A Framework for Quality Improvement and Evaluation of a Clinical

Decision Support System in NICU Environment in Cross-Cultural Settings

By

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A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of

Master of Health Science

In

The Faculty of Health Sciences Program

University of Ontario Institute of Technology

November 2013

Statement of Authentication

I certify that this thesis is submitted to partial fulfill the requirements for the Degree of Master of Health Sciences in Health Science program at the University of Ontario Institute of Technology. The work presented in this thesis is my original work otherwise is referenced and acknowledged. This document has not been submitted either in full or in part at this or any other academic institution to meet requirements for any degree.

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Abstract

The primary purpose of this quality improvement research is to design a structured study to improve clinical process and outcomes in healthcare. This thesis presents a framework for quality improvement and evaluation of a clinical decision support system in cross-cultural settings. The framework extends a SPO model to a SPOE model, combines with the CRISP-DM model and the Patient Journey Model Architecture (PaJMa); with the purpose of providing a new approach for quality improvement in a NICU environment and evaluating the effectiveness of the CDSS which was implemented as a tool to support the quality improvement research. The approach is extending mining of physiological data in real-time to develop a new clinical practice model that can be used to improve the process of caring, provide patient-central care, support clinical decision- making, and increase efficacy in acute care settings. This thesis demonstrates the framework within the neonatal care units through a case study of late onset neonatal sepsis in Canada and China, uses the CRISP-DM for the process mining and PaJMa for presentation of routine clinical practice and clinical process improvement. This research is extending McGregor's research "A process mining driven framework for clinical guideline improvement in critical care" in 2011.

Keywords: quality improvement, clinical decision-making support, neonatal intensive care environment, cross-cultural settings, SPOE, CRISP-DM, PaJMa

Acknowledgement

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Table of Abbreviations

AAP: American Academy of Pediatrics

ANN: Artificial Neural Network

BP: Blood Pressure

CBC: Canadian Broadcasting Cooperation

CDSS: Clinical Decision Support System

CPS: Canadian Paediatric Society

CIHI: Canadian Institute for Health Information

CIS: Clinical Information System

CRISP-DM: CRoss Industry Standard Process for Data Ming Methodology

DSS: Decision Support System

DDSS: Diagnostic Decision Support System

ECG: Electrocardiogram

EPR: Electronic Patient Record System

HIS: Hospital Information System

HR: Heart Rate

ICU: Intensive Care Unit

IT: Information Technology

LONS: Late Onset Neonatal Sepsis

NICU: Neonatal Intensive Care Unit

PaJMa: Patient Journey Modeling

PDSA: Plan-Do-Study-Act

QI: Quality Improvement

RCT: Randomized Controlled Trial

RR: Respiratory Rate

SPO: Structure-Process-Outcome

SPOE: Structure-Process-Outcome-Evaluation

SpO$_2$: Blood Oxygen Saturation

WHO: World Health Organization

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Chapter1: Introduction

This thesis presents a framework for the implementation and evaluation of clinical decision support systems (CDSSs) to support and measure quality improvement (QI) in healthcare. It enriches quality improvement using techniques from patient journey modelling (PaJMa) and knowledge discovery. The framework is demonstrated in this research through a case study in a neonatal intensive care unit (NICU) in cross-cultural settings. The overall goals and objectives of the research are to define a framework for QI that improves the clinical process by utilizing CDSSs that specifically use real-time sensor data obtained from various monitoring and supportive medical devices and to evaluate the effectiveness of the CDSS on clinical outcomes. This research is motivated by a number of factors including recent dramatic advanced information technology (IT) application in acute care settings together with rapid growth in the availability of physiological data from the medical devices used to monitor neonates in the critical care environment; existing issues in terms of QI in the NICU environment, inefficient utilization of physiological data to support clinical decision-making, and the needs of measurement of the CDSS impact on outcomes. This research is further motivated by potential benefits to the neonatal critical care domain where quality of care can be continually improved by new approaches to redesign the clinical process and the patient journey, develop a new clinical practice model, and to evaluate the CDSS in actual practical settings through analysis of physiological data in real-time.

Quality of care has been defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with

current professional knowledge" (Lohr, 1990, p.707). There are three key themes that are emphases in the definition of quality: individual, desired health outcomes, and professional knowledge (Lohr, 1990). Based on this definition, in this thesis, quality of care defines: 1) the individual as an unique patient on whom the provided health services should be focused (referred to as patient-centered care); 2) the desired health outcomes are the clinical goals of the healthcare services being provided; and 3) the current professional knowledge that refers to the acquired knowledge and tools that are used to support the healthcare providers achieve the clinical goals. To expand the concept of quality of care in more detail, the Institute of Medicine illustrates six components of quality of care that include safe, timely, effective, efficient, equitable, and patient-centered as shown in table 1-1 (Institute of Medicine, 2001).

Component	Explanation
Safe	Avoiding injuries to patients from care that is intended to help them
Effective	Providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those unlikely to benefit (avoiding underuse and overuse)
Patient-centered care	Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide clinical decisions
Timely	Reducing waits and sometimes harmful delays for both those who receive and give care
Efficient	Avoiding waste, such as waste of equipment, supplies, ideas, and energy
Equitable	Providing care that does not differ in quality because of personal characteristics such as gender, ethnicity, geographic

Table 1-1: Six components of quality of care (Source: Institute of Medicine, 2001)

Quality improvement refers to healthcare activities that aim to use current knowledge, technology, and available resources to change professional behaviours include critical thinking, professional practice, clinical performance, and clinical decision-making to increase efficiency; such activities to expand clinical practice to provide a consistent, appropriate, patient-focused, and efficient healthcare services to improve outcomes (Committee on Quality of Healthcare in America, 2001; Fan, Laupacis, Pronovost, Guyatt, & Needham, 2010). The recent increased application of information technology in healthcare domain results in an impact to healthcare services not only at an individual level, but also impacts aspects of quality of care, organization culture, public relation, economy, and healthcare structure (Mainz, 2001). Many numbers of QI initiatives have accelerated and become a high priority in the healthcare domain globally as a consequence of recent dramatic developments in application of IT in the healthcare, healthcare re-organization, and transformation of healthcare systems (Mainz, 2003). There have been increased numbers of research studies on QI conducted in healthcare organizations during the last two decades; which the focus of these studies was to improve the process of caring and healthcare outcomes, increasing patient and employee satisfaction, and increase efficiency to improve quality of care (Curtis, Cook, Wall, Angus, Bion, Kacmarek, Kane-Gill, Kirchhoff, Levy, Michell, Moreno, Pronovost, & Puntillo, 2006; Kaplan, Provost, Froehle, & Margolis, 2012). Although some of them have achieved and documented significant improvements in patient outcomes, others indicated poor clinical outcomes and research results (Fan, et al, 2010; Kaplan, et al, 2012). QI is not a simple medical procedure; it is a high level of constructive concept that the process includes continuing of thinking, learning, designing, analyzing, implementing, evaluating, and reflecting (Kaplan, et al, 2012). There are many factors in relation to

individual QI's objectives, structure, design, process, support, and capacity that influence the success of QI according to the individual context of QI and the QI method (Kaplan, et al, 2012). To better facilitate Canadian healthcare organizations' ability to achieve quality improvement goals, the Canadian Health Services Research Foundation provides the best available evidence to key stakeholders to enable the success in QI by summarizing the six QI themes, which are also the six indicators (principles) that are presented in table 1-2 (Leatherman & Sutherland, 2010). Therefore, understanding the QI objectives and to make progress towards the goals for the QI, together with establishing a well-structured framework to guide practitioners' intervention is a crucial component in this QI framework to enable achievement in clinical outcomes improvement.

Quality Domain	Principle	Examples of measures
Effectiveness	Healthcare services should be based, as far as possible, on relevant rigorous scientific and research evidence	1. Mortality rates 2. Compliance rates with evidence-based guideline
Access	Healthcare services should be provided at the time they are needed within the appropriate settings	1. Provision of emergency care 2. Availability of specialist care or rehabilitation
Capacity	Healthcare systems should be sufficiently well resourced to enable delivery of appropriate services	1. Staffing levels 2. Number of scanners 3.Information technology
Safety	Patient should not be harmed by the care that they receive or exposed to unnecessary risk; avoiding injuries to patients from care that is intended to help them	1. Nosocomial infections 2. Medication errors 3. Falls
Patient-central	Healthcare should be:	1. Patient evaluations of

		care
	-based on a partnership between practitioners and patients(and where appropriate, their families) -delivered with compassion, empathy and responsiveness to the needs, values and preferences of the individual patient	2. Shared decision-making 3. Patient experiences and interactions with staff
Equity	Healthcare should be provided: - on the basis of clinical need, regardless of personal characteristics such as age, gender, race, ethnicity, language, socioeconomic status or geographical location - in such a way to reduce differences in health status and outcomes across various subgroups	1. Comparison of care provided across different sub-populations (for example, older people versus entire populations0 2. Mortality rates by socioeconomic status

Table 1-2: Six quality improvement indicators (Source: Leatherman & Sutherland, 2010)

The remainder of this chapter is structured as follows: in section 1.1, the definition of QI and its issues are discussed; section 1.2 briefly describes evaluation of the CDSS and its issues; section 1.3 identifies the research motivations; the research aims and objectives are discussed in section 1.4; section 1.5 introduces a research method used in this research; section 1.6 addresses the research hypothesises; contribution of this thesis will be summarized in section 1.7; and section 1.8 presents the thesis overview.

1.1 Quality Improvement and Current Issues

The concept of QI in the healthcare domain is widespread and has become a high priority for healthcare systems globally; it links organizational setting, healthcare delivery method, technologies used to support in decision making, clinical practice supported by

evidence based practice, collaboration between multidisciplinary professional teams, patient and employee satisfaction, and health outcomes (Batalden & Davidoff, 2007; Leatherman & Sutherland, 2010; Kaplan, et al, 2012). Batalden and Davidoff defined their concept of QI as the combination and effort from everyone involved in healthcare delivery activities: patients, healthcare professionals, researchers, payers, planners, and educators working together to lead changes to have a better healthcare outcomes (health), a better system performance (care), and better professional development (learning) (2007). Batalden and Davidoff's concept of QI emphasized the effort and contribution from the collaboration of multidisciplinary teams and composed a big picture of QI at a high management level and illustrated an organizational level of structure; however, there were insufficient details addressing questions such as: how to structure the QI, what needs to be improved in the QI concept, and how to evaluation QI outcomes (Batalden & Davidoff, 2007). There are a wide range of QI projects and research studies that have been initiated to promote efficiency and quality in acute care settings during the last two decades; some of them documented their success in improving clinical outcomes based on their contexts (Kaplan, et al, 2012), other studies shown poor QI results and low research publication rates due to the lack of framework and structure to guide practitioner interventions (Curtis, et al, 2006; Fan, et al, 2010; Leatherman & Sutherland, 2010). Because the QI is a complex continual process of thinking, learning, designing, analyzing, implementing, evaluating, and reflecting (Kaplan, et al, 2012); factors within the QI that are essential include the establishment of goals to achieve the QI objectives; designing a structure of QI; monitoring progress; and evaluating the outcomes. Clinical components such as mortality, morbidity, health status measurement, length of stay, use of protocols, and the role of collaborative team work have been used as success indicators to measure

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QI outcomes (McMillan & Hyzy, 2007; Mainz, 2003). Although all these indicators reflect the QI interventions to some degree in certain circumstances, some of them are too general to be measured without clinical guidelines and appropriate interpretation (Curtis, et al, 2006; Mainz, 2003). Furthermore, there is a cause-effect relationship between structure and outcomes of QI; the process measure based on the scientific evidence also plays a key role and needs to be addressed to ensure the quality of QI (Leatherman & Sutherland, 2010). However, current issues such as the process of measuring QI remains an open research area within the healthcare context, as well as standards for measurements of QI are inconsistently described in the literature (Medscape Multispecialty, 2007). To be able to better guide professionals to design a QI, Curtis, et al. summarized Donabedian's "structure-process-outcome (SPO)" model which is presented in table1-3 (2006). As presented in the table, there is a lack of description and explanation of the type of technology used and the number and individual staff roles who are involved in the QI process in their model.

Structure	Process	Outcomes
1. Represents the quality of care model (the way we organize care)	1. What we do for patient and the patient's family	1. Morbid event (e.g. nosocomial infections, venous thromboembolism, serious adverse drug event)
2. How the ICU is integrated into the hospital or healthcare system	2. The synchronous efforts of a large numbers of clinical and nonclinical processes	2. Health-related quality of life
3. Size of unit	3. The important process-of-care focus for quality initiatives is transfer of	3. Patient and family satisfaction of care

	patients between the ICU and other parts of the hospital or between different clinicians with the ICU	
4. Type and amount of technology available		4. Risk-adjustment mortality and standardized mortality ratios
5. The number, roles, and responsibility of ICU staff		5. Organ dysfunction

Table 1-3: the Structure-Process-Outcome model (Source: Curtis, et al, 2006)

1.2 Evaluation of a Clinical Decision Support System and Current Issues

Garg et al. defined a CDSS as an information system or a computer technique, such as software, designed to aid in improving quality of care, safety, and efficiency in healthcare (Garg, Adhikari, McDonald, Rosas-Arellano, Devereaux, Beyene, Sam, & Haynes, 2005). There are some differences in existing definitions of the CDSS based on the types of decisions that need to be made and phases of decisions that need to be supported. For instance, various CDSSs focus on checking drug interactions, preventive care alert, adverse drug event detection, disease prediction, disease management, cognition support, and workflow support (Weber, 2009; Wright, Sitig, Ash, Sharma, Pang, & Middleton, 2009; Richardson, Ash, Sittig, Bunce, Carpenter, Dykstra, Guappone, McCormack, McMullen, Shapiro, Wright, & Middleton, 2010).

The dramatic innovation of using CDSS to support clinical decision-making in the acute care environment is widespread globally. Although IT professionals believed all the CDSSs they developed for the healthcare system would have a positive impact on improving clinical decision making and outcomes, there are still demands for evaluating

the system and desired outcomes because it is not only a cost analysis for implementation, but also the effects on further clinical process improvement, clinical performance, and quality of care delivered to the public (Gary, et al, 2005). The characteristics of having multiple perspectives and types of CDSS have advantages in supporting clinical decision making in multidimensional ways to meet many aspects of healthcare demands; the lack of universal definition of and consensus of CDSS also has disadvantages in the system designing, implementation, and utilization which makes it even more difficult to evaluate the effectiveness of the CDSSs (Richardson, et al, 2010). Hunt, et al completed a systemic review of evaluating the effectiveness of the clinical support systems for which they concluded that the CDSS has a positive impact on physician performance and to improve patient care outcomes, however, it contained insufficient discussion on the effectiveness of the support for disease diagnosis (Hunt, Haynes, Hanna, & Smith, 1998). The limitations of the study, however, were that there was no information provided about how the evaluation was completed, which research methods were used, and what were the indicators about improved outcomes (Hunt, et al, 1998). Gary, et al also completed a systematic review of effects of CDSS for which their results agreed that the CDSS improved clinicians' performance; however, different from Hunt's study, the effects on patient outcomes were understudied and less well described (Gary, et al 2005). Another review was conducted by Kaplan in 2000; She concluded that the existing issues in the demonstration of the effectiveness of clinical decision support systems include the CDSS is more equivocal for guideline development and aid physician with diagnosis, there is a lack of naturalistic design in routine clinical setting with real patients, and lack of demonstration why and how the system were used (Kaplan, 2001).

1.3 Research Motivations

With advances in IT application and biomedical engineering in the acute care environment, babies who are admitted in the NICU usually are connected to various medical devices to support their life (e.g. a mechanical ventilator) or monitor their clinical condition. Modern medical devices have capabilities in acquiring, processing, analyzing, and provide limited rolling memory storage of individual physiological parameters such as heart rate (HR), respiratory rate (RR), blood pressure (BP), blood oxygen saturation (SpO_2), and electrocardiogram (ECG) outputs and display them on the screens for clinicians to review, to support decision-making about potential diagnoses, and the plan of treatment (Blount, Ebling, Eklund, James, McGregor, & Percival, 2010; Catley, Smith, McGregor, James, & Eklund, 2010). The data obtained from these medical devices are considered crucial and essential in supporting clinical decision making to enable clinicians to provide high quality of care and improve clinical outcomes (Griffin, O'Shea, Bissonette, Harrell, Lake, & Moorman, 2003; Blount, et al, 2010; Catley, et al, 2010). In addition to the advantages that are described above, the innovation of the application of IT in the healthcare domain has been designed to take many roles and expand its capacity in many aspects of healthcare such as: medical diagnosis, physician order entry, condition monitoring, disease management, communication, as well as relationships between effective utilization of CDSS and QI outcomes (Weber, 2009). The relationship between the QI and the CDSS support is an open research area that causes a motivation to conduct this research. Additionally there is a need to better utilize the physiological data collected by information systems and medical devices to support QI. The existing issues in the current status of QI and CDSS have also motivated this research of discovering how CDSS can support QI in the NICU environment. In terms of current states of evaluation

of the CDSS, unfortunately there is lack of a definitive model to study the evaluation and effectiveness of CDSS, little objective documentation in regards to how CDSS impacts clinical practice, and a lack of a standard framework for evaluation of effects and outputs of implementation (Rahimi & Vimarlund, 2007). The following issues in the current state of QI and CDSS have contributed to motivation of conducting this research study:

1. There is lack of structure to design QI which reflects relationship about how the CDSS to support QI

2. The traditional health science studies do not take high frequency physiological data analysis into consideration when it comes to supporting decision making, because it was not possible previously with information technology solution; as a result, there is a lack of study on using real-time physiological data to support QI

3. Most of current QI were conducted at high levels; as a result, the description of QI processes in routine practice is under studied

4. The application of IT in NICU environment requires that obtained clinical information should be utilized to enable increased efficiency and improve quality of care, for the additional desired outcome of effective support in clinical decision making

5. There are no methods to investigate whether or not CDSS utilizing physiological stream behaviours impacts clinical practice and if so, in what ways

6. To investigate the impact of CDSS on clinical outcome and decision support

7. As there is little evidence of reported improvements to date frameworks are required that encourage clinicians to adapt to use CDSSs that utilise the behaviour analysis of multiple high frequency physiological streams to improve clinical processes and clinical practice based on evidence-based practice, to increase value of patient care and professional knowledge application

1.4 Research Aims and Objectives

The aims and objectives of this research are to:

a. To define a QI by using real-time measurable physiological data

b. To design a framework to support QI in NICU environment

c. To assess the effectiveness of the CDSS on clinical process improvement and clinical outcomes

d. To demonstrate the framework through a case study in different cultural settings

1.5 Research Method

The research method that is used for this study is a constructive research method. Constructive research can be described as a case study method that aims to produce innovative solutions to solve specific practically and theoretically relevant problems in the real world, which results in the creation of new application theory and knowledge and to make contributions to the theory of the discipline as presented in figure 1-1 (Kasanen, Lukka, & Siitonen, 1993, p. 246). The constructive approach means problem solving through the construction of models, diagrams, plans, and organization. The aim of using a constructive research model is to "take a real world practical problem and produce a real world solution" (Dodig-Crnkovic, Lüders, Höst, & Feldt, 2010).
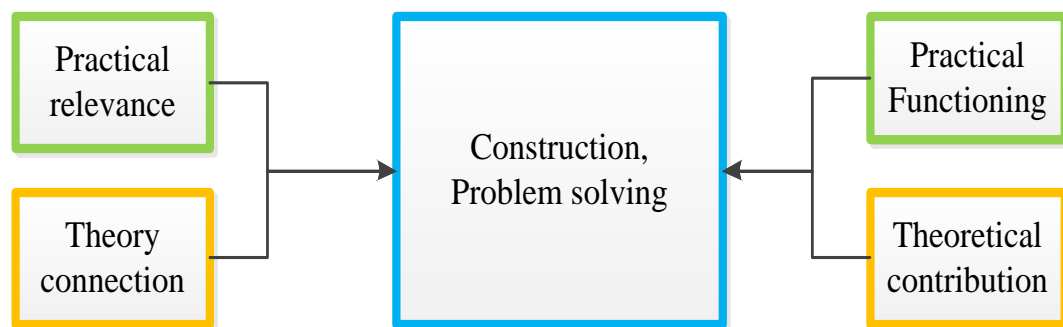
Figure 1-1: Elements of Constructive Research

1.6 Research Hypotheses

A systemic review of existing literature, establishes that there is a relationship between physiological data, real-time data analysis, clinical decision support, routine clinical practice processes, and quality of care and outcomes improvement. We hypothesize that:

1. A framework can be defined to enable the QI through implementation of the CDSS in the NICU environment

2. That the framework can be supported by knowledge obtained from analysis of high frequency physiological data in real-time

3. That the framework can be demonstrated to support clinical process improvement

4. That the framework can be demonstrated within the healthcare setting where clinical practice is routinely taken place in different cultural settings

5. The clinical decision support system can effectively support clinical decision making

1.7 Scope of Research in the Health Informatics Research Team

The Health Informatics Research (HIR) team at the University of Ontario Institute of Technology is composed of undergraduate students, graduate students, postdoctoral fellows and Faculty[1]. Each member of the team has a different research focus that is based on the individual's background and interests. For the Artemis project, the Artemis platform was implemented in the NICU at The Hospital for Sick Children, Toronto, in August 2009 and in the NICU at The Children's Hospital of Fudan University in October 2012. Several research projects have been completed by the team members since the implementation of the Artemis system in the two NICUs. Most of these projects were focused on real-time data acquisition, processing, analysis and storage; some projects focused on parameters such as pain that potentially affect physiological data streams. The

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[1] Professors: McGregor, Eklund, Percival, and James.

area of utilizing real-time data to support clinical decision-making through implementation the CDSS had not been studied yet.

The work presented in this thesis is part of the Artemis Project that mainly focuses on 1) supporting clinical decision-making through the implementation of the CDSS; 2) finding out whether or not the CDSS will have positive impact on clinical outcomes and clinical process thus to improve quality, and 3) using real-time to evaluate the effectiveness of the CDSS.

Limitations also exist in this thesis: 1) This framework design is based on completion of validation phase of the Artemis system. Therefore, technological issues such as how to handle false alarms; modify the Artemis system to ensure it is compatible with medical devices in China have been completed in the previous works or are currently in process; ensure the data is acquired and transmitted from China and stored in the HIR Laboratory are beyond the scope of this thesis. 2) The focus of this thesis is to design the QI framework. Regrettably, due to time restriction, the framework has not been implemented in the NICUs yet. As a consequence of awaiting the implementation of the framework, data collection, data analysis for validating results, and evaluation of the CDSS are not components of this thesis: they are the next steps of the project. 3) Paper documentation remains as primary document format in China. There are potential risks of missing participants' original gestational and delivery information in the process of data collection, which potentially affects research result when it comes to the point of data analysis and generalize research reports. Therefore, the Chinese research partners may need to provide an alternative means of documentation for data collection and analysis. In addition, some original documents in the Children's Hospital of Fudan University are

written in language other than English. Obtaining technical translation of the documents to English may be difficult due to financial constraints, the needs of human assistance is an alternative solution.

