63] According to ISDTs, the proposed framework for designing RHMS is presented below in Figure 2-1:

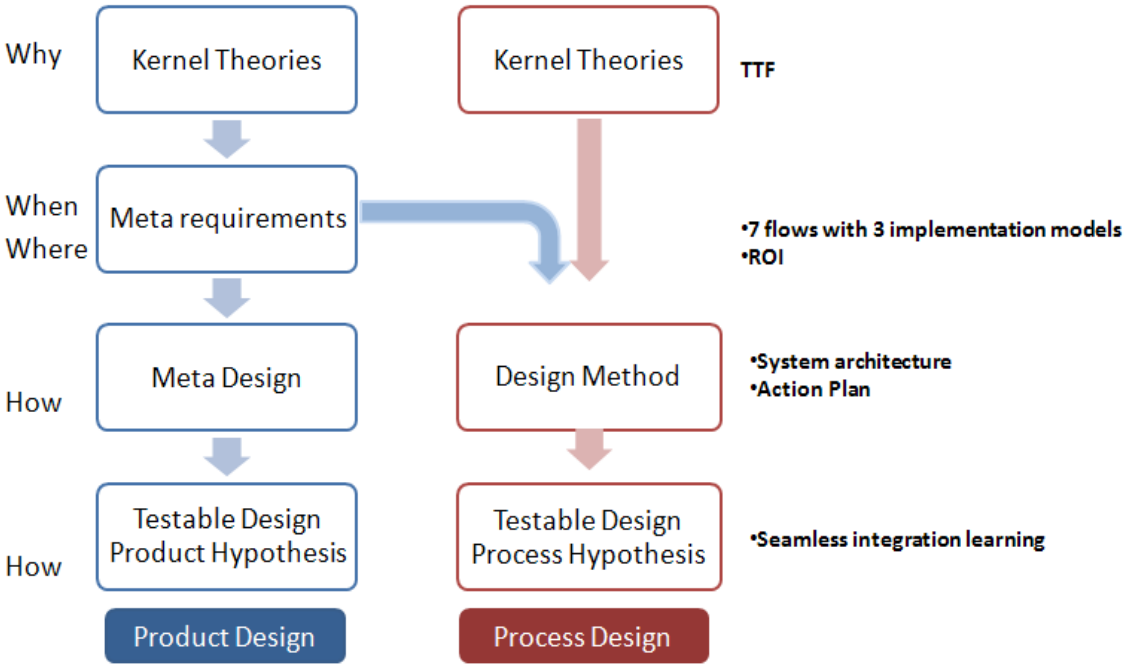
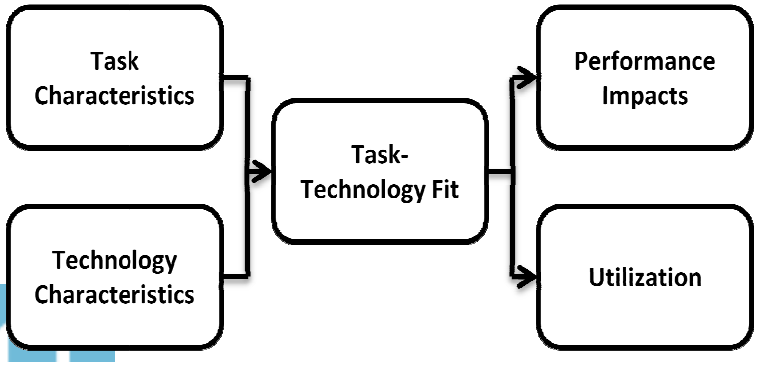


Figure 2-1 Framework for Designing RHMS

2.4.1. Why: Task-Technology Fit (TTF)

The Task-Technology Fit model proposed by Goodhue et al. [66] is used to examine the impact of "fit" between task characteristics and technology characteristics on individuals. In order to explore the adoption of a new hospital information system, the concept of task-technology fit is applied to offer a suitable starting point as an adoption method of Kernel theories. By and large, the question 'why' to implement RTLS in a hospital will be addressed by a rather loose interpretation of TTF. Figure 2-2 depicts key components of the conceptual TTF model:



The original TTF model provides some foundational factors to evaluate the adoption of technologies in completing tasks. Thus, some of those factors are inherited for identifying important factors contributing to the adoption of RTLS in healthcare organizations. Considering the advantages of tracking the location and real-time information supplied from RTLS, the empirically testable prediction related to adopt RTLS for healthcare management improvement is summarized in Figure 2-3:

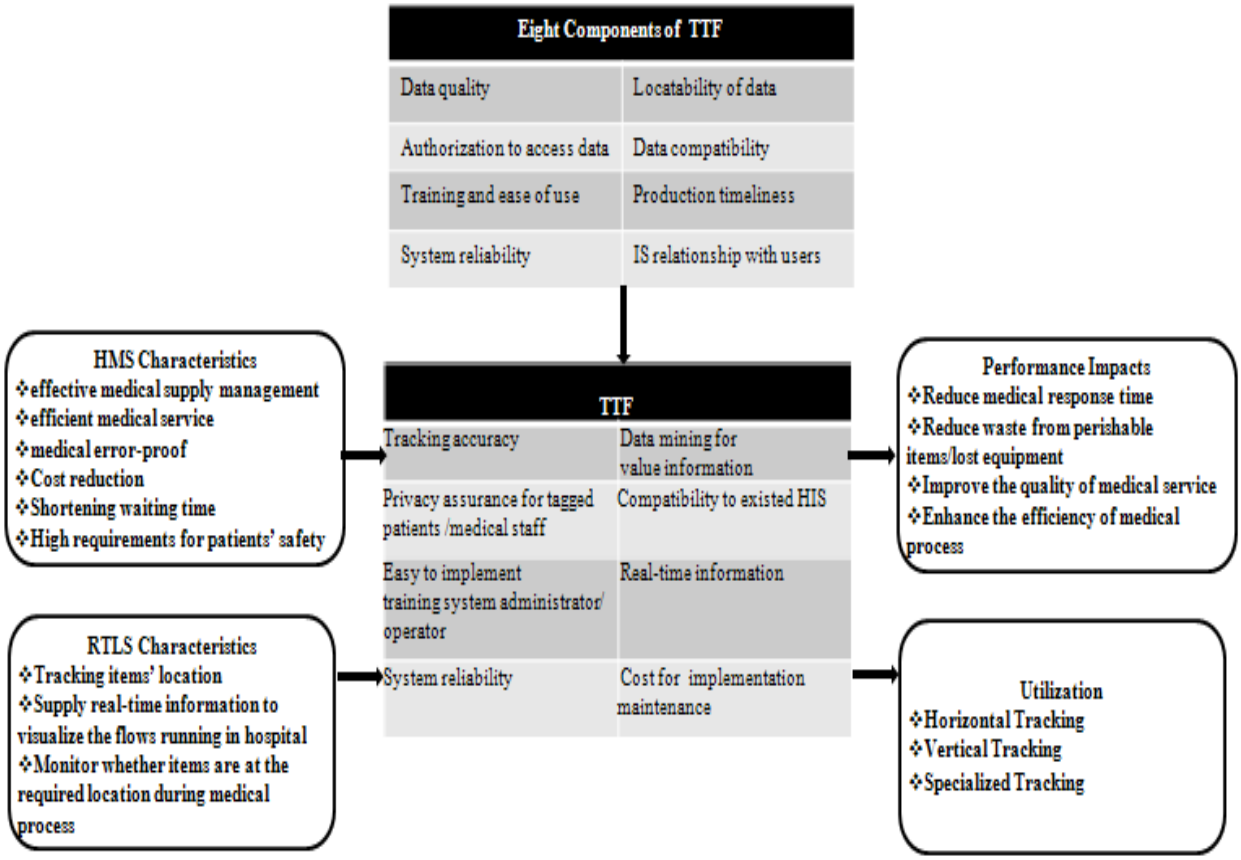


Figure 2-3 TTF Analysis to Adopt RTLS for Healthcare Management

2.4.2. Where: Meta Requirements

Meta requirements describe the class of goals to which the theory applies [63]. These requirements are used to analyze the objectives or potential adoption of RTLS in a

hospital. Based on lean management methodology, healthcare management has been subdivided to monitor and facilitate the seven flows running in the daily operation: the flow of supply, equipment, information, patient, clinician, medication, and engineering (such as cleaning reusable equipments). The initial deployment should focus on assets, people, and work flows which will deliver the highest return on investment and can be used as a foundation for future RTLS growth and system wide implementation. Thus, the primary problems involved with the time-sensitive and location-sensitive flows should be tackled first in order to have measurable outcomes.

In the past few years, RTLS technology providers have developed horizontal solutions for tracking assets and vertical solutions for monitoring work flows in manufacturing, warehouse management and retailer. However, healthcare is considered too unique to target since there are different types of specialized applications, such as standard operation process for cleaning reusable medical equipments. In order to optimize the seven flows running in the daily operations in a hospital, three of tracking models will be adopted to create the RTLS-based healthcare management system. The prototype with seven flows for RHMS is shown in Figure 2-4.

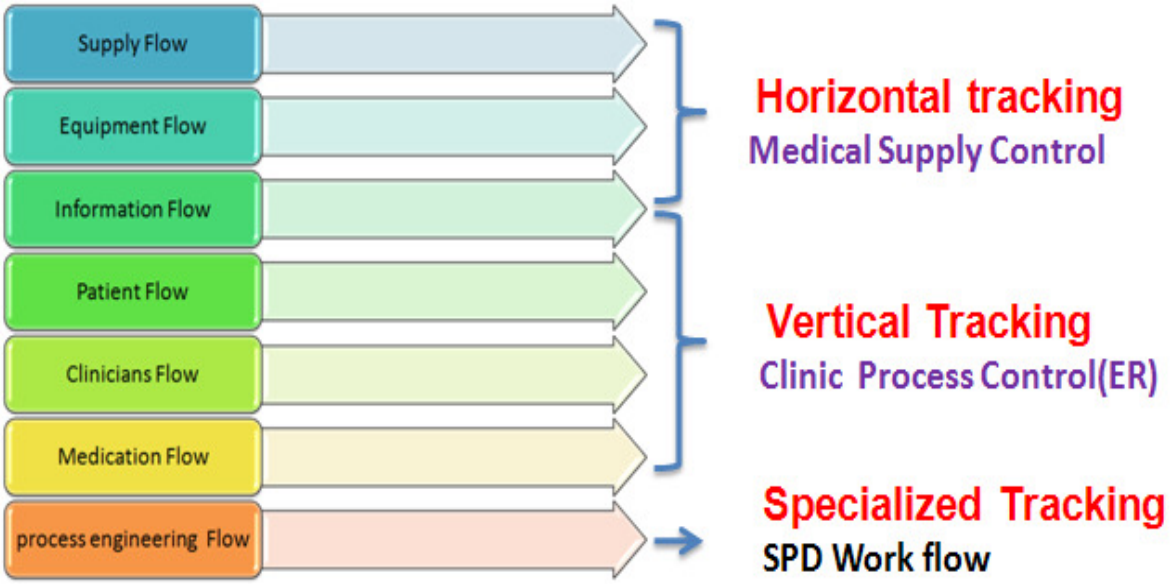


Figure 2-4 Prototype with Seven Flows for RHMS

- **Horizontal tracking model for medical supply control**

Management of medical and surgical supplies is one of the targeted areas of early implementation when considering ROI in a hospital setting. Hospitals lose a considerable amount of money each year due to unexpected low stock of needed supplies, inaccurate on-hand inventory levels, and undetected expiration of supplies. Consequently, some medical treatments have to be delayed or cancelled due to the shortage or unavailability of required assets. Therefore, it is crucial to improve the visibility of medical supply management.

Meanwhile, the accurate location information of assets in a timely manner could decrease labor costs associated with searching misplaced items and reduce the revenue due to asset unavailability or duplication of purchases. This location tracking data could optimize the flows of supply, equipment, and information, and facilitate the horizontal

management through multi-level inventories. Management of supplies in clinical areas such as the Cardiac Catheterization Lab (CCL) or the Operating Room can be considered as early adoption areas since they typically have the most expensive supplies and the highest consumption rate.

- **Vertical tracking model for clinic process control**

Significant problems as noted by healthcare quality control indicate lengthy wait times and risks for medical errors as two of the top concerns in the industry. Among the seven flows, improving the quality and efficiency of medical service requires better organization of four flows, which are information flow, patient flow, clinician flow, and medication flow. Vertical management, which is designed to track objects according to the timeline of process operation, can be used to analyze and manage patients' location and status in the healthcare delivery process. The Emergency Room (ER) can be considered one of the most complicated and busiest areas in a hospital, where patients must receive adequate treatment in the shortest possible time. Considering the time-sensitive services in the ER, RTLS technology could be implemented as a solution to reduce waiting time and eliminate errors in clinical services.

- **Specialized tracking model for SPD work flow control**

When considering patient safety, one can look at the cleaning process for reusable medical equipments (RMEs). This process is often complex and variable, which is dependent on the manufacturer and model of the device. Healthcare facilities often utilize Standard Operating Procedures (SOP's) that are based on Manufacturer's Instructions to guide staffs in SPD to complete the cleaning process thoroughly and consistently each

time. To ensure the sterilization processes in proper operations, the specialized tracking model is in demand to monitor the work flows according to SOPs. Advanced autoclave tags could withstand rigorous sterilization processes including ultrasonic cleaning, high pressure liquid sterilization and steam autoclaving. Consequently, autoclave tags with RTLS solution could allow hospitals to improve staff efficiency, automate SPD management and optimize RME reprocessing procedures.

2.4.3. When: Return on Investment

Before taking action to deploy the system, the Return on Investment (ROI) should be estimated. This estimation helps decide whether it is a good time to select this approach since the price points are coming down while technology is continuing to innovate. Estimating ROI analysis requires an understanding of the required investment for the project and a prediction of benefits that will be derived from RTLS implementation. The cost components for RTLS implementation are listed in Table 2-1:

Table 2-1 The Cost Components for RTLS Implementation

Cost Components for RTLS Implementation	
Main Hardware cost	RFID tags/ readers
	servers/client-end computor
	network swithes
	wireless access points/ signal amplifier
	other accessory equipments(such as PDA)
Software Cost	database
	data analysis package
	user interface system
	maintance fee
	updating fee& Frequency
Integration	hardware connection to existed HIS
	software integration
	customization cost for specific application
Labor Cost	training for internal staff
	new employees(System administrator)
	process analyst
	Support from other party(RFID experts, consultants)
Installation Services	setting up or update the network
	design the topology of RTLS infrastructure
	hardware installation, such as tags. Readers
	hardware/ software maintainance and management
	testing the performance of system after implementation
Business Process Reengineering	business process optimization
	new additional options with real-time information

As a key solution of Automatic Identification Data Capture (AIDC) technology, RFID could easily identify and track the location of items, which will release labor from the inefficient manual operations. When RTLS has been implemented in the healthcare industry, hospital should anticipate the expected benefits, which may happen to be quantitative data, from cost reduction, improve service performance improvement and increase revenue. These three key drivers for benefits are summarized in Table 2-2:

Table 2-2 Three Key Drivers for Benefits from RTLS Implementation

Three Key Drivers for Benefits	
Cost Reduction	reduce required labor force /time
	reduce the medical supply shortage rate, emergent order, expiration waste and inventory level
	reduce the missing assets/rental rate of equipments
	reduce paper-based documentation
Service Improvement	increase capability of medical error-proof
	reduce the patients' revisit rate
	increase working efficiency
	increase patients' effective treatment time
Revenue Increasement	increase the amount of patients served
	increase the capability to serve patients from other hospitals
	speed up the revenue-capture rate
	increase the utilization rate of equipments

2.4.4. How: System Architecture Design

In this section, the researcher will design an architecture framework of the RTLS-based healthcare management system (RHMS), which consists of seamless control in the three main adoption areas. The logic of the architectural system and functions of each flow are described as follows in Figure 2-5. The architecture framework of the RHMS is consisted of seven flows (Information Flow, Patient Flow, Clinicians Flow, Medication flow, Supply flow, Equipment Flow, Process Engineering Flow). The new designs of each flow based on RTLS are also described below:

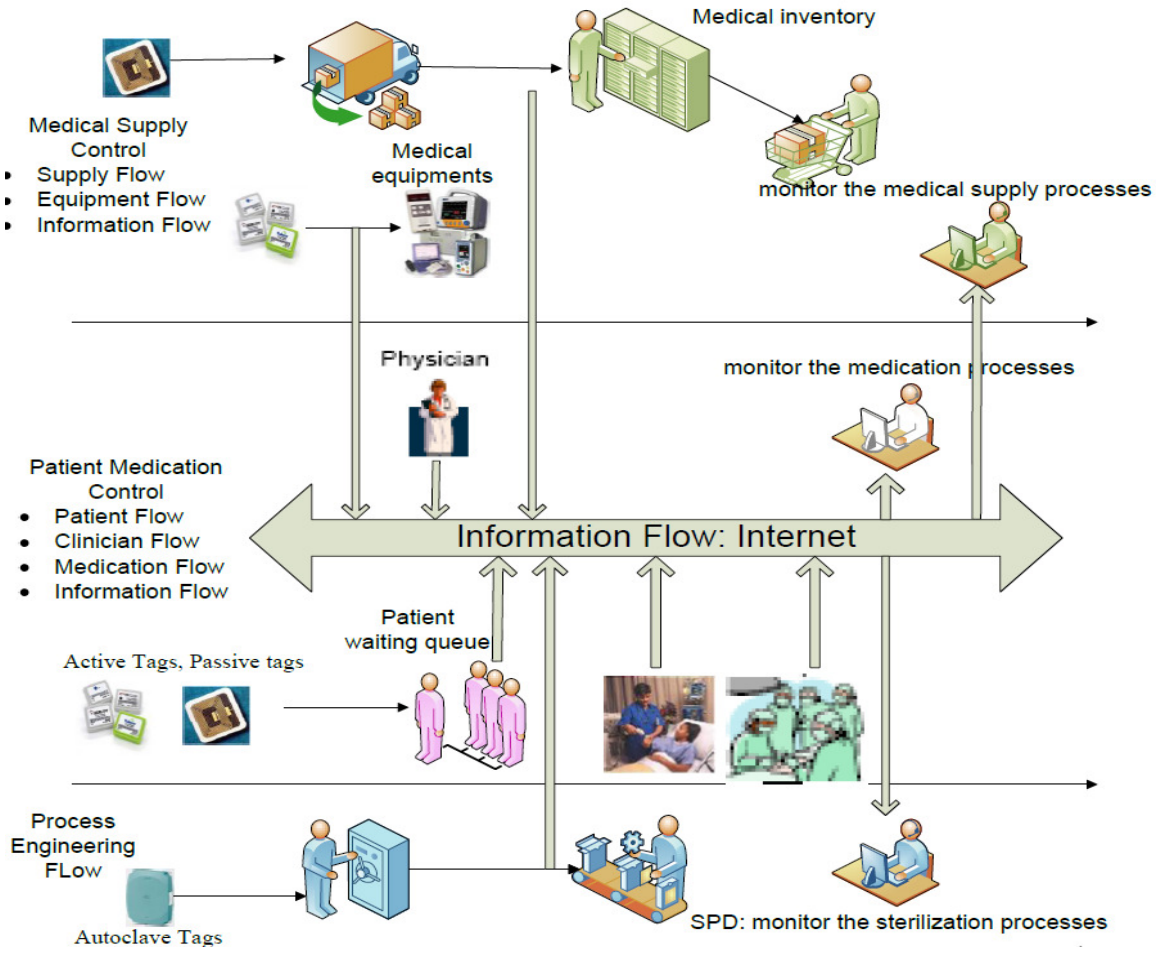


Figure 2-5 System Architecture

- **Information Flow**

RFID wristband will be issued to every patient at the registration step and will be worn by patients during the entire hospitalization period. Some important patient information (such as name, patient ID, drug allergies, clinicians on-duty) will be stored in the RFID wristband in order to identify patients accurately. The status of process for delivering healthcare and diagnosis results will be transmitted efficiently based on

electronic files. This could eliminate the risk of medical errors and release medical personnel from manual entries for all required data and paper reports.

