

**An Intelligent Risk Detection Model to Improve Decision  
Efficiency in Healthcare Contexts:  
The Case of Paediatric Congenital Heart Disease**

**A thesis submitted in fulfilment of the requirements for the degree of  
Doctor of Philosophy (PhD) in Health Informatics**

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## Declaration

I certify that:

- Except where due acknowledgement has been made, this work is that of the author alone;
- This work has not been submitted previously, to qualify for any other academic award;
- The content of this thesis is the result of work which has been carried out since the official commencement date of the approved research program;
- Any editorial assistance carried out by a third party is acknowledged.

Hoda Moghimi



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## **List of abbreviations**

AA	Aortic Atresia
ACG	Ambulatory Care Group
AS	Aortic Stenosis
AS	Aortic Stenosis
ASD	Atrial Septal Defect
ACD	Atrioventricular Canal Defect
BAV	Bicuspid Aortic Valve
BCPS	Bidirectional Cavo-Pulmonary Shunt
BA	Business Analytics
BI	Business Intelligence
CHD	Congenital Heart Disease
CDSS	Clinical Decision Support Systems
CRG	Clinical Risk Group
CPOE	Computerized Physician Order Entry
CA	Coarctation of the Aorta
CCHB	Complete Congenital Heart Block
CCTGAGV	Congenitally Corrected Transposition of the Great Arteries or Great Vessels
CAA	Coronary Artery Anomaly
DCRV	Double Chamber Right Ventricle
DAA	Double Aortic Arch
DORV	Double Outlet Right Ventricle
DM	Data Mining
EA	Ebstein's Anomaly
ES	Eisenmenger's syndrome

EF	Endocardial Fibroelastosis
EHR	Electronic Health Record
HC	Hypertrophic Cardiomyopathy
HLHS	Hypoplastic Left Heart syndrome
HRHS	Hypoplastic Right Heart syndrome
IC	Intelligence Continuum
IRD	Intelligent Risk Detection
IAA	Interrupted Aortic Arch
INCLVM	Isolated Non-Compaction of Left Ventricular Myocardium
KD	Knowledge Discovery
LVOTO	Left Ventricular Outflow Tract Obstruction
LQS	Long QT syndrome
MAPCA	Major Aorta/Pulmonary Collateral Arteries
MS	Marfan syndrome
MA	Mitral Atresia
MS	Mitral Stenosis
MVP	Mitral Valve Prolapse
NHCO	Networkcentric Health Care Operations
NS	Noonan syndrome
RACHS	Risk Adjustment for Congenital Heart Surgery
PAPVR	Partially Anomalous Pulmonary Venous Return
PDA	Patent Ductus Arterious
PA	Pulmonary Atresia
PS	Pulmonary Stenosis
RVOTO	Right Ventricular Outflow Tract Obstruction

SDM	Shared Decision Making
SV	Single Ventricle
TF	Tetralogy of Fallot
TAPVDTAPVR	Total Anomalous Pulmonary Venous Drainage or Total Anomalous
TGAV	Transposition of the Great Arteries or Vessels
TA	Tricuspid Atresia
OODA	Observe, Orient, Decide, and Act
UCD	User Centred Design
VSD	Ventricular Septal Defect
WS	Williams syndrome

## **Abstract**

**Objectives:** Healthcare is an information rich industry where successful outcomes require the processing of multi-spectral data and sound decision making. The exponential growth of data and big data issues coupled with a rapid increase of service demands in healthcare contexts today, requires a robust framework enabled by IT (information technology) solutions as well as real-time service handling in order to ensure superior decision making and successful healthcare outcomes. Such a context is appropriate for the application of a real time intelligent risk detection decision support systems using business analytics and data science technologies. To illustrate the power and potential of business analytics and data science technologies in healthcare decision making scenarios, the use of an Intelligent Risk Detection (IRD) Model is proffered for the context of Congenital Heart Disease (CHD) in children, an area which requires complex high risk decisions that need to be made expeditiously and accurately in order to ensure successful healthcare outcomes. The main aim of this research is reducing burden of complex surgeries in patients, their family and society through early detecting of surgical risk factors prior to surgery. The research question is: How can an intelligent risk detection (IRD) Model be developed in the healthcare contexts?

**Method:** This study is exploratory in nature and endeavours to explore the main components, barriers, issues and requirement to design and develop an Intelligent Risk Detection framework to be applied to healthcare contexts. In this research a qualitative approach using an exemplar data site as a single case study is adapted to address research objectives and to answer the research question. Data collection is through semi-structured interviews, questionnaires, observation and the analysis of documents, files and data bases from the study site. After conducting the data collection phase thematic analysis is applied to analyse all collected qualitative data.

**Results:** This study has a significant contribution to practice and theory; namely confirming a role for business analytics and data science technologies in healthcare contexts. Also, this research serves to demonstrate that the selection of risk detection, prediction by data mining tools as one of the data science techniques and then decision support are very important for decision making in the complex surgeries. IRD, in practice, can also be used as a training tool to train nurses and medical students to detect the CHD surgery risk factors and their impact on surgery outcomes. Moreover, it can also provide decision support to assist doctors to make better clinical and surgical decisions or at least provide a second opinion. Furthermore, IRD

can be used as a knowledge sharing and information transferring tools between clinicians, between clinicians and patients or their families and also between patients with the other patients.

In this study also main components, barriers, issues and requirement to design and develop an Intelligent Risk Detection solution are explored and a comprehensive real time Intelligent Risk Detection Model in the healthcare context is designed.

## CHAPTER 1

### **Introduction**

In the healthcare context, and in some diseases in particular, surgery is not always considered a final cure, as it can result in a considerably high rate of complications and side effects as well as the possibility of co-morbidities, for example, types of cancer and the development of bowel disease. Additionally, there is the direct adverse impact on the patients and their families. Therefore, decision-making regarding surgery for these types of disease is multi-faceted and complex.

To facilitate the surgical decision making process, it is contended that such a context is appropriate for the application of real time intelligent risk detection decision support. I proffer a suitable solution which combines the application of data mining tools and Knowledge Discovery (KD) techniques to score key surgical risk levels, assess surgical risks and thereby help medical professionals to make appropriate decisions.

The aim of this study is to improve the outcomes and benefits of surgical interventions and support a healthcare value proposition of excellence for patients, their families, healthcare providers, healthcare organizations and society by developing an intelligent risk detection framework to improve surgical decision making processes. While such strategies have been used in other industries (ie. banking and finance), it appears that our study is one of the first studies focused on the healthcare context.

However, the lack of interaction between healthcare industry practitioners and academic researchers makes it hard to discover the type and extent of surgical risks, and limits opportunities for the application of Business Intelligence (BI) techniques, and hence weakens the value that knowledge discovery and data mining methods may bring to surgical risk detection.

In the context of surgical risk detection many dimensions and perspectives are of importance (Yoshio et al., 2012) and these mainly focus on the pathological process, physiological

variables, some general health perceptions, social paradigm and also quality of life (Rizzo & Kintner, 2013).

Detecting the risk factors in all of these dimensions is not easy or trivial but based on two approaches to assess the risks, with contributions from clinical experts; this research aims to cover these main dimensions.

The use of KPIs as a set of metrics is not only a novel idea to control the risk factors and finding their level and defining their relationships, it also enables effective monitoring of several key items during surgery. Thus, it is found that monitoring these key factors will also be one of the valuable outcomes of the IRD Model.

Another advantage of the proposed IRD model that should be noted is its continuous nature. Most importantly, by comparing anticipated results and actual outcomes, and also performing risk auditing, risk factors will be amended to improve future predictions. A further important feature of the proposed IRD model is the integration of the three IT solutions, risk detection, knowledge discovery and clinical decision support systems, to solve a clinical issue in the definition and assessment of “outcomes” of patients, combined by some assessment measures.

To understand the purpose, aims and significance of this research, this chapter is organized in 4 main sections, describing the background of this research (Section 1.1), context of this research (Section 1.2), objective of this research and the research questions (Section 1.3), significance of this research (Section 1.4) and finally the outline of this thesis (Section 1.5).

## **5.1 Background**

Due to difficulties associated with the significant role of addressing surgical risk factors (Wetters et al., 2013), predicting surgery results prior to surgeries (Kim et al., 2010), estimating the quality of life (Quintana et al., 2009) and planning relevant wellness services (Kersten et al., 2012) to the mortality and morbidity rates in the healthcare context, this study suggests that an Intelligent Risk Detection (IRD) model may be beneficial in attempting to facilitate and provide decision support for clinicians and patients. Therefore, in developing such a solution, it is necessary to combine three key areas of knowledge discovery and risk detection with clinical decision support systems, drawn from the body of literature (Figure 1). These key components are described in following sections.



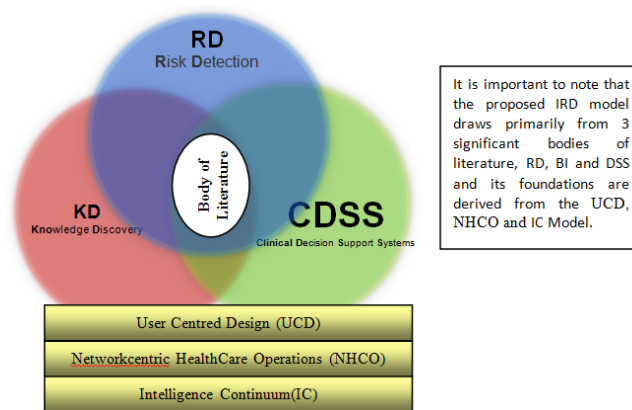


Figure 1. The designed body of literature to develop the IRD Model

### 5.1.1 Clinical Decision Support Systems (CDSS)

Clinical Decision Support Systems (CDSS) are computer driven technology solutions, developed to provide support to physicians, nurses and patients using medical knowledge and patient-specific information (De Backere et al., 2012). Decision Support systems can be found in widely divergent functional areas. However, in e-health contexts, because of the importance of real time outcomes and the multi-spectral nature of care teams (Wickramasinghe et al., 2012), the following key features are most essential:

- Intelligent timing – this includes the application of various intelligent techniques such as cluster analysis and artificial neural networks and at what stage these techniques are applied to which data sets
- Multidimensional views of data – this enables access to cross references of data sets and tables in order to support complex decision making that requires data from various data bases to be integrated
- Calculation-intensive capabilities – this utilizes various mathematical and statistical tools and techniques in order to provide in depth analysis of data

These decision making systems will give advice and support to clinical staff rather than the decision making systems replacing clinical staff. Studies have already proved that CDSS enhance quality, safety and effectiveness of medical decisions through providing higher performance of the medical staff and patient care as well as more effective clinical service (Fichman et al., 2011; Garg et al., 2005; Restuccia et al., 2012).

A variety of CDSS programs designed to assist clinical staff with drug dosing, health maintenance, clinical diagnosis, and other clinically relevant healthcare decisions (Haug et al., 2007).

It is noted that patients' demand for participation in medical decisions has been increasing (Kuhn et al. 2006). Therefore, to be respectful of patients and parents/guardians participation and decisions, shared decision-making (SDM) between health care professionals, patients, parents and guardians is widely recommended today (Lai, 2012). SDM is defined as the active participation of both clinicians and families in treatment decisions, the exchange of information, discussion of preferences, and a joint determination of the treatment plan (Barry & Edgman-Levitan, 2012; Charles et al., 1997; Légaré et al., 2011; Makoul & Clayman, 2006).

Although SDM is supported in many disease management domains such as diabetes, some concerns and issues still remain regarding the adoption of SDM solutions, such as a perception among some practitioners that the ultimate responsibility for treatment should remain under their authority (Edwards & Elwyn, 2009; Schauer et al., 2007). Client capacity to participate in decisions (O'Brien et al., 2011), identifying the SDM components (Sheridan, et al. 2004; Van der Weijden et al., 2011) as well as SDM user acceptance (Scholl et al., 2011) are main issues to promote this type of CDCS in the healthcare context, SDM has also some limitations - for example SDM is appropriate for situations in which two or more medically reasonable choices exist (O'connor et al., 2009), regardless of whether the degree of risk is high or low (Whitney et al., 2003). Therefore, SDM is not appropriate in those cases while patients or their families would still like to have participation in the clinical care process. Therefore, more studies are needed to deepen the understanding of interactions between patient decision aid use and the patterns of patient-practitioner communication as well as format issues such as web-based delivery of patient decision aids. (Cousin et al., 2012; Flight et al., 2012; O'connor, et al., 2009; Parsons et al., 2012). Research on shared decision making is under way (Barry & Edgman-Levitan, 2012; Deegan & Drake, 2006), but much more research is needed in this area.

### **5.1.2 Knowledge Discovery (KD)**

The KD process involves using a database along with any required selection, pre-processing, subsampling, and transformations of the database; applying data mining methods (algorithms)

to enumerate patterns from it; and evaluating the products of data mining to identify the subset of the enumerated patterns deemed knowledge (Fayyad et al., 1996; Han et al., 2006; Cios et al., 2007). It is noted that data mining, as an intelligent computer-based solution, is being utilized in various healthcare contexts including applications of text mining and secondary uses for data (Safran et al., 2007), predict health insurance fraud, infection control, physician order entry and electronic health records (Wright & Sitting, 2006; Batal & Hauskrecht, 2010) and in the identification of high risk patients (Marschollek et al., 2012). In recent years associated with data mining, Business Intelligent/Analytics (BI/BA) is recognised as belonging in the longstanding KD field as a data-centric approach, and relies on various data collection, extraction, and analysis technologies and techniques (Chaudhuri et al., 2011; Turban et al., 2008; Watson & Wixom 2007).

The term intelligence has been used by researchers in artificial intelligence since the 1950s (Huhns 2012). However, in the late 2000s, business analytics was introduced to represent the key analytical component in BI (Davenport, 2006). More recently big data analytics and predictive analytics have been used to describe the data sets and analytical techniques in applications that are so large (from terabyte to exabyte) and complex (from sensor to social media data) that they require advanced and unique data storage, management, analysis, and visualization technologies (Siegel, 2013). Hence, in this research, BI/BA and data mining techniques are used, as unified terms and treat predictive analytics as a related field that offers a new direction for developing such a solution in the healthcare context.

Although data mining and knowledge discovery techniques are already applied in the healthcare context, it is suggested that developing guidelines on how to use data mining algorithms such as classification, clustering, decision tree and Neural Networks in different aspects of care process may enhance outcomes efficiency (Padhy et al., 2012). It is also emphasised that the domain experts play an important role in the different stages of data mining to extract specific knowledge by considering the user's requirements and other context parameters guide the system (Padhy et al., 2012).

### **5.1.3 Risk Detection**

Medical decisions always have to be made in a trade-off between benefit and risk (Cerrito 2011). Unfortunately, many decisions are based upon an incorrect knowledge of risk (Weijden et al., 2011; Cerrito 2011). Also different viewpoints concerning risk can result in different optimal choices because of different perspectives (Horn et al., 1985; Kuntz & Goldie

2002). Unfortunately, in this regard, treatments can be based on a complete misperception of risk (Cerrito, 2011). Identifying the basic types of risk and characterising them might be helpful to understand which types of risk are acceptable to different patient and clinical providers (Cerrito, 2011; Lacour-Gayet, 2002). In order to help patients understand potential risks and benefits of a procedure, and select the option that best accommodates their personal needs, information has to be coupled with high-quality decision counselling (Kuhn et al., 2006).

In the context of treatment risk detection many dimensions and perspectives are of importance (Yoshio et al., 2012). These dimensions and perspectives mainly focus on the pathological process, physiological variables, several general health perceptions, social paradigm and also quality of life (Rizzo & Kintner, 2013). Hence, risk adjuster systems such as ACGs (Ambulatory Care Group) (Weiner et al., 1996), the chronic disease and disability payment system (CDPS) (Kronick et al. 2000), clinical risk groups (CRGs) (Hughes et al., 2004), the clinically detailed risk information system for cost (CD-RISC) (Kapur et al., 2003), and DCG/HCCs (Pope et al., 2004), Risk Adjustment for Congenital Heart Surgery (RACHS-1) (Jenkins et al., 2002) and also the CMS hierarchical condition categories CMS-HCC (Pope et al., 2004), have been under development since the 1980s and have been implemented by the Medicare Choice program which was mandated for implementation in 2000 in U.S, numerous states, employer coalitions, and health plans. Such systems have been based on many factors, including diagnosis, prior utilization, demographics, persistent diseases, and self-assessments of health and/or functional status. An analytical review on these systems shows several limitations, such as lack of a dynamic risk assessment system, in the healthcare context (Fortinsky et al., 2004; Gambrill & Shlonsky, 2000; Greenland, 2012; Pancorbo-Hidalgo et al., 2006; Ryan et al., 2012; Twetman et al., 2013) and lack of a multidimensional risk detection model/algorithm (Anderson et al., 2012; Aylin et al., 2007; Gran et al., 2004; Staal et al., 2013; Trucco & Cavallin, 2006).

Therefore, regarding current systems, it is found that applying IT based techniques such as knowledge discovery followed by data mining would increase the performance of current risk assessment and adjustment methods significantly (Guikema & Quiring, 2012; Karaolis et al., 2010).

## **5.2 Context**

Congenital Heart Disease (CHD), as a common health problem affecting many children around the world (Marino et al., 2012), is involved a multi-faceted set of considerations including the immediate medical result, the ongoing increased risk of sudden death, exercise intolerance, neurological developmental and psychological problems as well as long-term impacts on the family unit (Long et al., 2012). This multi-faceted consideration is important because of the far reaching consequences that can result post-surgery and include consideration of mortality or morbidity.

The decision making process in the context of CHD surgery can be divided into three broad phases. In the first phase, or pre-operative phase, the surgeon, having received information about the patient and his/her medical condition, needs to make a decision relating to whether surgery is the best medical option. Once this decision is made but before surgery, the parents must then decide whether to accept or reject the surgeon's decision in consideration of the predicted outcomes. Typically, parents have met many medical staff and specialists before they meet the cardiac surgeon. Thus, already at stage one, two key decisions must be made. Once parents and surgeons have agreed to proceed, in phase two, critical decisions pertaining to the unique situations that may arise during the surgery must be addressed. Finally, in the post-operative phase, or phase three, decision making is primarily done at two levels; a) strategies to ensure a sustained successful result for the patient during aftercare and beyond, and b) a record of lessons learnt for use by clinicians in future similar cases.

To clarify the function of the decision making framework across CHD surgery for this study, I summarize current surgery steps and the associated decision making process in one of the common CHD classifications; Hypoplastic Left Heart Syndrome (HLHS). HLHS patients, usually have three types of surgery during their childhood treatment period. Norwood, BCPS and Fontan are most recent surgeries that are conducted on patients in different age and clinical condition groups. However, the Norwood surgery is still much more complex and risky with a high rate of mortality and morbidity.

## **5.3 Research Objective and Method**

Although reducing the burden of surgery on patients, patient's parents and society in general is a strategic benefit of this research, three important aims for this research are also listed as follows:

- Exploring main components, barriers, issues and requirement to design and develop an Intelligent Risk Detection Model for the healthcare context followed by the research case
- Providing superior decision support in the healthcare context examining decisions pertaining to CHD surgery.

To address these research objectives, this study is designed to answer this question:

***How can an intelligent risk detection (IRD) Model be developed in the healthcare contexts?***

This study has important contributions to both theory and practice in healthcare since the use of risk detection, while prevalent in many industries such as finance, has rarely if at all been incorporated into healthcare context. This in turn makes an intelligent risk detection framework the preferred choice in the healthcare context. Thus, our study proposes an intelligent application for high-level surgery risk detection and outcome prediction to support surgical decisions.

Throughout this research, a qualitative approach using an exemplar data site as a case study is adopted incorporating well established qualitative data collection techniques (Kvale & Brinkmann, 2009; Boyatzis, 1998; Yin, 1994) to collect requirements and capture main components to develop IRD Model, as an IT based framework in healthcare context.

#### **5.4 Significance and Limitations**

This thesis has outlined an exploratory research study to examine the potential benefits of combining a real time intelligent risk detection Model with decision support in the healthcare context. The emergent themes from this exploratory research study include:

- 1) Early identification of patients at risk,
- 2) Providing superior decision support,
- 3) Developing key performance indicators to detect the surgery risk factors.,
- 4) Predicting surgical results to identify patients at risk during surgery,
- 5) Standardizing clinical risk assessment and management processes to facilitate superior health outcomes,
- 6) Developing a risk profile for patients,

- 7) Improving knowledge and information sharing,
- 8) Developing a true picture of risk categories and factors,
- 9) Improving patients/parents empowerment during the care process
- 10) Monitoring the risk factors by using dashboards.

Another advantage of the proposed IRD model that should be noted is its continuously evolving nature. By comparing anticipated results and actual outcomes and also by performing risk auditing, risk factors will be amended to improve future predictions. A further and final important feature of the proposed IRD model is the integration of the three IT solutions [Knowledge Discovery, Risk Detection and Clinical Decision Support Systems] to solve a clinical issue in the definition and assessment of “outcomes” in patients with CHD, combined with some assessment measures. The next step for this research is prototyping the solution in a clinical trial environment.

This research has a strong contribution to practice by emphasizing the importance of knowledge sharing between clinicians as well as between clinicians and patients; clinicians’ involvement during systems development; acceptability and capability of the system and high demand of outcome predictions to improve decision efficiency. Also, this research has a contribution to theory by proving the importance of Intelligent Continuum (IC), Network Centric HealthCare Operations (NHCO) and User Centred Design (UCD) theory to developing such a solution in the healthcare context. Moreover, after considering the study findings, new elements are proposed to the IC Model and UCD theory. It has been determined that “time” can be an important element to IC Model. It is also understood that “information receivers” in the healthcare context have a significant role in contributing to the designing of clinical solutions. Therefore, information receivers should be involved within the design process.

However, discovering and capturing surgical risk factors is quite difficult, due to the lack of interaction between healthcare industry practitioners and academic researchers. Hence, this would provide limited opportunities for the application of predictive analysis techniques in the healthcare context. This research confirms that the selection of the risk detection, prediction by data mining tools and clinical decision support systems are very important for decision making in complex surgeries.

## **5.5 Thesis Outline**

This thesis is arranged as follows:

### **Chapter 1: Introduction**

The Introduction introduces the thesis in total and describes its components. The subsequent Chapters of the thesis provide argument and evidence to support the research question. The Introduction sets the scene (the research context and problem context) and establishes why the research topic is an issue worthy of research. The research question and any aims and objectives are also clearly stated and the scope and context of the research is introduced.

- **Chapter 2: Literature Review**

The literature review presents the position of this research within the disciplines' literature to make contribution in both theory and practice.

- **Chapter 3: Methodology**

This Chapter introduces the research method and research design as well as data collection and data analysis approaches and tools.

- **Chapter 4: Results**

The research qualitative results are presented in Chapter 4.

- **Chapter 5: Discussion**

The research implications, limitations and recommendations for the next steps are discussed in this Chapter.

- **Chapter 6: Conclusion**

This Chapter is an overview of the research contributions and outcomes.



## CHAPTER 2

### **Literature Review**

This Chapter is structured as follows:

In section 2.1 the specific outcomes and issues of the Clinical Decision Support Systems are presented.

Section 2.2 is devoted to examine data science solutions in healthcare

Section 2.3 describes risk adjusted outcomes.

Section 2.4 will discuss the context of the research case.

Section 2.5 will explore research gaps, issues, possibilities and the summary of theoretical views. Section 2.6 describes the contribution of this research to the body of knowledge on the topic.

### **6.1 Decision Support Systems in HealthCare**

Clinical Decision Support Systems (CDSS) are computer driven technology solutions, developed to provide support to physicians, nurses and patients using medical knowledge and patient-specific information (De Backere et al., 2012). Hence, these systems will give advice and support to support decision making to assist clinical staff. Studies have already shown that CDSS enhance quality, safety and effectiveness of medical decisions by providing higher performance of the medical staff and higher levels of patient care, as well as more effective clinical services (Fichman et al., 2011; Garg et al., 2005; Restuccia et al., 2012). Patients' demands for participation in medical decisions has been increasing (Kuhn et al., 2006). Therefore, to be respectful of patients and parents/guardians participation in the decision making process, shared decision-making (SDM) between health care professionals, patients, parents and guardians is widely recommended today (Lai, 2012).