1.8 Contribution of this Thesis

This section discusses the contributions made by this thesis to the development of health informatics and QI in NICU

1. To define a well-structured QI framework to make improvement in clinical practical processes using CDSS that improve quality of care which integrates the SPOE, CRISP-DM, and PaJMa models and enables the processing of high frequency physiological data

2. Demonstration of using a clinical case within the context of neonatal intensive care

3. To demonstrate QI can be improved by implementation of the CDSS

1.9 Thesis Overview

This thesis is structured as follows: chapter one introduced the research problems, research hypothesis, and describes the research methodology used in this study; chapter two consists of the literature review of relevant research questions; chapter three describes clinical background in relation to clinical research; chapter four describes current neonatal intensive care environment where the research has taken place; chapter five presents the framework design; chapter six demonstrates the case study; finally, chapter seven concludes with discussion, and identifies areas for future research.

Chapter2: Literature Review

2.1 Introduction

The motivations behind this thesis include an increased availability of data in the NICU for clinicians to use for clinical decision-making, an increased attention on QI in the NICU, to determine whether the CDSS can support QI in cross-cultural NICU environment and to evaluate the effectiveness of the CDSS on clinical outcomes and QI. This thesis will be demonstrated via a case study in the NICU environment where previous research have proved that a changed neonatal condition can be predicted and detected by monitoring changes of physiological time series data streams include HR, RR, and SpO_2 (Griffin; et al, 2003; Blount, et al, 2010; Catley, et al, 2010). This chapter is organized into two distinct areas focusing on the context of the research problems:

- Quality improvement in healthcare, in particular the NICU environment
- Evaluation of the clinical decision support systems

2.2 Review Method

The approach to literature review was divided into two sections based on the two research themes: the first section focused on literature related to the quality improvement in the NICU and the second section was concerned with work related with the evaluation of the CDSS. The initial search of quality improvement theme began with searching articles from the Medline/PubMed, CINAHL, PsycINFO, and Cochrane database for four themes consisting of quality improvement in healthcare, neonatal intensive care unit, method of quality improvement, and clinical decision support. Boolean result "AND" and "OR" were used to specify article keywords; English and Chinese languages were chosen to review articles; Articles were selected published from year 2000 to year 2012. The second section was seeking literature about the evaluation of the CDSS. Keywords included "health informatics interoperability within clinical decision support system", "real-time

data analysis in NICU" "randomized and nonrandomized trials" and "clinical decision support system evaluation". Boolean result "AND" and "OR" were used to specify article keywords. Published articles were chosen between the years of 1990 to 2012. In addition to above searching technique, review from article reference lists also contributed to article searching. An aforementioned technique and a snowballing search techniques also used in both sections in conjunction with previous systematic review for the purpose of expanding the criteria for additional articles.

2.3 Review Results

- Quality improvement theme: the literature search resulted in 3997 screened citations, 226 full-text articles were retrieved and of the total 100 met criteria for reviewing, among them, more than 20 articles were reviewed to support this research.

- Evaluation of CDSS theme: searched articles for the theme of "evaluation of CDSS" as presented in figure 2-1: a total of 213 articles were categorised into four sub-groups: cluster randomized trials, controlled before and after studies, and interrupted time series designs; among them, more than 15 articles were reviewed to support this research.

Evaluation of clinical decision support system
N=163213

Randomized control trials
Nonrandomized control trials
N=58983

Methods of evaluation of CDSS
N=873

Clinical effectiveness and increase efficiency
N=213

213 studies included:
- Cluster randomized trials
- Nonrandomized trials
- Controlled before and after studies
- Interrupted time series designs
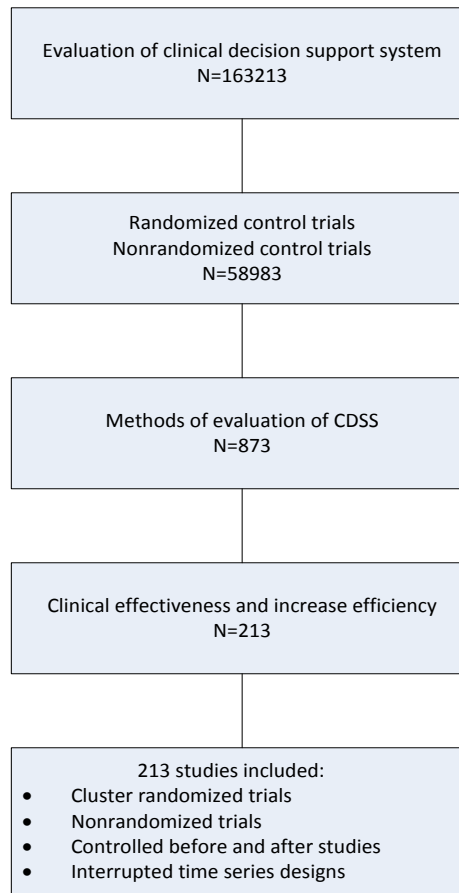
Figure 2-1: A total of 213 articles were categorised into four sub-groups

2.4 Quality Improvement in Healthcare

QI has been elevated to a high priority globally. The overall goals of QI are to increase collaboration within multi professional teams, enhance clinical processes, to improve clinical performance, and increase efficiency through means of setting goals, recognizing barriers, environmental scanning, examining current clinical processes, identifying gaps between current clinical processes and expected clinical outcomes, testing changes in these processes, and implementing those changes to improve clinical processes and healthcare outcomes (Healthcare providers service organization, 2007; Baker, King, MacDonald, & Horbar, 2003). In the past four decades, healthcare organizations have been continually seeking strategies and resources to improve quality of care to promote

healthcare outcomes while increasing efficiency. To be able to improve quality of care, one must first identify an area for improvement and define the concept of QI prior to setting a QI initiative. Lohr (1990) defined the quality of care as "the degree to which services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (p.707). In his definition, Lohr described different dimensions associated with the term of healthcare in his concept: individual, healthcare outcomes, and professional knowledge as presented in figure 2-2 (Lohr, 1990).
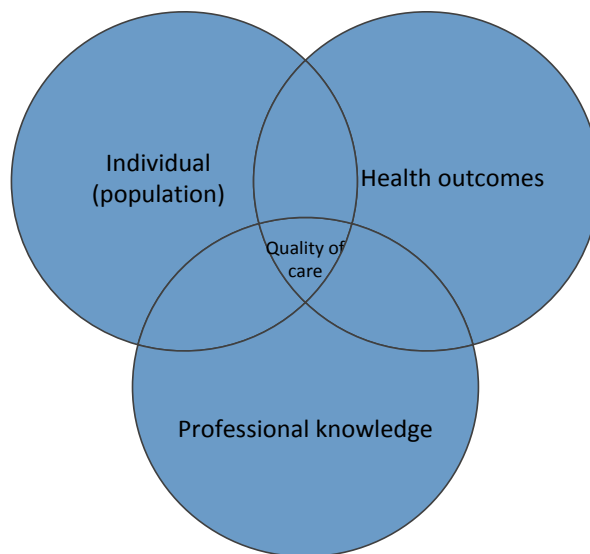
Figure 2-2: Three themes of quality of care: individual, health outcomes, professional knowledge

Based on the three key components of the concept of quality of care, Batalden and Davidoff illustrated the relationships between three components as presented in the

figure 2-3. Within this figure, Batalden and Davidoff attempted to explain that quality improvement is not a simple concept but rather a dynamic process which is affected by everyone who is involved in patient's care, using their best knowledge to promote better patient outcomes and better system performance (2007).
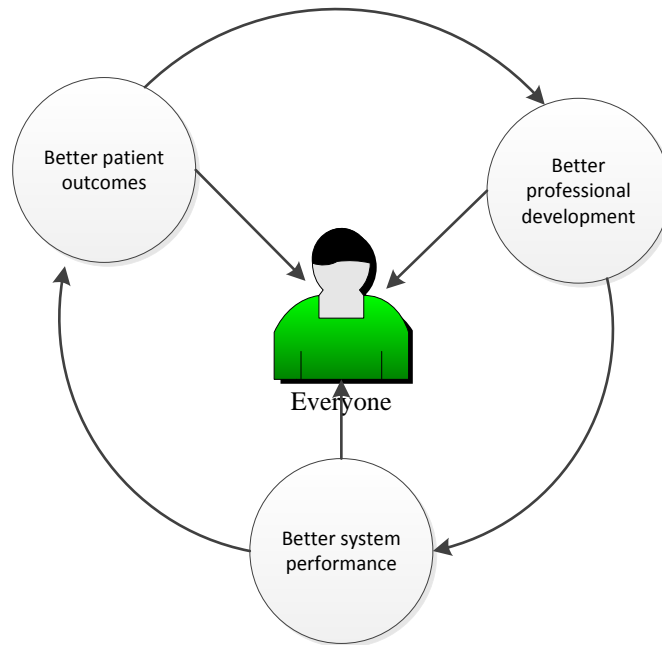
Figure 2-3: Linked aims of improvement (Reference: Batalden & Davidoff, 2007)

2.4.1: Overview of QI in Healthcare

Authors/year of published	Domain	Method	Structure	Intervention	Measurement	Evaluation
Scales, et al. 2011	ICU	A cluster randomized trial	NO	Improve quality by implementing multi-intervention include: 1). Evidence-based practice 2). Educational outreach 3). Reminders and other tools 4). Audit and feedback	1. Prevent ventilator-associated pneumonia 2. Prophylaxis against DVT 3. Daily spontaneous breathing trials 4. Prevent catheter-related infection 5. Early enteral feeding 6. Decubitus ulcer prevention	A cluster randomized trail 1). Process of care as indicator (improvement)
Ferrer, et al. 2008	ICU	A controlled before and after study	NO	Improve process by conducting staff education in particular areas: guideline and bundles treatment plans	1. Hospital mortality 2. Hospital length of stay 3. ICU mortality 4. ICU length of stay 5. Long-term follow up with clinical bundle	A controlled before and after study Process-of-care performance indicator
Baker, et al. 2003	NICU	Questionnaire/ interview	NO	Improve quality by utilizing the organizational assessment survey feedback: identify issues and changes	1. Organizational culture 2. Team work 3. Leadership 4. Communication	No
Horbar, et al. 2003	NICU	A controlled before	Yes (PDSA)	1. Multidisciplinary leadership team 2. Habit for change	1. Multidisciplinary team work 2. Nosocomial infection	A controlled before and after study

		and after study		3. Habit for systems thinking 4. Habit for collaborative learning 5. Habit for evidence-based practice	3. Chronic lung disease 4. Intrventricular hemorrhage and brain injury 5. Nutrition practice and necrotizing enterocolits 6. Family-centered care	
Horbar, et al. 2004	NICU	A randomized controlled trial	NO	1. Audit and feedback 2. Evidence reviews 3. Training workshop 4. Ongoing faculty support via conference calls and email	1. Death before discharge home 2. Pneumothorax	A randomized controlled trial
Lee, et al. 2009	NICU	A cluster randomized controlled trial	NO	Implementing the evidence-based practice guideline for QI method: a) using of evidence form published literature; b) using of data from participating hospital to identify hospital-specific practices for targeted intervention; c). using of a national network to share expertise	1. Incidence of nosocomial infection 2. Death and bronchopulmonary dysplasia 3. Death before hospital discharge	A cluster randomized controlled trial

Curran, et al. 2002	Hospital wide	A controlled before and after study	NO	Using process control tool to obtain monthly feedback meetings of infection rate with SPC control charts and actions to improve infection control further	1.Hospital wide MRSA rate reduction	A controlled before and after study
Stetler, et al. 2007	Hospital wide	A case study	Using Pettigrew and Whipp model of strategic change (Content, Context, and Process model for strategic change)	1. Routinely implement of evidence-based practice 2. Strategic management of change	1. The degree of evidence-base practice activity over time 2. The degree to which there is evidence that individual targeted EBP projects' goals/objectives and outcomes were met 3. Evidence regarding, and tracking of change in key nursing-sensitive outcomes 4. The degree to which there is evidence that needed strategic department changes per EBP-related goals 5. Evidence of the status of the organization in relation	NO
Sedlack 2010	Surgical unit	A controlle	NO	Using process control tool (six sigma and	1. Waiting time	A controlled before and after

		d before and after study		statistical process) to control charts for surgeon waiting time and LOS after colonic surgery		study
Needham, et al 2010	ICU	A controlled before and after study	Yes (4 step process improvement model)	Four steps model: 1. Summarizing the evidence 2. Identifying barriers 3. Establishing performance measures 4. Ensuring patients receive the intervention	1. Decrease length of stay in ICU 2. Narcotic using 3. Improved delirium status	A controlled before and after study
Korst, et al. 2011	Hospital wide	1.Cross-sectional design 2. On-line survey	NO	Health information exchange	1. Monitor process 2. Data sharing 3. Increase inter-organizational collaboration 4. Strength of organizational leadership in fostering a culture of QI	NO
Schonlau, et al. 2005	Asthma organizations	Survey	NO	1. Quality improvement collaborative to improve quality by increasing communication 2. Pre-intervention and	1. Patient self-management 2. Taking long-term medication	NO

				post-intervention evaluation		
Wirtschafter, et al. 2010	NICU	Prospective interventional cohort study	Yes	1. Develop leadership commitments 2. Describe potential best practice 3. Develop collaborative processes between members 4. Develop audit and feedback process 5. Teach quality improvement techniques	Self-report laboratory confirmed infection rate per 1000 central line days	NO

Table 2-1: Overview of QI in Healthcare

2.4.2 Discussion

Many existing systematic literature reviews have explored methods and tools that focus on different aspects of QI in healthcare domains. Table 2-1 presented the literature reviewed based on the categories of method of QI, structure of QI, means to support QI, and evaluation of QI.

Method of QI: Shaojania and Grimshaw summarized QI strategies that people attempted to use as a tool to improve quality. The categories of this method are as follows: providing education such as conferences or printed educational materials that detail recommendations for management a particular condition; use of reminder systems and decision support including adding a sheet on front of a chart alerting providers to date the patient's most recent test results; auditing and feedback to summary of clinical performance for individual intervention; patient education to enhance individual patients' knowledge in specific health condition; organizational changes such as changes in organizational structure or healthcare team to improve process of care; and financial incentives as well as policy to achieve target of level of care (Shaojania & Grimshaw, 2005).

Structure of QI: Many QI professionals have realized that existing QI reviews may overwhelm clinicians who are interested in QI. Curtis, et al conducted a survey in 2006 where they summarized and provided a guideline to assist designing the quality improvement in the ICU environment. They suggested clinicians use Donabedian's "structure-process-outcome" (SPO) model to first understand the elements and goals of quality improvement and then conduct an environmental scan to identify barriers, identify measurement variables, before developing and implementing an ICU QI program. Although the "structure-process-outcome" model was described as a guide to assist

developing a QI in the intensive care environment, the authors did not describe a specific model for clinical process improvement; they also noted they were lacking a method to evaluate QI outcomes which is a weakness in their study (Curtis, et al, 2006).

In the past few years, the PDSA model has been a popular model for QI in the healthcare domains. Amount of many articles, Speroff et al discussed how the plan-do-study-act model will assist success in quality improvement by increase process of care in detail (Speroff & O'Connor, 2004).

Evaluation of QI: In 2011, Scales et al. implemented a cluster randomized trial QI program in fifteen community hospitals in Ontario, Canada with goals of using evidence-based practices to improve ICU care outcomes and to determine the effectiveness of a multicenter QI program to increase care delivery (Scales et al, 2011). As a result of their study they concluded that a multi-intervention improved adoption of care practices. However, the limitations of study were failing to include a clinical process model, and a lack of documented processes of care (Scales et al, 2011).

Through the above systematic review of existing literature, it is notable that there are a few characteristics in current state of quality improvement in the intensive care environment: quality improvement in the intensive care environment has started to get much more attention than ever before. As a consequence, studies on quality improvement may overwhelm clinicians who are interested in quality improvement and have to critically analyze current state and literatures of QI. Problems with a current state of quality improvement includes issues such as a lack of descriptions of QI processes in detail when conducting a QI; there is an increased attention on using a randomized control study design for quality improvement research; using real-time data to improve

quality is still under-utilized; and the needs of attention on evaluating the effectiveness of

QI program is essential.

2.5 Overview Evaluation of a Clinical Decision Support System

CDSSs are computer systems and/or software that support clinician decision-making

(Berner & Lande, 2003). Although the CDSS has been used widely in the healthcare

domain and has played as an essential role in assisting clinician decision making during

the process of care, evaluation the effectiveness of CDSS remains a challenge due to lack

of a consensus of CDSS definition, in addition to the nature complexity of the CDSS

(Sintchenko, Magrabi, & Tipper, 2007; Rahimi &Vimarlund, 2007); therefore, by

understanding the CDSS in the healthcare domain will assist to evaluate effectiveness of

CDSS in clinical outcomes.

2.5.1 Understanding the using of CDSS to support quality improvement

The concept of a clinical decision support system was evolved from the concept of

decision support system (DSS), as Marakas defines

> *A decision support system is a system under the control of one or more decision*
>
> *makers that assist in the activity of decision making by providing an organized set*
>
> *of tools intended to impose structure on portions of the decision-making situation*
>
> *and to improve the ultimate effective of the decision outcome (Marakas, 2003, p.4)*

The CDSS then is defined as a designed decision support system(DSS) that aims to assist

clinicians' decision-making in the clinical setting (Berner & Lande, 2003). There are two

types of CDSS in general. This includes the knowledge-based system that applies rules to

patient data by using an inference engine and displays the results to the end user and the

nonknowledge-based system that relies on machine learning to analyze clinical data to

assist decision-making based on learning. Examples and features of the two types of CDSS are presented in table 2-2:

	Types of clinical decision support system	
	Knowledge-based clinical decision support system	Non knowledge-based clinical decision support system
Example	- Diagnostic decision support system - Clinical order entry system	- Also namely artificial intelligence system - Artificial neural networks (ANN)
Feature	- Provide information rather than analysis of information - Does not simulate an expert's decision making - Clinician make their own decision based on the information provided by the system	- Learn from previous experience - Simulate human thinking - Analysis of patterns in the data (training the artificial network) - Assist clinician decision making in real-time data - Make prediction based on data
Components of the CDSS	Three parts: - Knowledge base - Inference (reasoning engine) - Mechanism for communication	Five parts: - The data management system - The model management system - The knowledge engine - The user interface - The user

Table 2-2: Type of clinical decision support system (Source: Berner & Lande, 2003)

2.5.2 Review of evaluation of CDSS

There are many publications that have demonstrated that the use of CDSS has led to positive impacts on clinical outcomes and in reducing total cost of care (Berner & Lande, 2003). Several literature articles focused on how to and what to evaluate the CDSS are well documented by scholars, some of which are summarized in table 2-3:

Overview of Evaluation of the Clinical Decision Support System:

Authors/ Years of Publication	Aims of Study	Domain	Evaluated System	Method of Evaluation	Metrics used to evaluate the system	Limitations of the study
Littlejohns et al. 2003	To assess the benefits and cost of the health information system, daily use of the system, the clinical and managerial environment, and ultimately its effect on the quality of patient care and public health.	Hospitals	HIS	Mixed with A summative evaluation, A survey (Interview), and a randomized controlled trail	1) Training 2) Reliability of the system 3) Improve communication 4) Data protection is adequate 5) Quality and actual use of decision making information 6) Administration processes are more standardised and efficient 7) Cost per unit service, 8) Information is used for audit or research	
Garg et al. 2005	To review controlled trials assessing the effects of CDSS, to identify study characteristic predicting benefit		CDSS	Randomized and nonrandomized controlled trial	Practitioner performance	The effects on patient outcome remain understudied and/or studied inconsistent

Kaplan 2001	How the CDSS changed clinical performance, CDSS could improve patient care	Healthcare	CDSS	Mostly RCT, in addition to laboratory experiments	Professionals behaviour change (clinical performance)	Cannot identify why a CHSS may or may not be effective
Sim, et al. 2001	To describe and present recommendations for accelerating the development and adoption of CDSS for evidence-based medicine	Healthcare	CDSS	Quantitative and qualitative evaluation methodologies to assess multiple dimensions of CDSS use and design.	The use of CDSSs to facilitate evidence-based medicine therefore promises to substantially improve healthcare quality	The effect of CDSS on clinical outcomes remains uncertain
Aronsky et al. 2001	To develop and evaluate a diagnostic decision support system (DDSS), to assess the diagnostic performance of the DDSS	ER	DDSS	A quasi-experimental time-series design	Physicians' diagnostic performance	
Kastner et al 2011	To evaluate of a CDS tool for osteoporosis disease management	A family health teams in Hamilton area	CDS	A randomized controlled trial	1. Clinical decision support 2. To test the impact of the tools –analysis of bone mineral density	1. The instrumentati on is a common treat in

				tests 3. To measure treatment result 4. To measure nutritional supplements	medical record research 2. Individual profession practice behaviour may influence on clinical outcomes
Makela et al. 2005	To evaluate how well EPR system meet the needs of physician and other professional To determine if there are any significant difference between EPR system	Primary care	EPR system	Questionnaire	Physicians and other healthcare professional feedback	

Table 2-3: Overview of Evaluation of the Clinical Decision Support System

2.5.3 Discussion

Through a systematic review of evaluation of the CDSS, there are a few issues that remain as challenges and need more attention:

1). As the overall goal of the application of IT in the healthcare domain, up-to-date, there is lack of a standard and structured framework for evaluation of the effectiveness and output of implementation in the healthcare, as well as lack of research which focuses on and explores the impact of IT on the healthcare system's productivity and effectiveness (Littlejohns, et al, 2003; Rahimi & Vimarlund, 2007). It is noted that a needs of a structure of evaluation method for the objectively evaluate the effectiveness of IT is essential and urgent.

2). Liu and Wyatt conducted a randomized controlled trial in 2010, they commented that the randomized controlled trials have become a gold standard for clinical research in pharmacy, clinical outcomes measured; however, randomized controlled trials (RCT) have a limited role in evaluating clinical information system due to the nature of research design and the complexity of clinical sittings (Liu & Wyatt, 2011). They pointed out the limited role of RCT in evaluating clinical information system, causes and needs, outline challenges and potential alternations solutions of use RCT in the evaluating clinical information system.

3). Many studies involved field tests of a CDSS using different methods but there is lack of naturalistic study design in routine clinical settings with real-patients (Kaplan, 2001). In addition, the CDSS has been evaluated as stand-alone system, and was therefore not integrated into the clinical information system (Aronsky, 2001).