- **Patient Flow**

During the clinical process, patients always move to different locations for diagnosis, such as blood testing and X-ray examination. Sometimes the clinical processes have to be delayed due to the absence of patients, for example, patients do not come to their appointment ; they leave the hospital against medical advice; clinicians can't find the patient in their hospital room. Consequently, clinicians need to spend time searching for them or rescheduling the treatment. This unexpected change will slow down the original process and involve some non-value added operations. The rate of 'patient's leaving against medical advice and without being seen by a provider' is one of the key factors to consider when evaluating the performance of clinical services. Based on the middleware integrated in RTLS, a reminder alarm will be sent to corresponding clinicians to notify when patients leave unexpectedly. Meanwhile, RTLS could monitor the procedures that patients are receiving, such as the status of process and the staff members that are providing services. This could help the quality management department to record each step of the clinical process and improve the quality control of medical treatments.

- **Clinician Flow**

Normally, a group of clinicians, such as physicians, nurses, and technicians, cooperate to serve patients for specific medical treatments. In order to classify clinicians into different groups and identify them easily as shown on the management portal, unique color-coded RFID badges combined with an ID number could be issued to each group of

clinicians. Once the location of clinicians is tracked in this system, the length of valuable time they spend treating patients could be easily estimated, which might be used as objective evidence to demonstrate the performance of clinicians. In addition, an advanced function could be designed in RTLS middleware to better assign clinicians to specific patients nearby based on their location and the particular service they could supply.

- **Medication Flow**

Delivering the right medicine to the right patient at the right time is crucial for patient safety and effective medical diagnosis. When small RFID labels are tagged on each drug container for a unique patient as well as the original containers from the pharmaceutical factory, the location of the medicine could be roughly tracked. Some primary information, such as quantity, inventory level, and expiration date could be written on the RFID labels, which could facilitate automatic reminders for removing expired and recalled product items from the inventory shelves.

- **Supply Flow**

In supply chain management, there are three flows running in logistics operations: Information Flow, Material Flow and Money Flow. RTLS as an advanced automatic data capture system could facilitate the information flow, sharing information during the whole logistic management process. The benefits of RTLS implementation in perishable medical supplies are shown in Figure 2-6:

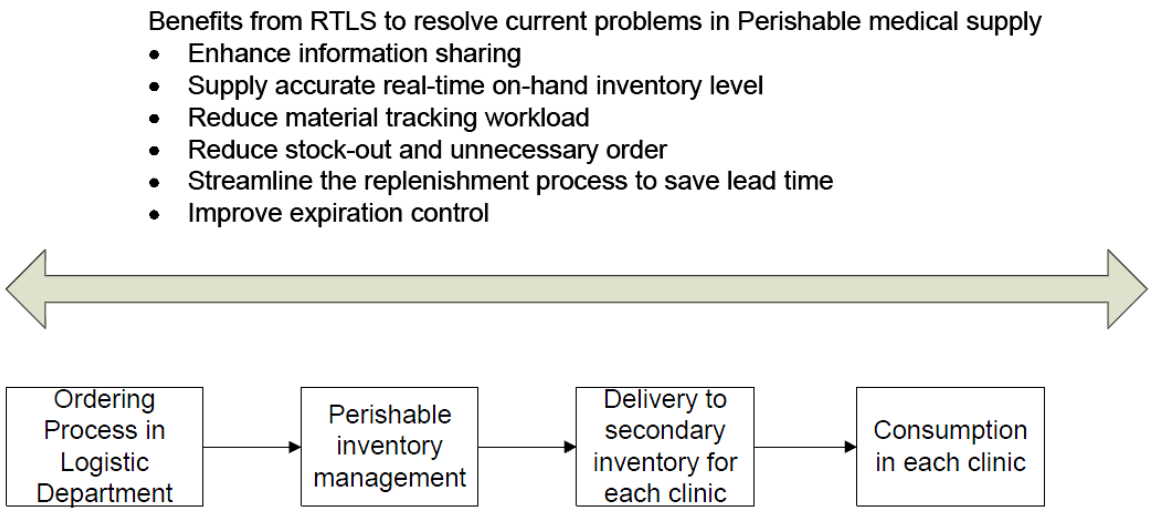


Figure 2-6 Benefits from RTLS Implementation in Perishable Medical Supply

- **Equipment Flow**

Misplaced or lost equipment can sometimes postpone medical treatment. When this happens, the logistics department has to rent equipment from nearby hospitals. Attaching RFID tags to the equipment makes it easier to track their location and status, such as 'available to serve' or 'in-use'. Consequently, the time need to physical search for it will be dramatically reduced, and the preparation process for surgery or medical diagnosis is also improved. Furthermore, an alert could be triggered if equipment is moved without clinicians' permission. This could eliminate the loss from stolen equipment.

- **Process Engineering Flow**

This section mainly focuses on SPD workflow reengineering based on the deployment of RTLS. By attaching autoclave tags, the location of reusable equipment during the cleaning process is tracked and verified to avoid skipping steps; the

temperature and pressure are monitored following standard operation process (SOP) rules; and the length of time for each cleaning step is recorded to ensure an adequate sterilization period. Meanwhile, Real-time visibility ensures that critical washing machines are available when needed, thereby increasing working efficiency, shortening SPD preparation time and increasing throughput. In addition, automated SPD management of RME equipment in multiple locations could enable adaptive planning and scheduling for the dynamic reprocessing operations. Based on the location information, RTLS could identify the status of RME equipment in the cleaning and sterilization process, such as wait-in-queue, work-in-process and finished. This will eliminate duplicating operations when some RME equipment has already completed certain steps.

2.5. Implementing an RTLS-based System in a Hospital

Although RTLS is an outstanding technology which can enhance healthcare system efficiency and automation, actual implementation of the technology can result in substandard and ineffective systems without a comprehensive pre-study that involves site visitation, an understanding of the technology, and rigorous implementation plans. The phase of 'design method' in ISDTs will be described in the following section.

2.5.1. Process Mapping and Optimization prior to RTLS Procurement

To support an optimal RTLS deployment, a graphic representation and written assessment study of the current state of work flows should be provided. This section will outline the key processes that are relevant to RTLS applications and/or key process performance metric variations, work standards and requirements, and the individuals

involved. It is important to categorize similar flows of work into unique groups. This could simplify process mapping processes and identify work flow patterns in order to reduce the complexity level for implementation. Based on lean management methodology, non-value-added activities should be eliminated to optimize standard operation processes and reduce cycle time. Finally, the suggested areas for automation utilizing RTLS technology and potential qualitative/quantitative measurements for improvement should be provided. A case study from a catheterization lab in one hospital is shown below in Figure 2-7.

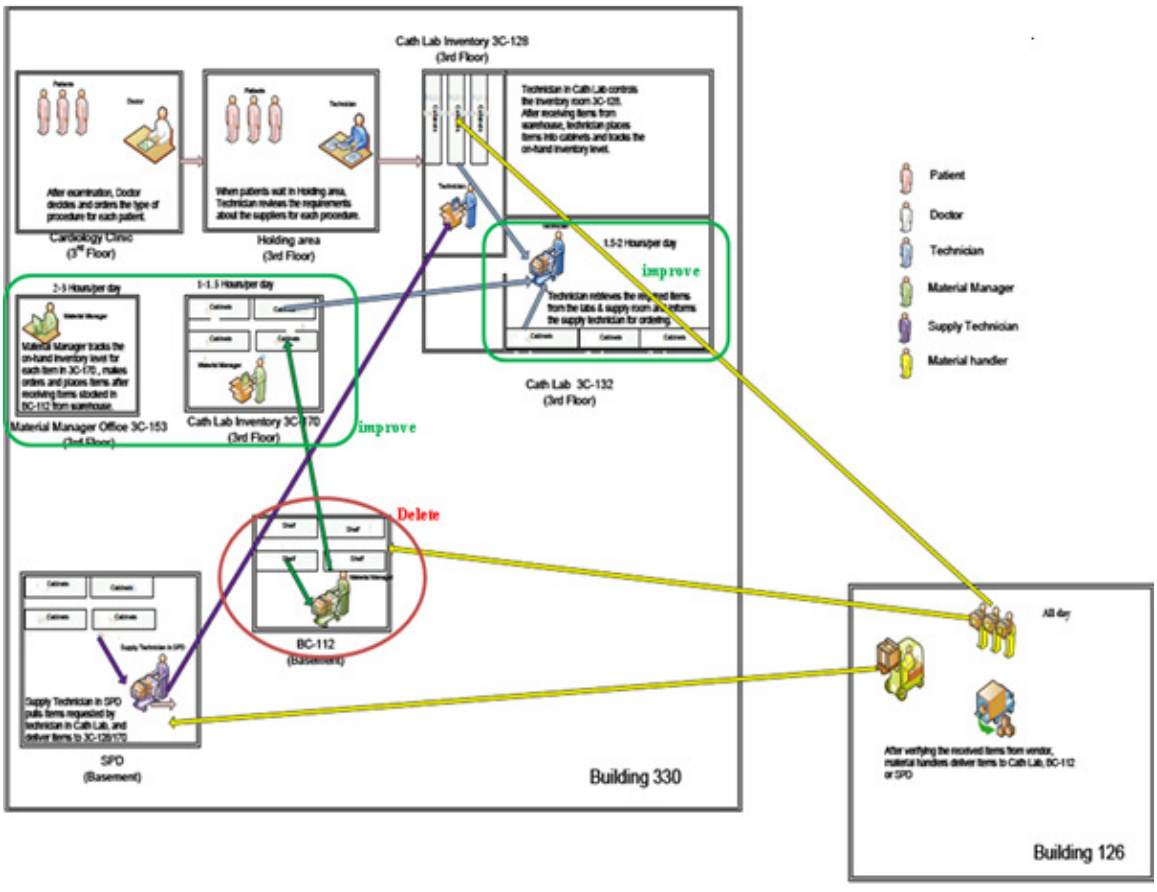


Figure 2-7 Process Mapping and Optimization from a Cardiac Catheterization Lab

The current steps which could be 'improved' by RTLS and non-value-added steps should be deleted are also highlighted.

2.5.2. Evaluating Technology and Vendor Performance

Typically, an RTLS system consists of several components, including tags, readers, and antennas. The tags are used to store the unique identification information of tagged objects; the readers are responsible for detecting and communicating with tags to extract information through the antennas coupled to them. Numerous types of RTLS technologies are emerging to support Service, Business and Support functions, such as Wi-Fi, Zigbee, UWB, Infrared, and active and passive RFID systems. However, no one form of RTLS technology can satisfy all requirements. Different resolution levels, costs to deploy the hardware and software, and interference from other medical and support equipment with RTLS are some of the primary obstacles. Consequently, the selection and evaluation of suitable solutions to meet specific objectives is essential to the success of an RTLS implementation. In our research, 12 factors have been identified to evaluate the strengths and weaknesses of each type of technology, shown in Table 2-3:

Table 2-3 12 Factors for Technology Evaluation

Technology Evaluation						
	Passive RFID	Active RFID	Wi-Fi	Zigbee	IR	UWB
Adopter Environment	indoor	indoor	indoor/outdoor	indoor	indoor	indoor
Cost	low	high	medium- high	low-medium	low-medium	high
Signal Frequency	0.125–0.1342, 0.140–0.1485, 13.56, 840–960 MHz		2.4GHz	915 MHz (USA),2.4GHz	300-10000GHz	3.1-10.6 GHz
Signal Coverage	low	medium	medium-high	low	low-medium	low
Resolution Level	room level	room-zone level	zone-building	room-precision	room	precision
Accuracy	1M-10M		1M-10M(more)	5M-8M	8M-10M	0.1M-0.5M
East to extend more functions	not available		available	not available		
Date Rate	0-10Mbit/s		10Mbit/s<, <100Mbit/s	0.01Mbit/s<, <0.5Mbit/s	<40 Mbit/s	100Mbit/s<,<1000Mbit/s
Battery Consumption	no	low	high	low	medium	high
Resistance to Interference	medium		high	Medium	low	high
Information Encryption	yes		yes	yes	no	yes
Metal/Water Content	not suitable	suitable				

High tracking accuracy requires higher technology and maintenance costs. Among these 12 factors, the Resolution Level for tracked objects is a key factor to choose technology solution and design architecture. Seven primary characteristics of tracking objects are suggested to define the resolution level, shown in Table 2-4:

Table 2-4 Resolution Level Setting

Resolution Level Setting	
Characteristics of tracking objects	Resolution Level Setting
The medical items with high priority	Precision level
The medical items with Low priority	Room Level
Large medical equipments	Room-zone Level
Personnel	Room-zone Level
Reusable equipments for surgery	Precision level
Medicine	Precision level
sample for lab (blood)	Precision level

With the wide-spread adoption of RFID technology, numerous vendors are anxious to join in this new market. Based on feedback from previous implementation sites and the facility-specific requirements identified in the evaluation, a Performance Matrix for vendor selection is shown in Table 2-5:

Table 2-5 Performance Matrix for Vendor Selection

Performance Parameters for RTLS selection	
Category	parameter
Function requirements	locating error rate
	real-time information(data update frequency)
	scope of signal detection
Handware	tag: easy to ware/operate small size/ low weight long battery life strength of signal
	integration of third-party devices
	additional hardware installation
Software	adaptive to existed database
	friendly user interface
	easy to configurate the system
	supplied software function
	frenqucy to update system
Business Rule	event definition
	data mining
Cost	price for hardware/software
	hire additional personnel to operate/monitor
	maintenance costs
	update cost
Service support	system warrenty scope/period

2.5.3. Selection of Tagged Objects

In a healthcare setting, there are numerous complex processes that involve the movement and relationship between equipment, staff, patients, and supplies. Considering the cost of hardware and the data processing capability of middleware, it is crucial to analyze the criteria to prioritize the tracked objects when considering the ROI a facility

will initially receive. As an example, when considering which medical supplies to track in a CCL, eight factors and suggested rules are listed in Table 2-6 below:

Table 2-6 Eight Factors and Suggested Rules for Selection of Tagged Objects

Selection of Tagged Objects	
Factors	Suggested criterion
Price	item with price more than $ 100 for active tags (based on budget)
Consumption rate	fast-moving item
Easy to order	item with specific characteristics / long production time
Expiration date	item with short life time
Level of perishable risk	item with high risk for safety if it's perished
Moving frequency	item / personnel moves frequently between multi-locations
Priority of responsibility in medical treatment	medical staff who has high responsibility to serve patients
Severity of disease	patients who are at high severity level for life safety

2.5.4. Business Event Definition and Objectives

Although RTLS can successfully track the location of assets and personnel in real time, RTLS can also provide support for other business processes. To assist with identifying these business cases, designers must provide a means to document the potential event resolutions within each RTLS application. A complex clinical path could be represented as a chronological sequence of events. Each event occurs at an instant time and marks a change of state in the operation. Based on the Discrete-Time Methods for the analysis of event composed by Allison [67], there are two alternative approaches. One is to assume an underlying continuous-time distribution and then estimate the model's parameters by methods that take into account the discrete character of the data. The other approach is to simply assume that events can occur only at the discrete intervals measured in the data and then apply discrete-time models using logistic methods.

The proposed model in this research is designed based on the latter approach. Based on the analysis of important steps, the whole process will be divided into sequential events and phases. For each event, an assigned milestone is used to define the beginning and ending point for an important event. Consequently, the objectives for each event and the aspects of elimination and improvement should be clarified. For example, the performance of a healthcare delivery process in an Emergency Room(ER) from one hospital could be measured by these discrete event points with non/value added analysis by red/ green color as shown in Figure 2-8.

