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Safety process innovation in medical service industry

Chih-Ming Luo · Hung-Fan Chang

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Abstract Safety issues are generally ignored in the innovation of services for internal and external customers. The purpose of this study is to provide a safety mechanism framework for process innovation in medical service industry. This study applies action research to develop a safety framework for process innovation. The practicality of the proposed method is demonstrated using a case study of Cesarean sections in Taiwan. The proposed step for safety process innovation and safety process innovation framework (SPIF) were verified by eight experts and tested with Delphi. The most important concept concerning SPIF is that it provides a clear framework for evaluating the risk of potential failure in each subsystem of process in innovation.

Keywords Medical service industry · Risk assessment · Action research · Safety process

1 Introduction

Innovation is essential to the creative value of any company. An enterpriser cannot survive in today's competitive market without innovation. However, most companies focus their resources on innovations in technology, new products and IT, ignoring safety in the process innovation of services for internal and external customers.

Medical service is a knowledge-intensive professional industry and medical professionals are highly respected and trusted. However, the Institute of Medicine's (IOM) report on medical errors, "To Err is Human" (Institute of Medicine (IOM) 2000), showed that at least 44,000

C.-M. Luo
SHI CHIA Industry Group Co. LTD.,
35, Cai Hong Road, Qing Gang Industry Area, Suzhou City, Jiangsu, China
e-mail: arthurmetoo@gmail.com

H.-F. Chang (✉)
Institute of Management of Technology, National Chiao Tung University,
1001 University Road, 300 Hsinchu, Taiwan, R.O.C.
e-mail: hfchang.mt98g@nctu.edu.tw

people died of avoidable medical errors, and that the number may be as high as 98,000. Medical service is not error-free or zero-risk. The publication of this report motivated a review of, and an emphasis on, patient safety in the provision of healthcare by the medical service industry.

The IOM report indicated that other high-risk industries, such as the aviation and nuclear energy industries, have already developed error-prevention management theories and solutions (Institute of Medicine (IOM) 2000). Some similarities exist between the medical and aviation industries: they both rely strongly on complex systems that require interaction between people and high technology. The medical industry can learn something from the aviation industry's failure theory, its family reporting system and its cabin crewmember resource management system.

Process innovation is a very important concept for the manufacturing and service industries and its potential is becoming recognized. Process innovation theory has been developed over the past 20 years, especially since the Hammer (1990) and Davenport (1993) papers were published. Davenport (1993) defined **process** as "a process is simply a structured, measured set of activities designed to produce a specified output for a particular customer or market". It implies a strong emphasis on ***how*** work is done within as, in contrast to a product focus's emphasis on ***what***. Davenport (1993) defined **process innovation** as "combines the adoption of a process view of the business with the application of innovation to key processes". Process innovation is a radical redesign of a process to achieve dramatic improvements in critical areas, such as cost, quality, speed and efficiency.

However, process innovation may be lack safety considerations. Cheng and Yeh (2004) proposed a new airline safety index that included four dimensions: management, operations, maintenance and planning. They argued that those concepts of safety process were of critical importance. Customers and businesses have accepted the concept of product safety that it is important, but proper action has not been taken on process safety because of the lack of safety considerations. Additionally, no realistic framework has been established that combines innovation and safety information (Tang et al. 2005). Thus, this study will concentrate on a more managerial concept for a safety process innovation framework (SPIF). This study emphasizes the importance of safety in innovation in the medical service industries.

This paper is structured as follows. Section 2 presents literature review. Section 3 presents the methodology for requirement analysis, planning and design of the research framework for SPIF. In Sect. 4, we present the logic of the SPIF. Section 5 purposely selects a case study of Cesarean-Section clinical pathway in a medical center in Taiwan to validate the differentiation between QFD and SQFD. Section 6 presents the results are discussed. Conclusions, limitations and suggestions for future work are all reported in the last section.

2 Literature review

Research on the information of customers' needs domain in process design has been mounting steadily for a number of decades. Quality function development (QFD) is typically adopted to investigate the needs of customers to enable products or service operations to suit them better (Belhe and Kusiak 1996). QFD is applied not only to investigate customers' needs to drive innovation, but also to reduce the risk that employees will resist innovation. However, the main problem associated with in the adoption of QFD in innovation is the lack of a built-in safety mechanism.

Systematic reliability analyses have become very important in recent years. Failure modes and effects analysis (FMEA) is a systematic process of reliability analysis (Teng 1996).

FMEA is a formal problem prevention methodology applied in the engineering of systems, products and processes. It is mainly adopted in industrial production of machinery, automobiles, airplanes and electronic components.