4). Their studies indicated factors that contribute to successful CDSS implementation including providing alert, suggestion, and computerizing the entire process (Berner &

Lande, 2003); how to (method) evaluate the CDSS remains under study (Wyatt et al, 2003).

5). Research mostly focuses on clinicians' performance measure and practice guideline improvement, but was inconsistent and inconclusive on patient outcomes due to lack of data (Sintchenko, et al, 2007).

6). There are limited studies on using physiological data as effectiveness variables to evaluate a CDSS, which provides research an area for future study

7). There are also limited studies on relationship between CDSS to support QI, which open a new research area for researchers

2.6 Implication and Impact on this research

The result of above literature review exemplifies the motivation for a structural QI framework supported by the clinical decision support system in cross-cultural NICU environment and evaluation of the clinical decision support system. The overview of existing QI from section 2.3 has shown the desired outcomes of having QI framework to enable researchers to reach goals of quality improvement. Moreover, to determine whether or not the clinical decision support system is effectively support QI, the needs of using realistic and measureable variables are the keys. This leads to the formulation of hypothesis 5 of the thesis: the clinical decision support system can effectively support clinical decision-making.

2.7 Summary

This chapter has presented a systematic literature review associated with the context of the research problems addressed in chapter 1. While there have been increased efforts on increasing utilization of physiological data to support clinical decision making, it has led to an opportunity to conduct this research. Since the CDSS has been used as a tool to

support QI, whether or not the CDSS impact on clinical outcome and in which degree provides another opportunity for clinical research.

Chapter 3: Background

Different from a simple procedure, quality improvement is a complex continuing dynamic process with many factors involved in order to achieve success in quality improvement in the healthcare field. The intent of this research is to design a conceptual framework for QI initiatives in the NICU environment by utilizing physiological data in real-time in combination with the CRISP-DM and the PaJMa models. The following sections discuss individual background components that relate to this research in detail. They include information about the CRISP-DM methodology, the PaJMa model, the Artemis clinical decision making support system, and previous research outcomes across these areas that formed foundational work in support of this research.

3.1 The CRISP-DM Methodology

The Cross Industry Standard Process for Data Ming methodology (CRISP-DM) was developed in 1990's as a model of the data mining process (Chapman, Clinton, Kerber, Khabaza, Reinartz, Shearer, & Wirth, 2000).
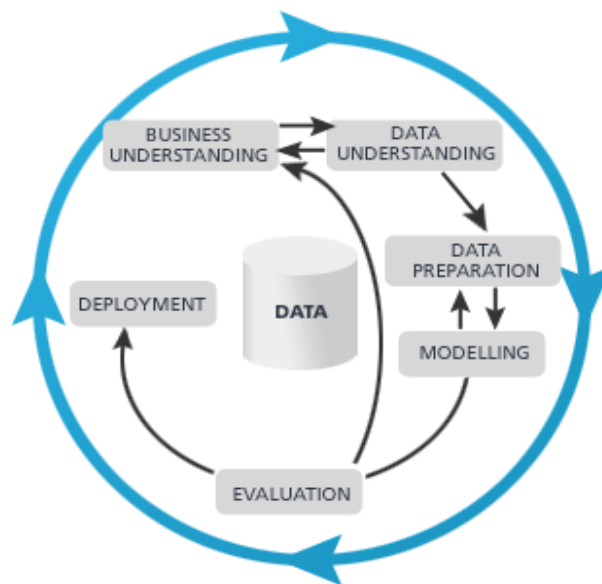
Figure 3-1: The phases of the CRISP-DM reference model (Chapman et al, 2000)

As shown in figure 3-1, the model breaks down a data mining life cycle into six phases:

    (1) business understanding

    (2) data understanding

    (3) data preparation

    (4) modeling

    (5) evaluation

    (6) deployment

The CRISP-DM methodology has been widely used and has become a standard model for data mining and knowledge discovery in many industry sectors, but has only been applied limitedly in the healthcare domain (McGregor, Catley & James, 2012). In particular it lacked provisions for multi-dimensional time series data mining (Catley, Smith, McGregor & Tracy, 2009).

In the early 2000s, McGregor and her team began to apply the CRISP-DM model in the field of health informatics and have made some significant achievements in the past few years. The concept of data process mining was first introduced and demonstrated by Heath and McGregor. To validate the suitability of the CRISP-DM model in healthcare domain, Heath (2006) in her Master's thesis demonstrated the CRISP-DM model's correlation with the scientific method showing that it can be suitable in medical research as presented in figure 3-2.
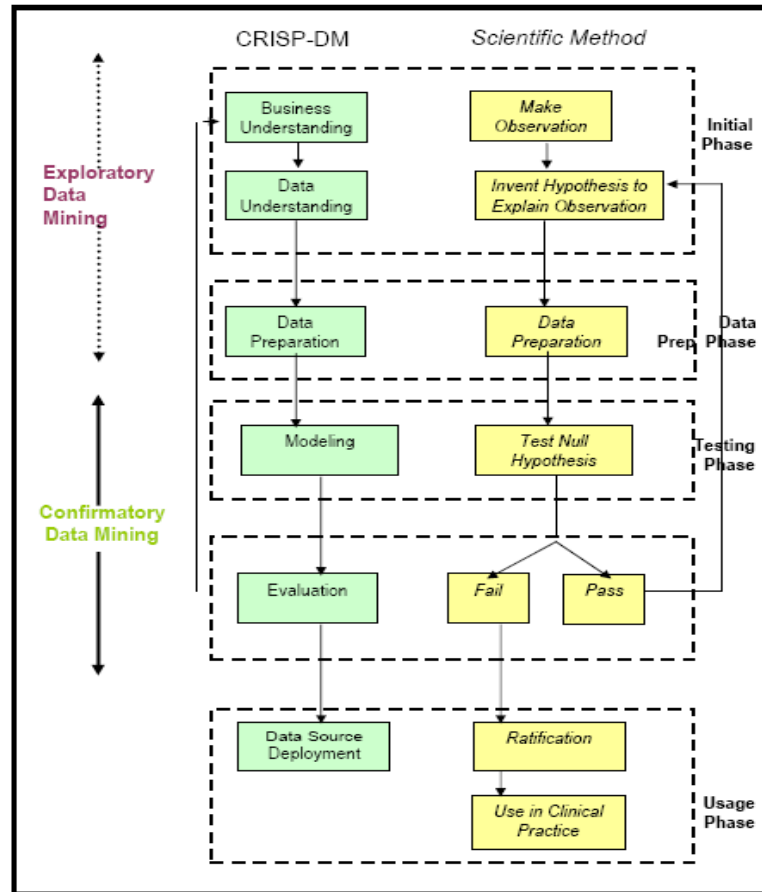
Figure 3-2: Parallelism between CRISP-DM and the Scientific Method (Heath, 2006)

In 2009, McGregor et al. first introduced the CRISP-DM principle in the critical care area by extending it to create the CRISP-TDM model. The focus of this new model was to process multidimensional physiological data streams and demonstrated its relevance for clinical research through a case study of earlier detection of late onset neonatal sepsis in the NICU environment as presented in appendix 1 (McGregor, et al, 2010). In this research, McGregor, et al. utilized the CRISP-TDM model to develop a framework for temporal data mining particularly focused on multi-dimensional time series data mining in the NICU environment. They concluded that the CRISP-TDM model was a successful approach to knowledge discovery from multi-physiological data together with complex

real-time data analysis, which demonstrated that the CDSS has its capacity in supporting clinical decision making (McGregor, et al., 2010).

McGregor et al. late on applied the CRISP-DM principle in the area of critical care area where they developed and designed a framework for clinical guideline improvement in critical care environment that was demonstrated with a neonatal apnoea case study (2012). In this particular research, McGregor and her colleagues not only focused on extending the capacity of CRISP-DM in the critical care arena, but also discovered the relationship between patient journey modelling (PaJMa) and process mining in critical care components as shown in figure 3-3 (McGregor, et al, 2012). The evolution of introducing the newly developed concept of PaJMa into process mining has significant impact on their later researches, which also funded the concept of this research, moving the concept of guideline improvement forward in the area of QI in NICU (McGregor, et al, 2012).
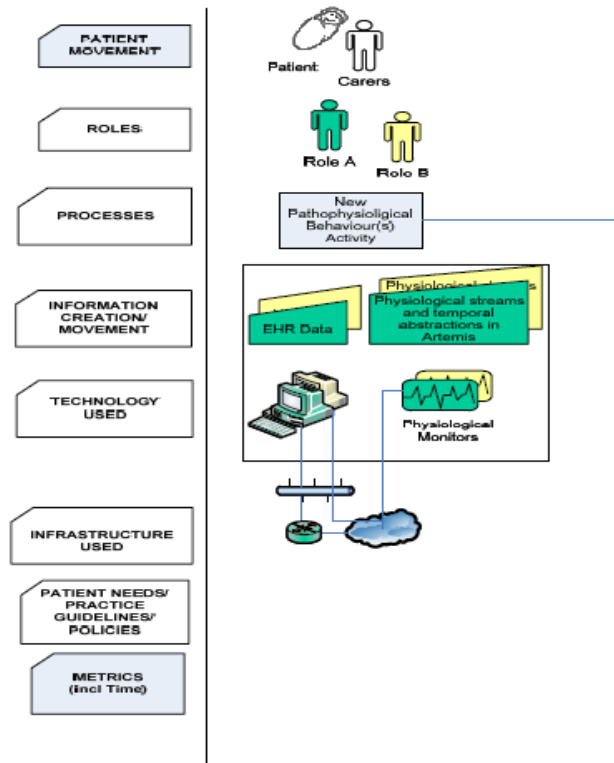
Figure 3-3: Relationship between PaJMa layers and process mining in critical care

components (McGregor, et al, 2012)

The results from this clinical research have made a significant contribution in data

process mining, especially with the multi-dimensional time-series data process mining in

real-time to support clinical decision making, as well as providing a scientific base for

this research.

3.2 Patient Journey Model Architecture

The Patient Journey Modelling Architecture (PaJMa) was designed specifically for

healthcare environment by McGregor et al in early 2000s (Percival, Catley, McGregor &

James, 2009). The PaJMa model provides a visual representation of related business

processes, data and information flow, technology and clinical guidelines that involved in

a patient journey in different clinical settings, individual professional roles in the process

of patient care, and timing spent on each clinical step (Percival, et al, 2009). It also "uses

horizontal lays to present independent information on different aspects of the patient's journey which lays are read vertically from left to right, with each process step moving across the page" (Percival, et al, 2009. P.7.).

3.2.1 Architecture of the Patient Journey Model
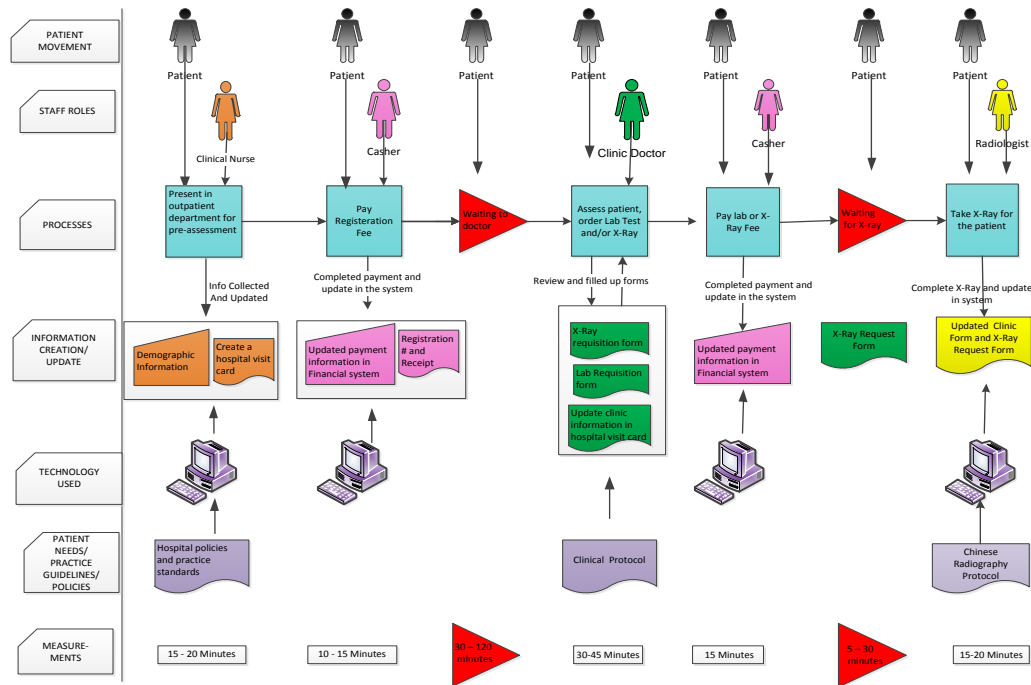
Figure 3-4: Patient Journey Model Architecture (PaJMa)

As Percival described in her article, the PaJMa shown in figure 3-4, working from the top-down, each layer provides important information related to the patient journey:

"(1) a patient's entry into the healthcare journey and consecutive interactions with staff

(2) staff roles, technologies, and processes within in the journey

(3) the individual roles involved in each step during the patient's journey that provides the concept of patient-centre care; processes and possible decisions made that comprise the clinical interventions and action of the journey

41

(4) the information required, obtained, and flowed by each process

(5) the technology involved in each step and underlying infrastructure support

(6) the patient's care needs and priorities are also presented in the diagram

(7)the policies and clinical guidelines support each decision making; the presentation of optional metrics in each step is an unique feature the PaJMa model "(Percival, et al, 2009. P.7).

3.2.2 PaJMa and Process Improvement

As an increased effort on improving clinical processes to increase outcomes and QI, various process improvement methods that have been created and applied in the area of QI are well documented: the using of the basic flowchart, process mapping and PDSA rapid cycle, and the cognitive workflow map, et al (Jun, Ward, Morris & Clarkson, 2009; Wall, Ely, Dlasy, Dittus, Forr, Wilkerson & Speroff, 2005; Malhotra, Jordan, Shortliffe, & Patel, 2007). Jun et al (2009) identified that systematic understanding of care processes is a necessary step to "effective quality improvement". They designed a process model called "two-fold" and aimed to improve quality which they described first step is to improve understanding and the second step is the documentation of a plan of QI in order to identify areas for improvement. Although they described eight modeling techniques that they used, they argued that the basic flowchart was unnecessarily complex. The key point of their model was understanding and documentation (Jun, et al, 2009).

Wall et al described a quality improvement initiative to reduce catheter-related bloodstream infection from central venous catheters in an ICU. By applying the technique of process mapping and the Plan-Do-Study-Act (PDSA) cycle in the unit, they were able to reduce the total number of infection cases as a result of embedding the process flow measures within the documentation system (2005).

In the other study, a complex workflow map was developed for the ICU environment for the purpose of identifying causes of medical errors and medication error prevention by Malhotra, et al. (2007). As a consequence of their study, the underlying cause of medical errors was able to be discovered to alert clinicians, however, the workflow map was very complex and also lack of provision of process of care provision.

The PaJMa model has been used in clinical settings in the last few years. Recent studies have indicated that PaJMa is effective modeling in playing different healthcare roles and associated process, has positive impact on caring process, and it able to represent the use of technology to support the process (Percival, et al, 2009). However, to date, PaJMa has not been used to support the events based activities that constitute clinical guideline models, where responses to events can trigger ad hoc pathways of patient journey (Percival et al, 2009). In this research, PaJMa modeling will be integrated with the new designed model to support QI by smoothing the patient journey process.

3.3 The Clinical Decision Support System

A CDSS refers to an information technology application system used to support clinicians in making clinical decision. The literature review chapter has described different types of the CDSS, including Artemis, an intelligent data analytical system that was designed to provide a real-time data processing environment in supporting the intensive care environment for clinical research (Blount, et al, 2010).

3.3.1 The CDSS Architecture

The Artemis system architecture is illustrated in figure 3-5:
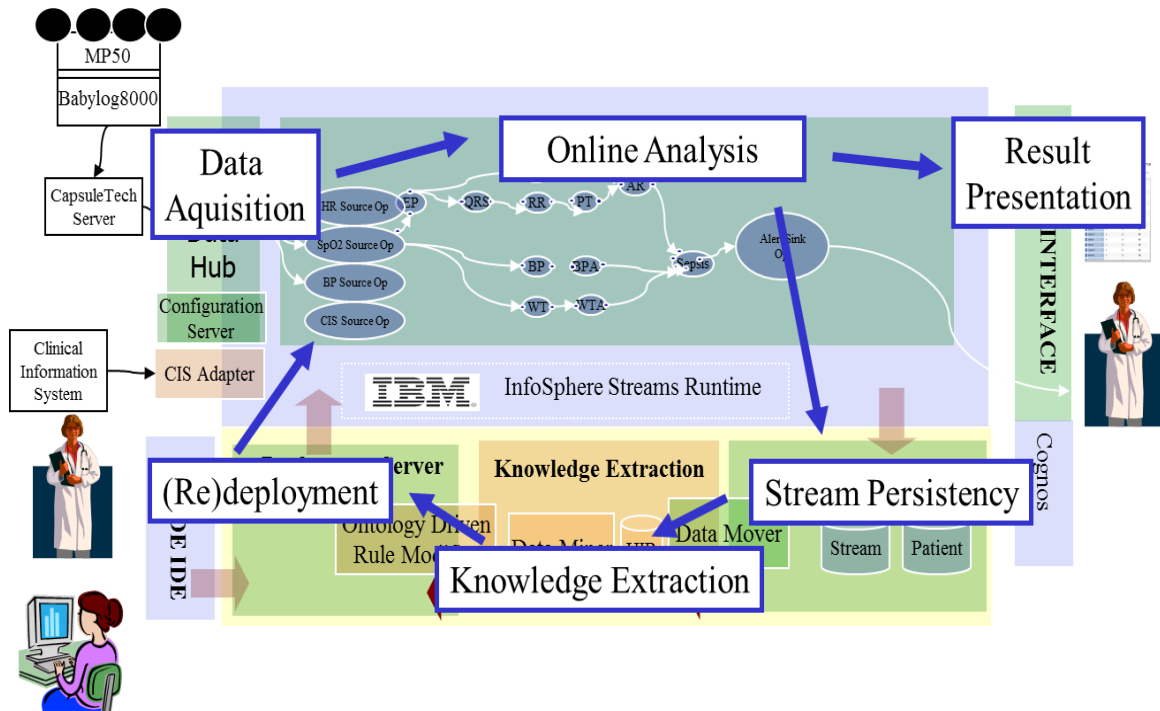
Figure 3-5: The Artemis System Architecture (Blount, et al, 2010)

As presented in figure 3-5, there are a few key components in the Artemis system: The Medical Data Hub is responsible for collecting existing data from various medical devices; the IBM's InfoSphere Steams software plays an important role in real-time steam processing with capacity in handling multiple steams of high volume and high rate data; an Clinical Information System(CIS) Adapter assists in accessing an individual patient's data from the CIS which is integrated in the Artemis system; and Data Integration Manager (DIM) server acts as a bridge between the streaming application as well data transmission in related database in different locations which allow data transmitted from different locations to the data centre for purposes of data storage and analysis (Blount, et al, 2010). As a consequence of the technique design, the Artemis system supports the capture of acquisition, collection, storage, transmission, and processing of multiple high frequency physiological data streams in real-time, perform data mining, and retrospective analysis of wave and numeric form of data streams combined with the supporting clinical

information management system (CIMS) and the laboratory information system (LIS) (Blount, et al, 2010; McGregor, et al, 2011).

3.3.2 Implementation of the Artemis in NICU environment
Since 2009, the Artemis system has been deployed in several NICUs in different hospitals and is able to acquire, collect, analyze, and store data containing electrocardiogram (ECG), heart rate (HR), respiratory rate (RR), and oxygen saturation (SpO_2) and blood pressure (BP) streams as well as CIMS observations for clinical research (Blount, et al, 2010).