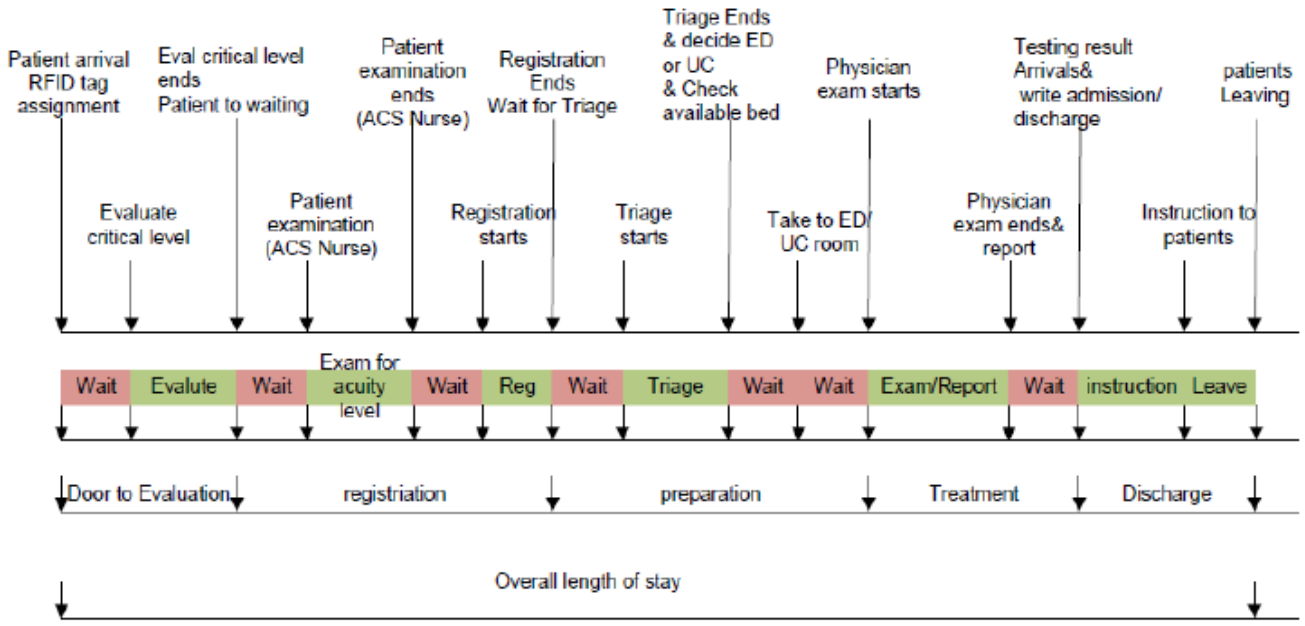


Figure 2-8 Discrete Event Analysis for Medical Process in an Emergency Room

Meanwhile, only the information about Location (equipment, patient) is insufficient to assist medical staff in decision-making. For example, a technician is looking for an available wheelchair, requiring information about the location and

occupied status of other patients synchronously. Business rules are designed for mining the valuable information from collected real-time data and creating links to combine two corresponding tracking objects. These rules are also called the rules engine. There are two primary components to set up a business rule for each event:

Conditions: the requirements which must be met in order for the rule to be applied.

Action: the action which should be taken when this condition is met.

An example of condition is the locations of a wheelchair and patient are identified at the exact same time. An example of an action is the wheelchair is occupied and not ready to serve others.

2.5.5. Getting the Right Cultural Emphasis at the Right Time for RTLS

Tapp et al, [68] discussed four primary reasons that ERP implementations fail. They are (1) inadequate education/training, (2) poor leadership from top management, (3) resistance to change, and (4) unrealistic expectations. Individuals are the key enablers in creating the right culture to adopt the new technology at the right time.

The three "value disciplines" to guide IS implementation successfully are product leadership, customer intimacy and operational excellence. In an early adopter field, it is critical for a project manager to press forward with "product leadership" but to do so with "customer intimacy" so that the project manager can learn what constitutes a full solution that will produce a compelling ROI. This requires the adopter's technical and business partners to work closely with each customer to identify the business processes that can be eliminated, automated, or otherwise improved through the introduction of the newly proposed technology.

The education and training of end users and the implementation group will play an important role in designing realistic expectations for benefits gained from new technology. The education could help everyone understand the aims and action plans to adopt the system, update and communicate with stakeholders. End-users are sometimes resistant to change, which is perhaps the greatest obstacle holding hospitals back from deploying new technology.

Operational excellence drives doing the same things faster, cheaper, and better—which is good only when you are sure that you are doing the right things in the first place. This requires establishing an excellent solution team with key technology experts who lead the design of the system infrastructure, project managers who own the business process, user representatives from adopter, IT technology members, and vendor members.

2.5.6. System Testing

Basic function testing will evaluate the fundamental performance of the RTLS system under normal operating situations after implementing it in early adoption and implementation applications. Several key factors should be considered during the testing phase, shown in Table 2-7:

Table 2-7 key factors for basic function testing

Key Factors to Test Fundamental Performance of RTLS	
Signal overage scope	Locating accuracy
Error rate	System compatibility
Data processing capability	User interface

Pressure testing is addressed to verify system reliability under extreme situations when the key components or operations are out of control. Specific experiments are designed to test the performance if tags/readers have large density, hardware fails, or software collapses. Finally, the implementation team should provide documentation of end-state and assessment of RTLS implementation within initial implementation areas and expand the deployment process by estimating the strategy value and reengineering previous business processes.

2.6. Concluding Remarks:

According to the theory of Information System Design Theory (IDST), lean management and task-technology fit (TTF), this paper presents a hybrid design and implementation framework to implement RTLS in a hospital. The contributions of this research are the infrastructure for 7 flows with horizontal, vertical and specialized tracking models and its implementation prototype. This system infrastructure has proved to be extremely comprehensive to address four groups of questions ('why, where, when, and how') when implementing RTLS in a hospital. The technology selection criterion is considered as a primary step in the design framework and the methodology for Revolution Level Setting and Tracked Object Selection are also explored. This study has demonstrated an action plan based on the proposed architecture. Process mapping and optimizing current process could reduce the complexity of implementation. To evaluate the technology and vendor performance, the feedback is collected from previous pilot sites and the key factors were summarized. Business rule setting is recognized as one of

the primary steps to retrieve real-time data more efficiently to mine valuable information. Culture creation could reduce user resistance to adopt new information systems in their traditional work style. Evaluation of system performance after implementation is also discussed. It is hoped that deep understanding of the design and development of RTLS in the healthcare sector will provide some guidance to implement RTLS successfully.

Chapter 3 Transforming Sterile Processing Departments by RFID-Based Business Process and Workflow Management in Healthcare

Summary:

Patient safety has become an urgent issue for healthcare today. One major cause that dramatically impacts patient safety is the use of unclean reusable medical equipments, delivered from a sterile processing department (SPD). Unfortunately, current practice in the sterile processing department is mostly driven by human labor and control. Therefore, the whole business process is error-prone and inefficient, compromising the quality of reusable medical equipments and eventually patient safety. The overall objective in this research is to monitor and display the real-time performance and status of business process management in SPD, detect errors in time, and identify their causes. It aims to reduce healthcare-associated infections caused by unclean reusable medical equipments. In this chapter, business process management concepts and workflow technologies are proposed to support modeling, automating, monitoring, and analyzing sterile reprocessing procedures. Service-Oriented Architecture is used for the publishing, discovery, reuse, and composition of interoperable services for different purposes. Radio frequency identification is used for automatically collecting real-time data for situational awareness

of events, timing/locating SPD reprocessing activities**,** identifying various resources and recording indicators for the operation environment.

3.1. Introduction

Patient safety, one of the nation's most critical health care challenges, has been recognized as an endemic concern by the World Health Organization. Each year, 1 in every 10 patients around the world have been harmed and killed by medical errors [3]. The major threat to patient safety among the most common adverse events in healthcare is healthcare-associated infections. According to the Centers for Disease Control and Prevention, nearly 1.7 million healthcare-associated infections occur yearly, leading to approximately 99,000 deaths every year. Many of these healthcare-associated affections are due to unclean *reusable medical equipments* (RMEs), reprocessed from a *sterile processing department* (SPD), which come into direct contact with patient skin, blood, and other body fluids and tissues.

3.1.1. Current Status in Sterile Processing Departments

The sterile processing department is one primary department in a hospital, which has a separate and distinct area with specialized expertise and direct responsibility for both reprocessing soiled reusable medical equipments and providing ready-to-use (disinfected, clean, and sterile) reusable medical equipments to patient care areas. Normally, the sterile processing department is typically divided into three major areas: 1) the decontamination area, where soiled RMEs that are collected from several clinics, such as dental clinic or operation rooms, are cleaned and disinfected; 2) the preparation area,

where machine-washed RMEs are packaged and labeled for steam or gas sterilization; and 3) the case cart area, where ready-to-use RMEs are stored in the sterile storage, and then retrieved into case carts according to the required medical equipment list for each patient's treatment.

Figure 3-1 presents a simplified business process in a sterile processing department**.** After being utilized in the operation room, soiled reusable medical equipments are collected in a case cart to the sterile processing department through an elevator, which only transports soiled items. Based on the appropriate standard operation

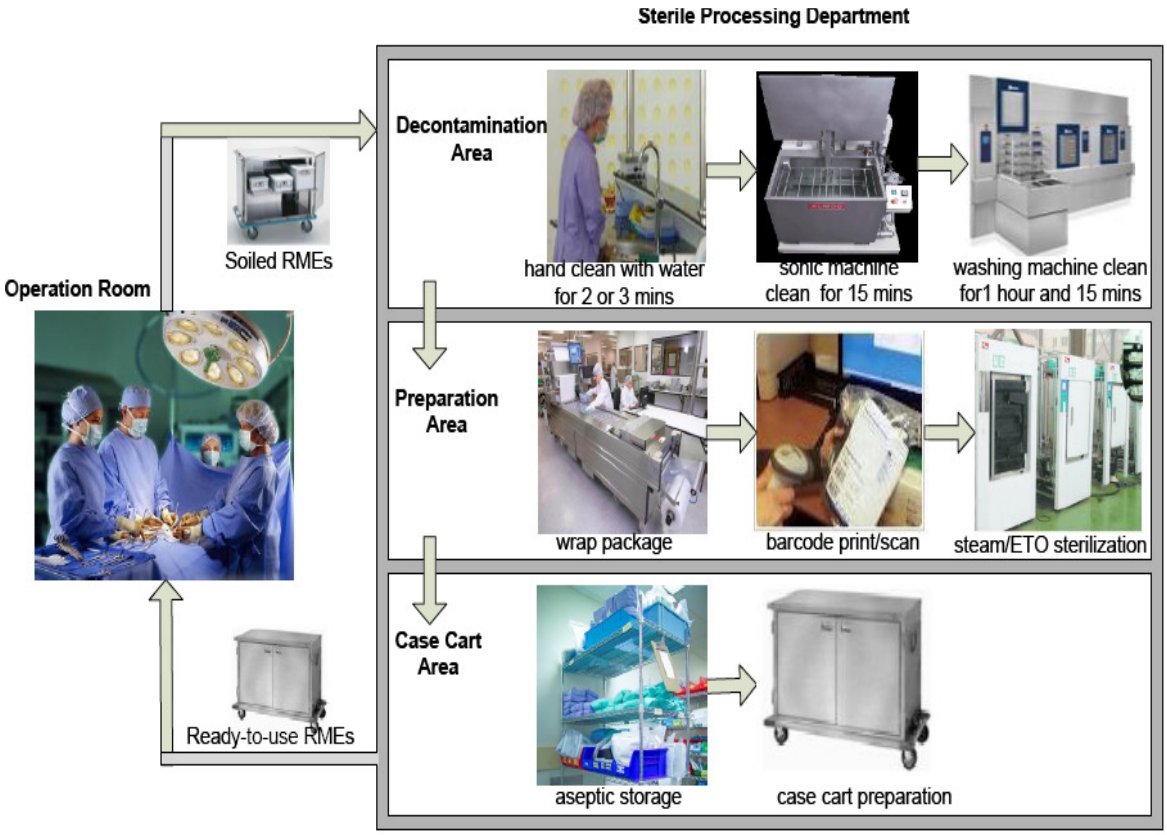


Figure 3-1 A simplified business process in SPD

procedure (SOP) rules, reusable medical equipments are disinfected in the decontamination area by some cleaning methods, such as hand cleaning, ultrasonic machine cleaning, and washing machine cleaning. In the preparation area, clean reusable medical equipments will be wrapped, packaged, and labeled by a new barcode, which shows the basic information of reusable medical equipments, such as item IDs, expiration dates when they should be reprocessed again, regardless of usage. Then, the sterilization step will be executed for several hours (such as 14 hrs for ethylene oxide (ETO) sterilization or 1 hr for steam sterilization) to destroy microorganisms or inanimate objects. In the case cart area, all the ready-to-use reusable medical equipments will be stored in the aseptic sterile processing department inventory. When an order from the operation room arrives, a technician will build a case cart according to the ordered reusable medical equipment list for each operation room case. Finally, the prepared case cart will be sent back to the operation room by another elevator, dedicated to transport ready-to-use reusable medical equipments.

3.1.2. Identification of Patient Safety Factors in SPDs

Any weaknesses in the sterile processing department policies and oversight in governing reusable medical equipments will pose great risks to patient safety. Although current practice in the sterile processing department aims to follow the standard operation procedures derived from device manufactures, based on a detailed investigation of the sterile processing departments, it's found that there are many factors that can directly or indirectly compromise patient safety. The analysis is summarized as a cause-effect

diagram in Figure 3-2, in which six groups of major factors effecting patient safety are identified:

- **Reusable Medical Equipments (RMEs):** Surgical-site infection can occur because surgical procedures breach the skin and allow bacteria to colonize and infect sterile tissues by using unclean or expired reusable medical equipments. Sometimes, clinics have to reactively cancel or postpone medical cases since the required reusable medical equipments are out of stock, delayed, broken, lost, misplaced, or mislabeled.

- **Process:** Errors could occasionally occur during the sterile processing department reprocessing procedures, such as skipping imperative steps, non-compliant operations, and operating based on wrong standard operation procedure rules. Without strict

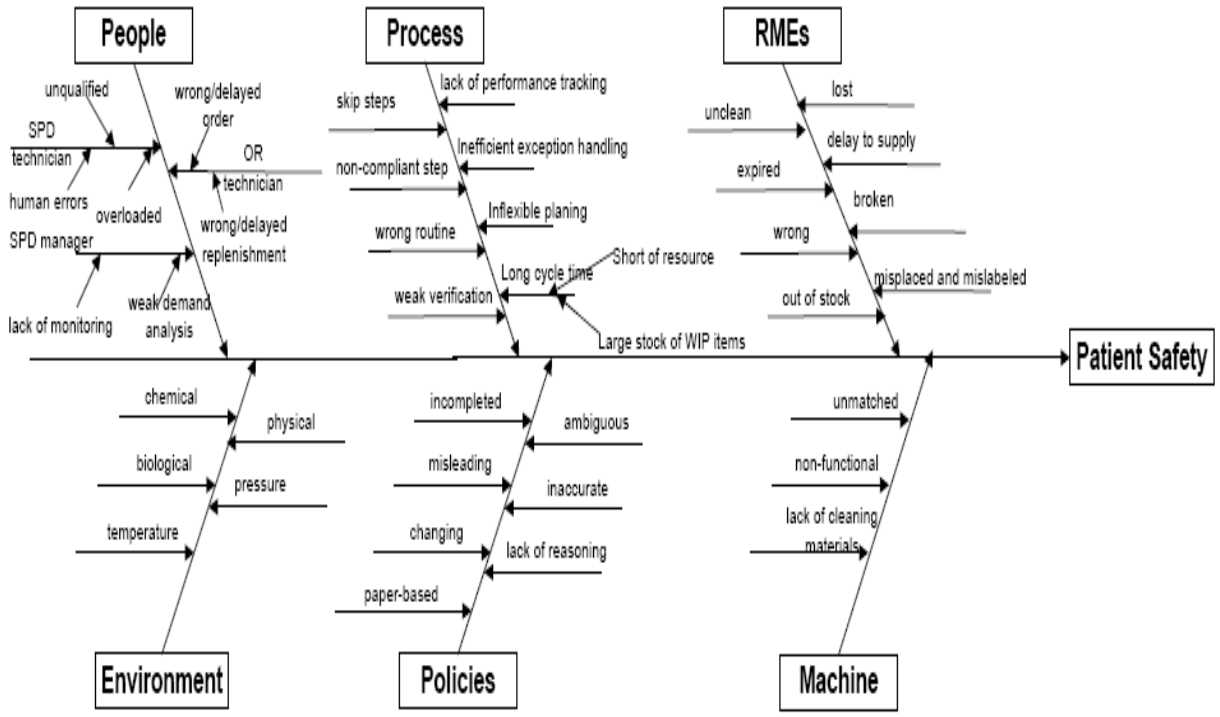


Figure 3-2 A Cause-Effect Diagram to Analyze the Weak Operation Management in SPD and Patient Safety

compliance checking between the sterile processing department operations and standard operation procedures standards, it is hard to verify each step and respond quickly and accurately to handle exceptions. Without displaying the real-time status of each operation in the reprocessing workflow, it is hard to make production control to streamline the cooperation of technicians and machines in different working areas. Consequently, when work-in-process items are stocked in some temporary inventories that are not strictly aseptic, some of the previous operations have to be repeated. As a result, the reprocessing cycle time is prolonged, which will delay the supply of reusable medical equipments and postpone the schedule of an operation for a patient, causing the patient to wait and more severe conditions.

- **Policy:** Standard operation procedure rules are the operation principles that guide staffs to complete the reprocessing operations thoroughly and consistently. Sometimes, the content of these paper-based documents are not comprehensive enough to describe all the operation requirements. Sterile processing department technicians may be misled by some inaccurate or ambiguous explanations to imperative steps. When an operation exception happens, the reasoning analysis is not included in the current version of standard operation procedure policy to intelligently help technicians to remedy the delinquent operations. Thus, these weaknesses of policy management cannot ensure that sterile processing department operations are performed properly, which can result in unclean or damaged reusable medical equipments.

