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著者(和文)	LiuHuchen
Author(English)	Huchen Liu
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Doctoral Dissertation

A Study on Industrial Engineering Approaches to Healthcare Management

By

Hu-Chen Liu

10D55132

Supervised by

Professor Kenji ITOH

Department of Industrial Engineering and Management

Graduate School of Decision Science and Technology

Tokyo Institute of Technology

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ABSTRACT

Interest in industrial engineering approaches as applied to healthcare management has increased considerably in all over the world. However, there are still some gaps which we would like to fill in. The objective of this dissertation includes research on reliability and operations management in healthcare based on two approaches: failure mode and effects analysis (FMEA) and key performance indicators (KPIs).

The first interest highlights on reliability management in healthcare which is an important component of healthcare management. FMEA is a prospective risk assessment tool that mitigates potential failures in systems, processes, designs or services and has been widely used within a wide range of industries. The conventional risk priority number (RPN) method has been criticized to have many deficiencies and various risk priority models have been proposed in the literature to enhance the performance of FMEA. However, there has been no literature review on this topic. Therefore, we reviewed 75 FMEA papers published between 1992 and 2012 in the international journals and categorized them according to the approaches used to overcome the limitations of the conventional RPN method. The intention of this review is to address the following three questions: (a) which shortcomings attract the most attention? (b) which approaches are the most popular? (c) is there any inadequacy of the approaches? The answers to these questions will give an indication of current trends in research and the best direction for future research in order to further address the known deficiencies associated with the traditional FMEA.

With increasing deployment, complexity, and sophistication of equipment and related processes within the health care environment, system failures are more likely to occur. These failures may have varying effects on the patient, ranging from no harm to devastating harm. FMEA is a tool that permits the proactive identification of possible failures in complex processes and provides a basis for continuous improvement. In traditional FMEA, the risk priorities of failure modes are determined by using RPNs, which can be obtained by multiplying the scores of risk factors like occurrence (O), severity (S) and detection (D). However, the crisp RPN method has been criticized to have several deficiencies. For this reason, linguistic variables, expressed in trapezoidal or triangular fuzzy numbers, were used to assess the ratings and weights for the risk factors O, S and D. For selecting the most serious failure modes, an extended VIKOR (VIsekriterijumska optimizacija i KOmpromisno Resenje) method was used to determine risk priorities of the failure modes that have been identified. As a result, a

fuzzy FMEA based on fuzzy set theory and VIKOR method was proposed for prioritization of failure modes, specifically intended to address some limitations of the traditional FMEA. A case study, which assesses the risk of general anesthesia process, was presented to demonstrate the application of the proposed model under fuzzy environment.

Based on KPIs, the second stream of this research focuses on operations management in healthcare. Because no indicator system has yet been developed for measuring and assessing performance of dialysis facilities under the Japanese context, we would like to develop a theoretical framework of holistic hospital management based on performance indicators which can be applied to dialysis hospitals, clinics or departments in Japan. Selection of a key indicator set and its validity tests were performed primarily by the use of two famous data sources as well as expert statements obtained through interviews: a systematic review of literature and a questionnaire survey among dialysis experts. The systematic survey searched PubMed and PubMed Central, and 24 papers were elicited as relevant. The expert questionnaire asked respondents to rate the degree of "usefulness" for each of 66 indicators on a three-point scale. Applying the theoretical framework, we selected a minimum set of performance indicators for dialysis management which can be used in the Japanese health care setting. The indicator set comprised 27 indicators and items which will be collected through three surveys: patient satisfaction, employee satisfaction and safety culture. The indicators were confirmed by expert judgment from viewpoints of face, content and construct validity as well as their usefulness. Finally, we established the theoretical framework of performance measurement for holistic dialysis management from primary healthcare stakeholders' perspectives. In this framework, performance indicators were largely divided into healthcare outcomes and performance shaping factors. Indicators of the former type may be applied to detection of operational problems or weaknesses in a dialysis hospital, clinic or department, while latent causes of each problem can be more effectively addressed by the latter type of indicators in terms of process, structure and culture/climate within the organization.

In addition to the investigation on dialysis experts, a questionnaire survey was also performed to another active player within healthcare that was healthcare management. The objective is to investigate current usage of performance indicators that can be potentially applied to dialysis management and managers' views of their usefulness based on the framework of a holistic dialysis management system. The questionnaire survey was conducted to ask usage, usefulness and organizational level of performance measurement for 44 potential indicators. By applying principal component analysis to

the entire sample, eleven performance measures were extracted from perspectives of patient, employee and management: nosocomial infection, patient satisfaction, patient safety, waiting & errors, work conditions, employee advancement, employee satisfaction & safety, financial effectiveness, mortality & operational efficiency, operational effectiveness, and staff and equipment efficiency. Among them, six measures were frequently used and nine measures were rated highly useful for measurement of performance in dialysis hospitals, clinics or departments in Japan. General hospitals and hospitals with more dialysis beds used the performance measures more common and the perceptions of usefulness were more positive. Managers' perceptions of usefulness were significantly associated with the usage of indicators in the current hospitals. Our results demonstrate that it is necessary to develop a limit number of important indicators for measuring and managing the dialysis system in Japan, and tailored strategies are needed to implement performance indicators in daily practice.

CHAPTER 1

INTRODUCTION

1.1 RESEARCH BACKGROUND

1.1.1 Healthcare management: need for a systemic perspective

In recent years healthcare systems have been involved in a number of different changes, ranging from technological to normative ones, all asking for increased reliability, effectiveness and efficiency. In addition, the biomedical progress in the last decades has contributed to raise the level of organizational complexity in hospitals, which is given by many different factors, such as multiple professional experiences, non-uniform management models, patient specificity, surgery complexity, reduced inpatient days, and a growing number of healthcare service users due to an increase in average lifetime. As a result, medicine complexity, driven by innovations in both science and technology, stresses the need for new managerial models (Bridges, 2006). Thus, this context highlights the necessity to develop systemic approaches able to healthcare management and to suggest organizational and/or technological solutions for continuous improvement.

"Health systems consist of all the people and actions whose primary purpose is to promote, restore or maintain health. They may be integrated and centrally directed, but often they are not. After centuries as small-scale, largely private or charitable, mostly ineffectual entities, they have grown explosively in this century as knowledge has been gained and applied. They have contributed enormously to better health, but their contribution could be greater still, especially for the poor. Failure to achieve that potential is due more to systemic failings than to technical limitations. It is therefore urgent to assess current performance and to judge how health systems can reach their potential" (WHO, 2000).

Following the success of the application of industrial engineering approaches to the manufacturing sector (Liker and Hoseus, 2008; Cagliano et al. 2011), healthcare organizations have developed and adopted the industrial engineering techniques to healthcare management (Carayon, 2007; Sahney, 1993; Smalley and Freeman, 1966).

The health care field has embraced the various models and approaches to safety and quality to analyze and evaluate risk and improve the quality and safety of care provided to patients in various institutions and venues (Joint Commission, 2010; Press, 2003; McDermott et al., 2008; Carey, 2002;Glasgow et al., 2010, Collins and Muthusamy, 2007).

Industrial engineering can be defined as a profession in which a knowledge of mathematical and natural sciences gained by study, experience and practice is applied with judgment to develop the ways to utilize economically the materials and other natural resources and forces of nature for the benefit of mankind (Patil et al., 2008).

American Institute of Industrial Engineers (AIIE) has defined industrial engineering as follows:

"Industrial engineering is concerned with the design, improvement and installation of integrated system of men, materials and equipment. It draws upon specialized knowledge and skill in the mathematical, physical sciences together with the principles and methods of engineering analysis and design to specify, predict and evaluate the results to be obtained from such systems."

Industrial engineering is a wide discipline that includes the study, analysis, design and improvement of any or all productive elements of any organization. There is a general trend of applying industrial engineering principles in service sector industries such as health care, transportation, hospitals, hotels, banks. The development of techniques like

- operations research,
- reliability analysis,
- human factors and ergonomics,
- systems analysis,
- performance evaluation, and
- mathematical and statistical tools,

have expanded the scope of activities of industrial engineering. Thus industrial engineering has taken up an important position in the organization and it is contributing maximum towards increasing productivity and efficiency in particular and quality of work environment in general (Khan, 2007).

However, the healthcare industry has been slow in accepting the proven operational practices utilized in other industries due to the unique characteristics of this industry. Some of these unique characteristics are listed below (Gomes et al., 2010):

- Differences between organizations due to their different roles in this industry. For example, this industry includes hospitals, with clear boundaries, where patients are admitted and discharged. It also includes primary healthcare organizations, which are open community-based systems with unclear boundaries.
- Differences between the services delivered (healthcare services) and patients' expectations (health). Hence, making it difficult to measure patient's satisfaction due to different service/patient contexts.
- The existence of different stakeholders with, sometimes, conflicting interests and expectations. These stakeholders include those who consume healthcare services (patients), those who ultimately pay for the services (taxpayers, or insured individuals), those who purchase the services on the public's behalf (fund holdings), and those who provide such services (healthcare delivery operational systems).
- The complex, and multidimensional nature of healthcare service quality, combined with the fact that many patients lack the clinical expertise to judge some key aspects of the healthcare service delivery systems. This tends to complicate the process of measuring and improving performance.

As a result, although some techniques from industrial engineering have been adapted to the health care field, it has been a struggle for health care professionals, hospitals and their monitors to come up with consistently successful methodologies that ensure better patient safety and better quality (Umble and Umble, 2006; Sheldon, 1998; Enthoven, 2000). The lack of a systemic, holistic approach to addressing health management issues would lead to fragmented solutions that do not solve the problem as intended and introduce new, unintended issues. There is a clear and desperate need to actively encourage and promote the successful transfer and application of relevant industrial engineering techniques to healthcare environments.

1.1.2 Industrial engineering approaches to healthcare management

As mentioned above, various issues have been raised in the health care sector along with changing healthcare landscape and it is necessary to develop systemic methods to solve these issues in a holistic way. A system is a set of interdependent elements interacting achieve a common aim. It requires systems that are designed for healthcare management-that is, systems in which the sources of health management issue have been systematically recognized and minimized. Efforts should be made as: collect data

on errors and incidents within the organization in order to identify opportunities for improvement and to track progress; the use of sophisticated methods for analysis of complex processes, and a striving for balance among standardization where appropriate, yet giving individuals the freedom to solve problems creatively (Kohn et al., 1999).

In this dissertation, I will propose a systemic methodology for healthcare management based on two industrial engineering techniques: failure mode and effects analysis (FMEA) and key performance indicators (KPIs). The FMEA will be used to address the specific health management issues and the KPIs will be used to identify the operational problems or weaknesses in a hospital/department. After detection of operational problems or weaknesses in a healthcare organization based on key performance indicators, the potential failure modes and latent causes of each problem can be addressed by using the risk evaluation method of FMEA in terms of product, process and sub-system within the organization. In this dissertation, I will make general anesthesia process as an example for failure mode and effects analysis and develop a holistic hospital management framework based on performance indicators for measuring performance in dialysis facilities.

(1) Risk evaluation in healthcare

Similarly to any other complex system, the complexity of healthcare systems generates adverse events if not controlled (Vincent, 2006). An adverse event may be defined as an unintended injury or complication resulting in disability, death or prolonged hospital stay that is caused by healthcare management rather than by the patient's underlying disease process (Ross Baker et al., 2004). An intrinsic characteristic of medical care is the fact that, whenever it is delivered, patients run the risk to suffer from a disease as an unwilling consequence of treatments (Thomas et al. 2000). Thus, the probability of errors and adverse events in general cannot be eliminated in healthcare organizations. However, it can be controlled by the application to risk management phases of a recursive process of continuous improvement inspired by the Plan-Do-Check-Act (PDCA) paradigm (Tonneau, 1997; Rath et al., 1999; Aryankhesal and Sheldon, 2010). According to the Project Management Institute, risk management includes the processes concerned with risk management planning, identification, analysis, response, monitoring, and control. The aim is to increase the probabilities and impacts of positive events and to decrease the probabilities and impacts related to adverse events (Project Management Institute, 2004). Risk management has been adopted to cover all healthcare risks, both clinical and non-clinical ones.

"Health systems make costly, even fatal mistakes far too frequently. In the United States alone, medical errors in hospitals cause at least 44 000 needless deaths a year, with another 7000 occurring as a result of mistakes in prescribing or using medication, making these errors more deadly than such killers as motor vehicle accidents, breast cancer and AIDS. The economic cost of these mistakes is at least $17 billion, of which health care costs are more than half" (WHO, 2000).

The present work focuses on risk evaluation in healthcare using FMEA, which has been defined by Stamatis (2003) as follows:

"FMEA is an engineering technique used to define, identify, and eliminate known and/or potential failures, problems, errors, and so on from the system, design, process, and/or service before they reach the customer."

FMEA is one of the most important early preventive actions in system, design, process, or service which will prevent failures and errors from occurring and reaching the customer. The analysis of the evaluation may take two courses of action. First, using historical data, there may be analysis of similar data for similar products and/or services, warranty data, customer complaints, and any other appropriate information available, to define failures. Second, inferential statistics, mathematical modeling, simulations, concurrent engineering, and reliability engineering may be used to identify and define the failures. The FMEA will identify corrective actions required to prevent failures from reaching the customer, thereby assuring the highest durability, quality, and reliability possible in a product or service.

The benefits of conducting an FMEA include the following (Stamatis, 2003):

- helps define the most significant opportunity for achieving fundamental differentiation.
- improves the quality, reliability, and safety of the products or service.
- helps select alternatives with reliability and high safety potential during the early phases.
- improves the organization's image and competitiveness.

Similar to other industrial engineering approaches, the FMEA has been applied into healthcare with the increasing deployment, complexity, and sophistication of the equipment and related processes within the healthcare environment. Improvement processes such as FMEA are no longer voluntary for hospitals that admit patients: Standard of the Joint Commission (formerly known as the Joint Commission on

Accreditation of Healthcare Organizations) requires that "leaders ensure that an ongoing (i.e., annual) proactive program for identifying risks to patient safety and reducing medical/health care errors is defined and implemented" (Joint Commission, 2010).

"In healthcare, failure of a process is refer to any malfunction, error, or defect that results in a process not performing as intended or not meeting desired requirements or standards; failure mode is refer to anything that could go wrong during the completion of a step in a process; causes of a failure include all possible mechanisms or means that result in the failure mode, and the effects of a failure typically include the customer's experience that results from the failure mode" (Thornton et al., 2011).

The modification of traditional FMEA known as healthcare failure mode and effect analysis (HFMEA) was introduced in 2001 by the US Department of Veterans Affairs National Center for patient safety. HFMEA combines concepts, components, and definitions from FMEA, hazard analysis, and critical control points, and root cause analysis. FMEA has been applied successfully in the healthcare setting to improve patient safety (Kuo et al., 2012; Woodhouse et al., 2004), evaluate the sterilization of surgical instruments (Linkin et al., 2005), analyze radiotherapy patent record systems (Chadwick and Fallon, 2013), prevent chemotherapy errors (Cheng et al., 2012), as well as improve safety in the radiology department (Thornton et al., 2011) and pediatric oncology ward (Tilburg et al., 2006).

(2) Performance measurement of healthcare

Due to the increasing needs for better direction and management of service organizations, operations management researchers and practitioners have started to apply operations management concepts and techniques developed in manufacturing sectors to service industries (Li et al., 2002; Buler et al., 1996; Gomes et al., 2010; Umble and Umble, 2006). As one significant segment of the service sector, health care service is a patient-oriented service that requires continuous interaction with customers. It utilizes facilities and equipment, and consumes a large volume of nursing care. In addition, healthcare organizations have been facing increasing competitive pressures due to recent environment, such as changing disease patterns, ageing population, poor quality, medical errors and lack of accountability and inequalities (Umble and Umble, 2006; Institute of Medicine, 2001; Arah et al., 2006). Therefore, it becomes increasingly important to health care executives to understand what kind of facility, equipment, and workforce decisions are critical to achieve the commonly acknowledged goal of

providing quality health service at a reasonable cost. The healthcare industry uses the management models in industrial engineering to improve its performance and the use performance indicators as measures of how well organizational objectives are accomplished is strongly emerging in healthcare (van der Geer et al., 2009; Freeman, 2002; de Vos et al., 2009; Klassen et al., 2010).

"Performance measurement can be described as a method of assessing the performance of individuals, organizations, services or processes as a means of assessing efficiency and effectiveness of action and to assess the alignment of the organizations' activities with its strategy and vision/mission statement. Thus the main aim of performance measurement is to generate qualitative and quantitative data, which then can be used to apply control in order to align the performance of an organization with its core principles" (Basu et al., 2010).

Assessing the performance of a health system cannot be seen in isolation from its ultimate purpose and thus we need to define the goals of a health system first. While there is an ongoing debate on the health system ultimate aims, the World Health Organization defined the goal of a health system to be the delivery of effective preventive and curative health services to the full population, equitably and efficiently, while protecting individuals from catastrophic health care costs (WHO, 2000). As core social institutions, health systems also need to be responsive to the needs and demands of the population (Freedman, 2005). Thus patient satisfaction, public participation in decision making, and accountability should be included as key aims of health systems, distinct from the clinical and economic goals. Essential health services are those that address the major contributors to death and disability in countries, ranging from child and maternal health services to prevention and treatment of infectious diseases to basic response to injuries and chronic disease (Kruk and Freedman, 2008).

"Health systems are valuable and important, but they could accomplish much more with the available understanding of how to improve health. The failings which limit performance do not result primarily from lack of knowledge but from not fully applying what is already known: that is, from systemic rather than technical failures. This is true even of most medical errors, because "the problem is not bad people; the problem is that the system needs to be made safer" (Kohn et al., 1999).

Assessing the quality of health care has become increasingly important to

providers, regulators, purchasers, and patients. Governments need tools to monitor and evaluate the functioning of the system on a routine basis and to allow for more informed decisions about health systems funding, organization and policies. Providers require meaningful measures to know how well they are performing and to have effective means of assessing and improving the quality of care they provide. Patients need information about quality of care in order to make informed choice. Performance indicators are also important to researchers who generate evidence relevant to health system scale-up and reform. Therefore, different stakeholders have shown interest in health systems performance assessment and management through the development of KPIs within supportive conceptual frameworks. There are now several major initiatives to standardize and harmonize the collection of health metrics globally and to make recommendations on the most useful measures. These include the United States (US) Healthcare Quality Report (National Healthcare Quality Report, 2011; Kelley et al., 2006), the International Quality Indicator Project (Thomson et al., 2004), the Organisation for Economic Co-operation and Development (OECD) Health Care Quality Indicator Project (Marshall et al., 2006; Arah et al., 2006; Kelley et al., 2006; Mattke et al., 2006), the National Health Service (NHS) Performance Assessment Framework (Chang et al., 2002; Arah et al., 2003), the Australian Council on Health Care Standards (ACHS) (Collopy et al., 2000; ACHS, 2012), the Danish National Indicator Project (Mainz et al., 2004; Mainz et al., 2009) and the Dutch Health Care Performance Report (DHCPR) (Ten Asbroek et al., 2004; van den Berg et al., 2010), among others (Berg et al., 2005; Groene et al., 2008; Kramers, 2003; Veillard et al., 2005; Gauld et al., 2011; Chiu et al., 2007; Tung and Yang, 2009; El-Jardali et al., 2011).

1.2 OBEJCTIVES OF THE DISSERTATION

The main theme of this dissertation is applying industrial engineering approaches to healthcare management and the systemic methodology for healthcare management is the application of FMEA and KPIs to the reliability and operations management in healthcare. Thus, there are overall two objectives in this dissertation. First, to propose a new FMEA model and apply it to reliability management in healthcare: to identify, evaluate and eliminate potential failures in healthcare systems. Second, to propose a holistic hospital management framework based on KPIs and apply it to operations management in healthcare: to monitor, measure, and manage the performance of health

systems and identify areas for improvement and benchmark sources. To fulfill these objectives, the themes focused in the dissertation are as follows:

I. To investigate the risk evaluation approaches currently used in FMEA. Specifically, to look at shortcomings surrounding the traditional method and identify which issues attract the most attention in FMEA literature. To describe the approaches used in FMEA literature and find which approaches were prevalently applied. To evaluate the approaches used in FMEA literature and to check whether there is any inadequacy of the approaches.

II. To propose a new risk priority model by using fuzzy sets theory and VIKOR (VIsekriterijumska optimizacija i KOmpromisno Resenje) method in order to deal with the risk evaluation problems in traditional FMEA. To analyze the risk of general anesthesia process by applying the new FMEA model and identify the most serious failure modes so as to take appropriate measures in advance and prevent the incidence of medical errors.

III. To review the literature on indicators currently in use to measure performance and highlight those indicators which were found to be in most common use. In addition, to present a framework for holistic hospital management, focusing on dialysis hospitals/departments. To support dialysis facilities in performing evidence-based management from holistic views.

IV. To uncover current usage of performance indicators used by dialysis staff in the Japanese dialysis settings; to understand managers' views of their importance based on the framework of holistic dialysis management system; to investigate the contributing factors to indicator usage and their judgments of usefulness.

1.3 STRUCTURE OF THE DISSERTATION

The dissertation is organized into three main parts in six chapters. The first part covered backgrounds on healthcare management research employing industrial engineering approaches through concerned literatures (Chapter 1). The second part presents healthcare management studies through a reliability management approach, i.e., FMEA and its application to general anesthesia process, and an operations management

approach, i.e., theoretical framework of holistic hospital management and usage of dialysis performance indicators (Chapters 2-5). The third part is the conclusions of the dissertation (Chapter 6). To clearly elucidate this, the structure of the dissertation was illustrated in Figure 1-1.

Chapter 1 sets the view point for the dissertation by providing relevant research backgrounds. The main theme of the dissertation is healthcare management applying industrial engineering approaches. This chapter identified existing trends and problems and formulated the objectives of the dissertation. It also briefly stated the structure of the dissertation.

Chapter 2 focuses on reliability management in healthcare which is an important component of healthcare management. Related articles appearing in the international journals from 1992 to 2012 are reviewed and categorized according to the approaches used to overcome the limitations of the conventional RPN method. Shortcomings surrounding the traditional method, the most popular approaches used in the FMEA literature and their inadequacies are identified and discussed.

Chapter 3 assesses failures in the general anesthesia environment. For selecting the most serious failure modes, an extended VIKOR method is used to determine risk priorities of the failure modes. As a result, a fuzzy FMEA based on fuzzy set theory and VIKOR method is proposed for prioritization of failure modes. A case study is presented to demonstrate the application of the new model under fuzzy environment.

Chapter 4 pays attention on operations management in healthcare. Based on key performance indicators, a theoretical framework of holistic hospital management is developed, which can be applied to dialysis hospitals, clinics or departments in Japan. Selection of a key indicator set and its validity tests are performed by the use of a systematic review of literature and a questionnaire survey among dialysis experts. Applying the theoretical framework, a minimum set of key performance indicators is selected for dialysis management which can be used in the Japanese context.

Chapter 5 investigates current usage of performance indicators that can be potentially applied to dialysis management and managers' views of their usefulness. Performance measures of dialysis management are discovered; current states of indicators, differences across hospital types and hospital sizes, and correlations between

usage and usefulness are also investigated. To overcome the disadvantages of performance measurement, a limit number of important indicators are also developed for measuring and managing the dialysis system in Japan.

Chapter 6 concludes the dissertation with a summary of key outcomes. This final chapter also presents the contributions of research in this dissertation as well as healthcare managerial implications. Limitations on this dissertation and expected future studies are also discussed.

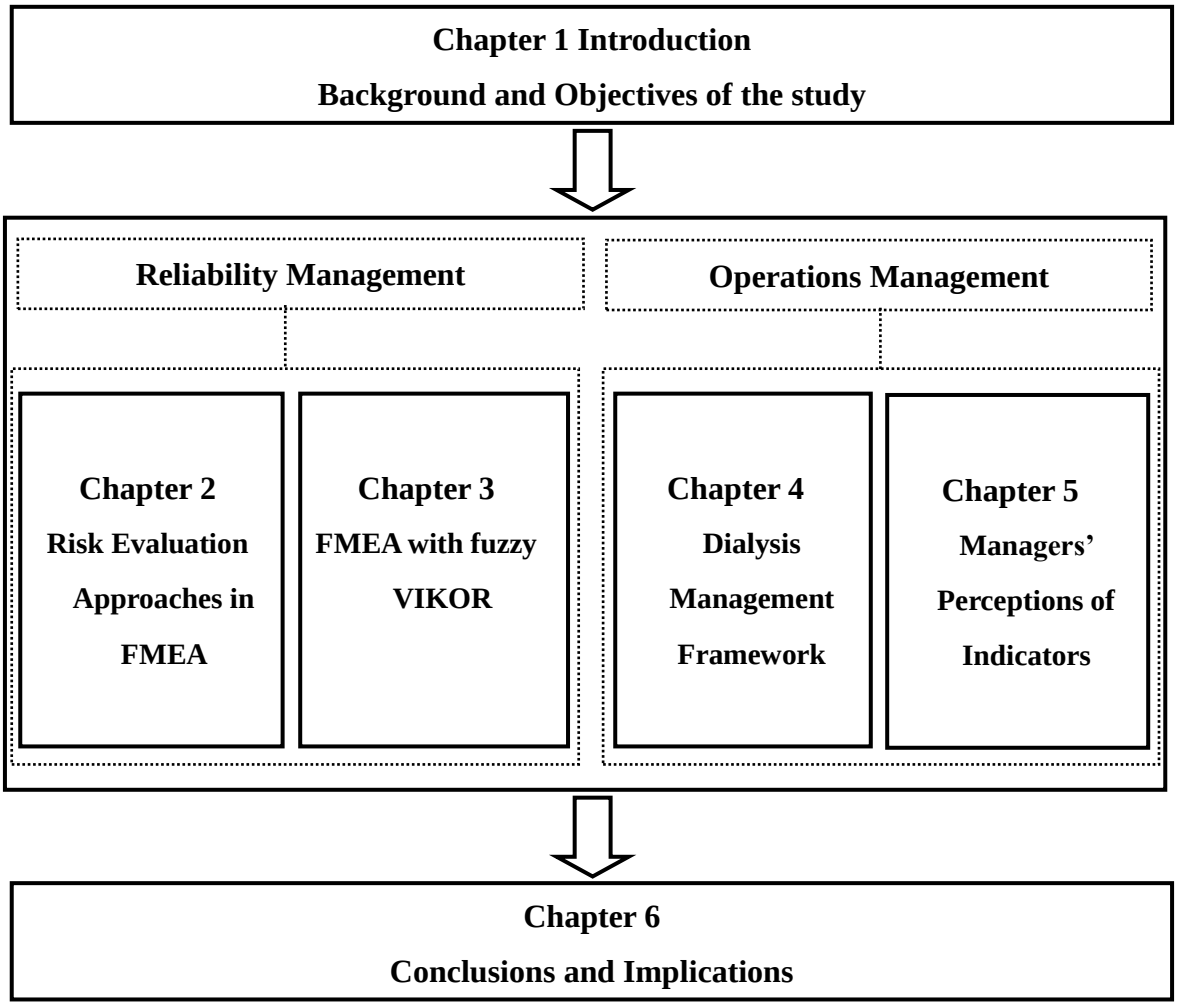

Figure 1-1 Structure of the dissertation

CHAPTER 2

RISK EVALUATION APPROACHES IN FMEA

2.1 BACKGROUND

Failure mode and effects analysis (FMEA), first developed as a formal design methodology in the 1960s by the aerospace industry (Bowles and Peláez, 1995), has proven to be a useful and powerful tool in assessing potential failures and preventing them from occurring (Sankar and Prabhu, 2001). FMEA is an analysis technique for defining, identifying and eliminating known and/or potential failures, problems, errors and so on from system, design, process, and/or service before they reach the customer (Stamatis, 1995). When it is used for a criticality analysis, it is also referred to as failure mode, effects and criticality analysis (FMECA). The main objective of FMEA is to identify potential failure modes, evaluate the causes and effects of different component failure modes, and determine what could eliminate or reduce the chance of failure. The results of the analysis can help analysts to identify and correct the failure modes that have a detrimental effect on the system and improve its performance during the stages of design and production. Since its introduction as a support tool for designers, FMEA has been extensively used in a wide range of industries, including aerospace, automotive, nuclear, electronics, chemical, mechanical, and medical technologies industries (Chang and Cheng, 2011; Chin et al., 2009b; Sharma et al., 2005).

Traditionally, criticality or risk assessment in FMEA is carried out by developing a risk priority number (RPN). Nevertheless, the crisp RPN method shows some important weaknesses when FMEA is applied in the real-world cases. Therefore, we focus on the calculation of the evaluation measures in FMEA in order to solve the problems and improve the effectiveness of the traditional FMEA. Many alternative approaches have been suggested in the literature to resolve some of the shortcomings of the traditional RPN method and to implement FMEA into real world situations more efficiently. To the best of our knowledge, no research has been done on the review of approaches employed to enhance the performance of FMEA. This chapter provides a review of those academic works attempting to deal with problems in the traditional RPN method and classify the existing literature by the approaches used. Related articles appearing in the international journals from 1992 to 2012 are gathered and analyzed. Based on the 75

journal articles collected, the specific objectives of this chapter are:

- to look at shortcomings surrounding the traditional method and identify which issues attract the most attention in FMEA literature.
- to describe the approaches used in FMEA literature and find which approaches were prevalently applied.
- to evaluate the approaches used in FMEA literature and check whether there is any inadequacy of the approaches.

The rest of the chapter is organized as follows. The traditional FMEA and its major shortcomings are provided in Section 2.2. In Section 2.3 we explain the framework used for classifying FMEA literature and present the results of literature review. Section 2.4 analyses the most prevalently used approaches and finds out the limitations of the approaches. Finally, we will make a summary in Section 2.5.

2.2 FMEA

2.2.1 The traditional FMEA

FMEA is an important technique that is used to identify and eliminate known or potential failures to enhance the reliability and safety of complex systems and is intended to provide information for making risk management decisions. In order to analyze a specific product or system, a cross-functional team should be established for carrying out FMEA first. The first step in FMEA is to identify all possible potential failure modes of the product or system by a session of systematic brainstorming. After that, critical analysis is performed on these failure modes taking into account the risk factors: occurrence (O), severity (S) and detection (D). The purpose of FMEA is to prioritize the failure modes of the product or system in order to assign the limited resources to the most serious risk items.

In general, the prioritization of failure modes for corrective actions is determined through the risk priority number (RPN), which is obtained by finding the multiplication of the *O*, *S* and *D* of a failure. That is

$$RPN = O \times S \times D, \tag{2-1}$$

where *O* is the probability of the failure, *S* is the severity of the failure, and *D* is the probability of not detecting the failure. For obtaining the RPN of a potential failure mode, the three risk factors are evaluated using the 10-point scale described in Tables 2-1, 2-2 and 2-3 (Ford Motor Company, 1988; Seyed-Hosseini et al., 2006; Sankar and Prabhu, 2001). The higher the RPN of a failure mode, the greater the risk is for

product/system reliability. With respect to the scores of RPNs, the failure modes can be ranked and then proper actions will be preferentially taken on the high-risk failure modes. RPNs should be recalculated after the corrections to see whether the risks have gone down, and to check the efficiency of the corrective action for each failure mode.