A variety of CDSS programs designed to assist clinical staff with drug dosing, health maintenance, clinical diagnosis, and other clinically relevant healthcare decisions have been

developed for the medical workplace (Haug, et al., 2007). For example, preventing potential medication-related adverse drug events (Tiwari et al. 2013), diagnosis of maternal depression (Carroll et al. 2013), chronic disease management and acute care (Sahota et al., 2011) are some of the recent areas of medicine to adopt CDSS (Jeffery et al. 2013b). CDSSs have improved the process of medical care in 52-64% of patients (Sahota, et al., 2011). For instance, the CDSS designed for diabetes care shown improvements in the process of care in 55% of patients (Jeffery, et al., 2013b). The recognised importance of CDSSs has led experts to propose many characteristics pertaining to the health care system that could contribute to a more effective system (Shiffman et al., 1999; Sim et al., 2001; Solberg et al., 2000; Trivedi et al., 2002; Wetter, 2002).

Most CDSSs are locally developed and integrated into a computerized physician order entry (CPOE) or electronic health record (EHR) system and have system-initiated recommendations delivered synchronously at the point of care and these recommendations do not require a clinician response (Bright et al., 2012). Table 1 is a modification of Bright's systematic review of the literature (Bright et al., 2012) to introduce a number of recent studies related to CDSSs and CDSS intervention.

**Table 1. Characteristics of CDSSs studies**

<b>Study</b>	<b>computerized CDSS intervention</b>	<b>Care type</b>	<b>Intensity of disease in participants</b>	<b>Study (country)</b>
Carroll et al. 2013	Automated screening and just in time delivery of testing and referral materials at the point of care for maternal depression through Child Health Improvement Computer Automation (CHICA) system	Diagnosis of maternal depression	Early stage of depression	USA
Gross et al. 2013	A classification algorithm and accompanying computer-based clinical decision support tool to help categorize injured workers toward optimal rehabilitation interventions based on unique worker characteristics	Selecting rehabilitation programs that lead to successful treatment	Injured workers with compensation claims for a wide variety of musculoskeletal disorders	Canada

Study	computerized CDSS intervention	Care type	Intensity of disease in participants	Study (country)
(Holbrook 2003)	<p>Web-based, colour-coded diabetes tracker (monitored 13 diabetes risk factors, their respective targets and give brief, prioritized advice, based on national guidelines)</p> <p>Interfaced with electronic medical record and an automated telephone reminder system for patients</p>	Diabetic care	Lower disease intensity in participants (few had comorbidities)	Canada
(MacLean et al., 2004)	Faxed and mailed reminders, flow sheets and reports. Used laboratory results and sent reminders when testing was overdue or results were elevated	Usual care	Lower disease Intensity in participants (few had comorbidities)	USA
(Cleveringa 2008)	Contained a diagnostic and treatment algorithm based on the Dutch Type 2 diabetes guidelines Patient-specific treatment advice, a diabetes consultation with a practice nurse, a recall system and feedback every 3 months	Diabetic care	More severely diseased population, cardiovascular disease in most patients	Netherlands
(Jeffery et al., 2013b)	Feedback based on patient self-reports to increase motivation and readiness to make lifestyle changes, and identify barriers to change -physicians received patient-specific counselling	Health education materials	Lower disease severity in participants (few had comorbidities)	USA
(Peterson et al., 2008)	<p>Visit reminders, patient-specific physician alerts, a monthly progress review and proactive support of patients at risk.</p> <p>Directed at patients, physicians (target high-risk patients, audit and feedback monthly, track outcomes and activity, educate</p>	<p>Data collection same as for intervention.</p> <p>Sites received baseline data on process and outcome measures and continued usual-</p>	Lower disease severity in participants (few had comorbidities)	USA

Study	computerized CDSS intervention	Care type	Intensity of disease in participants	Study (country)
		quality improvement practices		
(Jeffery et al., 2013a)	Cell-phone-based system that incorporates real-time patient coaching based on blood glucose measures taken with a Bluetooth-adapted OneTouch meter. Feedback for practitioners, including automated analysis and suggested medication changes	Diabetic care. Patients were also given OneTouch Ultra™ blood glucose meters (LifeScan, Milpitas, CA, USA) and asked to fax or phone in their blood glucose logbooks to their providers for review	Lower disease severity in participants (few had comorbidities)	USA
(Augstein et al., 2007)	Patient-specific data model glucose metabolism and simulate patient's therapeutic regime to optimize blood glucose Practitioners received glucose data	Use of continuous glucose monitoring system	Lower disease severity in participants (few had comorbidities)	Germany
(Jeffery et al., 2013b)	Displayed an electronic reminder and letter summarizing practice guidelines and benefits of anti-platelet drugs in high-risk patients with diabetes sent.	Diabetic care plus the letter summarizing practice guidelines	More severely diseased population included, 75% were high risk patients with diabetes	Italy
(Meigs et al., 2003)	Patient-specific information, including laboratory data, on a single screen	Usual care	More severely diseased population, Patient-specific information,	USA

Study	computerized CDSS intervention	Care type	Intensity of disease in participants	Study (country)
			including laboratory data, on a single screen over 50% have cardiovascular disease	
(Lobach & David, 1997)	Collected data from individual patient electronic medical records to generate eight personalized care recommendations for diabetes mellitus based on established guidelines. Recommendations were printed on 'encounter forms' used by clinicians to record consultation results	Diabetic care	Lower disease severity in participants (few had co-morbidities)	USA
(Nilasena et al., 1994)	Reminder reports describing diabetes preventive-health status and listing upcoming or past due preventive health activities for patients with diabetes. Clinical alerts for high-risk aspects of patient's profile placed at the front of patients' charts	Generic reports without patient-specific recommendations were generated	Lower disease severity in participants (few had co-morbidities)	USA
(Ådahl, 2012)	Computerized CDSS reminders were generated from the medical record system and placed in patients' clinic records whenever the computer detected history, physical, laboratory or pharmacy data indicating that a seminar recommendation should be considered	A 3.5-h seminar covering blood sugar regulation in non-insulin dependent diabetes mellitus. All participants received a course syllabus, key reprints and a reference book	Lower disease severity in participants (few had co-morbidities)	USA
(Thomas et	Updated medical records using data	Usual care	Lower disease	USA

Study	computerized CDSS intervention	Care type	Intensity of disease in participants	Study (country)
al., 1983)	entered by research staff, performed audits based on patient data and protocol-based algorithms, and generated recommendations that were printed in patient reports for physicians before each clinic session		severity in participants (few had co-morbidities)	
(Quinn et al., 2009)	Coach, primary care provider portal, decision support with feedback for practitioners, including automated analysis and suggested medication changes	Usual care	Lower disease severity in participants (few had co-morbidities)	USA
(Jeffery et al., 2013b)	Nurse puts printed form on top of the visit summary sheet on the examination room door, physician reviews the available diabetes treatment options printed on the form	Diabetes care	Lower disease severity in participants (few had co-morbidities)	

Clinical areas considered by CDSSs researchers are categorised by (Pearson et al., 2009) from 1990-2007, at Cardiovascular disease , Antibiotic therapy, Vaccinations , Respiratory conditions, Anticoagulant therapy , Elderly (multiple conditions and drugs), Osteoporosis and Other. Additionally, in recent years CDSS research studies in chronic disease, particularly diabetes care, have increased (Hussain et al., 2013; Jeffery, et al., 2013b).

Although many technologies for clinical decision support have been proposed worldwide, several authors have reported numerous challenges that current CDSSs need to overcome. Most challenges are as follows:

- Due to the importance of clinical workflow integration for CDSS success, efforts should be made for the integration of CDSS with clinical systems already present in hospitals and medical canters (Eichner & Das, 2010; Holbrook, et al., 2003; Kawamoto et al., 2005; Sanchez et al., 2013).

- Maintainability and extensibility are the second challenge to overcome (Peleg & Tu, 2006; Sanchez et al., 2013). Hence, cost-save solutions are needed to maintain the underlying knowledge criteria for the reasoning of the system (Sanchez et al., 2013).
- To enhanced clinical decision support systems value to clinicians, timely medical advice should be provided in CDSS (Peleg & Tu, 2006; Sanchez et al., 2013).
- Lack of a framework or mechanism for quantitative and qualitative evaluation of the performance of the system, as well as evaluation of the quality of the knowledge provided by CDSSs (Liu et al., 2006; Peleg & Tu, 2006; Sanchez, et al., 2013; Sim, et al., 2001)
- CDSS should be presented as complete solutions that assist clinicians during the many different tasks of their daily duties, and not only during specific activities (Sanchez, et al., 2013).

In this research, to the researcher has attempted to overcome these challenges by developing the IRD framework (Sittig et al., 2008).

### **6.1.1 Shared Decision Making in HealthCare**

The literature informs the reader that SDM is recognised as the active participation of both clinicians and families in clinical treatment decisions, the exchange of clinical information, discussion of treatment preferences, and the joint determination of a treatment plan (Barry & Edgman-Levitan, 2012; Charles, et al., 1997; Légaré, et al., 2011; Makoul & Clayman, 2006). A physician may sometimes make a decision unilaterally, obtaining the patient's consent without offering the patient a choice from all options; this is not an actual SDM but it is still information exchange between patients or their family with practitioners to improve the care process (Whitney et al., 2003). SDM has been conceptualized in several different ways, and usually involves a process in which an individual is informed of the seriousness of the illness; the benefits, harms, alternatives, and uncertainty of preventive or treatment options; weighs his or her options; and participates in the decision making process with the clinician in a shared role (Head et al., 2011; Pentz et al., 2012; Sheridan, et al., 2004).

The benefit of sharing the decision-making process is that it allows doctors to clarify with patients or their families' an understanding of key facts and relevant values, highlight the unique circumstances that might alter the decision for any individual, and add a considered

clinical perspective on the decision (Sheridan, et al., 2004). Several of these functions may not be necessary when decision aids are available, particularly if patients or their families are known to be health literate and the decision aid allows for deliberation on values and preferences (Kennedy et al., 2002). Instead, independent decision making by the doctor in a supporting role may sometimes be appropriate and improve patients or their families' self-efficacy for following through with a decision (Kiesler & Auerbach, 2006). Table 2 presents characteristics of CDSS studies.

**Table 2. Decision Types for Which Augmented Patient Involvement Is Particularly Important**

Adapted from (Whitney et al., 2003)

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Typically, cases using SDM are of major importance and high uncertainty in which patients' values, and hence shared decision making, are highly relevant. Continuing life support, for example, for patients in a persistent vegetative state, surgery for localized breast cancer, or care or termination of care for severely burned persons are in this category (Whitney et al., 2003). To date, SDM studies are developed in different domains of healthcare and this presented in table 2.

Although SDM is supported in many disease management domains, some concerns and issues still remain with respect to adopting SDM solutions, these concerns including a perception among some medical practitioners that the ultimate responsibility for treatment should remain under their authority (Edwards & Elwyn, 2009; Schauer, et al., 2007). Client capacity to participate in decisions (O'Brien, et al., 2011), identifying the SDM components (Sheridan, et al., 2004; Van der Weijden, et al., 2011) and SDM user acceptance (Scholl, et al., 2011) are the main issues to promote this type of CDCS in the healthcare context.



SDM has also some limitations - for example, SDM is appropriate for situations in which two or more medically reasonable choices exist (O'Connor et al., 2009), regardless of whether the degree of risk is high or low (Whitney et al., 2003). Therefore, SDM is not appropriate in these cases while patients or their families would still like to have participation in the care process. Hence, more studies are needed to deepen the understanding of interactions between patient decision aid use and the patterns of patient-practitioner communication. The format of delivery of patient decision aids, such as web based patient decision aids, also needs further consideration (Cousin et al., 2012; Flight et al., 2012; O'Connor et al., 2009; Parsons et al., 2012).

Research on shared decision making has been undertaken (Barry & Edgman-Levitan, 2012; Deegan & Drake, 2006), but much more research is needed in this area of clinical support. Future work might also explore other intervention components or component content that might make SDM interventions more effective in promoting shared decisions (Sheridan, et al., 2004).

### **6.1.2 Intelligent Decision Support Systems in Healthcare**

The field of intelligent support systems in healthcare is expanding at a rapid rate (Brahnam & Jain, 2011). Decision making is a multi-step process comprising problem recognition, information search, problem analysis,

alternative evaluation and choice (Zikmund et al., 2012). Decision support strategies that provide decision makers with effective, timely ways to access relevant information and to structure complex problems, need multi-functional and intelligent decision support solutions (Brahnam & Jain, 2011; Zhuang et al., 2012). Hence, in order to develop an Intelligent Decision Support Systems in a healthcare context, healthcare organizations are starting to make extensive use of state-of-the-art data mining technologies (Nanni et al., 2011). Zhuang et al. (2012), designed a framework for an intelligent decision support system in the case of pathology test ordering (Zhuang, et al., 2012), as presented in figure 2.

This framework demonstrates the role of data mining and text mining in intelligent DSSs and shows how data mining and text techniques were used to discover and extract useful knowledge/evidence from past pathology requests to use the care experience of these patients to the future similar cases.

Data mining lies at the interface of statistics, database technology, pattern recognition, machine learning, data visualization, and expert systems (Koh & Tan, 2011; Obenshain, 2004). There is vast potential for data mining applications in healthcare, which can be grouped as the evaluation of treatment effectiveness; management of healthcare; customer relationship management; and detection of fraud and abuse, predictive medicine and analysis of DNA micro-arrays (Koh & Tan, 2011). However, data mining in healthcare contexts have some limitations.

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**Figure 2. Simplified framework for intelligent decision support**

Adapted from (Zhuang et al., 2012)

The most important issues relating to adapting data mining in intelligent CDSS solutions is the accessibility of data, because the raw inputs for data mining often exist in different settings and systems, such as administration, clinics and laboratories (Koh & Tan, 2011; Mans et al., 2013; Mishra et al., 2013). Hence, several authors and researchers have suggested that data have to be collected and integrated before data mining can be done through building a data warehouse (Dutta 2013; Koh & Tan 2011; Mans et al., 2013; Mishra, et al., 2013).

### **6.1.3 Knowledge Management and Discovery in Healthcare Contexts**

According to Burstein and Carlsson in 2008, knowledge management is the “continuous process of acquiring and deploying knowledge to improve decision making”(Burstein & Carlsson, 2008) . Knowledge management (KM) is a multidisciplinary approach that takes a

comprehensive, systematic view of data assets of an organization by identifying, capturing, collecting, organizing, indexing, storing, integrating, retrieving and sharing these data assets (Geisler & Wickramasinghe, 2009).

Knowledge discovery in data bases (KDD) is defined as the nontrivial process of identifying valid, novel, potentially useful, and ultimately understandable patterns in data (Cios, 2007). One of the most relevant applications of KDD for healthcare contexts is the model of the Intelligence Continuum (IC) (Wickramasinghe & Schaffer, 2006).

**Table 3. A list of relevant previous works in using Knowledge discovery in healthcare area**

Title	Technologies	Objectives
Analysis of health care data using different data Mining techniques (Kumar & Gosain, 2009)	The potential use of classification based data mining techniques such as decision tree and association rules to massive volume of health care data.	In this study, objectives are to: (1) present an evaluation of techniques such as decision tree and association rules to Predict the occurrence of route of transmission based on treatment history of HIV patients. (2) Demonstrate that data mining method can yield valuable new knowledge and patterns related to the HIV patient; (3) assesses the utilization of healthcare resources and demonstrate the socioeconomic, demographic and medical histories of patient.
Intelligent heart disease prediction system using data mining techniques (Palaniappan & Awang, 2008)	data mining techniques, namely, decision trees, naïve bays and neural network	This research has developed a prototype Intelligent Heart Disease Prediction System (IHDPS) using medical profile such as age, sex, blood pressure and blood sugar, and it can predict the likelihood of patients getting a heart disease.
Knowledge discovery approaches for early detection of decomposition conditions in heart failure patients (Candelieri, et al. 2009b)	Several KD algorithms have been applied on collected data	They propose an innovative knowledge based platform of services for effective and efficient clinical management of heart failure within elderly population.

The IC model includes, but is not limited to, applying the techniques of data mining, business intelligence/business analytics (BI/BA) and knowledge management (KM) (Wickramasinghe & Schaffer, 2006). In order to maximize the value/utility of our IRD framework and because the importance of combining techniques of DM, BA/BI and KM in the present context, in this

research the IC model is applied as the foundation for the research framework. Table 3 presents some relevant studies in applying knowledge discovery in healthcare contexts.

The focus of knowledge discovery is usually data mining and how to achieve data mining tasks. However, the complete knowledge discovery into data base processing is not simply an application of highly sophisticated data mining algorithms and an immediate deployment of data mining results into the businesses.

Data mining is the application of specific algorithms for extracting patterns from data (Fayyad et al. 1996). It is a powerful technology with potential to help organizations focus on the most important information in their data warehouses (Dunham et al. 2006). Data mining tools predict future trends and behaviors, helps organizations to make proactive knowledge-driven decisions (Larose, 2005). The automated, prospective analyses offered by data mining move beyond the analyses of past events provided by prospective tools typical of decision support systems (Mishra et al. 2013). The different methods of data mining are used to extract the patterns and thus the knowledge from this variety databases (Fayyad et al. 1996). Selection of data and methods for data mining is an important task in this process and needs the knowledge of the domain. Several attempts have been made to design and develop the generic data mining system but no system found completely generic (Mishra et al. 2013).

Data mining is one of the main components of knowledge discovery as it is shown in figure 3.

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**Figure 3. The six-step KD model.**

Adopted from (Pal & Jain, 2005)

We emphasize that there is no universally “best” KD model. Each of the models has its strong and weak points based on the application domain and particular objectives (Cios et al., 2007). So, to address our research goals and domain I have chosen the KD model. Also, I have found Data Mining as a key step of KD models and is common in all of KD models.

Based on the intelligence continuum (IC) model (Wickramasinghe & Schaffer, 2006), using data mining technique is an approach of extracting patterns from large data sets and deducting knowledge insights from those patterns (Desouza, 2002). The IC is including but not limited to data mining, business intelligence/business analysis (BI/BA) and knowledge management (KM) (Wickramasinghe & Schaffer, 2006). In order to maximize the value/utility of the IC model, it is used as a platform to improve decision making process. Techniques of data mining are also used to detect risk factors and to predict some anticipated results through and after surgery.

Data mining is a computerized technology that uses complicated algorithms to find relationships, real or perceived, and trends in large databases, previously unknown to the retailer, with the aim of promoting decision support (Mishra et al. 2013). Data mining consists of several tasks and each task uses a variety of methodologies and figure 4 shows their relationships (Larose, 2005). Data mining commonly involves three classes of tasks (Seong-Pyo & Sungshin, 2000):

- Classification: Arranges the data into predefined groups. For example, an email program might attempt to classify an email as legitimate or spam. Common algorithms include Decision Tree learning, nearest neighbours, naive Bayesian classification and neural network.
- Clustering: Is like classification but the groups are not predefined, so the algorithm will try to group similar items together.
- Prediction: Is the same as classification or estimation except that the records are classified according to some predicted future behaviour or estimated future value.

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**Figure 4. The relationship of data mining methodologies to tasks.**

Source: adopted from (Seong-Pyo & Sungshin, 2000)

To find some valuable points and models, relevant research was extracted to make a critical analysis on data mining models and techniques. Table 3, has a look on their title, objects and also their using techniques to justify or prove their models and applications.

Across this research, knowledge discovery and data mining techniques are applied to predict results or effects based on pertinent historical data and relevant factors through treatment of patients, while discovering patterns and relationships between these key factors would be very effective in predicting care outcomes.

#### **6.1.4 User Acceptance**

According to Hauge et al's. (2007) study, two elements of clinical decision support applications are critical to the applications success, independent of the implementation environment, as follows (Haug et al., 2007):

- 1) The mechanism by which the systems acquire the data used in their decision algorithms;  
and
- 2) The interface through which they interact with clinicians/users to report their results.

User-centred design (UCD) is well recognized as an effective human factor engineering strategy to design ease of use into the total customer experience with products and

information technology (IT) that has been applied specifically to healthcare IT systems (Vredenburg et al., 2002).

The shift from ‘system-centred’ to ‘user-centred’ design has increased the effectiveness of software systems (Díaz et al., 2008). This is because of the iterative nature of user-centred design (UCD) that means all stages of the process can be revisited to make a more efficient development process which results in a product that is less likely to require major redesign after the final evaluation process is completed (De Matos et al., 2013).

Hence, in this study, users’ perspectives in order to enhance the CDSS usability and acceptability are a critical component.

## **6.2 Risk Definition and Categories in HealthCare**

Medical decisions always have to be made as a trade-off between benefit and risk(Cerrito, 2011). Unfortunately, many decisions are based upon an incorrect or incomplete knowledge of risk (Tsumoto & Hirano, 2010; Van der Weijden et al., 2007). Different viewpoints concerning risk can result in different optimal choices because of different perspectives (Tsumoto & Hirano, 2010; Kuntz & Goldie 2002). Unfortunately, in this regard, treatment can be based on a complete misperception of risk (Cerrito, 2011; Luo et al., 2014). Identifying the basic types of risk and characterising them might be helpful to understand which types of risk are acceptable to different patients and to different providers (Cerrito, 2011). Therefore, basic types of clinical risk and their characteristics are summarized in table 4:

**Table 4. Basic types of clinical risk and their characteristics**  
Adapted from (Cerrito 2012)

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issue, this table is  
omitted.

In order to help patients understand potential risks and benefits of a procedure, and select the option that best accommodates their personal needs, information has to be coupled with high-quality decision counselling (Kuhn, et al., 2006).



### 6.2.1 Benefit of Risk Detection to the Clinical Decision Making

In medicine, patients or their families are not the only decision makers (Cerrito 2012). Physicians, government and healthcare providers also contribute to the decision making process (Tremblay et al., 2012). Since quality of life, cost and access are three major issues for most of healthcare decision makers (Greenes, 2011), I need to investigate whether a shift to a solution will decrease cost and/or increase access (Claxton et al., 2011).

Surgical performance is usually indirectly measured by postoperative outcome of the initial hospital stay by means of risk-adjusted audits (Gayet 2002). Risk adjustment is important in allowing assessment of performance and comparing outcomes amongst individuals or institutions (Kang et al., 2004). Statistical inferences alone cannot be used to determine what is considered acceptable performance (Gayet et al., 2005). Today's available methods to capture clinical risk factors, look at the "big picture," from diagnosis to surgery and postoperative care (Larrazabal et al., 2007). It is somewhat misleading, however, to judge an individual surgeon's performance by using postoperative outcome data such as 30-day survival or hospital survival (Larrazabal et al., 2007). A poor outcome can be the result of a technical error, a nursing mistake, a drug error, or substandard intensive care monitoring (Larrazabal et al., 2007). Additionally patients undergoing congenital heart surgery face many other types of risks such as disabilities, affecting mortality rates during and after admissions (Benavidez et al., 2007). Therefore it is imperative that surgery-driven, validated, risk-adjusted outcome analysis is employed, and this can indeed lead to improvements in performance by both individual cardiac surgeons and cardiac surgery centres (Mavroudis & Jacobs 2002).