Figure 2. Overview of Integration
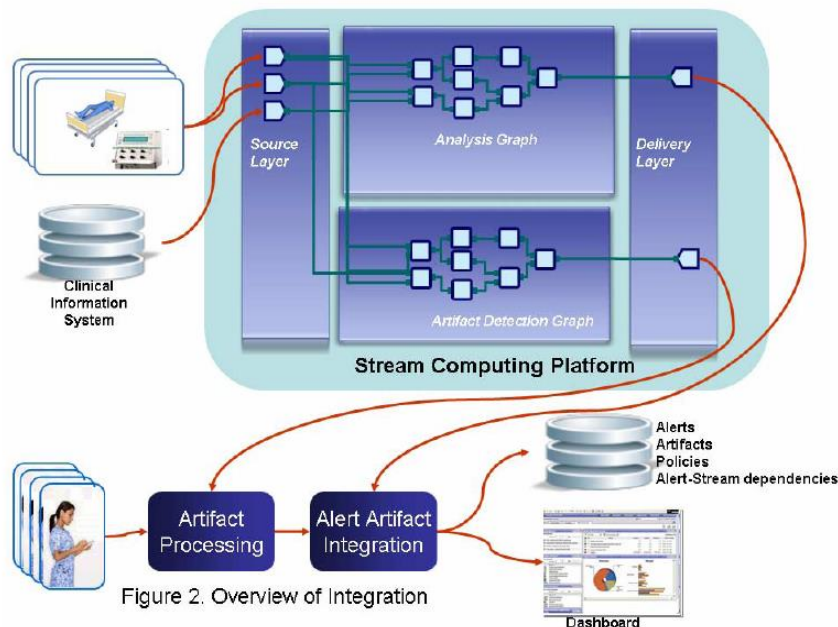
Figure 3-6: Overview of integration of Artemis system (Blount, et al, 2010)

For example, Catley et al had developed a framework for modeling and translating clinical rules to support complex real-time analysis of physiological and clinical data through the Artemis system support in figure 3-7 (Catley, et al, 2010). Their research demonstrated the Artemis analytic system has capacity in identifying and detecting data patterns in physiological data streams when indicative onset of clinically significant conditions via a case study of apnoea, which presented in figure 3-7 (Catley et al, 2010).
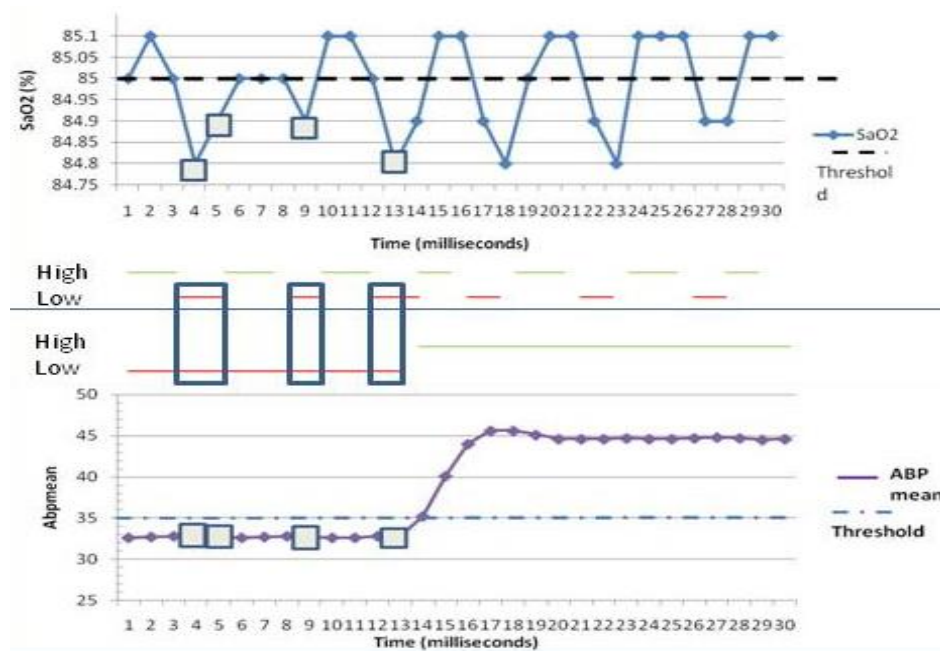
Figure 3-7: SaO2 values against a threshold of 85 and ABP mean values against a

threshold of 35 (Catley, et al, 2010)

Recently, by discovering and recognizing while the Artemis system has the capacity in detecting heart rate variability in premature infants to assist clinician decision making to identify late onset sepsis, the Artemis system sometimes also targets false alarms due to special medical circumstances such as postoperative status, suctioning, and usage of narcotics (McGregor, eal al, 2010). McGregor and her collogues designed and prototyped an artifact management and an artifact alert integration system to capture artifact event thus to minimized false alarm to increase the system's accuracy as presented in figure 3-8 (Blount, et al, 2010; McGregor, et al, 2012).
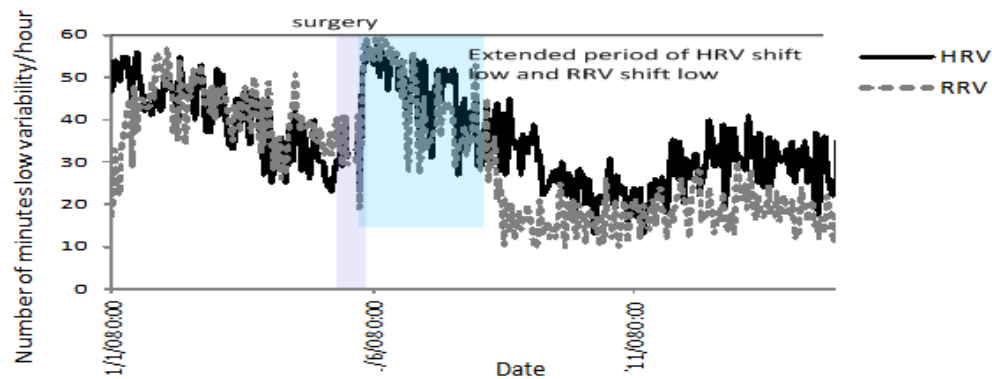
Figure 3-8: The capacity of the CDSS in identify HRV/RRV pattern for narcotics followed by Surgery + Narcotics (McGregor, et al., 2012)

The successful implementation of the CDSS in acute clinical settings and previous clinical research demonstrates that the CDSS has capacity in analysing high-frequency physiological data streams according to clinical rules to support clinical decision making which provided scientific evidence for further utilizing the CDSS as a platform to perform this research.

3.4 Summary

This chapter has provided background information relevant to this research. The first section provides an introduction and description of the CRISP-DM methodology, the application of the CRISP-DM in data mining, and utilization in health informatics field. The section presents the PaJMa model and recent studies of PaJMa to support process improvement, as well as new clinical process approach PaJMa and its potential capacity in QI. The last section discussed the CDSS that used in this research and it capacity in early detection of sepsis related conditions; to present how this research will be supported by the existing evidence based medicine practice and scientific evidence for the capacity of the CDSS.

Chapter4: The Neonatal Intensive Care Environment
4.1 Introduction

This chapter presents a review of the neonatal intensive care units in Canada and China.

A full-term baby refers to a baby who was born between 37 completed weeks of gestational age to 42 weeks of gestation (World Health Organization [WHO], 1977). Most infants who are delivered from 37 weeks of gestation completed to 42 weeks of gestation can be discharged from hospitals when they are two or three days old. Whereas other babies who are born less than 37 weeks gestation are referred to as "preterm infant". Under the large umbrella of preterm birth, preterm birth is also categorized into three sub-groups based on gestational age (Media centre, WHO, May 2012):

- Extremely preterm (<28 weeks)

- Very preterm (28 weeks to <32 weeks)

- Moderate to late preterm (32 weeks to 37 weeks)

As they are not mature enough, the preterm and low birth weight babies are major challenges for perinatal and neonatal care because their under developed and immature body systems attribute to their inability to adept to the natural living environment after they are born. As a consequence, the preterm and low birth babies have longer length of stay, higher mortality, and morbidity rates when compared with full term babies (Canadian Institute for Health Information [CIHI], 2009). They are clinically unstable, and are at high risk of developing a range of poor neonatal outcomes such as: respiratory distress syndrome, gastrointestinal complication, infection, as well as having series problems in their later life such as learning disability and development or behavioural issues (CIHI, 2009). They will not be discharged from hospitals until they are clinical

stable. Figure 4-1 present information about gestational age at birth and survival discharge from participating NICUs in Canada in 2010.
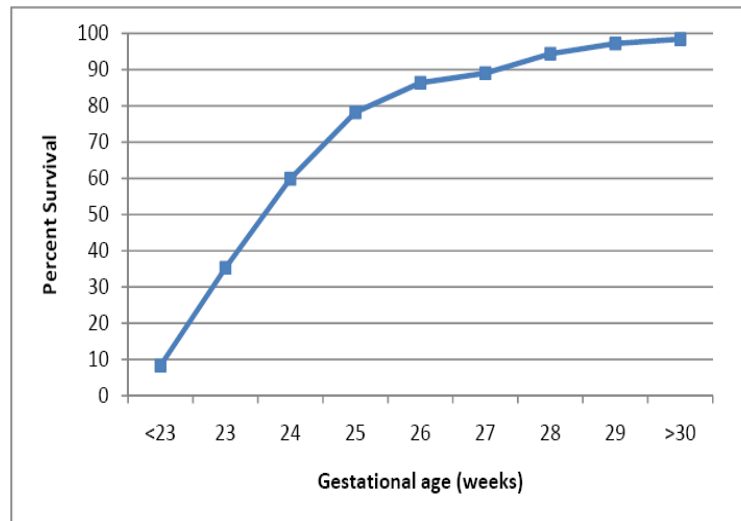
Figure 4-1: Gestational age at birth and survival to discharge from NICUs (CNN, 2010)

As shown in the above graphs and table, for the group of preterm and low birth weight infants, there is obviously a trend that indicates the closer to a full term, the higher infants' survival rate. The concept of a neonatal intensive care unit (NICU) therefore was designed and built to provide quality of care to ensure survival of preterm babies (Committee of Fetus and Newborn, 2004). A NICU is a dynamic healthcare professional team with advanced technology assistance to facilitate optimal outcomes and is an essential key to providing care to high-risk infants including those born preterm or with serious medical/surgical condition to improve outcomes (Committee on Fetus and Newborn, 2004).

The remainder of this chapter describes the context of NICU environment in Canada and in China. The chapter is structured as follows: section 4.2 describes the NICU context, physical environment, medical devices and monitors in Canadian NICU; section 4.3 describes the NICU in China, including detailed information about NICU context,

physical environment, and medical devices and monitors; section 4.4 briefly describes issues of neonatal sepsis, its complication, challenges clinicians are facing with diagnosis, and needs of better management to prevent this condition.

4.2 Neonatal Intensive Care in Canada
4.2.1. NICU Canadian Context

There are approximately 13 million premature babies born each year globally. In North America, approximately 10 per cent of newborns, or 500,000 babies, are preterm infants according to CBC news (CBC News October 4, 2009). A recent report from the CIHI indicated there were more than 54,000 preterm babies or low birth weight for their gestational age (GA) born in Canada in the year of 2009.

Infants admitted into the NICUs range from as small as less than 23 weeks of gestation to greater than 42 weeks of gestation (CNN, 2010). All these infants in NICUs need constant attention and monitoring for their condition based on individual infants' complexity of care needs. To be able to meet their care needs, the neonatal intensive care unit is organized into three designations at hospitals in Canada according to the Fetus and Newborn Committee in the Canadian Paediatric Society (CPS, 2004):

Level 1: Basic neonatal care (normal newborn nursery)

Level 1a:

> • Evaluation and postnatal care of healthy newborn infants; and
>
> • Phototherapy

Level 1b:

> • Care for infants with corrected gestational age greater than 34 weeks or weight greater than 1800 g who have mild illness expected to resolve quickly or who are convalescing after intensive care;

• Ability to initiate and maintain intravenous access and medications;

• Gavage feeding; and

• Nasal oxygen with oxygen saturation monitoring (eg, for infants with chronic lung disease needing long-term oxygen and monitoring)

Level 2: High-dependency neonatal care (special care newborn nursery)

Level 2a:

• Care of infants with a corrected gestational age of 32 weeks or greater or a weight of 1500 g or greater who are moderately ill with problems expected to resolve quickly or who are convalescing after intensive care;

• Peripheral intravenous infusions and possibly parenteral nutrition for a limited duration;

• Resuscitation and stabilization of ill infants before transfer to an appropriate care facility; and

• Nasal oxygen with oxygen saturation monitoring (eg, for infants with chronic lung disease needing long-term oxygen and monitoring)

Level 2 b:

• Mechanical ventilation for brief duration (less than 24 h) or continuous positive airway pressure; and

• Intravenous infusion, total parenteral nutrition, and possibly the use of umbilical central lines and percutaneous intravenous central lines

Level 3: Intensive neonatal care (neonatal intensive care nursery)

Level 3a:

• Care of infants of all gestational ages and weights;

• Mechanical ventilation support, and possibly inhaled nitric oxide, for as long as required; and

• Immediate access to the full range of subspecialty consultants

Level 3b:

• Comprehensive on-site access to subspecialty consultants;

• Performance and interpretation of advanced imaging tests, including computed tomography, magnetic resonance imaging and cardiac echocardiography on an urgent basis; and

• Performance of major surgery on site but not extracorporeal membrane oxygenation, hemofiltration and hemodialysis, or surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass

Level 3c:

• Extracorporeal membrane oxygenation, hemofiltration and hemodialysis or surgical repair of serious congenital cardiac malformations that require a cardiopulmonary bypass (CPS, 2004)

4.2.2 The NICU Environment in Canada

With rapid information technology application in acute care environment, new techniques and instruments play important roles in life support, monitoring, and treating sick babies. Neonates soon after birth are connected with various medical devices to monitor their condition and even to provide life support after admission is routine practice in most of level III NICUs.

Through the medical devices and adequate hospital information system, the babies' physiological data such as HR, RR, electrocardiogram, peripheral oxygen saturation, and blood pressure can be captured and constantly displayed on screens for clinicians to

review (Figure 4-2); however, in the current practice model, most of these data are snapshots on screens for clinicians review unless they document the data on paper for further use. This practice model has limitation in assist clinical decision making because of its inefficacy (clinicians have to manually document data on paper), inconsistence of data analysis, and not real-time data.

Figure 4-2: The NICU environment in Canada (Source: Kamaleswaran, 2011)

As one of the goals of this research is to improve current clinical practice, with implementation of the CDSS in this research, the availability and storage of neonatal physiological data in the clinical system usually as an hourly spot or summary reading, which provides health informatics professionals a great opportunity to utilize the data to assist clinical decision making and make predictions to improve clinical outcomes and quality.

4.2.3 The Medical Devices and Monitoring in the NICU in Canadian Context
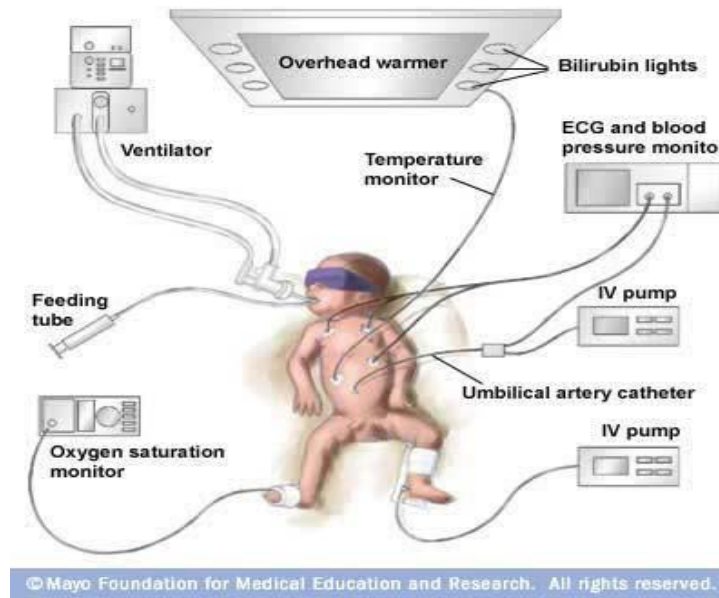
Figure 4-3: Medical devices used in Canadian NICU (Source: Kamaleswaran, 2011)

As displayed in figure 4-3, in order to closely monitor a neonate's condition; all neonates who stay in the NICU are connected with various medical devices to have life support and condition monitoring. Such equipment includes:

- Overhead warmer: an overhead warmer is a heating source that provides heat to a baby. A warmer usually used instead of an incubator if the baby needs to be handled frequently.

- Phototherapy lights: the bright blue fluorescent lights placed over the baby's incubator are used to treat jaundice. Babies with jaundice usually receive the "phototherapy" treatment for about one week based on doctor's order.

- Blood pressure monitor: a blood pressure monitor is a machine connected to a small blood pressure cuff wrapped around a baby's arm or leg. The cuff automatically takes the baby's blood pressure at regular time and displays the numbers on a screen for clinician to read.

- Cardiopulmonary monitor: a machine that tracks the baby's heart and breathing rates. It is connected to the baby by small adhesive monitoring pads placed on her chest. The monitor displays information on the screen, which can be printed onto paper. If the baby's heart or breathing rate becomes too fast or too slow, an alarm will sound.

- IV pump: a doctor or nurse will insert a very small needle or tube into a tiny vein in the baby's hand, foot, arm, leg or scalp. The needle is taped in place, and attached to a thin plastic tube (IV line). The tube goes to an IV pump connected to a pole next to the baby's bed. The baby can also receive medications and blood through the IV line.

- Umbilical artery catheter: a baby's umbilical cord has two arteries and one vein, which end in his belly button. A thin tube (catheter) can be inserted into one of these vessels and threaded to the aorta, the largest artery supplying oxygen to the body. Through this catheter, doctors and nurses can painlessly draw blood. They don't have to repeatedly stick the baby with needles. They can give him fluids, blood, nutrients and medications through this tube. A small device can be attached to the catheter to continuously monitor the baby's blood pressure.

- Oxygen saturation monitor: a small U-shaped device that is wrapped around a baby's foot or hand and secured with a stretchy bandage. It uses a light sensor to help determine if the baby has enough oxygen in her blood. This sensor does not hurt a baby at all. It helps doctors and nurses determine whether she needs more or less oxygen, while reducing the need for painful blood tests.

- Feeding tube: a medical device used to provide nutrition to neonate who cannot obtain nutrition orally.

- Ventilator: a mechanical ventilator is a breathing machine that delivers warmed and humidified air to a baby's lungs. The sickest babies receive mechanical ventilation, meaning that the mechanical ventilator temporarily breathes for them while their lungs recover. The air is delivered to the baby's lungs through an endotracheal tube (a small plastic tube that is inserted through a baby's nose or mouth down into the windpipe). The amount of oxygen, air pressure and number of breaths per minute can be regulated to meet each baby's needs. (March of Dimes, 2012).

4.3 The Neonatal Intensive Care in China

4.3.1 NICU Chinese Context

According to statistics from the WHO report in May 2012, there are about 1,172,300 preterm babies born in China each year (WHO, 2012).

There are three levels of hospitals in China according to the official standards including financial state, annual budgeting, total beds of hospital, and medical equipment; however, the levels of neonatal care provision in a hospital is not clearly identified and categorized due to complicated historical and political reasons (Feng, 2009). According to Feng, in an urban area, some hospitals are able to provide care to babies whose care is complex, while others are not. The hospitals that are able to provide quality of NICU services with modern medical devices are mostly located in big cities such as Shanghai and Beijing; others hospitals may provide level II NICU services in mid-size cities (Feng, 2009). Recently, following the American Academy of Pediatrics (AAP) standards, the Ministry of Health of China created "A guideline to build a NICU in China" with the purpose of

attempting to categorize neonatal intensive care units. Listed below are the described requirements in details:

Level I: Normal newborn nursery where provides basic neonatal care

- Neonatal resuscitation

- Healthy baby evaluation and postnatal care of healthy newborns

- Care for infants with slight deformity and high risk full term newborn with stable vital sign

- Initiative treatment and monitor those neonates who require to transfer to a NICU

Level II: (Neonate Special Care Unit)

Level II A:

- Care for infants whose vital sign stable pending to transfer to NICU for other diseases

- Care of infants with gestation ≥32 weeks or greater or has a birth weight of 1500 g or greater who are moderately ill with problems expected to resolve quickly or who are convalescing after intensive care

- Able to care of infant birth weight 2000 g or greater or gestation 35 weeks or greater

- Apgar 4-6 with stable vital signs

- Intravenous infusion, total parenteral nutrition, and possibly the use of umbilical central lines and percutaneous intravenous central lines

Level II B:

- Need 24 hours ventilation or continuous positive airway pressure (CPAP)

- Care of infants whose birth weight 1500 g or greater, or gestation 32 weeks or greater

- Less than 72 CPAP or less than 24 hours ventilation

- Onsite ultrasound

- Intravenous infusion, total parenteral nutrition, and possibly the use of umbilical central lines and percutaneous intravenous central line

Level III: (Neonatal Intensive Care Unit)

- Care of infants of all gestational ages and weights;

- Constantly RR, HR, HP, blood gas, electronic monitoring

- Mechanical ventilation support

- ECG, CT and MRI

Level III A:

- Care of infants birth weight 1000 g or greater or gestation of age 28 weeks or greater

- Severe sepsis

- Mechanical ventilation support

- Minimal deformity correction surgery

Level III B:

- Care of infants birth weight less than 1000 g or gestational age less than 28 weeks, need advance NICU care

- Comprehensive on-site access to subspecialty consultants;

- Performance and interpretation of advanced imaging tests, including computed tomography, magnetic resonance imaging and cardiac echocardiography on an urgent basis; and

- Performance of major surgery on site but not extracorporeal membrane oxygenation, hemofiltration and hemodialysis, or surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass

Level III C:

- Able to perform extracorporeal membrane oxygenation, hemofiltration and hemodialysis or surgical repair of serious congenital cardiac malformations that require a cardiopulmonary bypass (The Ministry of Health of China, 2012: Building NICU guidelines)

4.3.2 The Medical Devices and Monitoring in the NICU in Chinese Context

Figure 4-4: NICU Medical Monitoring Devices in China (Photo taken on Aug 26, 2011 at The Children's Hospital of Fudan University, Shanghai, China)

There are some similarities in level III NICUs in Canada and China in regards to the medical devices used in the NICUs, such as using an overhead warmer, billirubin lights,

umbilical artery catheter. However, there are some main differences between Canadian and Chinese NICU's as a consequence of policy:

1). Canadians do not have to pay any healthcare cost if they are hospitalized as a benefit from the public healthcare system whereas Chinese have to pay all hospital cost if a resident does not have fully instance coverage;

2). In China, clinicians use pulse rate that is derived from pulse oximetry to monitor cardiac function instead of using the ECG as part of routine practice;

3). Chinese clinicians tend to feed a baby with an oral syringe instead of a feeding tube as well as tend not to use an IV pump in the NICU

4). the biggest practical different between Chinese and Canadian clinicians are Chinese clinician do not offer any infant narcotics such as morphine for pain management as per their cultural believes and values while the Canadian infant will receive narcotics if it is necessary for the infants to have better pain management

All these differences in clinical routine practice have impact on the quality of care clinicians provide to infants; therefore, these factors have to be taken into consideration when designing the framework for QI to ensure the framework can be implemented in different cultural settings.

4.4 Neonatal Sepsis

Neonatal sepsis is a complex medical condition that remains a major cause of morbidity and mortality in children worldwide, with an especially high prevalence in low birth weight (LBW) and premature infants as shown in figure 4-5 (Goldstein, Giroir & Randoilph, 2005; Haque, 2010).
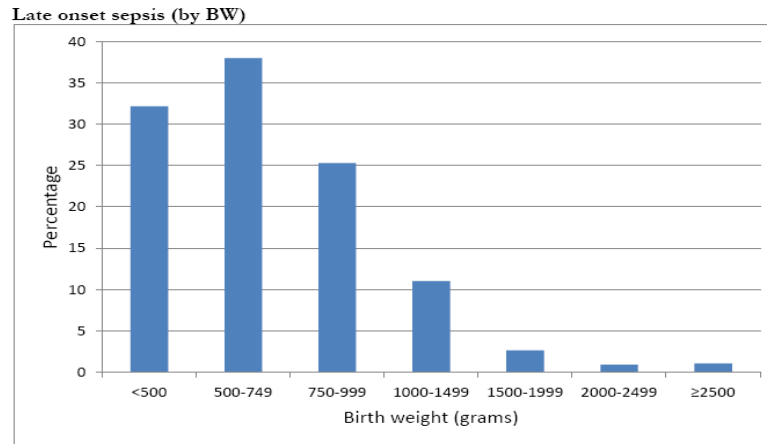
Figure 4-5: Prevalence of late-onset neonatal sepsis by birth weight (CNN, 2010)

Clinically, neonatal sepsis is usually described as a symptom rather than a disease and is categorized into two subgroups according to time to onset of clinical signs and symptoms. Early-onset sepsis usually occurs within the first 72 hours of neonatal life and late onset sepsis (LONS) occurs after 72 hours to 9 days of life (Ng, 2003; Vergnano, Sharland, Kazembe, Mwansambo, & Health, 2004). Clinical studies have found while early-onset sepsis mainly is caused by acquiring the infection agent prior to and/or during the process of delivering, late-onset sepsis is caused by acquiring the infection agent after infants were born (Vergnano, et al, 2004). Any delay in and/or inability to diagnose and commence treatment of sepsis can lead to severe complications, such as impaired neurologic function, cerebral palsy, intravascular coagulation, septicaemia shock, and death (Carcillo, 2005; Ng, 2003). By recognizing the importance of identifying sepsis on time, the Canadian Paediatric Society recommends screening and treating high risk mothers prior to delivering babies to prevent and decrease the risk of development of the early-onset sepsis (Barrington, 2007). However, early identification and detection of the late-onset sepsis remains a major challenge for clinicians due to vague and minimal clinical presentation of warming signs and symptoms of LONS (Ng, 2003). Traditionally,

clinical diagnosis of sepsis relies on clinical manifestations and confirmation of laboratory tests as a consequence of limited technological support (Haque, 2010; Mahk, Hui, Pennie & Kirpalani, 2003; Goldstein, 2005). Recent advanced development in clinical diagnostic technologies such as the biomarker detection technology and the quantitative cellular measurement promise the availability of improved diagnostic techniques (Haque, 2010; Mahket al, 2003; Goldstein, 2005), but they too have disadvantages as they rely on daily routine screening, invasive measurements, and a long turn-around time for results (Goldstein, 2005; Ng, 2003). Recommendations that early recognition and diagnosis of sepsis is beneficial for prevention, promotion, and improve clinical outcomes are well documented, thus clinicians desire a clinical support system to assist them in early identification of late-onset sepsis to promote better clinical outcomes (Chiesa, Panero, Osborn, Simonetti, & Pacifico, 2004).