Table 2-1 Suggested ratings for the occurrence of a failure mode

Probability of failure	Possible failure rates	Rank
Extremely high: Failure almost inevitable	≥ in 2	10
Very high	1 in 3	9
Repeated failures	1 in 8	8
High	1 in 20	7
Moderately high	1 in 80	6
Moderate	1 in 400	5
Relatively low	1 in 2000	4
Low	1 in 15,000	3
Remote	1 in 150,000	2
Nearly impossible	≤1 in 1,500,000	1

Table 2-2 Suggested ratings for the severity of a failure mode

Effect	Criteria: severity of effect	Rank
Hazardous	Failure is hazardous, and occurs without warning. It suspends operation of the system and/or involves noncompliance with government regulations	10
Serious	Failure involves hazardous outcomes and/or noncompliance with government regulations or standards	9
Extreme	Product is inoperable with loss of primary function. The system is inoperable	8
Major	Product performance is severely affected but functions. The system may not operate	7
Significant	Product performance is degraded. Comfort or convince functions may not operate	6
Moderate	Moderate effect on product performance. The product requires repair	5
Low	Small effect on product performance. The product does not require repair	4
Minor	Minor effect on product or system performance	3
Very minor	Very minor effect on product or system performance	2
None	No effect	1

Table 2-3 Suggested ratings for the detection of a failure mode

Detection	Criteria: likelihood of detection by design control	Rank
Absolute uncertainty	Design control does not detect a potential cause of failure or subsequent failure mode; or there is no design control	10
Very remote	Very remote chance the design control will detect a potential cause of failure or subsequent failure mode	9
Remote	Remote chance the design control will detect a potential cause of failure or subsequent failure mode	8
Very low	Very low chance the design control will detect a potential cause of failure or subsequent failure mode	7
Low	Low chance the design control will detect a potential cause of failure or subsequent failure mode	6
Moderate	Moderate chance the design control will detect a potential cause of failure or subsequent failure mode	5
Moderately high	Moderately high chance the design control will detect a potential cause of failure or subsequent failure mode	4
High	High chance the design control will detect a potential cause of failure or subsequent failure mode	3
Very high	Very high chance the design control will detect a potential cause of failure or subsequent failure mode	2
Almost certain	Design control will almost certainly detect a potential cause of failure or subsequent failure mode	1

2.2.2 FMEA procedure

As outlined by Pillay and Wang (2003), the process for carrying out an FMEA can be divided into several steps as shown in Figure 2-1 (Pillay and Wang, 2003; Sharma et al., 2005; Tay and Lim, 2006b). These steps are briefly explained here:

Step 1: Develop a good understanding of what the system is supposed to do when it is operating properly.

Step 2: Divide the system into sub-systems and/or assemblies in order to localize the search for components.

Step 3: Use blue prints, schematics and flow charts to identify components and relations among components.

Step 4: Develop a complete component list for each assembly.

Step 5: Identify operational and environmental stresses that can affect the system. Consider how these stresses might affect the performance of individual components.

Step 6: Determine failure modes of each component and the effects of failure modes on assemblies, sub-systems, and the entire system.

Step 7: Categorize the hazard level (severity) of each failure mode (several qualitative systems have been developed for this purpose).

Step 8: Estimate the probability. In the absence of solid quantitative statistical information, this can also be done using qualitative estimates.

Step 9: Calculate RPN: the RPN is given as the multiplication of the index representing the probability, severity and detectability.

Step 10: Determine if action needs to be taken depending on the RPN.

Step 11: Develop recommendations to enhance the system performance. These fall into two categories:

- Preventive actions: avoiding a failure situation.
- Compensatory actions: minimizing losses in the event that a failure occurs.

Step 12: Prepare FMEA report by summarizing the analysis in tabular form.

It should be noted that steps 6-9 correspond to risk evaluation in FMEA, which is also the focus of this chapter.

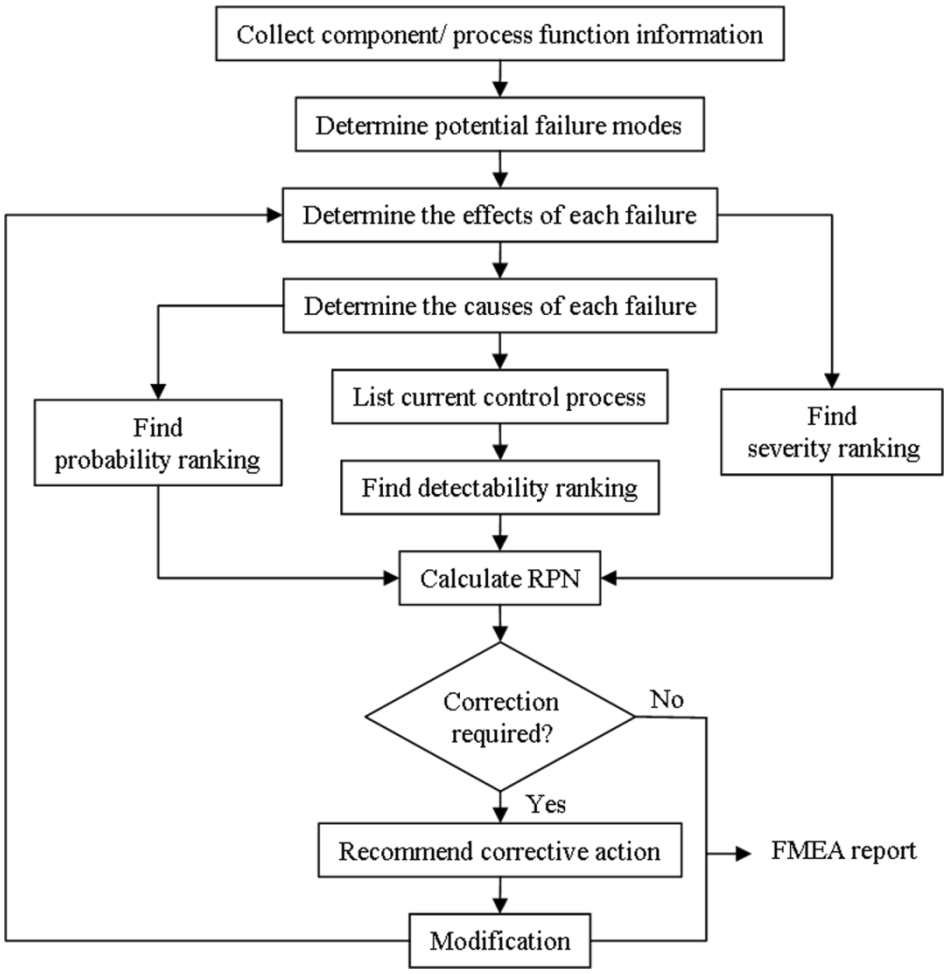

Figure 2-1 Main steps in FMEA

2.2.3 Shortcomings of FMEA

The traditional FMEA has been proven to be one of the most important early preventative management techniques which will prevent failures and errors from occurring and reaching the customer. However, the conventional RPN method has been criticized extensively in the literature for a variety of reasons. The major shortcomings reported in the FMEA literature are summarized in Table 2-4.

Table 2-4 Shortcomings of FMEA frequently reported in the literature.

Shortcomings	Frequency
The relative importance among O, S and D is not taken into consideration.	45
Different combinations of O, S and D may produce exactly the same value of RPN, but their hidden risk implications may be totally different.	33
The three risk factors are difficult to be precisely evaluated.	21
The mathematical formula for calculating RPN is questionable and debatable.	14
The conversion of scores is different for the three risk factors.	13
The RPN cannot be used to measure the effectiveness of corrective actions.	12
RPNs are not continuous with many holes.	10
Interdependencies among various failure modes and effects are not taken into account.	10
The mathematical form adopted for calculating the RPN is strongly sensitive to variations in risk factor evaluations.	9
The RPN elements have many duplicate numbers.	9
The RPN considers only three risk factors mainly in terms of safety.	9

Figure: Number of articles which pointed out the shortcoming of traditional FMEA.

2.3 REVIEW OF THE EXISTING LITERATURE

In this section, we present the results of an extensive literature search on risk evaluation in FMEA for priority ranking of failure modes. The source used for the literature review was academic journal articles published between 1992 and 2012. Publications in languages other than English and non-refereed professional publications, such as textbooks, doctoral dissertations and conference proceedings, were not included. Furthermore, we only included articles that report on a method or technique that specifically aims at overcoming some of the drawbacks of the traditional FMEA. This implies that articles merely describing the FMEA process or applying the traditional FMEA have not been included. Also, articles reporting on methods for automating FMEA implementation were excluded.

Vast majority of risk priority models are found in the literature to improve the criticality analysis process of FMEA. Therefore we propose a framework for classifying the reviewed papers depending upon the failure mode prioritization methods that have been identified. In this review, we divide the methods used in the literature into five main categories, which are multi-criteria decision making (MCDM), mathematical programming (MP), artificial intelligence (AI), hybrid approaches and others. The five categories, each with their own related approaches and references, are reported in Table 2-5. It should be noted that some references, like Gargama and Chaturvedi (2011) and Pillay and Wang (2003), include more than one method to solve the traditional FMEA problems. In this case it can be classified in more than one category in the table. Hence, the sum of the figures for the four categories (80 items) does not match the total number of reviewed papers (75 items). In what follows, we more specifically go into the references and show what has been done.

Table 2-5 Classification of risk evaluation methods in FMEA

Categories	Approaches	Literature	Total number
MCDM (22.50 %)	ME-MCDM	Franceschini and Galetto (2001)	1
	Evidence theory	Chin et al. (2009b), Yang et al. (2011)	2
	AHP/ANP	Braglia (2000), Carmignani (2009), Hu et al. (2009), Zammori and Gabbrielli (2011)	4
	Fuzzy TOPSIS	Braglia et al. (2003b)	1
	Grey theory	Chang et al. (1999), Chang et al. (2001), Sharma et al. (2007d, 2008b), Pillay and Wang (2003), Sharma and Sharma (2012), Geum et al. (2011)	7
	DEMATEL	Seyed-Hosseini et al. (2006)	1
	Intuitionistic fuzzy set ranking technique	Chang et al. (2010)	1
	VIKOR	Liu et al. (2012b)	1
Mathematical programming (8.75%)	Linear programming	Wang et al. (2009b), Gargama and Chaturvedi (2011), Chen and Ko (2009a, b)	4
	DEA /Fuzzy DEA	Garcia et al. (2005), Chang and Sun (2009), Chin et al. (2009a)	3
Artificial intelligence (40.00%)	Rule base system	Sankar and Prabhu (2001)	1

(to be continued)

Table 2-5 Classification of risk evaluation methods in FMEA (continued)

Categories	Approaches	Literature	Total number
	Fuzzy rule base system	Bowles and Peláez (1995), Moss and Woodhouse (1999), Xu et al. (2002), Zafiropoulos and Dialynas (2005), Chin et al. (2008), Nepal et al. (2008), Puente et al. (2002), Pillay and Wang (2003), Yang et al. (2008), Gargama and Chaturvedi (2011), Braglia and Bevilacqua (2000), Braglia et al. (2003a), Tay and Lim (2006a, 2010), Sharma et al. (2005, 2007a, 2007b, 2007c, 2007d, 2008a, 2008b, 2008c), Sharma and Sharma (2010), Sharma and Sharma (2012), Guimarães and Lapa (2004a, b), Guimarães and Lapa (2006, 2007), Guimarães et al. (2011)	29
	Fuzzy ART algorithm	Keskin and Ozkan (2009)	1
	Fuzzy cognitive map	Pelaez and Bowles (1996)	1
Integrated approaches (11.25%)	Fuzzy AHP & Fuzzy rule base system	Abdelgawad and Fayek (2010)	1
	WLSM, MOI & Partial ranking method	Zhang and Chu (2011)	1
	OWGA operator & DEMATEL	Chang (2009)	1
	IFS & DEMATEL	Chang and Cheng (2010)	1
	Fuzzy OWA operator & DEMATEL	Chang and Cheng (2011)	1

(to be continued)

Table 2-5 Classification of risk evaluation methods in FMEA (continued)

Categories	Approaches	Literature	Total number
	2-tuple & OWA operator	Chang and Wen (2010)	1
	FER & Grey theory	Liu et al. (2011)	1
	Fuzzy AHP & fuzzy TOPSIS	Kutlu and Ekmekçioğlu (2012)	1
	ISM, ANP & UPN	Chen (2007)	1
Other approaches (17.50%)	Cost based model	Gilchrist (1993), Ben-Daya and Raouf (1996), von Ahsen (2008), Kmenta and Ishii (2004), Dong (2007), Rhee and Ishii (2003)	6
	Monte Carlo simulation	Bevilacqua et al. (2000)	1
	Minimum cut sets theory	Xiao et al. (2011)	1
	Boolean representation method	Wang et al. (1995)	1
	Digraph and matrix approach	Gandhi and Agrawal (1992)	1
	Kano model	Shahin (2004)	1
	Quality functional deployment	Braglia et al. (2007), Tan (2003)	2
	Probability theory	Sant'Anna (2012)	1

2.3.1 MCDM approaches

Franceschini and Galetto (2001) presented a multi-expert MCDM (ME-MCDM) technique for carrying out the calculation of the risk priority of failures in FMEA, which is able to deal with the information provided by the design team, normally given on qualitative scales, without necessitating an arbitrary and artificial numerical conversion. In their method, risk factors were interpreted as evaluation criteria, while failure modes as the alternatives to be selected. The method considered each decision-making criterion as a fuzzy subset over the set of alternatives to be selected. After the aggregation of evaluations expressed on each criterion for a given alternative, the failure mode were determined with the maximum risk priority code (RPC). If two or more failure modes have the same RPC a more detailed selection was provided to discriminate their relative ranking.

Chin et al. (2009b) proposed an FMEA using the group-based evidential reasoning (ER) approach to capture FMEA team members' diversity opinions and prioritize failure modes under different types of uncertainties such as incomplete assessment, ignorance and intervals. The risk priority model was developed using the group-based ER approach, which includes assessing risk factors using belief structures, synthesizing individual belief structures into group belief structures, aggregating the group belief structures into overall belief structures, converting the overall belief structures into expected risk scores, and ranking the expected risk scores using the minimax regret approach (MRA). Yang et al. (2011) also adopted evidence theory to aggregate the risk evaluation information of multiple experts. However, all individual and interval assessment grades were assumed to be crisp and independent of each other in the proposed model. It did not considerate the occasion in FMEA where an assessment grade may represent a vague concept or standard and there may be no clear cut between the meanings of two adjacent grades.

Braglia (2000) developed a multi-attribute failure mode analysis (MAFMA) based on the analytic hierarchy process (AHP) technique, which views the risk factors (O, S, D, and expected cost) as decision criteria, possible causes of failure as decision alternatives, and the selection of cause of failure as decision goal. The goal, criteria, and alternatives formed a three-level hierarchy, where the pair wise comparison matrix was used to estimate criterion weights and the local priorities of the causes in terms of the expected cost attribute. The conventional scores for O, S and D were normalized as the local priorities of the causes with respect to O, S and D, respectively, and the weight composition technique in the AHP was utilized to synthesize the local priorities into the

global priority, based on which the possible causes of failure were ranked. Making reference to Braglia (2000), Carmignani (2009) presented a priority-cost FMECA (PC-FMECA), which allows for the calculation of a new RPN and the introduction of the concept of profitability taking into consideration the corrective action cost. On the other hand, Hu et al. (2009) presented a green component risk priority number (GC-RPN) to analyze the risks of green components to hazardous substance. Fuzzy AHP was applied to determine the relative weightings of risk factors. Then the GC-RPN was calculated for each one of the components to identify and manage the risks derived from them.

Zammori and Gabbrielli (2011) presented an advanced version of the FMECA, called analytic network process (ANP)/RPN, which enhances the capabilities of the standard FMECA taking into account possible interactions among the principal causes of failure in the criticality assessment. According to the ANP/RPN model, O, S and D were split into sub-criteria and arranged in a hybrid (hierarchy/network) decision structure that, at the lowest level, contains the causes of failure. Starting from this decision-structure, the RPN was computed by making pairwise comparisons. In order to clarify and to make evident the rational of the final results a graphical tool was also presented in the paper.

Braglia et al. (2003b) presented an alternative multi-attribute decision-making approach called fuzzy technique for order preference by similarity to ideal solution (TOPSIS) approach for FMECA, which considers the failure causes as the alternatives to be ranked, the risk factors O, S and D related to a failure mode as criteria. The failures were prioritized based on the measurement of the Euclidean distance of an alternative from an ideal goal. In the proposed fuzzy TOPSIS approach, the three risk factors and their corresponding weights of importance were allowed to be assessed using triangular fuzzy numbers rather than precise crisp numbers, giving a final ranking for failure causes that is easy to interpret.

Chang et al. (1999) used fuzzy method and grey theory for FMEA, where fuzzy linguistic variables were used to evaluate the risk factors O, S and D, and grey relational analysis was applied to determine the risk priority of potential causes. To carry out the grey relational analysis, fuzzy linguistic variables were defuzzified as crisp values, the lowest levels of the three risk factors were defined as a standard series, and the assessment information of the three risk factors for each potential cause was viewed as a comparative series, whose grey relational coefficient and degree of relational with the standard series were computed in terms of the grey theory. Stronger degree of relational means smaller effect of potential cause. Hence, the increasing order of the degrees of

relational represents the risk priority of the potential problems to be improved. In Chang et al. (2001), they also utilized the grey theory for FMEA, but the degrees of relational were computed using the traditional scores 1-10 for the three risk factors rather than fuzzy linguistic variables. Similar applications of fuzzy method and grey theory for prioritization of failure modes in FMEA can also be found in Sharma et al. (2007d, 2008b), Pillay and Wang (2003), and Sharma and Sharma (2012).

Geum et al. (2011) proposed a systematic approach for identifying and evaluating potential failures using a service-specific FMEA and grey relational analysis. Firstly, the service-specific FMEA was provided to reflect the service-specific characteristics, incorporating 3 dimensions and 19 sub-dimensions to represent the service characteristics. As the second step, under this framework of service-specific FMEA, the risk priority of each failure mode was calculated using grey relational analysis. In this paper, grey relational analysis was applied with a two-phase structure: one for calculating the risk score of each dimension: O, S and D, and the other for calculating the final risk priority.

Seyed-Hosseini et al. (2006) proposed a method called decision making trial and evaluation laboratory (DEMATEL) for reprioritization of failure modes in a system FMEA for corrective actions. In the proposed method, the failure information in FMEA was described as a weighted diagraph, where nodes indicate the failure modes or causes of failures and directed connections (edges) indicate the effects failure modes on together. Also, the connection weights indicate the degree or severity of effects of one alternative on another. An indirect relationship was defined as a relationship that could only move in an indirect path between two alternatives and meant that a failure mode could be the cause of other failure mode(s). Alternatives having more effect to another were assumed to have higher priority and called dispatcher and those receiving more influence from another were assumed to have lower priority and called receiver. As a result, the prioritization of alternatives can be determined in terms of the type of relationships and severity of influences of them on another.

Chang et al. (2010) proposed an approach, which utilizes the intuitionistic fuzzy set ranking technique, for reprioritization of failures in a system FMECA. The triangle intuitionistic fuzzy set for each unit fault was defined according to the experts' experiences. Then the influential power of each unit for the system and increasable reliability for the whole system were calculated based on the vague fault tree analysis definition proposed by Chang et al. (2006). The risk of failures was finally ranked according to the degree of influence of each unit fault.

Liu et al. (2012) applied the VIKOR method, which was developed for

multi-criteria optimization for complex systems, to find the compromise priority ranking of failure modes according to the risk factors in FMEA. In the methodology, linguistic variables, expressed in trapezoidal or triangular fuzzy numbers, were used to assess the ratings and weights for the risk factors O, S and D. The extended VIKOR method was used to determine risk priorities of the failure modes that have been identified.

2.3.2 Mathematical programming approaches

Wang et al. (2009b) proposed fuzzy risk priority numbers (FRPNs) for prioritization of failure modes to deal with the problem that it is not be realistic in real applications to determine the risk priorities of failure modes using the RPNs because they require the risk factors of each failure mode to be precisely evaluated. In the paper, the FRPNs were defined as fuzzy weighted geometric means of the fuzzy ratings for O, S and D, and can be computed using alpha-level sets and linear programming models. Finally, the FRPNs were defuzzified using centroid defuzzification method for ranking purpose. In addition, Gargama and Chaturvedi (2011) employed a benchmark adjustment search algorithm, rather than the linear programming approach, to determine the weighted fuzzy geometrical means of alpha level sets to compute the FRPNs. In Chen and Ko (2009a, b), the FRPNs was defined as fuzzy ordered weighted geometric averaging (FOWGA) (Xu and Da, 2003) of the three risk factors.

Garcia et al. (2005) presented a fuzzy data envelopment analysis (DEA) approach for FMEA in which typical risk factors O, S and D were modeled as fuzzy sets, and the fuzzy possibility DEA model introduced by Lertworasirikul et al. (2003) was used for determining the ranking indices among failure modes. Chang and Sun (2009) also applied DEA to enhance the assessment capability of FMEA; however, the inputs (O, S and D) of FMEA were crisp values (from 1 to 10) instead of fuzzy sets in their proposed model.

Chin et al. (2009a) argued that Garcia et al. (2005)'s approach is computationally very complicated and also could not produce a full ranking for the failure modes to be prioritized. Based on these arguments, they proposed a DEA based FMEA which takes into account the relative importance weights of risk factors, but has no need to specify them subjectively. The weights were determined by DEA models and they differed from one failure mode to another. The proposed FMEA measured the maximum and minimum risks of each failure mode. The two risks were then geometrically averaged to reflect the overall risks of the failure modes, based on which the failure modes can be

prioritized. Incomplete and imprecise information on the evaluation of risk factors was also considered in the FMEA.

2.3.3 Artificial intelligence approaches

(1) Rule base system

Sankar and Prabhu (2001) presented a modified approach for prioritization of failures in a system FMEA, which uses the ranks 1 through1000, called risk priority ranks (RPRs), to represent the increasing risk of the 1000 possible severity-occurrence-detection combinations. These 1000 possible combinations were tabulated by an expert in order of increasing risk and can be represented in the form of 'if-then' rules. The failures having a higher rank were given a higher priority than those having a lower rank.

(2) Fuzzy rule base system

Bowles and Peláez (1995) described a fuzzy logic-based approach for prioritizing failures in a system FMECA, which uses linguistic variables to describe O, S, D and the riskiness of failure. The relationships between the riskiness and O, S, D were characterized by a fuzzy if-then rule base which was developed from expert knowledge and expertise. Crisp ratings for O, S and D were fuzzified to match the premise of each possible if-then rule. All the rules that have any truth in their premises were fired to contribute to the fuzzy conclusion set. The fuzzy conclusion was then defuzzified by the weighted mean of maximum method (WMoM) as the ranking value of the risk priority. Moss and Woodhouse (1999) also suggested similar fuzzy logic approach for criticality analysis. Based on the fuzzy logic approaches described above, Xu et al. (2002) developed a fuzzy FMEA assessment expert system for diesel engine's gas turbocharger, Zafiropoulos and Dialynas (2005) presented a fuzzy FMECA assessment system for a power electronic devices such as a switched mode power supply (SMPS), Chin et al. (2008) developed a fuzzy FMEA based product design system called EPDS-1, and Nepal et al. (2008) presented a general FMEA framework for capturing the failures due to system/component interactions at the product architecture (PA) level.

Puente et al. (2002) presented a criticality assessment approach based on qualitative rules which provide a ranking of the risks of potential causes of failure. The method assigned a risk priority class to each cause of failure in an FMEA, depending on the importance given to the three risk factors (O, S and D) related to a failure mode. The structure of the qualitative rules was of the if-then rule type and all the 125 rules in the

FMEA were shown in the form of a three-dimensional graph. In order to optimize the risk-discrimination capabilities of the different causes of failure, a modified version of the technique integrating with fuzzy logic was also proposed by the authors.

Pillay and Wang (2003) proposed a fuzzy rule base approach that does not require a utility function to define the O, S and D considered for the analysis. This was achieved by using information gathered from experts and integrating them in a formal way to reflect a subjective method of ranking risk. The proposed approach needs to set up the membership functions of the three risk factors O, S and D first. Each of the failure modes was then assigned a linguistic variable representing the three risk factors. Using the fuzzy rule base generated, these three variables were integrated to produce linguistic variables representing the risk ranking of all the failure modes.

Yang et al. (2008) presented a fuzzy rule-based Bayesian reasoning (FuRBaR) approach for prioritizing failures in FMEA. The technique was specifically developed to deal with some of the drawbacks concerning the use of conventional fuzzy logic (i.e. rule-based) methods in FMEA. In their approach, subjective belief degrees were assigned to the consequent part of the rules to model the incompleteness encountered in establishing the knowledge base. A Bayesian reasoning mechanism was then used to aggregate all relevant rules for assessing and prioritizing potential failure modes.

Gargama and Chaturvedi (2011) proposed a fuzzy FMEA model for prioritizing failures modes based on the degree of match and fuzzy rule base to overcome some limitations of traditional FMEA. The proposed model employed the belief structure for the assessment of risk factors, and then converted randomness in the assessed information into a convex normalized fuzzy number. The degree of match (DM) was used thereafter to estimate the matching between the assessed information and the fuzzy sets of risk factors. This computed DM then became the inputs to the fuzzy rule-based systems where rules were processed resulting in failure classification with degree of certainty.

The fuzzy RPN mode typically requires a large number of rules, and it is a time-consuming and tedious process in acquiring rules from domain experts in building a fuzzy if-then rule base. Therefore, Braglia and Bevilacqua (2000) proposed the use of AHP for obtaining the rules for a particular fuzzy criticality assessment model. Another characteristic of this model was the use of a triangular approach as ‘crisp’ inputs in fuzzy models to evaluate the different opinions of the maintenance staff. Braglia et al. (2003a) proposed a risk function which permits fuzzy if-then rules to be generated in an automatic way. The risk function links the normalized RPN values obtained by every combination of the mode values of each membership function for each risk factor with

the corresponding linguistic variable sets of final failure risk evaluation, where the normalized RPN were defined as RPN/1000. Tay and Lim (2006a) argued that not all the rules are actually required in the fuzzy RPN model and proposed a guided rules reduction system (GRRS) to provide guidelines to the users which rules are required and which can be eliminated. By employing the GRRS, the users do not need to provide all the rules, but only the important ones when constructing a fuzzy if-then rule base. In Tay and Lim (2010), the authors also used fuzzy rule interpolation and reduction techniques to design weighted fuzzy RPN models and demonstrated the ability of the weighted fuzzy RPN model in failure risk evaluation with a reduced rule base.

Rule reduction method has been applied by many other researches to reduce the size of a fuzzy if-then rule base. In Pillay and Wang (2003), a total of 125 rules were generated when the proposed approach was applied to an ocean going fishing vessel. However, these rules were combined and the total number of rules in the fuzzy rule base was reduced to 35 rules. Sharma et al. (2005) employed 27 fuzzy if-then rules in their fuzzy FMEA for the feeding system in a paper mill, and they reduced a total of 125 fuzzy if-then rules to 30 rules in the applications to other systems of the paper mill, such as pulping system, forming and press systems, washing system, paper machine, and dryer system (Sharma et al., 2007a, b, c, d; Sharma et al., 2008a, b, c; Sharma and Sharma, 2010; Sharma and Sharma, 2012). Similar rule reduction was also applied by Guimarães and Lapa (2004a, b), Guimarães and Lapa (2006, 2007), and Guimarães et al. (2011) in their applications of fuzzy FMEA to an auxiliary feed-water system of a two-loop pressurized water reactor (PWR), a PWR chemical and volume control system (CVCS), a light-water reactors passive system of an independent loop boiling water reactor (BWR), a standard four-loop PWR containment cooling system (CCS), and a digital feedwater control system (DFWCS) of a two-loop PWR.

(3) Fuzzy ART algorithm

Keskin and Özkan (2009) applied the fuzzy adaptive resonance theory (Fuzzy ART) neural networks to evaluate RPN in FMEA. In the study, occurrence, severity, and detection values constituting RPN value were evaluated separately for each input. RPN values composed inputs and each input in its own was presented as O, S and D to the system. In each case, an input composed of three data (O, S and D) was presented to the system by efficient parameter results obtained from application of FMEA on test problems and similar inputs were clustered according to the three parameters. Finally, arithmetic mean of the input values in each obtained failure class was used for prioritization.

(4) Fuzzy cognitive map

Peláez and Bowles (1996) applied fuzzy cognitive maps (FCMs) to model the behavior of a system for FMEA. The FCM was a diagram to represent the causality of failures with failure node and causal relation path. The path was described by using linguistic variables such as 'some, always, often' and relative scales were assigned for each term. Then min-max inference approach was used to evaluate the net causal effect on any given node and weighted mean of maximum method was used as defuzzification technique to extract the resulting confidence values on linguistic variables.

2.3.4 Integrated approaches

Zhang and Chu (2011) described a fuzzy-RPNs-based method for FMEA under uncertainty integrating weighted least square method (WLSM), the method of imprecision (MOI) and partial ranking method. In this study, multi-granularity linguistic term sets were adopted by decision makers in FMEA team for expressing their judgments; a fuzzy WLSM was cited for aggregating these judgments in order to form a consensus group judgment; the MOI incorporated with a nonlinear programming model was used for calculating the fuzzy RPNs based on the group judgment; the partial order method based on fuzzy preference relations was employed for the final ranking of failure modes according to their scores of fuzzy RPNs.

Abdelgawad and Fayek (2010) extended the application of FMEA to risk management in the construction industry using combined fuzzy FMEA and fuzzy AHP. In the study, severity (S) was referred to as impact (I) and had three dimensions: cost impact (CI), time impact (TI), and scope/quality impact (SI). Fuzzy AHP was conducted to aggregate CI, TI, and SI into a single variable entitled aggregated impact (AI). Based on the assigned values for O and D together with the calculated AI, fuzzy FMEA expert system supported by fuzzy if-then rules was used to analyze and prioritize different risk events. Besides, a software system entitled "risk criticality analyzer" (RCA) was developed to implement the proposed framework.

Liu et al. (2011) proposed a risk priority model for FMEA using fuzzy evidential reasoning (FER) approach and grey theory. The FER approach was used to model the diversity and uncertainty of FMEA team members' assessment information, and the grey relational analysis was utilized to determine the risk priorities of failure modes. The core of the proposed FMEA includes assessing risk factors using belief structures, synthesizing individual belief structures into group belief structures, aggregating defuzzified group belief structures into overall belief structure, establishing comparative

series standard series, obtaining the difference between comparative series and standard series, computing grey relational coefficient and degree of relation and ranking the failure modes using the degree of relation.

Chang and Cheng (2011), Chang and Cheng (2010), and Chang (2009) argued that, when each cause of failure is assigned to only one potential failure mode, the risk ranking orders obtained by DEMATEL approach (Seyed-Hosseini et al., 2006) correspond with the ones obtained by the conventional RPN method. In order to solve the problem, Chang (2009) proposed a general RPN method, which combines the ordered weighted geometric averaging (OWGA) operator and the DEMATEL approach for prioritization of failures in a product FMEA; Chang and Cheng (2010) proposed a technique combining the intuitionistic fuzzy set (IFS) and DEMATEL approach to evaluate the risk of failure, and Chang and Cheng (2011) proposed an algorithm, which utilizes fuzzy ordered weighted averaging (OWA) operator and the DEMATEL approach, to evaluate the orderings of risk for failure problems.