Risk adjustment for paediatric congenital heart operations, in itself, is challenging due to the great diversity of the patient population in terms of the diagnoses, indications for operation, the operation performed, the age at which an operation is deemed necessary and feasible, and other factors (Kang et al., 2004). An internationally accepted procedural classification scheme, Risk Adjustment for Congenital Heart Surgery (RACHS-1)<sup>1</sup> (Jenkins et al., 2002), groups 79 different types of operations into six categories ranked in order of increasing risk, as perceived by clinicians. The RACHS-1 scheme has been validated in a range of contexts (Kang et al., 2004). The paediatric risk of mortality (PRISM) method in operative risk

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<sup>1</sup> RACH-1 is risk adjustment for congenital heart disease based on these variables: risk category, age, and pre-maturity, presence of a major non-cardiac structural anomaly, gender, race, insurance volume and combination of cardiac surgical procedure.

prediction after open-heart surgery in children is another well-known model used in predicting risks of heart surgery in children (Mildha et al., 2007).

As the two mainstream methods of assessing risk factors in heart surgery, Milth et al (2007) compared the performance of RACHS-1 with PRISM assessment systems in operative risk prediction after open heart surgery in children (Mildh et al., 2007). Their study showed that the performance of PRISM in this large-scale, non-selected paediatric open-heart surgery patient population was poor while the discriminatory power of RACHS-1 was good and in accord with other studies recently published in the literature. However, RACHS-1 failed to accurately predict death after paediatric open-heart surgery patients (Mildha et al., 2007). Their conclusion from their study was that a different and more precise approach in predicting the outcome of the surgical procedure for these patients was necessary (Mildha, et al., 2007). Table 5 presents some of well-known and old risk adjustment systems in healthcare contexts.

**Table 5. A review of selected risk adjustment systems in healthcare area**

Systems	Descriptions
ACG	This system was originally developed as a case-mix adjustment measure for ambulatory populations (Weiner et al., 1996). Later, it was extended to incorporate inpatient diagnoses as well. The system categorizes diagnoses based on duration, severity, ethology, diagnostic certainty and the likelihood that specialty services will be needed. ICD-9-CM codes are assigned to 32 ADGs (Adjusted Diagnostic Groups). The ACG system explains about 40-60 percent of the variation in concurrent health costs, and less for prospective health costs. The ACG system has been implemented by the Minneapolis Buyers Health Care Action Group. They reported a relatively smooth experience with the ACG system (Dunn, 1998).
DCG	This system was developed as a health adjuster for HMOs that enrol Medicare populations (Ash et al., 2001; Pope et al., 2001). DCGs are clinically oriented and resource-based, and use demographic and diagnostic information. Initially, the model was calibrated on the Medicare population. It was later extended to commercial and Medicaid populations. This model estimates beneficiary health status (expected cost next year) from demographics and the worst principal inpatient diagnosis (principal reason for inpatient stay) associated with any hospital admission. The Washington State Health Care Authority also incorporated a DCG model.
CMS-HCC	CMS (Centers for Medicare and Medicaid Services) was required by Congress's BIPA, in 2000, to use ambulatory diagnoses in Medicare risk-adjustment, to be phased in from 2004 to 2007. To this end, CMS evaluated several risk-adjustment models that use both ambulatory and inpatient diagnoses, including ACGs (Weiner et al., 1996), the chronic disease and disability payment system (CDPS) (Kronick, Gilmer, Dreyfus, & Ganiats, 2002), clinical risk groups (CRGs) (Hughes et al., 2004), the clinically detailed risk information system for cost (CD-RISC) (Tseng et al., 2003), and DCG/HCCs (Dunn, 1998). CMS chose

Systems	Descriptions
	the DCG/HCC model for Medicare risk adjustment, largely on the basis of transparency, ease of modification, and good clinical coherence.
CDPS	The Chronic illness and Disability Payment Systems were developed specifically to compensate more fairly for individuals with disabilities. It is a primarily resource-based system that is based on detailed clinical information for the disabled. The system has been developed for Medicaid and Medicare populations (Kronick et al., 2002). The system uses demographics and diagnostic information, and also used the length of enrolment, dates of services, type of provider, procedural information, and category of service. The model has over 700 diagnostic groups that are combined into over 50 diagnostic subcategories. The system predicts between 30 and 50 percent of the variance in a population with disability. However, it is important to note that this population is likely to have costs that easier to predict than the general population. The CDPS was implemented for the Medicaid population in Colorado. Plans did suffer from some selection, and required rates to be adjusted over time (Dunn, 1998).
GRAM	The Global Risk Assessment Model is a clinically based, hierarchical model of health care use (Tseng, et al., 2003). The model was developed on 100,000 individuals who were randomly selected from several HMOs. The model uses data on demographics, eligibility, diagnoses, and costs. The system uses Kaiser Permanente Clinical Behavioural Disease Classification System, which groups diseases by their clinical attributes and the expected responses to the disease. There are 350 diagnostic categories that are further grouped into 19 categories. The model explains 17 percent of the variance, or 70 percent of the explainable variance in prospective costs. This model has not been implemented to date.
CRG	This system was developed to predict costs for individuals with congenital and chronic health conditions (Hughes, et al., 2004). CRG is a categorical clinical system that classifies individuals into mutually exclusive categories and assigns each person to a severity level if he or she has a chronic health condition. The system uses demographic, diagnostic, and procedural information. The CRG grouper assigns each individual to a hierarchically defined health status group, and then to a specific CRG category and severity level if they are chronically ill. There are nine health status groups, and over 250 CRG categories. Unlike most other risk adjustment systems, the CRG is a categorical clinical model and not a regression model. The testing and refinement of CRGs included three large data sets representing different populations – Medicare, Medicaid, and an employer based population. Prediction performance varied depending on the population tested. For a Medicaid population, the CRG yielded a predictive power of 30 percent. CRG was implemented for several paediatric populations in Ohio and Maryland.

Based on the extensive review of the importance of risk detection in healthcare, it is found that applying IT based techniques such as BI followed by data mining has the potential to significantly increase the performance of the current risk adjustment methods. Although risk detection is an essential part of healthcare decision making, to the best of the authors' knowledge, very few intelligent systems exist in healthcare with specific real-time risk detection component.

Given the importance of risk detection in the context of Congenital Heart Disease for children (CHD) and the fact that, to date, real-time risk detection has not been incorporated into healthcare decision support in any meaningful way, the outcomes of this study have a significant contribution to practice.

### **6.3 CHD Context**

Congenital Heart Disease (CHD) is a common health problem affecting many children around the world. The term “congenital heart disease” refers to “disorders of heart or central blood vessels present at birth” (Larrazabal et al., 2007). “CHD is one of the biggest killers of infants less than one year old” (AIHW, 2009) and the risk of death remains significantly high for these patients throughout their life, with over 40% unable to reach the age of five. Unfortunately surgery is not considered a final cure, as it can result in a considerably high rate of complications, and the co-existence of certain other diseases such as diabetes or various types of cancer needs to be considered. As well as the direct adverse impact on the patients and their families, CHD also carries significant societal and economic implications. Furthermore, infants born with complex congenital heart disease are not only at risk of serious heart-related complications, but also of developing a deadly bowel disease, regardless of the type of surgical intervention they receive for their heart (Hospital, 2010).

In consideration of CHD surgery, it is important to consider not only immediate medical result, but also the ongoing risk of increased probability of sudden death, exercise intolerance, neurodevelopment and psychological problems as well as long-term impacts on the family unit as a whole. This multi-faceted consideration is important because:

- The risk of late sudden death for patients surviving operation for common CHD is 25 to 100 times greater than an age-matched control population (Silka et al., 1998).
- Exercise intolerance is significantly increased in many survivors of the surgery.
- More than 50% of patients after surgery demonstrate abnormalities in neurodevelopment testing.
- Between 1-in-8 and 1-in-3 of survivors exhibit post-traumatic stress disorder (PTSD) and a further similar percentage display signs of PTSD symptoms (Ben-Amitay et al., 2006).
- Children with complex CHD are rated by their parents and their teachers as being more withdrawn, experiencing more social problems and engaged in fewer physical activities.

- Fewer parents have attachment relationships with their CHD-affected infants compared to those of healthy infants (Goldberg & Rock, 1992) and parents of children with CHD are found to be overprotective, overindulgent and inconsistent in disciplining their children.
- Families of children with CHD experience more financial strain and greater familial/social stress compared to control groups (Casey et al., 1996) As can be seen the decisions relating to treatment strategies for children suffering from CHD are both complex and high risk.

Congenital heart defect/disease is a structural problem with the heart present at birth. Congenital heart defect/disease results when a mishap occurs during heart development soon after conception and often before the mother is aware that she is pregnant. Defects range in severity from simple problems, such as "holes" between chambers of the heart, to very severe malformations, such as complete absence of one or more chambers or valves (Shanley et al., 2007).

A number of differing classification systems exist for congenital heart defects. In 2000 the International Congenital Heart Surgery Nomenclature was developed to provide a generic classification system (Shanley et al., 2007), as followed:

- Hypoplastic left heart syndrome and Hypoplastic right heart syndrome

Hypoplasia can affect the heart, typically resulting in the underdevelopment of the right ventricle or the left ventricle (Shanley et al., 2007). This results in only one side of the heart capable of pumping blood to the body and lungs effectively (Shanley et al., 2007). Hypoplasia of the heart is rare but is the most serious form of CHD (Shanley et al., 2007). It is called hypoplastic left heart syndrome (HLHS) when it affects the left side of the heart and hypoplastic right heart syndrome (HRHS) when it affects the right side of the heart. In both conditions, the presence of a patent ductus arteriosus (and, when hypoplasia affects the right side of the heart, a patent foramen ovale) is vital to the infant's ability to survive until emergency heart surgery can be performed, since without these pathways blood cannot circulate to the body (or lungs, depending on which side of the heart is defective).

- Obstruction defects

Obstruction defects occur when heart valves, arteries, or veins are abnormally narrow or blocked. Common defects include pulmonic stenosis, aortic stenosis, and coarctation of the aorta, with other types such as bicuspid aortic valve stenosis and subaortic stenosis being

comparatively rare. Any narrowing or blockage can cause heart enlargement or hypertension (Jenkins et al., 2007).

- **Septal defects**

The septum is a wall of tissue which separates the left heart from the right heart. Defects in the interatrial septum or the interventricular septum allow blood to flow from the left side of the heart to the right, reducing the heart's efficiency (Jenkins et al., 2007). Ventricular septal defects are collectively the most common type of CHD (Minette & Sahn, 2006), although approximately 30% of adults have a type of atrial septal defect called probe patent foramen ovale (Jacobson, 2012).

- **Cyanotic defects**

Cyanotic heart defects are known as such because they result in cyanosis, a bluish-grey discoloration of the skin due to a lack of oxygen in the body tissues. Such defects include persistent truncus arteriosus, total anomalous pulmonary venous connection, tetralogy of Fallot, transposition of the great vessels, and tricuspid atresia (Jenkins et al., 2007).

This research is aiming to detect some risk factors associated with hypoplastic left heart syndrome in patients with CHD.

In this research, the hypoplastic left heart syndrome is seen as the condition with most risk associated with surgical procedures involving CHD surgery for children.

### **6.3.1 Hypoplastic Left Heart Syndrome**

Hypoplastic left heart syndrome is one of the more common congenital heart defects and is the most common anomaly resulting in death from congenital heart disease during the first year of life in the United States (Egan & Festa, 2012; Van der Bom et al., 2011).

The 1980s witnessed the simultaneous development and implementation of two surgical approaches to the neonate with HLHS. Norwood et al (Norwood, 1991; Norwood et al., 1983) reported the first successful application of staged reconstructive surgery and have subsequently reported studies involving a sizable group of patients undergoing such a

sequence of surgical therapy. Bailey et al, (Bailey et al., 1986) in contrast, have introduced and espoused transplantation in the neonatal period for HLHS. Both of these treatment options have their particular difficulties and limitations. Neonatal cardiac allotransplantation is acutely limited by the supply of suitable donor hearts (Chrisant et al., 2005). The reconstructive approach requires a sequence of technically demanding procedures that may be fraught with high operative mortality and significant interstage attrition (Jacobs et al., 2011). A previous analysis of one surgeon's experience with staged reconstruction, suggested that some HLHS subgroups are at a higher risk for mortality and attrition (Ghanayem et al., 2012). To address this apparent discrepancy and to identify any additional patient- or procedure-specific risk factors related to first-stage palliation of HLHS, the records of all patients' who underwent stage I palliation for HLHS were reviewed at Boston Children's Hospital between January 1983 and June 1993 (Ghanayem et al., 2012).

Specifically, stage I mortality, survival to second-stage palliation, and actuarial survival among patients who survived stage I palliation were examined.

[Due to the copy right issue, this figure is omitted.](#)

**Figure 5. Bar graph showing hospital mortality according to anatomic subtype**

(Ghanayem et al., 2012)

HLHS patients with MS/AS may undergo a course of reconstructive palliative surgery with overall results similar to those currently offered by cardiac transplantation (Kon et al., 2013). Patients with other anatomical subtypes faced significant early mortality but are now more likely to survive to subsequent palliative procedures (Marshall et al., 2012). Given the short supply of organ donors, the most appropriate HLHS patients for transplantation are those with either mitral or aortic valve atresia, particularly those who weigh <3 kg and/or have an ascending aorta diameter of <2 mm (Marshall et al., 2012).

### 6.3.2 HLHS Risk Factors

To identify all patients with HLHS seen at C. S. Mott Children's Hospital, University of Michigan Medical Center, between January 1990 and August 1995, the Pediatric Cardiology Diagnostic File and the Pediatric Cardiovascular Surgery Database were searched for the diagnosis of hypoplastic left ventricle and Norwood procedure, respectively (Horne et al., 2012). Records were reviewed for all identified patients whose birth dates fell between January 1, 1990 and August 31, 1995. A total of 164 patients with the diagnosis of HLHS were identified. Among the patients, 31 were considered at high risk and were categorized using the following items:

- Noncardiac congenital condition
- Prematurity/low birth weight
- Chromosomal anomaly
- Galactosemia
- Absent corpus callosum
- Anal atresia
- Chronic renal failure
- Multiple limb defects
- Congenital diaphragmatic hernia
- Recurrent left atrial tumor
- Hypothyroidism and portal fibrosis
- Pulmonary venous obstruction
- Age > 1 month

Although some relevant research identified a number of risk factors, I couldn't find such significant categories for detecting risk factors in HLHS. This lack of relevant information in the literature led us to design a multidimensional model that is based on other important categories of risk factors affected by HLHS.

From the literature review, different risk categories for CHD surgery are recognized and a number of them are presented through followed sections.



### 6.3.3 CHD Surgery Risks Presented Based on Surgery Phases

Based on available outcome data, it is clear that the risk is high for neuro-developmental impairments in patients with CHD postoperatively. For example several risk factors for adverse neurodevelopmental sequelae have been identified and can be classified into preoperative, intraoperative, and postoperative factors (Martinez-Biarge et al., 2013).

- **Preoperative factors**

The incidence of associated structural brain abnormalities and acquired lesions such as PVL and hypoxic ischemic injury is high in patients with CHD and can be detected by neuroimaging preoperatively (Chock et al., 2006). This obviously impacts neurodevelopmental outcome. Severe preoperative acidosis, hypoxia, and cardio circulatory insufficiency have also been correlated with poor outcome (Snookes et al., 2010). CHD can be a feature of several different genetic syndromes that have associated neurodevelopmental profiles. For example, Trisomy 21 and velocardiofacial (VCFS) syndrome, well known syndromes associated with CHD, are also characterized by developmental delay (Lajiness-O'Neill et al., 2006).

- **Intraoperative factors**

Cardiopulmonary bypass (CPB) allows for continued perfusion of vital organs during repair of CHD (Clark, 2006). Potential deleterious effects include embolic complications and activation of inflammatory pathways (Healy et al., 2012). Several studies have correlated prolonged CPB time with poor neurodevelopmental outcome. Deep hypothermic Circulatory Arrest (DHCA) is used in some infants who require extensive repair of complex CHD (Markowitz et al., 2007). Duration of DHCA likewise has been correlated with poor outcome. The duration of the safe period of DHCA has not been clearly delineated. However, very long DHCA times (>45–60 min) have been linked to greater mortality, neuromotor deficits, and global delays (Markowitz et al., 2007). The Boston Circulatory Arrest Trial provided further evidence for the disadvantageous effects of DHCA when compared to low-flow CPB (Straub et al., 2008). This is consistent with animal data that demonstrates reduction in neuronal apoptosis and histological injury when antegrade cerebral perfusion is preserved with LFB compared to DHCA (Markowitz et al., 2007). Emerging surgical techniques are now focused on improving neurologic outcome for patients with CHD. New hybrid strategies in the repair of hypoplastic left heart syndrome (HLHS) allow for avoidance of CPB and DHCA during the neonatal period (Straub et al., 2008) and regional low-flow cerebral perfusion (RLFP)

mechanisms allow for continued brain perfusion and avoidance of DHCA during aortic arch reconstruction (Visconti et al., 2006). Whether or not these will improve long-term outcomes in this population is still to be determined. Other intraoperative management strategies have also been examined with regard to neurodevelopmental outcome. Jonas et al. (2003) reported results from a randomized trial comparing a lower (20%) versus higher (30%) hematocrit hemodilution strategy during CPB and found that the lower hematocrit group had significantly lower Bayley PDI scores at 1 year follow-up (Jonas et al., 2003).

- **Postoperative factors**

The postoperative management is aimed at maintaining the delicate balance between the systemic and pulmonary vascular resistances and avoiding shifts of either one relative to the other (Bizzarro & Gross, 2005). Ideally, the systemic arterial oxygen saturation should be maintained at 75% to 80%, which generally indicates that the pulmonary-to-systemic blood flow ratio is less than 1.5 (Bizzarro & Gross, 2005). A continuous infusion of fentanyl, begun during the operation and maintained for 24 to 48 hours, is used to blunt the stress response of the pulmonary vasculature and prevent important fluctuations in systemic oxygen saturation that may be provoked with noxious stimuli, such as suctioning (Bizzarro & Gross, 2005).

Management of infants with CHD in the immediate postoperative period is crucial as several treatable or avoidable postoperative complications may have an impact on long-term outcome. Reports from the Boston Circulatory Arrest Trial demonstrated that transient postoperative clinical and electroencephalographic seizures were associated with worse neurodevelopmental outcomes at ages 1 and 4 years (Gaynor et al., 2006). However, a recent report by Gaynor et al. (2006) on a mixed population of cardiac lesions, suggested that postoperative seizures were not predictive of a worse outcome at 1 year of age (Gaynor, et al., 2006). Frontal onset of a seizure was associated with a worse psychomotor outcome in this population. Thus, it remains unclear if seizures are simply a marker of CNS injury or a true predictor of outcome, although there is some evidence for the latter (Marchi et al., 2007).

Postoperative temperature control is critical as hyperthermia is known to be detrimental in the presence of hypoxic ischemic injury (Polderman & Herold, 2009). Mild post ischemic hyperthermia has been shown to significantly exacerbate functional and structural neurologic injury after deep hypothermic circulatory arrest in animal models (Polderman, 2004). Similarly, decreased systemic oxygen delivery may also further contribute to CNS injury (Polderman, 2004).

In a small number of patients, Hoffman et al. (2005) showed that systemic venous oxygen saturation was a significant risk factor for poor neurodevelopmental outcome and that this risk was directly correlated to increasing time spent with systemic venous oxygen saturation <40% (Hoffman et al., 2005). Hamrick et al. (2003) reported outcomes in surviving patients with CHD supported with postoperative ECMO. Only 13% of patients survived completely intact, with 50% a suspect or abnormal cognitive outcome and 28% with a suspect or abnormal neuromotor outcome (Hamrick et al., 2003).

#### **6.3.4 Risk Factors Based on Prenatal and Postnatal Diagnosis**

HLHS is proportionately one of the most common congenital cardiac defects diagnosed prenatally, because standard 4-chamber views obtained during routine obstetrical ultrasounds demonstrate hallmark findings of either a small left side or an echogenic left ventricle (Friedberg et al., 2009). In addition, there is usually reversal (left to right) shunting across the foramen ovale and often retrograde aortic arch flow, all easily recognized by colour-flow Doppler imaging (Donofrio et al., 2004). Prenatal diagnosis of HLHS has clear advantages. It allows time to counsel parents and time for both parents and physicians caring for the patient to plan perinatal management and assess some relevant risk factors to enable surgery for new born. Table 6 defines some main variables in prenatally and Postnatal Diagnosed Patients Undergoing Stage 1 Palliation of HLHS in Boston hospital in 2001.

**Table 6. Demographic and Surgical variables in Prenatal and Postnatal Diagnosed Patients Undergoing Stage 1 Palliation of HLHS**  
(Donofrio et al., 2004)

Due to the copy right issue, this table is omitted.

Prenatal diagnosis of HLHS affords the opportunity for counselling and perinatal planning (Donofrio et al., 2004). For patients in whom surgical palliation is elected, prenatal diagnosis provides an opportunity to avoid the preoperative hemodynamic and metabolic insult so frequently seen in those diagnosed in postnatal (Donofrio et al., 2004). This improved preoperative state may, in turn, contribute to improved survival after first-stage palliation, as was seen to be the case in our experience.

### **6.3.5 Risk Factors Based on Surgery Procedures**

HLHS has three essential surgery procedures that they are Norwood surgery, Hemi-Fontan or BCPS surgery and Fontan surgery, respectively:

- **Norwood Procedure**

Although the basic principles for each of the three stages remain consistent, modifications in operative techniques continue to result in improved outcomes (Marshall, et al., 2012).

The essential elements of the Norwood operation are the provision of unobstructed systemic and coronary blood flow with aortic arch augmentation, relief of pulmonary venous obstruction by atrial septectomy, and control of pulmonary blood flow through a restrictive systemic to pulmonary artery shunt (Furck et al., 2010). The reconstruction of the aorta and its association with the pulmonary valve must be performed without excessive dilatation of the allograft patch in order to avoid compression of the left pulmonary artery.

Early in our experience, compression of the left pulmonary artery resulted in some often subtle-left pulmonary artery obstruction that only became hemodynamically significant after the Fontan procedure, when the entire cardiac output passes through the lungs (Marshall, et al., 2012). Obstruction to pulmonary artery blood flow was believed to be the most significant contributing factor to death among the early patients in this series undergoing the Fontan procedure. More streamlined tailoring of the allograft patch at the time of the Norwood procedure and routine augmentation of the left pulmonary artery at the time of the hemi-Fontan procedure has improved substantially this important problem in the more recent patients. Reconstruction of the aorta to provide unobstructed coronary artery flow presents a technical challenge when the ascending aorta is less than 2 to 3 mm in diameter (Marshall, et al., 2012). However, careful alignment of the aorta with the proximal pulmonary artery to avoid rotation or kinking is possible, even in patients with an extremely diminutive ascending

aorta. Prior analyses from this and other institutions failed to identify the size of the ascending aorta as a risk factor for death (Furck et al., 2010).

The control of pulmonary blood flow remains the most significant issue surrounding the Norwood operation and is the factor associated most often with early death. The dynamic balance between the systemic and pulmonary vascular resistance is altered easily and depends on many factors. Although the size of the shunt itself is one major element, this must be viewed in the context of the overall patient condition, particularly the status of the pulmonary vascular resistance. Older age at operation is likely to be associated with elevated resistance, and postoperative pulmonary blood flow may be inadequate if too small a shunt is used (Hehir et al., 2011). A similar, but usually transient, situation exists in patients with pulmonary edema resulting from excessive pulmonary blood flow or obstruction to pulmonary venous return. Conversely, a large shunt will provide too much flow when resistance is low, and the resultant pulmonary over circulation will lead to low cardiac output, systemic acidosis, and early death. Because postoperative condition is considerably more stable when right ventricular volume overload is avoided by using a small shunt, the optimal patient undergoing the Norwood procedure should have low pulmonary vascular resistance and no increase in extra vascular lung water (Furck et al., 2010). Thus, the patients undergoing first-stage reconstruction beyond the neonatal period and those with obstructed pulmonary venous return have posed a significantly greater risk. The group of patients presenting with prematurity and low birth weight also have posed an increased risk predominantly from the inability to sufficiently limit pulmonary flow, even when 3-mm polytetra fluoroethylene shunts are used (Hehir et al., 2011).