FMEA improves the operational performance of production cycles and reduces their overall risk of process. The global value of the damage caused by each failure is assigned a risk priority number (RPN). RPN is an index that is the product of three other indices–***Severity (S), Occurrence (O)*** and ***Detection (D)***. It is a number from 1 to 1,000). **Severity** is an assessment of the seriousness of the potential failure to the customer. **Occurrence** is the assessment of the projected frequency of the failure. **Detection** is the probability that the process-monitoring system will detect the cause of the failure before the process is released for service and the risk can reach the customer. RPN is defined as,

$$RPNi = Si \times Oi \times Di$$

where: S_i: item**i** of parameter S (***Severity***); O_i: item**i** of parameter O (***Occurrence***); D_i: item**i** of parameter D (***Detection***).

As a guide to evaluating these parameters, the FMEA team defines numerical scales that are adapted to the particular risk situation of the system (Stamatis 1995). Accordingly, every failure can be assigned a risk value. Risks are generally ranked from 1 to 10. Therefore, the SPIF analyzes the cause and effect of potential failures in each subsystem or component of the process. The information on reliability is fed back in to the QFD system to enhance the reliability of innovation. This study will overcome the QFD's lack of a built-in safety mechanism by introducing the SPIF.

One of the problems that have caused process innovation to fade as an approach to improving business processes is the lack of a clear framework for accomplishing it. A review of the literature fails to find any consensus on process innovation (Love and Gunasekaran 1997; Martinez-Ros 2000; Terziovski et al. 2003). Although there is general agreement on the theoretical approach outlined by Hammer (1990), Hammer and Champy (1993) and Davenport (1993). There is considerable disagreement among researchers about the implement step of the process innovation.

Love and Gunasekaran (1997) summarized eight steps for process innovation after reviewing a number of important studies: 1. State a case of process reengineering; 2. Establish process objectives; 3. Identify the process for reengineering; 4. Understand and measure the current process; 5. Identify and evaluate the enablers; 6. Create and design a new process; 7.Test the new process; and 8. Implement the reengineered process. However, there are different steps to process innovation according to different authors; for example, Davenport (1993) proposed six steps: 1. Select key process; 2. Identify process for innovation; 3. Identify change levels; 4. Develop process vision; 5. Understand existing process; 6. Design and prototype new processes. Gover and Kettinger (1998) proposed seven steps: 1. Commit to reengineering; 2. Analyze opportunities; 3. Decide on strategy, priority, sponsors, control process; 4. Design new a process; 5. Implement the new process; 6. Revise the new process; 7. Monitor improvement efforts. The steps of safety process innovation were validated by expert team A and were compared to the views of a number of researchers in Table 1. Expert team A was composed of eight experts including two general managers of public company, three senior process design and safety consultants, and three management professors.

Researchers disagree markedly about safety in innovation. Relatively little research has been conducted into safety in innovation. A review of the literature on innovation clearly shows that no study provides safety mechanisms in innovation that have actually been adopted to increase the safety of process. SPIF is intended to support the evaluation of safety in

Table 1 The step of safety process innovation

Steps	Hammer and Champy (1993)	Davenport (1993)	Love and Gunasekaran (1997)	Gover and Kettinger (1998)	Changchien and Shen (2002)
Phase I: Before PI					
1. Top managers commitment	Communicate the case for action (2)		State a case of process reengineering (1)	Commitment to reengineer (1)	
2. Build PI project team	Assign people to BPR team (3)				
3. Select core process	Select process (1)	Select key process (1)			Core process identification (2)
4. Recognize the need to change		Identify process for innovation (2)	Identify the process for reengineering (3)	Analysis of opportunities (2)	
5. Benchmarking					
6. Setting PI goal & strategy	Create a vision of the new process (5)	Develop process vision(4)	Establish process objectives (2)	Decide on strategy, priority, sponsors, control process (3)	Vision and objectives creation (1)
Phase II: Undergoing PI					
1. Evaluate exist process		Understanding existing process (5)	Understand and measure current process (4)		Current process analysis (3)
2. Build QFD to define customer requirements of PI					
3. Build FMEA to define safety			Identify and evaluate the enablers (5)		

Table 1 continued

Steps	Hammer and Champy (1993)	Davenport (1993)	Love and Gunasekaran (1997)	Gover and Kettinger (1998)	Changchien and Shen (2002)
4. Specify the need to change	Call redesign meeting (4)	Identify change levers (3)			
5. Redesign process	Redesign the process to achieve the vision (6)	Designing and prototyping new process (6)	Create and design a new process (6)	Design new process (4)	Innovative reengineering (4)
Phase III: After PI					
1. Test/ implement new process	Implement the new process (7)		Test the new process (7); Implement the reengineered process (8)	Implement the new process (5)	Evaluate new processes (5)
2. Revise new process to meet goal				Revise new process(6)	New process selection (6)
3. Modify process through continuous improvement				Monitor improvement efforts (7)	Transformation and Implementation (7)

* Number in parentheses indicate the original sequence of step by authors

innovation in service processes. This study summarizes two important points from the literature review in Table 1: they lack a clear framework and they have no clear mechanism for safety in process innovation. SPIF is intended to support the assessment of innovation in safety and methodology in medical service processes. This study proposes a SPIF that defines essential safety when performing process innovations, and can be used to enhance safety linked to process innovation. The purpose of this study is to providing a safety mechanism framework for process innovation. This study applies action research to build a safety framework for process innovation.