- **People:** Three types of medical staffs, sterile processing department technicians and manager, and operating room technicians are involved in the business process. Sometimes, sterile process department technicians cannot perform correctly because they are not qualified to reprocess the specific reusable medical equipments or too overloaded to concentrate on their work. Dynamic medical demands bring challenges to the sterile processing department manager to analyze customer demands and make flexible production plan to handle the exceptions to normal workflows when emergent orders arrive. Meanwhile, sterile processing department managers cannot efficiently monitor and trace the reprocessing workflows running in the sterile processing department floor. Wrong or delayed demands from operating room technicians will also introduce a risk to supply incorrect reusable medical equipments to patients subsequently.

- **Machine:** Multiple types of machine failures could occasionally happen in an unforeseeable way when executing a workflow. For examples: machines might decay and software services might fail due to their complexity; reusable medical equipments are sterilized in the wrong machine; or the procedure has to be ceased because of the shortage of raw cleaning materials. Such failures should be processed to resume operations or prevent unclean reusable medical equipments.

- **Environment:** Each operation should be performed under a specific environment. If the chemical, biological, physical or temperature indicators of reprocessing

environments are not standard, the quality of ready-to-use reusable medical equipments cannot be guaranteed effectively.

3.1.3. Problem Analysis

Many problems are compounded by the lack of effective *business process management* (BPM) with timely, accurate, and consistent data to monitor and control reprocessing operations in SPD. Most healthcare facilities design *Standard Operating Procedures* (SOPs) from diverse manufacturers and models of the medical devices to guide staffs to complete the reprocessing operations thoroughly and consistently. It is extremely critical to check the conformance between the actual business process operations and SOP rules [29], and analyze the reasons and the consequential influence by non-conforming operations. Under the dynamic and complex healthcare situation, business process management in SPD should be flexible and adaptive to supply required RMEs to unpredictable change and emergent cases. Thus, adaptive workload planning is required for each reprocessing area. Meanwhile, resource capacity should also be considered to adaptively assign orders to multiple machines with load balancing in mind. It aims to maximize the supply capability and optimize the utilization rate of reprocessing resources.

Consequently, healthcare professionals and managers anticipate an appropriate and deliverable approach to reengineer an SPD business process, and visualize, trace and control its execution. However, the methodology for SPD management is still in its infancy for healthcare management engineering. Few deliverable solutions and academic

research have focused on this topic. This motivates us to explore an innovative method to improve operation management in SPD.

Recently, there is an increasing interest in applying business process management (BPM) concepts and workflow technologies in the healthcare industry, to automate processes, improve efficiency, eliminate medical errors, and thus improve patient safety. According to Georgakopoulos et al. [69], workflow technology facilitates business processes management by providing methodologies and software to support the industry for modeling, reengineering, and executing business processes. It aims to track the routines of business processes, display the performance of each step, streamline process execution, and liberate human actors from routine work. These advantages of workflow management technology could assist an SPD manager to handle the problems in executing reprocessing procedures. Although much research has been done on business processes [70-73] in other industries, healthcare business process management poses many unique challenges when BPM and workflow technology are applied to healthcare[74, 75] as healthcare processes need to be patient-centered, policy-governed, quality-ensured, and event-driven, and the consequence of errors and inefficiency is more severe and costly. While some work has been done on healthcare workflow for some departments of a hospital [76-78], automating processes and improving patient safety in SPD is still an open topic for healthcare management engineering.

Recent developments in automatic data collection (such as Radio Frequency Identification (RFID), Zigbee, Wi-Fi, Bluetooth or Infrared) have provided a new

opportunity to capturing and managing real-time data from the business process[49, 61, 79, 80]. In this chapter, RFID-based healthcare BPM concepts and workflow technology is proposed as one attractive solution to automate and streamline the cleaning, disinfection, and sterilization operations in the sterile processing department. This RFID-based healthcare workflow system will provide a transparent operation management for SPD, which will facilitate the flexibility and adaptability to deal with dynamic demands and operations.

The main contributions of this chapter are summarized as follows:

a) To explore the key problems and define the specific objectives of SPD management based on its two functions for a hospital: reprocessing execution and ready-to-use RME supply.

b) To develop a business process management pattern for SPD, which includes business process modeling (pre-execution time), workflow management (execution time), and business process analysis (post-execution time).

c) To propose a service-oriented business process management framework for SPD to share information, integrate distributed systems, and manage heterogeneous resources among multiple stakeholders.

d) To develop a three-level infrastructure of an RFID-based real-time SPD operation management system. As one of main subsystems, a healthcare workflow system is designed to support the design, editing, execution, monitoring, and management of healthcare business processes in the sterile processing department.

e) RFID techniques are adopted to collect real-time location and identification information of RMEs and reprocessing resources, and sensor information of reprocessing environments.

To my best knowledge, this is the first effort in exploring business process management and workflow technology in the SPD domain.

The rest of this chapter is organized as follows: a) a brief review of healthcare workflow management and SOA-based workflow systems in healthcare; b) the introduction of proposed life-cycle for healthcare business process management and three phases in a business process management pattern; c) a description of the proposed framework about SOA-based healthcare business process management, d) an overview of three-levels infrastructure in an RFID-based real-time SPD operation management system, and e) Finally, insightful requirements for designing and implementing a healthcare workflow management system for SPD are discussed in the conclusions section.

3.2. Literature Review

3.2.1. Healthcare Workflow Management

Workflow management is the computing perspective of business process management (BPM) and designed to define, manage, and automate a procedure according to a set of business logic rules [81]. Currently, workflow technology is explored as diverse and rich technologies applied to numerous types of business

processes in industries, such as e-commerce [82], virtual company [83] and manufacturing systems [84-86].

Workflow technology has recently become an important IT trend in many healthcare enterprises [76, 77, 87-90]. Hospitals are embracing this technology to increase operational efficiency, improve healthcare quality, and ensure patient safety. However, research in healthcare workflow is still in its infancy, facing many new challenges that are characteristics of the healthcare domain [32, 89, 90]. To address the challenge of evolving patient conditions, the notion of adaptive workflows was proposed with support of context-aware activities [91], process adaptivity [92, 93], and exception handling [94]. Reijers et al. extended previous work on workflow and flexibility patterns and presented a methodology to discover, explore, select, and realize processes that possess the required degree of flexibility in the healthcare domain [95]. To ensure patient privacy, Russello et al. presented a framework in which patients can control the disclosure of their medical data by consent and needs [96]. To improve healthcare workflow security, Koufi et al. proposed an event-based dynamic authorization model that synchronizes authorization flow with the progress of workflow execution [77]. Finally, a number of case studies were reported that shared early experiences and pitfalls of workflow automation in healthcare [42, 44, 45, 88]. However, none of the existing work investigated the automation of sterile processing procedures, preventive SOP rule conformance check, and proactive elimination of medical errors that are proposed in this project.

3.2.2. SOA-based Business Process Management in Healthcare

Service-oriented architecture (SOA) is a set of principles and methodologies for designing and developing software in the form of interoperable services, which can be published, discovered, reused, and composed for different applications [97, 98]. SOA has become the foundation for developing software as a service (SaaS) [97] in the industry,. Some researchers have investigated various approaches of using SOA for enabling information sharing [99], mobile device access [100, 101], and system integration [102, 103].

The integration of Business Process Management (BPM) and Service-Oriented Architecture (SOA) is considered as a promising solution to support dynamic and flexible work practices by registering, discovering, and combining reusable services[104]. Hu et al. presented an SOA-based adaptive workflow framework to handle the emergency event in Tourism Information Change Management and provide relative solution [105].

Healthcare is considered as a potential field to more readily see the benefits of SOA-based workflow management since the workflow of medical cases are dynamic and unpredictable. Juneja et al. concluded that a service oriented architecture (SOA) can improve information delivering and data sharing among multiple stakeholders in care processes [106]. Some researches adopted SOA directly as the basis for many healthcare information systems [107-111] and to address the interoperability challenge of healthcare systems [99, 112].

However, none of the existing work used SOA to provide services in the sterile processing department, which manages functionalities provided by three working areas and intelligent heterogeneous objects, such as RMEs and washing machines.

3.3. Healthcare Business Process Management

Healthcare process management poses many unique challenges, including the complex conditions of healthcare environments, various physical and financial resource constraints, variations in patient conditions and treatments, policy and guideline conformance management, and flexibility and adaptivity to new requirements and emergency cases. To address these problems, healthcare organizations need to explore reengineering solutions to streamline, automate, and control healthcare processes by sharing a seamless information flow between multiple stakeholders at different locations.

3.3.1. Business Process Management: the Management Discipline and Strategy

Business process management is a holistic management approach [113] that promotes business effectiveness and efficiency while striving for innovation, flexibility, and integration with workflow technologies [114]. Though a set of methods, software and techniques, business processes involving human interaction can be edited, executed, and monitored . In this research, an SPD-targeted lifecycle of business process management is considered to consist of:

- **Business Goal Definitions:** Via an enhanced, interdisciplinary understanding of business process management in SPD, we identify the problem of current practice and then define business goals and rules (e.g., SOP rules).

- **Business Process Modeling:** A business analyst then models the above business goal definitions as detailed business process diagrams using some graphical modeling language, such as BPMN. These user-friendly diagrams include both activities and control and data flows among them. These conceptual diagrams are easily interpretable but not yet executable; they are the basis for discussions and refinement among business analysts, business managers, and technical developers (workflow engineers).
- **Workflow Design:** The modeled business process diagrams are then translated and implemented by some executable workflow language such as BPEL or SWL (Scientific Workflow Language). Each activity in the original business process diagram will be mapped to some concrete services or executable software programs. In contrast to a business process diagram, which is not executable, the resulting workflow is ready for execution.
- **Workflow Execution:** All the activities in a defined workflow will be orchestrated by the workflow engine, and their status can be monitored by workflow monitor, verified by an intelligent rule engine, and handle exceptions smartly.
- **Business Process Analysis：** The monitoring of each workflow execution will produce a series of event logs. Process mining techniques can be used to analyze the event logs to identify performance bottlenecks for optimizations and improvements, or to re-engineer the entire process cycle.

3.3.2. Business Process Management Pattern in SPD

Three main phases are involved in the business process management pattern in SPD. The pre-execution phase involves a business analyst to interact with customers and business managers to identify the problems and requirements in the current practice, define business goals for business process improvements, and model them as interpretable business processes diagrams. The execution phase implements business processes as executable workflows. The workflow engine will schedule and invoke tasks in workflows according to the specified workflow logic, orchestrating both human tasks and automated tasks. The post-execution phase analyzes event logs produced from workflow execution, aiming to identify bottlenecks and opportunities for continuous process improvements. The key components of the business process management pattern are shown in Figure 3-3.

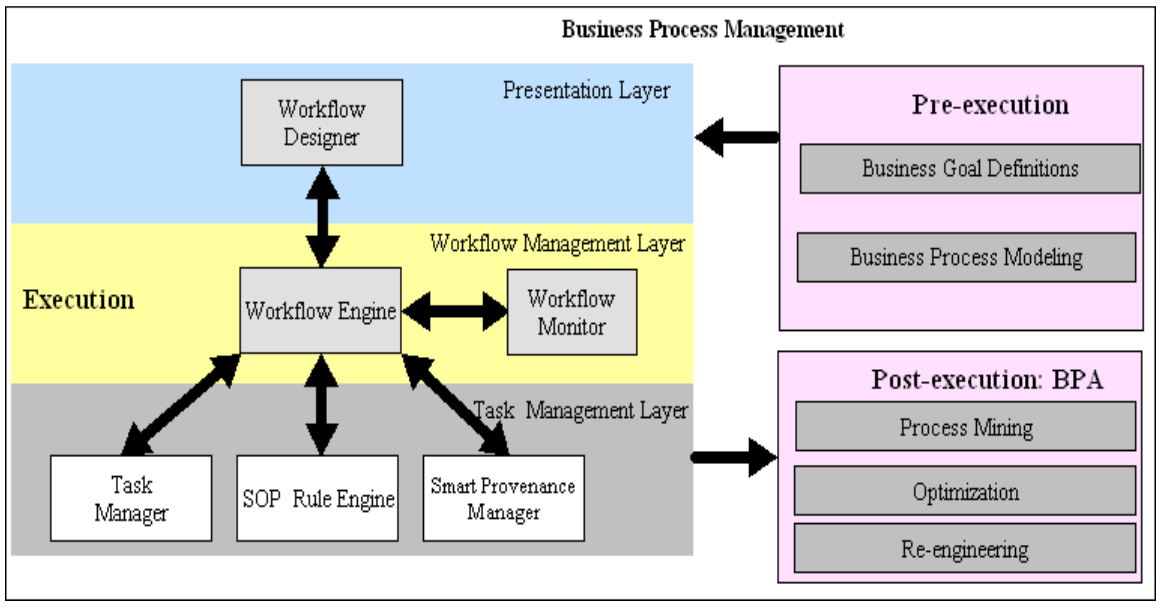


Figure 3-3 SPD Business Process Management Pattern.

3.3.3. Business Goal Definition: Key Requirements for Performance Management in SPD

The long-term objectives of business process management in SPD are to reprocess the right soiled RMEs at the right working areas by the right operations and supply them to the right end users at the right time. With an enhanced, interdisciplinary understanding of business process management in SPD by interviewing SPD staffs, the business goals for monitoring and controlling the reprocessing operations in SPD are as follows:

***R1: Event Log*:** Skipping imperative steps and operating based on wrong SOP rules are two significant errors in SPD. The SPD manager should cautiously monitor the real-time status of each activity execution and the whole workflow execution. Thus, event log should be designed as a process status tracking tool to capture and record any change of the business process status in SPD. It aims to support the visualization of effective workflow control and ensure all required tasks to be completed according to the right SOP operation routine. An example of event signature table for activity execution and workflow execution is as follows:

Table 3-1 Event Signature Table for Activity Execution and Workflow Execution

Activity Execution	Workflow Execution
Initializing	Creating a flowchart based on SOP
Executing	In the Process
Finished	Completed
Verifying	Approved
Cancel	Delete a step
Error	Exception control

R2: Compliance Check: Non-conforming operations in SPD reprocessing and distribution procedures will increase the risks of bacterial contamination to RMEs. SOP describes the requirements of each step in detail, such as operation time, temperature value within clean machines. Thus, compliance check between SPD operations and SOP standards should be automatically executed by an intelligent subsystem. When a check fails, the system should help a technician analyze its causes and impacts. It aims to remind SPD technicians when such a check fails and help them to analyze the reasons and the consequential influence by this delinquent operation. If approved, the workflow will continue to be executed automatically according to predefined routines.

R3: Smart Rerun Scheme: In practice, one of remedial reactions to operation errors is to duplicate the previous steps of the reprocessing procedure. Redundant duplications will increase the workload and cycle time and waste reprocessing resources. However, insufficient duplications could not ensure the quality of reprocessed RMEs. Thus, techniques for intelligent selection and execution of optimal rerun steps should be developed to remedy non-conforming operations.

R4: Effective Control of Work-in-Process (WIP) inventory: Physically tracing the inventory level and locations of WIP RMEs is a time-consuming operation. Inefficient WIP management will increase the amount of WIP items, require larger storage space, and increase the risk to shorten RMEs' shelf life. Sometimes, a rerun operation will be invoked to deal with long-time buffered WIP items, which increases the unnecessary workload for SPD staffs. Thus, the real-time inventory level, location and stocking time duration of WIP items should be recorded automatically. It aims to assist SPD technicians

to closely control their working items and streamline their operations for cycle time reduction.

R5. Failure Handling: Machines might decay and software services might fail due to their complexity. Such failures should be processed to resume operations or prevent unclean RMEs. Multiple types of operation failures could occasionally happen in an unforeseeable way when executing a workflow. Thus, a function should be developed to provide the support for failure monitoring at multiple levels. It aims to catch, localize and handle exceptions automatically or with minimal human intervention. For example, when the temperature indicator of steam sterilization machine does not correspond to the required value, an alarm message will send to SPD staff for instant reminding or temperature could be automatically adjusted.

R6: ***Adaptive Planning:*** Under the complex and dynamic healthcare environment, the schedule of medical treatment could be updated at the last minute. Thus, as an RME supplier, SPD should have the flexible supply capability to handle unpredictable change and emergent cases. Based on the priority of intraday medical treatments, adaptive workload plan should be made for each reprocessing area. Meanwhile, when multiple machines provide the same function, it should adaptively assign orders to these machines with load balancing in mind. It aims to maximize the supply capability and optimize the utilization rate of reprocessing resource.

R7: Real-time Supply Chain Management (SCM): Out of stock and delayed supply of ready-to-use RMEs are two key reasons for clinics to reactively cancel or postpone medical cases. Thus, an RFID-based real-time SCM should be achieved. It aims to trace

and transparentize the status of the supply process among multiple stakeholders; track the real-time inventory level in both SPD and clinic secondary inventories; remind SPD distribution technicians to replenish the storage immediately; finally, record the expiration date of each RME and call attention automatically to remove the expired RMEs off the shelf.

3.3.4. Business Process Modeling by BPMN

Business Process Model and Notation (BPMN) is a standard graphical notation language[115] to specify business processes as *Business Process Diagrams* (BPD) [116], which can be easily understood by both technical users and business managers. BPMN diagrams, which are not yet executable, can then be mapped to computerized business processes (workflows) in some underlying executable business process language, such as *Business Process Execution Language* (BPEL) [117]. Consequently, BPMN serves as a common language to bridge the communication gap between business process modeling and workflow implementation.

Based on the definitions of the business goals for SPD, as a preliminary case study, some business processes are modeled for the three working areas. A BPMN diagram for operations in the decontamination area is shown in Figure 3-4, which is self-describing. The implementation details will be discussed in the next chapter.