Efforts on developing non- invasive techniques to predict and identify late-onset of sepsis have accelerated in the last two decades (Chiesa, et al, 2004; Griffin, et al, 2003). Among them, Griffin et al. summarized reasons of being difficult and challenging to identify late-onset sepsis and sepsis-like illness at early stage due to the current clinical diagnostic laboratory and imaging techniques (Griffin, et al, 2003; Griffin, et al, 2007). The study facilitated them to conduct another study in which they discovered a significant clinical finding: the late-onset neonatal sepsis has characteristic early physiological changes 12 to 24 hours prior to clinically symptomatic presentation, particularly occurrence in changes of the heart rate (HR) characteristic of reduced variability and decelerations (Griffin, et al, 2007; Griffin & Moorman, 2001). Their findings are important in facilitating other clinical research and have significant clinical meanings that first provide the clinical evidence-based practice guidelines for further clinical research, as well as providing

potential opportunities in seeking a proper technique development for the early detection of the abnormal behaviour in physiological data to alert clinicians in clinical settings.

4.5 Quality Improvement in NICU

Literature in QI in the NICU's has been getting greater attention than ever before. Strategies of QI in the NICU are well documented, such strategies include increase collaboration between multi-professional teams (Horbar, et al, 2004; Horbar, et al, 2006;), improve process of care through educational programs (Ferrer, et al, 2008), reduce total number of medication use to prevent drug side effects, and efforts on reducing incidence of nosocomial infection (Payne & Avery, 2011). Although few researches have recommended ways of reducing nosocomial infection rate by removing IV catheter as soon as completing antibiotics treatment and emphasizing avoid necessary invasive contact, strategies of how to reduce nosocomial infection and how to predict potential infection are less documented and remain under study. As described in previous sections, the NICU contains various medical devices that produce a vast amount of physiological data for clinicians to review to facilitate care of neonates. The ideal model for a medical monitor has features and capabilities of not only capturing physiological data for displaying in seconds, but also extends its capacity to analyze and store data synchronization while displaying on screens to assist clinicians to plan treatment to prevent disease progress and improve clinical outcomes. Therefore, to design a proper computer-aided support tool such as implementation of the CDSS, create a new clinical practice model, and develop a framework to improve clinical process and outcomes in the NICU to facilitate reduction of nosocomial infection thus to improve quality of care in NICU are new areas for further clinical research.

4.6 Summary

This chapter described the NICU environment, medical devices used, and availability of physiological data acquisition and storage in NICU's in Canada and China. As there is an increasing availability of physiological data in the NICU, there is a trend in clinical research moving towards how to implement tool to properly utilize physiological data to support clinicians in early clinical decision making, with the intent of improving clinical outcome.

Chapter 5: Proposed a Quality Improvement Framework Design

5.1 Introduction

As described in chapter 1, the purpose of this research is to design a framework for the implementation and evaluation of clinical decision support systems to support and measure quality improvement in healthcare. It enriches quality improvement using techniques from patient journey modeling and knowledge discovery. This chapter is composed of two sections: the first section describes the overall structure of the framework through implementation of the CDSS to support quality improvement; the second section describes the plan of evaluation of clinical outcomes and the CDSS in further detail. This chapter addresses hypothesis 1 and 2 of this thesis in which a new approach is taken to support the QI framework design through building a structure-process-outcome-evaluation (SPOE) model, based on Donabedian's concept of quality-of-care framework in combination with the existing CRISP-DM data mining model and the patient journey modeling (PaJMa).

This chapter addresses the following research hypothesises of:

1. A framework can be defined to support quality improvement through implementation of the CDSS

2. That the framework can be supported by knowledge obtained from analysis of high frequency physiological data in real-time

5.2 Proposed Quality Improvement Framework Design

This section introduces the framework design for quality improvement primarily where the intervention is implementation of the CDSS. For the purpose of QI framework design, the QI strategy in this thesis is defined as a means of improving the clinical process and enhancing practical performance to improve quality of care in which activities focus on

providing optimal patient centric care, effectively utilizing clinical data, increasing efficiency, and increasing patient safety through support from the CDSS.

5.2.1 The SPOE Model Design

The structure, process, and outcome (SPO) are the three key dimensions that reflects Donabedian's concept of quality-of-care framework (Mitchell, Ferketich & Jennings, 2007). Donabedian clearly identified a simple cause-effect relationship in his framework as he assumed that the structure of healthcare model affects the caring process which further has impact on healthcare outcomes (Mitchell, et al, 2007). However, there was a lack of attempt for the incorporation of feedback for the continuation of quality improvement in his framework.

Based on Donabedian's concept of quality-of-care, Curtis and his colleagues extended Donabedian's model of quality-of-care with the addition of an evaluation phase in their model, but they failed to utilize objective data to evaluate the process (Curtis, et al, 2006).
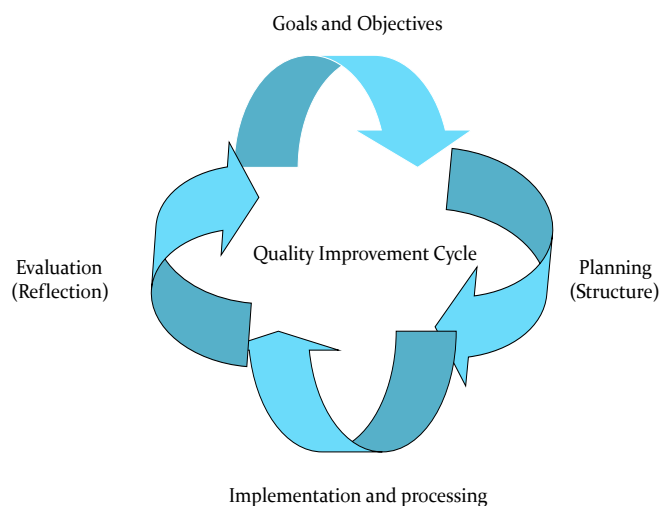
Figure 5-1: The Quality Improvement Cycle

To date, the concept of QI has been identified as a dynamic cycle that includes phases of identifying goals and objectives, planning, implementing and evaluation as illustrated in

figure 5-1. Within this cycle, organizational structure such as policy and protocol, model of healthcare delivery, practice guidelines, patient-staff ratio, size of the healthcare environment and resources are hard factors that directly affect patient movement which is part of patient journey and clinical process, thus impact on quality-of-care patient received; staff attitude, patient characteristics, and clinical intervention are also considered medicate (soft factors) which also affect clinical process and outcomes. The implementation and processing phase includes tools that used to support QI and its process.

Based on the QI cycle, the QI framework proposed in this thesis extends Curtis' model, with incorporation of an evaluation phase in the QI model which aims to seek feedback for the previous of three phases and to reflect the original framework design for further development and modification. In addition it utilises the structure of the CRISP-DM and the extended CRISP-TDM models to provide structure for the phases to identify the goals and objectives together with planning and evaluation. Support for the implementation phase is provided through the use of the PaJMa model to improve delivery of the new care process.

In this proposed framework, organizational structure refers to available resources, healthcare delivery model, policy and protocol, practice guideline, healthcare environment such as bed space, information technology, and information systems; the process documents the sequence and timing of activities that occurs between healthcare providers and patients and their families which is the key area that this framework will be focusing on; the outcomes refers to final results what's the goals of the research looking for. One of the biggest challenges of this framework is how to integrate the SPOE model

with the CRISP-TDM and PaJMa models; it is also one of the unique contributions of the thesis.

This section illustrates the extension made to create the SPOE model as highlighted in figure 5-2. Within this model, the evaluation phase is created to evaluate clinical outcomes as well as effectiveness of the CDSS to reflect the QI process for further study. The proposal conceptual SPOE model in this framework addressed hypothesis 1 of this thesis

> *"A framework can be defined to support quality improvement through*
>
> *implementation of the CDSS"*

Structure

- The size of the unit
- Staff-patient ratio
- Numbers, role, responsibilities of staff
- Type of medical device used
- Type of technology available
- The integration with hospital system
- Current clinical practice processes
- Policy and Guidelines

1. Identification of needs of and areas need to be improved
2. Goals and Objectives
3. Environmental scanning such as: available resources, opportunities, strengths et al.
4. Expected quality improvement outcomes
5. Identify gap between current clinical process and expect outcomes
6. Cultural elements ((Values, beliefs, attitude, and expectations) affect clinical decision making and clinical practice

Process

Clinical process model (Implementation of the CDSS)

- Patient movement
- Staff roles
- Process/ Activities
- Technology used
- Clinical Guidelines
- Metrics

PaJMa model

Outcomes

- Clinical indicators
- Patients satisfaction
- Staff satisfaction

Evaluation

- Outcome evaluation
- Evaluation of the CDSS
- Audit and feedback
- Accompanied by recommended targets
- Impact on clinical process

Feedback

Figure 5-2: SPOE Model

As presented in figure 5-2, prior to redesign of the SPOE model, expected improvement must be made in regards to the identification of needs and areas, the setting of QI goals and objectives, environmental scan to identify resources, opportunities and strengths with the system, identify expect QI outcomes and gap between current clinical process and expect outcomes; cultural elements such as values, beliefs, attitude and expectation are crucial in the SPOE model design to ensure reach goals and success in clinical improvement. In the designed SPOE model,

Structure:

> The size of unit (environmental factor, such as bed space, total number of patients in designed area)

> Staff-patient ratio

> The numbers, roles, responsibilities of staff

> Type of medical device used

> Type of available technology used

> The integration of CDSS system with the hospital information system

> Quality of resources, management system, and policy and guideline using

Process:

> Using the PaJMa to present patient journey, staff roles and responsibilities, information created and captured, technology used, and clinical guidelines

Expected Outcomes:

> Defined clinical indicators

> Patients' satisfaction

> Staff satisfaction

Evaluation:

- ➢ Clinical outcomes

- ➢ CDSS

- ➢ Audit and feedback

- ➢ Accompanied by recommended targets

- ➢ Impacts on clinical process

5.2.2 The Extended CRISP-DM to support QI framework

This proposed QI framework suggests the combination of the SPOE model with the extended CRISP-DM model to allow for a clearer understanding of business of goals based on a medical unit structure, followed by process and utilization of clinical data to assist with clinical decision making thus to improve quality-of-care. The following section briefly describes integration of the SPOE model and extended CRISP-DM tasks completed for the purpose of quality improvement within the context of the framework.

As described in previous section, the SPOE model has established a structure for QI, due to natural characteristics of acute care needs, how to utilize data to support the framework process is the key. This section discusses the framework of utilization of data to support QI in detail. The section support hypothesis 2 of the thesis *"That the framework can be supported by knowledge obtained from analysis of high frequency physiological data in real-time"*

PaJMa			
	PaJMa		

CRISP-DM CRISP-TDM	Business Understanding	Data Understanding	Model Understanding	Evaluation

Extended SPO	Structure	Outcomes	Process	Evaluation

1. Identification of needs of and areas need to be improved
2. Goals and Objectives
3. Environmental scanning such as: available resources, opportunities, strengths et al.
4. Expected quality improvement outcomes
5. Identify gap between current clinical process and expect outcomes
6. Cultural elements (Values, beliefs, attitude, and expectations) affect clinical decision making and clinical practice

Structure	Outcomes	Process	Evaluation
Size of unit (Environment)	Patient Perspectives:	Patient	Various clinical indicators
Bed space Total number of patients in a designed area	(Patient's satisfaction and clinical indicators)		Patients' satisfaction
Staff-patient ratio Staff Roles (# and type)	Staff perspectives: (Roles and satisfaction)	Staff Roles	Staff satisfaction
Activities	Activities	Activities	
Information Technology	Information Technology	Information system and Information Technology	
Medical Equipment	Medical Equipment	Medial Equipment	
Policy	Drug using	Drug Using	
Guideline and protocol	Guidelines	Guidelines	

Figure 5-3: Integration of the CRISP-DM and the extended SPOE to support QI framework

Figure 5-3 presents the new concept of the integration of the CRISP-DM model and the extended SPOE model together to support QI, with a particular focus on how CRISP-TDM will support QI framework to enhance clinical process improvement. The literature review section of this thesis has previously introduced the CRISP-DM methodology and its recent application and success in healthcare field. It defined the six phases of the CRISP-TDM model including business understanding, data understanding, data preparation, modeling, evaluation, and deployment (Chapman, et al, 2001). Figure 5-3 illustrates a supportive relationship between the CRISP-DM and the extended SPOE model that is applicable in the QI framework. As other researchers have not previously explored such supportive relationship, this new concept creates the unique contribution of the thesis. Discussion of the relationship between the CRISP-DM and the SPOE model is explored in the remainder of this section.

Business Understanding:

The primary purpose of the business understanding phase in the CRISP-DM model involves the identification of goals and objectives for the area that will be investigated and accomplished. To apply the business understanding phase in the QI framework, as illustrated in the figure 5-2, the direction of the SPOE model movement presents a cause-effect relationship within the QI framework, which indicates the organizational structure obviously directly affects patient journey and clinical outcomes; however, this one way cause-effect relationship failed in providing information about how and what kind of desired outcomes require structure to be designed in order to support its goals. From the business points of review, the expected outcomes demand the QI structure to support and process its requirement to reach the goals, thus the subtasks of

in the business understanding phase has been used to support both the structure (S) and the outcomes (O) process in the SPOE model as presented in figure 5-3.

Data Understanding and Modeling Understanding:

The data understanding and modeling understanding of the CRISP-DM phases aim to understand characteristics of data, describe the acquired dataset, data exploration to ensure the quality of data for mining, select a data mining model to process data, and to prepare dataset that will be used for data analysis. A data miner then looks for relationships between a predictor and desired outcomes. In this thesis, as illustrated in the figure 5-3 diagram, the data understanding and model understanding phases both fall in the process component of QI. As the intervention for the QI is a CDSS, it must receive data as input and output the results for the CDSS. To successfully implement the QI, a mechanism to feed the data to the CDSS must be created that can occur during the day-to-day function of caring for patients during their patient journey.

Evaluation:

The evaluation phase in the CRISP-DM model involves assessment of the data mining results for accuracy and generalizability to the initial business goals; it also assesses and determines the degree of the CRISP-DM model in meeting business objectives. In the redesigned SPOE model, the evaluation phase aims to evaluate whether the clinical outcomes and the effectiveness of the CDSS in the QI framework are reached.

5.2.3 The CRISP-DM specialised tasks to support QI framework in details

The background section of this thesis has previously introduced the successful application of CRISP-DM application in an acute care domain when used to discover new knowledge for new pathophysiological indicators for earlier onset detection of certain conditions and the previous section discussed the relationship between SPOE model and extended

CRISP-DM. This section will detail how the extended CRISP-DM known as CRISP-TDM gives step by step elements to enable the implementation of the CDSS within the clinical setting in support of QI. The summary of elements to document in each step is presented in figure 5-4.

Specialized tasks of the extended CRISP-DM support QI framework in detail:

1. Clinical application domain
2. Case condition
3. High dependency environment
4. Patient population base
5. Clinical objective
6. Clinical success criteria
7. Quality improvement goals
8. CDSS goals

Phase 1: Business Understand

Phase 2: Data Understand

Data description report

1.Secondary using data
2. Data collection period
3. real-time data supported
4.Diatributed data collection supported

Data Format

Temporal data...

Static data—

HIMS

Lab System

1. Change clinical process based on evident practice and cultural difference
2. Effectively support clinical decision making by utilizing real-time physiological data
3. QI can be supported by real-time physiological in NICU
4. The Artemis system has capacity to support clinical decision making in different cultural settings
5. PaJMa model contributes to QI in NICU

Phase 6: Deployment

CRISP Methodology QI Project

Phase 3: Data Preparation

1. Data set
2. Data resource
3.Data form
4. Additional data
5. Integrate data

1. Assessment of process mining
2. Test application of DM result in real application
3. Assess DM result in respect business success criteria
4.Compare evaluation result and interpretation
4.Conclusion

Phase 5: Evaluation

Phase 4: Modeling

1. DM Technique
2. DM Assumptions
3. Parameter Settings
4.Model Assessment (DM)
5. System Integration

Incorporating Knowledge

1. Incorporating clinical knowledge into DM process
2. Incorporating patient contextual knowledge into DM process

Figure 5-4: CRISP-TDM as extended to support QI framework

Phase one of CRISP-DM: Business Understanding

In this particular research, as it is a framework, the expected outcomes have to be taken into consideration when determining business understanding as it is part of business goals. Thus, the business understand phases including structure and outcomes

- Clinical application domain

- Case condition

- High dependency environment

- Patient population base

- Clinical objective

- Clinical success criteria

- Quality improvement goals

- CDSS goals

Phases two, three, and four of CRISP-DM: data understanding and data modeling in supporting the QI process

The data understanding phase of CRISP-DM aims to understand and prepare dataset to be used for quality improvement. Careful analysis of existing data and selection of data for QI are the key process to ensure QI support. The primary focus of this thesis is on using existing patient data obtained from the CDSS in real-time therefore the activities in data preparation and data modeling in phases three and four respectively are very similar to those described in the previous section.

Phase five of CRISP-DM: Evaluation to support clinical outcomes and CDSS:

Within the evaluation phase in the CRISP-DM, in addition to evaluate the model, there is also an option to test the model in the real world if time permits (Chapman, et al, 2000). For the purpose of creating a conceptual QI framework supported by the CDSS, this

thesis assumes to implement the CDSS in clinical settings to expand the CRISP-DM context in more broad clinical areas, therefore evaluation phases will be focusing on

- *Testing expected clinical outcomes in real clinical settings*

- *Assess DM with results with respect to the organization's business success criteria*

- *Pre-intervention and post-intervention result comparison and outcomes evaluation*

- *Through a real-time analysis of physiological stream date to test whether or the framework have positive impact on increasing clinical process*

- *Prove that QI can be supported by utilizing real-time physiological data*

5.2.4 The Using of PaJMa model to present clinical process to support QI
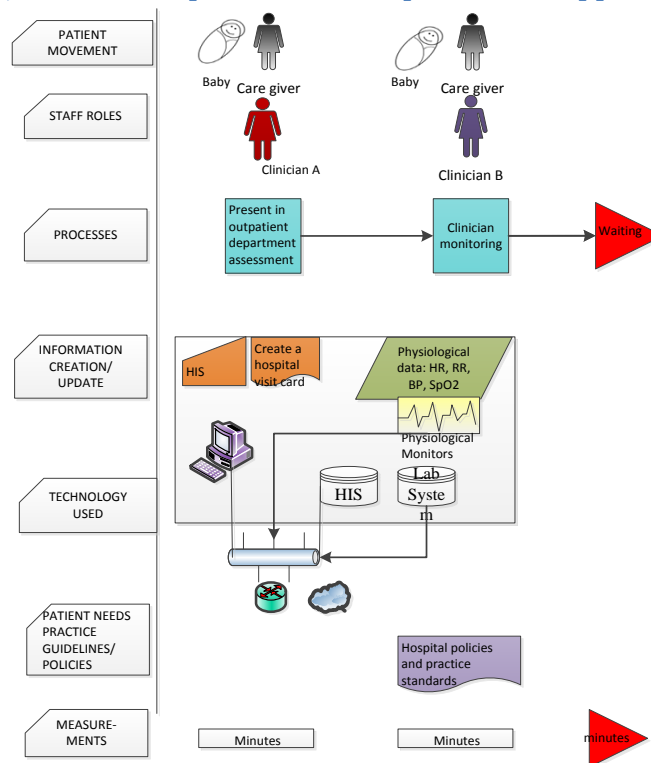
Figure 5-5: Clinical Process Presentation in the PaJMa Model

Figure 5-5 presents a clinical process in the PaJMa model. The PaJMa model has been briefly introduced in the background section. As the purpose of this thesis is to design a framework to improve clinical process and enhance clinical practice, therefore within the process of QI, the PaJMa plays a key role in intuitively presenting how the clinical process will be improved based on evidence based practice and/or clinical guidelines that supports patient-centric care. New technology will be used to increase efficacy by reducing waiting time, it will also demonstrate how patient centric care will be identified to ensure patients' safety, as well as displaying individual professional roles and activities involved in neonatal care and their contribution.

5.3 Method of evaluation of clinical outcomes and the CDSS

Chapter two has reviewed different evaluation methods used for evaluating the CDSS in various research studies, including a randomized controlled trial, nonrandomized controlled triall, a quasi-experimental time-series design, and questionnaire. The section describes an evaluation method used to evaluate the clinical outcomes and the CDSS.