3 Methodology

In this study we present a framework for linking customers' requirements and mechanism of prevent risk in the process innovation. The practicality of the proposed methodology is demonstrated through a case study. Holter and Schwartz-Barcott (1993) reported that action research methodology has the following characteristics: 1. new knowledge emerges through the cooperation of the researcher and the interviewee, 2. the resolution of real daily-life problems, 3. status quotes change, and 4. theory development. With the goal of improving the safety of process innovation and promoting customer safety, this study developed an SPIF using action research to cooperate with clinical professionals using interviews, Delphi, QFD and FMEA methods. This study used Triangulation to test the SPIF. Eight experts verified the steps for safety process innovation and SPIF proposed in this study, and were tested using Delphi (expert team A). Secondly, this study compares Safety QFD (SQFD) to QFD using a case study to check for significant differences between SQFD and QFD. Finally, this study invited four senior professionals to evaluate and validate the clinical contribution of the SQFD (expert team B).

3.1 Data collection

This study targets process innovation and safety-related literature and theories. This study employed two methods of data collection, literature review and in-depth interview.

3.2 Literature review

Articles from databases about process innovation, process design, process safety and reengineering were reviewed. The databases included SDOS-AP/ES, BSP/EBSCO host, COMPENDEX and Medline. All articles reviewed were published from 1990 to 2008.

3.3 In-depth interview

The in-depth interview is a non-structured interview. The interview targeted research-related subjects in order to understand the interviewees' views on and interpretations of certain topics (Babbie 1998). Johnson (2002) believed that in-depth interviewing means seeking "deep" information and understanding. Based on Babbie (1998) and Johnson (2002) points of view, a successful in-depth interview requires the researcher to have a clear understanding of the research object and to understand the interview questions and the information that the study intends to gain. The first phase interviews were carried out between October and December 2008. Tables 2 and 3 are in-depth interview questionnaire outlines.

Table 2 Medical professional (expert team): in-depth interview questionnaire

Questions	Purpose
1. Which items are required for C-Section process safety?	1. To understand internal customer' requirements
2. Which of the following happens most during C-Section: incident, near miss or adverse event?	2. To understand C-Section process risk information
3. How is C-Section process patient safety measured?	3. To understand how to evaluate C-Section process safety
4. What are the indicators of C-Section process safety?	4. To understand C-Section process safety indicators and the current status
5. How is C-Section process incidents prevented?	5. To understand the current situation of clinical process safety prevention
6. What is your view of IOM's (2000): "To Err is Human"?	6.To understand their views on process safety and patient safety

Table 3 Cesarean-Section patient in-depth interview questionnaire

Questions	Purpose
1. Which items are required for C-Section process safety?	To understand external customer needs
2. What is your most basic requirement for a C-Section process?	
3. What are your C-Section experience and feelings?	
4. What are your suggestions for C-Section process safety?	
5. What C-Section processes are you not happy with?	

3.4 Reliability and validity

In social science research, Triangulation is the use of different measurement tools to cross-examine the same variable or data (Neuman 1997). This study adopted two senior expert teams to validate (expert team A validated our steps for safety process innovation and SPIF; expert team B validated the practical value of the SQFD model) its methods, and executed a case study to compare QFD with SQFD absolute weight calculation results. If the measurement results from the three tools are highly consistent, it means the SPIF has high validity. This study used the following methods to attain the content validity required for the Cesarean-Section clinical pathway safety process:

1. The Cesarean-Section clinical pathway safety process requirement originated from Harvard Medical Practice Study (Leape et al. 2002). Since a Cesarean-Section clinical pathway is a surgical operation, the safety requirement needed for surgical operations should also extend to the Cesarean-Section clinical pathway operation, but require further modification.
2. The first phase of the in-depth interviews with six medical professionals and five patients who had received Cesarean-Section clinical pathway operations, see Tables 2 and 3.
3. The initial Cesarean-Section clinical pathway safety process requirements were gained through review of the literature and, after a second phase of five more in-depth interviews with medical professionals including discussions regarding the addition or deletion of the first phase initial requirement items, the Cesarean-Section clinical pathway process information that required for this study was accumulated.

This study adopted Lincoln (1995) argument that qualitative research should use the trustworthiness principle to replace quantitative research's reliability and validity principles. In other words, the research should describe the research process details to help the audience understand how the research data were obtained; the information obtained regarding the research objects, and the time and location of the study, with the hope that the audience can understand the description and exercise its own judgment regarding the credibility of the study. Kvale (1995) pointed out that the practicality generated from research is also an important factor in determining validity. Based on the above theories, the subjects of this study are described below.