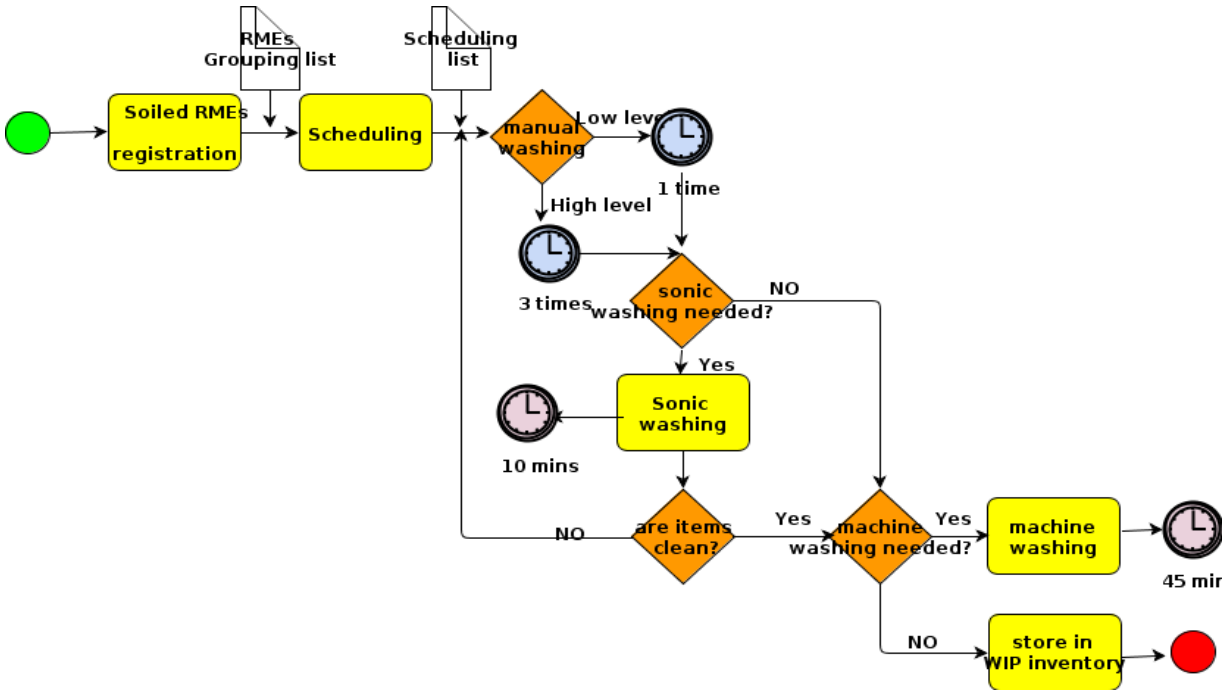


Figure 3-4 BPMN Diagram for Operations in the Decontamination Area

3.4. Service-Oriented Healthcare Business Process Management Framework for SPD

In order to improve the operational efficiency of a sterile processing department and reduce the risk of infections induced by reusable medical equipments, it is critical to share information, integrate distributed systems, and manage heterogeneous resources. A technician needs to know where each RME is and its status. Systems that work on different working areas and operation room need to be integrated. Different heterogeneous resources, including RFID-enabled RMEs, machines, and people, should be uniformly identifiable, locatable, and searchable. From one cycle of reprocessing and supply point of view, in order to supply high quality RMEs to the right patient at the right

time, information concerning reprocessing orders and operation status should be easily accessible to each stakeholder. Otherwise, the lack of information will delay the processing of RME requests, disorder the sequence of operations in multiple working areas, increase the work-in-process inventory level, and prolong the cycle time in the sterile processing department. Meanwhile, under the complex and dynamic healthcare environment, the schedule of medical treatment might be updated in the last minute. As an RME supplier, a sterile processing department should have the flexible supply capability to handle unpredictable change and emergent cases.

A *Service-Oriented Architecture* (SOA) is a set of principles and methodologies for software development based on published interoperable services that can be discovered, reused, and combined for different purposes. When adopting a business process and workflow management system in a dynamic and flexible environment such as healthcare, SOA is a promising solution to meet the requirements of flexibility, interoperability by registering, discovering, and combining reusable tasks as Web services. This research applies SOA as the underlying foundation to develop our healthcare business process management system. The proposed SOA-based business process management framework is shown in Figure 3-5, which consists of five layers.

For each working area, a working area navigator is in charge of managing all RFID-enabled resources as intelligent objects in that area, including RMEs, machines, and technicians, which are then abstracted as Web services and published in the second layer. The third layer integrates the underlying services, possibly provided by different working area navigators, as workflows, which are the building blocks of higher-level

applications in the fourth layer. Applications aim to provide BPM auxiliary services such as adaptive planning, RME registration and grouping and process mining. Finally, the floor navigator integrates all information and systems into one integrative system for the management of the whole floor.

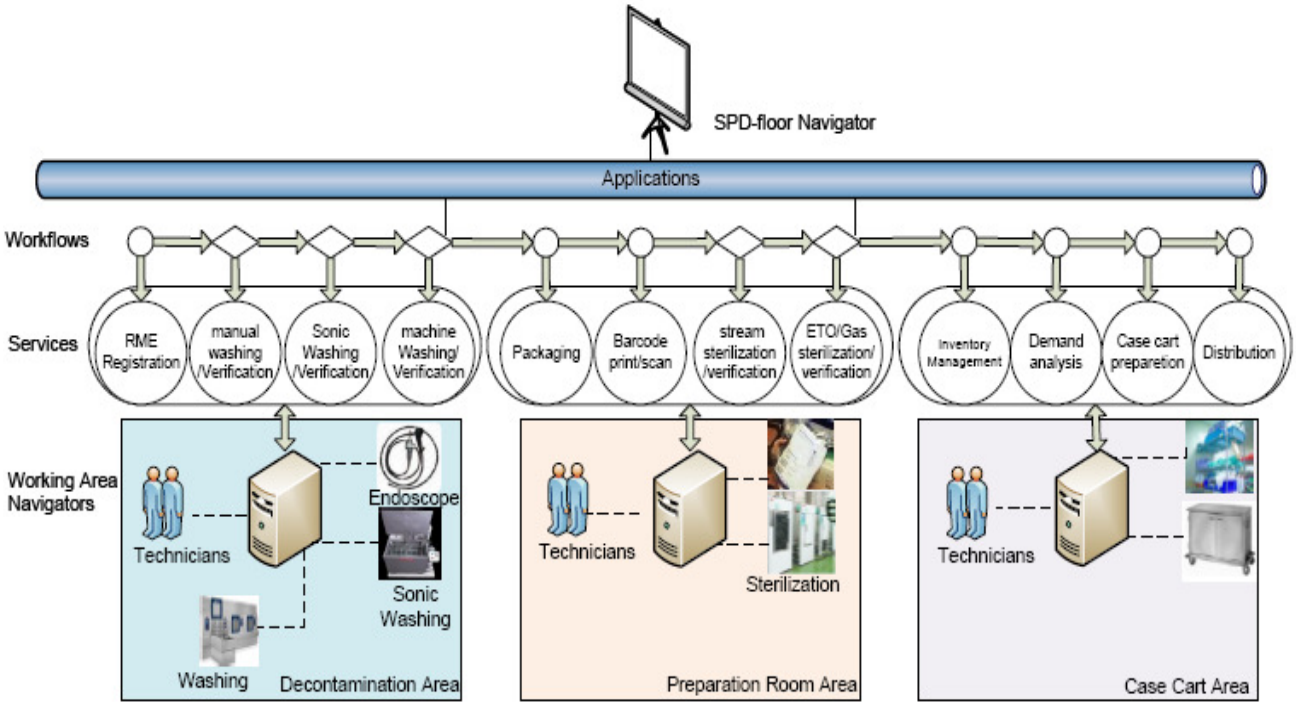


Figure 3-5 SOA-based Business Process Management Framework

Three main modules are included in Service-Oriented reference Architecture for SPD service management, shown in figure 3-6

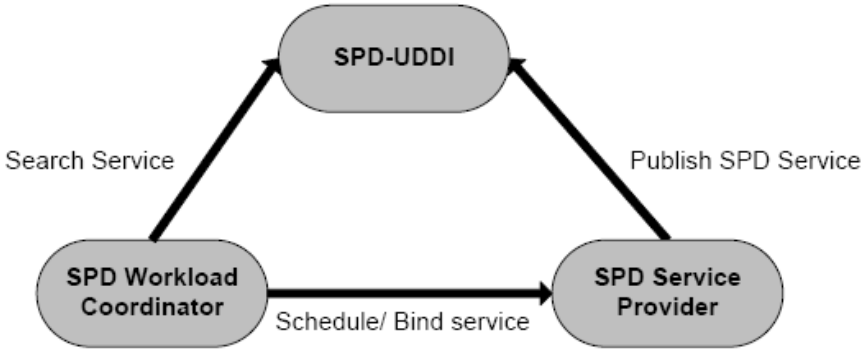


Figure 3-6 SOA Reference Architecture for SPD Service Management

Workload Coordinator: The workload coordinator schedules and invokes a reprocessing service based on the status of on-duty resources and priority of demands from end users. It aims to optimize the reprocessing procedures according to the information shared from operation room technicians and sterile processing department staffs. A suite of applications are designed to help the manager of sterile processing department plan the reprocessing procedures adaptively. The main functions are described as follows:

- *Registration of Soiled RMEs*: When soiled RMEs arrive in the sterile processing department for reprocessing, the basic information of RMEs, such as their item ID, due date of ready-to-use RMEs will be registered in a workload order list following the policy of 'first-in-first-out'. Different priority levels of demands from end users will be considered. For example, an emergent order will be processed immediately after it arrives.

- *Grouping of RME Reprocessing Procedures:* In order to optimize the reprocessing procedure, RMEs with similar standard operation procedure (SOP) requirements can be processed together. Thus, this function will convert customers' orders to reprocessing orders by categorizing RMEs of similar SOPs into one group. If the amount of RMEs from the same group exceeds the reprocessing capability, this group could be separated into several subgroups that have similar due dates.
- *Resource Management*: This function will trace and display the working status of staffs and machines, such as busy or free. It is designed to help the manager make a flexible scheduling. If the primary resources are available, undone tasks in the workload list could be immediately executed. Meanwhile, some reprocessing operations without precedence constraints are allowed to be executed in parallel.
- *Workload Planning:* Based on the above information, this function will assign work orders to each service provider and invoke appropriate services for reprocessing procedure execution.

➢ **Services Registration: SPD-UDDI**

The function of SPD-UDDI is similar to those of standard UDDIs (Universal Description, Discovery and Integration). It serves as a platform-independent framework for describing, discovering, and integrating business services. Five core information types of SPD-UDDI are described as follows:

- *Stakeholder Entity:* working areas, RFID-enabled intelligent personnel, RMEs and machines that offer one or more services.
- *Reprocessing Service:* a group of web services published by each working area. Each service serves a reprocessing function for certain purpose, which can be invoked over the Internet.
- *Binding Template:* the information that is necessary to convert working area functions into public Web services and invoke them to implement reprocessing services.
- *Technical Model:* the specifications that defines the type or categorization of service, such as data models for intelligent objects and smart services.
- *Publisher Assertion:* a relationship assertion between two stakeholder entities.

➢ **Service Provider**

One major function from each working area navigator is responsible for registering the functions from decontamination, preparation, and case cart working areas in the service registry as Web services. Each provider must decide which services to expose and in which category a service should be listed for each working area. By publishing services' interface and access information in the service registry, each task could be executed by a service provider when the corresponding service is invoked.

3.5. RFID-enabled SPD Operation Management System Infrastructure

In order to create a real-time SPD operation management for automatically tracing, monitoring and controlling the operation performance, RFID and SOA-based workflow system are integrated to achieve ubiquitous connectivity and interoperability between RFID tagged intelligent objects (SPD staff, RMEs, machines), services from SPD working areas and end users. Figure 3-7 shows an overview of the proposed infrastructure that demonstrates the three levels of an RFID-enabled real-time SPD operation management system.

- **SPD-floor Management Navigator**:

It is the top level and center of the overall system which is composed with the SPD workflow system and some application subsystems, such as SPD planning, SPD inventory management system and other packages, such as customer relationship management (CRM). It supervises the operation management in SPD floor-level, adaptive planning, inventory management and interoperability with other stakeholders. By adopting Service-Oriented Architecture into SPD operation management, three main components are included, i.e. SPD Workload Coordinator as a service requestor, SPD-UDDI to publish and invoke the service provider, Working Area Management Navigator as a service provider. It aims to achieve automatic and real-time management of entire SPD workflows.

A healthcare workflow management system for SPD is used to define and execute the business process through invoking Web services published by service providers. The SPD workflow designer can search necessary services from SPD-UDDI and configure them for a specific reprocessing procedure according to some SOP rules. During execution, the SPD manager could trace and control the status and performance of the running process, and make dynamic business routing based on verification results of a previous task. If one task is not approved, exception control will be performed, such as retrying the same operation. Thus, an SOP rule engine is critical to assist the SPD manager in rule-based decision making. The detailed design will be discussed in chapter 4.

- **Working Area Management Navigators**:

There are three independent operation management systems serving for the decontamination, preparation, and case cart working areas in SPD. They perform as service providers that take the responsibility to register the functionalities which each working area supplies in SPD-UDDI as Web services, and finally execute each service. Meanwhile, it is also an intelligent-object manager which physically connects all RFID-enabled intelligent objects to control and monitor the real-time information during the reprocessing operation. It aims to achieve service registration and RFID data management.

- **RFID-enabled Intelligent Objects**:

They are physical objects (such as personnel in SPD, RMEs, and SPD machines) attached with RFID tags. Considering the unique physical characteristics of tracking items, active RFID tags are assigned to monitor staffs since passive RFID tags are not good at tracing objects with water or metal. Passive UHF RFID tags with the high accuracy are selected to trace RMEs. Autoclave sensor tags, which could withstand rigorous sterilization processes including ultrasonic cleaning, high pressure liquid sterilization and steam autoclaving are equipped within reprocessing machines for recording the important chemical, biological and temperature indicators.

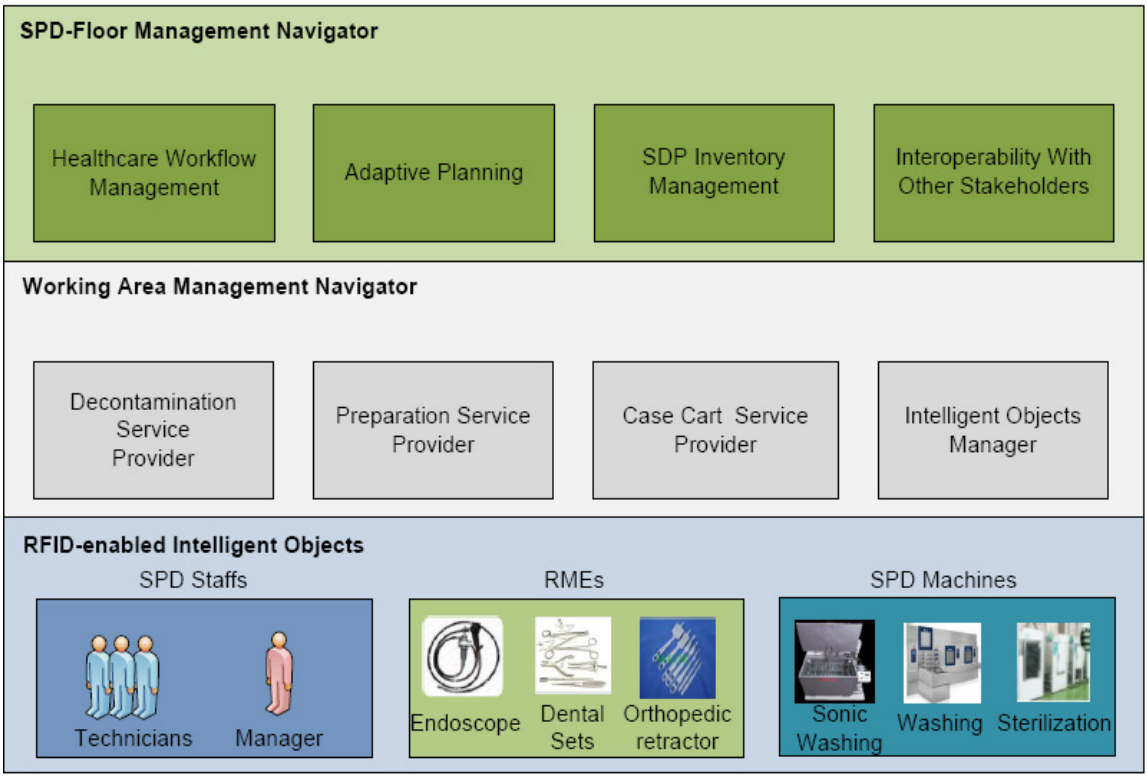


Figure 3-7 RFID-enabled Real-time SPD Operation Management System Infrastructure.

3.6. RFID-enabled Automatic Data Collection for Workflow Management in SPD

In order to achieve real-time monitoring and controlling of SPD reprocessing procedures, three types of information should be collected as data sources for the data flows running in the healthcare workflow management system in SPD. They are real-time location and identification information of RMEs and reprocessing resources such as SPD staffs, raw materials, and sensor information of reprocessing environments, such as temperature and pressure. With the development of Auto-ID technologies, multiple types of automatic data collection devices, such as passive and active RFID tags, Wi-Fi tags, autoclave sensor tags, can be deployed to retrieve real-time information automatically.

Passive UHF RFID tags are attached to RMEs to record the information of all locations each RME has passed during a reprocessing procedure. This information aims to trace the cleaning, disinfection, and sterilization tasks for which this identified RME has been processed, which supplies the real-time evidence to verify whether the imperative steps are skipped and reprocessing operations are executed based on the right workflows. The time duration of RMEs in each location can give a clue to reflect the operation time of each task, which is one of the key parameters to ensure the safety quality of RMEs.

Active RFID tags or Wi-Fi tags are attached to reprocessing resources, such as SPD technicians, SPD manager, raw cleaning materials to record the identification and location information. Considering the complexity of reprocessing tasks in SPD, SOP requires that only well-trained SPD technicians can be qualified to reprocess the specific

RMEs at certain machines, such as suction machine which is used to remove any debris inside scopes through the water flow. Before starting the tasks, active RFID tags or Wi-Fi tags can automatically retrieve the identification information of on-duty SPD technicians based on their location information and send it to the intelligent-object manager for verifying their qualification status. This helps the SPD manager effectively control the SPD resources.