Chang and Wen (2010) also proposed a technique, combining 2-tuple and the OWA operator for prioritization of failures in a product design failure mode and effect analysis (DFMEA). The 2-tuple method was used to solve the problem that the conventional RPN method loses some information which the experts provide to have the valued information. The OWA operator was used to overcome the issue that the conventional RPN method does not consider the ordered weight, which may cause biased conclusions. A case of the Color Super Twisted Nematic (CSTN) was adopted to verify the proposed approach, and the result was compared with the conventional RPN and linguistic ordered weighted averaging operator (LOWA) methods.

Kutlu and Ekmekçioğlu (2012) considered a fuzzy approach, allowing experts to use linguistic variables for determining O, S and D, for FMEA by applying fuzzy TOPSIS integrated with fuzzy AHP. Fuzzy AHP was utilized to determine the weight vector of the three risk factors. Then by using the linguistic scores of risk factors for each failure modes, and the weight vector of risk factors, fuzzy TOPSIS was utilized to get the scores of potential failure modes, which were ranked to prioritize the failure modes.

Chen (2007) pointed out that when performing a FMEA, in addition to the measurement of risks, it is important to involve the utility of potential corrective actions. Therefore, they proposed a new approach to determine the priority order of FMEA, which aims to evaluate the structure of hierarchy and interdependence of corrective action by interpretive structural model (ISM), then to calculate the weight of a corrective action through the ANP, then to combine the utility of corrective actions and

make a decision on improvement priority order of FMEA by utility priority number (UPN).

2.4 OBSERVATIONS AND FINDINGS

In this chapter, 75 journal articles, which appeared in the period from 1992 to 2012, tackling the traditional FMEA problems using alternative approaches were collected. The identified approaches, including multi-criteria decision making (MCDM), mathematical programming (MP), artificial intelligence (AI), and their hybrids, have been summarized in Table 2-5 and described in the previous section. Based on these journal articles, some observations are made in the following subsections.

2.4.1 The most popular approach

As found in the previous sections, the category of method most frequently applied to FMEA was found to be AI with 40.0% of all the reviewed papers. MCDM approaches were the next most applied methods with 18 papers or 22.5 %.

According to Table 2-5, the most popular approach is fuzzy rule base system, followed by grey theory, cost-based model, AHP/ANP and linear programming. The wide applicability of fuzzy rule base system is because fuzzy logic and knowledge-based approach possess unique advantages. Compared to the conventional FMEA method, the fuzzy expert system provides the following advantages (Bowles and Peláez, 1995; Xu et al., 2002; Sharma et al., 2005; Braglia et al., 2003a; Tay and Lim, 2006a, 2006b, 2010):

- Ambiguous, qualitative or imprecise information, as well as quantitative data can be used in criticality/risk assessment and they are handled in a consistent manner.
- It permits to combine the occurrence, severity, and detectability of failure modes in a more flexible and realistic manner.
- It allows the failure risk evaluation function to be customized based on the nature of a process or a product.
- The fuzzy knowledge-based system can fully incorporate engineers' knowledge and expertise in the FMEA analysis and substantial cost savings can thus be realized.

2.4.2 Evaluation of approaches

The last objective of this chapter is to critically analyze the approaches, and try to find out some drawbacks. Instead of analyzing every single approach, the main focus of this section is confined to fuzzy rule base system, which is the most popular approach. In essence, any fuzzy expert system is composed of three processes referred to as fuzzification, fuzzy inference, and defuzzification. In fuzzy FMEA, the risk factors, i.e. O, S and D, are fuzzified using appropriate membership functions to determine degree of membership in each input class. The resulting fuzzy inputs are evaluated in fuzzy inference engine, which makes use of well-defined rule base consisting of if-then rules and fuzzy logic operations to determine riskiness level of the failure. The fuzzy conclusion is then defuzzified to get risk priority number.

Although fuzzy inference technique has been widely used to enhance FMEA method, it still suffers from several limitations (Abdelgawad and Fayek, 2010; Tay and Lim, 2006a, 2010; Braglia et al., 2003a; Yang et al., 2008; Braglia et al., 2003b; Zhang and Chu, 2011; Braglia, 2000):

- It is difficult to define appropriate membership functions for the risk factors and risk priority level. Besides, any modification to the linguistic terms, for instance, using seven linguistic terms to define D instead of five, will require re-elicitation of the relevant membership functions.
- It suffers from the combinatorial rule explosion problem, which causes the fuzzy RPN model often has a large number of rules. The larger the number of rules provided by the experts, the better the prediction accuracy of the fuzzy RPN model.
- The construction of a fuzzy if-then rule base is not an easy task which requires experts to make a vast number of judgments and will be highly costly and time-consuming.
- The fuzzy if-then rules with the same consequence but different antecedents are unable to be distinguished from one another. As a result, the failure modes characterized by these fuzzy if-then rules will be unable to be prioritized or ranked.
- It is difficult to deal with complex calculations for producing “precise” risk results without losing too much information in the process of fuzzy inference.
- It is difficult to design appropriate software packages to realize the instant communication between risk input & output, and failure priority ranking.

2.4.3 Other observation

The distribution of the 75 journal articles between 1992 and 2012 is shown in Figure 2-2. It is observed that there is a significant growth in the study of dealing with traditional FMEA problems using various alternative approaches from the first 5 years (1992-1996) to the recent 5 years (2007-2011), 6 vs. 40. The growth could also mark a movement away from the conventional RPN method and towards increased use of MCDM, MP, AI, and their combinations. It is anticipated that the number will keep increasing in the coming years because of the importance of FMEA in improving the reliability of the systems and the increased interest in FMEA by researchers and practitioners.

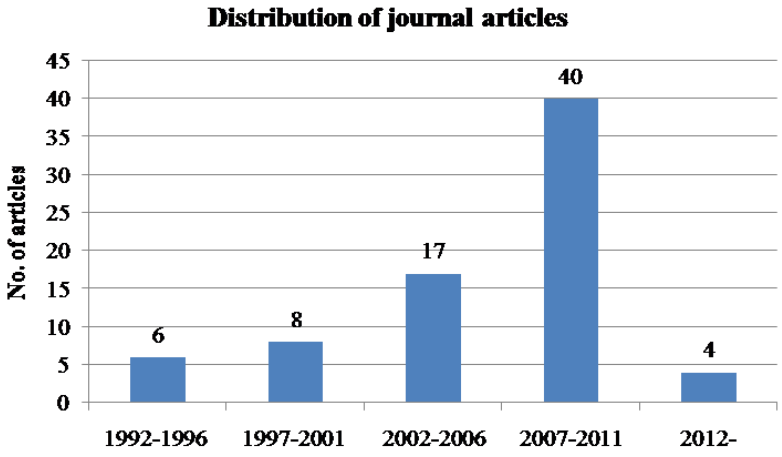

Figure 2-2 Distribution of the reviewed articles

2.5 CHAPTER SUMMARY

Due to the disadvantages of the traditional FMEA and the uncertainty of the risk factors, many risk priority models were proposed for prioritization of failure modes aiming at accurate and robust risk evaluation. This chapter is based on a literature review on the alternative methodologies for risk evaluation in FMEA from 1992 to 2012. To our best knowledge, this is the first comprehensive research reviewing the literature that solve the problems and improve the effectiveness of FMEA. This chapter has set out to provide a framework of the FMEA literature as an aid to the categorization of

research in this field.

First, it was observed that the traditional FMEA based on crisp RPN is not supportive and robust enough in priority ranking of failure modes. Of the shortcomings described in the reviewed literature, the ones that have received significant attention from the literature can be seen as being risk factor and RPN related issues. For instance, the relative importance among the three factors (O, S and D) is not considered; different combinations of O, S and D may produce exactly the same value of RPN; and the three factors are difficult to be precisely estimated.

Second, it was found that numerous alternative approaches were proposed to overcome the shortcoming of the traditional FMEA. They are all capable of addressing some of the problems associated with the traditional RPN method. It can be observed from the surveyed literature that fuzzy rule base system is the most popular method for prioritizing the failure modes, followed by grey theory, cost based model, AHP/ANP and linear programming.

Third, the fuzzy rule-based methods proposed in FMEA literature improve the accuracy of the failure criticality analysis by compromising the easiness and transparency of the conventional method. But some doubts remain concerning an actual applicability of fuzzy rule base system to real-life circumstances, by reason of the difficulties which arise during the fuzzy model design, i.e. in defining the (numerous) rules and membership functions required by this method.

There is a clear need to develop a new fuzzy logic approach for FMEA which can take advantage of the benefits of fuzzy logic without the need of asking experts too much. This is main motivation of next chapter.

CHAPTER 3

FMEA WITH FUZZY VIKOR

3.1 BACKGROUND

As introduced in the last chapter, the traditional FMEA method shows some important weaknesses when it is applied in the real-world cases. Therefore, a number of approaches have been suggested in the literature to enhance the FMEA method, such as technique for ordering preference by similarity to ideal solution (TOPSIS) (Braglia et al., 2003b), analytic hierarchy process (AHP) (Braglia, 2000), grey theory (Chang et al., 2001; Chang et al., 1999), data envelopment analysis (DEA) (Chin et al., 2009a; Garcia et al., 2005), decision making trial and evaluation laboratory (DEMATEL) (Seyed-Hosseini et al., 2006), evidential reasoning approach (Chin et al., 2009b), expert system (Bowles and Peláez, 1995; Braglia et al., 2003a; Puente et al., 2002; Sankar and Prabhu, 2001; Sharma et al., 2005; Tay and Lim, 2006; Wirth et al., 1996; Xu et al., 2002; Yang et al., 2008), hybrid approaches (Chang, 2009; Chang and Cheng, 2011; Chang and Wen, 2010; Gargama and Chaturvedi, 2011; Kutlu and Ekmekçioğlu, 2012; Liu et al., 2011; Pillay and Wang, 2003; Zhang and Chu, 2011) and so forth. Furthermore, it is usually difficult and inaccurate to give a "direct" and correct numerical evaluation of the risk factors, such as occurrence (O), severity (S) and detection (D), in FMEA (Braglia et al., 2003a, 2003b). Much information in FMEA can be expressed in a linguistic way such as *likely*, *important* or *very high* and so on (Xu et al., 2002). Fuzzy logic, or fuzzy set theory (Zadeh, 1965) is a way of addressing vague concepts and provides a means for representing uncertainty in order to handle the vagueness involved in the real situation. Compared to strictly numerical methods, the fuzzy logic approach provides the following advantages (Bowles and Peláez, 1995; Braglia et al., 2003b; Sharma et al., 2005; Xu et al., 2002): First, both quantitative data and, vague or imprecisely defined qualitative information can be used and managed in a consistent manner during FMEA analyses. Second, the risk associated with failure modes can be evaluated directly using the linguistic variables that are employed in making the criticality assessment. Finally, fuzzy logic allows imprecise data to be used, so it enables the treatment of many states of components and system and other fuzzy information included in FMEA.

In other way the VIKOR method was developed recently to solve multi-criteria decision making (MCDM) problems with conflicting and non-commensurable (different units) criteria, assuming that compromising is acceptable for conflict resolution, the decision maker wants a solution that is the closest to the ideal, and the alternatives are evaluated according to all established criteria. This method focuses on ranking and selecting from a set of alternatives in the presence of conflicting criteria, and on proposing compromise solution (one or more) (Opricovic and Tzeng, 2007). Recently, the usage of VIKOR method has been increasing in the literature. For example, Liu et al. (2012) used a method comprising DEMATEL, DEMATEL-based analytic network process (DANP) and VIKOR for improving tourism policy implementation in Taiwan. Wang and Tzeng (2012) utilized a MCDM model combining DEMATEL with ANP and VIKOR methods to identify the interrelated relationships and find the most important factor of brand marketing and Hsu et al. (2012) used a hybrid MCDM model combining DANP with VIKOR to select the best vendor for conducting the recycled material. Wu et al. (2012) applied a combined AHP and VIKOR method to rank universities based on performance evaluation and Kuo and Liang (2012) used an extension VIKOR method for tackling multi-criteria decision making problems with interval-valued fuzzy numbers. Yalcin et al. (2012) used an evaluation approach using both FAHP and VIKOR methods to rank the companies of each sector in the Turkish manufacturing industry. On the other hand, some researchers have employed VIKOR method under fuzzy environment. For instance, Yücenur and Demirel (2012) utilized an extended VIKOR method for insurance company selection under fuzzy environment and also Chou and Cheng (2012) used an integrated fuzzy ANP and fuzzy VIKOR method for evaluating website quality of professional accounting firms. Jeya Girubha and Vinodh (2012) dealt with the selection of materials for instrument panel used in electric car by using fuzzy VIKOR and environmental impact analysis.

The ability to treat patients in the hospital environment in order to provide comprehensive care using general anesthesia is a necessary step to some major operations, such as hip fracture surgery (Messina et al., 2013), endoscopic sinus surgery (Park, et al., 2013) and open abdominal surgery (Severgnini et al., 2013). It allows medical treatment to be rendered under optimal conditions theoretically ensuring ideal outcomes. However, system failures may be occurred during general anesthesia because of the increasing complexity and sophistication of the equipment and related processes. For example, endotracheal intubation is the most basic and important procedure for anesthesiologists in emergency situations as well as for routine situations in the operating room and intensive care unit. Generally, the location of the tube after

endotracheal intubation is verified using physical methods by checking the gradations on the tube, auscultation of both lungs, and observing symmetric expansion of the chest during respiration, and various indicators such as ECG, oxygen saturation, airway pressure, positive end expiratory pressure, and end-tidal carbon dioxide tension. However, even when the tube is properly positioned, a change in the position of the head or neck can cause accidental extubation or deep intubation, leading to a serious situation for the patient. Various monitoring equipment monitors the patient during surgery so when the location of the tube is altered, it is quickly noticed. However, airway damage caused by tube movement during extubation only appears as clinical symptoms after a certain amount of time has lapsed. Hence, the application of FMEA to general anesthesia process plays an important role to minimize the occurrence of failures and improve patient safety.

In this chapter, we applied the VIKOR method, which was developed for multi-criteria optimization for complex systems, to find a compromise priority ranking of failure modes according to the risk factors in FMEA. Linguistic variables, expressed in trapezoidal or triangular fuzzy numbers, are used to assess the ratings and weights for the risk factors O, S and D. The extended VIKOR method is used to determine risk priorities of the failure modes that have been identified. Thus, a new risk priority model based on fuzzy set theory and VIKOR method is proposed to deal with the risk evaluation problems in FMEA. Finally, we applied the new FMEA model to reduce risk of errors during general anesthesia for demonstrating its practicality and usefulness.

The remainder of this chapter is organized as follows. The fuzzy set theory and the VIKOR method are presented in Section 3.2. Section 3.3 extends the classic VIKOR by using the fuzzy set theory. Section 3.4 is about the proposed FMEA model for risk evaluation under fuzzy environment. A numerical example of a general anesthesia process is provided in Section 3.5 to demonstrate the feasibility of the proposed model and some conclusions are made in Section 3.6.

3.2 FUZZY SET THEORY AND VIKOR METHOD

3.2.1 Fuzzy set theory

(1) Fuzzy sets

Fuzzy set theory was developed by Zadeh (1965) to solve fuzzy phenomenon problems existing in the real world, such as uncertain, imprecise, unspecific, and fuzzy situations. This theory has an advantage over the traditional set theory when measuring

the ambiguity of concepts that are associated with human beings' subjective judgments.

Let X be the universe of discourse, $X = \{x_1, x_2, ..., x_n\}$, a fuzzy set $\tilde{A}$ of X is characterized by a membership function $\mu_{\tilde{A}}(x)$, which associates with each element x in X a real number in the interval [0, 1]. The function value $\mu_{\tilde{A}}(x)$ is termed the grade of membership of x in $\tilde{A}$ (Zadeh, 1965). The larger $\mu_{\tilde{A}}(x)$, the stronger the grade of membership for x in $\tilde{A}$.

(2) Fuzzy numbers

A fuzzy set $\tilde{A}$ of the universe of discourse X is convex if and only if for all x_1, x_2 in X, $\mu_{\tilde{A}}(\lambda x_1 + (1-\lambda)x_2) \geq \min(\mu_{\tilde{A}}(x_1), \mu_{\tilde{A}}(x_2))$, where $\lambda \in [0,1]$. A fuzzy set $\tilde{A}$ of the universe of discourse X is called a normal fuzzy set implying that $\exists x_i \in X, \mu_{\tilde{A}}(x_i) = 1$. A fuzzy number is a fuzzy subset in the universe of discourse X whose membership function is both convex and normal (Chen, 2001).

Triangular and trapezoidal fuzzy numbers are the most common used fuzzy numbers both in theory and practice. In fact, triangular fuzzy numbers are special cases of trapezoidal fuzzy numbers. When the two most promising values are the same number, the trapezoidal fuzzy number becomes a triangular fuzzy number. For sake of simplicity and without loss of generality, trapezoidal fuzzy numbers are preferred for representing the linguistic variables in this chapter. A positive trapezoidal fuzzy number $\tilde{A}$ can be denoted as (a_1, a_2, a_3, a_4), shown in Figure 3-1. The membership function $\mu_{\tilde{A}}(x)$ is defined as:

$$\mu_{\tilde{A}}(x) = \begin{cases} 0, & x < a_1, \\ \dfrac{x - a_1}{a_2 - a_1}, & a_1 \leq x \leq a_2, \\ 1, & a_2 \leq x \leq a_3, \\ \dfrac{x - a_4}{a_3 - a_4}, & a_3 \leq x \leq a_4, \\ 0, & x > a_4. \end{cases} \tag{3-1}$$

where $[a_2, a_3]$ is called a mode interval of $\tilde{A}$, and a_1 and a_4 are called lower and upper limits of $\tilde{A}$, respectively.

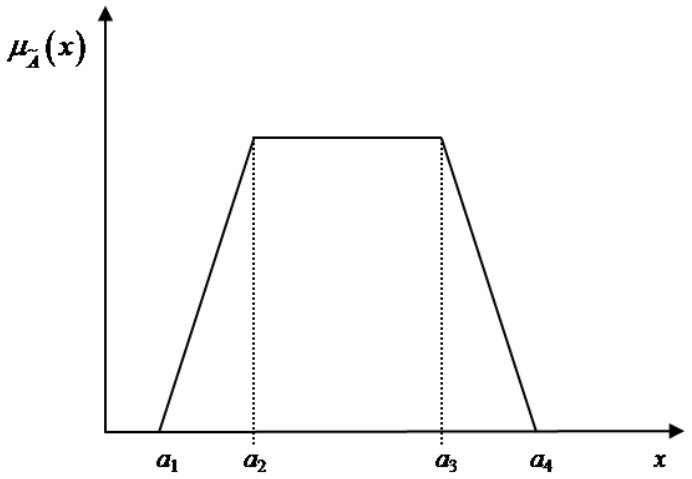

Figure 3-1 Trapezoidal fuzzy number $\tilde{A}$

Give any two positive trapezoidal fuzzy number $\tilde{A} = (a_1, a_2, a_3, a_4,)$, $\tilde{B} = (b_1, b_2, b_3, b_4,)$ and a positive real number *r*, the algebraic operations of the trapezoidal fuzzy numbers can be displayed as follows:

$$\tilde{A} + \tilde{B} = \left[a_1 + b_1, a_2 + b_2, a_3 + b_3, a_4 + b_4\right], \tag{3-2}$$

$$\tilde{A} - \tilde{B} = \left[a_1 - b_4, a_2 - b_3, a_3 - b_2, a_4 - b_1\right], \tag{3-3}$$

$$\tilde{A} \otimes \tilde{B} = \left[a_1 b_1, a_2 b_2, a_3 b_3, a_4 b_4\right], \tag{3-4}$$

$$\tilde{A} \otimes r = \left[a_1 r, a_2 r, a_3 r, a_4 r\right]. \tag{3-5}$$

(3) Linguistic variables

A linguistic variable is a variable whose values are expressed in linguistic terms. The concept of linguistic variable is very useful in dealing with situations which are too complex or too ill-defined to be reasonably described by traditional quantitative expressions (Zadeh, 1975). These linguistic values can also be represented by fuzzy numbers. In this chapter, the importance weights of risk factors and the fuzzy ratings of failure modes with respect to each risk factor are considered as linguistic variables. For example, these linguistic variables can be expressed in positive trapezoidal fuzzy numbers as Tables 3-1 and 3-2. Figures 3-2 and 3-3 show their membership functions for the sake of visualization.

Table 3-1 Linguistic variables for rating the failure modes

Linguistic terms	Fuzzy numbers
Very Low (VL)	(0, 0, 1, 2)
Low (L)	(1, 2, 2, 3)
Medium Low (ML)	(2, 3, 4, 5)
Medium (M)	(4, 5, 5, 6)
Medium High (MH)	(5, 6, 7, 8)
High (H)	(7, 8, 8, 9)
Very High (VH)	(8, 9, 10, 10)

Table 3-2 Linguistic variables for rating the weights of risk factors

Linguistic terms	Fuzzy numbers
Very Low (VL)	(0, 0, 0.1, 0.2)
Low (L)	(0.1, 0.2, 0.2, 0.3)
Medium Low (ML)	(0.2, 0.3, 0.4, 0.5)
Medium (M)	(0.4, 0.5, 0.5, 0.6)
Medium High (MH)	(0.5, 0.6, 0.7, 0.8)
High (H)	(0.7, 0.8, 0.8, 0.9)
Very High (VH)	(0.8, 0.9, 1, 1)

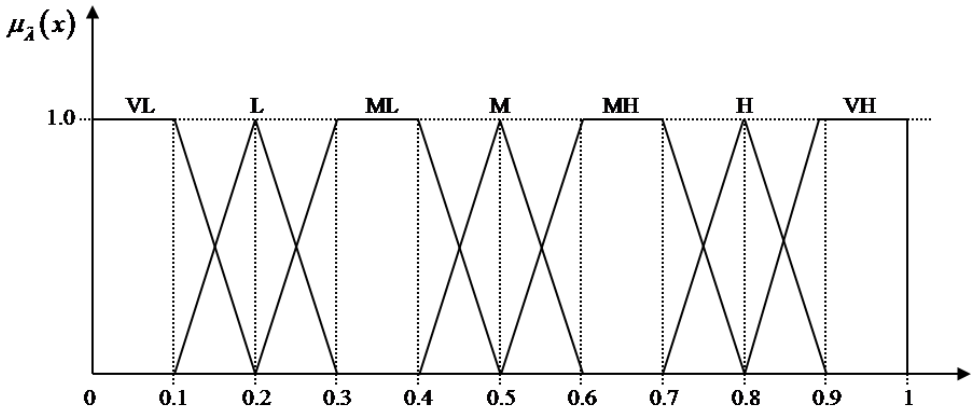

Figure 3-2 Membership functions for rating the weights of risk factors

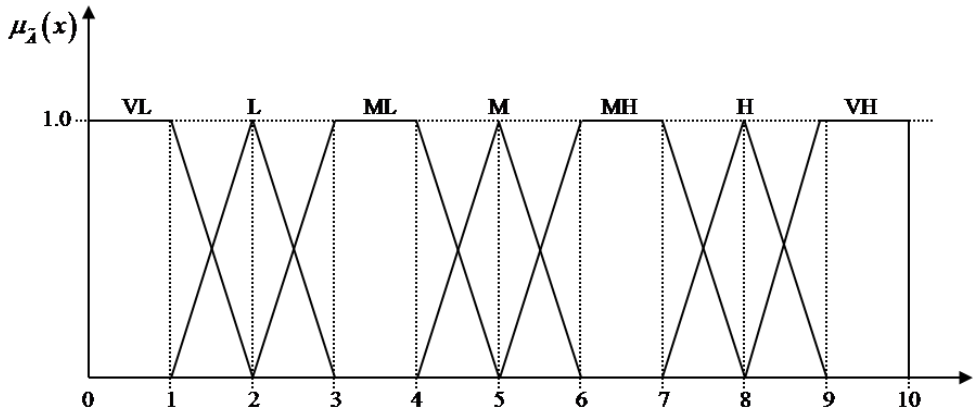

Figure 3-3 Membership functions for rating the failure modes

(4) Defuzzification

An important step in fuzzy modeling and fuzzy multi-criteria decision-making is the defuzzification task which transforms a fuzzy number into a crisp value. Many different techniques for this transformation can be utilized, but the most commonly used defuzzification method is the centroid defuzzification method, also known as the center of gravity (COG) or center of area (COA) defuzzification. The centroid defuzzification method can be expressed by following relation:

$$\bar{x}_0(\tilde{A}) = \frac{\int x\mu_{\tilde{A}}(x)dx}{\int \mu_{\tilde{A}}(x)dx} \tag{3-6}$$

where $\bar{x}_0(\tilde{A})$ is the defuzzified value. For trapezoidal fuzzy number (a_1, a_2, a_3, a_4), the centroid-based defuzzified value turns out to be (Ebrahimnejad et al., 2012):

$$\bar{x}_0(\tilde{A}) = \frac{1}{3}\left[a_1 + a_2 + a_3 + a_4 - \frac{a_4 a_3 - a_1 a_2}{(a_4 + a_3) - (a_1 + a_2)}\right]. \tag{3-7}$$

3.2.2 VIKOR method

The VIKOR method was first proposed by Opricovic and Tzeng (2002) for multi-criteria optimization of complex systems with the Serbian name: VIsekriterijumska optimizacija i KOmpromisno Resenje (means multi-criteria optimization and compromise solution) (Opricovic and Tzeng, 2004). This method focuses on ranking and selecting from a set of alternatives, and determines compromise solutions for a problem with conflicting criteria, which can help the decision makers to

reach a final decision. Here, the compromise solution is a feasible solution which is the closest to the ideal, and a compromise means an agreement established by mutual concessions (Opricovic and Tzeng, 2007).

The VIKOR method introduces the multi-criteria ranking index based on the particular measure of closeness to the ideal solution. This ranking index is an aggregation of all criteria, the relative importance of the criteria, and a balance between total and individual satisfaction. According to Opricovic and Tzeng (2004), the multi-criteria measure for compromise ranking is developed from the L_p-metric utilized as an aggregating function in a compromise programming method. The various m alternatives are denoted as A_1, A_2, ..., A_m. For an alternative A_i, the rating of the jth aspect is denoted by f_{ij}, i.e. f_{ij} is the value of jth criterion function for the alternative A_i; n is the number of criteria. Development of the VIKOR method started with the following form of L_p-metric (Zeleny, 1982):

$$L_{p,i} = \left\{ \sum_{j=1}^{n} \left[\frac{w_j \left(f_j^* - f_{ij} \right)}{f_j^* - f_j^-} \right]^p \right\}^{1/p}, \quad 1 \le p \le \infty, i = 1, 2, ..., m. \tag{3-8}$$

In the VIKOR method, $L_{1,i}$ (as S_i in Eq. (3-11)) and $L_{\infty,i}$ (as R_i in Eq. (3-12)) are used to formulate ranking measurements. The solution gained by min S_i is with a maximum group utility (‘‘majority’’ rule), and the solution gained by min R_i is with a minimum individual regret of the “opponent’’ (Sayadi et al., 2009; Sanayei et al., 2010).

Based on the above concepts, the compromise-ranking algorithm VIKOR consists of the following steps (Opricovic & Tzeng, 2004, 2007):

Step 1: Determine the best f_j^* and the worst f_j^- values of all criterion ratings, j = 1, 2,..., n.

$$f_j^* = \left\{ \begin{matrix} \max\limits_i f_{ij}, \text{ for benefit criteria} \\ \min\limits_i f_{ij}, \text{ for cost criteria} \end{matrix} \right\}, \quad j = 1, 2, ..., m, \tag{3-9}$$

$$f_j^- = \left\{ \begin{matrix} \min\limits_i f_{ij}, \text{ for benefit criteria} \\ \max\limits_i f_{ij}, \text{ for cost criteria} \end{matrix} \right\}, \quad j = 1, 2, ..., m. \tag{3-10}$$

Step 2: Compute the values S_i and R_i , i=1, 2,..., m, by the relations

$$S_i = \sum_{j=1}^{n} \frac{w_j \left(f_j^* - f_{ij} \right)}{f_j^* - f_j^-}, \tag{3-11}$$

$$R_i = \max_j \left[\frac{w_j \left(f_j^* - f_{ij} \right)}{f_j^* - f_j^-} \right]. \tag{3-12}$$

where w_j are the weights of criteria, expressing their relative importance.

Step 3: Compute the values Q_i, i=1, 2,..., m, by the relation

$$Q_i = v \frac{S_i - S^*}{S^- - S^*} + (1-v) \frac{R_i - R^*}{R^- - R^*}, \tag{3-13}$$

where $S^* = \min_i S_i, S^- = \max_i S_i, R^* = \min_i R_i, R^- = \max_i R_i$ and v is introduced as a weight for the strategy of the maximum group utility, whereas 1-v is the weight of the individual regret. Usually, the value of v is taken as 0.5.

Step 4: Rank the alternatives, sorting by the values S, R, and Q in increasing order. The results obtained are three ranking lists.

3.3 FUZZY VIKOR METHOD

In this section, we present a modified VIKOR method to solve group multiple criteria decision making (GMCDM) problems in which the criteria weights and the criteria values take the form of fuzzy linguistic variables.

Suppose that a GMCDM problem has K decision makers $DM_k \left(k = 1, 2, ..., K \right)$, m alternatives $A_i \left(i = 1, 2, ..., m \right)$, and n decision criteria $C_j \left(j = 1, 2, ..., n \right)$. Each alternative is assessed with respect to the n criteria. All the performance ratings assigned to the alternatives with respect to each criterion form a decision matrix denoted by $X = \left(x_{ij} \right)_{m \times n}$. Then, the fuzzy VIKOR method can be summarized as the following steps:

Step 1: Pull the decision makers' opinions to get the aggregated fuzzy weight of criteria, and aggregated fuzzy rating of alternatives and construct a fuzzy decision matrix.

Let the fuzzy rating and importance weight of the kth decision maker be $\tilde{x}_{ij}^k = \left(x_{ij1}^k, x_{ij2}^k, x_{ij3}^k, x_{ij4}^k \right)$ and $\tilde{w}_j^k = \left(w_{j1}^k, w_{j2}^k, w_{j3}^k, w_{j4}^k \right)$; i=1,2,...,m and j = 1,2,...,n, respectively. Hence, the aggregated fuzzy ratings ($\tilde{x}_{ij}$) of alternatives with respect to each criterion can be calculated as:

$$\tilde{x}_{ij} = \left(x_{ij1}, x_{ij2}, x_{ij3}, x_{ij4} \right) \tag{3-14}$$

where

$$x_{ij1} = \min_k x_{ij1}^k, \; x_{ij2} = \frac{1}{K} \sum_{k=1}^{K} x_{ij2}^k, \; x_{ij3} = \frac{1}{K} \sum_{k=1}^{K} x_{ij3}^k, \; x_{ij4} = \max_k x_{ij4}^k.$$

The aggregated fuzzy weights ($\tilde{w}_j$) of each criterion can be calculated as:

$$\tilde{w}_j = \left(w_{j1}, w_{j2}, w_{j3}, w_{j4} \right) \tag{3-15}$$

where

$$w_{j1} = \min_k w_{j1}^k,\ w_{j2} = \frac{1}{K}\sum_{k=1}^{K} w_{j2}^k,\ w_{j3} = \frac{1}{K}\sum_{k=1}^{K} w_{j3}^k,\ w_{j4} = \max_k w_{j4}^k.$$

A GMCDM problem can be concisely expressed in matrix format as follows:

$$\tilde{D} = \begin{bmatrix} \tilde{x}_{11} & \tilde{x}_{12} & \cdots & \tilde{x}_{1n} \\ \tilde{x}_{21} & \tilde{x}_{22} & \cdots & \tilde{x}_{2n} \\ \vdots & \vdots & \cdots & \vdots \\ \tilde{x}_{m1} & \tilde{x}_{m2} & \cdots & \tilde{x}_{mn} \end{bmatrix}, \quad \tilde{W} = \begin{bmatrix} \tilde{w}_1 & \tilde{w}_2 & \cdots & \tilde{w}_n \end{bmatrix},$$

where $\tilde{x}_{ij}$ the rating of alternative A_i with respect to C_j, $\tilde{w}_j$ the importance weight of the jth criterion holds, $\tilde{x}_{ij} = \left(x_{ij1}, x_{ij2}, x_{ij3}, x_{ij4} \right)$ and $\tilde{w}_j = \left(w_{j1}, w_{j2}, w_{j3}, w_{j4} \right)$; i=1,2,...,m and j = 1,2,...,n are linguistic variables can be approximated by positive trapezoidal fuzzy numbers.