Recently, I have used standard Blalock- Taussig shunts in patients weighing less than 2.5 kg and have noted more appropriate pulmonary blood flow, possibly because the smaller subclavian artery acts as the flow regulating vessel (Furck et al., 2010).

This modification recently has been used successfully in five consecutive patients weighing less than 2.1 kg. Between January 1, 1998 and June 30, 2001, 158 infants underwent the Norwood procedure at The Children's Hospital of Philadelphia. Patient and operative variables were assessed as potential risk factors of operative (hospital discharge and at least 30 days after surgery) and 1-year mortality (Table 7). Data are presented as medians and ranges (Tabbutt et al., 2012).

**Table 7. Potential risk factors of operative in the Norwood procedure**  
(Tabbutt, et al., 2012)

Due to the copy right issue, this table is omitted.

Many factors are likely to be responsible for the improvement in operative survival following the Norwood procedure. These factors include improved surgical techniques, improved perioperative management, and improved anesthetic techniques. Despite the improving outcome, early survival for these children is still significantly lower than for other forms of heart disease, which require neonatal surgical intervention.

- **Hemi-Fontan Procedure**

Removal of the ventricular volume overload resulting from the systemic shunt has proven to be an important step in reducing mortality from the Fontan procedure (Brown et al., 2011). However, when small shunts are used in the first stage, pulmonary blood flow will rapidly become insufficient for patient growth, and the second stage of the procedure will be required at an early age (Biglino et al., 2013). This has not resulted in an increased risk, however, and hemi-Fontan procedures have been performed successfully in patients as young as 1 month of age (Kung et al., 2013). The salutary effect of the hemi-Fontan procedure probably results from the fact that after this operation, patients generally remain well palliated, free of risk factors, until they reach an age when they are more suitable candidates for the Fontan procedure (Marshall et al., 2012). Therefore, it is essential that all risk factors be addressed at

the second stage, these risk factors including tricuspid regurgitation, pulmonary artery hypoplasia, residual obstruction to pulmonary venous return, and systemic outflow tract obstruction (Marshall et al., 2012). A potential connection for the inferior vena caval return must be provided at the subsequent Fontan procedure to simplify that stage surgically and avoid the need for additional dissection, which may damage the sinus node or its arterial supply.

- **Fontan Procedure**

After a properly constructed hemi-Fontan operation, the final stage of the reconstruction should be the simplest procedure. It remains our preference to construct an intra-atrial lateral tunnel, channeling the inferior vena cava to the pulmonary arteries through the connection made at the previous operation (Louw & Gewillig, 2013). Removal of the temporary wall separating the superior vena cava to pulmonary artery anastomosis from the right atrium will result in a large unobstructed pathway (Giordano et al., 2013). Therefore, the operative dissection is kept to a minimum, which reduces blood loss and potential injury to the conduction system and phrenic nerves (Giordano, et al., 2013). Total cardiopulmonary bypass time and aortic cross clamp time also are minimized, resulting in less perioperative edema and pulmonary dysfunction (Rebeyka et al., 2013). Since adopting these strategies at our institution, the risk of the Fontan procedure has decreased dramatically and the postoperative courses have been mostly uncomplicated.

Ten criteria which would permit a good outcome after the Fontan operation have been identified. The ten commandments included data which could be obtained before surgery by examining the patient, and carrying out tests like echocardiography and cardiac catheterization.

Here is a list of the ten criteria (Rebeyka et al., 2013):

- Age above 4 years
- No distortion of lung arteries from prior shunt surgery
- Normal venous drainage
- Normal ventricular function
- Adequate pulmonary artery size
- No atrio-ventricular valve leak
- Low pulmonary artery pressure (below 15 mmHg)

- Low lung blood vessel resistance
- Normal heart rhythm
- Normal right atrial size

In effect, all these criteria relate to ensuring that the resistance of blood vessels in the lung was not too high. A high resistance would interfere with passive lung blood flow. This could be produced by very small pulmonary arteries, blood vessel wall thickening and hardening, mitral valve leak or reduced function of the left ventricle. In all of these conditions, a Fontan operation would not be performed, or modified to reduce the risks.

The Fontan operation has been modified many times since its first description (Hirsch et al., 2008). Each modification aimed to avoid one of the drawbacks of the previous types of surgery. While some are definitely better, others are not very different (D'Udekem et al., 2007). I am still striving to devise the "best" type of Fontan repair for each group or individual.

As the researcher has mentioned earlier, in the original Fontan operation, the venous blood was diverted to the lungs directly from the right atrium, and the ASD was closed (D'Udekem, et al., 2007). While the original. Fontan operation used an artificial valve between the inferior vena cava (IVC) and the right atrium, future modifications eliminated this (Louw & Gewillig, 2013).

The aims of the "ideal" Fontan operation are (Louw & Gewillig, 2013):

- To achieve a smooth stream-lined blood flow from veins to the lungs
- To retain growth potential as the child becomes older
- To avoid use of artificial materials
- To be adaptable to patients of any age group

**Table 8. Independent risk factors in stage 1 for death through Fontan completion**

(Louw & Gewillig, 2013)

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### 6.3.6 Risk Factors Based on Surgery Stages

Staged reconstructive surgery has radically altered the prognosis of hypoplastic left heart syndrome (HLHS). Antenatal diagnosis allows for appropriate counseling and time to consider treatment options. In table 9, some risk factors in different surgery stages are presented.

**Table 9. Risk factors based on surgery stages**

Stage 1		Stage2	
<b>Boston Group</b>		<b>Boston Group</b>	
a smaller Ascending Aorta ( $P<.001$ ),		ascending aorta diameter $<2.5$ mm ( $P=.018$ ) and those in whom synthetic tube grafts were used in neo-aortic reconstruction ( $P=.03$ ) were less likely to survive to a second-stage operation	
Aortic Atresia ( $P<.001$ ),			
Mitral Atresia ( $P=.002$ )			
<b><u>Risk Factor</u></b>	<b><u>P</u></b>		
<hr/>			
Sex	.146	Sex	.362
Anatomic subtype	.063 <sup>12</sup>	Age at operation	.543
RV function	.119	Weight $<3$ kg	.946
Restrictive ASD	.212	Anatomic subtype	.001 <sup>23</sup>
Stage I procedure type	.542	Ascending aorta $<2.5$ mm	.018 <sup>3</sup>
Delayed chest closure	.218	Stage I procedure type	.059 <sup>3</sup>
Lowest recorded pH	.191	Surgeon	.845
Ascending aorta $<2$ mm	.002 <sup>2</sup>	PA-Ao material	.030 <sup>23</sup>
Circulatory arrest $>$ median	.170	Shunt type	.025 <sup>3</sup>
Weight $<3$ kg	.024 <sup>12</sup>	Delayed sternal closure	.024 <sup>3</sup>
Coarctation	.375	CPB $>$ median	.748
Tricuspid regurgitation	.723	Circulatory arrest $>$ median	.623
		Year of operation	.001 <sup>23</sup>
		PA-Ao (pulmonary artery	

Surgeon	.439	<sup>1</sup> aorta) material indicates type of prosthetic material used in neoartotic reconstruction; Shunt type, type of systemic-pulmonary shunt; and CPB, cardiopulmonary bypass.  <sup>2</sup> Significant by multivariate analysis ( $P<.05$ ).  <sup>3</sup> Significant by univariate analysis ( $P<.05$ ).
Shunt type	.521	
Age	.638	
Immed. pre-op pH	.017 <sup>12</sup>	
CPB >median	<.001 <sup>2</sup>	
Year of operation	.242	
RV indicates right ventricular; ASD, atrial septal defect; Immed. Pre -op pH, plasma pH immediately before stage I operation; and CPB, cardiopulmonary bypass.  Significant by multivariate analysis ( $P<.05$ ).  Significant by univariate analysis ( $P<.05$ ).		

### 6.3.7 Process Across CHD Surgery

To clarify the effective place of intelligent solutions in CDSSs, in this research the broad definition of decision support activities is adapted from (Marakas, 2003). As demonstrated in figure7, it is defined as the set of activities within unstructured or semi-structured decision context that are aimed to support rather than replace the decision maker (DM), facilitate learning on the DM's behalf, and are using underlying data and models to focus on the effectiveness of the decision making process (Marakas, 2003).

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#### Figure 6. The clinical decision context

Adapted from (Marakas, 2003; Zhuang et al., 2009)

Decision-making regarding surgery for infants with congenital heart disease (CHD) is especially multi-faceted and complex. Patients may have a variety of symptoms, but are often quite functional, and therefore, it is appealing to lean towards a complete anatomical repair (Reddy et al., 1997 ). However, if the decision is for late repair, risks and benefits of surgery must be weighed against potential risks of not proceeding with the surgery (Stamatis, 2010). Moreover, the decision to treat CHD with either drugs, or surgery, or a combination of both depends on a large number of factors (Roy & Brunton, 2008 ).

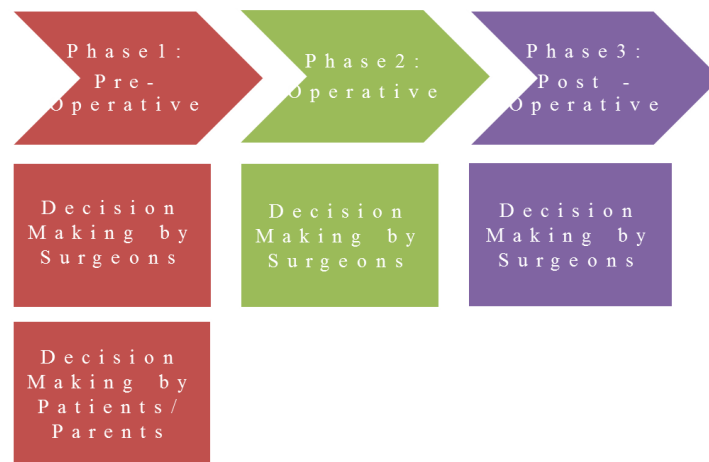
The decision making process in the context of CHD can be divided into three phases (Figure 8). In the first or pre-operation phase, the surgeon, having received enough information about the patient and his/her medical condition, makes a decision relating to whether surgery is the best medical option. Once this decision is made but before surgery, the parents must decide whether to accept or reject the surgeon's decision in consideration of the predicted outcomes. Once parents and surgeons have agreed to proceed, in phase 2, ad-hoc decisions pertaining to the unique situations during the surgery must be addressed. Finally, in the post operating phase, or phase 3, decision making is primarily done at two levels;

a) Strategies to ensure a sustained successful result for the patient during aftercare and beyond, and

b) Record of lessons learnt for use in future similar cases.

To capture this complexity, two steps of decision making are defined in three different and key phases of the decision making process for CHD surgery. The first type of decision making is called “surgical decision making” as it is primarily associated with the surgeons.

The second type is called “parental decision making” because some surgery outcomes (such as “quality of life”) directly affects the parents and therefore they have a critical say in whether to proceed with the surgery. Figure 8 shows the decision making framework I have developed based on the key phases explained above.



**Figure 7. Decision making framework across the CHD surgery (Moghimi et al. 2011)**

To clarify the function of the decision making framework across CHD surgery for this study, I summarize current surgery steps and the associated decision making process in one of the common CHD classifications; Hypoplastic Left Heart Syndrome (HLHS) in figure 9. HLHS patients, usually have three types of surgery during their childhood treatment period. Norwood, BCPS and Fontan are most recent surgeries that are conducted to patients in different age and conditions. However, the Norwood surgery is still much more complex and risky with a high rate of mortality and morbidity.

As is depicted in figure 8, the current state typically involves the parental decision, and whilst the parental decision is significant, is often not recognized as a key component of the healthcare outcome. The surgical decision making process, on the other hand, is clear in all critical steps. Thus, our proposed IRD Model will be a valuable Model to apply in the highlighted steps in Figure 9, in all three surgery phases and surgery types to predict the

operation outcomes by detecting risk factors to assist parents as well as surgeons in making superior decisions.

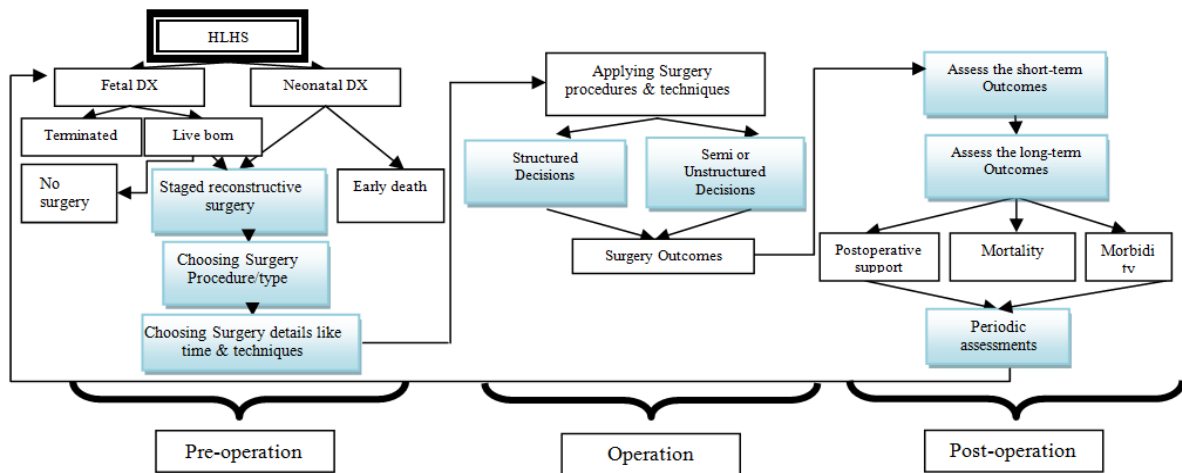


Figure 8. Flow Diagram of Key Steps with CHD Surgery in the case of HLHS to Demonstrate the Importance of the IRD Model

Although DSSs in the healthcare area is generally well discussed, acceptance of such solutions tends to be low because doctors (the primary users) are reluctant to use computers (Baldwin, 2001). Close consideration must also be paid to ensuring the clinical utility of any proposed solution. This research contend that by incorporating real time risk detection, the IRD Model is likely to then become more relevant and helpful which in turn will enhance its utility and thus adoption.

#### 6.4 Implication of Literature to This Study

After conducting a comprehensive literature review around key concepts of this study, it has been found that an Intelligent Risk Detection (IRD) model in support of better treatment decisions made during and after surgery can provide superior healthcare outcomes for the patients and their families. In developing a solution such as the IRD, it is necessary to combine the three key areas of knowledge discovery, risk detection with decision support systems (figure 10). This then represents the important contribution that this research makes to both theory and practice in the healthcare context.

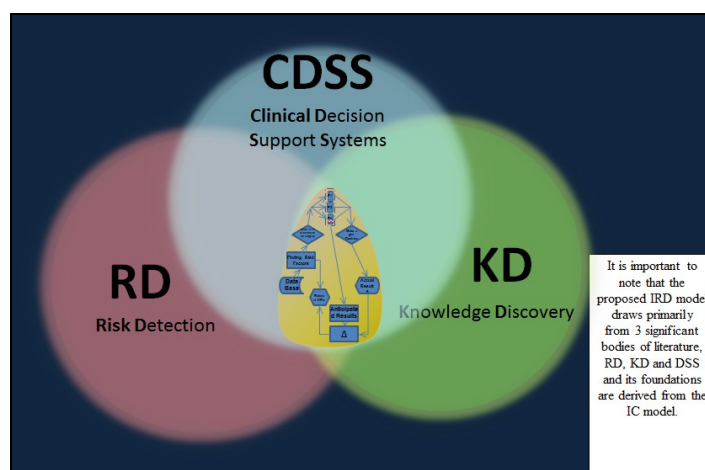


Figure 9. Key contexts of the literature review (Moghimi et al 2011)

Table 10, presents key findings through the literature review mostly in recent in 10 years (2003-2013).

Table 10. Key Findings in Literature review in 10 years (2003-2013)

Authors and year	Quotations	Key findings
(Gagnon et al., 2012)	Review investigating facilitators and barriers to HIT implementation: design, technical concerns, familiarity with technology, time consuming nature of use or increased workload, lack of compatibility with existing work practices, interoperability, concerns about validity of resources, cost, legal issues, patient/health professional interaction, applicability to patients, attitude of colleagues toward technology, role boundaries and changes in tasks, material resources.	patient/health professional interaction
(Cresswell & Sheikh, 2012)	A number of social aspects surrounding technological innovation are highlighted throughout the literature as increasing the chances of “successful” implementation.	Socio –technical aspects of technological innovation in healthcare
(Keshavjee et al., 2006)	Canadian review of what makes EMR implementation successful, developed a framework based on review of qualitative implementation literature, followed principles of systematic review, 125 included qualitative articles <ul style="list-style-type: none"> <li>• high incidence of failure in EMR implementation</li> <li>• there are several existing models that describe factors for successful implementation but none of these is inclusive enough</li> <li>• technology is implemented over a certain amount of time, people/processes and technology are involved, strong leadership is important, stakeholder communication</li> </ul>	Importance of three factors of people, process and technology

Authors and year	Quotations	Key findings
	<p>and engagement is important, implementation is a dynamic and evolving learning process, usability is important</p> <p>Framework:</p> <ul style="list-style-type: none"> <li>• divides implementation into three time periods: pre-implementation, implementation and post-implementation</li> <li>• any factors identified can be in either one, some, or all of the phases</li> <li>• identified factors can have relationship with each other</li> <li>• factors divided into categories of people, process and technology</li> </ul>	
(Ludwick & Doucette, 2009)	<p>Canadian review of EMR adoption in primary care looking at articles from a range of countries with a view to identify lessons learned from EMR implementations (but examined evidence from a range of care settings), found that focus of articles was on sociotechnical factors, similar factors seemed important across care settings, also included grey literature/government and professional bodies literature</p> <ul style="list-style-type: none"> <li>• Found that socio-technical factors were most important for successful implementation, important that the new system fits in with existing organizational goals and practices</li> <li>• Barriers were identified to be perceived negative impact on patient safety, privacy, impact on healthcare professional–patient relationship, reservations from users, implementation time needed, cost issues</li> </ul>	The importance of socio-technical factors
(Mair et al., 2007)	<p>Examined barriers and facilitators to the implementation of HIT and found technology design factors, health professional interactions, and organizational factors to be Important Key barriers include: inadequate information management, inadequate inter-agency cooperation, intrusive technology/rigidity of system, cost, lack of testing</p> <p>Key facilitators include: positive inter-agency co-operation, flexibility, ease of use, organizational willingness, ability to order information</p> <p>Other factors: health professional/patient relationships</p>	The importance of , inadequate inter-agency cooperation and positive inter-agency co-operation
(Kuhn, et al., 2006)	To identify current challenges and development in health	The importance of socio-technical

Authors and year	Quotations	Key findings
	information systems, socio-technical issues were ranked highly important in interactive and communicative health information systems environment. Also patient empowerment was identified as an important issue to improve the practice of healthcare by patients to be active participants in the care process.	factors and also patient empowerment
(Kuhn, et al., 2006)	Through updating a systematic review on the barriers and facilitators to implement shared decision-making in clinical practice, potential contribution of shared decision making models to the improvement of the decision making process quality is emphasized. Also, it is stated that "Patients' demand for participation in medical decisions has been increasing. In order to help patients understand potential risks and benefits of a procedure, and select the option that best accommodates their personal needs, information has to be coupled with high-quality decision counselling."	The importance of shared decision making process
(Elwyn et al., 2010)	Creation of a platform of tools to provide information to doctors and patients should be the first step in giving patients choice about their treatment.	The importance of shared decision making process
(Bates et al., 2003)	To develop an effective decision support system, clinician information needs must be anticipated and deliver to clinicians in real time. Also, Maintaining the knowledge within the system and managing the individual pieces of the system are critical to successful delivery of decision support. Moreover, it is found that it is useful to track the frequency of alerts and reminders and user responses and have someone, usually in information systems, evaluate the resulting reports on a regular basis.	Technical factors: <ul style="list-style-type: none"> <li>• Anticipate needs and deliver in real time</li> <li>• Adapting Knowledge driven approach</li> <li>• Regular evaluations</li> </ul>
(Kawamoto, et al., 2005)	To identify features of successful clinical decision support process, four features are identified: automatic provision of decision support as part of clinician workflow, provision of recommendations rather than just assessment, provision of decision support at the time and location of decision making, and computer based decision support.	computer based decision support
(Rosenstein & O'Daniel, 2005)	The factor most influential in reducing sentinel events and their potentially negative effects on clinical outcomes is improvement of relationships among clinicians.	Importance of relationships among clinicians
(Zwarenstein & Reeves,	Policymakers, managers and clinicians have a growing	Importance of clinicians'



Authors and year	Quotations	Key findings
2006)	interest in intervening in clinicians' relationships through two major approaches: 1) quality and safety improvements by systematically analysing care processes, and 2) Inter professional education and interventions to foster collaboration	relationships
(Meneer et al., 2012)	Now more than ever, there is a need to embed knowledge translation (KT) strategies within care practice and research to ensure application of relevant findings in practice, overcome the typically slow uptake of evidence into everyday care, and support primary care reforms. Advancing both the practice and science of KT will necessarily require that the worlds of care practice and research be brought much closer together.	Importance of knowledge translation
(Lai, 2012)	To be respectful of patients and parents/guardians participation and decisions, shared decision-making (SDM) between health care professionals, patients, parents and guardians is widely recommended today.	Importance of shared decision-making (SDM)
(Whitney, et al., 2003)	Typically, cases using SDM are of major importance and high uncertainty in which patients' values, and hence shared decision making, were highly relevant, for example, continuing life support for patients in a persistent vegetative state, surgery for localized breast cancer, or care or termination of care for severely burned persons	Importance of shared decision-making (SDM)
(Haug, et al., 2007)	According to Hauge et al. (2007) study, two elements of medical decision support applications are critical to their success, independent of the implementation environment, as followed: 1) The mechanism by which the systems acquire the data used in their decision algorithms; and 2) The interface through which they interact with clinicians/users to report their results.	The importance of design factors
(Cerrito, 2011)	Unfortunately, many decisions are based upon an incorrect knowledge of risk (Cerrito, 2011)	The importance of risk assessment and detection
(Van der Weijden, et al., 2008)	In communicating cardiovascular disease risk, primary care physicians must be aware that they mostly encounter low-risk patients and that the perceived risk does not necessarily correspond with the actual risk. Physicians should be skilled in the use of effective formats for risk communication that are ideally integrated within patient decision aids for cardiovascular risk management.	The importance of risk assessment and detection
(Karmali & Lloyd-Jones,	It is suggested that estimation of lifetime risk and other	The importance of risk assessment

Authors and year	Quotations	Key findings
2013)	novel methods of risk communication, such as risk-adjusted age, should be used as an adjunct to 10-year risk estimation.	and detection
(Anthony Tony Cox, 2008)	Inputs to risk matrices (e.g., frequency and severity categorizations) and resulting outputs (i.e., risk ratings) require subjective interpretation, and different users may obtain opposite ratings of the same quantitative risks. These limitations suggest that risk matrices should be used with caution, and only with careful explanations of embedded judgments.	The importance of risk assessment and detection
(Farooq et al., 2012)	Clinical risk assessment of chronic illnesses in the cardiovascular domain is quite a challenging and complex task which entails the utilization of standardized clinical practice guidelines and documentation procedures to ensure clinical governance, efficient and consistent care for patients	The importance of risk assessment and detection
(Ahmad et al., 2012)	In conclusion, further development and implementation of the computer-assisted health-risk assessments for psychosocial health risks should pay close attention to context-specific social aspects of the technology.	The importance of risk assessment and detection
(Sequist et al., 2012)	To determine if electronic risk assessment and alerts to physicians can improve the quality and safety of chest pain evaluations.	The importance of risk assessment and detection
(Jiang et al., 2012)	Developing a patient-driven adaptive prediction technique to improve personalized risk estimation for clinical decision support is critical.	The importance of risk assessment and detection
(Mani et al., 2012)	Risk forecasting can be used to plan prevention and intervention strategies.	The importance of risk assessment and detection
(Amin et al., 2013)	Data mining techniques have been very effective in designing clinical support systems because of its ability discover hidden patterns and relationships in medical data.	The importance of data mining followed by knowledge discovery in clinical decision support
(Gosain & Kumar, 2009)	The study outcomes are to: (1) present an evaluation of techniques such as decision tree and association rules to predict the occurrence of route of transmission based on treatment history of HIV patients. (2) Demonstrate that data mining method can yield valuable new knowledge and pattern related to the HIV patient; (3) assesses the utilization of healthcare resources and demonstrate the socioeconomic, demographic and medical histories of	The importance of data mining followed by knowledge discovery in clinical decision support

Authors and year	Quotations	Key findings
	patient.	
(Srinivas et al., 2010)	This research has developed a prototype Intelligent Heart Disease Prediction System (IHDPS) using medical profile such as age, sex, blood pressure and blood sugar it can predict the likelihood of patients getting heart disease.	The importance of data mining followed by knowledge discovery in clinical decision support
(Candelieri et al., 2009a)	The authors propose an innovative knowledge based platform of services for effective and efficient clinical management of heart failure within elderly population.	The importance of a knowledge based techniques
(Peter & Somasundaram, 2012)	In this research paper, the use of pattern recognition and data mining techniques into risk prediction models in the clinical domain of cardiovascular medicine is proposed. Also, in this research by use of classification models which can implicitly detect complex nonlinear relationships between dependent and independent variables as well as the ability to detect all possible interactions between predictor variables.	The importance of data mining followed by knowledge discovery in clinical decision support
(Bernabe et al., 2012)	In this study, which examined decision theory, specifically through the expected utility theory and multi attribute utility theory, enable for an explicit and ethically weighted risk-benefit evaluation. This makes a balanced ethical justification possible, and thus a more rationally defensible decision making.	The importance of risk assessment in clinical decision making process

## 6.5 The Theoretical Approach of the Research

Identified gaps in literature review in order to develop an intelligent risk detection application are presented at table 11.