Autoclave sensor tags are attached within reprocessing machines, such as a sterilization machine. Multiple types of sensor tags aim to record the chemical, physical, or temperature indicators of reprocessing environment, which are important factors to ensure that each operation is performed under a standard environment.

3.7. Conclusions

One major reason that dramatically impacts patient safety is the use of unclean RMEs delivered from the Sterile Processing Department in healthcare facilities. In this chapter, a solution of RFID-based BPM concepts and workflow technology is proposed to improve the execution performance and quality management of SPD business process. By an enhanced, interdisciplinary understanding of business process management in SPD, seven requirements to real-time control of the SPD operation procedures were summarized. A business process management pattern for SPD was defined, which includes business process modeling (pre-execution time), workflow management (execution time), and business process analysis (post-execution time). Service-oriented architecture was deployed to share information, integrate distributed systems, and manage heterogeneous resources among multiple stakeholders in SPD business process

management. A three-level framework of an RFID-based real-time SPD operation management system is developed. As one of main subsystems, a healthcare workflow system is designed to support the design, editing, execution, monitoring, and automating SPD business processes. Finally, RFID technologies were used to collect real-time data about the status of SPD business process and indicator value of reprocessing environment.

However, several issues need to be investigated further. First, the architecture for a healthcare workflow management system in SPD should be designed to meet the specific requirements in SPD business process management. Second, the methodology of compliance check between SPD operations and SOP requirements should be developed. Third, the smart rerun scheme should be designed to refine the optimized routing for exception control. Finally, the selection of SPD operations for Web services implementation should be considered as a challenging topic in the development of an SPD workflow system. The answers to some of these questions will be discussed in Chapter 4.

Chapter 4 Service-Oriented Architecture for SPDFLOW: A Healthcare Workflow System for Sterile Processing Departments

Summary

Healthcare workflow has recently become an enabling technology in the healthcare industry to automate processes, improve care quality, and enhance patient safety. Although some work has been done on healthcare workflow for some departments of a hospital, automating processes and improving patient safety in the Sterile Processing Department (SPD) is still an open problem. The main contributions of this chapter are: i) the key architectural requirements for a healthcare workflow system in SPDs are identified; ii) based on these requirements, a service-oriented architecture is proposed and validated with the SPD workflow prototyping system, SPDFLOW. iii) an event-condition-action based rule engine is designed to automate the conformance check between the SPD operations and standard operation procedure policies. A case study is provided to validate this design.

4.1. Introduction

Healthcare workflow has recently become an enabling technology in the healthcare industry to automate processes, improve care quality, and enhance patient safety [32]. Although much research has been done on business processes [33] and scientific workflows [37], healthcare workflow poses many unique challenges, including the complex conditions of healthcare environments, various physical and financial resource constraints, variations in patient conditions and treatments, policy and guideline conformance management, and flexibility and adaptivity to new requirements and emergency cases.

While some work has been done on healthcare workflow for some departments of a hospital [76, 77], automating processes and improving patient safety in the Sterile Processing Department (SPD) is still an open problem. The sterile processing department is responsible for the cleaning, disinfection, and sterilization of soiled reusable medical equipments (RMEs) and the supply of ready-to-use RMEs. Unfortunately, current practice in the sterile processing department is mostly driven by human labor and control, and as a result, steps might be skipped or performed improperly, patient safety can be compromised.

Automating and managing the reprocessing procedures in SPD is a challenging task. First, it is critical to share information, link distributed systems together, and manage heterogeneous devices and resources across different working areas. For example, a technician needs to know where each RME is and its status. Second, although current

practice in the sterile processing department aims to follow the standard operation procedures (SOPs) that are derived from device manufactures, such conformance check is manual and relies on technicians' skills, experiences, and professional merits. Such manual policy conformance check is often error-prone and cannot ensure that each operation will be conducted in full conformance to SOP policies. Finally, the quality of RMEs need to be well managed during the whole reprocessing procedure, including selecting the right workflow to process, and checking the precondition of running a step, and performing smart rerun optimization.

To address these issues, this research aims to develop healthcare workflow technologies to automate and streamline the cleaning, disinfection, and sterilization operations in the sterile processing department in our pilot facility. As a first step, we focus on studying the architectural design for a healthcare workflow system for SPDs.

The main contributions of this chapter are:

i) Based on an enhanced, interdisciplinary understanding of the current practice of a sterile processing department, the key architectural requirements for a healthcare workflow system for SPDs are identified.

ii) To develop a service-oriented healthcare workflow architecture to support the design, editing, execution, monitoring, and management of various disinfection and sterilization processes in the sterile processing department. The functionalities of each subsystem in the SPD workflow prototyping system, SPDFLOW, are defined in detail.

iii) To develop an event-condition-action based rule engine to automate the conformance check between the sterile processing department operations and standard operation procedures policies;

iv) To develop smart reasoning techniques to preventively reduce errors, proactively improve workflow management, and efficiently producing high-quality ready-to-use reusable medical equipments.

The remainder of the chapter is organized as follows. In Section 2, the literature review of architecture design for workflow systems is presented. In Section 3, key architectural requirements for SPDFLOW are summarized. In Section 4, the overall architecture for SPDFLOW is proposed and the advantages of Service-Oriented Architecture (SOA) in healthcare workflow are discussed. In Section 5, a case study in SPD of one hospital is provided.. In Section 6, conclusions and future work are discussed.

4.2. Literature Review

A system architecture defines the fundamental organization of a system which specifies. system components, the properties of these components, the relationships among them, and the principles governing its design and evolution [118]. In the following, the existing architecture designs for business workflow management system (BWFMS) and scientific workflow management system (SWFMS) will be investigated and reviewed.

In the 1980s, the initial business workflow management system was designed as a business process automation software to facilitate the office automation process. With the development of technologies and theories for business process modeling and re-engineering, workflow management systems were adopted in multiple business processes[119], such as machine shops, insurance claim processing. Centralized-server architecture defines a centralized workflow enactment server, which can be easily accessed when executing tasks in a business workflow[120, 121]. The FlowMark system[122], a typical example for replicated-server architecture, consists of multiple workflow enactment servers which works as a client to a database server. Based on Localized-server architecture, multiple servers cooperate with each other to execute large-scaled distributed workflow tasks in BWFMS. Each server should be located near to the place where the tasks are processed [123-125]. Server-less architecture assigns each client with functionalities from BWFMS server, so the execution status of workflows can be recorded over the whole workflow system [126]. The YAWL system has deployed Service-Oriented Architecture as the BWFMS architecture foundation by abstracting four main components as services. (YAWL worklist handler, YAWL web services broker, YAWL interoperability broker, and custom YAWL services)[127].

Compared to business workflows, which mainly focus on control-flow patterns and events, scientific workflows contribute more to data-flow patterns. Service-oriented architecture is also accepted in SWFMS design. One grid-aware workflow management system, the Taverna system, supplies scientists with distributed resources to perform data-intensive *in silico* experiments[128, 129]. The Kepler system is designed based on

actor-oriented architecture. Its actor-oriented modeling can build system models based on the assembly of pre-designed components, called actors[38, 130, 131]. According to Federation-based architecture, a complex set of interacting components cooperate together to create the complete system, such as the Triana system [132-134].

However, for the healthcare workflow management system, the architecture design should not only focus on the major system components and interaction between them, but also consider the specific requirements or policies from each healthcare business process. None of existing architecture design has satisfied with the complex and dynamic healthcare situation. In this research, based on service-oriented architecture, the architecture of a healthcare workflow management system for SPD is developed.

4.3. Key Architectural Requirements

To address the issues and weaknesses that lead to unclean reusable medical equipments and compromised patient safety, identified in chapter 3, the requirements to design and develop an innovative real-time healthcare workflow system are summarized as follows.

R1: Heterogeneous Information Sharing:

A technician needs to know where each RME is and its status. Systems that work on different working areas and operation room need to be integrated. Different heterogeneous resources, including RMEs, machines, and people, should be uniformly identifiable, locatable, and searchable. From one cycle of reprocessing and supply point

of view, in order to supply high quality RMEs to the right patient at the right time, information concerning reprocessing orders and operation status should be easily accessible to each stakeholder in SPDFLOW. Otherwise, the lack of information will delay the processing of RME requests, disorder the sequence of operations in multiple working areas, increase work-in-process inventory, and prolong the cycle time in the sterile processing department.

R2: Heterogeneous System and Service Integration:

Under the complex and dynamic healthcare environment, the schedule of medical treatment might be updated in the last minute. As a ready-to-use RME supplier, a sterile processing department should have the flexible supply capability to handle unpredictable change and emergent cases from multiple end users in different clinics. In SPDFLOW, heterogeneous system and service integration should be developed to facilitate system integration, optimize resource usage, improve functionality reusability, and enhance process flexibility.

R3: Automated SOP Rule Conformance Check for Each Operation:

Non-conforming operations in SPD reprocessing and distribution procedures will increase the risks of bacterial contamination to RMEs. SOP describes the requirements of each step in detail, such as operation time period, temperature value within clean machines, times. For example, if an operation with normal-level disinfection is needed, then the first operation needs 3 minutes and no repeat is needed, on the other hand, if an intensive-level disinfection is needed, then the first operation needs 3 minutes and 3

iterations will be carried out. Such workflow varying and RME dependant parameters are very common in reprocessing operations, and if not verified carefully and correctly, can often lead to wrong steps and the skipping of important steps. Currently, SOP rule conformance check fully relies on technicians' skill, experience, and commitment. Such manual conformance check is error-prone and cannot fully ensure that each operation will be conducted fully in conformance with the SOP policies, leading to unclean RMEs that eventually compromise patient safety. In SPDFLOW, compliance check between SPD operations and SOP standards should be automatically executed by an intelligent subsystem. It aims to remind SPD technicians when such a check fails and help them analyze the reasons and the consequential influence by this delinquent operation. If approved, the workflow will continue to be executed automatically according to predefined routines.

***R4: Event Signature*:**

One major cause that compromises patient safety in the sterile processing department is the use of unclean or expired RMEs that lead to healthcare associated infections. Skipping imperative steps and operating based on wrong reprocessing procedures are two significant errors which must be forbidden in SPD process management. It requires the SPD manager to cautiously monitor the real-time status of each activity execution and the whole workflow execution. In SPDFLOW, event signature should be designed as a process status tracking tool to capture and sign a change of the business process status in SPD. It aims to support the visualization of

effective workflow control and ensure all required tasks to be completed according to a right SOP operation routine.

R5: Smart Rerun Scheme:

In practice, one of remedial reactions to operation errors is to duplicate the previous steps of the reprocessing procedure. As we know, redundant duplications will increase the workload and cycle time in SPD and waste reprocessing resources. However, insufficient duplications could not reach the objectives of cleaning, disinfection and sterilization. In SPDFLOW, the intelligent selection and execution of optimal rerun steps should be included as a smart function. It aims to guide the SPD staffs to make up the non-conforming operations.

R6. Failure handling:

Machines might decay and software functionality might fail due to their complexity. Such failures should be processed to resume operations or prevent unclean RMEs. Multiple types of operation failures could occasionally happen in an unforeseeable way when executing a workflow. In SPDFLOW, a function should be developed to provide the support for failure monitoring at multiple levels. It aims to catch, localize, and handle exceptions automatically or with minimal human intervention. For example, when the temperature indicator of steam sterilization machine does not correspond to the required value, an alarm message will send to SPD staff for instant reminding or temperature could be automatically adjusted.

4.4. Overall Architecture for SPDFLOW

The long-term goal of our SPDFLOW project is to develop a healthcare workflow system to automate and streamline the cleaning, disinfection, and sterilization operations in the sterile processing department. RFID technology is deployed to collect real-time data automatically about the location and identification of RMEs, SPD resources and indicators of an operation environment during the reprocessing procedures. In order to demonstrate the feasibility and flexibility of our proposed architecture of SPDFLOW, the advantages of adopting Service-Oriented Architecture (SOA) in SPDFLOW is firstly discussed. Then, the overall architecture for SOA-based SPDFLOW is presented with the description of each major subsystem.

4.4.1. Advantages of Service-Oriented Architecture in SPDFLOW

Healthcare is considered as one of the most promising fields to more readily see the benefits of SOA-based workflow management since it often involves multiple heterogeneous IT systems, their integration, and changing healthcare service requirements. SOA can have an impact on healthcare by enabling information sharing, facilitating system integration, virtualizing infrastructure resources, improving functionality reusability, and enhancing process flexibility. Based on these impacts, the advantages of using SOA specifically for the development of SPDFLOW are identified by abstracting SPDFLOW subsystems, SPD functionalities, and RFID-enabled intelligent objects as services. This advantage analysis is based on three levels: SPDFLOW with other healthcare systems, SPDFLOW subsystems, and task management in SPDFLOW.

1) Enabling collaboration between SPDFLOW and other systems via information sharing and integration

Under the complex and dynamic healthcare environment, the schedule of medical treatment could be updated at the last minute. As a primary hub in hospitals to supply various types of RMEs to different clinics, SPD should have the flexible supply capability to handle unpredictable change and emergent cases adaptively. In order to supply high quality RMEs to the right customers at the right time, all necessary information from SPD and multiple clinics should be easily accessed and transparent. It will help the SPD manager integrate information from various service providers and systems to optimize SPD reprocessing planning and control process performance, which aims to maximize the supply capability and increase the utilization rate of reprocessing resources. With SOA, SPD functionalities are wrapped as services with semantic description and registered in SPD-UDDI, so that they can be easily discovered, selected, and reused for SPDFLOW and other healthcare systems, such as ORFLOW (an operation room workflow management system) on dynamic and unpredictable demands. Information can be shared and integrated easily across SPD and other clinics. For example, SOA provides opportunities to transparentize the scheduling of operation room (OR) cases with related RMEs list from ORFLOW to SPDFLOW as they are packaged and shared as services. When an emergency order arrives that requires the processing of high-level disinfection workflow, SPDFLOW can schedule the reprocessing procedure adaptively for priority updates of RME demands by invoking required services. The reprocessing services for an RME in a normal-level priority can be flexibly delayed or

stopped, so that the sonic cleaning machine can become available for use by the emergency order first.

2) Facilitating SPDFLOW subsystem development by programming and platform independence.

SOA is considered as an emerging architectural paradigm for distributed system development with advantages of discoverability, reusability and interoperability by publishing each subsystem as a service [135, 136]. SOA enables development independence of six SPDFLOW subsystems by defining a group of programming language and platform independent interfaces. With SOA, all the functionalities from six SPDFLOW subsystems are encapsulated as services and registered in a specific service registry, such as SPDFLOW Universal Description Discovery and Integration (SPDFLOW-UDDI). Via these abstract and standard interface descriptions, each service exposed by SPDFLOW subsystems can be easily discovered from SPDFLOW-UDDI. Through standard communication protocols, each SPDFLOW subsystem can be reused by other healthcare workflow management systems. Meanwhile, SOA-enabled SPDFLOW supports service interoperability as service providers and service requestors can be developed independently with different languages and in different platforms.

3) ***Virtualizing Infrastructure Resources and SPD functionalities in the SPDFLOW Task Manager***

Two main service components are managed by the SPDFLOW task manager, which are SPD functionalities and real-time data management functionalities from RFID-

enabled intelligent objects. These two types of service components require different execution environments and management systems. For example, three working area navigators are designed to manage the operations in the decontamination, preparation, and case cart areas in SPD. Different heterogeneous resources, including RMEs, machines, and people, should be uniformly identifiable, locatable, and searchable by multiple types of auto-ID/RFID devices [85]. These devices have unique communication interfaces and protocols. It is crucial to create a standard model to wrap different types of devices as uniform units. SOA enables the SPDFLOW task manager to virtualize all SPD functionalities and various types of RFID-enabled intelligent objects by wrapping them as services. Via an abstract interface defined by WSDL, services from the two types of service components can be published, discovered, reused, and composed for different purposes. The details of the SOA-enabled SPDFLOW task manager will be discussed later.

4.4.2. Overall Architecture for SPDFLOW

Workflow Management Coalition (WfMC) [137] defined the workflow reference architecture which illustrates the major components and interfaces, shown in Figure 4-1,

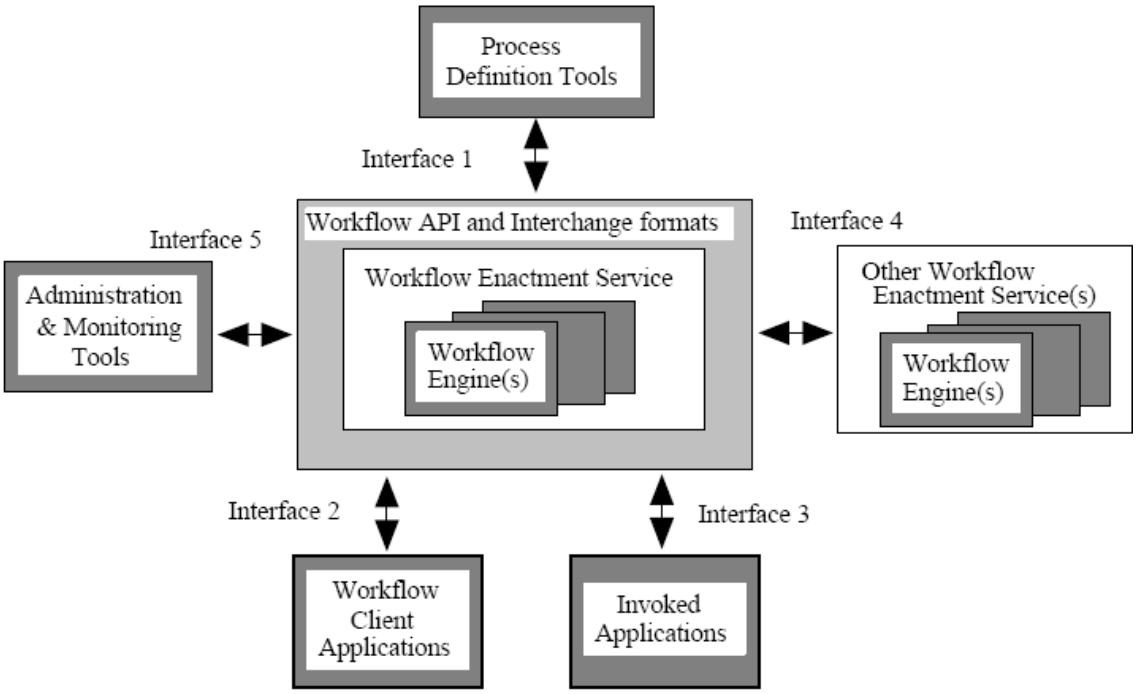


Figure 4-1 Workflow Reference Model - Components & Interfaces

According to this workflow reference model, the overall architecture of SPDFLOW is designed to satisfy the specific requirements in business process management in SPD. The SPDFLOW system (shown in Figure 4-2) consists of six subsystems that deal with specific requirements for SPD workflow management. The SPD workflow designer in the presentation layer is deployed to model and design SPD reprocessing procedures. In the workflow management layer, the SPD workflow engine communicates with other subsystems by interfaces I_{WD}, I_{WM}, I_{TM}, I_{RE}, and I_{SPM}. In the task management layer, a service oriented task manager is designed to manage functionalities provided by three working areas, RFID-powered RMEs and machines as services; a standard operation procedure (SOP) rule engine is developed to automate rule conformance check; a smart provenance manager is innovated to enable provenance-

based quality control of RMEs. In the intelligent object management layer, all the RFID-powered resources are governed by an intelligent object manager, which automatically collects real-time information of identification and locations from RFID-enabled intelligent objects. This information will then be exposed by the intelligent object manager to the task manager as services. In the following section, the architectural details of major SPDFLOW subsystems are discussed.