Step 2: Defuzzify the fuzzy decision matrix and fuzzy weight of each criterion into crisp values.

The defuzzification of fuzzy decision matrix and fuzzy weight of each criterion is done by using the centroid defuzzification method (Eq. (3-7)).

Step 3: Determine the best f_j^* and the worst f_j^- values of all criterion ratings, j = 1, 2,..., n.

$$f_j^* = \begin{Bmatrix} \max_i x_{ij}, \text{ for benefit criteria} \\ \min_i x_{ij}, \text{ for cost criteria} \end{Bmatrix}, \quad i = 1, 2, ..., m, \tag{3-16}$$

$$f_j^- = \begin{Bmatrix} \min_i x_{ij}, \text{ for benefit criteria} \\ \max_i x_{ij}, \text{ for cost criteria} \end{Bmatrix}, \quad i = 1, 2, ..., m. \tag{3-17}$$

Step 4: Compute the values S_i and R_i , i=1, 2,..., m, by the relations

$$S_i = \sum_{j=1}^{n} \frac{w_j \left(f_j^* - x_{ij} \right)}{f_j^* - f_j^-}, \tag{3-18}$$

$$R_i = \max_j \left(\frac{w_j \left(f_j^* - x_{ij} \right)}{f_j^* - f_j^-} \right). \quad (3\text{-}19)$$

where w_j are the weights of criteria, expressing their relative importance**.**

Step 5: Compute the values Q_i, i=1, 2,..., m, by the relation

$$Q_i = v \frac{S_i - S^*}{S^- - S^*} + (1-v) \frac{R_i - R^*}{R^- - R^*}, \quad (3\text{-}20)$$

where $S^* = \min_i S_i, S^- = \max_i S_i, R^* = \min_i R_i, R^- = \max_i R_i$ and v is introduced as a weight for the strategy of maximum group utility, whereas 1-v is the weight of the individual regret. The value of v is set to 0.5 in this chapter.

Step 6: Rank the alternatives, sorting by the values S, R, and Q in increasing order. The results are three ranking lists.

Step 7: Propose a compromise solution, the alternative ($A^{(1)}$), which is the best ranked by the measure Q (minimum) if the following two conditions are satisfied:

C1. Acceptable advantage: $Q\left(A^{(2)}\right) - Q\left(A^{(1)}\right) \geq DQ$, where $A^{(2)}$ is the alternative with second position in the ranking list by Q; $DQ = 1/(m-1)$.

C2. Acceptable stability in decision making: The alternative $A^{(1)}$ must also be the best ranked by S or/and R. This compromise solution is stable within a decision making process, which could be: "voting by majority rule" (when $v > 0.5$ is needed), or "by consensus" ($v \approx 0.5$), or "with veto" ($v < 0.5$).

If one of the conditions is not satisfied, then a set of compromise solutions is proposed, which consists of:

- Alternatives $A^{(1)}$ and $A^{(2)}$ if only the condition C2 is not satisfied or
- Alternatives $A^{(1)}$, $A^{(2)}$,..., $A^{(M)}$ if the condition C1 is not satisfied; $A^{(M)}$ is determined by the relation $Q\left(A^{(M)}\right) - Q\left(A^{(1)}\right) < DQ$ for maximum M (the positions of these alternatives are "in closeness").

3.4 PROPOSED MODEL

It has been extensively argued that the risk factors, O, S and D, are not easy to be precisely evaluated and the traditional FMEA takes no account of the relative importance of the risk factors (Chin, et al., 2009b; Gargama and Chaturvedi, 2011; Liu, et al., 2011; Tay and Lim, 2010; Wang, et al., 2009; Zhang and Chu, 2011). Fuzzy logic

is the tool for transforming the vagueness of human feeling and recognition and its decision-making ability into a mathematical formula. It also provides meaningful representation of measurement for uncertainties and vague concepts expressed in natural language. So a fuzzy multi-criteria decision making method is preferred instead of crisp decision making methods for overcoming the FMEA procedure (Kutlu and Ekmekçioğlu, 2012).

In this chapter the risk factors and their relative importance weights are considered as linguistic variables. Because linguistic assessments merely approximate the subjective judgment of decision makers, we can consider linear trapezoidal membership functions to be adequate for capturing the vagueness of these linguistic assessments. A systematic approach to apply the fuzzy VIKOR is proposed to determine risk priorities of failure modes under a fuzzy environment in this section. The flowchart in Figure 3-4 shows the proposed approach to rank the failure modes, which are identified in the FMEA process.

To sum up, the risk priorities of failure modes are determined through the following steps:

Step 1: Identify the objectives of the risk assessment process and determine the analysis level.

Step 2: Arrange the FMEA team, list the potential failure modes and describe a finite set of relevant risk factors.

Step 3: Determine the appropriate linguistic variables for risk factors and their relative importance weights.

Step 4: Evaluate the importance of the risk factors and the ratings of failure modes with respect to each risk factor using the linguistic variables.

Step 5: Apply fuzzy VIKOR approach:

- FMEA team members' linguistic evaluations of each failure mode with respect to risk factors and the risk factor weights are aggregated.
- Fuzzy decision matrix and fuzzy weight of each risk factor are defuzzified into crisp values.
- Best f_j^* and worst f_j^- values are determined.
- The values *S*, *R*, and *Q* are calculated, respectively.

Step 6: Determine the ranking order of all failure modes according to the decreasing order of the values *S*, *R*, and *Q*.

Step 7: Analyze the results and develop recommendations to enhance the system performance.

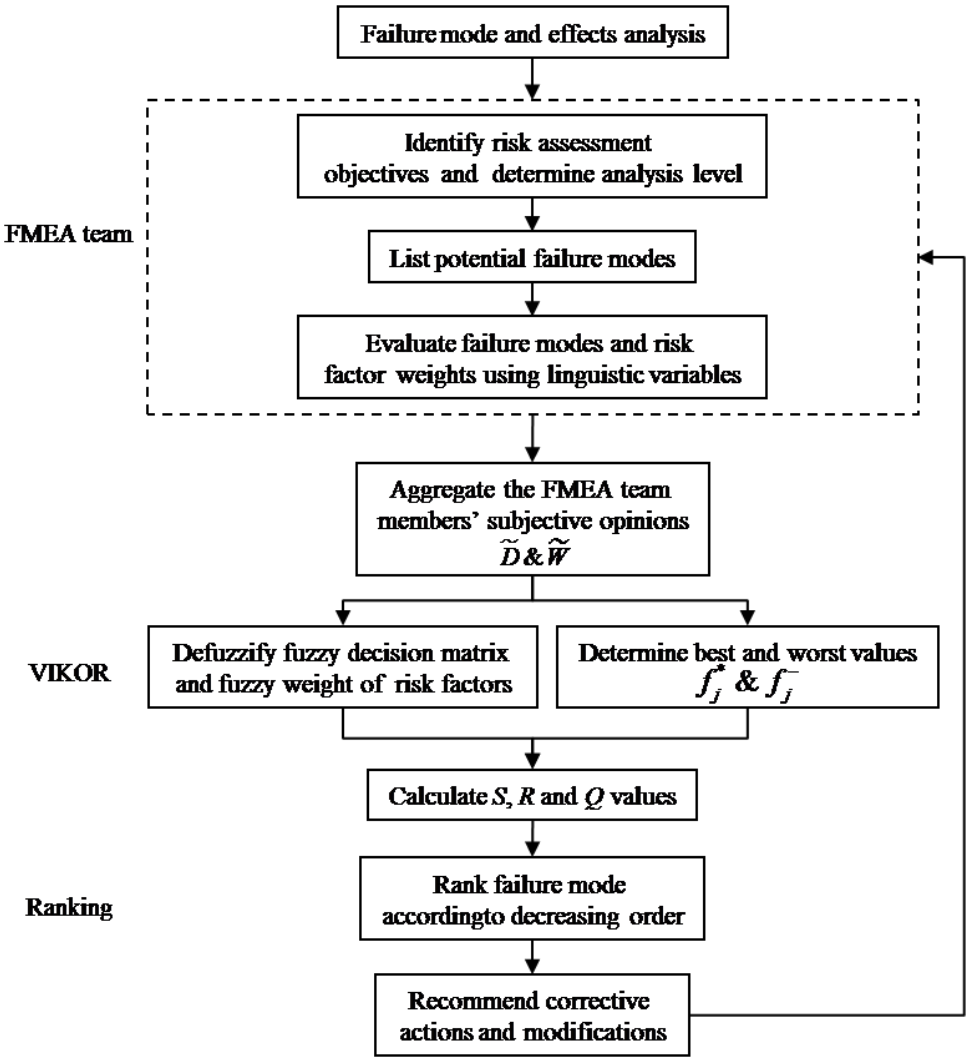

Figure 3-4 Flowchart of the proposed approach

3.5 CASE STUDY

3.5.1 Application to general anesthesia

The proposed model has been applied to the medical risk management of a tertiary care university teaching hospital which aimed at preventing from a medical accident by reducing medical mistakes and non-iatrogenic diseases. The risk analysis was carried out between August and October, 2012, collecting data from doctors, anesthetists and nurses working in the university hospital which had approximately 850 beds. This hospital was acknowledged as a typical hospital in big urban areas. We analyzed the risk of general anesthesia process because it was higher level of risk. The specific topic of the FMEA was determined through conversations between the department of anesthesiology, the department of surgery and the hospital's quality management group. The executive hospital administrative group then formally commissioned the FMEA to be formed.

The steps of the risk assessment process can be described as follows:

Step 1: The hospital desired to identify the most serious failure modes during general anesthesia process to take appropriate measures correspondingly in advance and prevent the incidence of medical errors.

Step 2: A FMEA team of five decision makers, DM1, DM2, DM3, DM4 and DM5, has been formed in the hospital in order to evaluate the failure modes in general anesthesia process. The team was composed of two anesthetists from the anesthesiology department, two chief physicians from the surgery department and one operating room nursing supervisor. During the course of the FMEA, the team gathered information form interviews, meetings and published materials. A traditional FMEA using the RPN ranking system was carried out in the first instance and the overall FMEA of the general anesthesia process is summarized in Table 3-3. All potential failure modes of the general anesthesia process were identified by a session of systematic brainstorming. The FMEA director created a preliminary flow diagram after initial discussions by the FMEA team. The team then expanded and edited the diagram into its final form using their knowledge of the various facets of the process. Given its complexity and length, the original flow diagram was divided into 15 sub-processes. To limit the FMEA to a more manageable scope, the team chose 6 of the 31 potential failure modes for the current investigation that were thought to have the system errors most in need of correction. The proposed new FMEA model was applied to analyze the following failure modes: arterial gas bolt (FM1), go esophageal (FM2), respiratory depression (FM3), not

estimate surgery enough (FM4), blood transfusion wrong (FM5), and visceral injury (FM6).

Step 3: The third step of the proposed model is to define the risk factors, O, S and D using linguistics terms. In this regard, each variable is defined using membership functions that cover the universe of discourse of each variable. To define the linguistic terms for each variable, several interviews were arranged with the FMEA team members. The objective of the first meeting was to introduce our proposed risk priority model and to explore options to implement this technique. Fortunately, the design of the risk matrix, as implemented by the hospital, is based on linguistic definitions for the three risk factors occurrence (O), severity (S) and detection (D). Table 3-4 present seven linguistic terms and their definition for the three risk factors; however, the meaning of each linguistic term can be calibrated to suit a different organization or context. The next step entailed the development of the membership functions for each of the three risk factors. During this process, the FMEA team members were asked to define seven membership functions for each of risk factors according to the definitions shown in Table 3-4. Triangular and trapezoidal membership functions shapes were chosen, since they are intuitive to experts. To elicit the membership functions from the experts, questions similar to this were asked: "What is the degree of membership of 1 in 'Medium Low?'" Figure 3-3 shows the findings from the elicitation process. The membership functions for occurrence, severity and detection are similar as they both cover the same universe of discourse.

Table 3-3 The overall FMEA of the general anesthesia process

No.	Process description	Potential failure modes	Occurrence	Severity	Detection	Risk priority number
1	Check anesthesia apparatus	Force through anesthesia machine self-checking	2	3	4	24
2		Medication errors	3	5	4	60
3		Incomplete anesthesia equipment inspection	3	3	3	27
4		Intraoperative in an appliance without checking	2	3	3	18
5	Patient identify	Unable to confirm the patient	2	6	4	48
6	Confirm anesthetic solution	Not estimate surgery enough	3	6	8	144
7		Not recognized by patient	2	3	2	12
8	Connect the monitor	Joint poor contact	3	5	5	75
9		Surgical instrument disturbance monitoring	2	5	4	40
10	Vein and artery open	Patient infected	4	5	3	60
11		Arterial gas bolt	3	8	6	144
12		Open vein and artery failed	2	6	4	48
13	Oxygen to mask	Oxygen flow in short supply	2	4	3	24
14		Mask conurbation is bad	2	4	2	16
15	Inject anesthetic	Medication errors	2	6	5	60
16		Allergic reaction occur	4	4	2	32

(to be continued)

Table 3-3 The overall FMEA of the general anesthesia process (continued)

No.	Process description	Potential failure modes	Occurrence	Severity	Detection	Risk priority number
17	Trachea cannula	Accidentally injure tooth	3	5	2	30
18		Go esophageal	3	8	4	96
19		Failed intubation	3	6	2	36
20	Check breathing cycle	Patient vital signs is not smooth	2	5	5	50
21	Adjust anesthesia depth degree	Inhibit the patient breathing and circulation	3	9	6	162
22		Visceral injury	4	9	5	180
23		Patient intraoperative awareness	3	2	2	12
24	Balance blood volume	Variations in heart rate	3	4	2	24
25		Insufficient organ blood flow	2	3	3	18
26	Stop using anesthetic	Withdrawal order is wrong	3	5	2	30
27	Inject antagonist agent	Respiratory depression	4	3	2	24
28		Muscle recovery slow	3	3	2	18
29	Extubation	Born door damage	2	5	3	30
30		Aspiration of gastric contents	2	2	3	12
31	Anesthesia post-processing	Blood transfusion wrong	4	8	6	192

Table 3-4 Linguistic definitions of risk factors

Linguistic terms	Occurrence	Severity	Detection
Very Low (VL)	No known occurrence	No injury to the patient or impact on the system	Error will always be detected
Low (L)	Rare failures (yearly)	Very minor to the patient	Very high probability that error will be detected
Medium Low (ML)	Occasional failures (quarterly)	Minor injury to the patient	High probability of detection
Medium (M)	Monthly	Moderate injury to the patient	Moderate chance that error will be detected
Medium High (MH)	Frequent (weekly)	Moderate high injury to the patient	Remote chance of detection only
High (H)	Inevitable and predictable failure	May result in major injury to the patient	Remote or low likelihood of detection
Very High (VH)	Daily or every time	May cause death of the patient	No chance that error will be detected; no mechanism exists

Step 3: Five decision makers used the linguistic weighting variables shown in Figure 3-2 to assess the relative importance of the risk factors. The importance weights of the risk factors determined by these five decision makers are shown in Table 3-5. Also the decision makers used the linguistic rating variables shown in Figure 3-3 to evaluate the ratings of failure modes with respect to each risk factor. The ratings of the six failure modes by the decision makers under the three risk factors are shown in Table 3-6.

Step 4: The linguistic evaluations shown in Tables 3-5 and 3-6 were converted into trapezoidal fuzzy numbers. Then the aggregated weight of risk factors and aggregated fuzzy rating of failure modes were calculated to determine the fuzzy weight of each risk factor and construct the fuzzy decision matrix, as in Table 3-7.

Step 5: The crisp values for decision matrix and weight of each risk factor were computed as shown in Table 3-8.

Step 6: The best and the worst values of all risk factor ratings were determined as follows:

$$f_O^* = 3.800,\ f_S^* = 4.038,\ f_D^* = 2.189,$$
$$f_O^- = 8.044,\ f_S^- = 8.000,\ f_D^- = 5.962.$$

Step 7: The values of *S*, *R* and *Q* were calculated for all failure modes as Table 3-9.

Step 8: The ranking of the failure modes by *S*, *R* and *Q* in decreasing order is shown in Table 3-10.

As can be seen in Table 3-10, the failure mode FM3 is apparently the most serious failure mode according to *Q* values and should be given the top risk priority by the hospital, this will be followed by failure modes FM6, FM2, FM5, FM1, and FM4.

Table 3-5 Importance weight of risk factors from FMEA team members

Risk factors	Team members				
	DM1	DM2	DM3	DM4	DM5
Occurrence	H	H	VH	H	MH
Severity	VH	VH	H	VH	VH
Detection	MH	MH	M	H	MH

Text: assessments of risk factor weights by decision makers; M: Medium; MH: Medium High; H: High; VH: Very High; their definitions have been given in Table 3-1.

Table 3-6 Judgments on failure modes by FMEA team members under risk factors

Risk factors		Occurrence					Severity					Detection				
Team members		DM1	DM2	DM3	DM4	DM5	DM1	DM2	DM3	DM4	DM5	DM1	DM2	DM3	DM4	DM5
Failure	FM 1	M	M	M	MH	M	ML	ML	ML	M	M	M	ML	ML	ML	ML
modes	FM 2	H	MH	H	MH	MH	H	MH	H	H	H	M	M	ML	M	M
	FM 3	VH	MH	VH	VH	VH	MH	MH	MH	MH	MH	MH	M	MH	MH	M
	FM 4	M	M	L	M	M	M	M	ML	M	M	VL	ML	VL	ML	VL
	FM 5	M	ML	M	M	M	M	MH	MH	M	M	L	ML	L	L	L
	FM 6	MH	H	M	MH	M	H	H	H	H	H	L	M	L	L	VL

Text: assessments of failure modes by decision makers; VL: Very Low; L: Low; ML: Medium Low; M: Medium; MH: Medium High; H: High; VH: Very High; their definitions have been given in Table 3-2.

Table 3-7 Aggregated fuzzy rating of failure modes and aggregated fuzzy weight of risk factors

Failure modes	Occurrence	Severity	Detection
FM 1	(4, 5.2, 5.4, 8)	(2, 3.8, 4.4, 6)	(2, 3.4, 4.2, 6)
FM 2	(5, 6.8, 7.4, 9)	(5, 7.6, 7.8, 9)	(2, 4.6, 4.8, 6)
FM 3	(5, 8.4, 9.4, 10)	(5, 6, 7, 8)	(4, 5.6, 6.2, 8)
FM 4	(1, 4.4, 4.4, 6)	(2, 4.6, 4.8, 6)	(0,1.2, 2.2, 5)
FM 5	(2, 4.6, 4.8, 6)	(4, 5.4, 5.8, 8)	(1, 2.2, 2.4, 5)
FM 6	(4, 6, 6.4, 9)	(7, 8, 8, 9)	(0, 2.2, 2.4, 6)
Risk factor weights	(0.5, 0.78, 0.82, 1)	(0.7, 0.88, 0.96, 1)	(0.4, 0.62, 0.68, 0.9)

Table 3-8 Crisp values for decision matrix and weight of each risk factor

Failure modes	Occurrence	Severity	Detection
FM 1	5.756	4.038	3.922
FM 2	7.038	7.244	4.244
FM 3	8.044	6.500	5.962
FM 4	3.800	4.244	2.189
FM 5	4.244	5.855	2.756
FM 6	6.393	8.000	2.759
Risk factor weights	0.768	0.878	0.650

Table 3-9 The values of *S*, *R* and *Q* for all failure modes

	Failure modes					
	FM 1	FM 2	FM 3	FM 4	FM 5	FM 6
S	0.653	1.650	1.964	0.046	0.581	1.445
R	0.354	0.710	0.768	0.046	0.403	0.878
Q	0.343	0.817	0.934	0	0.354	0.865

Table 3-10 The ranking of the failure modes by *S*, *R* and *Q* in decreasing order

	Failure modes					
	FM 1	FM 2	FM 3	FM 4	FM 5	FM 6
By *S*	4	2	1	6	5	3
By *R*	5	3	2	6	4	1
By *Q*	5	3	1	6	4	2

3.5.2 Comparisons and discussion

In order to evaluate the proposed FMEA approach, we used the above case study to analyze some comparable methods, which include the conventional RPN method and the fuzzy TOPSIS method (Chen, 2000; Kutlu and Ekmekçioğlu, 2012). Table 3-11 exhibits the ranking results of all the six failure modes as obtained using these approaches. Based on the results in Table 3-11, the advantages that the proposed method has over other two methods have been identified.

Table 3-11 Ranking comparisons

Failure modes	Proposed method	RPN method	Fuzzy TOPSIS
FM 1	5	4	4
FM 2	3	6	2
FM 3	1	3	1
FM 4	6	4	6
FM 5	4	1	5
FM 6	2	2	3

First, from Table 3-11, we can find that except for FM 6, the risk priority orders of other failure modes obtained by the proposed method are all different from those by the conventional RPN method. The main reasons for these differences can be explained by the shortcomings of traditional FMEA mentioned in Chapter 2. According to the conventional RPN method, FM 5 (RPN=192) is assumed to be most important and has a higher priority than FM 3 (RPN=162). However, the result of our proposed method shows that FM 3 has a higher priority compared with FM 5, which is tally with the actual situation because the former has a higher severity rating and is therefore ranked higher than the latter. In addition, in the case of more than one failure modes having

same RPN values, such as FMs 1 and 4, the proposed method can distinguish them from each other, thus providing more information than that of traditional FMEA does. As expected, the proposed method considering the subjective weights of risk factors achieves a more accurate risk priority ranking, discriminating among the results far more accurate than the conventional RPN method.

Second, there is not much difference between the two sets of risk priority rankings obtained by the proposed method and the fuzzy TOPSIS method. But the most and least serious failure modes are the same, which are FM3 and FM4 respectively. The fuzzy TOPSIS method introduces two "reference" points, but it does not consider the relative importance of the distances from these points. Thus, the ranking produced by the fuzzy TOPSIS method may be biased. For example, based on the fuzzy TOPSIS method, FM 6 is ranked behind FM 2. However, in reality, the former is more important than the later and the results of the proposed method also show that FM 6 has a higher priority in comparison with FM 2. This is also true for FMs 1 and 5. Therefore, a more accurate ranking can be achieved by using the proposed fuzzy VIKOR method to evaluate the risk priority orderings for failure problems.

The analysis of the results produced by the fuzzy VIKOR, the conventional RPN and the fuzzy TOPSIS methods shows that a more accurate, reasonable risk assessment can be achieved by applying a combination of the fuzzy logic and VIKOR method.

3.5.3 Model verification

To verify the validity of the proposed fuzzy FMEA model for risk management, a meeting was conducted with a group of six experts at the participating hospital consisting of two risk analysts, the manager of the quality management office, two chief physicians, and the operating room nursing supervisor. The purpose of the meeting was to present the traditional approach of applying FMEA, its drawbacks, and the proposed risk priority model to address these limitations. Thereafter, the expert group was encouraged to raise questions and provide feedback. The feedback received on the proposed approach from all experts was positive. According to the domain experts, the proposed risk priority model is more suitable for the risk evaluation problem examined and can find the most critical failures effectively. Consequently, the reliability of general anesthesia process can be assured by using the proposed risk assessment methodology.

3.6 CHAPTER SUMMARY

Conventionally, criticality or risk assessment in FMEA is performed by developing a risk priority number, which is determined by finding the multiplication of risk factor scores. Although showing much attractiveness, the crisp RPN method still suffers from some important weaknesses concerning the rationality of the approach. In addition, risk evaluation in FMEA is often influenced by uncertainty in real-life applications, and in such situation fuzzy set theory is an appropriate tool to deal with this kind of problems. In real decision making process, the decision maker in FMEA team may be unable (or unwilling) to express his assessments precisely in numerical values and the evaluations are very often expressed in linguistic variables.

In this chapter an extension of the VIKOR, a recently introduced MCDM method, in fuzzy environment is used to deal with the risk factors and identify the most serious failure modes for corrective actions. The VIKOR method focuses on ranking and selecting from a set of alternatives in the presence of conflicting criteria. It determines a compromise solution that could be accepted by the decision makers. Therefore, a new fuzzy FMEA based on fuzzy set theory and VIKOR method is proposed to deal with the risk evaluation problems in FMEA. The main originalities of this chapter lie in: firstly, this chapter extended the VIKOR method by using fuzzy set theory for decision making under fuzzy environment; secondly, this chapter proposed a new risk priority model based on the fuzzy VIKOR method to solve the problems of the traditional FMEA; and thirdly, the new model were applied to analyze the risk of general anesthesia process to identify the most serious failure and prevent the incidence of medical errors in a hospital.

The provided case study has demonstrated the capability of the proposed FMEA model to manage a criticality analysis in an intuitive and easy manner. Compared with the conventional RPN and its kinds of variants, the proposed FMEA has the following advantages:

- It can be used for systems where safety data is unavailable or unreliable, as it does not force precision.
- The relative importance weights of risk factors are taken into consideration in the process of prioritization of failure modes, which makes the proposed FMEA more realistic, more practical and more flexible.
- There is no need to build any if-then rule base which proves to be highly subjective, costly and time consuming.

- Risk factors and their relative importance weights are evaluated in a linguistic manner rather than in precise numerical values. This enables the experts to express their judgments more realistically and makes the assessment easier to be carried out.
- Failure modes can be fully ranked and well distinguished from each other unless some of them are assessed to be the same.
- More risk factors can be included if necessary. The proposed FMEA is not limited to occurrence, severity, and detection, but applicable to any number of risk factors.

CHAPTER 4

FRAMEWORK FOR DIALYSIS MANAGEMENT

4.1 BACKGROUND

In most countries, various issues have been raised in the health care sector along with changing healthcare landscape. Adverse events in healthcare have been one of the most crucial social problems in the last decades (e.g., Kohn et al., 1999). In addition, healthcare officers and authorities have continuously received strong pressures for cost containment due to increase of expenditure that are attributed to aging population, nature of contemporary diseases and the extensive use of costly biomedical technology (Aletras et al., 2007). Moreover, they have been required to achieve higher efficiency and effectiveness in providing services to their clients (Weir et al., 2009). Consequently, healthcare providers must work long hours (Rogers et al., 2004), which causes them excessive workload and fatigue, and in turn leads to lower motivation and satisfaction with work (Holden et al., 2011). Each of these managerial issues has been typically handled independently by a different section, although they are inter-related. In general, a patient safety issue has been administered in the risk management section while efficiency or productivity of clinical activities has been addressed as operations management. However, these issues are closely inter-related and their contributing factors may often be the same. For instance, it was suggested that continuous long-hour work may, on the one hand, temporarily yield positive effects on higher equipment utilization and reduced personnel expenditure, but on the other it must lead to higher risk of medical errors (Lockley et al., 2007). As another important issue, no or only a few healthcare organizations, particularly small-sized hospitals and clinics – as in the case of most dialysis facilities, have a specific section that formally take charge of managerial issues, but does not simply clerical tasks. Therefore, it is of critical importance to address various management issues from *holistic* points of view, e.g., from daily operations management and patient safety activities to strategic planning and decisions for the hospital's future goals.

Another requirement for hospital management may be its performance by an *evidence-based approach*. As evidence of how well organizational goals are achieved, performance measurement has been emerged in the modern healthcare, using key performance indicators (van der Geer et al., 2009). In this regard, it was suggested that

hospitals in Japan hold fewer data for measuring performance indicators than those in Europe, e.g., Denmark (Traberg et al., 2010), although hospital leaders or department managers may implicitly retain approximate values of important indicators for management purposes. Therefore, Japanese hospitals must particularly take an evidence-based approach to their management.

In other way, health system performance measurement has become increasingly important to policymakers, health care providers and patients as a response to the issues mentioned (El-Jardali et al., 2011; Mainz et al., 2004). Performance measurement provides not only an organization but also a government and health authorities with fundamental information related to healthcare management from operational to strategic level. For one thing, a typical example of its application at the operational level is operations management, which covers measuring and assessment of operations and processes within a hospital. The government can demonstrate accountability for operational and financial performance of the country's or community's health systems by benchmarking specific performance indicators with other countries or local areas. Measurement of performance indicators, for another, allows hospital management to make strategic decisions on hospital goals, and the government to establish future initiatives required for sound and sustainable national health systems. Additionally, data gathering on the performance (e.g., clinical performance, financial performance, and performance in the area of patient satisfaction) of health care providers can also be used by patients and relatives to know how their unit is performing and to decide where to seek care based on its performance.

With such increasing requirements for performance measurement in healthcare, there have been a number of national projects specifically conducted in Western countries, e.g., USA (Institute of Medicine, 2001), UK (Department of Health, 2001), Denmark (Mainz et al., 2004) and Australia (National Health Performance Committee, 2001), as well as several international projects, for instance, initiated by WHO (Veillard et al., 2005) and OECD (Arah et al., 2006). One of the most well-known international projects, the PATH (performance assessment tool of quality improvement in hospitals) project, was launched in 2003, coordinated by the WHO Regional Office for Europe. In this project, a conceptual model was built to measure hospital performance in terms of the following six dimensions (including 51 indicators): clinical effectiveness, safety, patient centeredness, responsive governance, staff orientation and efficiency (Veillard et al., 2005). In the Performance Assessment Framework (PAF) project conducted by the National Health Service (NHS), UK, a total of 48 performance indicators were classified into six dimensions which were different from the PATH framework: health

improvement, fair access, effective delivery of appropriate health care, efficiency, patient/care experience of the NHS, and health outcomes of NHS health care (Chang et al., 2002). As Groene et al. (2008) summarized from ten national and international projects, each had different purposes and therefore used a different assessment model which comprised a different set of dimensions, including various numbers of performance indicators, i.e., 36-308 indicators. For this reason, it was suggested that there has been yet no framework unanimously accepted as a tool for measuring quality and performance of healthcare services (Ondategui-Parra et al., 2004).

Although many quality improvement frameworks have been developed in Western counties, relatively few in Japan (but see Chen et al., 2006). Several studies have shown that differences in national culture make it questionable to transfer results across cultural borders (Helmreich, 2000; Tayeb, 2001). In addition, most of the performance indicator studies were conducted for the purposes of measurement and assessment of quality or performance in a specific hospital or healthcare organization. Indicators used in these studies were applied to general type of hospitals or designed for common use in any type of hospitals. Some of the indicators are also applicable to measurement of dialysis performance, but others do not seem to make sense to use for this purpose. Moreover, no indicator system has yet been developed for measuring and assessing performance in dialysis hospitals or departments. Therefore, it seems required to create an indicator set specifically for the purpose of dialysis management.