1. Senior clinic workers as interviewees: Senior medical clinical professionals as interviewees can increase the credibility of the research as per Benner and Tanner (1987)–their research required 5 years of experience for nursing professionals. This study has four stages of professional group interviews; the average experience for the professional groups varied from 21.5 years (Expert team B) to 11.5 years. The least experienced subject was a gynecologist-obstetrician with 6.5 years; and the most experienced had 32 years of experience.
2. Medical professionals as interviewees: The medical professionals came from 10 Taiwan hospitals and included nine gynecologist-obstetricians, two anesthetists, two anesthetic technicians, two head nurses, five nurses, four nursing specialist practitioners and one Cesarean-Section clinical pathway lecturer and designer.
3. The interview methods varied for different interview purposes and phases. In addition to face-to-face interviews, follow-up phone talks and e-mails were also used in the content validity test stage, as it involved the Delphi method, in order to get the complete data.

4 The logic of the safety process innovation framework

This section describes how FMEA was integrated with QFD to develop SPIF. The results of FMEA are integrated into the QFD system to enhance the safety of process innovation. The most important concept of SPIF is the evaluation of the risk of potential failures for every subsystem in process innovation. This information is fed back to the QFD system to enhance the reliability of innovation. The integration of FMEA results in the QFD system is critical. QFD can use the characteristic FMEA results, which also include results concerning all those preventive measures that are considered regarded as basic elements in determining the reliability of innovation.

Papinniemi (1999) proposed a model that introduced the basic relationships among the source, object and performance characteristics of process innovation at a conceptual level. This model of process innovation provides a clear framework, but neglects safety. Silva et al. (2004) proposed a model that claimed that the quality function deployment with value analysis (QFDVA) was a new tool obtained from the integration of the QFD and the VA. The concept of QFDVA is the joint use of the QFD and VA to define essential elements when developing products. The QFDVA aims at fulfilling consumer requirements and supplying financial decision parameters that are based on formal company engineering terms, but still lacks safety considerations for product innovation. Chan and Lewis (2000) developed a model in which manufacturing and cost information is integrated into the engineering design process, but they also neglected safety considerations in process redesign. Aldakhilallah and Ramesh (1998) proposed an integrated framework for automated process planning, but also failed to consider safety in process redesign.

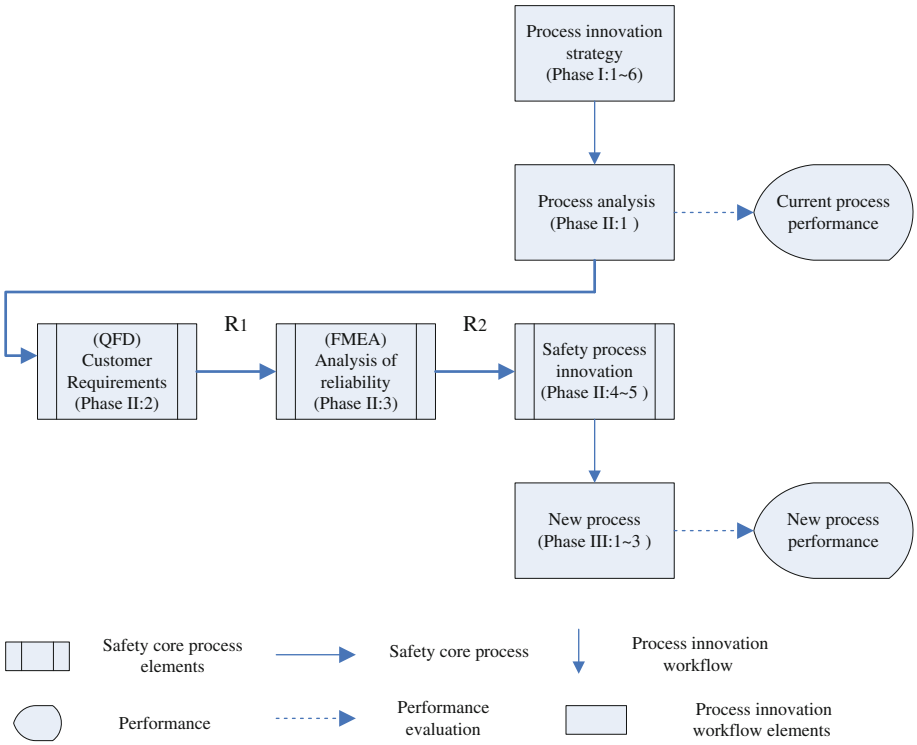

Fig. 1 Structure of the SPIF

For the above reasons, the logic of this study follows Papinniemi (1999) frame of process innovation and Cantamessa and Villa's (2000) concept of concurrent engineering, and integrated QFD and FMEA to make SPIF in order to define essential safety concerns when pursuing process innovation. This study stresses not only the importance of clear step and framework for safety process innovation but also the importance of process safety as a concept.