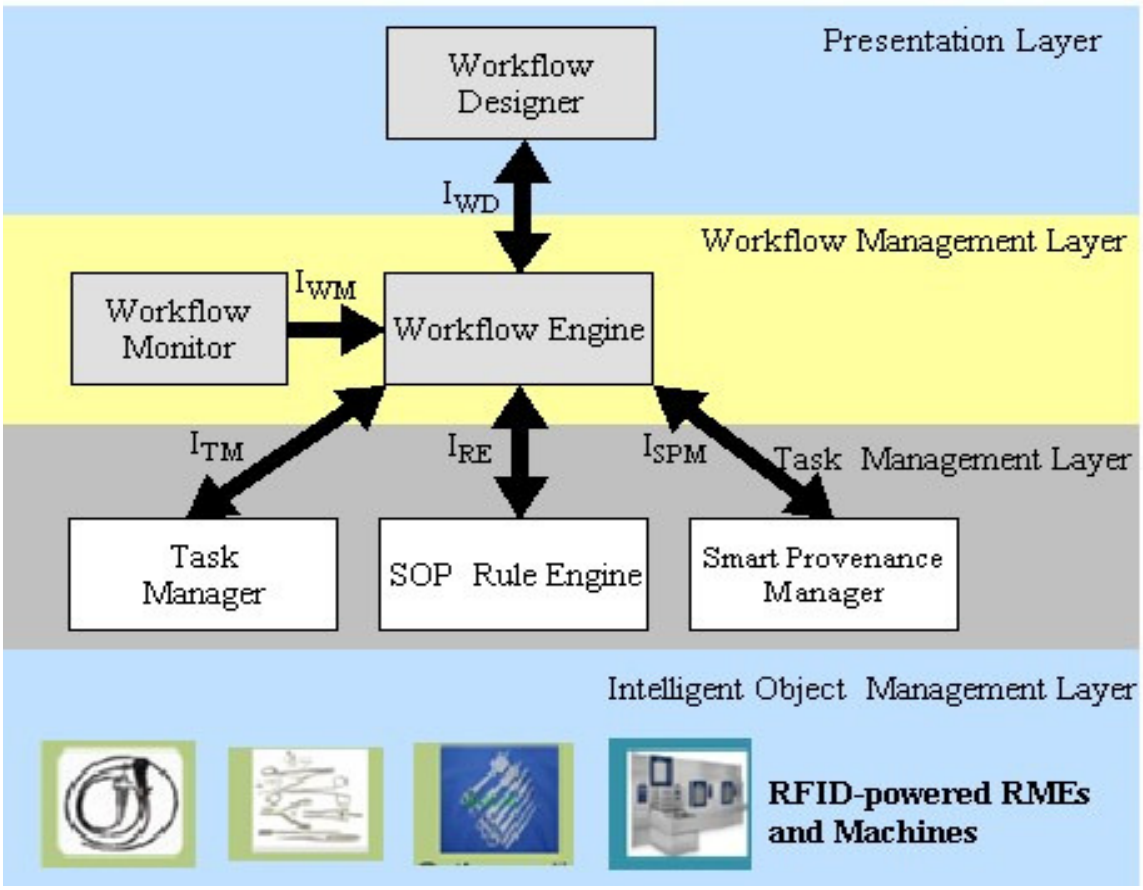


Figure 4-2 An overview of SPDFLOW architecture.

4.4.3. SPDFLOW Workflow Designer:

It provides a user-friendly graphical interface to design and modify SPD workflows. An SOP expert can drag and drop published services into the design panel and link them together in parallel or sequential patterns to model reprocessing procedures. It aims to provide the workflow definition function in SPDFLOW. These process definitions model standard operation procedures that an SPD technician is required to follow strictly. It ensures that the right procedures will be done. These definitions will also include descriptions that prescribe exception handlers to deal with situations in which procedures are not executed as expected，including what should be notified if some exceptions cannot be handled by the system automatically.

4.4.4. SPDFLOW Workflow Engine:

It is the center of SPDFLOW that supplies a run-time environment where process instantiation and activation are achieved. It is used to create and manage the data flows and control flows of an SPD reprocessing procedure, display the workflow status, and record particular aspects of the workflow, such as data provenance. When major events occur, the workflow engine is notified to invoke the following steps. For example, a soiled RME being collected from the operation room for reprocessing, a working schedule being made, and a verification step being proved are all examples of events in the SPD operation management that require the workflow engine to process. The workflow engine can perform both human tasks, which involve human input and interaction, and automated tasks, which do not require human intervention. For example,

when the water cleaning time is not long enough as SOP rules requires, an alarm can be automatically sent to on-duty SPD technicians.

Within the SPDFLOW Workflow Engine, each workflow status is collected and stored via I_{WM} to provide the foundation for event signature (R4) and exception handling (R7) in the Workflow Monitor component. There is an interface I_{TM} to supply the communication between the Workflow Engine and the Task Manager, which separates workflow scheduling from each task execution. At many times, a complex decision among multiple options should be made based on the execution performance of a running process. The SOP Rules Engine is called by the Workflow Engine through I_{RE} to analyze the decision logic. Finally, all provenance information is collected by the Workflow Engine and stored in the Smart Provenance Manager via I_{SPM}.

4.4.5. SPDFLOW Workflow Monitor:

It records and reports the execution status of an SPD workflow. They are historical data which are useful for SPD performance management, such as the completion time for a task, the stock time of WIP items in one working area.

4.4.6. SPDFLOW Service-oriented Task Manager:

It shows which tasks are in the queue to be carried out for processing. By selecting a task, an SPD technician can retrieve a predefined workflow and begin to perform a service. Under a hectic, multidisciplinary and dynamic clinical care

environment, service oriented architecture is applied as the underlying foundation to manage SPDFLOW tasks (R1, R2).

As described above, the tasks from two types of service providers (RFID-enabled intelligent objects and SPD working areas) should be managed by the SPDFLOW task manager, as shown in Figure 4-3. In order to build up an execution and platform independent environment, SOA is deployed to encapsulate multi-types of SPD functionalities and RFID devices with different parameters, such as frequency (UHF, HF), device type (passive, active RFID, Zigbee or Wi-Fi). RFID-enabled SPD staffs, RMEs and SPD machines and three working area functionalities are wrapped as uniform services. The standard interface format defines primary information about each service by a WSDL file, including elements such as types, messages, port type, binding, service name and address. It enables service accessibility.

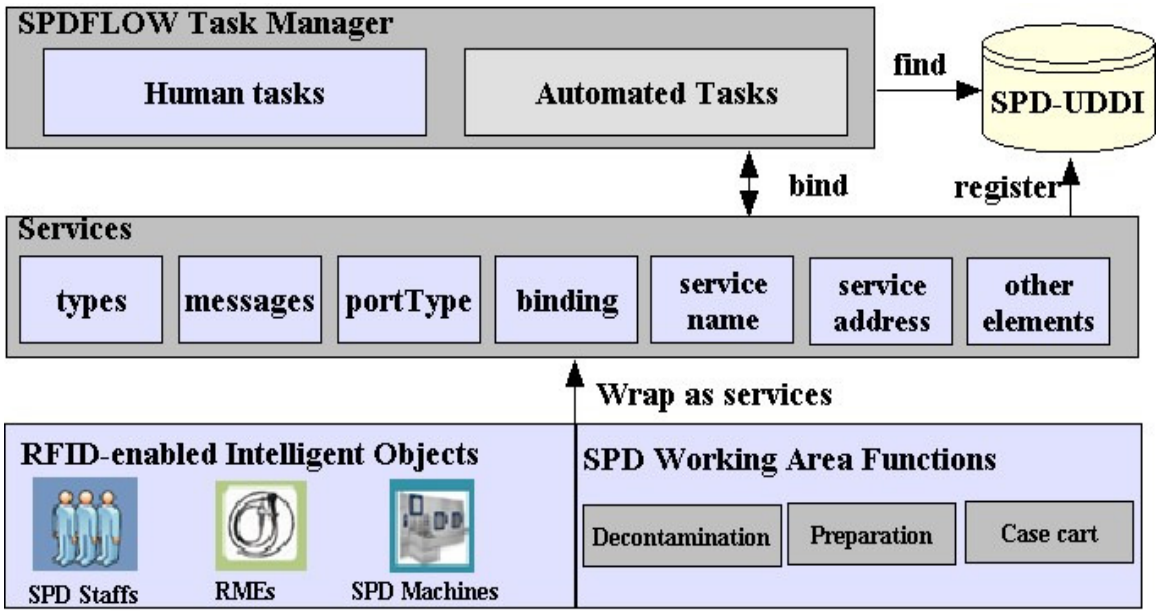


Figure 4-3 SOA enabled SPDFLOW Task Manager

The service registry (such as SPD-UDDI) serves as a platform-independent framework for describing, discovering, and integrating services from multiple service providers. Through a semantic description, each registered service can be invoked over the Internet.

Considering the requirements of SPD operation management, tasks can be divided into two groups. One group is human tasks, which require human interaction, such as clean result verification that the SOP rule engine cannot check. For example, SPD technicians should physically verify whether the body tissue is still on a bistoury scalpel after washer machine cleaning. Another group is fully automated tasks, which can be executed by SPDFLOW itself. For example, when the verification fails, an alarm message can be sent automatically to SPD technicians for reminding. The SPDFLOW task manager provides functions for these two types of task management, including registration, searching, execution and data management for the SPDFLOW task manager.

4.4.7. SPDFLOW SOP Rule Engine:

It is the intelligent subsystem that is innovated in the SPDFLOW to assist and guide end users to react correctly to real-time events of SPD workflows. Event-Condition-Action rules (ECA rules) are developed in the SOP Rule Engine to govern and constrain each reprocessing operation in the business processes of the sterile processing department. Via a logic-based ECA rules language, paper-based SOP rules are transformed to electronic SOP policies that are event-driven, logic-based, and action-oriented in the Rule Engine. In terms of ECA rules, the SOP requirements and actions

that need to be taken when requirements are violated are encoded in this rule engine. It can communicate with the SPD reprocessing workflow engine to automate the compliance check between SPD operations and SOP requirements.

Most healthcare facilities design Standard Operation Procedures (SOPs) from diverse manufacturers and models of the medical devices to guide staffs to complete the reprocessing operations thoroughly and consistently. These paper-based documents are normally posted as operation principles on some whiteboard of the sterile processing department where technicians could read the requirements of each operation. While different RMEs require different SOP documents, such documents can be roughly divided into 7 groups, with each group of RMEs following similar sequences of operations but the requirement for each operation can be different. Currently, SOP policy conformance check fully relies on technicians' skill, experience, and merits. Such manual policy conformance checking is error-prone and cannot fully ensure that each operation will be conducted fully in conformance with the SOP policies, leading to unclean RMEs that eventually compromise patient safety. This research proposes to transform paper-based SOP policies into electronic ones, and develop **Event-Condition-Action rules (ECA rules)** to govern and constrain each reprocessing operation in the business processes of the sterile processing department.

The SOP rules can be categorized into three types, which are pre-execution rules, execution rules and post-execution rules. Figure 4-4 shows four SOP policy snippets that are extracted from an SOP document, which is used to govern the reprocessing of Evis Exera II Gastrointestinal Videoscope.

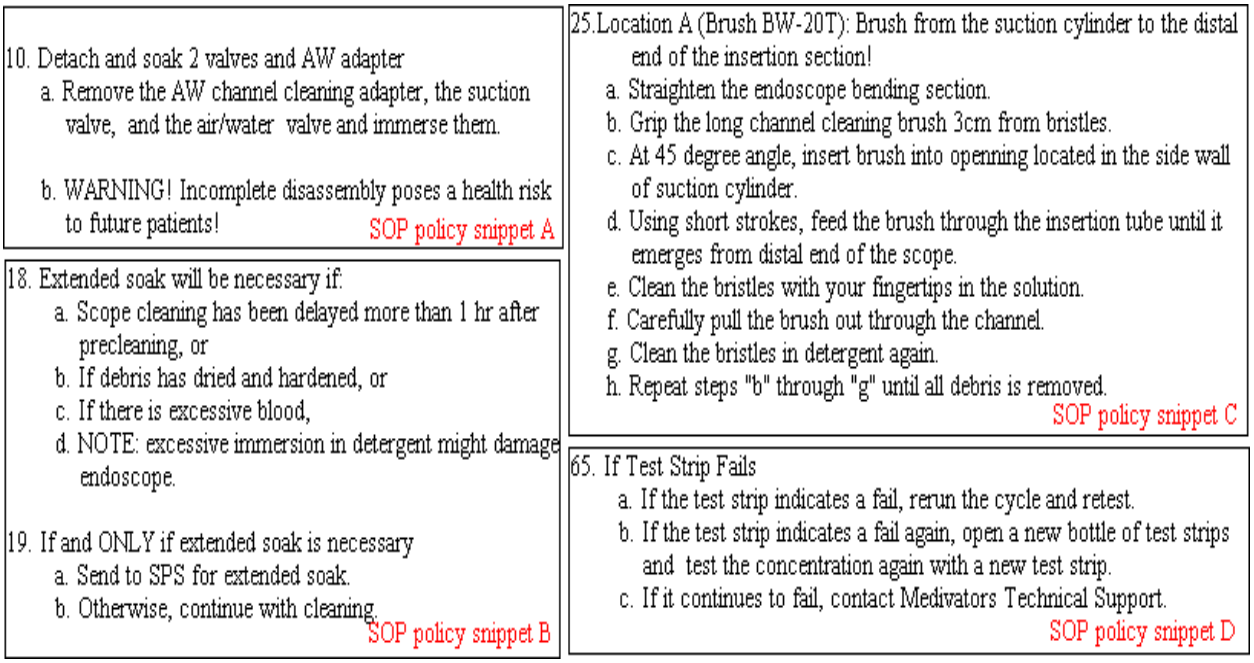


Figure 4-4 SOP Policy Examples

- Rule No.18, 19 are examples of pre-execution rules which specify the trigger requirements of one operation, extended soak.
- Rule No.10, 25, 65 are examples of post-execution rules which specify the following requirements when one operation has been done.

There are also lots of rules describing the requirements for execution parameters, such as the reprocessing environment (temperature, pressure), the time period of reprocessing (1 hour) and the times. One example is as follows: the high level of

disinfection. These items are cleaned for three times with a solution of water and Endozyme for 2 to 3 minutes. Then Air is blown to dry the items.

Automating SOP policy conformance check to such kind of SOP policies poses several challenges. First, SOP documents are typically lengthy, incomplete, and ambiguous, making it hard for a technician to understand and follow. For example, the original document for Figure 7 has 11 pages, 72 steps, with many steps containing 3-8 substeps, such as snippet C in Figure 4-4. Snippet A provides a warning for incomplete disassembly but neither preventive nor retroactive action is specified. Therefore, if incomplete disassembly happens, it is not clear what should be done to remedy it. Second, SOP policies often contain many constraints that are logical in nature, using terms such as “if”, “if only”, “if and only if”, “if not”, “and”, “or”, etc. If these logical terms and sentences are not correctly interpreted, wrong steps might be performed or some steps might be skipped or duplicated unnecessarily. Snippet B shows such an example. Third, some step is implemented as the iteration of a sequence of sub-steps and a condition is used to monitor the termination condition of the iteration. Snippet C shows such an example. For such iteration, it is critically important that the exact sequence of steps will be followed for each iteration until the condition is met. This is not easy for manual conformance since the technician needs to remember each iteration and not confuse the current iteration with previous ones; if not, the technician might skip some steps, which are performed in the previous iteration but not in the current iteration. Finally, failure handling must be properly handled. Snippet D shows such an example. Failure handling

also needs to be automated whenever possible so that exception can be handled by a technician properly, or propagated to the next person in the escalation chain.

To address these challenges, a logic-based event-condition-action rule (ECA rules) language is developed to represent, reason, and enforce SOP policies that are event-driven, logic-based, and action-oriented.

Three types of operation compliance check are designed for pre-execution, execution and post-execution rules to address the requirement. As an illustration of our approach, below, the following examples show how to use the ECA rules to deal with these three checking types:

- Examples for task pre-execution check

For rule No.18, 19, the following rules can be used to enforce them:

cona(b) :- precleaning(b, T1), scopecleaning(b, T2), T2-T1 > 60.

conb(b) :- detect_dried_debris(b), detect_hardened_debris(b).

conc(b) :- detect_excessive_blood(b).