With the background mentioned so far, we report a conceptual framework of holistic dialysis management based on performance indicators in this chapter. The main purpose of the framework is to support dialysis facilities in performing evidence-based management from holistic views, including not only safety, quality and efficiency of dialysis services but also other important aspects such as patient and employee satisfaction. The framework was examined and a minimum set of indicators were determined by the use of systematic review of literature and expert rating in a questionnaire survey. We also discuss some prospects of the theoretical framework, in particular for its qualitative improvement, i.e., to obtain a more useful and effective set of performance indicators for dialysis management.

4.2 THEORETICAL FRAMEWORK

In this section, we describe a theoretical framework of holistic dialysis management, i.e., concept and structure of performance indicators required for the

management system. Schematic illustration of the theoretical framework is shown in Figure 4-1. In this study, an indicator is referred to indication of a specific state or phenomenon which can be *quantitatively* measured from its related data. A sub-indicator is defined as indication of the same state or phenomenon as its superordinate indicator, but more specifically expressed based on case or condition such as professional group, disease, procedure and period. As taxonomy of performance indicators in healthcare, the framework involves three primary axes of indicator characterization: (a) stakeholder perspective, (b) assessment property, and (c) whole-part hierarchy. Each of these axes corresponds to an intended application purpose of the framework: (a) performance assessment from a stakeholder's views, (b) translation of measurement results into improvement actions, and (c) creation of various management tools, corresponding to specific organizational levels, ranging from an organization-wide system to a department/specialty based system.

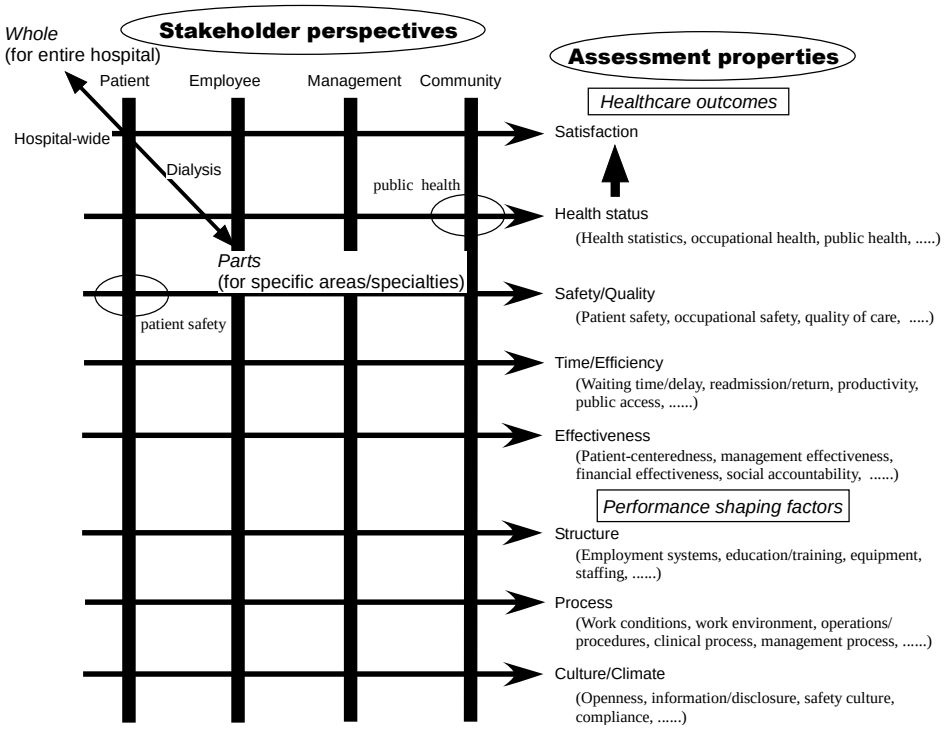

Figure 4-1 Theoretical framework of holistic dialysis management

The whole-part hierarchy is related to the level of decomposition from the entire hospital to a specific department or specialty (Rasmussen, 1986). Along with this axis, indicators for specific cases or specialties can be located. In this study, we focus on applications of the framework to the dialysis services or performance. Therefore, we

used two entries on this axis: indicators commonly applicable to any type of hospitals in one side, and those applicable only to dialysis facilities in the other side. Elements in the theoretical framework are described in Table 4-1.

Various stakeholders such as patients, families/relatives, employees, hospital owners, leaders and managers, policy makers, authorities and industries (e.g., pharmaceutical and medical equipment companies) are involved in modern healthcare. Healthcare performance must be required to capture from various important stakeholders' perspectives. In this study, we selected the following four groups as entries for stakeholder perspectives: patient (including family and relative), employee, management, and community. On the one hand, these stakeholders are active players within the hospital/clinic and as influential external actors, and all of them, on the other, have different interests in health and related issues.

Each of existing healthcare indicator systems introduced several aspects or dimensions that can classify indicators in terms of assessment properties. For example, Donabedian's framework adopted three aspects of outcome, structure and process for healthcare performance assessment (Donabedian, 1966, 1998). The balanced scorecard directed more to its strategic applications rather than merely a performance measurement tool (Kaplan and Norton, 1992, 1996), and therefore it makes performance assessment from three aspects that can drive a firm's changes or innovation, i.e., customer satisfaction, internal processes, and learning and growth, as well as another aspect that directly measures financial performance. In this study, we take a comprehensive approach to classification of assessment properties, adopting a hierarchical structure with a number of managerial characteristics in healthcare.

Regarding assessment properties, the framework involves a total of eight aspects, which are largely classified into two categories: *healthcare outcome* and *performance shaping factor* (PSF). The former category is composed of five aspects related to consequences directly or indirectly derived from healthcare activities and operations within a hospital. The latter category, which was named after a term of human reliability analysis/assessment (HRA) (Hollnagel, 1993), represents conditions or factors that may impact on healthcare outcomes. Thus, indicators in the PSF category may be "formative" elements which lead to changes in the value of latent conditions, while those in the healthcare outcome category may work as "reflective" variables which are the results of the changes in the PSFs. This formative-reflective distinction will help us provide useful implications for improvement actions or initiatives, e.g., a combination of particular indicators can interpret what problems may exist in the hospital or what actions/initiatives should be taken. However, an isolated view of hospital performance

Table 4-1 Structure of performance indicators

Components in framework	Description
Stakeholder perspectives	Classification of measures, indicators and sub-indicators from key healthcare stakeholders that are the most concerned. The following four stakeholders are focused on in this study: patient, employee, management and community.
Assessment properties	Characterization of indicators and sub-indicators from evaluation aspects or management purposes. Assessment properties are composed of eight aspects, i.e., satisfaction; health status; safety/quality; time/efficiency; effectiveness; structure; process; and culture/climate, which are largely divided into two types: (1) healthcare outcomes – that are consequences or goals of healthcare activities, and (2) performance shaping factors (PSFs) – which may impact on healthcare outcomes.
Measures	Each aspect of assessment is composed by multiple measures, which represent characterization of present states as an abstract factor within an organization/department, based on stakeholder perspectives, e.g., "patient safety" measure is fallen into the safety/quality aspect of patient perspective. Each stakeholder perspective generally has one or more measures, but does not necessarily have a measure in every aspect in its nature, depending on the combination of aspects and stakeholder perspectives, e.g., no measure of "structure" aspect for the patient perspective. Each measure includes one or multiple indicators.
Indicators	Indication of specific states or phenomenon which can be quantitatively measured or assessed by use of management data, operational records, questionnaire responses collected by a particular type of healthcare stakeholders, and other methods.
Sub-indicators	Subsets of a particular indicator for specific cases, e.g., based on the professional groups, diseases or period. Indices which applied different calculation procedures, e.g., indices of "mean waiting time for consultation" and "percentage of waiting time longer than two hours" for waiting time, or different labeling for similar concepts, e.g., "injury incidents" and "sentinel events" for adverse events, were registered as different sub-indicators. However, we must determine a single quantitative method (definition) or typical label for each indicator or sub-indicator which will be selected for construct validity in implementing a dialysis management system.

by a single indicator may possibly lead to wrong interpretation of the current states, and therefore we should carefully assess the hospital performance with combination of indicators in both the PSF and the outcome category, considering their inter-relationships for a particular phenomenon or problem.

The five aspects in the healthcare outcome category are satisfaction, health status, safety/quality, time/efficiency and effectiveness. This configuration of the outcome category almost corresponds to six aspects for hospital goals recommended by the Institute of Medicine: safe, effective, patient-centered, timely, efficient and equitable (Institute of Medicine, 2001). As stated by Donabedian that patient satisfaction is an expression of their judgment on all aspects (Donabedian, 1966), performance results of the "satisfaction" aspect may be influenced by all other aspects of healthcare outcomes such as safety/quality and time/efficiency. Therefore, measurement of the satisfaction aspect may be a promising means for capturing overall hospital performance approximately but quickly. For this purpose, we should use indicators not only from patient satisfaction but also from employee (and possibly management) satisfaction.

The PSF category consists of the following three aspects: structure, process and culture/climate. The first two aspects were also included in Donabedian's framework. However, there has been no other framework that explicitly described "PSF" or related dimensions. It is well known that organizational culture – or a related concept, organizational climate as its surface manifestation – is correlated with various indices of organizational performance (Schein, 1992; 2000). Focusing on the safety aspect as an outcome property, for instance, it has been acknowledged that safety performance is affected not only by structural and process factors, but also by employee attitudes to and perceptions of their job roles, safety-related issues, and their organization and management, i.e., *safety culture* (Itoh et al., 2012). Therefore, it seems natural to include a culture/climate aspect in the PSF category. For these reasons, the indicator system proposed in this chapter can be considered as a framework extended from the Donabedian approach in that healthcare performance can be measured and assessed *more comprehensively* by broad factors contributing to healthcare outcomes.

As mentioned previously, each indicator (and its sub-indicators) is characterized as a combination of *stakeholder perspective* and *assessment property.* An intersection of a particular aspect of assessment and a stakeholder type represents a *measure* or dimension, which refers to an issue related to the aspect from the stakeholder's view as an abstract factor (see Figure 4-1). Each intersection typically contains one or a few measures, but does not necessarily have one, depending on its combination. For instance, regarding the time/efficiency aspect, two dimensions possibly come from the patient

perspective, i.e., waiting/delay and cancelation, and more from management perspective, e.g., readmission/return, organizational efficiency, equipment efficiency and staff efficiency, whereas no measure may be attributed to this aspect from the employee perspective because of no or little concern of hospital staff with these or related issues. One or more indicators and sub-indicators are typically assigned to each measure. For instance, possible indicators on the patient safety measure (from the safety/quality aspect, and the patient perspective) may be incident/near-misses, centesis errors and shunt infections.

4.3 STUDY METHODS

According to the theoretical framework mentioned in the last section, a set of performance indicators were selected by the use of two famous data sources as well as a questionnaire survey to dialysis experts. In the selection process of indicators, we tried to ascertain face validity, content validity and construct validity of indicators as well as their usefulness and relevance to the given context, i.e., application to holistic management for dialysis hospitals/clinics/departments in Japan. As Johantgen et al. (1998) reported that no study has performed well-defined, reliability and validity tests of performance indicators; it seems of great difficulty to undertake formal tests of validities for indicators. Therefore, in this chapter, validity tests were performed primarily by expert judgment through interviews with dialysis professionals. For face validity, we examined whether the indicator set is acceptable by its potential use for dialysis management. Content validity of the indicators was checked whether all the measures or dimensions are covered by selected indicators properly. We confirmed construct validity by examination of the indicators in terms of internal reliability, i.e., inter-related but not too similar each other, in each measure.

4.3.1 Systematic review

We searched for articles in PubMed and PubMed Central (PMC) published between November 1965 and June 2012. The following six sets of keywords were used for searching in all fields: (1) “performance indicator(s)”, (2) “safety indicator(s)”, (3) “quality indicator(s)”, (4) “management indicator(s)”, (5) “operations management” AND “indicator(s)”, and (6) “performance measurement” AND “indicator(s)”. Only

peer-reviewed journal articles written in English were included for review. Articles in reference lists of selected papers as "relevant" to this study – for which we use the term "relevant articles" – were also reviewed. The screening process was composed of the following steps: removing duplicated articles, title screening, abstract screening, and full-text screening (as is shown in Figure 4-2).

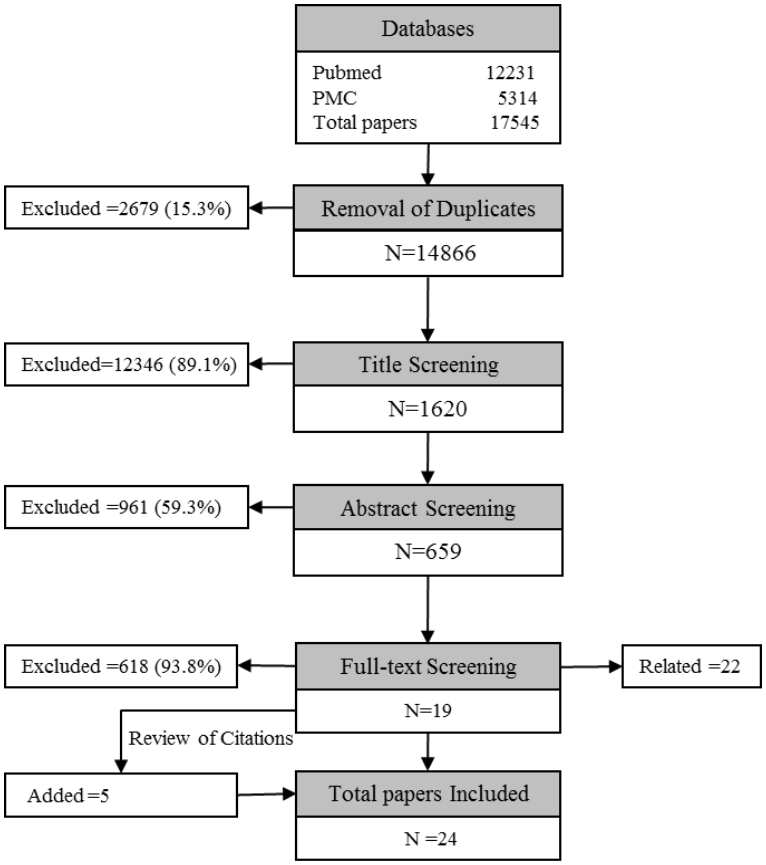

Figure 4-2 Flowchart of article selection process

The following selection criteria were used to elicit the relevant articles:

- *Clear description of indicators*: an article included clear description of indicators.
- *Application to work setting*: indicators were applied to actual work setting in healthcare.
- *Multiple measures*: an article included indicators from not only one but multiple measures.
- *Measurable indicators*: indicators were not only defined but also quantitatively measured or assessed.
- *Management purpose*: indicators were used for the purpose of management of a hospital or departments.

An article that fulfilled all these five conditions was determined as relevant to our study. We summarized each relevant article in terms of essential information for future use of indicator selection, as shown in Table 4-2. Example summary descriptions of a relevant article are provided in Appendix A, taking Basu et al. (2010) as a case. An example of mapping of indicators to the theoretical framework can be seen in Appendix B for the same case.

Table 4-2 Elicited information from each relevant article

Information	Description/categories
Source of article	Authors, title, journal, vol., no., pages and year
Outline of article	Objectives, main conclusions, strengths and weaknesses, etc.
Place and period of study	City, country and investigation period
Setting applied	Hospital type, specific department or specialty, etc.
Organizational level applied	Entire hospital, all departments, some /part of departments/work units, etc.
Indicators and sub-indicators	Indicator labels, definitions, and calculation
Data collection method	Operational/achievement record, observation, questionnaire, interview, expert rating/judgment, etc.
Purposes of indicators	Just recording, statistics generation, intervention, operational performance assessment, strategic goal planning, tactical planning, operational status monitoring/tracking, etc.
Validity/reliability of indicators	Internal reliability, test-retest reliability, inert-rater reliability, external reliability (criterion validity), content validity, etc.
Implementation as tool/instrument	Whether indicators were implemented as a tool or instrument for ease of use to other organizations

4.3.2 Questionnaire to dialysis experts

A major purpose of the questionnaire-based survey was to select a limited number of indicators, which are useful for management of dialysis facilities in the Japanese context, from viewpoints of dialysis experts, including both hospital leaders and employees. The questionnaire comprised a main part of "usefulness" rating and an extra part of open-ended questions about "other" indicators for dialysis management. In the main part, respondents were asked to give their "usefulness" rating for each indicator on a three category scale, including two extreme response options. Expression of one extreme (positive) option was "the indicator is of *critical* importance for dialysis management". The other extreme (negative) was instructed in the following statement: "the indicator does *not make sense* for dialysis management. It is just waste of time to collect the data". Therefore, the intermediate response option was *not* neutral, but ranging broadly from "slightly disagree" (negative) to "slightly agree" (positive) in the sense of a Likert-type scale (Likert, 1932). The intention of using this scale was to select only a limited number of indicators to which a majority of dialysis experts acknowledged extremely high value, but no or very few exhibited strong objection.

A total of 66 indicators (cf. Appendix C) were offered in the questionnaire. These indicators were selected based on the results of the systematic review and interviews with healthcare professionals. No indicator from the community perspective was included in the questionnaire since most "community" indicators were labeled identical or similar to those from the patient or management perspective, e.g., adverse event, waiting time and mortality rate, and were calculated by aggregated data from hospitals within a local area.

As mentioned in the introduction, there has been *no* performance indicator study which specifically targeted at the dialysis hospital or department. Therefore, dialysis-specific indicator was neither included in the indicator set obtained by the systematic review (cf. Appendix D) nor in the questionnaire. Besides the closed-ended items of the offered indicators, respondents were invited to indicate "other" important indicators that were specific to dialysis management as their answers to open-ended questions. One type of open-ended questions asked each respondent to indicate "other" important indicators from each healthcare stakeholder perspective. The other type was a question related to a specific issue to dialysis management. All of these questions are shown in Table 4-3.

We collected a total of 19 responses from dialysis experts, all of who were Japanese citizens working in dialysis hospitals/clinics, including a medical professor

who was responsible for dialysis department of a university hospital, two hospital leaders and two deputy hospital leaders who were physicians, three physicians, six nurses and five clinical engineers.

Table 4-3 Open-ended questions specific to dialysis management

Issues	Questions (Please indicate … …, if any)
Nosocomial infection	specific germs or events of nosocomial infection to which the dialysis facility should pay attention
Dialysis operations/ procedures	specific operations or procedures which should be recorded their frequencies in the dialysis facility
Indicator like "survival/revival"	a possible "dialysis-specific" indicator which has the same or similar meaning to "survival/revival" in the general hospital
Indicator like "length of stay"	a possible "dialysis-specific" indicator which has the same or similar meaning to the "length of stay" in the general hospital
Indicator like "equipment utilization"	a possible "dialysis-specific" indicator which has the same or similar meaning to the "equipment utilization" in the general hospital
Devices individually book-kept	specific devices or instruments which should be book-kept individually in the dialysis facility
Patient transfer	specific cases of patient transfer to which the dialysis facility should especially pay attention

4.4 RESULTS

4.4.1 Performance indicators frequently used

Among the 24 relevant articles, more than a half of healthcare indicator studies (15 articles) were conducted in Western countries, i.e., USA (Coyne, 1982; Curtright et al., 2000; Griffith et al., 2002; Orton et al., 2003; Radford et al., 2007; Shukla et al. 1997), New Zealand (Gauld et al., 2011) and Europe (Chang et al., 2002; Basu et al., 2010; Forster et al., 1990; Rath et al., 1999; Traberg and Jacobsen, 2013a, 2013b; Verzola et al., 2009), including a cross-cultural study performed inside of Western countries (Kazandjian et al., 2003), whereas seven studies, one of which was a cross-national project between Japan and China (Chen et al., 2006), were conducted in Asia (including Near-East countries) (El-Jardali et al., 2011; Chiu et al., 2007; Chu et al., 2009; Gross,

2004; Rabbani et al., 2011) and Africa (van Eygen et al., 2007). The other studies compared hospital performance between countries exceeding a cultural border, including the US, Europe and Asia (de Korne et al., 2010; Kazandjian et al., 1996). Besides these studies, as mentioned in the Introduction section, there have been a number of international and national projects on performance indicators – we had detected 31 projects by the use of a different search method – mostly in Western countries. However, most of these projects were published in non-peer-reviewed articles, e.g., government's or institution's reports and websites, which rarely included application results of their indicators although they were actually measured in healthcare settings. Primary objectives of these projects were generation of nation-wide statistics and cross-national comparisons on healthcare performance for accountability. In contrast, the aim of our systematic review was to elicited "performance indicator" studies that tried to conduct with management purposes. For these reasons, only a few articles of these projects fulfilled the selection criteria of our systematic review.

As results of the systematic review, we identified a total of 761 indicators and sub-indicators – including those with overlapped and similar labels – from the 24 relevant articles. Grouping indicators having the same or very similar concept into one, all the indicators and sub-indicators extracted from these studies are provided in Appendix D. Frequency of use for indicators (and sub-indicators) is shown for each combination of the assessment property and the stakeholder perspective in Table 4-4. As can be seen in this table, nearly a half of indicators elicited from the relevant articles were attributed measures from the management perspective. In particular, "management" indicators from the time/efficiency and the health status aspects occupied a large part. Followed by the management perspective, indicators from the patient perspective frequently appeared in existing indicator systems. Most of these indicators were characterized either as patient satisfaction, patient safety or efficiency-related measures. In contrast, only a small proportion of indicators derived from the employee and the community perspective. From these results, we would suggest that measures (and therefore indicators) from the employee perspective should be more frequently applied to hospital management, since great contributions of professional staff are appreciated as key players and increasing attention to human factors issues has been paid in healthcare (e.g. Kohn et al., 1999).

A majority of indicators elicited from the relevant articles (76%) were fallen into measures related to the healthcare outcomes. In contrast, only less than a quarter of indicators (24%) came from PSF measures. Although it has been well acknowledged that organizational problems frequently become *latent causal factors* that contribute to

the occurrence of human error made by frontline personnel (Reason, 1997), percent usage of structure- (2%), process- (5%) and culture-related measures (1%) were rather small even from the management perspective. Therefore, we would suggest that percentage of application of indicators on PSF measures should be increased for health system assessment and quality improvement.

Individual indicators used in relatively frequent in the relevant papers are shown in Table 4-5. The most frequently used indicator was length of stay, which appeared in almost half of the former studies. There was a slight variation about percent usage of indicators, depending on the stakeholder perspectives. There were almost as many "frequent-to-use" indicators from the management perspective as from the patient perspective. Taking a decision criterion of "frequently used" indicators as appearing in five or more relevant articles, seven, three, eight and no indicators were elicited from the patient, employee, management and the community perspective, respectively. Only a single indicator was selected on any specific measure from the patient and employee perspective except for the patient safety – which hospital experts themselves acknowledged one of the most crucial problems. In contrast, multiple indicators were comprised of each measure from the management perspective, e.g., length of stay and bed occupancy on the organizational efficiency measure; and unscheduled readmission and unexpected return on the readmission/return measure. This may indicate that more indicators should be included in each measure from the patient and the employee perspective in a set of "key" performance indicators, which will be discussed in the Discussion section, from the viewpoint of construct validity. It may also be suggested that indicators on other measures from the management perspective can be added in the indicator set for improving content validity.

Table 4-4 Number and proportion of indicators appearing in former studies

Perspectives	Healthcare outcomes					Performance shaping factors			Total
	Satisfaction	Health status	Safety/ Quality	Time/ Efficiency	Effectiveness	Structure	Process	Culture/ Climate	
Patient	34	0	32	26	4	0	3	10	109
	7.9%	0.0%	7.5%	6.1%	0.9%	0.0%	0.7%	2.3%	25.5%
Employee	13	10	5	0	0	21	17	0	66
	3.0%	2.3%	1.2%	0.0%	0.0%	4.9%	4.0%	0.0%	15.4%
Management	1	51	3	73	30	10	21	3	192
	0.2%	11.9%	0.7%	17.1%	7.0%	2.3%	4.9%	0.7%	44.9%
Community	0	19	0	5	19	16	2	0	61
	0.0%	4.4%	0.0%	1.2%	4.4%	3.7%	0.5%	0.0%	14.2%
Total	48	80	40	104	53	47	43	13	428
	11.2%	18.7%	9.4%	24.3%	12.4%	11.0%	10.0%	3.0%	100.0%

Upper row: the number of indicators; Lower row: percentage of indicators.

Table 4-5 Indicators frequently used in former studies.

Perspectives	Measures	Indicators	Frequency
Patient	Patient satisfaction	Overall satisfaction	7
		Satisfaction with specific professionals	4
		Satisfaction with specific care/service	3
	Patient complaint	Overall complaints	8
	Patient safety	Incident/Errors (specific cases)	8
		Accident/adverse event	7
		Nosocomial infection	6
		Nosocomial infection (specific cases)	5
		Incident/Errors	3
	Waiting/Delay	Waiting time for specific cases	5
		Waiting time in emergency room	4
		Waiting time for treatment/consultation	3
	Information	Information by specific staff groups	4
		Received written information	3
	Cancelation	Cancelled operations	4
Employee	Employee satisfaction	Overall satisfaction	6
	Occupational health	Sickness leave	5
	Occupational safety	Errors/incidents	4
	Work conditions	Staff turnover	6
	Employee competence	Research opportunities (academic papers written)	3
Management	Health statistics	Mortality/Death	7
		Mortality/Death (specific disease)	7
		Number of operations/procedures (specific cases)	6
		Survival/Revival	3
	Readmission/return	Unscheduled readmission	6
		Unexpected return (to specific site)	5
		Unscheduled readmission (specific cases)	4
	Organizational efficiency	Length of stay	11
		Bed occupancy	6
	Financial effectiveness	Financial measures	7
		Cost effectiveness (cost per case)	4
		Cost/expenditure	3
	Staffing	Full-time equivalents	3
		Full-time staff	3
	Management process	Patient transfer	3
Community	Waiting/Delay	Waiting time	3
	Public access	GP availability	3

4.4.2 Expert ratings of performance indicators

Results of expert rating are summarized in Tables 4-6 and 4-7 in terms of the number of positive and negative responses to the question about “usefulness” of each indicator for dialysis management, respectively. These tables included only indicators that were rated either positive (useful) or negative (meaningless) by many respondents. As can be seen in Table 4-6, several indicators from the patient perspective were rated negatively by approximately a half of respondents. These “meaningless” indicators were related either to operation (surgery), examination, admission or emergency room. All of these activities (and a workplace – Emergency Room) were ones much less frequently performed (or used) in dialysis facilities than general hospitals. As another view of these “meaningless” indicators, all of them stemmed from two measures that inter-related each other: waiting time and cancelation. These results may suggest that indicators related to waiting time and cancellation are not useful for dialysis context in Japan – probably because of different health system, although these indicators have been commonly used in Western countries.

Except for the indicators related to waiting time and cancellation, there was no indicator to which a majority of dialysis experts, e.g., at least more than a half of respondents, rated “meaningless” for hospital/department management. Therefore, the “meaningless” criterion should be more overestimated, i.e., taken four negative responses as a threshold, in Table 4-6. Even for the indicators that met this overestimated criterion, a few or more respondents expressed opposite (positive) perception, i.e., viewed as “useful” indicators, except for the number of emergency patients per doctor. Moreover, the number of negative respondents was even smaller than or equal to that of positive respondents for some indicators, e.g., scientific projects and resident physicians. This relatively positive trend may imply rating bias specific to Japanese respondents that they are likely to respond more sensitively to a “positive” item rather than a “negative” item, similar to another famous response bias that Japanese are likely to respond neutral and are reluctant to rate extremes. Assuming this trend, we should interpret the rated score with slightly more weight on the negative side.

Two “meaningless” indictors from the employee perspective, i.e., resident physicians and scientific projects, were categorized to the employee competence measure. Regarding indicators from the management perspective, most indicators termed admission (and readmission), inpatient or emergency in the questionnaire were rated “meaningless” by relatively many – to be overestimated negative responses –

Table 4-6 Indicators rated negatively by many dialysis experts

Indicators	No. rated		Indicators	No. rated	
	positive	negative		positive	negative
(1) Patient perspective					
Cancelled operations	1	10	Cancelled examinations	1	9
Waiting time for operation	3	9	Waiting time for admission	2	9
Waiting time in Emergency Room	1	9	Outpatient waiting times	4	7
(2) Employee perspective					
Resident physicians	5	5	Scientific projects	5	4
(3) Management perspective					
Number of emergency patients per doctor	0	7	Admissions per bed	2	6
Autopsy rate	2	7	Number of inpatients per day	4	6
Inpatient admission	3	5	Unscheduled readmission	3	5
Unscheduled returns to ICU/OR	5	5	Admission from unexpected return	4	4
Day case	2	6	Emergency admission	4	4

Note: The negative responses were slightly overestimated for the “meaningless” criterion because of the positive trend of respondents.

Table 4-7 Indicators rated positively by many dialysis experts

Indicators	No. rated		Indicators	No. rated	
	positive	negative		positive	negative
(1) Patient perspective					
Overall satisfaction	16	0	Satisfaction with treatment	13	0
Satisfaction with nurses	14	0	Satisfaction with physicians	13	0
Satisfaction with instrument clean	13	0	Satisfaction with care/service	12	0
Patient complaint	12	0	Accident/adverse event	14	1
Incident/Errors	15	0	Nosocomial infection	12	1
Received written information	10	0			
(2) Employee perspective					
Overall employee satisfaction	13	0	Satisfaction with organization	13	0
Satisfaction with job	12	0	Satisfaction with hospital facilities	13	0
Satisfaction with staff, workplace	12	0	Satisfaction with IT	8	1
Needle stick injury	11	0	Overtime	13	0
Staff turnover	10	0	Sickness leave	11	0
Number of staff per bed	13	2	Length of service	11	0
Occupied position	11	0	Ave. experience at current dept.	9	1
Education possibilities	12	3	Specialists (based on specialty)	11	2
(3) Management perspective					
Mortality/Death	13	1	Morbidity	8	1
Survival/Revival	8	2	Number of patients per day	13	0
Number of outpatients per day	14	1	No. of operations/procedures	9	1
Full-time staff	11	1	Equipment utilization (specific dev.)	8	1
Full-time equivalents	10	1	Cost/expenditure	9	1
Cost effectiveness	9	1			

respondents. Regarding indicators from the management perspective, most indicators termed admission (and readmission), inpatient or emergency in the questionnaire were rated “meaningless” by relatively many – to be overestimated negative responses – respondents. As mentioned above, these terms have little relation with dialysis treatment and process since a dialysis patient typically comes to hospital or clinic as the predetermined schedule to receive the dialysis service with no admission and no emergency. Therefore, we should exclude indicators related to clinical elements rarely performed or used for dialysis treatments from the key indicator set for the dialysis management.

As can be seen in Table 4-7, a number of “useful” indicators for dialysis management were identified from all the stakeholder perspectives selected in the theoretical framework. From the patient perspective, all indicators related to patient satisfaction and patient safety offered in the questionnaire were acknowledged their importance by a majority of dialysis experts. In particular, overall patient satisfaction was perceived useful by almost all dialysis experts. The trend of the highest rank of patient satisfaction and patient safety indicators shared with the relevant studies elicited by the systematic review. This may suggest that indicators of patient satisfaction and patient safety are universally important for hospital management regardless of organizational types and countries.