A before and after research method was chosen to measure the clinical outcomes and the effectiveness of the CDSS in this thesis as presented in figure 5-6:
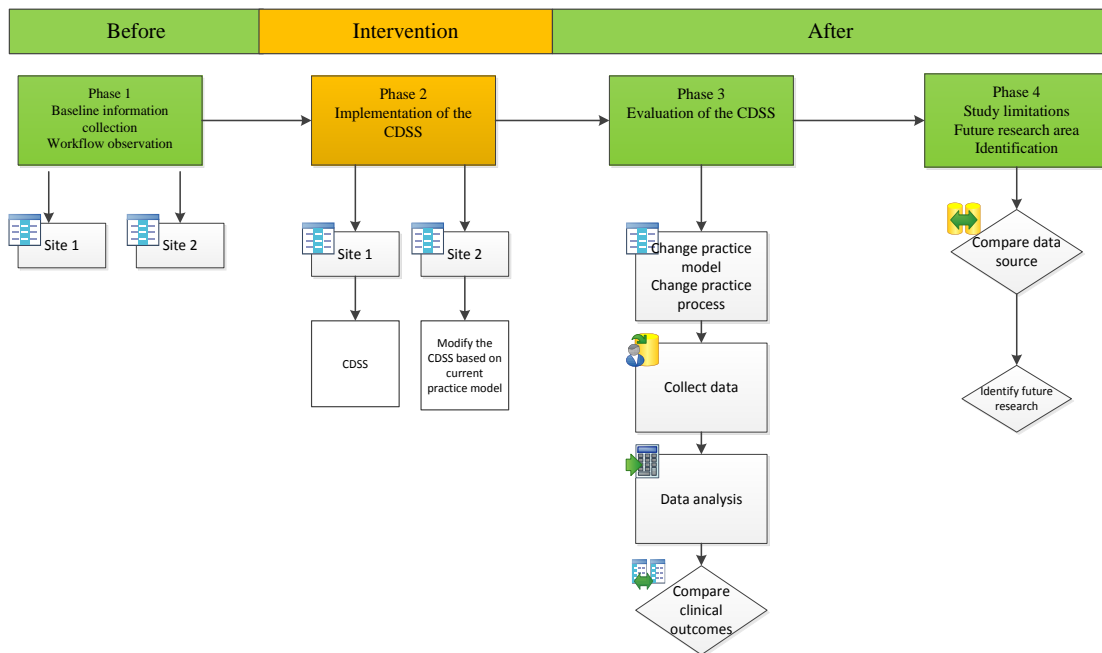
Figure 5-6: Evaluation of the CDSS

The before and after study has its advantages in measuring changes in a phenomenon, situation, and attitude as it is "most appropriate design for measuring the impact or effectiveness of a program" (Kumar, 2005. p. 95). A comparison between pre and post intervention will be made to measure the expected clinical outcomes and determine whether the CDSS support QI, which clinical indicators will be used to evaluate the effectiveness of the CDSS, clinical effectiveness, patient satisfaction, quality of service, and efficiency of service delivered. This section demonstrates hypothesis 3 and 5 of the thesis

"The framework can be demonstrated to support clinical process improvement" and *"The clinical decision support system can effectively support clinical decision making"*

5.4 Summary of the Proposed QI Framework

This chapter has addressed research hypotheses one and two where the clinical context is added in the existing CRISP-DM framework to extend CRISP-DM capacity in the area of

QI. The proposed framework brings together with the concept of quality improvement, clinical management, and clinical research in an environment that will quality of care will be improved by implementing the CDSS which has been demonstrated its capacities in analysis of real-time physiological data along with an explanation of how the PaJMa model can be integrated with the CRISP-DM to contribute to QI provide patient centric care.

Chapter 6: A Case Study Demonstration
6.1 Introduction

Chapter 5 described the QI framework design, directly addressing the research questions introduced in chapter 1. In this chapter, a case study is presented to demonstrate the designed framework for QI and to demonstrate how the evaluation of the CDSS would occur what within the context of the cross-cultural setting. This chapter supports hypotheses 3, 4, and 5 of the thesis:

3. The framework can be demonstrated to support clinical process improvement

4. The framework can be demonstrated with the healthcare setting where clinical practice is routinely taking place in different cultural settings

5. The framework can be used to support the measurement of the effectiveness of the clinical decision support system to support clinical decision-making and improve healthcare outcomes

This chapter also demonstrates the successful integration of the extended SPOE model, the CRISP-DM model, and the PaJMa model together, to facilitate with utilization of real-time data in improving clinical processes and enhance clinician performance for QI through the case study.

As detailed in chapter 1, the objectives of this constructed framework include: assisting clinicians in adapting to the modern high tech clinical environment; maximizing the utilization of available real-time data to assist with clinical decision-making; improve routine clinical practice supported by the CDSS; and implementation of the CDSS to promote better quality of care and clinical outcomes throughout the entire neonatal journey in the NICU. The designed framework is a new innovation in the NICU field.

The remainder of this chapter is structured as follows: Section 6.2 introduces the clinical problem; Section 6.3 introduces the current NICU clinical practice process in Canada and China; the entire framework is presented in 6.4 through a case study based on demonstration of late onset of neonatal sepsis in NICUs in Canada and China; and 6.5 provides a discussion of this framework to conclude the chapter.

6.2 Clinical Problem

Hospital associated infection such as neonatal sepsis has a high prevalence in the low birth weight and premature infant population (Canadian Paediatric Society, 2007). Clinical statistics have indicated that neonatal sepsis has been considered a major cause of neonatal mortality and morbidity in the neonatal population (Canadian Paediatric Society, 2007). The majority of neonates who are admitted in the NICU have developed complex conditions, thus they require close monitoring to prevent critical complications. In addition to complex medical status, neonates' inability to express their feelings, rapid changes in their condition and disease development makes their cases more difficult for clinicians to make the best clinical decisions in regards to establishing the most appropriate treatment plan to promote optimal clinical outcomes; as a consequence of above circumstances, clinicians must rely on diagnostic tests to support their decision of treatments.

6.2.1 Clinical decision making issues in regards to diagnosis of late onset sepsis

Clinically, neonatal sepsis is categorized as early onset and late onset sepsis, in accordance with onset of clinical signs and symptoms (Canadian Paediatric Society, 2007). Of those diagnosed with early onset sepsis, 85 % to 90% of neonates have clinical signs and symptoms occurring in the first 24 hours of life, 5 % -10 % of them have clinical signs and symptoms present at 24-48 hours after birth, and a small group of

neonates have clinical signs and symptoms occurring in 48-72 hours of their life (Anderson, Berry, Belling, & Ohning, 2012). Late onset sepsis presents itself approximately at 4 to 90 days of life and is mostly acquired from the surrounding healthcare environment (Anderson, et al, 2012).

To date, the diagnosis, prediction, and confirmation of neonatal sepsis remains a significant challenge for clinicians that may delay clinical decision making about the treatment plan. Clinically, the characteristics of the development of neonatal sepsis include rapid progression but subtle initial clinical signs and symptoms such as, instability of temperature, tachycardia, poor peripheral perfusion, and respiratory distress (Anderson, et al, 2012). These described symptoms are too general to detect underlying causes (Anderson, et al, 2012). In other words, all these symptoms are not significant indicators to identify a specific disease, which increase the difficulty of conforming the clinical diagnosis thus delay planning of care and treatment (Anderson, et al, 2012). Although there are many advanced diagnostic tests that have played important roles in diagnosing and confirmation of neonatal sepsis, include the using of biological markers for neonatal sepsis identification and diagnosis; some of these tests have the disadvantage of: low sensitivity and specificity in early confirmation; they are expensive; unavailable in routine practice; and invasive to body system (Litmanovitz, 2008). Therefore, in many cases, clinicians are unable to rely on test reports to assist their decision-making.

In a clinical setting, if an infant is suspected to have an infection; the infant should be assessed and treated immediately following a prompt full diagnostic evaluation. Any delay in diagnosis of such a condition between gaps of presentation of clinical signs and being treated will increase risks of poor outcomes and prognosis, thus negatively impacting the neonate's quality of life and resulting in an increase length of stay, cost,

and resources (e.g. number of days requiring the use of antibiotics) (Anderson, et al, 2012). Studies indicate early onset sepsis is mostly caused by mothers and preventive strategies have been in place to prevent development of early sepsis for those infants who are gestation greater than 35 weeks and at high risk of developing sepsis (Canadian Paediatric Society, 2007); however, recommendation and strategies for preventing and predicting late onset of sepsis in the neonatal population need more attention (Canadian Paediatric Society, 2007). There are many reasons contributing to the current difficulty in diagnosing late onset sepsis in a timely manner. One of them is due to the lack of an effective clinical decision support system in the NICU to assist clinicians to monitor risky infants routinely, also to facilitate them to understand, interpret, and utilize data from medial monitors in a timely manner. In such circumstance, the implementation of the CDSS to effectively support clinicians' decision-making has significant clinical meaning to prove invaluable in the effort of caring for septic neonates to improve quality of care as well as clinical outcomes. This framework makes recommendations for clinicians to utilize available data obtained from the medical devices to make positive prediction and speed up the decision making process to improve clinical process to ensure the quality of care they provide.

6.2.2 The potential of using of high technology to support clinical decision-making
The case study demonstration illustrates the framework's ability to assist clinicians in establishing a quality improvement initiative for understanding real-time physiological data acquired from medical monitors, supporting early detection of late onset sepsis, and assist clinical decision-making to improve clinical practice supported by the CDSS. Late onset neonatal sepsis is an ideal condition to demonstrate routine clinical process improvement by utilizing real-time physiological data to support clinical decision-

making. The framework allows clinicians to initiate early clinical assessment, full diagnostic evaluation, update plan of care, and take early intervention to deal with a complex medical condition, as well as improve awareness by the clinical team for reduced risk for disease development thus to improve clinical outcomes and quality of care through a method of changing process of caring, to improve QI.

This case study demonstrates the following research hypothesis:

3. The framework can be demonstrated to support clinical process improvement

4. The framework can be demonstrated with the healthcare setting where clinical practice is routinely taken place in different cultural settings

6.3 Current NICU Clinical Practical Processes Presentation

The clinical processes in Canada and China are similar to each other as they both follow the international guidelines; however, there are slight differences because of different cultural background and clinical practice model used in different settings. The individual clinical practical process in Canada and China will be presented in PaJMa model.

6.3.1 NICU Clinical Process in Canada
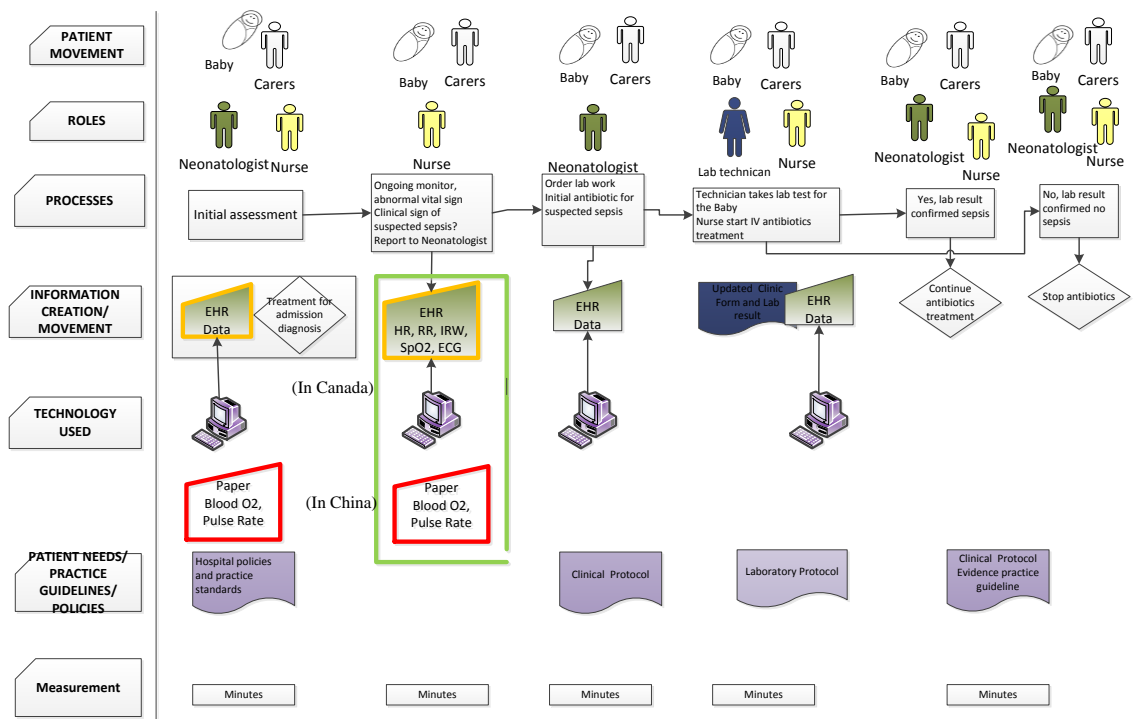
Figure 6-1: NICU Clinical Practice Process in Canada and in China

Figure 6-1 presents the journey of current clinical practice process, clinicians' roles, clinical guidelines and technology are currently using in Canada and in China in the PaJMa model. In The Hospital for Sick Children in Toronto, clinicians use international evidence-based practice guidelines and protocols to guide their clinical process: in step 1, a baby is admitted in the NICU for medical reasons and care needs other than a septic condition; a neonatologist and a NICU nurse conduct their initial assessment and document it in the EHR (highlighted in greenish color): the baby is connected with medical devices to monitor his/her vital signs which their physiological data including

ECG with HR, RR, BP, IRW, SpO_2 together with the derived pulse rate will be detected for monitoring the baby's condition. The baby's physiological data is checked hourly to continue monitoring the baby while he/she is receiving the initial treatment in the entire journey of being treated in the NICU; the baby will be discharged from the NICU from The Hospital for Sick Children after the completion of treatment and he/she is medically stable. However, step 2 shows that if any abnormal signs and symptoms of septic infection occur during the treatment period, the nurses report it to the neonatologist for further investigation. The neonatologist will assess and investigate in more depth to see whether the occurrence of abnormal vitals sign are caused by non-response to treatment or the infant is developing a new condition such as sepsis. If the baby is expected to develop a new condition, he/she will have more laboratory tests to go through and will receive antibiotics treatment is suspicious with sepsis. The normal laboratory turn-around time is about 2 to 4 days, if the laboratory test confirms "yes, positive blood culture indicate sepsis", antibiotics treatment will continue until completed; if the laboratory text confirms "no, negative blood culture", then the delivery of antibiotics will stop immediately. There are two problems in such clinical process: delayed detection of septic infection until clinical symptomatic appearance and long laboratory turn-around time which delays the clinical diagnosis thus delay the treatment initiation.

6.3.2 NICU Clinical Process in China

Figure 6-1 also presents the journey of current clinical practice process, clinician's roles in the process of caring a neonate, and clinical guidelines and technology are currently using in China. At this stage, the clinical processes in the Children's Hospital of Fudan University in Shanghai, China are similar to those in Canada because they both follow the international evidence-based practice guidelines and protocols: in step 1, a baby is

admitted in NICU for medical reasons and care needs other than a septic condition; a neonatologist and a NICU nurse conduct their initial assessment and document the base line information in a paper chart. A significant difference between The Hospital for Sick Children and the Children's Hospital of Fudan University are highlighted in red color in the figure 1: instead of documenting in the EHR in the NICU in The Hospital for Sick Children, paper format documentation is currently used in China which clinicians have to manually read the physiological data from medical devices and write in a paper chart hourly. In step 2, the baby is connected with medical devices to monitor his/her vital signs. A green highlight indicates that only pulse rate and blood oxygen have been monitored in China while the infant is being treated with the admission diagnosis after treatment plan is completed. The NICU nurses continue to monitor the baby while they are receiving the initial treatment in the step 2; the baby will be discharged from NICU after the completion of treatment and he/she is medically stable. However, step 3 shows that if any abnormal signs and symptoms of septic infection occur during the treatment period, the nurses report it to the neonatologist for further investigation. The neonatologist will then conduct further investigation to determine if the occurrence of abnormal vital signs is caused by non-response to treatment or if the infant is developing a new condition such as sepsis. If the baby is expected to develop a new medical condition, he/she will have more laboratory tests to go through and will receive antibiotics treatment is he/she is expecting developing sepsis. The normal laboratory turn-around time is about 2 to 4 days, if the laboratory test confirms "yes, positive blood culture indicate sepsis", antibiotics treatment will continue until completed; if the laboratory test confirms "no, negative blood culture", then the delivery of antibiotics will stop immediately. There are two problems in such clinical process: detection of septic

infection is delayed until the appearance of clinical symptoms followed by long laboratory turn-around time which in turn delays the clinical diagnosis thus delaying the treatment initiative.

6.4 Framework Demonstration

In this section, the designed framework will be demonstrated through the implement of the CDSS to improve the clinical process (highlight in figure 6-2) in the NICU settings where this research is performed. This addressed hypothesis of 5 in this research:

5. *The clinical decision support system can effectively support clinical decision making*

6.4.1 The SPOE model to Improve Clinical Process
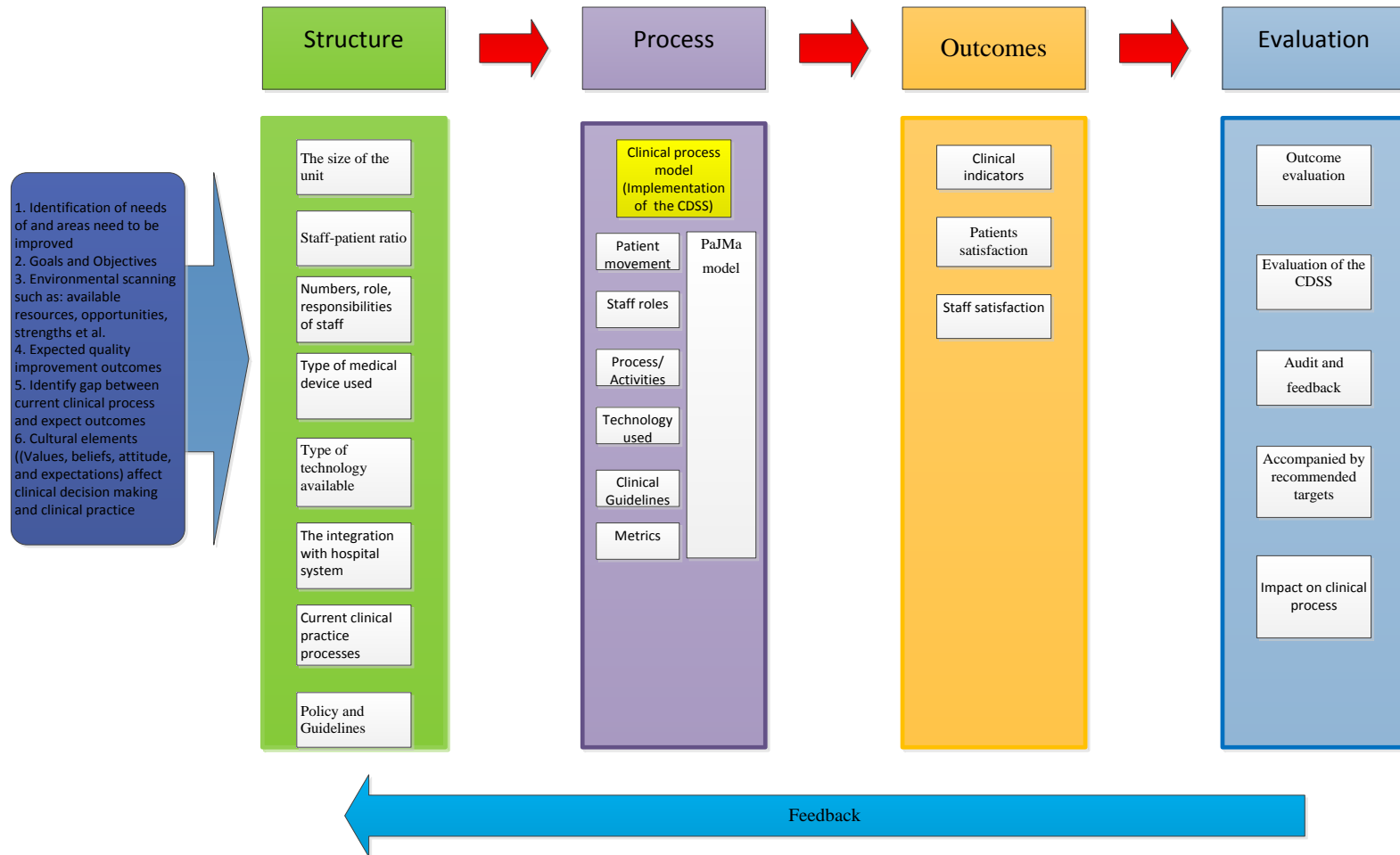
Figure 6-2: SPOE model in case study

6.4.2 The CRISP-DM model integration in the SPOE process

1. Clinical application domain
2. Case condition
3. High dependency environment
4. Patient population base
5. Clinical objective
6. Clinical success criteria
7. Quality improvement goals
8. CDSS goals

Phase 1: Business Understand

Phase 2: Data Understand

Data description report

1.Secondary using data
2. Data collection period
3. real-time data supported
4.Diatributed data collection supported

Data Format

Temporal data...

Static data — HIMS

Lab System

CRISP Methodology QI Project

Phase 3: Data Preparation

1. Data set
2. Data resource
3.Data form
4. Additional data
5. Integrate data

1. Change clinical process based on evident practice and cultural difference
2. Effectively support clinical decision making by utilizing real-time physiological data
3. QI can be supported by real-time physiological in NICU
4. The Artemis system has capacity to support clinical decision making in different cultural settings
5. PaJMa model contributes to QI in NICU

Phase 6: Deployment

1. Assessment of process mining
2. Test application of DM result in real application
3. Assess DM result in respect business success criteria
4.Compare evaluation result and interpretation
4.Conclusion

Phase 5: Evaluation

Phase 4: Modeling

1. DM Technique
2. DM Assumptions
3. Parameter Settings
4.Model Assessment (DM)
5. System Integration

Incorporating Knowledge

1. Incorporating clinical knowledge into DM process
2. Incorporating patient contextual knowledge into DM process

Figure 6-3: CRISP-DM integrate with the SPOE model in case study

In this framework, phase one, two, three, and four of CRISP-DM are presented and described in details in the chapter 5.2, in addition to the clinical context is also added and addressed in phase one. This section focuses on phase five and six in which the utilization and analysis of physiological data are contained within CRISP-DM through the case study of this research to demonstrate how changes in clinical process to support clinical decision making contribute to early intervention to improve quality of care in NICU using the late onset neonatal sepsis case and its representation within an updated PaJMa.