Event: step 18 is initiated

Condition: cona(b) or conb(b) or conc(b)

Action: send b to SPS for extended soak

Event: step 18 is initiated

Condition: not(cona(b)) and not (conb(b)) and not (conc(b))

Action: initiate step 20

- Example of task execution check:

Cona(b):- pre_disinfection (b,T1), post_disinfection (b, T2), 3 min>=T2-T1>=2 min

Times-disinfection (b) = 0;

If (cona(b)) then {

Disinfection.times (b) = disinfection.times (b) + 1

}

Conb(b) :- disinfection.times(b) = 3

Event: high-level disinfection is completed

Condition: Conb(b)

Action: initiate next step: air is blown to dry the items.

- Examples of task post-execution check:

For rule No.10,

Event: step 10 is completed

Condition: incomplete_disassembly

Action: completely disassemble it

For rule No.25 with loop constraints

Event: last task ‘g’ is done

Condition: not all debris is removed

Action: repeat steps ‘b’ through ‘g’

For rule No.65 with multiple choices of following actions

Event: task 64 is done

Condition: test Strip fails

Action: rerun the cycle and retest

Condition: test Strip fails

Action: open a new bottle of test strips and retest with a new strip

Condition: test Strip fails

Action: contact Medivators Technical Support

4.4.8. SPDFLOW Smart Provenance Manager:

In the sterile processing departments, typically, different RMES have different requirements for cleaning, disinfection, and sterilization, and as a result, following different reprocessing procedure. A technician needs to read the SOP rules carefully in order to choose the right reprocessing procedure and the right parameters for each operation to ensure the quality of RMEs. Unfortunately, SOPs rules are often paper-based, posted on a whiteboard, and following such SOP rules to choose the right reprocessing procedure is manual and error prone. When a wrong reprocessing procedure is followed, unclean RMEs will be produced, often unnoticed or reported, and eventually affect the

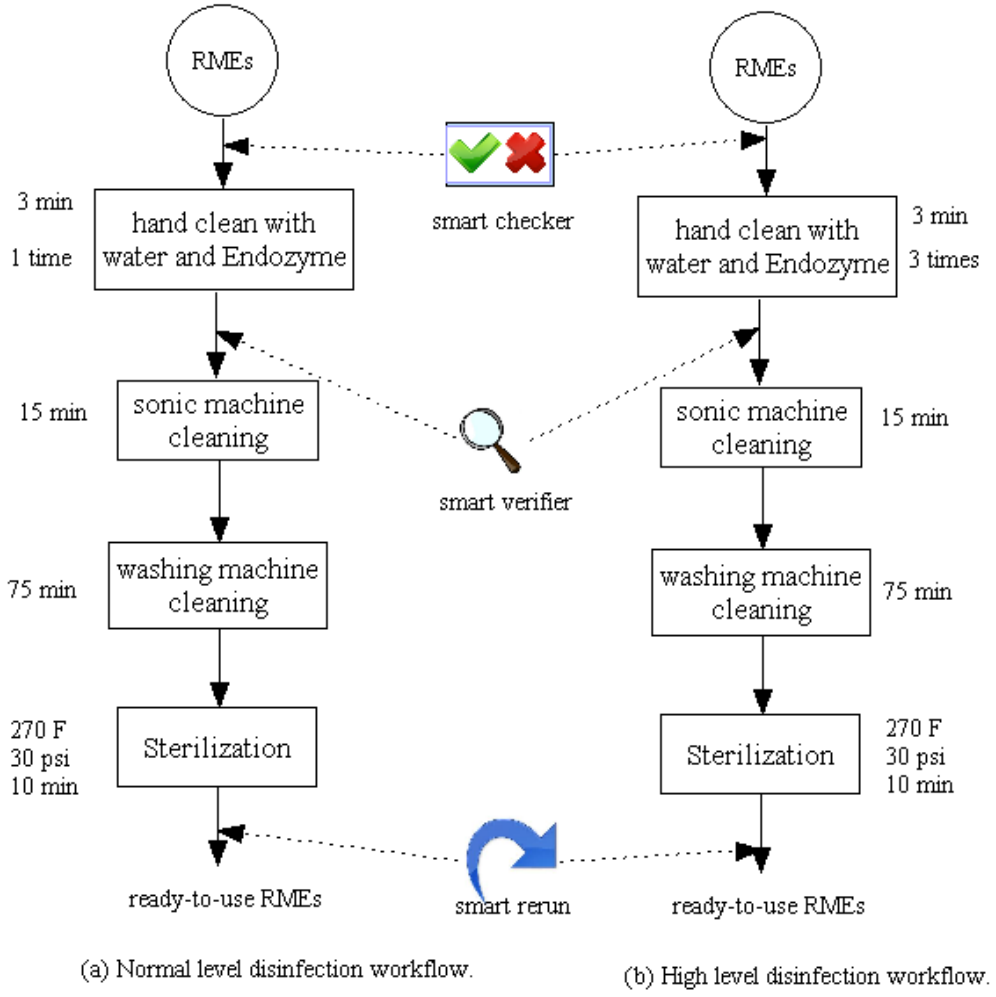


Figure 4-5 Two Cleaning Workflows

safety of patients. Figure 4-5 shows two RME cleaning workflows. If an RME requires a normal level disinfection, then the left workflow should be executed. If a high-level disinfection is needed, then the right workflow should be used. However, if a technician mistakenly put an RME that is supposed to use high-level disinfection into the left workflow, then that RME will be unclean at the end of the cleaning procedure, and if used, will compromise the safety of the patient. Meanwhile, all the steps should be processed successfully. Any skipped step will affect the cleaning results.

Event-based smart reasoning techniques are developed in the smart provenance manager to preventively reduce errors, proactively improve workflow management, and efficiently produce high-quality ready-to-use RMEs.

An event-enabled smart checker is to ensure that the right RME is performed by the right workflow and no required steps are skipped. All historic and current log information of an RME is automatically tracked and recorded, including their group information. In addition, the procedure requirements are encoded as smart workflow rules. The smart checker, based on these smart workflow rules, will check the information of the RME, and make sure that the proper workflow has been chosen for a particular RME. If a wrong workflow is chosen, the workflow will stop the RME from the pipeline and a notification will be sent to the responsible technician for exception handing. If the technician does not respond in a timely manner, then another notification will be sent to the next person in the escalation chain, such as the floor manager.

For example: check whether a right soiled RME into a right relative reprocessing workflow.

Group1_RMEs (a1, a2, a3,…..a20);

Group2_RMEs (b1, b2, b3,…..b18);

Smart_workflow_checker(X, w1) :- Group1_RMEs (X);

Smart_workflow_checker(X, w2) :- Group2_RMEs (X);

Event: reprocessing ai is initiated;

Condition: Smart_workflow_checker (ai, w1);

Action: initiate w1 for ai.

To ensure that each operation in a workflow is performed exactly without skipping steps according to the requirements for that operation (R4), an event-based smart verifier is included to verify that the necessary steps that should have been performed.

For example, verify whether all required steps in SOP rules are completed.

```
If (disinfection(b).execution(i).status = Success)
{
 W1(b).totalSuccess = W1(b).totalSuccess + 1;
```

}

If (W1(b).totalSuccess = W1(b).totalNumberOfSteps)

{

}

Event: w1 is completed.

Condition: W1(b).totalSuccess = W1(b).totalNumberOfSteps

Action: report “no step is skipped”

It is critical to catch and locate the delinquent operation step and decide the necessary rerun steps to remedy the nonconforming operations. A provenance-based smart rerun algorithm is running in the smart provenance manager: 1) to identify under what conditions rerun should be invoked, and 2) to select the optimal steps for smart rerun in terms of cost and time so that the overall objective of high-quality and high-throughput RMEs can be achieved. This research will be done in the future work.

4.5. Implementation and Case Study

In this section, the prototype system is presented, called SPDFLOW (stands for Sterile Processing Department workFLOW)[29], a healthcare workflow prototyping system. It supports a preliminary mechanism for operation process management in a sterile processing department. Based on the Service Oriented Architecture, SPDFLOW is developed upon our previous developed Interactive Visual Navigator (IVN) and the

VIEW (stands for Visual scIEntific Workflow) workflow system[138] by wrapping functionalities and subsystems from both IVN and VIEW as services. IVN is a user-friendly navigation software module that uses human factors engineering principles and the touch screen technology to instruct work process, conduct automatic time studies, and maintain detailed work process information. Inherited from VIEW, the SPDFLOW system features a Service-Oriented Architecture [136]. First, this research reuses a workflow designer to visually design workflows, a workflow engine to execute workflows, a workflow monitor to monitor the status of workflow execution and handle run-time exceptions. Second, three new subsystems: the SOA-based task manager, the SOP rule engine, and the smart provenance manager are developed to control the SPD reprocessing performance. Third, some functions from IVN or RFID-enabled smart object management system are encapsulated as services.

A case study for the SPD decontamination working area is shown in Figure 5. The workflow task 'registration' is used to record the basic information of soiled RMEs, such as ID, due date. The reprocessing schedule is made by task 'workflow scheduling' based on the priority of demands. The SOP rule engine and smart checker will be called to assist SPD technicians to select one of the two manual cleaning options (high-level and normal level) based on the specific SOP requirements. A condition parameter is set to automatically decide whether the sonic machine cleaning is needed based on the messages from the smart checker function. When one step is finished, a smart verifier helps SPD technicians verify whether the cleaning results for the RME are satisfactory, such as loop function. When it is not approved, the smart rerun function will inform SPD

technicians to repeat sonic machine cleaning or all previous steps. The multiple steps for sonic machine cleaning are encapsulated into a task by SPDFLOW. This demo system shows how SPDFLOW automates and streamlines the cleaning, disinfection, and sterilization operations in the sterile processing department

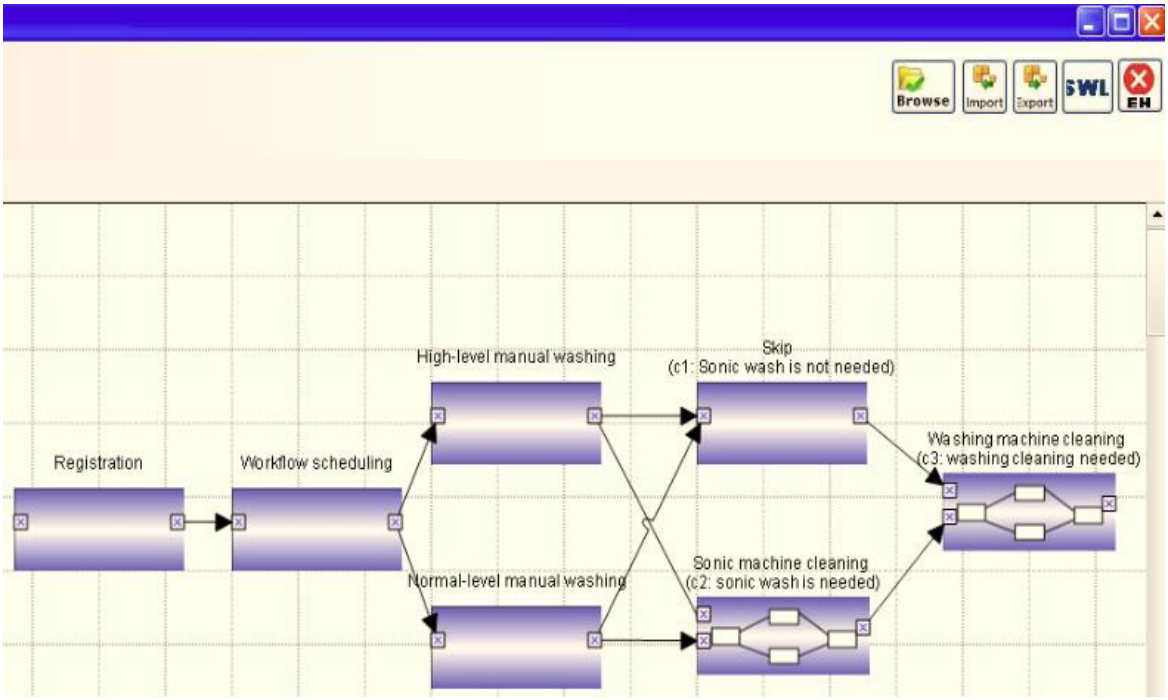


Figure 4-6 A Case Study in the Decontamination Area

4.6. Conclusions

In this chapter, first, the key architectural requirements were explored for a healthcare workflow system for SPDs. Second, a service-oriented architecture was designed for SPDFLOW subsystems and task manager. Third, ECA-based SOP rule engine was designed to achieve compliance check between SPD operations and SOP rules. Fourth, an SOA-based task manager was developed to control the human tasks,

automation functions from SPD working areas. Fifth, a smart provenance manager was defined to verify skipped steps and right workflow routine. Finally, initial implementation and a case study were discussed.

Chapter 5 Conclusions and Future Work

This dissertation presented a design and implementation framework of RFID-based business process management and workflow technology in a hospital. First, a roadmap of RFID implementation in a healthcare environment was presented with three tracking models. Second, the sterile processing department (SPD) was selected as a pilot deployment field for the RFID specialized tracking model. RFID was used to collect real-time data automatically for situational awareness of events, timing, and locations of reprocessing activities, and identification of various SPD resources. Business process management and workflow technologies were deployed for the modeling, automation, monitoring, and analysis of dynamic and complex sterile processes in SPDs. Third, the architecture of SPDFLOW, a healthcare workflow system for SPD was introduced in detail.

The contributions of this research are:

1). A roadmap to implement an RFID-based real-time location system in hospitals was proposed according to the Information System Design Theory, Lean Management, and Task-Technology Fit.

2). The performance matrixes to evaluate key technologies and vendor performance were discussed. The criteria to set the resolution level for tracking objects were presented. Business rule setting was recognized as one of the primary steps to retrieve real-time data more efficiently to mine valuable information.

3). During the implementation process, culture creation was considered one key step to adopt a new information system successfully in the traditional healthcare work style. Finally, the evaluation of system performance after implementation was discussed.

4). The lifecycle of business process management in clinical processes was proposed with five main steps. Three main phases for the business process management pattern, pre-execution, execution, and post-execution, were clearly claimed to show the relationship between BPM and workflow technology.

5). After exploring the main factors and issues that affect patient safety in SPD operation management, a five-layer service-oriented healthcare business process management framework for SPD was proposed.

6). Based on the key architectural requirements for SPDFLOW, the six subsystems in the SPDFLOW architecture were designed. This research deeply explored an ECA-based SOP rule engine to achieve compliance check, an SOA-based task manager to control human tasks, automation functions from SPD working areas, a smart provenance manager to verify skipped steps and right workflow routine.

7). Service-Oriented Architecture was applied to the SPDFLOW system development to enable collaboration between SPDFLOW and other systems via information sharing and integration; facilitate SPDFLOW subsystem development by programming and platform independence; virtualize RFID-based infrastructure resources and SPD functionalities as services in the SPDFLOW task manager.

There are still some open problems to be solved:

1). The design of the SOP rule engine to support the verification of more RME reprocessing procedures;

2). The development of techniques for smart provenance data management, such as the optimization methodology for a smart rerun scheme;

3). The development of optimization algorithms for the task manager to schedule optimal workload to each stakeholder.

4). Implementation of the SPDFLOW prototype system in one SPD for performance comparison between traditional business process management in SPD and improved solutions by the SPDFLOW system.

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ABSTRACT

RFID-BASED BUSINESS PROCESS AND WORKFLOW MANAGEMENT IN HEALTHCARE: DESIGN AND IMPLEMENTATION

by

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August 2012

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The healthcare system in the United States is considered one of the most complex systems and has encountered challenges related to patient safety concerns, escalating costs, and unpredictable outcomes. Many of these problems share a common cause – a lack of efficient business process management and visibility into the real-time location, status, and condition of medical resources. The goal of this research is to propose a newly integrated system to model, automate, and monitor healthcare business processes using an automatic data collection technology to record the timing and location of activities and identify their various resources.

This dissertation makes several contributions to the design and implementation of RFID-based business process and workflow management in healthcare. First, I propose a road map to implement RFID in hospitals with performance matrixes for technology evaluation, key criteria for resolution level setting, and business rules for information extraction. Second, RFID-based business process management (BPM) concepts and

workflow technologies are used to transform the reprocessing procedures in a Sterile Processing Department (SPD) for the purpose of reducing infections caused by unclean RMEs. In the proposed pattern for healthcare business process management, the importance of execution status control is emphasized as a key component to handle complex and dynamic healthcare processes. A five-level framework for service-oriented business process management is designed for SPDs to share information, integrate distributed systems, and manage heterogeneous resources among multiple stakeholders. This research proposes a healthcare workflow system as a deliverable solution to manage the execution phase of reprocessing procedures, which supports the design, execution, monitoring, and automation of services supplied in SPDs. RFID techniques are adopted to collect relative real-time data for SPD performance management. Finally, by identifying key architectural requirements, the subsystems of a service-oriented architecture for the SPD workflow prototyping system, SPDFLOW, are discussed in detail. This research is the first attempt to explore healthcare workflow technologies in the SPD domain to improve the quality of RMEs and ensure patient safety.

AUTOBIOGRAPHICAL STATEMENT

Ms Xiaoyu Ma is a Ph.D. candidate from the Industrial & Systems engineering department of Wayne State University. She has obtained M.S. in Computer Science from Southeast University, B.S. in Electronic Engineering from Chongqing University in China. Her main interests include operational decision support for RFID-based visualization management, real-time healthcare workflow management, and smarter facility design. Currently, she works as a program analyst for VA Center for Applied Systems Engineering (VA-CASE) and has participated in multiple projects for healthcare system redesign. She is a member of IIE and IEEE, and a guest member of the Scientific Workflow Research Laboratory (SWR Lab), one of the top five leading scientific workflow research groups in North America. She has published several refereed papers for designing RFID-based business process and workflow management.