Similar to the patient perspective, all indicators of employee satisfaction and occupational safety, i.e., needle stick injury, were rated “useful” by a majority of dialysis experts. This trend also shared with the former studies conducted in the other countries. In addition to this universal trend, a Japanese specific trend was seen to work conditions: several indicators on this measure, specifically related to workload, i.e., overtime, length of service and the number of staff per bed, were highly acknowledged important for hospital management. As can be seen in Table 4-7, dialysis experts assigned high values of “usefulness” to a number of indicators from the management perspective, most of which also appeared in the former Western studies.

4.4.3 Indicators specific to dialysis performance

Analysis regarding open-ended questions, first we mention expert responses to “other” important indicators from each stakeholder perspective. As an overall trend, there was no “other” important indicator suggested by three or more dialysis experts. In particular, no specific indicator from the patient perspective was implied by multiple respondents as important. Several experts suggested individual items of patient

satisfaction, e.g., satisfaction with clinical engineers, staff reactions and centesis. This as well as responses to individual closed-ended satisfaction items offered in the questionnaire may indicate that patient satisfaction must be measured by the use of multiple component items. As "other" important indicators from the employee perspective, some workload related indicators were paid attention by several respondents, e.g., the number of staff per dialysis patient, the number of dialysis patients per day and the number of staff per bed. These indicators were inter-related with a slight difference in their expression, and therefore only a single indicator must be selected among such similar indicators from the viewpoint of construct validity. It was pointed out by some respondents of critical importance to determine what indices should be selected for indicators termed broadly such as cost/expenditure and financial measures. Operational cost and maintenance cost of major devices for dialysis treatment were suggested as example sub-indicators of the cost/expenditure.

Responses to open-ended questions about specific issues to dialysis management are summarized in Table 4-8. Regarding nosocomial infections in the dialysis room, Methicillin-Resistant Staphylococcus Aureus (MRSA) was most commonly paid attention as in the general hospital. Several respondents indicated their attentions to the following infection events specific to dialysis facilities: influenza, bloodstream infections, hepatitis C, and shunt infections. As sub-indicators of dialysis specific operations/procedures, the numbers of Percutaneous Transluminal Angioplasty (PTA) and shunt surgery may be required to be recorded. It may be suggested that patient survival can be measured as dialysis period, i.e., lapsed years from the start of dialysis. In addition, equipment utilization and moreover utilization of the entire dialysis facility may be assessed by utilization of dialysis beds within the hospital/clinic as an overall indicator about this measure.

Among various devices, materials and medicines such as dialysis machines, dialyzers, circuits and anticoagulant are used for dialysis treatment, there are no or few instruments or materials for which dialysis professionals reported the necessity of measuring their utilization. In contrast, relatively many dialysis experts expressed their attention to a sudden change in the patient's state and reduction in his/her blood pressure during dialysis process, and they suggested that the frequency of patient transfer for these causes should be measured as indicators.

Table 4-8 Common responses to open-ended questions

Questions	Responses commonly suggested by dialysis experts
Nosocomial infection	Infection of MRSA (6); influenza (4); bloodstream infections (3); Hepatitis C (3); shunt infections (3)
Dialysis operations/ procedures	Percutaneous Transluminal Angioplasty (PTA; 6); shunt surgery (4); shunt revisions (2)
Indicator like "survival/revival"	Lapsed years from start of dialysis (5); survival rate (3); crude mortality rate (1)
Indicator like "length of stay"	Period of dialysis (3); averaged length of stay (2)
Indicator like "equipment utilization"	Utilization of dialysis bed (3); empty rate of dialysis bed (1); utilization of dialysis device (1); number of dialysis patients per bed per day (1)
Devices individually book-kept	Dialyzer (2); circuit (2); dialysis membrane (1), dialysis device (1); dialysate (1); centesis needles (1); anticoagulant (1)
Patient transfer	Sudden change during dialysis (4); reduction in blood pressure (4); deterioration of heart function (1); cerebral hemorrhage (1)

Figure in parentheses: Number of respondents

4.4.4 Indicator selection for Japanese dialysis context

Integrating results of the literature review and the questionnaire survey mentioned so far, as well as interviews with healthcare professionals, a tentative, probably a minimum set of indicators were selected for holistic management of the dialysis facility in the Japanese context (Table 4-9). These indicators were determined in the following procedure: we firstly selected indicators that frequently appeared in the relevant articles, i.e., the minimum indicator set for general hospitals. Secondly, we modified – i.e., removed "meaningless" indicators for dialysis management from; and inserted additional "useful" indicators to – the first selection of indicators by taking into account the Japanese dialysis context from the results of the questionnaire survey and expert interviews. Finally, this set of indicators was confirmed by some dialysis professionals, from viewpoints of face, content and construct validity.

Table 4-9 Minimum set of performance indicators for dialysis facilities in Japan

Perspectives	Measures	Indicators
Patient	Patient satisfaction	Patient satisfaction survey (multiple items)
	Patient safety	Incident/Errors
		Accident/adverse event
		Centesis errors
		Nosocomial infection (specific cases, e.g., infection of MRSA, bloodstream infections, and shunt infections)
	Waiting/Delay	Waiting time from arrival at Dialysis Room to centesis
Employee	Employee satisfaction	Employee satisfaction survey (multiple items)
	Occupational safety	Sickness leave
		Needle stick injury
	Work conditions	Staff turnover
		Overtime
		Length of service
		Occupied position
	Employment conditions	Number of staff per dialysis bed
		Number of nurses & clinical engineers having dialysis license
Management	Health statistics	Mortality (specific causes, e.g., death/cardiopulmonary arrest during dialysis treatment)
		Crude mortality rate per year
		Lapsed years from start of dialysis
		Number of dialysis patients per day
		Number of shunt surgeries
	Operational efficiency	Dialysis bed occupancy
		Equipment utilization (for major device; e.g., dialysis bed)
	Financial effectiveness	Financial measures
		Cost/expenditure
	Staffing efficiency	Full-time equivalents
		Full-time staff
	Safety culture	Safety culture survey (multiple items)

Overall satisfaction – both patient satisfaction and employee satisfaction – has been typically assessed by a survey using a questionnaire which includes multiple items of healthcare elements. Thus, the questionnaire must cover other satisfaction indicators such as satisfaction with treatment, instrument cleanliness, physicians and nurses. Therefore, all satisfaction indicators from the patient and the employee perspective were substituted to the patient satisfaction survey and the employee satisfaction survey, respectively. No culture/climate indicator was observed in expert responses to open-ended questions. However, a safety culture survey was included to generate indicators from the management perspective for the importance for hospital management.

Several sub-indicators of nosocomial infection, mortality and survival/revival based on specific germs or diseases were suggested by the dialysis experts as their answers to open-ended questions. Superordinate indicators can typically be calculated by summation of their relevant sub-indicators. Therefore, typical sub-indicators were selected and the original indicators were removed from the entire set from the viewpoint of construct validity. Example sub-indicators of the nosocomial infection were infection of MRSA, bloodstream infections and shunt infections. Crude mortality rate, lapsed time from the start of dialysis, the number of dialysis patients per day and the number of shunt surgeries were selected as indicators of the health statistics measure specific to dialysis management.

4.5 DISCUSSION

4.5.1 Requirements for measuring performance

As one of the pioneering studies in healthcare, Donabedian (1966, 1988) proposed to assess care quality in terms of outcome, structure and process. Several studies adopted the Donabedian approach to assess the quality of healthcare (e.g., Mainz et al., 2004; Chiu et al., 2007; van Eygen et al., 2007). Another major approach to assessment of healthcare services is application of Balanced Scorecard (BSC) (Kaplan and Norton, 1996, 1992), in which organizational performance is measured from the following four aspects: financial performance, customer satisfaction, internal processes, and learning and growth. There have been a number of studies that applied the BSC framework to selection of indicators for measuring quality performance in healthcare (e.g., Chang et al., 2002; Chen et al., 2006; Curtright et al., 2000; Radford et al., 2007). However, the literature review indicates a lack of conceptual framework to measure and improve the

performance of health systems from multi-stakeholder perspectives. Various stakeholders such as patients, employees, and hospital managers are active players within healthcare, but as influential external actors, all of them have different requirements and uses of performance information (Ibrahim, 2001). There is therefore a need to develop theoretical frameworks that can assess quality performance from key healthcare stakeholders of the health care system.

Although performance indicators potentially have great advantages, e.g., evidence-based management and holistic management, several difficulties and disadvantages have been frequently reported for their applications to hospital management. Most performance measurement tools or systems included a large number of indicators. Therefore, great efforts were required to obtain voluminous data for calculating performance indicators (Mainz, 2003). In addition, hospital managers and decision makers constantly suffered a problem for selecting proper ones among a vast, diversified set of indicators (Gordon et al., 1998). These efforts have led to administration fatigue and information overload (Bovier and Perneger, 2003). Such administration burdens yielded no contribution to higher operational performance, but provided only greater administrative work (Traberg and Jacobsen, 2013a). For these reasons, performance measurement systems have been universally acknowledged to work poorly and viewed negatively by both hospital managers and employees (Furnham, 2004). These negative views – and actually poor performance – of performance measurement might be primarily derived from a number of indicators that will be never utilized but must be collected. Therefore, it is of critical importance to determine a *limited number* of essential indictors which meet management purposes in a given context.

4.5.2 Implementation in Japan

As mentioned above, most frameworks and indicator sets have been developed in Western countries, and very few in Japan. Several studies have suggested that differences in national culture make it questionable to transfer results across cultural borders (Tayeb, 2001). It is therefore necessary to create a conceptual framework of performance measurement which well fit healthcare situations – and more specifically dialysis hospitals and clinics – in Japan, where healthcare systems, rules and regulations as well as national culture are different from Western countries. As one of the major challenges, this dissertation aims to support particularly small-sized dialysis hospitals and clinics, most of which have neither full-time personnel nor enough time even for

fundamental tasks concerning risk and operations management, in performing management activities through a computer-based tool. Accumulated data of performance indicators sent from hospitals/clinics must be essential sources of hospital management. Each hospital/clinic compares its current values of performance indicators with the national standard, e.g., mean values of the indicators over the country, and also benchmarks the best hospital (best practice) selected among those having similar organizational characteristics, e.g., size (the number of dialysis beds) and other clinical specialties in the organization. Such benchmarking allows any dialysis facility to identify its strengths and weaknesses both for operations performance and their organizational factors. These management activities and functions can be automated, and will be implemented as a management tool in the near future.

4.6 CHAPTER SUMMARY

In this chapter, we developed a theoretical framework of performance measurement based on performance indicators, aiming at its application to holistic management of dialysis facilities in the Japanese context. The framework emphasized applicability to evidence-based assessment from primary healthcare stakeholders' perspectives, and interpretation of assessment results into improvement actions taken within a dialysis organization. We selected patients, employees, management and community as important stakeholders in healthcare. Performance indicators were arranged from assessment properties as well as stakeholder perspectives. The theoretical framework included two types of assessment properties: (a) healthcare outcomes – by which operational problems, faults or weaknesses in the entire organization or the dialysis department in a hospital can be identified, and (b) performance shaping factors – through which hospital managers can effectively address latent causes of each problem from aspects of process, structure and culture/climate within the organization.

Applying the theoretical framework, a minimum set of performance indicators was tentatively selected for holistic dialysis management in the Japanese context. Selection of the indicator set and its validity tests were performed primarily by the use of a systematic review of literature and a questionnaire survey to dialysis experts. The indicator set comprised 27 indicators and items which will be collected through three surveys: patient satisfaction, employee satisfaction, and safety culture. The indicators were confirmed by expert judgment from viewpoints of face, content and construct validity as well as their usefulness. The major purpose of the proposed theoretical

framework was its application to management of dialysis facilities from holistic views. For this purpose, the theoretical framework can be used in an actual dialysis hospital/clinic through development of its own indicator set. A hospital manager will be able to customize a set of key performance indicators for its own purposes by including additional “important” indicators (if any) to and/or removing “meaningless” ones from the set mentioned in the results section. Such an indicator set comprising only a limited number of “essential” indicators will be required for dialysis management.

CHAPTER 5

MANAGERS' PERCEPTIONS OF PERFORMANCE INDICATORS

5.1 BACKGROUND

Measuring performance is expected of great importance in health system through the world, and has attracted increasing interest and resources over the past decades. Performance indicators based on existing or purposefully collected data sources are one way to measure healthcare performance (Scobie et al., 2006). They have been increasingly applied to healthcare management, e.g., to document the quality of care, facilitate regulation, ensure accountability, and support quality improvement (Mainz, 2003b; Mannion and Goddard, 2002). This has been driven by a range of factors including the demand for performance improvement with increasing expenditure yet confined resources, for delivering high-quality services in a timely manner to the right population groups, and concerns about equity (Gauld et al., 2011). The establishment and use of performance indicators lead to consideration of their use not only as internal quality tool but also as comparative measures of performance between organisations. They provide qualitative or quantitative information about the performance of healthcare provider and the appropriateness of healthcare delivery. Thus, decision makers in the healthcare organisations can take actions that will achieve better performance not only on financial effectiveness but also other aspects such as safety, efficiency and patient satisfaction. Comparable information on health system performance and the key factors that explain observed variations can strengthen the scientific foundations of health policy. To improve quality of care, performance indicators can be used to inform policy and strategy making (Curtright et al., 2000; Voelker et al., 2001), to monitor performance of services and of funding bodies (Brownell et al., 2001; Perkins and Seddon, 2006), to empower consumers to help make decisions about where to seek care (Mainz, 2003a; Mainz et al., 2004) and to identify poor performance (Mant, 2001).

Thousands of performance indicators can be identified by a systematic review of articles from electronic database systems (cf. Chapter 4). However, hospitals that adopt performance indicators have continuously faced with problems concerning

implementation. For example, if used incorrectly, indicators can stifle innovation by rewarding the status quo (Evans et al., 2009); they can lead to selection bias of patients and gaming of the healthcare for gaining strategic advantage (Rosenthal and Frank, 2006). Also, hospital management teams often receive voluminous data from a wide variety of sources, but are unable to distill the essential data they require to make good decisions (Gordon et al., 1998). One possible reason for the adverse effects is that successful implementation of performance indicators requires a consistent conceptual framework which defines what systems should seek to achieve and how to measure attainment (Evans et al., 2001; Arah et al., 2003; Murray and Frenk, 2000).

Despite lingering concern about the adverse effects that measurement may have on the healthcare system, increased momentum are being generated in many countries to develop performance indicators and quality improvement frameworks for monitoring, measuring, and managing health systems. For example, Gauld et al. (2011) developed a national scorecard for assessing health system performance and applied basic ratio scores to compare New Zealand performances to benchmarks. 64 indicators were included in four assessment categories: healthy lives, quality, access, and efficiency. Love et al. (2008) surveyed health care executives in United States hospitals and identified a set of performance indicators considered critical for operational management and quality improvement. The findings of this study suggested that traditional measures of financial performance continue to be critical for health care decision maker but they are being complemented by clinical indicators including employee satisfaction, medical error rates, infection control and more. Radford et al. (2007) developed a comparative performance scorecard for the federally funded Community Health Centers (CHCs) in North Carolina. The scorecard includes 19 indicators in four performance dimensions (access to care, financial performance, human resources, and utilization and productivity). A survey of participating CHC executive directors showed that the comparative performance scorecard is a useful tool for managing and evaluating the performance of CHCs. In order to support hospital management's strategic and operational decision making, Sower et al. (2001) developed an instrument, the key quality characteristics assessment for hospitals (KQCAH) scale, from the perspectives of hospital providers, hospital employees and patients. In the study, eight dimensions of hospital service quality were identified and incorporated into the KQCAH instrument: respect & caring, effectiveness & continuity, appropriateness, information, efficiency, meals, first impression, and staff diversity.

Although research on performance indicators has become a major academic and public concern in most countries, very few studies have developed performance

indicators and performance measurement frameworks specifically for the purpose of dialysis management. Moreover, indicators developed in most of the previous studies are generic indicators relevant for all hospital departments independent of the medical domain (Rath et al., 1999). Some of the indicators can be applied to measuring and assessing performance in dialysis hospitals or departments, but most of them do not seem to make sense to use for this purpose. Therefore, work on performance indicators that can be used for holistic dialysis management constitutes an important step toward evidence-based dialysis care assessment and quality improvement. In the previous chapter, we created a conceptual framework of holistic dialysis management based on performance indicators that can be applied to dialysis hospitals/departments in Japan following a systematic literature review and a questionnaire survey to dialysis experts. It aims to support dialysis facilities in performing evidence-based management from holistic views, tackling not only safety, quality and efficiency of dialysis services but also other important aspects such as patient and employee satisfaction.

As the second phase of the research on holistic dialysis management, the objectives of this chapter are three-folded: first, to uncover current usage of performance indicators to be used by dialysis staff in the Japanese dialysis settings; and second, to understand managers' views of their importance based on the framework of holistic dialysis management system. In addition, we also investigated the contributing factors to indicator usage and their judgements of usefulness.

5.2 QUESTIONNAIRE SURVEY

5.2.1 Questionnaire

We developed a questionnaire which comprised three sections besides a demographic part: (a) patient related indicators, (b) employee related indicators, and (c) management related indicators. In the questionnaire development process, we first extracted important indicators in dialysis performance measurement from a systematic review (cf. Chapter 4) and discussions with some dialysis experts. From these results, we selected 44 indicators including 10 indicators related to patients, 14 indictors related to employees and 20 indicators related to management. For each indicator, respondents were asked their perceptions of: (a) the usage of the indicator in the hospital in which they are working; (b) the organizational level of the indicator applied in the hospital; and (c) the usefulness of the indicator to dialysis management. There were four options for the usage of the indictors: "1 = yes, definitely", "2 = yes, but implicitly", "3 = no" or

“4 = don’t know”. Respondents replied “yes” were further asked to choose whether the indictors were applied in “1 = the entire hospital”, “2 = all the departments”, “3 = some departments”, “4 = only dialysis department” or “5 = don’t know”. For the usefulness of the indictors, five-point Likert-type scale was used from “1 = not at all” to “5 = absolutely required”. For detail of the indictors used in the questionnaire, please refer to Appendix E.

5.2.2 Survey sample

The questionnaire survey was conducted from July to September in 2012. All facility members (3, 443 facilities) registered in the Japanese Society for Dialysis Therapy were selected as the target population for the survey. Then we sent the questionnaire to each of the facilities’ representatives by mail with a returned envelope. When a respondent completed the questionnaire, he or she sealed the envelope to ensure confidentiality. Finally, the sealed response of each hospital was returned to the author by mail. A total of 264 valid responses were collected; the response rate was 8%. As it can be seen in Table 5-1, respondents were from many types of hospitals: general hospitals (including university hospitals, 28.4%), hospitals with dialysis facility (33.0%), dialysis specific clinics (13.3%), clinics with dialysis facility (22.7%) and some others. In which, 23.1% and 66.7 % were public and private hospitals, respectively. Respondents were working not only in small size (23.5%), middle size (43.2%), but also large size (32.2%) hospitals. The majority of them (71.6%) have worked in the hospitals for over 6 years.

Table 5-1 Characteristics of the survey sample

Characteristics	*n*	%
Organization Type		
General hospital	75	28.4
Hospital with dialysis facility	87	33.0
Dialysis specific clinic	35	13.3
Clinic with dialysis facility	60	22.7
Others	7	2.7
Ownership Type		
Public	61	23.1
Private	176	66.7
Others	27	10.2
Dialysis beds		
<20 beds	62	23.5
20-39 beds	114	43.2
≥40 beds	85	32.2
NA	3	1.1
Work experience		
<6 years	66	25.0
6-12 years	76	28.8
12-20 years	55	20.8
>20 years	58	22.0
NA	9	3.4
Total	264	

5.3 RESULTS

5.3.1 Performance measures of dialysis management

The principal component analysis with Varimax rotation was applied to the "usefulness" data of the questionnaire responses from patient, employee and management perspectives. The objectives of using this analysis procedure were to validate the dimension structure of the holistic dialysis management framework developed in Section 4.2 and to acquire performance measures useful for dialysis management in the Japanese context. The measures derived by using the principal component analysis will be used for the following statistical analysis to uncover the current usage and usefulness of performance measures and to check their differences by hospital attributes.

The Kaiser-Meyer-Olkin measure of sampling adequacy was more than 0.74, and Bartlett's test of sphericity was significant at $p < 0.001$, indicating that the data were appropriated for factor analysis. The analysis yielded 4, 3 and 4 principal components, respectively, with 75.1%, 57.2% and 64.2% of cumulative variance accounted for. Eigenvalues were higher than 1.0 for all these components. The analysis result is summarised in Table 5-2 in terms of factor label, component items, factor loadings and Cronbach's alpha for each principal component. As can be seen in this table, reliability, as measured by Cronbach's alpha (Cronbach, 1951), was higher than the standard level ($\alpha > 0.70$) for nine out of eleven performance measures. But the reliabilities of the rest two measures (waiting & errors and employee satisfaction & safety) were not high enough ($\alpha = 0.64$ and 0.59) on the basis of the criterion. Possible reasons for the low Cronbach alpha are discussed later.

Based on the holistic dialysis management framework described in the preceding chapter, the identified factors can be named as follows. As for the first component from patient perspective, indicators highly loaded were mainly related to nosocomial infection (nosocomial infection, infection of MRSA, blood infection, and infection in shunt). Accordingly, we labelled this component as "nosocomial infection". In this way, we labelled all the eleven performance measures as: nosocomial infection (4 indicators), patient satisfaction (2 indicators), patient safety (2 indicators), waiting & errors (2 indicators), work conditions (6 indicators), employee advancement (4 indicators), employee satisfaction & safety (4 indicators), financial effectiveness (6 indicators), mortality & operational efficiency (7 indicators), operational effectiveness (4 indicators), and staff and equipment efficiency (3 indicators).

Table 5-2 Performance measures elicited by principal component analysis

Performance measures (Variance [Cumulative variance]) (Cronbach alpha)	Indicators related to measure	Loading
Patient related measures		
1. Nosocomial infection	P6. Nosocomial infection	0.859
(25.8% [25.8%]) (α = 0.82)	P7. Infection of MRSA	0.821
	P9. Blood infection	0.801
	P8. Infection in shunt	0.629
2. Patient satisfaction	P1. Patient satisfaction	0.893
(17.4% [43.2%]) (α = 0.81)	P2. Patient complaint	0.863
3. Patient safety	P4. Incidents/Near-misses	0.876
(16.8% [60.0%]) (α = 0.86)	P3. Accidents/adverse events	0.866
4. Waiting & Errors	P5. Frequency of centesis errors	0.849
(15.1% [75.1%]) (α = 0.59)	P10. Waiting time at Dialysis Room	0.754
Employee related measures		
5. Work conditions	E6. Number of staff per dialysis bed	0.706
(22.6% [22.6%]) (α = 0.84)	E5. Overtime	0.663
	E4. Staff turnover	0.661
	E7. Length of service	0.654
	E8. Average experience at the current department	0.619
	E2. Paid leave	0.523
6. Employee advancement	E11. Academic papers written	0.833
(20.8% [43.4%]) (α = 0.82)	E12. Education possibilities	0.806
	E13. Number of nurses & clinical engineers having dialysis staff license	0.704
	E14. Number of specialists	0.674
7. Employee satisfaction & safety (13.8% [57.2%]) (α = 0.64)	E1. Employee satisfaction	0.699
	E9. Occupied position	0.585
	E10. Expenditure on medical research	0.583
	E3. Needle stick injury	0.535

(to be continued)

Table 5-2 Performance measures elicited by principal component analysis (continued)

Performance measures (Variance [Cumulative variance]) (Cronbach alpha)	Indicators related to measure	Loading
Management related measures		
8. Financial effectiveness (20.3% [20.3%]) (α = 0.85)	M17. Cost/expenditure	0.876
	M20. Outpatient activity	0.778
	M18. Operation & Maintenance cost of medical devices	0.764
	M16. Financial measures	0.745
	M19. Medical benefit cost per FTEs	0.571
	M10. Dialysis bed occupancy	0.547
9. Mortality & operational efficiency (20.2% [40.5%]) (α = 0.86)	M9. Number of shunt operations	0.801
	M8. Number of PTA operations	0.755
	M1. Mortality/Death	0.738
	M3. Crude mortality rate per year	0.607
	M4. Elapsed years from start of dialysis	0.604
	M2. Number of death/cardiopulmonary arrest during dialysis treatment	0.584
	M5. Number of dialysis patients per day	0.533
10. Operational effectiveness (14.6% [55.1%]) (α = 0.74)	M14. Control of haemoglobin for haemodialysis patients (Hb >11 g/dL)	0.841
	M15. Adequacy of haemodialysis (Kt/V ≧ 1.2)	0.832
	M6. Number of dialysis patients with hepatitis C products	0.506
	M7. Percentage of dialysis patients using ESA	0.488
11. Staff and equipment efficiency (9.0% [64.2%]) (α = 0.78)	M11. Equipment utilisation	0.444
	M12. Full-time equivalents (FTE)	0.753
	M13. Full-time staff	0.587
		0.432

5.3.2 Assessment of framework validity

Establishing the validity and reliability of any performance measurement system or quality improvement framework is critical. Currently there is no framework that has been shown to be reliable and valid for the measurement of performance in dialysis hospitals. The conceptual framework of holistic dialysis management was subjected to a number of different measures of validity and reliability and was shown to be both valid and reliable. In the following sections, we first check the construct validity of our proposed framework by analyzing the loadings of indicators. Next, we analyze the assessment properties of indicators in each measure from the patient, employee and management perspectives. Finally, the Cronbach's alphas of the measures are explained to show the reliability of the framework.

Validity is the measure of the ability of a constructs' indicators to accurately measure the concept under study (performance measure in the framework, e.g., patient satisfactions). Construct validity is the extent to which a scale is an appropriate operational definition of an abstract variable (Sower et al., 2001). There is no direct measure of construct validity. Factor analysis is a means of assessing construct validity by evaluating the degree to which the theoretical indicators represent the hypothesized constructs (perspectives and measures). In a pilot study, exploratory factor analysis can be used to determine the true dimensionality of the model. Factor analysis examines the data for the dominant dimensions (factors) actually present and shows which indicators are associated with each factor. Factor loadings of 0.4 indicate significance at the alpha < 0.03 level (Hair et al., 1969). Indicators with factor loadings of 0.4 and or greater are retained in the factor and contribute significantly to the overall variation observed in the factor.

In the developed conceptual framework (cf. Figure 4-1), each performance measure, e.g., patient safety, was represented as an intersection of a particular assessment property, e.g., safety, and a particular stakeholder perspective, e.g., patient. Following this structure, a particular performance measure, which is corresponding to a factor elicited by the principal component analysis, must be composed by performance indicators from a single stakeholder perspective and a single assessment property. By checking the results of the principal component analysis (Table 5-2), we can find that almost all of the elicited performance measures matched this condition, partially supporting the construct validity of our framework. From the patient perspective, the measures nosocomial infection and patient safety only include the indicators from the safety property and all the indicators in patient satisfaction are from the property of

satisfaction. From the employee perspective, the measure of work conditions only includes the indicators which are related to the process property and the indicators of employee advancement belong to the structure property exclusively. As for the management related measures, financial effectiveness and operational effectiveness only consist of the indicators from the property of effectiveness and the indicators in staff and equipment efficiency are from the time/efficiency property.

Reliability is an analysis of a measure's ability to provide consistent results. Internal consistency using Cronbach's alpha (Cronbach, 1951) is an approach to evaluating questionnaire reliability that avoids the weaknesses inherent in the test-retest and split-half approaches. Cronbach's alpha has been shown to be appropriate with five-point Likert scale data. Alphas of approximately 0.7 or higher indicate good internal consistency reliability (Nunnally, 1978).

In summary, the results of principal component analysis indicate that the proposed holistic dialysis management framework has high level of construct and high reliability.

5.3.3 Current states of indicators

The percentage of respondents selecting 5 (absolutely required) or 4 (somewhat required) on the usefulness question was computed for each measure in the patient, employee and management perspectives. Except waiting & errors (56. 5%) and staff and equipment efficiency (77.3%), the percentages for the remaining performance measures exceeded 80%, which means that managers in the Japanese hospitals perceived them as required (somewhat or absolutely) for management of the dialysis department/clinic. Percentages for all the eleven measures from the three perspectives and their related indicators were listed in Table 5-3. As shown in Table 5-3, patient safety was the most useful measure perceived by hospital managers and waiting & errors was the least useful one, both of these two measures are related to patient perspective. In addition, the measure of work conditions was perceived as the most useful measure in the employee perspective, and operational effectiveness was perceived as the most useful one in the management perspective. In contrast, employee satisfaction & safety was not evaluated as so important as the measures mentioned above.

Out of the 44 indicators offered to respondents from the three perspectives, 34 indicators received a percentage of 80 or higher on the usefulness question. For example, the most required patient related indicators for the dialysis management according to percentages are nosocomial infection, infection of MRSA, blood infection, infection in shunt, patient satisfaction, patient complaint, incidents/near-misses, and accidents/

adverse events.

We also computed the percentage of respondents rating 1 (explicitly hold) on the usage question and the percentage of respondents selecting 1 (hold in entire hospital) on the organizational level question for each of the eleven performance measures in the patient, employee and management perspectives. These measures and their usage percentages were also shown in Table 5-3. As shown in Table 5-3, the most commonly used performance measures (percent > 70% on the usage question) are nosocomial infection, patient safety, employee advancement, mortality & operational efficiency, and operational effectiveness. Sixteen indicators received a percentage of 70 or higher on the usage question. For example, the most definitely used indicators in patient perspective according to percentages are nosocomial infection, infection of MRSA, blood infection, incidents/near-misses, and accidents/adverse events.

As for the organizational levels of the eleven performance measures, only one measure (patient safety, 79.4%) received a percentage of above 70 on the organizational level question. And the most widely used indicators are incidents/near-misses and accidents/adverse events. This is can be understood from the fact that most of the indicators provided in the questionnaire are dialysis specific indicators, which can only be applied to dialysis departments or clinics.

In comparing measures required to those that used (usefulness vs. usage), it was determined that there are two patient related measures (nosocomial infection and patient safety), one employee related measure (employee advancement) and two management related measures (mortality & operational efficiency and operational effectiveness) that were perceived as required by more than 80 percent of the respondents on the usefulness question and rated as definitely used by over 70 percent of the respondents on the usage question. That is to say, these measures should be composed in each of the patient, employee and management perspectives for dialysis management in Japan. There are five measures that received a percentage of 80 or above on the usefulness question but not received a percentage of 70 or above on the usage question. There five measures are patient satisfaction, work conditions, employee satisfaction & safety, financial effectiveness, and staff and equipment efficiency.