4.1 Structure of the SPIF

Figure 1 is summarized from Table 1. Figure 1 illustrates the structure and elements to be examined in accordance with the SPIF. This framework includes two main process flows.

1. The top-down flow is called the process innovation workflow and the process innovation workflow elements include process innovation strategy, process analysis, safety process innovation and new process.
2. The flow from left to right is called the safety core process and describes the relationships between the ***QFD, FMEA*** and ***Process Innovation*** in the safety core process.
3. The performance includes two parts: one is current process performance, and the other is innovation process performance. There are three factors essential to the evaluation of project management: cost, time and performance. This study stresses the importance of process safety.

4.2 Process innovation workflow

The process innovation workflow in this model consists of four elements: process innovation strategy, process analysis, safety process innovation and outcome.

1. Process innovation strategy drives the organization's guidelines for the development of projects of process innovation.
2. Analysis of the current process is performed for selected process sequences. It is important to understand an existing process before implementing safety process innovation. The purpose of the process analysis is to evaluate the pros and cons of the current process, especially with regards to safety, and produce a performance description of process.
3. In this study, safety process innovation is a core procedure; it is produced by the safety core process and discussed in the safety core process section. This is the main subject of this study.
4. Outcome elements show the potential results of the innovation procedure.

After assessing the process innovation workflow procedure, we can carry out the process innovation plan and begin to implement the safety core process.

4.3 Safety core process

Safety in innovation is equivalent to the customer core value process, because it leads safety innovation throughout QFD and FMEA. In safety innovation, elements of SQFD are adopted to determine customer requirements using QFD, and evaluate risk of process using FMEA, to generate reliability information to support the innovation of a complete between safety and process. The safety in innovation consists of three elements-application of QFD to determine customer requirements, application of FMEA to analyze the components of the reliability of process, and application of safety in innovation.

1. This study uses the QFD methodology to investigate internal customer requirements in the safety process innovation phase. The goal of this procedure is to enhance customer satisfaction. QFD can be adopted not only to investigate customers' need for process innovation but also to reduce the risk that employees resist process innovation.
2. The reliability analysis element shows a number of candidates for innovation activity in every key component. This study uses FMEA to evaluate the reliability of process in this phase. The purpose of reliability analysis is to reduce operations risk of process for safety in innovation.
3. The element of safety in innovation integrates the above information in customer requirements and process risk to evaluate a complete innovation. Safety innovation depends on a pool of candidate innovation activities. Based on reliability and customer requirements, the innovation project team selects the safety goods/processes components of process innovation.

4.4 Systemically building the reliability information feedback system

The goal of this step is to evaluate the risk of processes using the FMEA procedure and to feedback reliability information to the QFD matrix. For the purposes of this study, the integration operates on three columns of process innovation associated with the reliability information from the process in the QFD matrix, which are RPN_j, Risk value (R_j) and SQFD (SAW_j). This procedure is called SQFD, as shown in Table 4. The results of the FMEA evaluation will then be fed back to the QFD system. The SQFD promotes the innovation by

Table 4 SQFD for Cesarean-Section clinical pathway

VOP	Safety Validation				Medical safety				Medication safety		Others	Qi
	Validated by nurses	Validated by examiners	Validated by equipment	Biochemical test	Applicability to operations	Patient ID verification	Doctor's professional skills	Vital sign check	Validated by pharmacists	Validated by nurses	Patient fall	
VOC	1	2	3	4	5	6	7	8	9	10	11	
Patient safety	●	●	●	△	●	●	●	●	●	●	●	5
Newborn safety	○	○	○	△	●		●	●	○	○	△	5
Examination safety	●	●	●	●	○	●						4
Medication safety	△	△				●	○		●	●		5
Operating efficiency							○					2
AW_j Weighting	101	101	96	46	102	126	111	90	105	105	50	
Ranking	**6**	**6**	**8**	**11**	**5**	**1**	**2**	**9**	**3**	**3**	**10**	
RPN_j =2013	448	288	210	50	180	50	50	50	343	294	50	
Risk value (R_j)	0.22	0.14	0.10	0.02	0.09	0.02	0.02	0.02	0.17	0.15	0.02	
SQFD(SAW_j)	22.48	14.45	10.01	1.14	9.12	3.13	2.76	2.24	17.89	15.34	1.24	
Ranking	**1**	**4**	**5**	**11**	**6**	**7**	**8**	**9**	**2**	**3**	**10**	

Note The corresponding relationship of VOC and VOP ● score 9; ◯ score 3; △ score 1

Table 5 Comparing QFD with SQFD absolute weight calculation

QFD	SQFD
$AW_j = \sum_{i=1}^{n} r_{ij} Q_i$	$SAW_j = R_j \sum_{i=1}^{n} r_{ij} Q_i$
$j = 1 \ldots m$	$R_j = \frac{RPN_j}{\sum_{j=1}^{m} RPN_j}$
AW_j: Absolute weight of the jth column	R_j: The jth item risk value of the FMEA
r_{ij}: The weight relationship in the matrix	RPN_j: The jth item value of the RPN of the FMEA
Q_i: Quality important degree of customer requirements of the i row.	SAW_j: Safety absolute weight of the j column (j=1,…, m)
m: The item of the process design requirements deploy	
n:Customer requirement item.	

evaluating the impact of each failure on the final quality of operations, and prevents failures of goods/processes that influence customer satisfaction.