6.4.2.1 CRISP-DM Business Understanding in the Clinical Process

The purposes of the CRISP-DM business understanding phase in this research are to: identify overall business objectives, determine business goals, implement the designed framework in clinical settings, investigate whether the framework will contr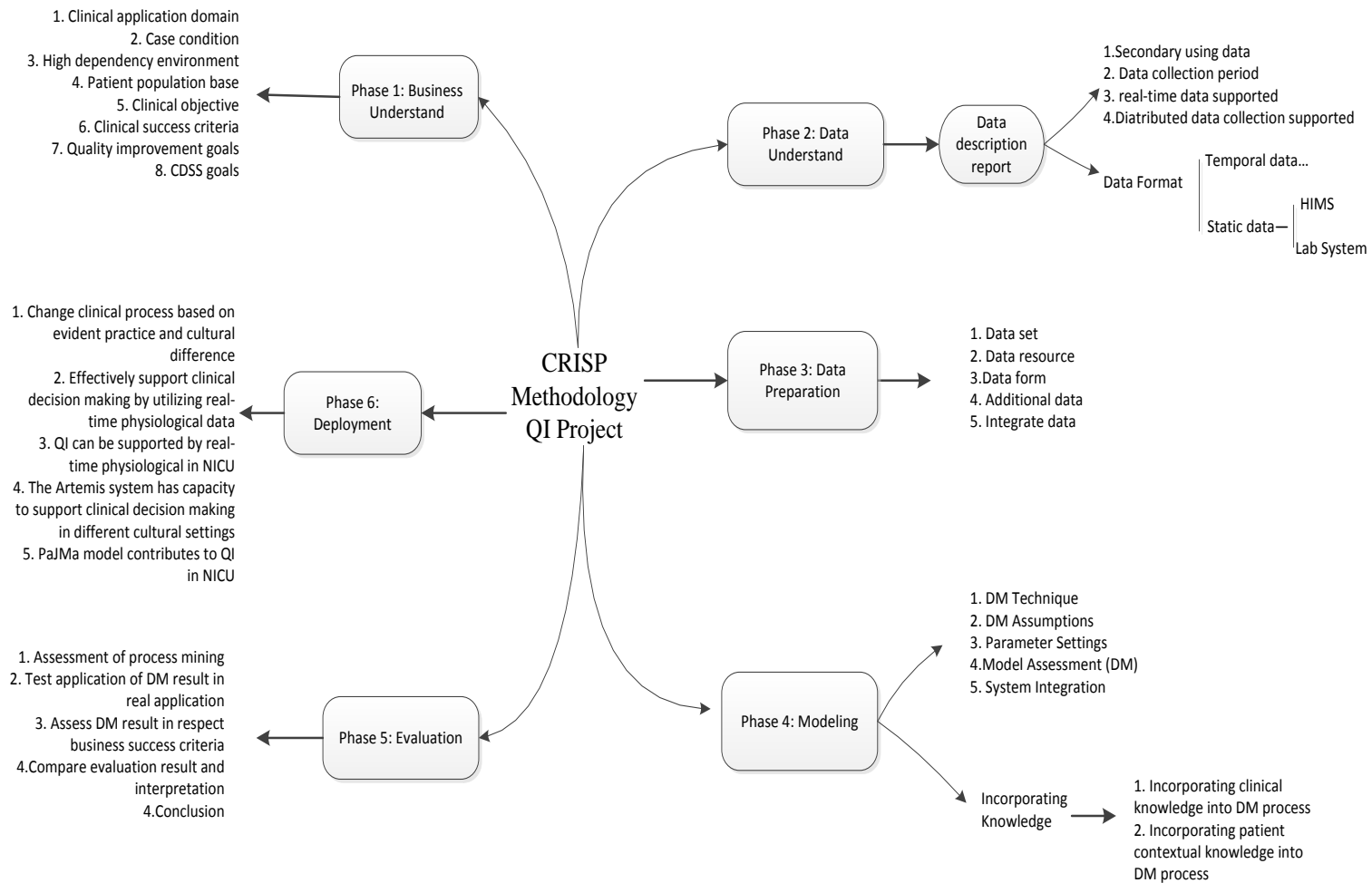ibute to quality improvement in NICU, and evaluate the effectiveness of the CDSS. In the other words, the business understanding phase is the stage of setting goals to investigate whether the CDSS effectively support the clinical decision making, has impacts on changing clinical process and clinical outcomes, increasing efficacy, and improve quality of care. Therefore, the components of the research context in the business understanding phase are:

- *Clinical application domains*: there are two cross-cultural collaborative NICUs where this research is preformed: The Hospital for Sick Children in Toronto and the Children's Hospital of Fudan University, Shanghai, China. The Hospital for Sick Children is a level III neonatal care unit with the most advanced medical devices and highly trained professionals to monitor neonates. The Children's Hospital of Fudan University is one of the biggest children's hospitals with advanced medical equipment in China

- *Neonatal condition*: late-onset neonatal sepsis condition. The unique characteristics of late onset of neonatal sepsis in early stages include reduced variability and decelerations of heart rate in 12 to 24 hours prior to clinically symptomatic presentations (Griffin, et al, 2001) provides us the evidence-base practice guideline for research and an opportunity to work on early detecting abnormal reduced variability of heart rate to support clinical decision making

- *Clinical objectives:* to extend the process mining and abstractive mining research into routine clinical practice to implement research knowledge in real settings to improve clinical practice process, determine whether the use of the designed framework will improve clinical process and outcomes and increase efficiency; whether the use of the CDSS will effectively support clinical decision making to improve clinician's performance

- *Quality improvement goals:* to provide patient centric care by focusing on individual situation and needs; to improve clinical outcomes by utilizing real-time physiological data analysis; and to improve clinical practice process by getting support from the CDSS in combination with the PaJMa model

- *Evaluation of CDSS goals:* to investigate whether or not the Artemis system has capabilities in assisting with clinical decision making to support QI

6.4.2.2 CRISP-DM Data Understand and Data Preparation in Clinical process

The second and third phases of CRISP-DM are data understanding and data preparation, in which data miners attempt to understand data requirement, initial data collection, and criteria for data collection, descript method of data capture and value (Chapman, et al, 2000). Data collection for this research through the Artemis platform was captured in real-time and transmitted from two locations to a server located in the Health Informatics

Research Laboratory at the University of Ontario Institute of Technology, Oshawa, where the data was stored. Data collection from The Hospital for Sick Children commenced in August 2009 and at the Children's Hospital of Fudan University in December 2012. The study relating to the detection of late onset sepsis represents the primary use of this data. There are slight differences in clinical variables used in this research between Canada and China. In Canada, the Philips Monitor MP 70 used to monitor neonates while the Philips Monitor MP 50 used in China (Table 6-1). In addition to the usage of different monitors, the Artemis system has been integrated with hospital EHR and laboratory system in The Hospital for Sick Children; however, the electronic health record (EHR) and laboratory system is currently not used in the Children's Hospital of Fudan University in China which required a slight infrastructure modification (has been completed in other team research). These differences in clinical variables and data storage one must take into consideration when it comes to data analysis to support decision-making.

➢ Data types from Canada: BP, RR, SpO_2 , HR, ECG

➢ Data types from China: SpO_2 , Pulse rate (instead of HR in Canada)

NICU Canada		NICU China	
Philips Monitor MP 70		Philips Monitor MP 50	
Physiological data stream	**Types**	**Physiological data stream**	**Types**
Blood pressure: diastolic	Measurable	Blood pressure: diastolic	Measurable
Blood pressure: systolic	Measurable	Blood pressure: systolic	Measurable
Blood oxygen saturation	Measurable	Blood oxygen saturation	Measurable
Electrocardiograph parameters	Measurable	Electrocardiograph parameters	Measurable
Heart rate	Measurable	Pulse rate	Measurable
Respiration rate	Measurable	Respiration rate	Measurable

Table 6-1: Physiological data used for analysis in Canada and in China

6.4.2.3 CRISP-DM Data Modeling in the clinical process

The phase of data modeling was completed in previous research by Catley, et al in 2009 that used the modeling structure in CRISP-TDM (Figure 6-3) through a quantitative analysis of the temporal abstractions performed on physiological streams. The difference in data types and system integration required modification to the Artemis infrastructure in order to get accurate data mining results to support real-time analysis:

> - In Canada, physiological BP, RR, SpO_2, HR, and ECG data streams were processed with the integrated hospital information system and the laboratory system to perform the process of data mining to obtain new knowledge for data analysis as presented in table 6-1

> - In China, only SpO_2 and pulse streams are automatically collected for data mining due to neither the hospital information system, nor the laboratory system have not been integrated in the Artemis system as presented in table 6-1. As a result information from these systems needed to be collected manually for the data mining

6.4.2.4 CRISP-DM Evaluation in the SPOE model

The CRISP-DM evaluation phase allows researchers to test the application in real settings to evaluate whether or not the designed framework meets the business objectives (Chapman, et al, 2000). In this phase, the modified clinical practice process model implemented in late-onset sepsis case combines with the PaJMa model in the two cross-cultural NICU settings to evaluate whether or the framework will improve clinical outcomes.

As described in 6.3, the clinical process in NICU includes three steps: assessment (clinical data collection from interview patients and clinical examination to obtain base

ling information), planning of care (treatment planning), and re-assessment (assess individual response to treatment and adjust treatment if needed) prior discharge home (Figure 6-1).

 Figure 6-5 uses the PaJMa model to present the framework in the late onset neonatal sepsis case study in The Hospital for Sick Children in Toronto. Following the clinical guidelines, as soon as the neonates are admitted into NICU, all the administrative, obstetric and gestational history, delivery, and demographic information, and base line physiological data are obtained and stored in EHR that has been integrated in Artemis System (step one of practice process). To better monitor the neonates' condition and support the clinicians' decision making and assist them adapt in the high technique environment, we introduce the Artemis system at the beginning of the clinical process in which high risk infants will be monitored closely. The neonate's physiological data (e.g. HR, RR, BP, SpO$_2$, and ECG) is not only displayed on screen for clinicians' review; they are also simultaneously acquired and processed via the Artemis system for real-time online analysis. Neonates are monitored closely while they are receiving treatment, if no abnormal vital signs are detected, they will be discharged home after completion of their treatment. However, if the Artemis system detects educed heart rate variability above the threshold allowed without a complementary fall in the respiration rate variability; the clinician can use this together with other indicators to start the testing and antibiotics. At this time, although neonates may not present any clinical signs and symptoms, the alert assists clinician in changing their treatment usually after clinical feature appear, to take early intervention which they start order laboratory investigations and start antibiotics to treat neonates immediately. The neonatologist will then evaluate laboratory results to

adjust treatment plan based on confirmation of laboratory tests and other clinical signs and symptoms other than sepsis.

6.4.3 CRISP-DM Deployment

The deployment phase documents QI outcomes by using CRISP-DM method as structure, developing a new clinical process based on evidence-based practice and utilization of physiological data in real-time, generating a new evidence clinical practice process based on the case study of the demonstration. As a result of this demonstration:

➢ The QI framework can be defined in NICU by using CRISP-DM method

➢ As presents in PaJMa model, quality of care can be improved through analysis physiological data in real-time

➢ The framework can be implemented in different cultural setting, although culture different influence of clinical practice, the framework can be adjust according to cultural condition to support clinical decision making

➢ The Artemis system has capacity to support clinical decision making in different cultural settings

➢ QI needs a structure to provide a blueprint for clinicians; and the designed QI framework actively guides clinician performance and behaviour to in order to quality improvement

6.5 PaJMa Model in Quality Improvement Research

Throughout the case study, the PaJMa model has its unique contribution to QI in a way of:

➢ Presentation of data flow: the PaJMa presents different data from different clinical perspectives and data flow through the journey of patient in NICU which promote clinicians' decision making in choose an optimal care plan to improve outcomes

➢ Patient centric care: individual infant's parents are involved and participate in the process of caring which presented in the PaJMa. Parents' interaction with clinicians from different perspectives will empower them involving in the clinical decision making, which encourage parents participation in improving health care delivery; it will promote patients satisfaction. During this process, PaJMa acting as an interactive tool that allows parents to explore relevant information that can foster shared clinical decision making process, which also contribute to assist clinical decision making

➢ Increase communication: in NICU, clinicians are unable to communicate with neonates, on-going communication with parents who are the primary care givers provides patient-centre care, give them opportunities to express their experience, perspective on care and will promote increase satisfaction rate. This enables PaJMa to act as a tool to translate family satisfaction data into quality improvement (Dodek, Heyland, Rocker, & Cook, 2004).

6.5.1 The PaJMa model integrated in the SPOE model in Canadian Context
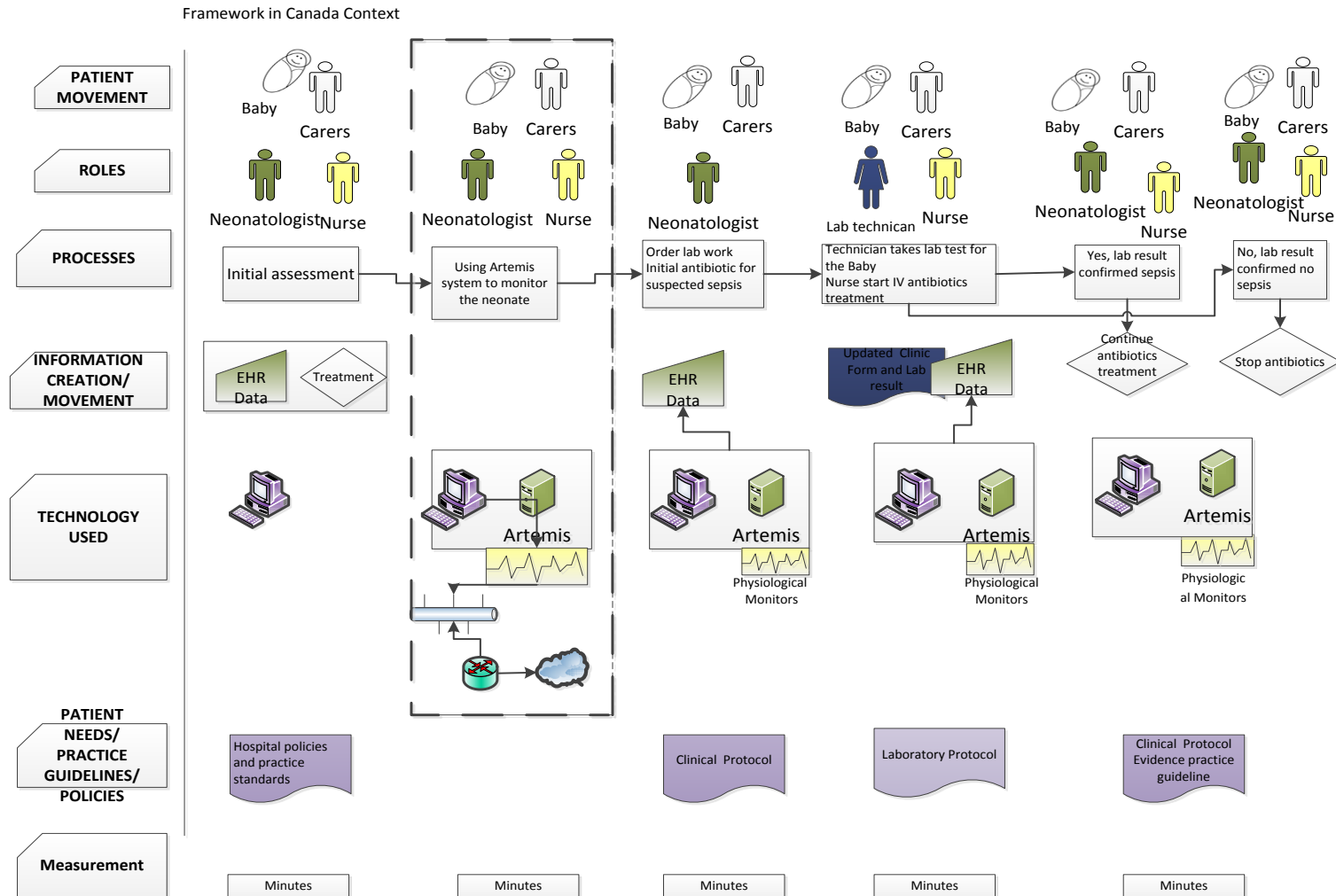
Framework in Canada Context

Figure 6-4: Modified Clinical Process in Canada

Figure 6-4 illustrates the implementation of the framework in The Hospital for Sick

Children: as presented in step 1, as soon as the neonate is admitted to the NICU, the

baby's administrative, obstetric and gestational history, delivery, and demographic

information are obtained, stored in the EHR. For high risk infants who were premature

and had low birth weight, they will be assessed by neonatologists and nurses to get base

line information and document in the EHR. The neonate will then be connected with

medical devices to monitor their vital signs while all physiological data ECG, HR, RR,

BP, and SpO_2 will be acquired and processed by the Artemis system for real-time online

analysis. The neonate is monitored closely while he/she is receiving treatment for initial

medical problem. If no abnormal vital signs are detected, they will be discharged home

after completion of the treatment. However, if the Artemis system detects reduced heart

rate variability over the threshold allowed without a complementary fall in the respiration

rate variability; the clinician can use this together with other indicators to start the testing

and antibiotics. At this time, although neonates have no clinical signs and symptoms, the

neonatologist will review all collected base line information in conjunction with

reviewing individual demographic information in the EHR to decision whether the

neonate is undergoing development last-onset sepsis or not. The alert assists clinicians to

change their thinking and clinical practice to take early intervention which they start order

laboratory investigations and start antibiotics to treat neonates immediately. The next step

is to confirm the diagnosis of late onset sepsis: the neonatologist will review all

laboratory results combined with clinical feature to modify the treatment plan; if the

laboratory confirms positive detection of infection in blood work, the treatment will need

to be completed, otherwise the treatment will be discontinued if laboratory results are

negative.

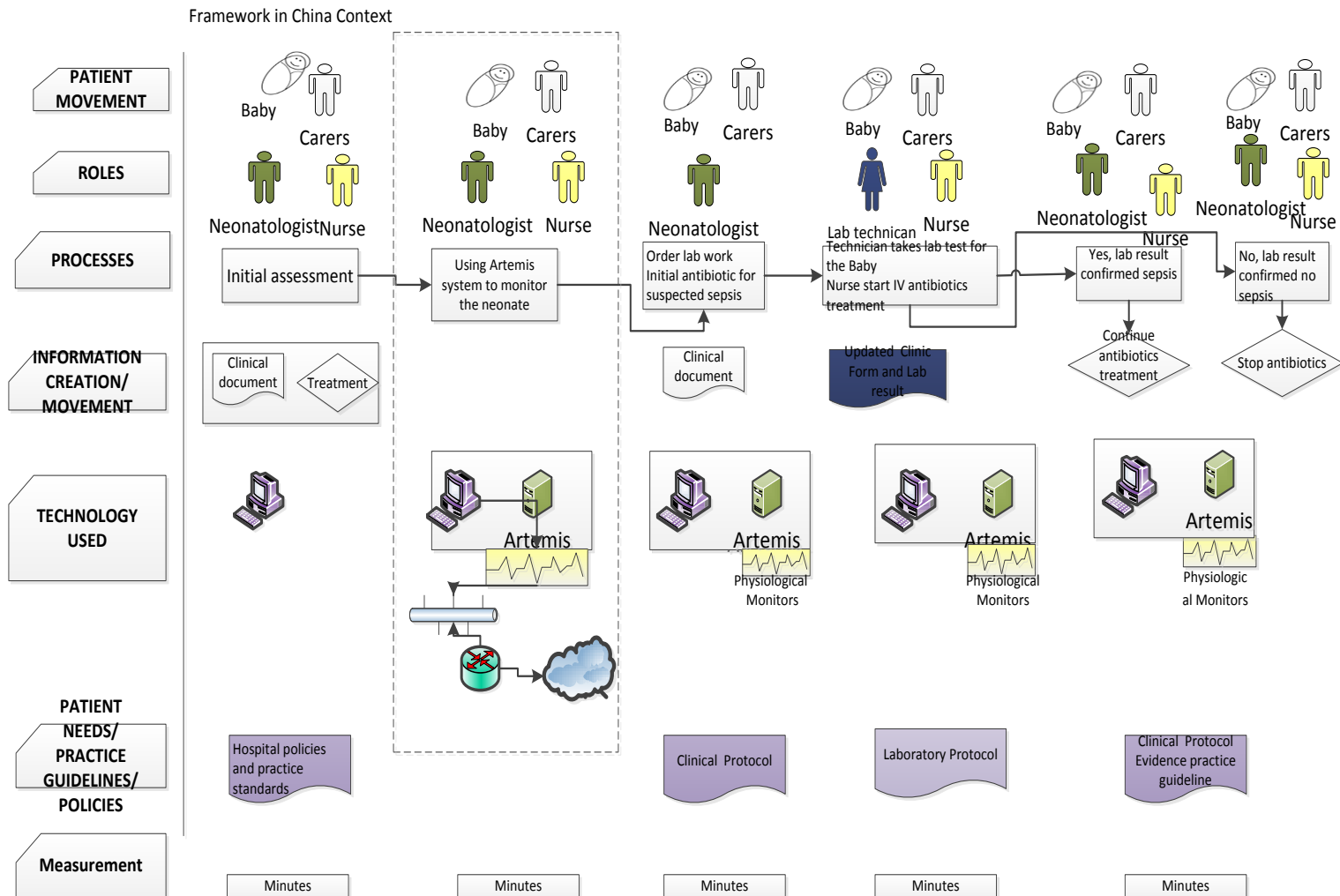## 6.5.2 PaJMa model integrated in SPOE model in Chinese Context

Figure 6-5: Modified Clinical Process in China

Figure 6-5 illustrates the implementation of the framework in The Children's Hospital of Fudan University. Similar to clinical process in The Hospital for Sick Children, as soon as neonates are admitted to the NICU, all the administrative, obstetric and gestational history, delivery, and demographic information are obtained and document in the paper chart. For high risk infants who were premature and have low birth weight, they will be assessed by neonatologists and nurses to get base line information and document in their charts. Following that, the neonate will be connected with medical devices to monitor their vital signs while physiological data including pulse and SpO_2 will be acquired and process to the Artemis system for real-time online analysis. Neonates are monitored closely while they are receiving treatment. If no abnormal vital signs are detected, they will be discharged home after completion of the treatment. However, if the Artemis system detects reduced heart rate variability consecutively above the threshold allowed without a complementary fall in the respiration rate variability; the clinician can use this together with other indicators to start the testing and antibiotics treatment. This is presented in figure 6.4.3. At this time, although neonates may not present with clinical signs and symptoms, the neonatologist has to review all collected base line information in conjunction with reviewing individual demographic information in the chart to decision whether the neonate is developing last onset sepsis or not. The alert assists clinicians to change the plan of treatment to begin early intervention by ordering laboratory tests and antibiotics to treat neonates immediately. The next step is to confirm the diagnosis of late onset sepsis: the neonatologist will review all laboratory results and combines with clinical features to modify the treatment plan, if the laboratory confirms positive detection infection in blood work, the treatment needs to be completed. The treatment will be discontinued if laboratory results are negative.