Table 5-3 Responses to usefulness and usage of performance measures

Perspectives	Indicators related to measure	Usefulness (%)	Usage (%)
Patient	1. Nosocomial infection measures	**94.4**	**70.2**
	P6. Nosocomial infection	97.3	82.8
	P7. Infection of MRSA	95.7	82.8
	P9. Blood infection	94.0	71.0
	P8. Infection in shunt	90.8	44.1
	2. Patient satisfaction	**86.5**	**32.2**
	P1. Patient satisfaction	84.5	29.0
	P2. Patient complaint	88.5	35.3
	3. Patient safety	**98.8**	**89.4**
	P4. Incidents/Near-misses	98.8	90.4
	P3. Accidents/adverse events	98.8	88.4
	4. Waiting & Error	**56.5**	**15.9**
	P5. Frequency of centesis errors	63.3	20.9
	P10. Waiting time at Dialysis Room	49.6	10.9
Employee	5. Work conditions	**85.0**	**67.2**
	E6. Number of staff per dialysis bed	87.6	57.9
	E5. Overtime	91.4	78.0
	E4. Staff turnover	78.0	56.5
	E7. Length of service	91.1	74.1
	E8. Average experience at the current department	73.2	55.8
	E2. Paid leave	88.4	80.8
	6. Employee advancement	**84.5**	**70.4**
	E11. Academic papers written	78.0	64.0
	E12. Education possibilities	81.6	57.6
	E13. Number of nurses & clinical engineers having dialysis staff license	89.3	76.3
	E14. Number of specialists	89.2	83.8
	7. Employee satisfaction & safety	**80.9**	**49.2**
	E1. Employee satisfaction	79.7	18.0
	E9. Occupied position	82.1	57.1
	E10. Expenditure on medical research	64.1	37.6
	E3. Needle stick injury	97.7	84.0

(to be continued)

Table 5-3 Responses to usefulness and usage of performance measures (continued)

Perspectives	Indicators related to measure	Usefulness (%)	Usage (%)
Management	8. Financial effectiveness	**85.1**	**54.1**
	M17. Cost/expenditure	90.8	59.6
	M20. Outpatient activity	84.7	63.4
	M18. Operation & Maintenance cost of medical devices	93.4	48.8
	M16. Financial measures	86.3	58.5
	M19. Medical benefit cost per FTEs	71.1	33.5
	M10. Dialysis bed occupancy	84.5	61.1
	9. Mortality & operational efficiency	**88.1**	**72.2**
	M9. Number of shunt operations	86.1	79.7
	M8. Number of PTA operations	86.7	72.8
	M1. Mortality/Death	90.0	64.9
	M3. Crude mortality rate per year	80.0	50.6
	M4. Elapsed years from start of dialysis	93.0	80.1
	M2. Number of death/cardiopulmonary arrest during dialysis treatment	89.3	62.2
	M5. Number of dialysis patients per day	91.6	95.1
	10. Operational effectiveness	**89.1**	**70.5**
	M14. Control of haemoglobin for haemodialysis patients	90.9	62.7
	M15. Adequacy of haemodialysis	91.5	67.1
	M6. Number of dialysis patients with hepatitis C products	94.6	88.2
	M7. Percentage of dialysis patients using ESA	79.4	64.2
	11. Staff and equipment efficiency	**77.3**	**61.5**
	M11. Equipment utilisation	63.1	29.8
	M12. Full-time equivalents (FTE)	80.3	68.1
	M13. Full-time staff	88.4	86.6

Figure in the usefulness column: Percentage of respondents selecting 5 (absolutely required) or 4 (somewhat required) on the usefulness question; Figure in the usage column: percentage of respondents rating 1 (explicitly hold) on the usage question.

5.3.4 Differences by hospital attributes

Table 5-4 provides the results of the current usage and the perceived usefulness of performance measures comparing four hospital types (general hospitals, hospitals with dialysis facility, dialysis specific clinics, and clinics with dialysis facility) and three hospital sizes (< 20 beds, 20-39 beds, and ≥ 40 beds) by the Kruskal-Wallis test. Overall, measures were used more common and perceived more important in general hospitals and in hospitals having a larger number of dialysis beds. Next, the results regarding the most useful and the most commonly used performance measures are examined in more depth.

As can be seen in Table 5-4, measure of nosocomial infection was used significantly more common in general hospitals, hospitals with dialysis facility and clinics with dialysis facility than in dialysis specific clinics. In other words, for this measure, general hospitals, hospitals with dialysis facility and clinics with dialysis facility had more data compared with dialysis specific clinics. Patient safety was more frequently used in general hospitals and hospitals with dialysis facility than in dialysis specific clinics and clinics with dialysis facility; employee advancement was more frequently used in general hospitals, dialysis specific clinics and clinics with dialysis facility than in hospitals with dialysis facility. However, there are two measures (mortality & operational efficiency and operational effectiveness) in the management perspective which were used significantly more common in dialysis specific clinics and clinics with dialysis facility than in general hospitals and hospitals with dialysis facility.

According to the size of the hospitals, significant differences in views of usage were identified in eight performance measures. With an increase of dialysis beds at the current hospital, the measures in the management perspective (mortality & operational efficiency and operational effectiveness) were significantly more likely used for dialysis management. The measures, patient safety and employee advancement, were significantly more likely used for dialysis management in large size hospitals than in middle and small size hospitals. However, nosocomial infection was significantly more likely used for dialysis management in large and small size hospitals than in middle size hospitals.

Table 5-4 Differences in usage and usefulness of performance measures by hospital attributes

Perspectives	Measures	Type					Beds			
		GH	HD	DC	CD	p_1	< 20	20-39	≥ 40	p_2
Usage										
Patient	1. Nosocomial infection	71.5	71.0	62.9	70.4	0.253	72.2	66.9	72.5	0.421
	2. Patient satisfaction	42.1	29.6	27.9	29.0	0.173	22.3	31.8	41.0	0.009
	3. Patient safety	91.2	89.9	85.3	87.5	0.689	86.1	86.6	95.2	0.075
	4. Waiting & Errors	11.4	14.8	13.4	25.6	0.040	12.2	17.2	17.5	0.099
Employee	5. Work conditions	74.2	61.4	61.5	71.7	0.019	65.1	66.3	69.7	0.976
	6. Employee advancement	75.9	61.9	73.4	73.3	0.140	68.6	65.1	78.0	0.067
	7. Employee satisfaction & safety	61.4	47.9	38.4	42.4	0.000	50.3	47.9	49.9	0.332
Management	8. Financial effectiveness	56.8	51.7	47.3	57.2	0.030	48.6	55.3	56.2	0.840
	9. Mortality & operational efficiency	72.0	67.7	74.5	76.7	0.219	65.3	71.9	76.7	0.580
	10. Operational effectiveness	69.0	61.7	79.6	78.8	0.009	61.8	71.7	75.0	0.204
	11. Staff and equipment efficiency	69.2	59.4	52.9	57.2	0.000	57.5	63.0	61.7	0.163

(to be continued)

Table 5-4 Differences in usage and usefulness of performance measures by hospital attributes (continued)

Perspectives	Measures	Type					Beds			
		GH	HD	DC	CD	p_1	<20	20-39	≥40	p_2
Usefulness										
Patient	1. Nosocomial infection	95.2	94.1	91.6	94.9	0.819	94.2	93.4	95.8	0.999
	2. Patient satisfaction	85.3	91.2	82.0	82.1	0.754	81.9	85.4	90.7	0.151
	3. Patient safety	98.7	97.6	100.0	100.0	0.578	98.3	98.2	100.0	0.677
	4. Waiting & Errors	49.7	54.9	63.1	63.4	0.032	52.5	52.8	64.8	0.284
Employee	5. Work conditions	85.3	87.2	79.3	83.5	0.300	84.6	83.9	86.2	0.281
	6. Employee advancement	89.4	84.1	81.0	79.0	0.008	82.1	81.2	89.8	0.035
	7. Employee satisfaction & safety	80.8	84.5	76.8	76.4	0.157	79.7	78.2	84.7	0.278
Management	8. Financial effectiveness	84.5	85.2	83.7	85.9	0.452	82.7	85.7	86.5	0.325
	9. Mortality & operational efficiency	91.8	87.1	84.1	86.3	0.488	85.8	86.4	91.4	0.005
	10. Operational effectiveness	89.9	87.5	86.9	90.7	0.215	87.2	88.9	90.7	0.040
	11. Staff and equipment efficiency	80.7	78.6	78.6	71.8	0.288	71.4	79.5	78.2	0.161

Figure: percentage of responses to performance measures; p_1: *p*-value between"General hospital", "Hospital with dialysis facility", "Dialysis specific clinic" and "Clinic with dialysis facility" groups by Kruskal-Wallis test; p_2: *p*-value between "<20 beds", "20-39 beds" and "≥40 beds" groups by Kruskal-Wallis test; GH=General hospital; HD= Hospital with dialysis facility; DC=Dialysis specific clinic; CD=Clinic with dialysis facility.

As also can be seen from Table 5-4, significant differences in the manager perceptions of usefulness between the four hospital type groups were identified in eight measures from the patient, employee and management perspectives. The measures in the employee perspective (work conditions, employee advancement and employee satisfaction & safety) which were perceived as significantly higher usefulness in general hospitals and hospitals with dialysis facility than in dialysis specific clinics and clinics with dialysis facility. Mortality & operational efficiency were perceived as significantly higher usefulness in general hospitals than in other three types of hospitals. But financial effectiveness was perceived as significantly higher usefulness in clinics with dialysis facility, hospitals with dialysis facility, and general hospitals than in dialysis specific clinics; operational effectiveness was perceived as significantly higher usefulness in clinics with dialysis facility and general hospitals than in hospitals with dialysis facility and dialysis specific clinics.

In terms of the hospital size, significant differences between the three hospital size groups were identified in nine measures from the three perspectives. With an increase of dialysis beds in the present hospital, one measure in the patient perspective (patient satisfaction) and three measures in the management perspective (financial effectiveness, mortality & operational efficiency and operational effectiveness) were rated significantly more important. In addition, the measures in the employee perspective, such as work conditions, employee advancement, and employee satisfaction & safety, were evaluated significantly more useful in large and small size hospitals than in middle size hospitals.

5.3.5 Correlations between usage and usefulness

To understand the contribution of indicator usage to the judgement of usefulness, the correlation between usage and usefulness was examined by using the Chi-Square test and the results are shown in Table 5-5. We divided the usage responses into three categories (1 = the indicator was definitely used in the current hospital, 2 = the indicator was implicitly used, and 3 = the indicator was not used) and divided the usefulness responses into five ranks (1 = the indicator not required at all for dialysis management, 2 = the indicator is probably not required, 3 = neutral, 4 = somewhat required, and 5 = absolutely required). Then we examine the difference of usefulness between the three categories of usage by using the Chi-Square test for each indicator. The contingency coefficient defined as $C = \sqrt{\chi^2/(\chi^2 + n)}$ was used to explore the strength of association between usage and usefulness.

Generally, managers' perceptions of usefulness were significantly associated with the usage of indicators in the current organisations towards all the performance indicators. For the 44 indicators, the differences in positive response rate between the three usage groups were significant based on Chi-Square test. The highest correlation was shown for the indicator equipment utilisation (C = 0.57) and the lowest correlation was for number of dialysis patients per day (C = 0.28). From table 5-5, we can see that the percentage of respondents selecting 5 (absolutely required) or 4 (somewhat required) on the usefulness question for equipment utilisation in the three categories were 91.5, 68.5 and 42.3 respectively. Percentage of positive responses on the usefulness question was significantly higher for individuals who felt that the indicator was definitely used in their hospitals. Furthermore, almost half of these indicators have strong relationships with contingency coefficient greater than 0.5. It means that, for these indicators, the more definitely used for dialysis management in the current hospital, the higher level of usefulness perceived by the hospital managers.

In addition, we also examined the correlations between organisational levels and manager perceptions of usefulness for the 44 performance indicators. As a result, all of the indicators have weak relationships with contingency coefficient less than 0.5, although their perceived usefulness was correlated with the applied organisational level at the present hospital. That is to say, for the dialysis indicators, the manager perceptions of usefulness were not strongly associated with the organisational levels the indicators used or applied in the current hospitals.

Table 5-5 Correlations of performance indicators between usage and usefulness

Perspectives	Indicators	Usage (%)			χ^2 (*df*)	*C*
		1	2	3		
Patient	P1. Patient satisfaction	95.8	91.8	74.6	75.52 (8)	0.50
	P2. Patient complaint	94.4	90.6	77.3	58.88 (8)	0.45
	P3. Accidents/adverse events	99.6	96.0	50.0	90.52 (6)	0.52
	P4. Incidents/Near-misses	99.1	95.0	100	49.13 (6)	0.40
	P5. Frequency of centesis errors	98.0	66.6	39.8	105.9 (8)	0.56
	P6. Nosocomial infection	99.0	92.3	77.8	74.38 (8)	0.49
	P7. Infection of MRSA	98.5	84.6	75.0	94.25 (8)	0.53
	P8. Infection in shunt	96.3	89.3	75.9	50.98 (8)	0.42
	P9. Blood infection	98.3	86.8	76.5	77.24 (8)	0.50
	P10. Waiting time at Dialysis Room	81.5	59.1	30.7	48.43 (8)	0.42
Employee	E1. Employee satisfaction	93.2	86.9	70.1	53.49 (8)	0.44
	E2. Paid leave	92.2	76.7	53.8	55.90 (6)	0.43
	E3. Needle stick injury	99.5	84.6	100	90.32 (4)	0.52
	E4. Staff turnover	89.8	74.5	45.7	88.25 (8)	0.53
	E5. Overtime	92.9	85.0	88.9	39.75 (6)	0.37
	E6. Number of staff per dialysis bed	95.9	81.7	53.6	89.33 (8)	0.52
	E7. Length of service	96.8	77.5	80.0	54.81 (6)	0.43
	E8. Average experience at the current department	85.7	63.5	23.8	88.13 (8)	0.51
	E9. Occupied position	93.3	82.7	50.0	81.16 (8)	0.53
	E10. Expenditure on medical research	86.2	72.2	40.4	66.56 (8)	0.53
	E11. Academic papers written	88.5	76.3	47.6	54.18 (8)	0.45
	E12. Education possibilities	92.4	79.4	39.1	85.55 (6)	0.52
	E13. Number of nurses & clinical engineers having dialysis staff license	92.8	78.7	66.7	51.01 (8)	0.41
	E14. Number of specialists	91.9	81.5	70.0	54.46 (8)	0.43

(to be continued)

Table 5-5 Correlations of performance indicators between usage and usefulness (continued)

Perspectives	Indicators	Usage (%)			χ^2 (*df*)	*C*
		1	2	3		
Management	M1. Mortality/Death	96.4	80.0	64.7	73.37 (6)	0.48
	M2. Number of death/cardiopulmonary arrest during dialysis treatment	92.8	87.0	71.4	58.79 (8)	0.45
	M3. Crude mortality rate per year	93.0	72.9	54.1	79.39 (8)	0.51
	M4. Elapsed years from start of dialysis	96.1	82.1	66.7	40.35 (8)	0.37
	M5. Number of dialysis patients per day	92.5	72.7	50.0	21.90 (6)	0.28
	M6. Number of dialysis patients with hepatitis C products	96.0	86.4	50.0	91.90 (6)	0.52
	M7. Percentage of dialysis patients using ESA	86.3	72.3	46.7	59.69 (8)	0.45
	M8. Number of PTA operations	90.2	78.6	75.0	39.90 (8)	0.38
	M9. Number of shunt operations	90.5	83.9	27.3	55.50 (8)	0.45
	M10. Dialysis bed occupancy	91.5	79.7	57.7	59.60 (8)	0.44
	M11. Equipment utilisation	91.5	68.5	42.3	66.67 (6)	0.57
	M12. Full-time equivalents (FTE)	89.8	73.3	42.1	71.79 (8)	0.51
	M13. Full-time staff	91.1	78.9	50.0	43.33 (8)	0.39
	M14. Control of haemoglobin for haemodialysis patients	95.7	87.1	57.1	92.96 (8)	0.52
	M15. Adequacy of haemodialysis	95.9	80.4	81.0	53.24 (6)	0.43
	M16. Financial measures	95.5	84.8	66.7	62.17 (8)	0.51
	M17. Cost/expenditure	96.5	86.0	75.0	72.30 (6)	0.52
	M18. Operation & Maintenance cost of medical devices	97.4	93.7	83.3	57.47 (6)	0.47
	M19. Medical benefit cost per FTEs	87.8	76.5	56.3	50.54 (6)	0.50
	M20. Outpatient activity	93.1	76.7	66.7	49.33 (8)	0.46

Figure in the usage columns: Percentage of respondents selecting 5 (absolutely required) or 4 (somewhat required) on the usefulness question; 1 = the indicator was definitely used in the current hospital, 2 = the indicator was implicitly used, and 3 = the indicator was not used; all *p*-values for Chi-Square tests were <0.001; *df*: Degree of freedom; *C* represents contingency coefficient.

5.4 DISCUSSION

We described the second stage of the research on holistic dialysis management. This is the first research to identify current usage of performance indicators and managers' views of their importance by surveying health care executives from the dialysis facilities in Japan. Another goal of this chapter was to understand the factors that influence indicator usage and managers' perceptions of indicator usefulness.

By the principal component analysis based on "usefulness" data of the questionnaire responses, eleven performance measures were extracted for dialysis management in the Japanese hospitals: nosocomial infection, patient satisfaction, patient safety, waiting & errors, work conditions, employee advancement, employee satisfaction & safety, financial effectiveness, mortality & operational efficiency, operational effectiveness, and staff and equipment efficiency. The survey of hospital managers revealed that six measures were commonly used and nine measures were rated highly useful for dialysis management in the Japanese context. Based on a systematic literature review, we have identified a set of performance indicators frequently used in former studies (cf. Table 4-5). All of the indicators are generic indicators (Rath et al., 1999) and can be used in any type of hospitals. Some indicators that were currently being used in dialysis hospitals compared closely to the results obtained by the literature review. For example, from the patient perspective, nosocomial infection, incidents/near-misses, accidents/adverse events were also the most cited indicators in the literature for assessing quality of health care in general types of hospitals. But we also identified some indicators that are specifically used or only useful for measuring and assessing performance in the dialysis hospitals or departments. For instance, from the employee perspective, the indicators such as number of staff per dialysis bed, overtime, average experience at the current department, and number of nurses & clinical engineers having dialysis staff license were commonly used in the dialysis facilities and perceived as very useful by hospital managers for dialysis management. But these indicators did not appear at the list frequently employed for hospital management in previous studies.

On the other hand, the negative views of performance measurement were primarily derived from a number of indicators that will be never used but must be collected. Consequently, great efforts were required to obtain voluminous data for indicators, which implied an administrative burden for employees and hospitals (Bovier and Perneger, 2003). Therefore, it is of critical importance to determine a limited number of

essential indictors which meet management purposes of the organization. Based on the results of the manager questionnaire survey, we selected a minimum set of key performance indicators (see Table 5-6) that were rated highly useful and were widely held in the Japanese dialysis hospitals, departments or clinics. These indicators were determined in the following procedure: we first selected performance measures that were perceived useful by hospital managers. The measure of waiting & errors including two indicators were excluded in this step because it was the least useful measure perceived by hospital managers. Subsequently, we removed "meaningless" indicators by considering the usage and the usefulness of the indicators in the included measures. As a result, eight indicators were removed in this step because they were little required and not definitely used for performance measurement in the Japanese dialysis facilities. Finally, 34 key performance indicators were obtained based on the questionnaire survey to the dialysis managers. In the last chapter of this dissertation, we tentatively determined a minimum set of performance indicators (cf. Table 4-9) for dialysis management based on a questionnaire survey to dialysis experts. Comparing the indicator set determined in this chapter with the one obtained in the last chapter, we found that most of the indicators appeared in Table 4-9 were also identified as important indicators in this chapter. However, they are some indicators, such as centesis errors, waiting time from arrival at dialysis room to centesis, employee satisfaction, sickness leave, equipment utilization, and safety culture, that were not considered as critical for dialysis management in this chapter. In addition, nine new indicators as shown in Table 5-6 were identified as key performance indicators for measurement of dialysis performance in this chapter. The possible reasons for the differences between the two sets of performance indicators are mainly because the indicator set developed in the last chapter was only based on the usefulness of indicators and only 19 dialysis experts participated in the questionnaire survey. We also noticed that there are nine indictors (marked in italics in Table 5-6) which were perceived as highly useful by hospital managers but not frequently used in the dialysis facilities. Therefore, it is our future direction to apply these indictors into actual settings and found the advantages and problems in their implementation.

Table 5-6 Minimum set of key performance indicators for dialysis facilities in Japan

Perspectives	Measures	Indicators
Patient	Nosocomial infection	Nosocomial infection
		Infection of MRSA
		Blood infection
		Infection in shunt
	Patient satisfaction	*Patient satisfaction*
		Patient complaint (new)
	Patient safety	Incidents/Near-misses
		Accidents/adverse events
Employee	Work conditions	*Number of staff per dialysis bed*
		Overtime
		Length of service
		Paid leave (new)
	Employee advancement	*Education possibilities* (new)
		Number of nurses & clinical engineers having dialysis staff license
		Number of specialists (new)
	Employee safety	Occupied position
		Needle stick injury
Management	Financial effectiveness	Cost/expenditure
		Outpatient activity (new)
		Operation & Maintenance cost of medical devices (new)
		Financial measures
		Dialysis bed occupancy
	Mortality & operational efficiency	Number of shunt operations
		Number of PTA operations (new)
		Mortality/Death
		Crude mortality rate per year
		Elapsed years from start of dialysis
		Number of death/cardiopulmonary arrest during dialysis treatment
		Number of dialysis patients per day
	Operational effectiveness	Control of haemoglobin for haemodialysis patients (Hb >11 g/dL) (new)
		Adequacy of haemodialysis (Kt/V ≧1.2) (new)
		Number of dialysis patients with hepatitis C (new)
	Staff efficiency	Full-time equivalents (FTE)
		Full-time staff

Our analyses have shown that hospital type and hospital size have significant effects on the usage and the perceived usefulness of performance measures. Generally, most of the indicators were used more common in general hospitals and hospitals with lager number of dialysis beds. These results are similar to the literature suggesting that wide variations in indicators' measurement were existed in hospitals including formulas and tools (El-Jardali et al., 2011). Nevertheless, there are still some indicators which do not support such a claim. This corresponds with claim in the literature that indicators can be generic measures that are relevant for most patients or disease-specific, expressing the quality of care for patients with specific diagnoses (Mainz, 2003a). In addition, our results showed that managers' perceptions of usefulness were significantly associated with the usage of indicators in the current hospital for all the performance indicators. These findings are in line with those reported by Love et al. (2008). This study conducted a survey with hospital executives in American hospitals and showed that most of the indicators that were currently being used by health care management were also considered critical (useful) for organizational assessment and performance improvement. However, there are no indicators, for which the perceived usefulness have strong relationships with their applied organisational levels at the present hospitals. This is not unexpected because most of the indicators employed in the questionnaire survey are dialysis specific indicators and the focus of this chapter is to investigate the current status of performance measurement in the dialysis hospitals/departments.

5.5 CHAPTER SUMMARY

In this chapter, we conducted a survey of 264 leaders and managers in the dialysis hospitals/clinics in Japan to learn about the current usage of performance indicators and their perceptions of importance with regard to dialysis management. This chapter produced three major findings. First, eleven performance measures were extracted based on the "usefulness" data of the questionnaire responses. Some of the indictors included were similar to the generic indicators suggested in the former studies but most of them are measures specific for measuring performance in the dialysis facilities. Second, based on the results of the manager questionnaire survey, we determined a set of performance indicators identified as the most important ones to decision makers of dialysis hospitals. Finally, the usage and organisational level of most measures were significantly affected by hospital attributes, such as hospital type and hospital size. In general, performance measures were used more common and perceived more important in general hospitals

and hospitals with lager number of dialysis beds. In addition, the perceived usefulness of a performance indicator was rated significantly more important if the data was held, but not so related to its applied organisational level at the present hospital.

Despite the increased interests in using performance indicators in daily practice in order to improve the quality of care, few studies were conducted for the purposes of measurement of quality in the dialysis settings. The present chapter is the first study with a structured method to identify current usage and importance of performance indicators that can be potentially applied to dialysis management in Japan. Moreover, a minimum set of key performance indicators were selected for assessing performance of dialysis facilities in the Japanese context. It could serve as a starting point for dialysis professionals and organisations to identify local performance indicators in more detail and to develop tailored strategies for the implementation of performance indicators in their organisations.

CHAPTER 6

CONCLUSIONS

6.1 RESEARCH OUTCOMES

The manufacturing industry is known for its revolutionary industrial engineering techniques and cutting-edge efficiency. These methods now are being used in healthcare management, resulting in improved operational efficiency, staff utilization and patient safety, while reducing overall costs. However, the utilization of such models and tools represents a stand-alone effort, which lacks systemic integration. In this dissertation, the reliability and operations management in healthcare organizations were explored based on two approaches: failure mode and effects analysis and key performance indicators. Many sound conclusions were elicited from the two aspects.

6.1.1 Risk evaluation in healthcare

From the reliability management aspect, according to the literature review on FMEA, it yielded several major outcomes on the alternative methodologies for risk evaluation in FMEA.

- First, the traditional FMEA is not supportive and robust enough in priority ranking of failure modes. Of the shortcomings described in the reviewed literature, the ones that have received significant attention from the literature can be seen as being risk factor and RPN related issues. For instance, the relative importance among the three factors (O, S and D) is not considered; different combinations of O, S and D may produce exactly the same value of RPN; and the three factors are difficult to be precisely estimated.
- Second, numerous alternative approaches were proposed to overcome the shortcomings of the traditional FMEA. They are all capable of addressing some of the problems associated with the conventional RPN method. It can be observed from the surveyed literature that fuzzy rule base system is the most popular method for prioritizing failure modes, followed by grey theory, cost-based model, AHP/ANP and linear programming.
- Third, the fuzzy rule-based methods proposed in the FMEA literature improve

the accuracy of the failure criticality analysis by compromising the easiness and transparency of the conventional method. But some doubts remain concerning an actual applicability of fuzzy rule base system to real-life circumstances, by reason of the difficulties which arise during the fuzzy model design, i.e. in defining the (numerous) rules and membership functions required by this method.

Risk evaluation in healthcare is often influenced by uncertainty in real-life applications, and in such situation fuzzy set theory is an appropriate tool to deal with this kind of problems. In many situations, the decision maker in FMEA team is unable (or unwilling) to express his assessments precisely in numerical values and the evaluations are very often expressed in linguistic variables. Therefore, an extension of the VIKOR in fuzzy environment is used to deal with the risk factors and identify the most serious failure modes for corrective actions. The VIKOR method focuses on ranking and selecting from a set of alternatives in the presence of conflicting criteria. It determines a compromise solution that could be accepted by the decision makers. We applied the new FMEA model to analyze the risk of general anesthesia process and identify the most serious failure modes. The provided case study has demonstrated the capability of the proposed FMEA model to manage a criticality analysis in an intuitive and easy manner. According to the final score, failure mode respiratory depression is the most serious failure mode during the general anesthesia process. Failure modes visceral injury and go esophageal are the next high risk failure modes according to the risk factors: occurrence, severity and detection.

6.1.2 Performance measurement of healthcare

From the operations management aspect, we conducted a research on holistic hospital management to support dialysis facilities in performing evidence-based management from holistic views. At the first phrase of the research we developed a theoretical framework of performance measurement, aiming its application to holistic management of dialysis facilities in the Japanese context. Major outcomes in the first phrase can be summarized:

- First, the current national and international projects used different assessment models each of which comprised a different set of dimensions, including a number of performance indicators. There has been yet no framework unanimously accepted as a tool for measuring quality and performance of healthcare services.

- Second, the negative views of performance measurement might be primarily derived from a number of indicators that will be never utilized but must be collected. It is of critical importance to determine a limited number of essential indictors which meet management purposes in a given context.
- Third, it is necessary to create a conceptual framework of performance measurement and key indicators which will fit healthcare situations – and more specifically dialysis hospitals and clinics – in Japan, where healthcare systems, rules and regulations as well as national culture are different from Western countries.
- Finally, applying the developed theoretical framework, a minimum set of key performance indicators was selected for holistic dialysis management which can be used in the Japanese context.

As another active player within healthcare, views of healthcare management on dialysis performance indicators were studied at the second stage of the research on holistic dialysis management. The study identified current usage of performance indicators and managers' views of their importance and explored the factors that influence indicator usage and managers' perceptions of indicator usefulness. First, eleven performance measures were extracted for dialysis management in the Japanese hospitals. Among them, six measures were commonly used in the Japanese dialysis hospitals and nine measures were rated highly useful for dialysis management. Some indicators that were currently being used in dialysis hospitals compared closely to the results obtained by the literature review. But there were also some indicators that are specifically used or only useful for measuring and assessing performance in the dialysis hospitals or departments. Second, a minimum set of key performance indicators were selected that were rated highly useful and were widely held in the Japanese dialysis hospitals, clinics or departments. We found that most of the indicators obtained at the first phrase of the research were also identified as important indicators in the manager questionnaire study. However, they are some indicators that were not considered as critical for dialysis management and some new indicators were identified as key performance indicators for measurement of dialysis performance at the second stage of our research. Third, hospital type and hospital size have significant effects on the usage and the perceived usefulness of performance measures. Specifically, most of the indicators were used more common in general hospitals and hospitals with lager number of dialysis beds; managers' perceptions of usefulness were significantly associated with the usage of indicators in the current hospital for all the performance indicators.

6.2 RESEARCH IMPLICATIONS

The proposed FMEA permits the proactive identification of possible failures in complex processes and provides a basis for continuous improvement. With the increasing complexity of healthcare services, the new risk priority model offers tools for predicting failure and for implementing changes to prevent such failures from occurring in the future. It can be used during the initial conceptual design and development phase of a process or for subsequent process control as a component of continuous improvement. In addition, some suggestions are made so as to further solve the known deficiencies of the traditional FMEA. There is need to split risk factors to reduce their vagueness and add other risk factors in the determination of risk priority of failure modes. The objective and combination weighting methods should be applied to the risk assessment in FMEA because they evaluate the relative importance objectively without decision makers. MCDM approaches are the second most methods employed to prioritize failure modes considering multi-criteria. There is a trend in using more than just one MCDM model to enhance the efficacy and empirical validity of risk assessment results. Recent literature also shows a shift towards using integrated methods, so that synergies can be maximized.

Defining and enhancing health system performance has become increasingly important for healthcare organizations to adjust to freemarket conditions, forcing management to specifically address quality and efficiency of care. Performance indicators are therefore strongly emerging in healthcare. In this dissertation, a conceptual framework for holistic dialysis management was created based on performance indicators. The major purpose of the proposed theoretical framework was its application to management of dialysis facilities from holistic views. For this purpose, the theoretical framework can be used in an actual dialysis hospital/clinic through development of its own indicator set. A hospital manager will be able to customize a set of key performance indicators for its own purposes by including additional “important” indicators (if any) to and/or removing “meaningless” ones from the set mentioned in Chapter 5. Such an indicator set comprising only a limited number of “essential” indicators will be required for dialysis management.

6.3 LIMITATIONS

There are several limitations in this dissertation. Two limitations are existed in the FMEA study:

- First, as in other qualitative investigations, it is difficult to demonstrate a statistically or clinically significant decrease in rare events, and it is impossible to demonstrate a decrease in events that have not occurred. Thus, we cannot prove that the FMEA will increase the safety of patients at the institution nor can we perform a cost-benefit analysis.
- Second, the resources and expertise required to support FMEA were not considered. The risk analysis process is time intensive and the monetary resources required to carry out FMEA have not been evaluated in this dissertation. However, the release of members of the team from their routine duties to partake in the process in itself has monetary implications. In addition, for an FMEA process to be effective, the actions proposed by the team should be fully aligned with the vision and mission of an institution. As such, resources should be made available, including personnel, time, and training.