Traditional QFD and SQFD have different absolute weight value calculations, as presented in Table 5. In this study, SQFD used R_j in the matrix to address the reliability information column while traditional QFD was adopted to calculate the absolute weight.

5 Case study

Hospitals are complex systems, which depend markedly on human performance. Improving process safety in hospitals is not simple, but it is important. (Warburton 2005) The US Institute of Medicine (IOM) estimates that 44,000–98,000 Americans die annually from preventable errors in hospitals (Institute of Medicine (IOM) 2000). Numerous more patients suffer from non-fatal errors; the IOM estimates the costs of deaths and injuries at between $17 and $29 billion US dollars per year in the US (Institute of Medicine (IOM) 2000), and the UK Department of Health estimates that 850,000 adverse events occur annually in hospitals, adding an estimated G2 billion to hospital costs (Expert Group on Learning from Adverse Events in the NHS (EGLAE) 2000).

Based on the above reasons, this study will target the safety process design of Cesarean-Section clinical pathway, as they involve both operating rooms and OB/GYN. The goal of the clinical pathway project at hospitals as it related to obstetrics and gynecology was to reduce clinical practice variance for the diagnostic-related group (DRG) Cesarean-Section clinical pathway with complications and ultimately decrease length of stay and hospital costs associated with this DRG.

A Cesarean-Section clinical pathway in a medical center in Taiwan was used to differentiate between QFD and SQFD. To determine process reliability, related operations must first be analyzed to elucidate the interactions in the system. The block diagram of the Cesarean-Section clinical pathway process includes three levels of reliability: the first is the system level; the second is the sub-system level, and the third is the process operation level. The system herein work refers to a Cesarean-Section clinical pathway process. Four sub-systems, 1. delivery room (DR), 2. operating room (OR), 3. post-anesthesia recovery room (PAR), and 4. postpartum ward (Ward), are considered (see Fig. 2).

The Cesarean-Section clinical pathway process is analyzed to differentiate between QFD and SQFD. Five items were identified from the voice of customers (VOC). They were patient

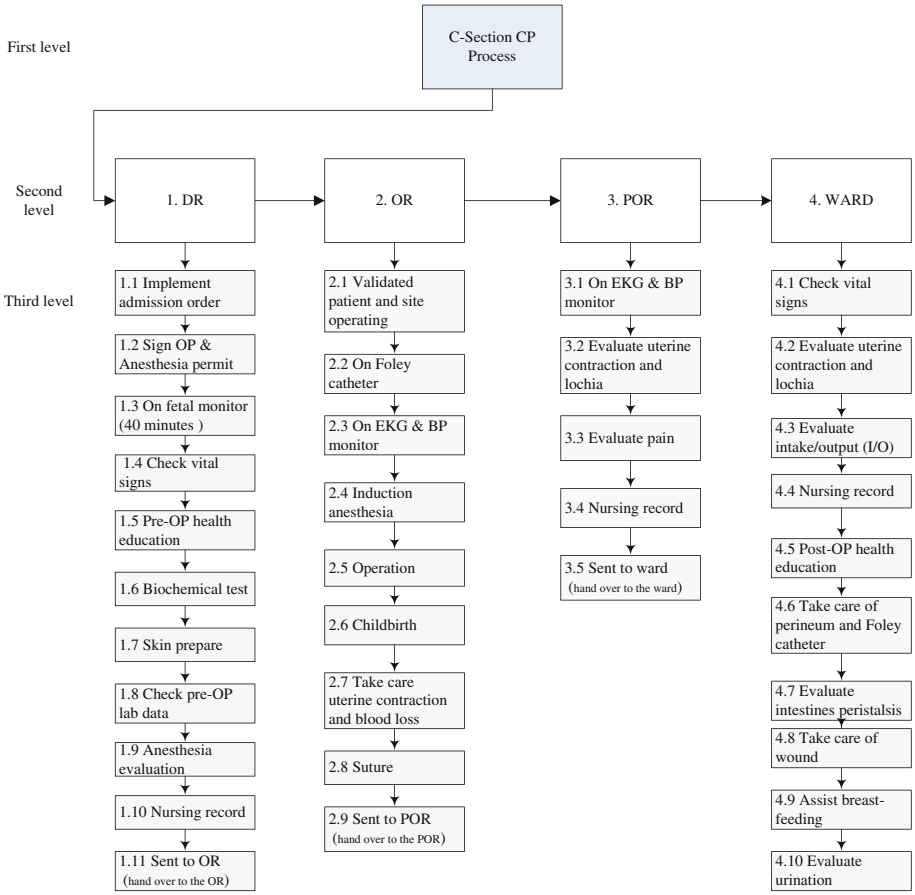

Fig. 2 Reliability block diagram of Cesarean-Section clinical pathway process

safety, newborn safety, examination safety, medication safety and operating efficiency. Four categories and 11 items were identified from the voice of process (VOP). They were safety validation, medical accuracy, medication safety and other (see Table 4 for details).