**Table 11. Gaps in the literature review**

Gaps in the literature review	Description
Real time communication/ relationship and knowledge transition between care parties	Lack of communication facilitators to share information, knowledge and decision between clinicians and between clinicians to patients of their families in order to support clinical decisions by understanding the treatment risk factors and anticipated outcomes, in real time.
Socio-technical issues	Lack of some specific Socio-technical components in healthcare to make a successful implementation of a new technology to address data importance and timing issues.
Technology Acceptance Issues	Resistance between healthcare professionals to accept new compute based technologies due to the importance of accuracy and privacy.

To address the gaps and challenges described in table 11, the proposed IRD framework has been designed based on the three following theoretical foundations. The first theoretical foundation is User Centred Design (UCD), an information system design approach with a strong focus on the design of a system through understanding and supporting the interests, needs and work practice of the intended users (Avison & Fitzgerald, 2008; Gulliksen et al., 2003; Norman & Draper, 1986). The second theoretical foundation is based on Network Centric HealthCare Operations (NHCO), as an unhindered networking operation within and among all three domains that govern all activities conducted in healthcare space. NHCO are based on free, Multi-directional flow and exchange of information and utilizing all available means of (Information Computer/Communication Technology) IC2T to facilitate such operations (Lubitz and Wickramasinghe 2006a,b). The third theoretical foundation is the Intelligence Continuum (IC) Model, defined as a collection of key tools, techniques and processes used in today's knowledge economy. The tools, techniques and processes include but not limited to data mining, BI/BA and KM, and taken together they represent a very powerful system for refining the raw data material stored in data marts and/or data warehouses by maximizing the value and utility of these data assets for any organization (Wickramasinghe and Schaffer 2006).

### **6.5.1 Development of the Conceptual Framework**

In order to realise the proposed IRD model, it is necessary to develop a conceptual model of the decision making stages and risk assessment (figure 11). The left-most block in figure 11 depicts the first stage of risk assessment. The output of the risk assessment process will help in determining important surgery risk factors and will also assist in predicting outcomes (in risk detection block) based on the specific risk factors. The predicted results enable the surgeons to then make better informed decisions regarding whether (or not) to proceed with the surgery in first phase, to be followed by a second and third surgical phase.

If the decision is indeed to proceed with the surgery, all relevant information then needs to be passed on to the patients/parents, in pre-operative phase, in order to allow them to make their final decision regarding the surgery. Depending on their decision there will be a move to second phase of surgery, or the process will be concluded. Any such conflicts become feedback into the system for future risk assessments for the same or other similar patient conditions.

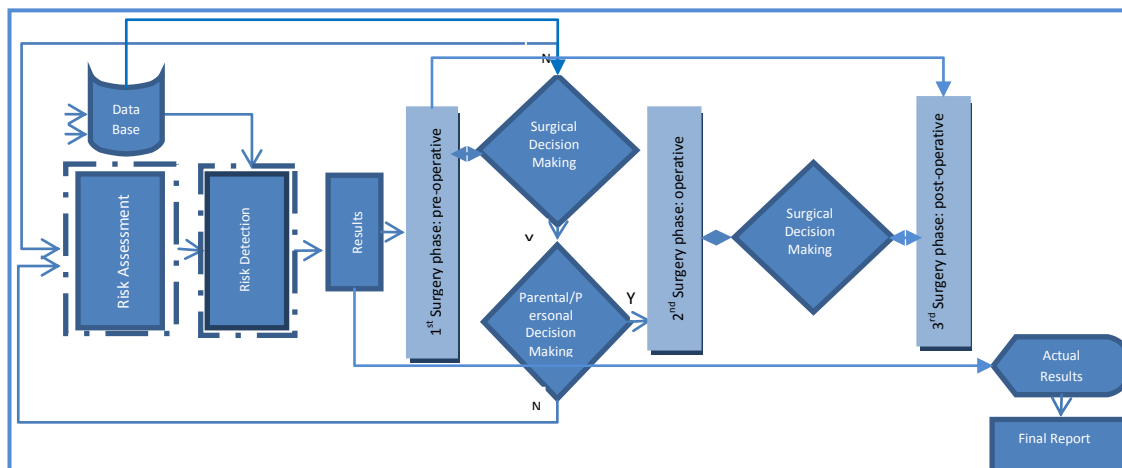


Figure 10. Preliminary conceptual framework (Moghimi et al. 2011)

- **Risk Assessment**

Detecting the risk factors based on a risk assessment process using knowledge discovery techniques is a useful way to assess improvements in surgery (Larrazabal et al., 2007). After first identifying important risk factors in the literature, expert input will seek at two distinct stages to address this subject. The specific stages involved in the risk assessment process are shown in figure 11. In the first stage, the specialists through an expert group of surgeons are presented with risk factors identified from the literature. The experts will then nominate (or introduce) some main risk categories or dimensions as well as risk factors to be used in the surgical decision making process. In the next stage, in order to design a scoring mechanism, the expert group will be asked to evaluate the risk factors and also define the relationships between these factors or between these factors and present some actual or anticipated surgery results.

In the Scoring Mechanism, the surgeons can achieve consistent strategy execution and monitoring of performance by tracking a patient situation in the surgery procedures, and enhancing their relevant data. The Balanced Scorecard can provide a complete view of the risk factors, their level of risk and their impact on surgical results via a risk detection process. A value range of the risk factors will then be extracted by the expert group, in order to define the relevant key performance indicators (KPIs). Finally, risk auditing, the last step of the risk assessment process, will serve to keep the model up to date by using results from a report made by comparing actual and anticipated results.

- **Risk Detection Using Knowledge Discovery**

To incorporate an intelligent technology process into the proposed risk assessment process, this research proposes a data mining process followed by knowledge discovery. In the research case, the data types have a significant impact on the data mining tasks. Hence, after finishing the data collecting phase, the suitable tools for extraction will be neural networks and association rules. This research will design a small database that includes the patients' data and also data to show risk factors. This will assist the research in applying the necessary data mining techniques and in developing and implementing the risk model. The research process then moves through steps 1 to 6 (below).

Step 1. Understand all clinical requirements, dataset structure and data mining tasks and designing a dimensional data mart

Step 2. Prepare target datasets: select and transform relevant features; data cleaning; data integration. Communicate any findings during data preparation to domain experts.

Step 3. Train multiple data mining models in randomly sampled partitions

Step 4. Evaluate data mining models using a set of performance metrics.

Step 5. Discuss the data mining results with domain experts. Explore potential patterns from data mining results. If identify new risk factors or patterns, communicate the rule(s) with decision makers and determine the appropriate actions.

Step 6. Go back to Step 1 if some new questions are raised during the process or new KPIs or risk factors are discovered. Otherwise, finish and exit the process.

- **Applying Anticipated & Actual Results**

In the proposed conceptual model evolved to evaluate a risk detection process, the actual results will be compared with the anticipated results. This is because on occasions actual results present new risk factors or new measurements helpful in assessing the risk factors. This comparison would be an effective solution to create a final report to show some important items, and finally apply them to the risk assessment process, for next iterations of evaluations.

## 6.6 Summary and Significance of Study Based on the Literature

Overall, considering the study aims and goals to improve the surgical decision efficiency by detecting risk factors, more than 500 relevant publications in total in the period 2003 to 2013 were reviewed while almost 350 of publications were focused on Information Systems and Health Informatics. Approximately 150 of reviewed papers were related to healthcare contexts. Through the initial literature review in healthcare contexts, the following issues and challenges have been identified and demonstrate the importance of designing and developing such a computer based risk detection decision support solution as the IRD.

- Lack of communication facilitators to share decisions between clinicians, and between clinicians and patients or their families, in order to support clinical decisions by understanding the treatment risk factors and anticipated outcomes (Bates et al., 2003).
- Lack of some specific Socio-technical components of people, process, technology and environment in healthcare to make a successful implementation of a new technology to address data importance and accuracy issues (Kuhn et al., 2006; Candelieri et al. 2009; Gosain and Kumar 2009; Srinivas et al. 2010; Peter and Somasundaram 2012; Bernabe et al. 2012; Yoo et al 2012; Padhy et al 2012; Amin et al. 2013).
- Lack of a dynamic risk assessment system, in the healthcare context (Fortinsky et al., 2004; Gambriell & Shlonsky, 2000; Greenland, 2012; Pancorbo-Hidalgo, Garcia-Fernandez, Lopez-Medina, & Alvarez-Nieto, 2006; Ryan et al., 2012; Twetman, Fontana, & Featherstone, 2013)
- Lack of a multidimensional risk detection model/algorithm (Anderson, Brodie, Vincent, & Hanna, 2012; Aylin, Bottle, & Majeed, 2007; Gran, Fredriksen, & Thunem, 2004; Staal, Hermanns, Schrijvers, & Van Stel, 2013; Trucco & Cavallin, 2006).

Therefore, to facilitate the surgical decision making process, it is realized by the researcher that such contexts are appropriate for the application of an intelligent risk detection decision support. This study proffers a suitable solution which combines the application of data mining tools followed by Knowledge Discovery (KD) techniques to score key surgery risk levels, assess surgery risks and thereby help medical professionals to make appropriate clinical decisions.

## CHAPTER 3

### **Methodology & Research Design**

This Chapter examines the research methodology and research design adopted in this study. Chapter 3 first outlines the philosophy that underpins the approach taken with the research and discusses the researcher's approach. The next section (section 3.1) discusses the rationale for the research design and data analysis. The Chapter then outlines the reasons for the adoption of a single case study method. Chapter 3 also provides an overview of the data collection methods used for the study, as well as the means used to analyse the data. Chapter 3 concludes with sections on the limitations of the research and ethical considerations.

#### **7.1 Methodology**

The research reported in this thesis is exploratory in nature and is designed to achieve the research aim of reducing the burden of surgery on cardiac patients, their parents and society. The strategic benefits of this research are well aligned with the research main objectives of:

- Exploring the main components, barriers, issues and requirements to design and develop an Intelligent Risk Detection framework to healthcare contexts which is then applied to the research case.
- Providing superior decision support in the healthcare context specifically examining decisions pertaining to CHD surgery.

To address the research objectives, this study is designed to answer this question:

***❖ How can an intelligent risk detection (IRD) Model be developed in the healthcare contexts***

Throughout this research, a qualitative approach using an exemplar data site as a case study is adopted and the approach incorporates well established qualitative data collection techniques (Boyatzis, 1998; Glesne & Peshkin, 1992; Yin, 1994, 2003). The data collection techniques



will assist in collecting requirements and capturing the main components to develop the IRD Model, as an IT based framework in healthcare contexts (Mantzana et al, 2007).

Qualitative approach methodology has been increasingly applied in much information systems and health informatics research (Barbour, 1999; Bradley et al., 2007; Katsma et al., 2007; Mantzana et al., 2007; Myers, 1997; Yen & Bakken, 2012). Qualitative methodology has been shown to be a suitable approach to explore requirements, possibilities and issues with regard to developing a clinical IT/IS solution (Kaplan et al., 2004; Mantzana et al., 2007).

The goal of qualitative research typically involves understanding a phenomenon from the point of view of the participants to discover the actual process involved in producing the results of such studies which often lead to specific outcomes (Kaplan & Maxwell, 2005) . Therefore, due to the importance of users' perspectives in designing and developing a computer based system, a qualitative research approach can contribute to the explanation of user's behaviour and requirements with respect to the system and thus to the system success and failure (Kaplan & Shaw, 2004).

The many traditions of qualitative research include, but are not limited to, cultural ethnography (Agar, 1994; Quinn, 2005), institutional ethnography (Campbell & Gregor, 2002), focus groups (Krueger & Casey, 2000), in-depth interviews (Glaser & Strauss, 2009; Quinn, 2005), participant and nonparticipant observations (Spradley, 1980) and hybrid approaches that include part or complete multiple study types (Bradley et al., 2007).

This study has important contributions to both theory and practice in healthcare since the use of risk detection, while prevalent in many industries such as finance, has rarely if at all been incorporated into a healthcare context. This in turn makes an intelligent risk detection framework the preferred choice to detect surgical risk factors. Thus, our study proposes an intelligent application for high-level surgical risk detection and outcome prediction to support surgical decisions.

## **7.2 Case Study**

In the field of information systems (IS) research, the case study methodology is an accepted method used to investigate contemporary phenomena in their context (Runeson & Höst, 2009). For example, Benbasat et al. (1987) provide a brief overview of case study research in

information systems. In this research the general definition of the term of “case study” is applied, as used by Robson (Robson, 2002), Yin (Yin, 2003) and Benbasat (Benbasat, Goldstein, & Mead, 1987).

Case study methodology was originally used primarily for exploratory purposes, and some researchers still limit case studies to this purpose, as discussed by Flyvbjerg (2006).

(Flyvbjerg, 2006). The main criteria for a case study are (Perry et al., 2004):

- Has a research question been determined at the beginning of the study
- Data is collected in a planned and consistent manner
- Inferences are made from the data to answer the research question
- Explores a phenomenon, or produces an explanation, description, or causal analysis of the research question
- Threats to validity are addressed in a systematic way.”

According to Runeson & Höst (2009), the key characteristics of a case study should be its flexibility to cope with the complex and dynamic characteristics of real world phenomena, like software engineering. The case study conclusions are based on a clear picture of evidence, whether qualitative or quantitative, collected from multiple sources in a planned and consistent manner. The case study analysis adds to existing knowledge by being based on previously established theory, if such exist, or by building new theory (Runeson & Höst, 2009). In this research study, the single case study has been chosen in the contexts of Congenital Heart Disease (CHD) in children, an area which requires complex high risk decisions that need to be made expeditiously and accurately in order to ensure successful healthcare outcomes. The power and potential of Business Intelligent and Data Mining techniques to support treatment decision making scenarios is shown in this healthcare context. The case study was conducted at the biggest public children’s’ hospital in Melbourne, Victoria, Australia.

The aspect of generalization is considered in this research in the context of to what extent it is possible to generalize the findings thorough a case study method, and to what extent are the findings are of interest to other people outside the investigated case (Flyvbjerg, 2006). Investigation of the relevance for other cases of this research was done through external validity to assist in generalising the research findings.

### 7.3 Research Design

To demonstrate the research design steps and phases, figure 11, is presented. The research consists of three main phases being study design, qualitative data collection and data analysis.

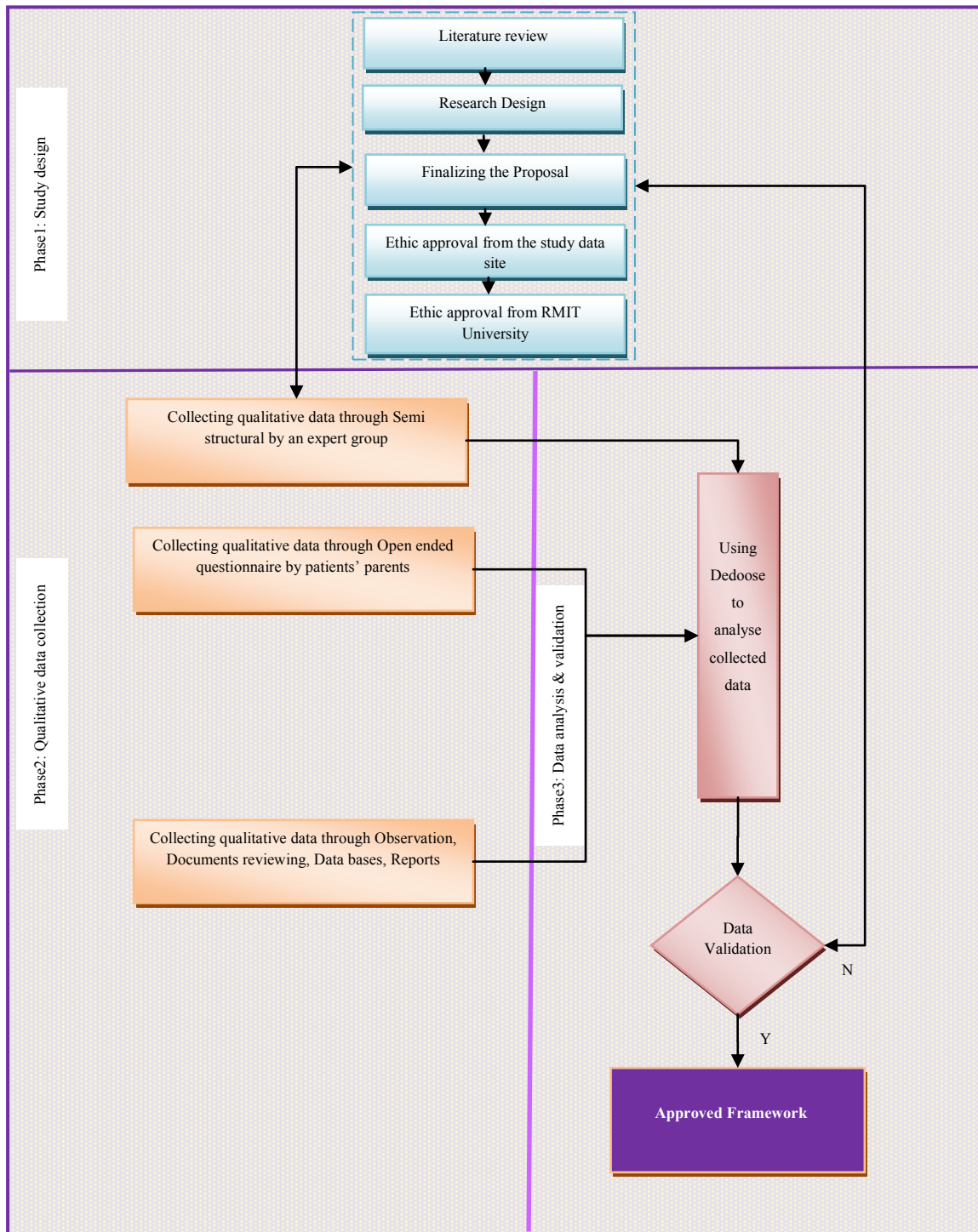


Figure 11. Research Design

#### **7.4 Ethical Considerations**

At the time of designing a case study, ethical considerations must be made (Singer & Vinson, 2002). The research study is to be strictly confined to ethical research processes and it is has to be approved by the Human Research Ethics Committee (HREC) of the case study site, as a low risk study. However, at RMIT University this research study was assessed as a high risk study due to access to sensitive data. Therefore, ethics approval was obtained from RMIT University in 2011 as a high risk study.

After obtaining ethics approvals from RMIT University and the Children's hospital, qualitative data was collected at the case study site, using the following methods:

- Individual semi-structured interviews
- Questionnaire
- Observation
- Reviewing Data bases
- Reviewing documents/files/reports

All patient data was treated with the highest level of confidentiality. All collected data and information was double de-identified to ensure the highest level of confidentiality and anonymity. Any /all patient data collected was disclosed only with the participants' permission, except as required by law. Parents of patients were only selected if they volunteered to participate in this study, at which time they were given the semi structured questionnaire to complete and return. Consent forms and information statements were issued to potential participants at this time. In this way the researchers minimized/negated any interaction with the parents' of CHD sufferers and the researchers were at all times mindful of the sensitivity of the clinical context and made efforts to avoid intruding into their lives and unduly providing them any extra stress or grief.

All information was stored securely in the Cardiology department at The Hospital and /or the School of Business IT and Logistics at RMIT University.

The following people may access information collected as part of this research project:

- The research team involved with this project
- The Hospital Human Research Ethics Committee
- The RMIT University Research Ethics Committee

The information was double de-identifiable. This means that the participants' names are removed and gave the information a special code number. Only the research team can match the name to the code number, if it is absolutely necessary to do so.

It is planned to keep the information for at least 7 years; however, based on Victorian government law and the Hospital protocol, patients' information will be stored until they are 25 years of age. After this time, the information will be securely destroyed. In accordance with the relevant Australian and/or Victorian privacy law and other relevant laws, participants have the right to access and correct the information that are collected about them and store. Participation in this research was voluntary. Participants in this study had the right to withdraw their participation at any time and have any unprocessed data withdrawn and destroyed.

### 7.5 Data Collection & Participants

In this study, qualitative data are collected through data sources such as an expert group of Surgeons, Cardiologists and ICU clinicians, patients' parents, hospital data bases, relevant reports and documents, and observing clinical regular meetings in the study site. The populations under study and participant numbers in all data collection phases are presented at table 12.

Significant amounts of qualitative data are collected by individual semi-structured interviews and open ended questionnaires.

The study data set included 115 records of CHD patients from the case study site in Melbourne Australia. Patients are children who are diagnosed as CHD patients categorised in the first pre operation stage diagnosis by HLHS (Hyponastic Heart Left Syndromes), from 2006 to early 2012.

**Table 12. The population/s under study and participant numbers**

Data Collection Techniques	Participants/Records	Participant Numbers
Semi-structured interviews	An expert group of: <ul style="list-style-type: none"> <li>• Surgeons</li> <li>• Cardiologists</li> <li>• ICU Consultants</li> </ul>	<ul style="list-style-type: none"> <li>• An expert group: 20 relevant clinical experts as cardiologist, CHD surgeons and ICU consultants identified in the research site.</li> </ul>
Open ended Questionnaires	Parents of children, who affected by CHD-HLHS	<ul style="list-style-type: none"> <li>• Parents: 115 CHD patients affected by HLHS identified in the research site, between 2006 to early 2012, while 27 of them were diseased by the data collection time. Hence, I mailed our open-ended questionnaire and consent form to the 88 patients' parents not only in Melbourne, but around Australia.</li> </ul>

Data Collection Techniques	Participants/Records	Participant Numbers
Reviewing data bases/reports and documents	CHD-HLHS Patients' records through the hospital data bases	<ul style="list-style-type: none"> <li>• Patients' records: Records of 115 CHD patients affected by HLHS are reviewed through the hospital data bases.</li> <li>• Clinical Reports: Operation Reports, Echo Cardio Reports and Conference reports</li> <li>• Historical documents: Hard copy of documented historical forms and clinical assessment reports</li> </ul>
Observation	Clinical regular meeting	<ul style="list-style-type: none"> <li>• Observing Clinical Meetings conducted at the research site: Several Clinical Meetings observed and recorded between December 2011 (after taking ethics approval) and August 2012.</li> </ul>

The data set is constructed based on the patient's operation reports in all major surgeries which include Norwood, BCPS and Fontan, patients' diagnosis reports, operation reports, echo cardiology reports and cardiac catheter reports. As presented in Fig.12, 68% of HLHS patients was Male.