6.6 Evaluation of the CDSS

This section describes the method used to evaluate the clinical outcome and effectiveness of the CDSS. There are two comparison charts that will be made to provide evidence of the improvement of quality and the CDSS. One chart is made to compare between pre- and post- intervention to evaluate the effectiveness of the CDSS which includes indicators such as: evaluation of laboratory results that confirm or reject the diagnosis, clinical process of care, duration of antibiotics used, total cost of care, length of stay, patient satisfaction, quality of service, and efficiency of service delivered. The second chart provides a comparison between different cultural settings. This section demonstrates the hypothesis 3 and 5 of the thesis:

 3: That the framework can be demonstrated to support clinical process improvement and

 5: The clinical decision support system (the Artemis system) can effectively support clinical decision making

6.6.1 Evaluation Method

Method: a before-and-after non-experimental study design

Rational: the before-and-after study design provides primarily evidence for intervention effectiveness, especially when supplemented with complementary information, it is the most appropriate study design sued to evaluate the effectiveness of the CDSS

Before: baseline measurement documentations at time of Artemis alarm onset, any change nature and frequency of the problem and its consequences

Interventions (Randomization and Masking): Implement the CDSS to acquire, process, and analysis physiological data in real-time to alarm clinicians. In this case, use the Artemis system to monitor ECG with heart rate, respiratory rate, blood oxygen saturation

characteristics in The Hospital for Sick Children; and use the Artemis system to monitor pulse rate and blood oxygen saturation in Children's Hospital of Fudan University.

After: After admission, neonates will be contacted with the CDSS to monitor their condition. Document the time of onset of the Artemis alarm (onset, any changes in RR, HR, SpO$_2$ readings) and duration, time of clinical manifestation (maybe vary in subjects depends on clinicians' observation), and time of laboratory confirmation.

Populations and sample size: low birth weight and premature neonates who admitted in the NICUs

Sample size: 100 neonates in The Hospital for Sick Children in Canada while 100 in The Children's Hospital of Fudan University in China

Result: compare results between pre and post the implementation of the CDSS

6.6.2 Evaluation of the CDSS

Before	Intervention	After

Phase 1
Baseline information collection
Workflow observation

Phase 2
Implementation of the CDSS

Phase 3
Evaluation of the CDSS

Phase 4
Study limitations
Future research area
Identification

Canada

China

Canada

China

CDSS

Modify the CDSS based on current practice model

Change practice model
Change practice process

Collect data

Data analysis

Compare clinical outcomes

Compare data source
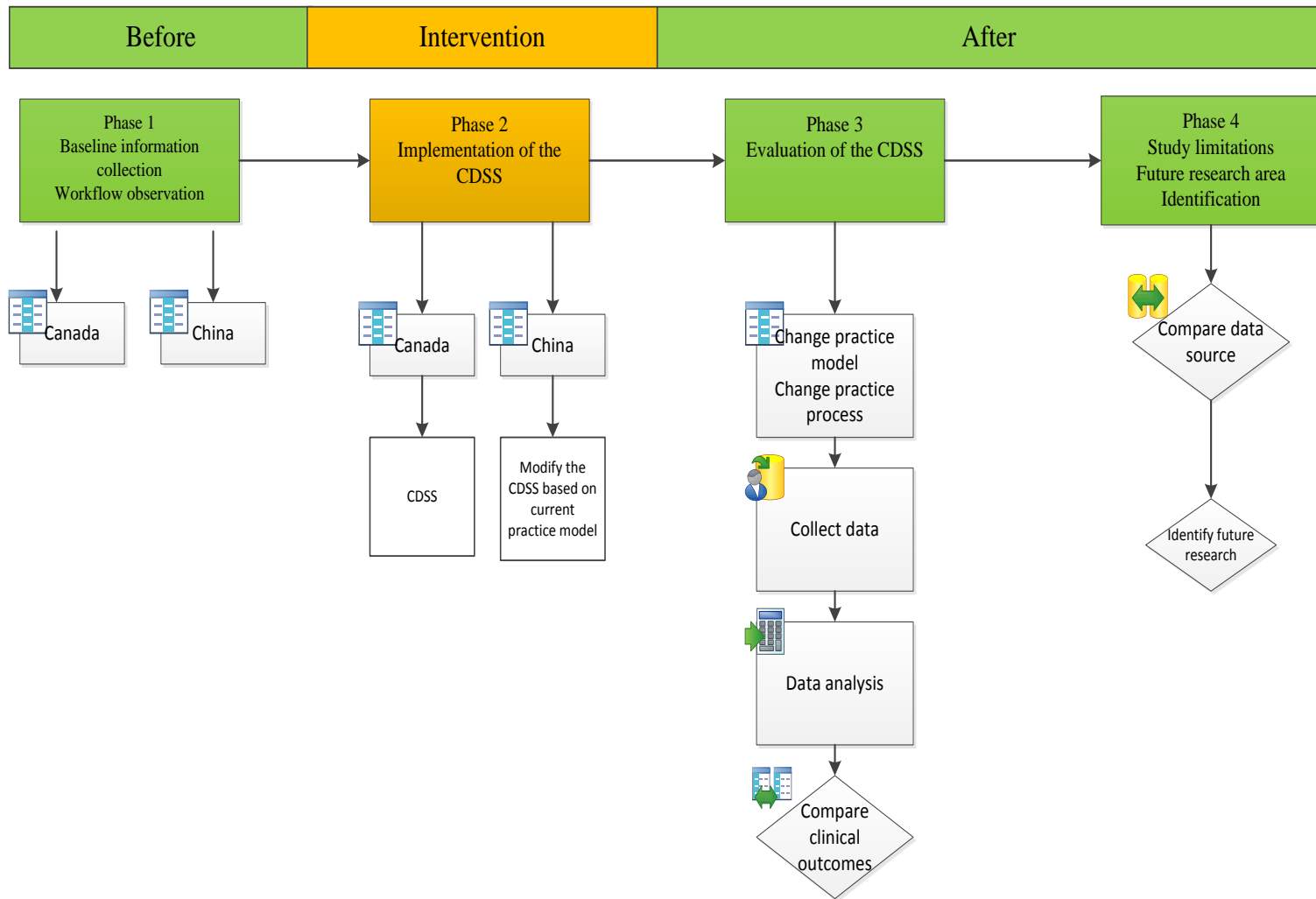
Identify future research

Figure 6-6: Evaluation of the CDSS

Data collection and data management:

Pre intervention data collection: base line data will be collected at the time of admission; then hourly after admission

Post intervention: data collection starts automatically as soon as the neonate is been monitored by the Artemis system. The physiological data include time of alarming and duration (e.g. onset, any changes in RR, HR, SpO_2 readings).

Clinicians have to manually document time of clinical manifestation appearance (which may vary in subjects depending on clinicians' observation), and time of laboratory confirmation.

Expected outcomes:

Primary outcome: looking for the total number of identification and prediction of later onset sepsis cases (in two groups in Canada, two groups in China)

Secondary outcome: looking for the total number of confirmation case, confirmed with (laboratory result, neonatologist: clinical sign and symptoms) in Canada and China

Third outcome: observation of validation rates in two different settings

6.6.3 Pre- and post-intervention comparison

A pre-and post-intervention comparison is presented in table 6-2:

	Pre-	Post-
Laboratory		
Time to order diagnostic test		
Turn-around time (waiting time)		
Clinical process		
Time to order diagnostic tests		
Time to order antibiotics		
Length of antibiotics using		
Length of stay		
Total cost		
Parents' satisfaction		

Table 6-2: Pre- and post-intervention comparison

6.6.4 Comparison of differences in Canada and China

	Canada	China
Human factors:		
Difference in Philosophy		
Difference in cultural, examples	Pain management in infants	Do not use pain medication in infants
Environmental difference		
Practical standards difference		
Attitude of facing problem		
Difference solutions		
Health informatics capacity		
Clinical process		
The Artemis system		
ECG		No
Data Capture		
Data transmission		
Data storage		
Data analysis		
Data integration	Hospital system integration	Locate monitor system
Interpret knowledge		
Difference monitors (functional differently)	Philips Monitor MP 70	Philips Monitor MP 50
Study population	Outborn infants	Outborn infants
Data collection		
Data presentation different (information different)		
How we are going to handle the difference		
Patient Journey Modeling (Capacity difference)		
Hospital information system	Integrated	N/A

Table 6-3: Comparison of difference in Canada and China

6.7 Discussion and summary of the case study demonstration

This chapter has addressed research hypotheses 3, 4 and 5where the clinical process is

improved by implementing of the SPOE model that integrates the CRISP-DM and the

PaJMa model. The clinical case demonstrates how the CDSS utilizes real-time data to support clinical decision-making which clinical process was presented that extend CRISP-DM capacity in the area of QI and PaJMa.

Chapter 7: Conclusion

This thesis has presented a framework for quality improvement and evaluation of the clinical decision support system in the NICU environment. The framework is demonstrated through a case study supported by implementation of the CDSS that captures, stores, and analyzes acquired physiological data in real-time. The conclusion chapter provides a summary of the proposed framework that is described in previous chapters, discusses clinical implication, illustrates contributions of the thesis, identifies limitations of the thesis, and highlights impact and future research opportunities. The reminder of the chapter is organized as follows: section7.1 provides a summary of the proposed framework; section 7.2 discusses clinical implication; section 7.3 describes contributions of the thesis to the research area; section 7.4 identifies limitation of the research; section 7.5 provides potential opportunities and future in the research and advancement of the proposed framework; section 7.6 presents the final conclusion to this thesis paper.

7.1 Summary

This thesis presents a framework for QI and evaluation of the CDSS to support and measure QI through implementation of the CDSS in the NICU environment. The proposed framework extends the SPO model to the new practical SPOE model, uses the CRISP-DM data mining principle to specifically address the research problems, together with the PaJMa model to improve clinical process to assist clinician's decision making in NICU environment in cross-cultural settings. The contributed framework is unique in the sense of utilizing physiological data in real-time to support clinical decision making, though implementation of the CDSS to improve quality of care.

A literature review was completed for the purpose of exposing current status of utilization of the CDSS, identify the needs of, and potential opportunities of designing this framework; definitions of QI, current researches in QI, and methods of CDSS evaluation were reviewed in chapter two. The literature review focused on two major areas: QI and evaluation of the CDSS. The first section of the review focused on the existing studies of QI, which results indicated although many QI projects have been introduced and implemented in the last two decades, there are some existing issues in current status: such as an absence of using real-time data to structure QI in the NICU environment; lack of using measureable variables to improve clinical process and outcomes; limited implementation of QI and description of QI process in real-time in routine practice setting remains under study; et al.

The second section of the literature review focused on existing studies of evaluation of the CDSS and current issues. Methods of evaluating the CDSS are vary according to different perspective and types of the CDSS needed to be evaluated; the literature results found there are some issues remaining that are under studied, such as the traditional health science study is not applied to high frequency health informatics environment because it does not take physiological data into consideration when it comes to supporting clinical decision making; the application of IT in critical care setting is not only focused on increased utilization to enable the improvement through QI, but also the desires for outcomes that effectively support that clinical decision making to increase efficiency; the impact of CDSS on clinical process and outcomes should be measured by a designed evidence based scientific study; and encourage clinicians to adapt the high information technology environment thus revision of practice model based on evident practice. The results of the literature review provided information and opportunities for research and an

impetus for the clinical researcher to design this framework to address above problems and solutions to solve these problems to fit the gaps. Therefore, the following hypothesises were generated:

1. A framework can be defined to enable the quality improvement through implementation of CDSS in the NICU environment

2. That the framework can by supported by knowledge obtained from analysis of high frequency physiological data in real-time

3. That the framework can be demonstrated to support clinical process improvement

4. That the framework can be demonstrated within the healthcare setting where clinical practice is routinely taken place in different cultural settings

5. The clinical decision support system can effectively support clinical decision making

Chapter 3 provided background information related to the proposed framework design in three main themes: the CRISP-DM methodology, the PaJMa model and its implementation in clinical settings, and the Artemis CDSS. This framework extends previous SPO model to SPOE practical model by implementing of the CDSS, together with integration of CRISP-DM and PaJMa; previously there was little research that has been completed by other members within the Health Informatics Research Team at the UOIT, therefore, this research and its outcomes from team members were also described in this chapter which demonstrates evidences to ensure success in designing of the framework.

Chapter 4 introduced the contexts of the neonatal intensive care unit globally which is application domain for the framework. Through full description of similarities and

differences in two different cultural settings to ensure the designed framework can be successfully implemented in the two settings.

The framework was introduced in chapter 5. The chapter described and discussed the framework design in details to addresses research hypothesises of

1. A framework can be defined to support quality improvement through implementation of the CDSS;

2. That the framework can be support by knowledge obtained from analysis of high frequency physiological data in real-time

This chapter described the extension of the SPO model to the SPOE model, together with the CRISP-DM and the PaJMa to improve clinical process to reach the goals of support QI. This chapter also introduced the before-after method as the chosen evaluation method for using in the framework for evaluation of the CDSS.

Chapter 6 demonstrated and explained the designed framework through a case study of late onset neonatal sepsis in different cultural settings. The chapter 6 described and discussed the framework design in details to addresses research hypothesises of

3. The framework can be demonstrated to support clinical process improvement

4. The framework can be demonstrated with the healthcare setting where clinical practice is routinely taking place in different cultural settings

5. The framework can be used to support the measurement of the effectiveness of the clinical decision support system to support clinical decision making and improve healthcare outcomes

Through full description of the case study, chapter 6 instantiated that the objectives of the research have been met by the proposed framework, with those being:

1. A well-constructed quality improvement research framework have been designed by extending the SPO model, in combination of the CRISP-DM model and the PaJMa model

2. The framework has been demonstrated through a case study in cross-cultural settings

3. The effectiveness of the clinical decision support on clinical outcomes

4. The Artemis analytic system has capability in detecting early changes in the high frequency physiological streams in suspected neonatal sepsis has been demonstrated by the case study

7.2 Clinical Implications

Although QI has received much more attention in the past two decades than ever before, most of them through methods such as increase patients' and employees' satisfaction et al (Baker, et al, 2003), implementation of multi-intervention including evidence-base practice (Scales, et al, 2011), staff education (Ferrer, et al, 2008), utilization organizational assessment survey (Baker, et al, 2003), and increase leadership (Horbar, et al, 2003). Questions such as how to maximum utilize of IT resource to improve QI and in which degree of IT to QI remain under study.

CDSSs have played key roles in supporting healthcare in many aspects, such as helping in the analysis of patient data to determine diagnosis of disease. In the modern critical care environment such as NICUs, due to the nature of infants' inability of providing symptoms to clinicians; in addition to analyze clinical signs and symptoms, clinicians have to rely on analysis of laboratory tests results and physiological data collected from medical devices attached to infants to assist them determine disease diagnosis thus make proper treatment plan to treat sick infants, to ensure quality of care provide to infants. However,

many doctors and nurses have no confidence in understanding and analyzing the acquired data from the medical devices in the NICU to make their decision, other than rely on IT professionals and/or the CDSS to assist them for clinical decision making.

In the NICU environment, from a health informatics perspective, one way to assist clinicians to predict and diagnose diseases on time is to implement the CDSS to analyze patient data in real-time to ensure quality of care delivered. In this research, the framework is designed through the implementation of the CDSS that is able to obtain and analyze of patient data in real time to support clinical decision making to improve the clinical process. Many factors have been taken into consideration when designing this framework for QI, including: differences in medical equipment used; data used for analysis; different culture beliefs and values; attitude toward narcotics use for infant pain management; and NICU physical working environment. The QI framework is expected to have positive impact on improving clinical process and outcomes, increase efficiency and increase effectiveness of the CDSS in cross-cultural clinical settings. The research results should be recommended for use as a new practical model and an example to implement in real acute clinical settings to improve clinical process thus to improve quality of care.

7.3 Contributions of the Framework

This is a unique action research design, the contributions of the proposed framework are:

1. Definition of a QI framework in NICU for further research to ensure QI outcomes

2. Extensions to a SPOE clinical practice model for clinical process improvement to improve quality and outcomes in the NICU by utilizing and analysis of real-time physiological data

3. Enables the integration of CRISP DM and the PaJMa for QI framework

4. Evaluation of the CDSS through analysis of acquired physiological data in real-time

5. The PaJMa model has significant impact on improve clinical process thus improve quality

6. Demonstration using a clinical case study

7.4 Limitations

Clinical research is an on-going process made more complex, given slight different clinical practices in two different cultural background hospitals. In addition to the need of having substantial time and resource needed to conduct a trials, particularly in the area of NICU, this trial may not be unable to enrol sufficient patients for adequate statistical power to conduct a RCT to evaluate the CDSS.

Second, for many clinical informatics interventions, the potential effect on patient outcomes is affected by clinician behaviors; such as if the clinician does not use the intervention, the patient cannot reap the benefits (Bakken, 2009). Therefore, in China, the lack of using ECG to support this research may lower research results. Finally, the difference in clinical practice behaviour can also affect the research, for instance, the routine of using narcotics for pain management in Canada will have slight difference research result compare with in China where using narcotic in infants is not a routine practice.

7.5 Impact and Further Research

The significance of the QI framework design and success according to defined QI has been described in previous chapters. Although there are a few differences in terms of routine clinical intervention in cross-cultural settings; including the difference in clinical contexts and current practical models; difference in resource allocation such as the health information management and laboratory system are not integrated with the CDSS in

Chinese setting but it is in The Hospital for Sick Children Toronto, the framework will have positive impact on QI in the NICUs.

In terms of future research, potential and possibility of using the randomized control trial research methodology to evaluation the CDSS as an innovation in evaluating the application of IT in healthcare domain is next research area. Moreover, cultural belief has impact on supportive of QI: values, beliefs, and norms present in the microsystem that emphasise teamwork, communication, freedom to make decisions and commitment to improve. In China, clinicians do not use narcotics such as morphine for post-operative pain management; usually they use Tylenol to control pain; therefore, how and in which degree of pain effect on physiological data changes is another potential research opportunity.

7.6 Conclusion

QI is a complex concept that consists of components of safe, effective, patient-centered care, timely, efficient, and equitable (Committee on Quality of Health in America, 2001). Many QI initiatives have accelerated in the past two decades; however, most of them focused on increasing patient and employee satisfaction and improving process of caring (Curtis, et al, 2006; Kaplan, et al, 2012). It is unfortunate that there is lack of study on implementation of CDSSs to improve QI, especially in an acute care setting such as NICU environment (Fan, et al, 2010; Kaplan, et al, 2012).

This thesis presents a framework design for implementation and evaluation of the CDSS to improve QI in NICU in cross-cultural settings. The proposed framework extends an existing SPO model to SPOE model through implementation of the CDSS, and the integration of CRISP-DM and the PaJMa model to improve clinical process thus assist clinical decision making, finally reach QI goals of patient-centered care, timely, increase

efficient and effective. This thesis has demonstrated capturing, storage, and analysis of patient physiological data will support QI and evaluation of effectiveness of the CDSS. The designed framework will continue with its future investigation in the post narcotics pain management as next step of QI research, as to measure degree of pain effect on physiological data changes.

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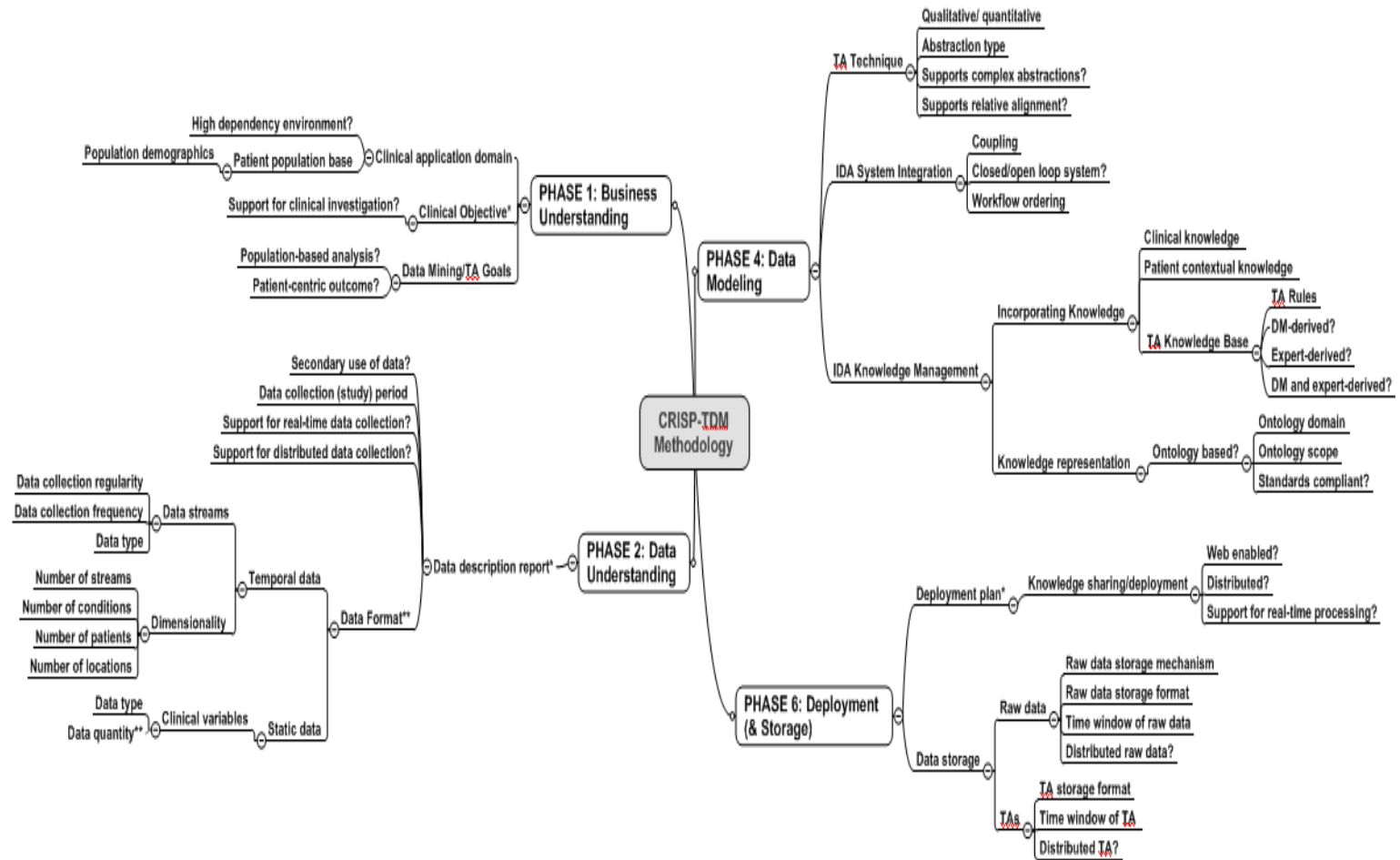Percival, J., Catley, C., McGregor, C., James, A. (2009). A design for modelling the

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Appendix

Appendix 1: Extended the CRISP-TDM to incorporate multi-dimensional data

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