The importance of the customer-demanded quality (Q_i) was determined by the participating medical professionals and patients. They judged the importance of each item based on their own needs for quality of process. A higher score indicates greater importance to the assessor. The maximum score was 5.

Absolute weighting (AW_j) was calculated as $AW_j = \sum_{t=1}^{n} r_{ij} Q_t$, where

AW_1 (validated by nurses): $9 \times 5 + 3 \times 5 + 9 \times 4 + 1 \times 5 \times 101$

After FMEA evaluation of the common requirements of VOC and VOP, the items that affected process risk information were fed back to QFD following risk analysis. If a risk of impact applied, then the Process Risk Value (R_j) was entered into the FMEA R_j column of SQFD. If no risk of impact existed, then $RPN_j = 50$ was entered Table 4.

Nine OB/GYNs and two doctors from the Patient Safety Committee were invited to perform the FMEA professional evaluation in this case study. The risk value of each process was obtained from a calculation that involved the RPNs from the 12 professionals using the

formula $\mathrm{RPN}_i = \mathrm{S}_i \times \mathrm{O}_i \times \mathrm{D}_i$, where S is Severity, O is probability of Occurrence, D is probability of Detection, each ranked on a scale from 1 to 10. The risk value was calculated as the summation of RPN_j, which from Table 4 was 2013.

$$\mathrm{RPN}_1(\textbf{validatedbynurses}) = \mathrm{S}_1 \times \mathrm{O}_1 \times \mathrm{D}_1 = 8 \times 8 \times 7 = 448$$

Safety absolute weighting (SAW_j) was calculated as $\mathrm{SAW}_j = \mathrm{R}_j \sum_{i=1}^{n} r_{ij}\mathrm{Q}_i$, and the process risk value was calculated as $\mathrm{R}_j = \frac{\mathrm{RPN}_j}{\sum_{j=1}^{m} \mathrm{RPN}_j}$ follows:

SAW_1 (validated by nurses):

$$R_1 = \frac{\mathrm{RPN}_j}{\sum_{j=1}^{m} \mathrm{RPN}_j} = \frac{448}{2013} = 0.22$$

$$\mathrm{SAW}_1 = 101 \times 0.22 = 22.48$$

The ranking of the items in Table 4 was changed. Three elements in the process differed markedly between QFD and SQFD. They were items 1, 6 and 7, which were **validation by nurses**, **patient ID identification of medication** and **doctor's professional skills**. After the FMEA evaluation, the risk value of the process requirement factor (VOP) was incorporated simultaneously with the quality of VOC into the process design to improve process safety.

The knowledge required to build safety into the process cannot be gained without the help of the employees who are most familiar with the process. The SQFD results required further validation to see whether there were significant differences in the QFD results. Kvale (1995) pointed out that the practicality generated from research is also an important factor to determine validity. Expert team B, which included two senior nursing experts and two senior OB/GYN directors with an average of 21.5 years of experience, examined the factors for validity. A summary of the comments made by the team regarding SQFD is shown in Table 6.

6 Discussion

Papinniemi (1999) proposed a model that introduced the basic relationships between the sources, object and performance characteristics of process innovation at a conceptual level. This model provides process innovation with a clear frame, but lacks a clear step and safety considerations for process innovation. There was a general lack of agreement in the literature regarding the procedure for process innovation, and most methods lacked a safety mechanism. This study proposes a clear step that includes three phases and 14 steps to implement a safety process innovation by validity expert team A. The present study enhances the previous studies' findings of process innovation by providing a much more detailed steps and a safety mechanism of process innovation.

The results suggest that SQFD may be having an advantage over QFD in prevent risk factor of process innovation. These data may be lending support to that idea. Three elements in the process differed significantly between QFD and SQFD: items 1, 6 and 7, which are validation by nurses, patient ID identification of medication and doctor's professional skills. These differences have many possible explanations. Two OB/GYNs doctors reviewed these differences.