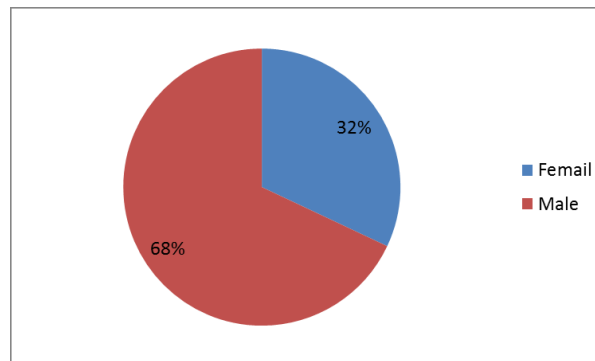


Figure 12. The study characteristics based on the gender

## 7.6 Data Analysis

There is no singularly appropriate way to conduct qualitative data analysis, although there is general agreement that analysis is an ongoing, iterative process that begins in the early stages of data collection and continues throughout the study (Bradley et al., 2007).

The use of thematic analysis is applied in the analysis of data in this research as it provides a structured way of understanding how to develop thematic codes and sense themes (Boyatzis, 1998).

Once the data have been reviewed and there is a general understanding of the scope and contexts of the key experiences under study, coding provides the analyst with a formal system to organize the data, uncovering and documenting additional links within and between concepts and experiences described by the data (Bradley et al., 2007).

Some qualitative research experts (Miles and Huberman 1994) describe a more deductive approach, which starts with an organizing framework for the codes. In this approach, before reviewing all data in detail, the initial step defines a structure of initial codes.

Following this approach in this research, five code types (in table 13), are adapted from (Bradley, et al., 2007) that they are helpful in generating taxonomy, themes, and theory, all of which have practical relevance for health services research (Corbin & Strauss, 2008; Lincoln, 1985; Lofland & Lofland, 1995; Miles & Huberman, 1994).

**Table 13. Code types,**  
Adapted from (Bradley et al., 2007)

[Due to the copy right issue, this table is omitted.](#)

In this study, the semi-structured interviews are transcribed and codes are identified from transcriptions as well as from the other collected data, and codes mapped to captured themes derived from the literature review are then determined.

The derived codes are then applied to the chosen case (CHD) to further explore the specific components and benefits of IRD Model to the research question. Qualitative techniques are employed to analyse data collected through questionnaires, observation and other resources such as data bases, reports and clinical documents.

## **7.7 Summary**

Qualitative inquiry can improve the description and explanation of complex, real-world phenomena pertinent to health services research (Bradley et al., 2007). In this research a qualitative approach using an exemplar data site as a single case study is adapted to address research objectives and to answer the research question. This study is exploratory in nature and endeavours to explore the main components, barriers, issues and requirement to design and develop an Intelligent Risk Detection framework to be applied to healthcare contexts, in particular of CHD for children. Data collection was through semi-structured interviews, questionnaires, observation and the analysis of documents, files and data bases from the study site. After conducting the data collection phase thematic analysis is applied to analyse all collected qualitative data.



## CHAPTER 4

### Data Collection and Analysis

This Chapter describes the analytical approach to the study and details the results of the semi-structured interviews, questionnaires, observations, and the database reviews, reports and documents analysis and was conducted at the biggest public children's hospital in Melbourne, Australia, by using as an exemplar case study. The analysis and interpretation of the data assists the researcher in assessing the analytical result's impact on elucidating the research question:

*“How can an intelligent risk detection (IRD) Model be developed in the healthcare context?”*

This Chapter is organized into seven main sections.

- the first section describes the case study site,
- the second section describes the early management of infants with HLHS at the hospital,
- section 3 presents the surgical procedures at the hospital,
- section 4 describes themes (thematic codes and sense themes) allowing categorization the collected data within the case study ,
- section 5 describes the study findings
- the summary is presented in the section 7.

#### 8.1 The Case Study Site<sup>2</sup>

The hospital is the biggest public children's hospital in Australia, and has provided outstanding care for children and their families for over 140 years in parts of Australia.

The Hospital is the major specialist paediatric hospital and care extends to children from Tasmania, southern New South Wales and other states around Australia and overseas.

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<sup>2</sup> All clinical information of this section has been adapted from a clinical document/procedure approved by the following department heads, at the Hospital:

Dr Lara Shekerdeman, Director of Intensive Care

Professor Dan Penny, Director of Cardiology

Dr Christian Brizard, Director of Cardiac Surgery

Dr Ian McKenzie, Director of Anaesthesia

Dr Michael Stewart, Director of Neonatal Emergency Transport Services

With a passionate, highly skilled and committed staff of close to 4,000, the hospital provides a full range of clinical services, tertiary care and health promotion and prevention programs for children and young people. The Hospital is the designated a state-wide major trauma center for paediatrics in Australia and a Nationally Funded Centre for cardiac and liver transplantation.

In 2011–12 the Hospital treated 34,784 inpatients. There were 246,140 outpatient clinic appointments and 10,741 children underwent surgery. The Hospital had 73,602 children present at the emergency department and approximately 200 children received care in the community every day through the Hospital at home.

The Hospital is a key member of the Paediatric Clinical Network, working to implement the Department of Health Strategic Framework for Paediatric Health (2009)., The Hospital also actively contributes to the implementation of Victoria's Cancer Action Plan 2008–11 through membership of the Paediatric Integrated Cancer Service (PICS) and the Victorian Comprehensive Cancer Centre (Victorian CCC).

The Hospital leads a number of state-wide services, including:

- Victorian Paediatric Rehabilitation Service (with Southern Health, Bendigo Health, Eastern Health and Barwon Health- established in regional cities of Victoria): delivering paediatric rehabilitation services to children, adolescents and their families.
- Victorian Paediatric Palliative Care Program (with Southern Health and Very Special Kids): providing a multidisciplinary approach to palliative care for children across Victoria.
- Victorian Forensic Paediatric Medical Service (with Southern Health and Victorian Institute of Forensic Medicine): providing assessment and care for abused, assaulted and neglected children and adolescents.
- Victorian Infant Hearing Screening Program: conducting hearing screenings of newborn babies whilst they are in hospital. The delivery of this service involves working with diagnostic audiology and early intervention services from across Victoria.
- Victorian Paediatric Orthopaedic Network (with Barwon Health, Southern Health and Western Health): fostering collaboration amongst service providers to support the coordination and delivery of quality paediatric orthopaedic care in Victoria.

The Hospital has always held a special place in the hearts of all Victorians and in 2010, as testament to leadership and advocacy role, the hospital was awarded the prestigious Committee for Melbourne 2010 Melbourne Achiever Award, for outstanding contributions to the Melbourne community.

### **8.1.1 Department of Cardiology**

The Hospital is one of the largest Children's hospitals in the Southern hemisphere, and, from the point of view of paediatric cardiology and cardiac surgery, provides a service for the states of Victoria, Tasmania and the Southern part of New South Wales. A tertiary referral service is provided for patients with complex congenital heart disease and for infant cardiac surgery for South Australia and also for the Northern Territory. A small number of infants with complex cardiac defects - in particular "Hypoplastic Left Heart Syndrome", are referred from Western Australia, New South Wales and Queensland for surgical management of their heart problems.

The Department of Cardiology is home to the National Paediatric Heart Transplant Centre and caters for patients needing heart transplantation from all over Australia. The Department of Cardiology also caters for a number of overseas patients, principally from South East Asia. The surgical unit within the Department of Cardiology carries out in excess of six hundred surgical procedures per year. Approximately, one third of open heart procedures are performed in the first six months of life (half of these in the first month of life). The surgical practice encompasses the full range of palliative and reconstructive procedures, including heart transplants.

The Department of Cardiology has ten staff cardiologists who work full-time and part-time at the Hospital. A smaller service exists at one of the medical centers in the State (a major suburban hospital), which operates on a predominantly out-patient basis and is managed independently of the Hospital service. The Department of Cardiology runs approximately 25 outpatient clinics per week in Melbourne, and peripheral clinics in referral centres in Victoria, Tasmania and Southern New South Wales. Approximately 8,000 echocardiograms are carried out annually - these including M-mode, 2D, Doppler and color flow mapping, and transoesophageal studies. Approximately 500 cardiac catheter procedures are performed each year, including interventional procedures such as balloon valvuloplasty, balloon dilatation of coarctation, coil embolization, device occlusion of persistent ductus arteriosus, device closure

of Atrial Septal Defects and muscular Ventricular Septal Defects (VSDs), balloon angioplasty and stent implantation.

A comprehensive arrhythmia investigation and treatment service includes Holter monitoring, exercise testing, electrophysiology studies, and radiofrequency ablation used for the elimination of arrhythmias.

The Department has a wide range of research activities and interests, publishes extensively in academic journals and presents its results at National and International meetings several times each year.

## **8.2 Early Management of Infants With HLHS at the Hospital**

Infants with hypoplastic left heart syndrome (HLHS) are amongst the most challenging subgroups of cardiac patients to care for and manage. This challenge may begin at birth, it may begin earlier in those with a prenatal diagnosis, and the period of greatest acute risk often continues until the time of stage II palliation, when the patient is between 4 to 6 months. Infants with hypoplastic left heart syndrome often respond poorly to seemingly minor external stresses, or to subtle changes in their medical management. These events can lead to significant morbidity and mortality.

The goal of these guidelines is to establish a streamlined approach to the early care of infants with hypoplastic left heart syndrome at the Hospital, with the aim of optimising their condition from birth until the postnatal period after stage 1 palliation.

### **8.2.1 Prenatal Management for Those With an In-utero Diagnosis**

Steps for prenatal management of patients with an in-utero diagnosis are described, as follows:

1. Where possible, delivery will be scheduled to occur in one of the women's hospitals in Melbourne.
2. Fetal echo scans will be reviewed by the Hospital cardiologists at 18, 30 and 36 weeks' gestation to confirm diagnosis, and to determine the adequacy of interatrial communication. The exact timing of these scans will be determined by the perinatal obstetrician responsible for overall management of the pregnancy.

3. For interstate patients, relocation to Melbourne will, in general, be scheduled for around 35 weeks' gestation. It is expected that a perinatal obstetrician in Melbourne will be provided with comprehensive details of the pregnancy as soon as a decision for delivery in Victoria has been made.
4. For each patient, a joint meeting will be arranged with the Hospital care manager(s), a social worker, the consultant cardiologist and the consultant cardiac surgeon. This meeting will be arranged by the Fetal Management Unit, or by the referring cardiologist (for Mercy Hospital / Monash Medical Centre patients). The Hospital ICU nursing unit manager will be informed of all pending deliveries at this time.
5. The attending perinatal obstetrician and the Hospital cardiologist are responsible for ensuring that significant new findings that arise during the pregnancy e.g diagnosis of another serious abnormality, are communicated to all management team members at the perinatal hospital and the Hospital
6. The attending perinatal obstetrician has primary responsibility for determining the timing of delivery. Normal vaginal delivery following spontaneous labour at term is the goal for otherwise uncomplicated pregnancies. In the case of induction of labour the timing will be determined by consideration of clinical and social factors as well as availability of obstetric and cardiac surgical resources. It must be remembered that following an induction of labour, delivery may occur anywhere from 0-72 hours later.

### **8.2.2 Immediate Post-natal Care at Referring Hospital**

Due to the importance of post-natal care, several immediate post-natal care are planned, as follows:

1. Birth suite management will be directly supervised by a Neonatal Consultant or Fellow. The baby will be transferred to the local NICU for ongoing stabilization once initial resuscitation has been completed.
2. Intravenous access – a triple lumen UV line should be inserted and established before transport (or two separate peripheral lines if a UV line cannot be inserted).
3. Umbilical arterial access should be obtained at the discretion of the attending neonatologist, and in general only if the neonate is ventilated and/or requiring vasoactive drugs.

4. Prostin delivery (10-20ng/kg/min) should be commenced immediately after obtaining first route of intravenous access.
5. The referring neonatologist will contact NETS to arrange transfer to the Hospital.
6. Target oxygen saturations 75-85%; avoid additional oxygen unless sat < 70%.
7. At least 1 hour's observation period for prostin-related apnoeas / other instability prior to transfer.
8. Ventilation should not be routine in the stable, non-acidotic patient.
9. Blood gas (arterial or umbilical venous, not capillary), glucose, lactate prior to transfer.
10. NETS team to inform on-call cardiologist + ICU of birth and patient condition, and likely time of transfer to the Hospital.
11. All infants will be transferred to the Hospital PICU in the first instance.

### **8.2.3 Management of the Infant With Suspected or Confirmed Restriction of the PFO**

Restriction of the Patent Foramen Ovale (PFO) may be suspected from in-utero imaging; alternatively restriction of PFO should be suspected in the infant with a known diagnosis of HLHS in whom there is severe metabolic acidosis, with poor oxygenation, and Xray appearance suggesting obstructed pulmonary venous drainage. Pre-operative survival and neurological outcome of these infants depends on early surgical or transcatheter intervention to enlarge the restrictive communication.

When suspected prenatally, a Consultant Neonatologist should directly supervise the delivery room management of these infants. If the clinical findings immediately after birth are consistent with HLHS with restrictive PFO, the baby should be intubated, commenced on prostin, muscle relaxed and sedated (see below), and transferred *with supplemental oxygen therapy*, as early as possible to the Hospital. Other standard resuscitative measures are generally ineffective in this situation. For these infants, the neonatal transport team should be available to transport them to the hospital immediately after birth.

The on-call Consultant Cardiologist should be present to do an echo cardiogram immediately on arrival of the infant at the Hospital. Cardiac catheter laboratory and cardiac surgery staff should be on standby for immediate intervention.

### **8.2.4 Pre-operative care at the Hospital**

The Hospital has some rules and policies to pre-operative care for patients affected by HLHS, as follows:

1. All infants will initially be admitted to Pre ICU (PICU).
2. The Cardiology Fellow and Consultant, and 7West AUM or care manager, should all be informed when the infant arrives on PICU. An echo cardiogram should be performed within 2 hours of arrival (with the exception of infants with restriction of PFO). CXR & ECG in all cases.
3. *Bloods* - On arrival, routine bloods – FBC, blood gases + lactate, electrolytes, glucose, Coagulation studies, chromosome analysis, blood group and save serum.
4. Stable patients who are not acidotic and who have a normal lactate, with secure central or peripheral intravenous access (two), may be transferred to 7West after review by the ICU consultant.
5. *Surgery* - This will, where possible, be planned for day 3 or 4 of life, but may be planned earlier if there is circulatory instability –particularly when this related to excessive pulmonary blood flow.
6. *Other Health Professionals* - Families will meet with Care Managers and social workers after admission, either on 7West or in ICU.

#### *7. Associated abnormalities*

Routine pre-operative ultrasound scans of head + kidneys will be performed.

#### **8.2.4.1 Other Aspects of Pre-operative Management**

In pre-operative management process there are some important procedures that should be considered, at the Hospital:

##### **1. Feeds**

Infants with HLHS are at high risk of gut ischaemia, and our current approach is not to feed them. Infants arriving at the Hospital within the first 24hours of life, who have CV access should be given TPN until surgery. Those without TPN should receive 10%dextrose / 0.45% saline as maintenance fluid.

## **2. Vascular Access**

Insertion of peripheral drips can cause fluctuations in systemic vascular resistance secondary to agitation and pain multiple attempts at vascular access should be avoided, as this can be traumatic for the infant, and can increase the incidence of intravascular thrombus formation. Experienced personnel should obtain access in these patients.

### *a) Peripheral lines*

In a conscious patient, sucrose and / or paracetamol, or a small dose of sedation should be routinely given prior to this being done. Access should be attempted by a senior ICU doctor (senior registrar or consultant), in the treatment room on 7West or in intensive care.

### *b) Central lines*

Central venous access should not be attempted in a non-anaesthetised patient.

If umbilical venous access is not present, and CV access required, then femoral venous lines should be inserted, under anaesthesia, by a senior ICU doctor or cardiac anaesthetist. Neck lines should be avoided wherever possible. Heparin (10u/kg/hr) should be routinely infused to central venous lines.

### *c) Arterial lines (The hospital)*

Where possible, aim for access in the right upper limb is preferred. Avoid multiple unsuccessful attempts before referring to the Consultant Cardiac Surgeon re: cut-down right arm will also provide optimal monitoring during intra-operative period of isolated cerebral perfusion.

## **3. Management of a Low Systematic Cardiac Output**

Four distinct causes should be considered & systematically excluded; an echocardiogram is essential to guide management.

## **4. Intubation (at referral hospital / the Hospital).**

*Indications are included in:*

- i. Apnoeas,
- ii. Shock, severe circulatory disturbance
- iii. Pulmonary over circulation (Saturations >90%) with systemic hypoperfusion (lactic acidosis)



Intubation can cause considerable instability to infants with a duct-dependent systemic circulation. Intubation should ideally be performed by a senior neonatologist / intensivist using the guidelines outlined below.

- *Drugs* - Pancuronium 0.1mcg/kg *then* Fentanyl 5mcg/kg (give muscle relaxant first to avoid chest wall rigidity & bradycardias which may be associated with intravenous fentanyl)
- Colloid (4% albumin) or saline should be available (20ml/kg)
- Consider low-dose dobutamine infusion (up to 5mcg/kg/min) prior to intubation.

Target blood gases:

- pH – normal
- PaO<sub>2</sub> – 35-45
- PaCO<sub>2</sub> – 35-45
- At the Hospital (the Hospital): *Consider* additional nitrogen to reduce FiO<sub>2</sub> to minimum 0.18, only in the infant *with pulmonary overcirculation and evidence of systemic hypoperfusion* after appropriate circulatory resuscitation, with or without an intravenous systemic dilator. However, this is only a temporary measure, and infants with these clinical signs warrant urgent surgery.

### **8.2.5 Intra-operative Management**

At the Hospital, there are also some rules and polices during the operation, as follows:

**1. Intubation** – as above

**2. Central Venous Access:**

- Where possible existing central lines (UV/femoral) will be used for induction of anaesthesia, pre-bypass management. Otherwise, a single lumen jugular line will be inserted for this, and removed as early as possible.
- A direct atrial line will be left in situ by the cardiac surgeon at surgery

**3. Arterial access** – as above

**4. Drug therapy:**

Vasodilators:

*α blockade:*

Phentolamine may be used intra-operatively, in favour of phenoxy benzamine which is much longer-acting.

*Nitrates:*

Nitroprusside rather than GTN, as it is more effective arterial dilator. This may be used in preference to phentolamine as its effects can be rapidly reversed by discontinuing the infusion

Inotropes:

Dobutamine should be routinely used on weaning from bypass.

Noradrenaline – consider low-dose noradrenaline in the event of excessive systemic vasodilation on separation from bypass.

### **8.2.6 Post-Operative Management**

Post-operative process at the Hospital is described, as follows:

#### **1. Drug Therapy**

Vasodilators: as above initially, with the introduction of phenoxybenzamine when adequate haemodynamic stability. Captopril should be introduced once enteral feeds have been established.

Inotropes:

Dobutamine; escalation with low dose adrenaline if poor contractility on echocardiogram.

Noradrenaline should be weaned early.

#### **2. Central Lines**

It Should be removed as early as possible. Systemic heparin (10u/kg/hr) should be given early after surgery, if no major bleeding.

#### **3. Principles of Management of Ventilation and Circulation:**

*These are detailed in the existing ICU protocol*

#### **4. Echocardiograms On ICU or 7West**

All infants should have at least weekly echocardiograms (on a specified day of each week) after the Norwood operation, to assess the presence/absence of the following conditions:

- Patency of BT shunt / Vmax across RV-PA conduit
- Function of systemic RV

- Degree of Tricuspid Regurgitation
- Adequacy of ASD
- Neo-aortic obstruction & arch obstruction
- Thrombus (intracardiac, SVC)
- Effusions

### 5. Line Insertion for Extubated, Non-sedated Patients

The same guidelines should be followed as for pre-operative patients, to minimise the risk of sudden decompensation due to changes in systemic vascular resistance.

### 6. Long Term Central Venous Access

Broviac lines (single lumen, 3F) should be considered early in infants likely to require longer term inotropes or parenteral nutrition.

### 8.3 Surgical Procedures at the Hospital

Infants with HLHS will undergo three stage operations at the Hospital. The first operation is called Norwood, performed on infants less than 30 days of age. The second one is Bidirectional Cavo-Pulmonary Shunt (BCPS) generally performed on infants between 3 to 6 months of age. The third stage is called Fontan, usually will be conducted for children at the age of 4 to 6 years old.

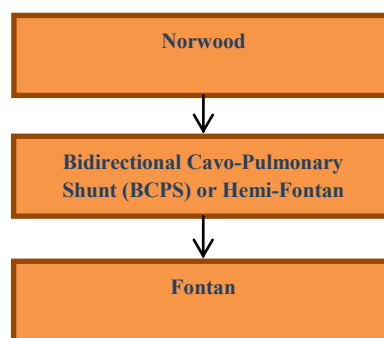


Figure 13: Three stages of surgical Procedures at the Hospital

#### 1. Stage 1 Norwood

The aim of the Norwood surgery is:

- To establish reliable, unobstructed outflow to the systemic circulation and to balance systemic and pulmonary circulations.
- To apply the following descriptions to the diagram below:

A. The ductus arteriosus is ligated and divided and the central and branch pulmonary arteries are detached from the main pulmonary artery

B. The hypoplastic aorta is then opened and a patch augmented to this region.

C. The augmented aorta is then attached to the cardiac end of the main pulmonary artery stump.

- An atrial septectomy, to ensure unobstructed pulmonary venous flow, is performed, as is a right-sided Blalock-Taussig shunt which ensures blood supply to the pulmonary circulation (see following diagrams).

[Due to the copy right issue, this figure is omitted.](#)

**Figure 14: Norwood Procedures**  
(Blythe, 2011)

## **2. Bidirectional Cavo-Pulmonary Shunt/ Bidirectional Glen (BCPS)**

BCPS surgery is defined, as follows:

- BCPS generally performed on infants between 3 to 6 months of age.
- This decreases the work of the right ventricle by decreasing the 'volume load' - (the volume of blood that the heart needs to pump with each beat).
- Involves transecting the superior vena cava at the right pulmonary artery level and anastomosing the cephalad portion of it to the proximal right pulmonary artery. The cardiac end of the superior vena cava is oversown.

Due to the copy right issue, this figure is omitted.

**Figure 15: BCPS Operation**  
(Blythe, 2011)

### **3. Fontan**

- This completes the reconstructive surgery required and available for the HLHS patient
- The superior and inferior vena cava are connected to the lung arteries allowing blood to flow directly to the lung circulation, bypassing the right ventricle.
- This optimizes cardiac output.

There are two types of Fontan procedures:

#### **A. Extracardiac Fontan**

- Most commonly performed Fontan procedure at present as no suturing needs to take place within the right atrium, and right atrium pressures are minimized.

Due to the copy right issue, this figure is omitted.