About the study concerning dialysis management framework, there are two major limitations: First, a small number of studies related to the objective of the literature review study, i.e., 24 “relevant” articles, had been identified by the systematic review of literature. This seems to derive primarily from the stringent selection criteria that we adopted, in particular indicators from multiple measures and application to actual setting. Therefore, we should have applied more lenient criteria, excluding one or a few of these conditions from the selection criteria, to obtain a larger number of relevant papers. However, the main purpose of the systematic review was not identification of an exact set of “useful” indicators for hospital management, but preliminary selection of potential indicators. Therefore, we believe that the indicators extracted from the 24 relevant articles were enough applicable for this purpose. Second, only a small number of dialysis experts participated in the questionnaire-based survey for rating “usefulness” of potential indicators and providing “other” important indicators. Besides a small sample of the questionnaire responses, the data collected in the survey were somewhat biased since all the respondents were healthcare staff working for the organizations of the project members. They were likely to make more positive rating rather than negative, and were reluctant to view indicators negatively for their usefulness. This is a pilot study on holistic hospital management which will apply to the Japanese context, and to

the dialysis setting. This study aimed to establish its theoretical framework rather than to propose the complete set of key performance indicators. Therefore, we had used the results of the expert judgment to determine a *tentative* set of indicators. We believe that the data of expert rating as well as their comments to open-ended questions collected in this study are applicable enough to this objective of the present study.

There are mainly two limitations in the management survey study:

- The response rate of hospital managers was very low in our study (approximately 8%). This means a biased sample. One possible reason is that it may be difficult for managers, especially hospital administrators such as secretary-generals, to understand several indicators and to know the current status of these indicators in their organizations. So we caution against generalizing the results to the context of the entire country. However, this study contributes substantially to the evidence base about the usage and usefulness of performance indicators for holistic dialysis management in Japan. Future studies should survey more and various multidisciplinary health care organizations.
- The Cronbach's alpha was not high enough for two measures, especially for waiting & errors ($\alpha = 0.59$). There may be several reasons for the low Cronbach's alpha. As one possible reason, it was seen that a smaller sample which cannot be assumed normality was likely to result in underestimation of the internal reliability (Spiliotopoulou, 2009). The sample collected in this study was not large, including only 264 valid responses. As Cronbach's alpha is a function of the interrelatedness of the indicators in a test, it represents a consistent level of respondents' perceptions of the indicators in a measure. As shown in Table 5-2, indicators in both of the two measures come from different measures of the theoretical framework introduced in Chapter 4. Therefore, they might not be acknowledged consistently, and this may have resulted in low Cronbach's alpha. However, this limitation doesn't affect the reliability of the set of performance indicators obtained in Chapter 5 because the measure of waiting & errors and indicators related to employee satisfaction were excluded from the study finally.

6.4 FUTURE STUDIES

Corresponding to the limitations mentioned above, future studies are also suggested; all the limitations hopefully can be improved. Following the results of the FMEA study, it would not be appropriate to recommend the use of FMEA alone as a tool for preventing patient harm. Thus, improving the FMEA outputs maybe achieved by allowing the FMEA teams to use other sources, besides their experience and knowledge, such as hospital audits or incident report databases, to list as many potential failures as possible. In addition to this, as new evidence-based medicine continues to evolve and guidelines and protocols continue to be periodically updated, along with the introduction of new technologies such as electronic prescribing, clinical decision support or bar-coding, a given set of FMEA results will only be valid for a limited time period and should therefore be updated regularly.

In the future research on holistic dialysis management, i.e., practical use of the theoretical framework as a management system, we must elaborate the set of key performance indicators based on analysis results of proper data collected from other important stakeholders in healthcare, such as employees and patients. In the present dissertation, the indicator set was selected on the basis of "usefulness" for hospital management with consideration of face, content and construct validity. In addition to these three types of validities, we must further take into consideration other requirements for design of performance indicators such as "collectability" of indicators (how easily data are collected for a specific indicator), methods for reliably collecting data, and clear definitions of indicators (how to calculate each indicator; numerator and denominator). Regarding pilot implementation of the holistic dialysis assessment framework, we need to build a computer-based dialysis management system once we establish the effective set of performance indicators. Feedback of information received from the system can assist each participant's own quality improvement efforts by identifying potential problem areas. Such information permits frontline healthcare providers to analyse quality problems and effect changes and supports continuous quality improvement.

In addition to improvement of research in the dissertation, other studies on healthcare management can be also conducted especially the relationships between risk evaluation and performance measurement. After detection of operational problems or weaknesses in a healthcare organization based on key performance indicators, the potential failure modes and latent causes of each problem can be addressed by using the risk evaluation method of FMEA in terms of product, process and sub-system within the organization.

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APPENDIX

A. Summary Example of Relevant Article

(1) Source of article

Basu, A., Howell, R. and Gopinath, D. (2010). Clinical performance indicators: Intolerance for variety? *International Journal of Health Care Quality Assurance*. 23 (4), 436-449.

(2) Outline of article

[Objectives] To analyze the data regarding the different clinical quality indicators mentioned in the Intelligent Board (2006) and to determine whether the results could be reliably used to interpret hospital performance.

[Results and main conclusions] Each indicator was measured monthly and calculated its mean over a year and a moving average, and its trend was analyzed. Based on the application results, they concluded that the performance of this hospital can be interpreted as unchanged, better or worse, depending on the indicator used. A background intention of this paper may be to apply the indicators to performance comparisons between hospitals. However, they suggested that the use of clinical performance indicators to rank hospitals may be questionable due to lack of reliable data collection systems, lack of reliable comparative data, and multiplicity of factors which contribute to the performance. Instead, they suggested that a suitable alternative application of the indicators could be to compare the hospital's own statistics with those from previous years which would reflect an effective process of ongoing improvement.

[Strength] Indicators examined in this study were discussed from various viewpoints with previous studies.

[Weakness] Only one hospital data were applied to the indicators, and data application period was very short.

(3) Place and period of study

Manchester, UK; April 2006 – March 2007

(4) Setting applied

A single hospital, i.e., Trafford General Hospital; periodical comparisons of performance indicators in the same hospital.

(5) Organizational level applied

Entire hospital.

(6) Indicators (and sub-indicators)

1) Mortality → (1-1) Total mortality, (1-2) Mortality as percentage of the patients discharged;

2) Readmission → (2-1) Readmissions within 28 days of discharge, (2-2) Readmissions as percentage of the total number of patients discharged;

3) Infections → (3-1) Infections with two specific types of bacteria, which were determined by NHS or hospital trusts, (3-2) Infections with MRSA (methicillin resistant staphylococcus aureus), (3-3) Infections with Clostridium difficile;

4) Claims against the hospital.

(7) Data collection method

Operational/managerial data in the hospital; the data were requested to collect from those provided to the Trafford General Hospital's Trust Board.

(8) Purposes of indicators

Assessment of non-financial performance of the hospital: the hospital could compare with its own statistics from previous years.

(9) Validity/reliability of indicators

No test of validity/reliability; just discussion of the indicators examined.

(10) Implementation as tool/instrument

NA.

B. Example of Indicator Mapping

Original Description		Mapping to the proposed framework				
Indicators	**Sub-indicators**	**Perspectives**	**Measures**	**Indicators**	**Sub-indicators**	**Assessment properties**
Mortality	Total mortality	Management	Health statistics	Mortality	Total mortality	Health status
	Mortality as a percentage of the patients discharged	Management	Health statistics	Mortality (for specific cases)	Mortality of the patients discharged	Health status
Readmission	Readmissions within 28 days of discharge	Management	Readmission/return	Unscheduled Readmission		Time/Efficiency
	Readmissions as a percentage of the total number of patients discharged	Management	Readmission/return	Unscheduled Readmission		Time/Efficiency
Infections	Methicillin resistant staphylococcus aureus (MRSA)	Patient	Patient safety	Infections (for specific cases)	Infection of MRSA	Safety/Quality
	Clostridium difficile (C. difficile)	Patient	Patient safety	Infections (for specific cases)	Infection of C. difficile	Safety/Quality

C. Indicators Offered in the Expert Questionnaire

(1) Patient perspective

- Overall patient satisfaction
- Patient satisfaction with physicians
- Patient satisfaction with nurses
- Patient satisfaction with care/service
- Patient satisfaction with treatment
- Patient satisfaction with instrument cleanliness
- Patient complaint
- Accident/adverse event
- Incident/Errors
- Nosocomial infection
- Received written information
- Waiting time for operation/surgery
- Outpatient waiting times
- Waiting time for admission
- Waiting time in Emergency Room
- Cancelled operations
- Cancelled examinations

(2) Employee perspective

- Overall employee satisfaction
- Employee satisfaction with job
- Employee satisfaction with colleagues and workplace
- Employee satisfaction with hospital facilities
- Employee satisfaction with organization
- Employee satisfaction with IT
- Sickness leave
- Needle stick injury
- Staff turnover
- Overtime
- Number of staff per bed (based on professional group)
- Length of service (based on professional group)
- Average experience at the current department
- Occupied position (based on professional group)
- Expenditure on medical research

- Academic papers written
- Scientific projects
- Education possibilities
- Specialists (based on specialty)
- Resident physicians

(3) Management perspective

- Mortality/Death (for specific cases)
- Morbidity
- Survival/Revival (for specific cases)
- Number of patients per day
- Number of outpatients per day
- Number of inpatients per day
- Inpatient admission
- Autopsy rate
- Number of operations/procedures (for specific cases)
- Unscheduled readmission
- Unscheduled returns to ICU/operating room
- Admission from unexpected return
- Bed occupancy
- Number of outpatients per doctor
- Number of emergency patients per doctor
- Admissions per bed
- Length of stay
- Equipment utilization
- Equipment utilization (for specific instruments)
- Full-time equivalents
- Full-time staff (based on department)
- Patient transfer (for specific cases)
- Emergency admission
- Day case
- Cross match/transfusion ratio
- Financial measures
- Cost/expenditure
- Cost effectiveness
- Net outpatient revenue/net patient revenue

D. Performance Indicators Used in the Selected Articles

(1) Patient perspectives

Measures	Indicators	Sub-indicators	Property
Patient satisfaction	Overall satisfaction		SF
	Satisfaction with specific professionals	Satisfaction with physicians, primary care physicians, nurses, administrative staff, etc.	SF
	Satisfaction of specific patients	Satisfaction of outpatients, inpatients, emergency patients, etc.	SF
	Satisfaction with specific care/service	Satisfaction with primary care, subspecialty care, nursing, laboratory services, emergency care services, administrative service, etc.	SF
	Satisfaction with waiting time (for specific cases)	Satisfaction with waiting time to admission, with prolonging stay, etc.	SF
	Satisfaction with treatment		SF
	Satisfaction with specific information	Satisfaction with information to general practitioner, written and oral treatment information, etc.	SF
	Satisfaction with staff reactions to encountered failures		SF
	Satisfaction with accessibility	Satisfaction with ease of obtaining referrals, assortment of medications, etc.	SF
	Satisfaction with instrument cleanliness		SF
	Proportion of patients recommending hospital to others		SF
	Trust in staff		SF
Patient complaint	Overall complaints		SF
	Claims	Patients with chronic conditions who think the health system needs to be rebuilt	SF
Patient safety	Accident/adverse event		SQ
	Specific adverse events	Severe adverse drug events	SQ
	Incident/Errors	Entire cases	SQ
		Specific cases	SQ
	Nosocomial infection	Entire cases	SQ
		Specific cases	SQ
	Delinquent medical record		SQ
Clinical quality	Overall quality of care and services		PR
	Pain alleviated		PR
	Overall coordination of care		PR
Information	Received written Information		CC
	Information by specific staff groups	Information provided by physicians, nurses, etc.	CC
	Coherence in information		CC
	Communication with doctor		CC
	Consulting room open		CC
Waiting/Delay	Waiting time for operation/surgery		TM
	Outpatient waiting times		TM
	Waiting time for admission		TM
	Waiting time for treatment/consultation		TM
	Waiting time in Emergency room		TM
	Waiting time for other specific cases		TM
	Delayed discharge		TM
Cancelation	Cancelled operations		TM
	Cancelled examinations		TM

	Cancellation in Emergency Department		TM
Patient-centered care	Mental health in primary care		EF
	Returning home following treatment	Returning home following treatment for a stroke, a fractured hip, etc.	EF
	Convenience of office hours		EF
	Barrier-free	Wheel-chair friendly lifts	EF

<Assessment properties> (Healthcare outcomes) SF: Satisfaction, HS: Health status, SQ: Safety/Quality, TM: Time/Efficiency, EF: Effectiveness; (Performance shaping factors) ST: Structure, PR: Process, CC: Culture/Climate.

(2) Employee perspectives

Measures	Indicators	Sub-indicators	Property
Employee satisfaction	Overall satisfaction		SF
	Satisfaction with job		SF
	Satisfaction with colleagues		SF
	Satisfaction with on-campus facilities		SF
	Satisfaction with organization		SF
	Satisfaction with supervisors		SF
	Satisfaction with IT		SF
Employee complaint	Employee complaints about interpersonal skills		SF
Occupational health	sickness leave		HS
	Sickness leave of specific professionals	Doctor, nurse, other professionals	HS
	Long-term sickness absence		HS
	Mental sickness		HS
	Physical sickness		HS
	Staff wellbeing		HS
Occupational safety	Errors/incidents	Specific cases	SQ
	Work hazards		SQ
Employment conditions	Personnel upgrade on career ladder		ST
	Part-time employees		ST
	Available posts		ST
	Number of staff per bed		ST
	Educational positions		ST
Work conditions	Staff turnover		PR
	Overtime		PR
	Hand hygiene	Measuring alcohol consumption	PR
	Work shift	Work shift of emergency medicine specialists	PR
	Workload of specific personnel		PR
	Length of service	Specific professionals	PR
	Average experience at the current department		PR
	Occupied position	All professionals	PR
		Specific professionals	PR
Employee competence	Research opportunities	Expenditure on medical research	ST
		Academic papers written	ST
		Scientific projects	ST
		Resources for research	ST
	Education opportunity	Resources for further education	ST

		Education possibilities	ST
		Teaching ability	ST
	Specialists	Specific specialties	ST
	Resident physicians	Specific specialties	ST
	Percentage of qualified nurses		ST
Training	Training opportunity/hours		ST
	Nurses in training		ST
	Training received	Specific training	ST

<Assessment properties> (Healthcare outcomes) SF: Satisfaction, HS: Health status, SQ: Safety/Quality, TM: Time/Efficiency, EF: Effectiveness; (Performance shaping factors) ST: Structure, PR: Process, CC: Culture/Climate.

(3) Management perspectives

Measures	Indicators	Sub-indicators	Property
Management satisfaction	Superior satisfaction		SF
Health statistics	Mortality/Death	Entire cases	HS
		Specific cases	HS
		Specific age groups	HS
		Specific setting	HS
	Morbidity		HS
	Survival/Revival	Entire cases	HS
		Specific cases	HS
	Patient attributes	Severity of disease	HS
		Percentage of elder patients	HS
		Percentage of younger patients	HS
		Patients hospitalizing in hospital (for specific term)	HS
		Number of patients with artificial respiration	HS
		Patient mix by geography and payer group	HS
		Patient enablement	HS
	Number of patients	Entire patient	HS
		Outpatient	HS
		Inpatient	HS
	Acute inpatient days		HS
	Payer mix		HS
	Inpatient admission	Specific ward	HS
	Autopsy rate		HS
	Number of operations/procedures	Entire hospital	HS
		Specific sites	HS
		Specific cases	HS
Organizational safety	Medical accidents leading to law suit rate		SQ
	Imperfect mandatory report		SQ
	Safety rules/procedures	Specific rules/procedures	SQ
Readmission/return	Unscheduled readmission	Entire cases	TM
		Specific cases	TM
	Unexpected return	Entire cases	TM
		Specific case	TM
		To specific site	TM
		Unplanned stay after daycare procedure	TM
	Unexpected stay （to specific case)		
		Unplanned stay following endoscopy	TM
	Admission from unexpected return		TM
Organizational efficiency	Throughput	Entire cases	TM
		Specific cases	TM
	Turnaround time	Entire cases	TM

		Specific cases	TM
	Operational time		TM
	Bed occupancy	Entire hospital	TM
		Specific setting	TM
	Clinical productivity		TM
	Outpatients per doctor		TM
	Emergency patients per doctor		TM
	Admissions per bed		TM
	Admitted inpatients per doctor		TM
	Acute load		TM
	Length of stay		TM
		In specific departments	TM
	Generic prescribing		TM
	New outpatients per inpatient discharge		TM
	Outpatient clinic sessions per available bed		TM
	Radiology film reject rate		TM
	Transfer time from ward to ICU		TM
	Paid hours per admission		TM
	Day surgery rates		TM
	Test results not available or test repeated unnecessarily		TM
	Went to ED for condition that could have been treated by regular doctor		TM
	Perception of inefficient care		TM
	Attendance at specialty clinics		TM
	Emergency triage times		TM
Staff efficiency	Employee Utilization		TM
	Medical productivity per medical team FTE		TM
Equipment efficiency	Equipment Utilization	In entire hospital	TM
		Of specific equipment/materials	TM
Staffing	Full-time equivalents		ST
	Full-time staff	For specific departments/cases	ST
	Staff qualification		ST
	Experience of the staff		ST
	Staff age		ST
Equipment	Available equipment	Specific machines/equipment	ST
Management process	Patient transfer	Specific cases	PR
Management process	Emergency admission	Specific cases	PR
	Observation requirement		PR
	Consultation rate	Specific cases	PR
	Discharge against medical advice		PR
Clinical process	Day case	Entire hospital	PR
		Specific case	PR
	Surgical prophylaxis		PR
	Clinical diagnosis and pathological diagnosis		PR
	Colonies developed after decontamination		PR
	Unexpected reoperation rate		PR
	Reintubation in recovery room		PR
	Patients receiving blood products		PR
	Initiation of antibiotics		PR
	Blood products transfused		PR
	Cross match/transfusion ratio		PR
Management effectiveness	Cost effective prescribing		EF
	Duration of consultation		EF

	Outpatient attendance		EF
	In time documentation of discharge summaries		EF
	Hospitalised patients with new treatment: medications reviewed at discharge		EF
	Improved access to elective surgery		EF
	Health administration costs		EF
Financial effectiveness	Financial measures		EF
	Cost/expenditure		EF
	Admission effectiveness		EF
	Cost effectiveness	Cost per case	EF
		Cost per patient day	EF
		Pay per day	EF
		Expense per relative value unit	EF
		Dental cost per dental encounter	EF
		Medical benefit cost per full-time equivalents (FTE)	EF
		Total benefit cost per full-time equivalents	EF
	Outpatient activity		EF
Safety culture	Patient safety culture		CC
Compliance	Restraint compliance documentation rate		CC
	Management compliance for safety		CC

<Assessment properties> (Healthcare outcomes) SF: Satisfaction, HS: Health status, SQ: Safety/Quality, TM: Time/Efficiency, EF: Effectiveness; (Performance shaping factors) ST: Structure, PR: Process, CC: Culture/Climate.

(4) Community perspectives

Measures	Indicators	Sub-indicators	Property
Public health	Deaths/mortality in the area	Entire area	HS
		Specific causes	HS
	Discharge and deaths in the area		HS
	Potential years of life lost		HS
	Healthy life expectancy		HS
	Self-rated general health		HS
	Justified school absence rate		HS
	Obesity		HS
	Daily smoker		HS
	Hazardous alcohol consumption		HS
	Prevalence of diagnosed diabetes mellitus		HS
	Injuries in the area	Specific causes	HS
	Adult dental registrations		HS
Health statistics in the region	Net patient flow		HS

	Procedures/operations	Specific cases	HS
	New outpatients		HS
	Total outpatients		HS
Waiting/Delay (community)	Waiting for admission		TM
	Waiting time	Specific cases	TM
	Waiting list		TM
Public access	Unit size		ST
	Available beds		ST
	Information for citizens	By specific media	ST
	GP availability		ST
	Information for GPs		ST
	Outpatient session		ST
	Visit to a private physician		ST
	Physicians per thousand population		ST
	Uncollected prescription due to cost in the previous 12 months		ST
	Oral health care service availability		ST
	Primary health care provider available within 24 h		ST
	Population over 60 min from ED		ST
	Population over 30 min from GP		ST
Effective healthcare	Day cases		EF
	Elective surgery rates		EF
	Early detection of cancer		EF
	Better help for smokers to quit		EF
	Adults with mood disorder receiving medication		EF
	Children who are receiving treatment for asthma		EF
	Diabetes not under control		EF
	Adults with Hypertension who received plans for self-management or have a nurse		EF
Cooperation with other healthcare providers	Any discharge gaps after hospitalization		PR
Preventive services	Immunizations	Flu vaccination	EF
		Childhood immunizations	EF
	Disease screen	Cervical screening	EF
		Mammograms for women	EF
		Cardiovascular assessment	EF
		Children who had one or more teeth removed due to decay/abscess /infection/gum disease	EF
		Blood pressure measurement	EF
Social accountability	Hospital's contribution to society		EF
	Board of Governors' environmental scan		EF
	Market share		EF
Community support	Community support provided per admission		EF

<Assessment properties> (Healthcare outcomes) SF: Satisfaction, HS: Health status, SQ: Safety/Quality, TM: Time/Efficiency, EF: Effectiveness; (Performance shaping factors) ST: Structure, PR: Process, CC: Culture/Climate.

APPENDIX E
Dialysis Management Questionnaire

Dialysis Management Survey

State of the art of performance indicators utilized in dialysis department of hospitals and leaders' views of their contributions to hospital management

Preface

The purposes of this survey are to portray the usage of performance measurement in the dialysis department of Japanese hospitals, and to explore further direction for "*operations management*" in healthcare organisations from their leaders' views of key performance indicators.

Effective operations management can be carried out not only with management related performance indicators such as efficiency, productivity and profitability, but also with those related patients, which are primary users in healthcare – e.g., patient satisfaction and concerns in clinical processes should be properly captured –, and those with healthcare employees – e.g., to exert themselves to work effectively in well-established work environment. For such an effective hospital management, we need to comprehensively configure key performance indicators from three major healthcare stakeholder perspectives, i.e., patients, employees and management (or operations). Applying such a framework of the key performance indicators, we are monitoring current states in healthcare outcomes and their contributing factors for managing daily healthcare operations. In addition, based on the current level and the transition of performance indicators, we can establish a strategic goal for healthcare management, its tactical plans and interventions for further improvement of healthcare operations.

This questionnaire is constructed in order to assess which indicators are used in the dialysis department of your hospital. The questionnaire is divided into three main groups of indicators, Patients, Employees and Management. There are three columns which need to be filled with information, *Usage, Organisational level* and *Usefulness.*

Responses to this questionnaire are entirely anonymous and data are thus confidential and will be analysed and presented at the level of groups only. Moreover, it will not be possible to identify individual departments or units. So, feel free to express your opinion. *Your participation in the study is valued and appreciated!*

After completing the questionnaire, please, put it into the envelope, seal it and post it *no later than two weeks* after you have received the questionnaire. Tests have shown that it takes around 20 minutes to fill out in the questionnaire. Please do not copy the questionnaire or discuss any of the questionnaire items with your colleagues before you have completed and returned your response.

We will make a survey report after we complete data analysis of all responses, and send it to a leader of your hospital (and therefore we would ask the name of your hospital only for this purpose in the last page of the questionnaire). If you have any questions, please call or write to:

Kenji Itoh, Ph.D.
Professor, Department of Industrial Engineering and Management,
Tokyo Institute of Technology
2-12-1 Oh-okayama Meguro-ku Tokyo 152-8552 Japan
Phone/FAX: +81-3-5734-2362
E-mail: itoh.k.aa@m.titech.ac.jp

Yours sincerely

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Items to be answered appear in the next page.

[Questions] You will be asked about indicators listed from the next page in terms of three aspects, *Usage*, *Organisational level* and *Usefulness*. Please select one from response options shown below for each of the aspects.

<Usage> Do you hold data related to the indicator in your organisation/department?

1	2	3	4
Yes, definitely (held as explicit data)	Yes, but implicitly (held as tacit knowledge by a leader/manger)	No (Not in use)	Unknown (Don't know)

<Organisational level> Where do you hold the data in your organization?

1	2	3	4	5
Entire hospital	All departments (clinical specialties/wards)	Some departments, including dialysis department	Only dialysis department	Unknown (Don't know)

<Usefulness> To what extend are the data required for management of your hospital/department?

1	2	3	4	5
Not at all (Even better with no data)	Probably not required	Neutral (neither required nor not)	Somewhat required	Absolutely required

The first column indicates whether or not your hospital or department currently hold the indicator. For an indicator that is not completely, but partly held at your hospital, please select 1 or 2. Please insert a tick in the leftmost column, "NA" (not applicable) for an indicator that you don't understand. If you indicate that the indicator is "*Not in use*" (3) or "*Don't know*" (4) at the hospital, the following column, "organisational level" should ***not*** be filled in. In the second column, you should indicate at which organisational level, the indicator is used or applied to hospital management. The third column should indicate whether a specific indicator is useful for management of the dialysis department regardless of whether your hospital currently holds the indicator or not.

(1) Patient related indicators

Insert one tick to "usage", "organisational level" and "usefulness" for each item listed below.

		Usage				Organisational level					Usefulness				
		1. Yes, definitely 2. Yes, but implicitly 3. No 4. Don't know				1. Entire hospital 2. All departments 3. Some departments 4. Only dialysis dept. 5. Don't know					1. Not at all 2. Probably not required 3. Neutral 4. Somewhat required 5. Absolutely required				
	NA	(1)	(2)	(3)	(4)	(1)	(2)	(3)	(4)	(5)	(1)	(2)	(3)	(4)	(5)
Patient satisfaction (multiple items in questionnaire)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Patient complaint	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Accidents/adverse events (events causing major effects to patient)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Incidents/Near-misses (events causing no or minor effects to patient)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Frequency of centesis errors	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

	NA	Usage 1. Yes, definitely 2. Yes, but implicitly 3. No 4. Don't know				Organisational level 1. Entire hospital 2. All departments 3. Some departments 4. Only dialysis dept. 5. Don't know					Usefulness 1. Not at all 2. Probably not required 3. Neutral 4. Somewhat required 5. Absolutely required				
		(1)	(2)	(3)	(4)	(1)	(2)	(3)	(4)	(5)	(1)	(2)	(3)	(4)	(5)
Nosocomial infection	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Infection of MRSA	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Infection in shunt	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Blood Infection	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Waiting time from arrival at Dialysis Room to centesis received	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Please describe below if there are important performance indicators from patient perspectives.

(2) Employee related indicators

Insert one tick to "usage", "organisational level" and "usefulness" for each item listed below.

	NA	Usage 1. Yes, definitely 2. Yes, but implicitly 3. No 4. Don't know				Organisational level 1. Entire hospital 2. All departments 3. Some departments 4. Only dialysis dept. 5. Don't know					Usefulness 1. Not at all 2. Probably not required 3. Neutral 4. Somewhat required 5. Absolutely required				
		(1)	(2)	(3)	(4)	(1)	(2)	(3)	(4)	(5)	(1)	(2)	(3)	(4)	(5)
Employee satisfaction (multiple items in questionnaire)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Paid leave	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Needle stick injury	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Staff turnover	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Overtime	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of staff per dialysis bed (based on professional group)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

	NA	Usage 1. Yes, definitely 2. Yes, but implicitly 3. No 4. Don't know				Organisational level 1. Entire hospital 2. All departments 3. Some departments 4. Only dialysis dept. 5. Don't know					Usefulness 1. Not at all 2. Probably not required 3. Neutral 4. Somewhat required 5. Absolutely required				
		(1)	(2)	(3)	(4)	(1)	(2)	(3)	(4)	(5)	(1)	(2)	(3)	(4)	(5)
Length of service (based on professional group)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Average experience at the current department	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Occupied position (based on professional group)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Expenditure on medical research	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Academic papers written, including conference papers	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Education possibilities	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of nurses & clinical engineers having dialysis staff license	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of specialists (related to dialysis)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Please describe below if there are important performance indicators from employee perspectives.

(3) Management related indicators

Insert one tick to "usage", "organisational level" and "usefulness" for each item listed below.

	NA	Usage 1. Yes, definitely 2. Yes, but implicitly 3. No 4. Don't know				Organisational level 1. Entire hospital 2. All departments 3. Some departments 4. Only dialysis dept. 5. Don't know					Usefulness 1. Not at all 2. Probably not required 3. Neutral 4. Somewhat required 5. Absolutely required				
		(1)	(2)	(3)	(4)	(1)	(2)	(3)	(4)	(5)	(1)	(2)	(3)	(4)	(5)
Mortality/Death (for specific causes)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of death/cardiopulmonary arrest during dialysis treatment	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Crude mortality rate per year	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

	NA	Usage 1. Yes, definitely 2. Yes, but implicitly 3. No 4. Don't know				Organisational level 1. Entire hospital 2. All departments 3. Some departments 4. Only dialysis dept. 5. Don't know					Usefulness 1. Not at all 2. Probably not required 3. Neutral 4. Somewhat required 5. Absolutely required				
		(1)	(2)	(3)	(4)	(1)	(2)	(3)	(4)	(5)	(1)	(2)	(3)	(4)	(5)
Elapsed years from start of dialysis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of dialysis patients per day	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of dialysis patients with hepatitis C	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Percentage of dialysis patients using ESA products	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of PTA (Percutaneous Transluminal Angioplasty) operations	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Number of shunt operations	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Dialysis bed occupancy	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Equipment utilisation (for major devices)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Full-time equivalents (FTE)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Full-time staff (based on department)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Control of haemoglobin for haemodialysis patients (Hb >11 g/dL)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Adequacy of haemodialysis (Kt/V ≧1.2)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Financial measures	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Cost/expenditure (Personnel expenditure, expenditure of medications and supplies, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Operation & maintenance cost of medical devices	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Medical benefit cost per full-time equivalents	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Outpatient activity (net outpatient revenue/net patient revenue)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Please describe below if there are important performance indicators from management perspectives.

[Organisational attributes]

1) Name of organization: _____

(We will send a report of this survey to the leader of your hospital when we complete the analysis.)

2) Organisation type: ☐ University hospital ☐ General hospital
☐ Dialysis specific hospital ☐ Dialysis specific clinic
☐ Hospital with dialysis facility ☐ Clinic with dialysis facility
☐ Other: _____

3) Ownership type: ☐ National ☐ Public ☐ Social insurance related
☐ Public benefit corporation ☐ Private ☐ School corporation
☐ Social welfare corporation ☐ Firm-belonging ☐ Practitioner
☐ Other: _____

4) Number of dialysis beds: ☐ Less than 10 beds ☐ 10~19 beds ☐ 20~39 beds
☐ 40~69 beds ☐ 70~99 beds ☐ 100~149 beds ☐ 150~199 beds
☐ 200 or more beds

[Respondent attributes]

5) Job/position: ☐ Hospital owner/management ☐ Hospital leader/director
☐ Deputy leader ☐ Secretary-General ☐ Leader of dialysis department
☐ Manager of dialysis department ☐ Risk or quality manager
☐ Other: _____

6) Working experience in the current hospital/clinic: _____ years

Pease describe your opinions about operations management in healthcare and/or any other things related to this questionnaire survey, if any.

Thank you for your cooperation!