The validation by nurses requirement in the Caesarean-Section clinical pathway had the highest ranking: it had a QFD ranking of 6 but a SQFD ranking of 1. This process risk ranking is reasonable for clinical situations in Taiwan. According to the National Health Insurance System, the working environment of nursing staff has become difficult, because

Table 6 Confirm practical value on SQFD from experts team B

Experts	Are the C-Section risks presented?	Comments
Expert A	Yes	1.Very thorough research results 2. Larger contributions could be made if it were to be applied to nursing management 3. As the QFD is too difficult for medical people to understand, it may need further evaluation 4. Is it possible to come up with a more simplified SOP for reference?
Expert B	Yes	1. It's a study with practical value 2. Both process safety and patient safety are important subjects and the medical treatment industry does lack solid methods to follow up. Commonly used methods are QCC, SOP, PDCA and HFMEA 3. If the study chose higher risk medical treatment flow as the research objective, it ought to have more obvious results with better contributions
Expert C	Yes	1. Very concrete research results. It's much needed clinically 2. This study focused on patient safety and process safety and tried to provide risk process information to help managers, process designers, and medical professionals with risk prevention
Expert D	Yes	1. The study is very interesting with practical value 2. The researcher does not have medical background, but was able to perform such a thorough and deep C-Section process analysis. I greatly respect the research 3. It will be more beneficial if similar medical flow research can be applied to the area of women's cancer

of reduced pay and an increased workload. For example, a nurse in Taiwan takes care of an average of 12 patients at one time, whereas in the USA, a nurse may care for an average of 3.4 patients. Sometimes, even postpartum nurses can make mistakes. One possible source of error is the similarity in the appearances of several postpartum medicines, which cause problems in distinguishing among them. The other possible source of error is in dispensing: nurses may make dispensing mistakes, thinking that medications are just oral antibiotics that will not have serious effects. This factor causes incidences that include near misses and adverse events. An adverse event is defined as an event that results in unintended harm to the patient by an act of commission or omission, rather than by the underlying disease or condition of the patient (Institute of Medicine (IOM) 2004).

The ranking of the safety requirement that the patient identifies medication in the Cesarean-Section clinical pathway fell from a QFD rank of 1 to an SQFD rank of 7, and the ranking of the doctor's professional skills fell from a QFD rank of 2 to an SQFD rank of 8. These rankings are reasonable in clinical situations. The patient's identification of medication and the doctor's professional skills and human factors that were of great concern after the publication of the JCAHO's report on sentinel events and the IOM's report, "To Err is Human" (Institute of Medicine (IOM) 2000). The low risk information regarding patient identification of medication was evaluated using FMEA and fed back into the process redesign.

This study stresses not only the importance of clear step and framework for safety process innovation but also the importance of process safety as a concept. The proposed SPIF allows

the requirements of the customer to be integrated into the QFD and FMEA of a process innovation. By including these customer-oriented process characteristics in the process innovation and ensuring that they are used to assess the reliability of the new process, the new process will then be both customer and safety oriented. The reliability test carried out in the process development phase tested not only the reliability of the process but also of the safety.

7 Conclusions, limitations and suggestions of the study

Customers' wants and needs have to be translated into the process design phase when pursuing process innovation and the reliability of each element of the core process should be considered in process innovation. The satisfaction of the customer may be susceptible to each element in the process, not just the final outcome of the process. When developing a new process, it is difficult to increase problem detection before the service or product is delivered to customers in order to guarantee maximum consumer satisfaction. This involves diverse aspects that need to be considered and that appear to be answered by SPIF. The process-planning phase in the SPIF sequence served to enhance reliability and safety for the new process design. The case study reported in this article have demonstrated that the SQFD can be practically implemented and provide adequate results. This study has indicated that it might be a fruitful line of continued inquiry for SPIF. From this study, managers may gain insights into the steps and safety considerations of process innovation and ways to integrate these insights into their managing.

7.1 Limitations and suggestions of the study

In this study we present a framework for linking customers' requirements and mechanism of prevent risk in the process innovation. The practicality of the proposed methodology is demonstrated through a case study. We acknowledged that our research is exploratory and that there are problems with the research scope and limitation on the experts involved. In addition, it is important to emphasize that methodological problems in the research design limit our interpretations. Since the study involved only covers four sub-systems of Cesarean-Section clinical pathway case study, the results cannot be generalized. However, the safety process innovation framework of this study could be useful to managers responsible for process planning in process innovation.

7.1.1 The research scope

This case study focuses only on the four departments of Cesarean-Section clinical pathway process safety: DR, OR, PAR and Ward. Other supporting departments like laboratory medicine and the pharmacy are not discussed in this study.

7.1.2 Limitation on the experts involved

Due to research time limitations, this study limited its scope to the DR, OR, PAR and Ward departments. Therefore, only experts directly involved in those four departments were invited to comment, such as nurses, nurse heads, nurse specialist practitioners, OB/GYNs and anesthetists. Other experts such as pharmacists and laboratory technicians were purposefully uninvited. As the literature review suggests, this study includes discussions of medication errors and laboratory medication test errors. But without expert pharmacists and laboratory technicians to make proper judgment, the related research results are potentially biased.

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