**Figure 16: Extracardiac Fontan**  
(Blythe, 2011)

## **B. Intracardiac Fontan/ Total Cavo-Pulmonary Connection.**

- Less commonly used due to the suturing required. Such suturing can cause arrhythmias. This also leads to increased pressure in the part of the right atrium that is used to carry the IVC blood to the Pulmonary Arteries.

[Due to the copy right issue, this figure is omitted.](#)

**Figure 17: Intra-cardiac Fontan**

(Blythe, 2011)

### **8.4 Themes – Development of Thematic Codes and Sense Themes.**

The use of thematic analysis is applied in the analysis of data in this research as it provides a structured way of understanding how to develop thematic codes and sense themes (Boyatzis 1998). The semi-structured discussions are transcribed and codes are identified from transcriptions as well as the other collected data and then codes are mapped to captured themes as discussed in the literature review. Then findings from this process are applied to the condition under study - congenital heart disease (CHD) to further explore the specific components and benefits of IRD Model to the research case study. Qualitative analysis techniques are employed to analyze data collected through questionnaires, observation and other resources such as data bases, reports and clinical documents. The study results are presented based on the clinical and the non-clinical perspective. The clinical perspective is based on data collected through the expert group as well as clinical observations, data bases and reports. The non-clinical perspective is based on parents' point of views, collected by the questionnaire.

Identified Themes from clinical and non-clinical perspectives are presented at below tables:

**Table 14. Identified themes from clinical perspective**

<b>Clinical perspective</b>
<ul style="list-style-type: none"><li>▪ Clinicians' intention to use IRD</li><li>▪ Clinicians' recommendations</li><li>▪ Enables towards risk factor screening</li><li>▪ Contributing factors to assess patients' quality of life</li><li>▪ Clinicians' barriers to use</li><li>▪ Clinicians' confident to address surgical risk factors</li></ul>

**Table 15. Identified themes from non-clinical perspective**

<b>Non Clinical perspective</b>
<ul style="list-style-type: none"><li>▪ Social impact on the family life</li><li>▪ Patients' quality of life after the surgery</li><li>▪ Parents' level of understanding about the surgery outcomes and risks</li><li>▪ Parents' intention to use IRD</li><li>▪ Parents' attitude towards surgery decision making process</li></ul>

### **8.5 Categories of Collected Data Within the Case Study**

This study has identified two major categories of analysis within the case study, clinical perspective and non-clinical perspective. These two categorize are described, as followed.

### 8.5.1 Clinical Perspective

The clinical perspective is derived and elucidated from the following data collection techniques:

❖ **Collecting data through semi-structured interviews with an expert group of:**

- Cardiac Surgeons
- Cardiologists
- ICU Consultants

**Table 16. Units of analysis and reference for semi-structured interviews**

No	Interviewee-Code	Interviewee Category	Number of times interviewed
1	EC1	Clinical- Expert group, Cardiologist	1
2	EC2	Clinical- Expert group, Cardiologist	1
3	EC3	Clinical- Expert group, Cardiologist	1
4	EC4	Clinical- Expert group, Cardiologist	1
5	EC5	Clinical- Expert group, Cardiologist	1
6	EC6	Clinical- Expert group, Cardiologist	1
7	EC7	Clinical- Expert group, Cardiologist	1
8	EC8	Clinical- Expert group, Cardiologist	1
9	EC9	Clinical- Expert group, Cardiologist	1
10	EC10	Clinical- Expert group, Cardiologist	1
11	ES1	Clinical- Expert group, Cardiac Surgeon	1
12	ES2	Clinical- Expert group, Cardiac Surgeon	1
13	EI1	Clinical- Expert group, ICU Consultant	1



No	Interviewee-Code	Interviewee Category	Number of times interviewed
14	EI2	Clinical- Expert group, ICU Consultant	1
15	EI3	Clinical- Expert group, ICU Consultant	1
16	EI4	Clinical- Expert group, ICU Consultant	1
17	EI5	Clinical- Expert group, ICU Consultant	1
18	EI6	Clinical- Expert group, ICU Consultant	1
19	EI7	Clinical- Expert group, ICU Consultant	1
20	EI8	Clinical- Expert group, ICU Consultant	1

In the semi-structured interviews, through the first set of questions, the expert groups asked about the importance of detecting surgical risk factors and predicting surgical results to improve decision making in CHD surgery. 75% of clinicians had positive point of views pertaining to the use of such a solution as the IRD to improve surgical decision making process. For example when asked - “Do you think detecting surgical risk factors and predicting surgical results will help to improve decision making in CHD surgery?”, EC3 stated -

*“...yes. It would be useful. Surgical techniques have changed in different ways, particularly during last 5 years & surgical risk factors are changing as well. Therefore, detecting surgical risk factors and predicting surgical results might be useful”.*

*“E.C.3, Cardiologist”*

E.I.4 added -

*“...yes, I think it can be useful. Not everybody knows about integrated formal analysis, so, potential IT solutions can do that.”*

*“E.I.4, ICU Consultant”*

E.C.5, states that:

*“Potentially, it could be useful. As you said the decision making processes involved in this type of surgery are complex and we make these decisions based on past experience. We can have more structure to plan the surgeries.”*

*“E.C.5, Cardiologist”*

EI6 believes that:

*“...The IRD can be beneficial to serve research, education, and medical communities, improving access to medical technology for diverse populations, and positively impacting quality of life for children around the world who affected by CHD. However training and ease of use are two important factors to facilitate the use such a solution in a clinical environment....”*

*“E.I.6, ICU Consultant”*

Although most of interviewees had a positive intention to use IRD, 10% of participants in the expert groups had doubt with respect to its use 15% of participants had negative point of view. For example, E.C.1 was not sure how IRD can be beneficial to improve surgical decision making process:

*“I never had an experience or necessity to use IT solutions. So, I’m not sure how it can be useful. Moreover, I’m not sure whether it is reliable enough or not”*

*“E.C.1, Cardiologist”*

15% of participants in expert group had negative point of view pertaining to the use of the IRD Model to improve surgical decision making processes. The cardiac surgeon’s expert group feel mostly negative toward the IRD Model, as they believe they can predict surgery results based on their experience. The cardiac surgeons also believe that during an operation there is no chance to use such a solution. However, before and after surgery the IRD can be useful but its reliability and accuracy should be proven. For example ES2 feels:

*“...No, I believe general use of this solution is not yet widespread during an operation. Consequently, during the surgery, surgeons should rely on their ad-hoc decisions based on their experience...”*

*“E.S.2, Cardiac Surgeon”*

*“...No, It is not clear what specific usability issues exist, also I’m not sure how the system can be updated to detect new risk factors and their effects...”*

*“E.S.1, Cardiac Surgeon”*

*“... I don’t think this solution works well to improve decision making process, as I didn’t hear any positive feedback or success stories relating to the use computer based solutions in clinical treatment process, particularly in surgical process...”*

*“E.C.9, Cardiologist”*

The potential benefits of IRD Model were examined in the second set of interview questions and participant’s views were discussed. Some of their ideas are stated below -

*“... I think reducing the time that care providers spend repeating and sharing information across surgical decision making processes is a potential benefit of the solution...”*

*“E.C.8, Cardiologist”*

*“...With more complete information about a patient in the IRD data base, potentially it might enable this outcome through providing health providers as well as patients’ parents with access to surgical risk factors that contain concise surgery information and expected outcomes for a patient ...”*

*“E.C.9, Cardiologist”*

*“...supporting the information and knowledge sharing across patients’ parents and also between cardiologists, surgeons and ICU consultants can be a benefit of IRD solution, particularly during post-operative process...”*

*“E.I.7, ICU Consultant”*

To design the IRD framework, it is important to define suitable risk groups to categorise surgical risk factors. Hence, through the third set of questions, three different categories are collected through interviewees. These categories are stated as followed. However, they mostly suggest a category based on types of the surgery (Norwood, BCPS & Fontan).

For example, EC1 proposes a category based on:

*“...Demographical factors, Echo features & ICU components...”*

*“E.C.1, Cardiologist”*

E.C.2 suggests a category based on

*“...age group...”*

*“E.C.2, Cardiologist”*

The rest of participants in the expert group propose a risk category based on surgery types:

*“...categorising risk factors based on three stages of surgeries - Norwood, BCPS and Fontan- is the best way to detect risk factors. It is easier and more efficient...”*

Participants were also asked to rate captured surgical risk factors from low risk to high risk. Tables 18, 19 and 20 present relative weighting of these risk factors.

#### **❖ Collecting data through reviewing data bases/reports and documents:**

- Patients' Medical Record

At the hospital, a medical record is a manual (paper based) or electronic (scanned) record containing a patient's health and personal information, status and treatment. The purpose of the medical record is to serve as a means of communication between different health professionals involved in a patient's care. Information recorded in the medical record also provides information for research, education, audits, quality management, clinical and resource management. Relevant reports and documents include:

- Eco-Cardiogram Report
- Conference Report
- Operation Report
- Discharge Report

The results of reviewing data bases/reports and documents are presented in tables 3, 4 and 5. In these tables all captured risk factors and relevant measurements across the Norwood,

BCPS and Fontan surgical techniques in the three phases of pre-operation, at operation and post-operation. The variety of risk factors and their risk level in each surgical technique and phase emphasize the importance of analytic techniques, such as data mining, in the study context.

**Table 17. Units of analysis and reference for reports and documents**

No	Reports-Code	Category of Reports	Number of Reports/Documents
1	ER	Clinical, Eco- Cardiogram Reports	50
2	CR	Clinical- Conference Reports	50
3	OR	Clinical- Operation Reports	115
4	DR	Clinical- Discharge Reports	85
5	PMR	Clinical- Patients' Medical Record	115

**Table 18. Captured risk factors & relevant measurements across Norwood surgery**

<b>Norwood risk factors -Pre op</b>	<b>weight(1-5 or low to high)</b>	<b>Measurement</b>
Weight	5	As continuous variable (<3 kg) and any weight lower than 2.5 kg
preoperative acidosis	3	pH < 7.20
Intact or restrictive atrial septum	5	Can result in severe pulmonary congestion. Severely affects preoperative state
Ascending aortic size	5	As continuous variable and any diameter of 2 mm or less
Associated genetic anomalies	5	Strongly influence both early and long-term outcome
Ventricular function	2	Difficult to separate on multivariate analysis because of many competing factors
Preoperative ventilation	2	
Tricuspid regurgitation	2	If moderate or severe tricuspid regurgitation
Diminutive ascending aorta	3	< or = 2.0 mm
Prematurity	3	Any gestation before 36–40 weeks. On multivariate analysis is a separate factor to weight alone
Age at surgery	5	Especially if present late
Cardiopulmonary bypass time and deep hypothermic circulatory arrest time	2	Reflect ischaemic and inflammatory insult. Might be surrogate marker of difficult anatomy to repair
Anatomic subtype	2	Aortic or mitral atresia groups do less well than aortic or mitral stenosis
Anatomic subtype of aortic and mitral atresia	3	
<b>Norwood risk factors - op</b>	<b>weight</b>	
Age at surgery	5	
Surgeon	4	
Weight at surgery	4	(kg)
Shunt size	5	(3.0, 3.5, or 4.0 mm)
Total support time	5	(CPB time 1 DHCA time)
CPB time	5	(min)
DHCA time	5	(min)
Myocardial ischemia time	5	(min)
Type of Norwood Reconstruction	4	(standard, 'Double-Barrel', or other)
Delayed sternal closure	5	(yes or no)
Need for post-operative ECMO or VAD support	5	
Bleeding		
<b>Norwood risk factors - post op</b>	<b>weight</b>	
Cardiopulmonary bypass time	5	
Postoperative diastolic pressures	5	
Time to sternal closure	4	
initial base excess	3	mmol/l
Minimum base excess	3	mmol/l
duration of ventilation	4	
time to establish enteral feeds	3	
length of intensive care unit stay	3	
AV valve regurgitation	4	> moderate
poor heart function	4	> moderate
Bleeding	4	
Low blood pressure	4	
initial serum lactate	4	mmol/l
maximum serum lactate	4	mmol/l
Ventricular assist device	3	
Extracorporeal Membrane Oxygenation (ECMO)	4	

Table 19. Captured risk factors & relevant measurements across BCPS surgery

BCPS risk factors -Pre op	weight(1-5 or low to high)	Measurement
length of stay after norwood in ICU	4	
pulmonary artery size	5	
type of shant	5	
tricuspid regurgitations	4	
type of LV	4	
size od BT shant at Norwood	4	
AV valve regurgitation	3	> moderate
Poor heart function	3	> moderate
Ventricular function	2	
Intraoperative non-CPB(Cardiopulmonary Bypass) to CPB conversion	3	
Cardiopulmonary Bypass time	3	min
Age at Surgery	5	
BCPS risk factors - op	weight	
Age at surgery	5	
Surgeon	4	
Shunt size	5	(3.0, 3.5, or 4.0 mm)
Total support time	5	(CPB time 1 DHCA time)
CPB time	5	(min)
DHCA time	5	(min)
Myocardial ischemia time	5	(min)
Delayed sternal closure	5	(yes or no)
Need for post-operative ECMO or VAD support	5	
Sano operation	3	
Bleeding	4	
BCPS risk factors - post op	weight	
Total hospital length of stay	5	D
Postoperative length of stay	5	D
Operative mortality	4	
Any complication	3	mmol/l
Systemic venous obstruction	3	mmol/l
Reoperation (bleeding)	4	
Sternum left open	3	
Persistent neurologic deficit	3	
Infection (wound infection)	4	> moderate
Infection (mediastinitis)	4	> moderate
Pneumothorax	4	
Pleural effusion	4	
Pneumonia	4	mmol/l
Prolonged mechanical ventilation	4	mmol/l
Need for reintubation	3	
Tracheostomy	4	
Phrenic nerve paralysis	3	
Cardiac arrest	4	
ECMO	4	
Arrhythmia	3	
Chylothorax	3	

**Table 20. Captured risk factors & relevant measurements across Fontan surgery**

Fontan Risk Factors-pre op	weight(1-5 or low to high)	Measurement
Age at Surgery	5	
Low cardiac output	3	
pleural effusions	2	
chylothoraces	2	
ascites	4	
hepatomegaly	2	
peripheral oedema	4	
malabsorption of fat	4	
hypoalbuminaemia	4	
Progressive exercise intolerance	3	
AV valve insufficiency	3	
Hypoxaemia	3	
Norwood risk factors - op	weight	
Age at surgery	5	
Surgeon	4	
Shunt size	5	(3.0, 3.5, or 4.0 mm)
Total support time	5	(CPB time 1 DHCA time)
CPB time	5	(min)
DHCA time	5	(min)
Myocardial ischemia time	5	(min)
Delayed sternal closure	5	(yes or no)
Need for post-operative ECMO or VAD support	5	
Sano operation	3	
Bleeding	4	
Norwood risk factors - post op	weight	
Cardiopulmonary bypass time	5	
Postoperative diastolic pressures	5	
Time to sternal closure	4	
initial base excess	3	mmol/l
Minimum base excess	3	mmol/l
duration of ventilation	4	
time to establish enteral feeds	3	
length of intensive care unit stay	3	
AV valve regurgitation	4	> moderate
poor heart function	4	> moderate
Bleeding	4	
Low blood pressure	4	
initial serum lactate	4	mmol/l
maximum serum lactate	4	mmol/l
Ventricular assist device	3	
Extracorporeal Membrane Oxygenation (ECMO)	4	
arrhythmia	3	



### ❖ Collecting data through observation

At the hospital, there is a regular weekly clinical meeting to investigate all complex clinical cases in the cardiology department to share issues with the other experts, and to discuss decision making related to time and type of the surgery.

**Table 21. Units of analysis and reference for observation**

No	Observation-Code	Category of Observations	Number of observed meetings
1	CM	Clinical- Clinical Meetings	10

The main findings through observation are:

- Capturing critical milestones across three phases of surgery (Pre-operation, Operation and Post operation)
- Benefits of applying IRD to the CHD treatment process.
- Barriers of applying IRD to the CHD treatment process.

### **8.5.2 Non-clinical Perspective**

In this qualitative study, the non-clinical perspective is captured by participants completing a questionnaire. There were 85 questionnaires, information statements and consent forms mailed to parents. However, only 35 parents signed the consent form and filled out and returned the questionnaire.

### ❖ Collecting data through distributing questionnaire to patients' parents:

Patients' parents described their point of view related to the surgical decision making process by completing the questionnaire. The questionnaire sought parent's attitude to understanding the surgical risk factors and their intention to be involved in the surgical decision making process. The questionnaire asked parents about their children's quality of life after surgery, the possible role of knowledge sharing and the importance of the IRD Model in improving their home care management and their children's quality of life.

**Table 22. Units of analysis and reference for questionnaire**

No	Questionnaire - Code	Category of Questionnaires	Number of received questionnaires and consent form
1 to 35	P1,..., P35	Non-Clinical, Questionnaire	35

In the United States of America, low-income adults experience substantial health and health care inequities when compared with higher-income individuals (Berenson, Doty, Abrams, & Shih, 2012). In consideration of this fact, the first set of questions in the questionnaire asked parents to state their household income. The aim of ascertaining participant’s income was to examine any relation between parents’ income and their level of receiving and understanding of clinical information. The participant’s interest in using an intelligent application like IRD during their child care process was also investigated by the first set of questions. Results from the questionnaire pertaining to parents’ income are shown in below table:

**Table 23. Parents’ total annual household Income**

Income	Questionnaire Code	% response
Less than \$40k	P11, P18, P21, P31	11%
\$40k-\$60k	P1, P2, P12, P13, P25, P29, P33, P34	23%
\$60k-\$80k	P7, P10, P14, P15, P16, P17, P23, P27, P28, P30, P32 , P35	34%
\$80k-\$120k	P3, P4, P5, P19, P20, P22, P26	20%
More than \$120k	P6, P8, P9, P24	11%

- **Parents' level of understanding about the surgery outcomes and risks**

The next set of questions in the questionnaire is designed to seek information with respect to the level of understanding of parents in understanding surgical risk factors and expected outcomes. Most parents stated that:

*“... Surgeons and cardiologists described the surgery process and possible outcomes very well and our level of understanding was high...”*

*“P3, P4, P5, P8, P9, P12, P18, P19, P21, P32, P33, P35, Parents”*

*“The internet was fantastic. It provided a lot of information that was simple to read and understand. There was a lot of negative feedback on his condition by the 1st cardiologist. We saw evidence of this, as did the sonographer who did the 2nd scan. The cardiologist did not even have the latest information and we received a lot of pressure to ‘let nature take its course’. It was not until we went to Melbourne and the specialist was able to put our worries at ease. Our cardiologist we have now is fantastic and informative...”*

*“P13, Parents”*

However, some parents had a medium level of understanding and one of them had no interest to know about surgical risk factors and possible outcomes.

*“...We had a basic knowledge of the risk factors which were explained in great detail. However, we think our level of understanding was medium because of lots of clinical terms...”*

*“P31, Parents”*

*“...It was not too easy for us to understand what’s going on, although Sam’s cardiologist tried to describe all conditions in details...”*

*“P29, Parents”*

*“... During that time we were very disappointed and confused. My wife was really depressed. So, we had no interest to hear about the surgery risks. We were trying to think positive and be hopeful...”*

*“P14, Parents”*

- **Parents' attitude towards the surgery decision making process**

In the next set of questions in the questionnaire, parents were asked about details of their decision making process before agreeing to surgery for their child. The aim of this set of questions was to elucidate how understanding the surgical risk factors may affect the parents’ decision to agree to surgical procedures for their child.

All parents answered that they accepted undertaking surgery without consideration of surgery risks and outcomes.

*“...doesn't matter how many risks is involved. We accepted to do the surgery even when the chance of treatment was 1% because it was the only way to keep him alive...”*

*“P08, Parents”*

- **Parents' intention to use IRD**

In the other part of the questionnaire parents were asked about their intention to use a Model such as IRD to seek information about the surgical risks and outcomes prior to undertaking surgery. Most parents had an intention to use the IRD Model.

**Table 24. Parents' intention to use IRD**

Parents' Intention to use IRD	
70%.....	Positive
10%.....	Negative
20%.....	No Idea

Parents' positive point of view to use the IRD Model is expressed in the following comments:

*“...I preferred to get more information to predict my kid's status because often I'm surprising about his reactions...”*

*“P04, Parents”*

*“...I preferred to receive more information also after surgeries when we are taking care him at home...”*

*“P05, Parents”*

*“...Because of my background that is clinical I was familiar with the surgery risks however, I'm always seeking new information and knowledge in this area...”*

*“P06, Parents”*

*“...Overall we got enough information but at some key moments there were situations where doctors failed to communicate with us. So, this solution might be helpful in these serious conditions...”*

*“P08, Parents”*

*“...We received lots of information during all surgeries but in the gap between surgeries we didn't any source of information to ask about any new condition or any sudden changes...”*

*“P09, Parents”*

*“...I would like to know more about similar patients who are growing up with the same problems...”*

*“P11, Parents”*

*“...Enough information but I wish it was explained in more simple terms through this application as it was a lot to take on board given the circumstances...”*

*“P12, Parents”*

20% of parents were ignorant with respect to using a computer based clinical application and 10% of parents didn't like to use any clinical application to know more about their child's health, surgery risks or the surgery outcomes.

*“... I prefer to discuss with doctors directly rather than rely on the application or receive information via a computer based system...”*

*“P26, Parents”*

*“...I'm not good in using computer...”*

*“P31, Parents”*

*“... I don't like to know too much or in details about clinical procedures or conditions ...”*

*“P14, Parents”*

- **Patients' quality of life after the surgery**

In this set of questions parents were asked about their child's quality of life after undergoing the Norwood surgical procedure. The aim of this question was comparing the anticipated surgical outcomes with the actual surgical outcomes to support the importance of the IRD solution in predicting the surgical results before doing the surgery. Although most of parents were informed about the expected surgical outcomes, the parents would like to receive detailed information as they are aware of the current status of their child's health condition. They ascertained their child's quality of life after Norwood surgery and remarked as followed:

*"...Excellent. Issac is incredibly sensitive and aware of life and everyone in his life. He is a very happy little boy."*

*"P02, Parents"*

*"Good. He is a healthy happy boy but less active than his 2 years age."*

*"P04, Parents"*

*"Mental health issues 18 months post surgery. We still see a psychologist regularly. It was out of our expectation"*

*"P03, Parents"*

*"Good. Oscar's physical health is now great, however he still suffers severe mental health problems as a result of a lengthy a complicated hospitalization 18 months ago. Although we were informed about these possible outcomes we were still surprised on some occasions"*

*"P05, Parents"*

*"Excellent. He is doing very well in the school. Better than our expectation"*

*"P06, Parents"*

*"Not really good. But it is not because of the surgery. He is affected by some physical problems because of staying in the hospital for a long time."*

*"P08, Parents"*

*“Slightly, less than normal. I am already informed than he might have some physical or neurological issues but I didn’t know what it means exactly. So, it was out of my expectations.”*

*“P10, Parents”*

*“Mildly limited. Breathlessness / fatigue only real issues (they are still quite mild at this stage). Gross .... Development, particularly leg strength as tight issue, as is stamina”.*

*“P12, Parents”*

*“She has a smaller frame and it is very difficult for her to put on weight. She is approximately 16 k at 6.5 years old. She has a 6000 points appetite. However, she burns a lot of energy for daily tasks. The biggest concern I have is her mental development. She has a very poor memory, struggles to retain information, comprehend new info, and gives up very quickly.”*

*“P16, Parents”*

*“She has delayed physical and mental development but I wasn’t surprised because of my information about these possible limitations for CHD patients. However, I don’t consider them too much reducing her quality of life. She is a happy girl and enjoys all aspects of her childhood just like any other children.”*

*“P19, Parents”*

*“I must say, when we had spoken to by that 1<sup>st</sup> cardiologist, we didn’t think he would be this good! Thanks goodness for medical staff with correct up to date information!*

*“P20, Parents”*

*“He does get short of breath; he also suffers from frequent bouts of croup due to an airway stricture from repeated intubations...We didn’t know about these special possible conditions”*

*“P23, Parents”*

*“Less than normal. Shortage of breath, blueness around the lips & limitation in physical activities are his main problems”*

*“P28, Parents”*

*“Sam had a stroke as a result of the surgery but has no residual effects. Stroke was not discussed before the surgery. He had so many complications that can occur in the post-surgery but still surgery was Sam’s best option.”*

*“P32, Parents”*

- **Social impact on the family life**

The last set of questions was related to social impact of CHD and surgical intervention on parents’ family life and seeks to find out how IRD can improve these sorts of issues. Table 25, shows that 65% of parents considered that their child’s CHD had a negative impact on their family and social life.

**Table 25. Social impact of CHD on parents’ family life**

Social impact on the family life	
26%.....	Positive
65%.....	Negative
9%.....	Both

*“Negative impact. My husband has suffered chronic depression”*

*“P01, Parents”*

*“Negative impact. Unpredictable health conditions; school and work absences; hospital visits’ inpatient/outpatient and organizing the other 2 children are some of my problems.”*

*“P04, Parents”*

*“The answer to this question depends on the day you ask it. Initially it had a negative impact, nowadays mostly positive. A really difficult question to answer honestly. ”*

*“P10, Parents”*

*“Negative impact. Moved house due to living in a remote area & having less access to the hospital. Also I had to reduce my work hours significantly due to my sons’ recurrent hospitalizations.”*

*“P14, Parents”*



*“Negative-mainly financial (travelling from country NSW to Melbourne for check-ups / surgeries. Emotional- Father can get quite down about condition.”*

*“P19, Parents”*

*“Positive impact. Numerous lengthy procedures, hospitalizations plus frequent medical appointments plus ongoing mental health issues associated with hospitalization are challenging, however I feel blessed every day for all that I have, especially my heart kid.”*

*“P03, Parents”*

*“Positive impact. It has brought us closer together. We don’t worry about trivial things anymore. So overall we are less stressed.”*

*“P07, Parents”*

*“Positive impact. We have made some new friends, my job has changed to support and help families with heart problems and I love doing it to be more appreciate of life.”*

*“P09, Parents”*

*“Positive impact. We have learnt to be more grateful and appreciate what we have.”*

*“P21, Parents”*

## 8.6 Findings

In the previous sections, the findings of this study are discussed in two perspectives - clinical and non-clinical. A summary of key findings are presented in Table 26:

**Table 26. Summary of key findings in each step of data collection**

<b>Data Collection</b>	<b>Data Sources</b>	<b>Summary of Key Findings</b>
<b>Interviews</b>	Expert Group of: -Cardiac Surgeons -Cardiologists -ICU clinicians	<ul style="list-style-type: none"> <li>• Benefits of IRD to facilitate CHD decision making complexity</li> <li>• Barriers to apply IRD to CHD treatment process</li> <li>• Facilitators to adopt IRD</li> <li>• Importance of IRD to the CHD decision making process</li> <li>• Importance of analytic techniques such as data</li> </ul>

Data Collection	Data Sources	Summary of Key Findings
		mining in the study context. <ul style="list-style-type: none"> <li>• Issues to design and develop the IRD application in practice.</li> </ul>
<b>Questionnaire</b>	Patients' Parents	<ul style="list-style-type: none"> <li>• Benefits of IRD to facilitate parents' decision making during the care process and also to assist them to assess their child's quality of life in different steps.</li> </ul>
<b>Observation</b>	Clinical Meetings	<ul style="list-style-type: none"> <li>• Benefits and Barriers to apply IRD to the CHD treatment process</li> </ul>
<b>Data Base/ Documents</b>	Relevant clinical Data bases and reports	<ul style="list-style-type: none"> <li>• Importance of analytic techniques such as data mining in the study context.</li> </ul>

In this study, additional investigation is required to determine the expected findings (EF), emerging themes (ET) and significant findings (SF).

Expected findings are already discussed in the literature review. In planning to respond to a certain development problem or opportunity toward developing the IRD Model, it is necessary to develop EF that assist in conceptualizing the initial framework.

Emerging themes (ET) are categories of analysis by using existing theoretical constructs to examine data. Emerging themes will also be discussed to develop future relevant studies.

The significant findings (SF) are identified specifically with the findings which are significant only to the research case study conducted at the public hospital located in Melbourne. The SF are based on interview and questionnaire data as well as observation and document reviewing. These SF were found to substantially eliminate difficulties and barriers to developing and implementing the IRD Model in the hospital. Table 27, reveals the findings categorized with respect to each developed theme.

Table 27. Findings Categorization

Themes - Clinical perspective	Findings Category
<ul style="list-style-type: none"> <li>▪ Clinicians' intention to use IRD</li> <li>▪ Clinicians' recommendations</li> <li>▪ Enables towards risk factor screening</li> <li>▪ Contributing factors to assess patients' quality of life</li> <li>▪ Clinicians' barriers to use IRD</li> <li>▪ Clinicians' confident to address surgical risk factors</li> </ul>	<p>SF</p> <p>ET</p> <p>EF</p> <p>ET</p> <p>ET</p> <p>EF</p>
Themes - Non Clinical perspective	Findings Category
<ul style="list-style-type: none"> <li>▪ Social impact on the family life</li> <li>▪ Patients' quality of life after the surgery</li> <li>▪ Parents' level of understanding about the surgery outcomes and risks</li> <li>▪ Parents' intention to use IRD</li> <li>▪ Parents' attitude towards surgery decision making process</li> </ul>	<p>SF</p> <p>EF</p> <p>ET</p> <p>SF</p> <p>EF</p>

### 8.6.1 Expected Findings (EF)

The initial conceptual framework highlights a mechanism to enable risk factor screening to detect risk factors. The literature review confirms that applying data mining techniques is a possible solution to detecting surgical risk factors and predicting surgical outcomes prior to undertaking surgery (Fayyad et al 1996; Han and Kamber 2006; Cios et al., 2007; Kumar and Reinartz 2012). However, the literature review shows that clinicians can predict the surgical outcomes and detect the surgical risk factors but with less accuracy than applying data mining techniques (Koh & Tan, 2011; Srinivas, Rani, & Govrdha, 2010).

As discussed in the literature review (Parolari et al., 2012; Yagi, Akilah, & Boachie-Adjei, 2011), clinicians' confidence to address surgical risk factors is one of the main components in the clinical decision making process. Clinicians should exchange their information with patients or their families, and undertake discussions with the other clinical staff before surgery to investigate and determine the best treatment and decision making processes for the patient. Hence, they have to address surgical risk factors at the highest clinical level.

It is important to continuously evaluate and update the IRD framework to maintain its relevance and application. The evaluation should be based on anticipated surgical outcomes being compared with actual surgical outcomes to identify and record new risk factors and different surgical outcomes within the IRD. Patients' quality of life after surgery should be monitored to capture the actual surgical outcomes and to identify any new post-operative risk factors. In the literature review, it has been determined that surgical risk factors and the level of surgical risk change over time (Bateman et al., 2012; Kavousi et al., 2012). It is therefore necessary to ensure that the IRD framework is up to date and relevant. The interview findings support the fact that most of clinicians feel that the framework should be evaluated regularly by relevant clinicians to make sure all new risk factors are captured and the risk measurements are still valid. The accuracy and efficiency of the IRD would be confirmed in the course of consistent evaluation of the IRD.

Parents' attitude towards the surgical decision making process is another important component in the IRD initial framework. As already discussed in the literature review (Barry & Edgman-Levitan, 2012; Charles, et al., 1997; Légaré, et al., 2011; Makoul & Clayman, 2006), the patients' family and parents would like to contribute more to the surgical decision making process. This is based on the fact that the parents and family prefer to receive more information during the surgical decision making process rather than just signing the consent form before surgery. Hence the parents' attitude towards the surgical decision making process is one of the expected findings in this study. Most of parents in the research case had a positive attitude towards using IRD during the surgical decision making process. However, in the research case, parents would like to use the IRD to improve knowledge sharing between clinicians and parents rather than using IRD to assist them to make a decision whether to perform the surgery or not. This is because all parents stated that there had no choice except to do the surgery.

### **8.6.2 Emerging Themes**

The following section reports potential emerging themes and developments relevant to the IRD application in the healthcare context:

- 1) Early identification of patients at risk through information transferring between patients' parents and clinicians,

- 2) Providing superior decision support through knowledge sharing between clinicians,
- 3) Developing key performance indicators to monitor the surgery risk factors,
- 4) Predicting surgical results to identify patients at risk during the surgery,
- 5) Standardizing clinical risk assessment and management processes to facilitate superior health outcomes,

The emerging themes are mapped (figure 18) according to their perceived degree of impact on surgical decision efficiency, in all phases of Software Development Life Cycle (SDLC). The places of bubbles in this map are estimated based on defined data measurements to analyse collected data. For example, information transferring between patients' parents and clinicians to identifying patients at risk, as one of the captured emerging themes (the first bubble from left), should be considered at the first stage of the solution development (design) as demonstrated in Figure 18. Also, based on the study findings, the importance of designing appropriate functions and components to facilitate transferring information between patients' parents and clinicians is very high.

Predicting surgical results (bubble 4) is also the other emerged themes that should be considered during the design phase while the importance of this capability for patients' parents and clinicians is very high.

Providing functionalities to facilitate knowledge sharing between clinicians (bubble 2) is the other emerged theme that is important to address during the design phase. However, the findings show knowledge sharing between clinicians is very challenging and without an acceptable protocol defined by the hospital, it is not possible to run such a process.

Monitoring and assessing key performance indicators (bubble 3) also should be possible through the IRD solution and sufficient technical features should be developed to facilitate it. The study findings show having this functionality is not really clinical for clinicians, due to regular check up at the hospital.

Standardizing clinical risk assessment and management processes (bubble 5), is one of the important emerged themes that should be considered during the solution implementation. In fact, clinician believe the solution should be audited and evaluated by experts regularly and to do this a standard risk assessment and management process should be organized by the hospital executives to keep the system up to date and enough capable during years.

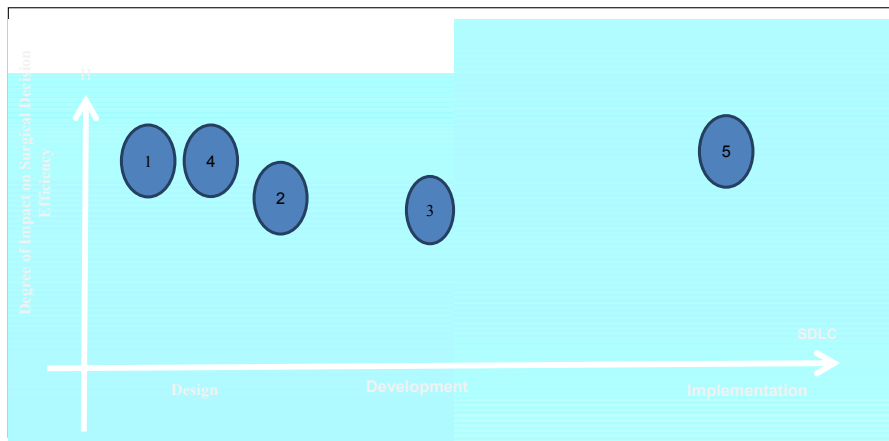


Figure 18. Mapped emerging themes

### 8.6.3 Significant Findings (SF)

This research study has revealed findings that are significant in the research case study of children affected by CHD who underwent surgery at the Hospital. Of the hospital clinicians who were participants in the study interviews, many had a positive intention to use the IRD to detect surgical risk factors and to predict surgical outcomes more accurately. The participants also commented and believed that the IRD can be useful in improving knowledge sharing between clinicians.

Three clinical specialities in the management of CHD surgery are cardiologists, cardiac surgeons and specialists in neonatal cardiac intensive care. The interview content showed that most of the clinical specialists mentioned that communication and knowledge sharing between their relative specialities is very important and IRD might be a suitable facilitator to improve knowledge sharing between these clinicians. The participants made the comment that there are always some hidden risk factors or possibly an inaccurate translation of risk factors. It can be said then that in these cases IRD can be helpful in assisting clinicians to make the better decisions particularly during the pre-operation phase in the treatment of CHD.

The findings of this study pertaining to CHD cases, suggest that clinicians feel that the IRD cannot be helpful during surgery. This is because the cardiac surgeons believe that the IRD might be more efficient before and after surgery, due to the nature of critical ad-hoc decision making during surgery. The cardiac surgeons commented that they prefer to make some ad-

hoc decisions which rely on their experience and knowledge, rather than using an application such as the IRD.

CHD for children is one of the most common health problems and it affects many children around the world. As CHD is diagnosed after birth, it creates a very emotional situation for the parents and the patients' family. The impact of CHD on the parents and their social and family life is significantly negative. The study questionnaires, in fact, showed that 65% of parents stated that their child's health problem had a negative impact on their social and family life. 70% of parents had a positive intention to use the IRD Model with the view its use would alleviate, to some extent, stress and anxiety associated with CHD in their child. Therefore using the IRD Model to predict surgical outcomes and to detect surgical risk factors in each step of surgery might be helpful in reducing parents stress and emotional pressure during the treatment and surgical process. The parents and family of the patient believe that the IRD Model can be useful to keep them informed about the clinical process and surgical risks.

## **8.7 Summary**

This Chapter presented all the results and findings from semi-structured interviews, questionnaires, observations and databases, documents and reports reviewing. The use of thematic analysis was applied in the analysis of data in this research. The study results are presented based on the two different perspectives, that is, clinical and non-clinical. The clinical perspective was obtained from analysis of collected data through the expert group as well as clinical observations, data bases and reports. The non-clinical perspective came from the parents' thoughts and feelings, collected by the questionnaire.

The benefits of the IRD as determined through semi-structured interviews with the clinician expert groups include:

- Facilitating CHD decision making complexity,
- Barriers to apply IRD to CHD treatment process,
- Facilitators to adopt IRD,
- Importance of IRD to the CHD decision making process,
- Importance of analytic techniques such as data mining in the study context,

issues to design and develop the IRD application in practice. The study findings through analysing data captured by the parents' questionnaires include the benefits of the IRD to facilitate parents' decision making during the care process and to assist parents to assess their child's quality of life in different steps of their child's clinical management.

The benefits and barriers in applying the IRD to the CHD treatment process and the importance of analytic techniques such as data mining in the study context are the other significant findings of this study and were determined through observation and reviewing data bases, reports and documents.

A detailed discussion of the results, their implications and limitations and the conceptual framework will be discussed in the next Chapter.



## CHAPTER 5

### Discussion

The results of this study reveal mixed support for existing theories and models such as User Centred Design (UCD), Network-Centric Health Care Operations (NHCO) and the Intelligence Continuum (IC) Model and provided a deeper understanding of these theories by proposing new elements within them. Based on the research findings and emerging themes, the IRD framework was developed to address the research question:

*“How an intelligent risk detection application can be developed in the healthcare context”.*

Further analysis of emerging themes indicated that there are several facilitators, barriers and recommendations derived from the research case and this constitutes the significant contribution of this research to the practice of paediatric cardiac surgery. The participants from within the hospital who completed the questionnaires and interviews provided some suggestions and strategies to extend the application of the IRD Model to other clinical contexts, such as hip and knee replacement in orthopaedic surgery.

In order to provide an in-depth understanding of the results, this Chapter discusses each of the main components of the research framework –

- Contextual components of the research framework (section 5.1)
- Implications and recommendations for practice (section 5.2),
- Implications and recommendations for theory (section 5.3),
- The IRD Framework (section 5.4),
- Model verification and validation (section 5.5),
- Lessons learnt from the Hospital (section 5.6),
- Lessons learnt from this study (section 5.7),
- The study limitations and the chapter summary (sections 5.8, 5.9).

### 9.1 Contextual Components of the Research Framework

As already described in section 2.5.1, the main components of the IRD initial conceptual framework (figure 11) are related to risk assessment, risk detection, anticipated results in the

parental decision making process and the surgical decision making process, actual surgery results and also surgery final report. These components (table 27) are included in some elements that are captured from the content of the literature review.

**Table 28. Main contexts of the initial conceptual framework**

Main contexts of the initial conceptual framework	Elements
Risk Assessment	Monitoring and evaluating risk factors
Risk Detection	Analytical techniques such as data mining
Anticipated Results	Predicting the surgery results by applying analytical techniques such as data mining
Parental decision making support	Facilitators to assists parents to understand surgery risk factors
Surgical decision making support	Facilitators to improve complex surgical decision making process
Actual surgery results	Patients' quality of life after doing the surgery
Final report of the surgery	Comparing the surgery actual results and anticipated results

The study findings suggest more components that make up the IRD Model (table 28), such components including

- Risk factor screening,
- Contributing factors to assess patients' quality of life,
- Parents' intention to use IRD,
- Clinicians' recommendations,
- Clinicians' intention to use IRD,
- Parents' attitude towards surgery decision making process,
- Benefits of IRD to facilitate surgical decision making complexity,
- Clinicians' confident to address surgical risk factors,
- Parents' level of understanding about the surgery outcomes and risks,
- Social impact on the family life,
- Benefits to apply IRD to CHD treatment process,
- Clinicians' confident to address surgical risk factors,

- Parents’ level of understanding about the surgery outcomes and risks,
- Social impact on the family life,
- Benefits and barriers to apply IRD to CHD treatment process.

These components are also included in some elements that are captured through data collection which assists in describing the components functionality.

**Table 29. Main contexts of the study finding**

Contexts	Elements
Enables risk factor screening	<ul style="list-style-type: none"> <li>• Business analytics tools</li> <li>• KPIs</li> <li>• Dashboards</li> <li>• Risk Profile</li> </ul>
Contributing factors to assess patients' quality of life	<ul style="list-style-type: none"> <li>• Business analytics tools (Data Mining-Neural Network technics)</li> <li>• Web based application</li> </ul>
Parents' intention to use IRD	<ul style="list-style-type: none"> <li>• Decision sharing</li> <li>• Knowledge sharing</li> </ul>
Clinicians' recommendations	<ul style="list-style-type: none"> <li>• Analytical Reports</li> <li>• Training facilities</li> <li>• Importance of Usability</li> <li>• Importance of Accuracy</li> </ul>
Clinicians' intention to use IRD	<ul style="list-style-type: none"> <li>• Training</li> <li>• Using the application in pre-op</li> <li>• Using the application in post-op</li> </ul>
Parents' attitude towards surgery decision making process	<ul style="list-style-type: none"> <li>• Information exchange between parents</li> <li>• Knowledge sharing between parents and clinicians</li> </ul>
Benefits of IRD to facilitate surgical decision making complexity	<ul style="list-style-type: none"> <li>• Risk detection</li> <li>• Risk assessment</li> </ul>
Clinicians' Confident to Address Surgical Risk Factors	<ul style="list-style-type: none"> <li>• Risk profile</li> <li>• KPIs</li> <li>• Access to surgical information</li> <li>• Possibility for knowledge sharing between clinicians</li> </ul>
Parents' Level of Understanding about the Surgery Outcomes and Risks	Knowledge sharing between parents and clinicians
Social Impact on the Family Life	Information exchange between parents
Benefits to apply IRD to CHD treatment process	Real time risk detection
Barriers to apply IRD to CHD treatment process	Delay to detect risk factors

In this qualitative study, cardiologists, surgeons and clinicians in ICU as well as patients' parents described their participation in surgical decision making. For example, researchers often query patients' preference to participate in a clinical share decision making (Head et al., 2011; Pentz et al., 2012; Sheridan et al., 2004). However, in this research case study, all patients' parents described their intention to be involved in the decision making process because of a wish for exchanging information with clinicians rather than being involved directly in clinical decision-making. In fact, the parent's description of how they view their role (i.e. during the treatment process) is a reflection of the expert's suggestions concerning the care of their sick baby rather than sharing in the decision-making process.

Studies examining parents' participation in clinical decision making have usually focused on the choice of treatment (Kiesler et al., 2006; Say et al., 2006). However, this study's findings show there is no opportunity for patients' parents to discuss one or more decisions with regard to the clinical treatment their children. Due to the nature of CHD, the only possible curative treatment is the surgery. Hence, parental decision making is not meaningful in the research case study.

This study compares the differences in parents' point of view to conceptualize surgical risk factors with clinical experts' point of view to conceptualize surgical risk factors. In previous research pertaining to the treatment of CHD there is no evidence to suggest these differences were examined. Consequently, the current study findings show parents and clinicians have completely different points of view with respect to examining surgical risk factors. For example, physical limitation is a surgery risk factor after Norwood surgery and is recognised by cardiologists, while parents cannot understand exactly what these physical limitations are. Parents would like to more details, such as any limitation on walking, running or walking up or down stairs. Clinicians usually define the level of risk by comparing all relevant clinical facts and factors together to provide parents with an estimation of the risk level. However, this research shows that parents would like an accurate assessment of their child's level of risk rather than a generalisation.

Clinicians in this study also discuss the importance of changing the surgical risk factors and level of risks over time. Hence, the most useful approach to enabling clinicians to use the IRD in their complex decision making is developing a real-time solution. This would involve all of clinical conditions and observations of the patients, even their current conditions and observations, being applied to the IRD during the risk detection and decision making process.

A review of relevant literature (Vredenburg et al 2002) examines the importance of useability and acceptability to develop a clinical computer-based solution. The current study findings and the literature review are consistent with the role of useability and acceptability to design and develop the IRD solution, as presented in table 29.

Clinical decision making is viewed in the initial conceptual framework in all three phases of surgery (pre-operation, at operation and post operation). However, the current study findings show that there is no feasibility/possibility to use IRD solution during the operation phase. This is because CHD surgeons stated that during surgery they prefer to rely on their own experience to detect surgical risks rather than using such a solution as IRD. Cardiologists and specialists in ICU, however, feel comfortable to use IRD during pre-operative and post-operative phases. There is, therefore, consistency between the initial framework and the study findings. Data supporting this finding is presented in Table 29.

Clinical experts in this study frequently emphasized their need to produce analytical reports by using a computer based solution like IRD to compare actual surgical results with anticipated surgical results. Previous studies examine the significant role of business analytical tools and data mining techniques to develop analytical reports in healthcare contexts (Burstein & Carlsson, 2008). Therefore, there is consistency between the study findings and the initial conceptual framework to apply business analytics tools and data mining in the IRD Model.

Risk detection and risk assessment are identified as two key components of the IRD solution, captured in both the initial framework as well as the study findings.

**Table 30. Capturing Consistency between the study findings with the initial conceptual model**

Elements	Consistency with initial conceptual model
Analytical reports	Yes
Training facilities	No
Usability and acceptability	Yes
Using the IRD application in pre-op	Yes
Using the IRD application in post-op	Yes
Information exchange	No

Elements	Consistency with initial conceptual model
Knowledge sharing between parents and clinicians	Yes
Risk detection	Yes
Risk assessment	Yes
Access to surgical information	No
Knowledge sharing between clinicians	No
Real-time decisions	No

The study findings show that of fourteen initially identified elements, only six elements were consistent with the conceptual Model. These elements are:

- Analytical reports
- Using the IRD application in pre-op
- Using the IRD application in post-op
- Knowledge sharing between parents and clinicians
- Risk detection
- Risk assessment

Therefore, the research findings suggest that these six elements could explore key components of the IRD framework as a solution to show how an intelligent framework application can be developed in the healthcare context – namely paediatric cardiac surgery.

### 9.1.1 IRD Framework

The research findings and emerging themes explore key components of the IRD framework (Figure 18), to demonstrate how an intelligent risk detection application can be developed for the healthcare context. Applying two theories and one of IC Model, NHCO and UCD made a strong foundation for the IRD framework.

This study has found that interviewed clinical experts believed that detecting and managing of surgical risk factors during all three surgery phases is often very complex, due to

difficulties and costs of managing large-scale data. However, relevant studies have shown that the integration of modified information and knowledge management into the concepts of network-centric operations and the employment of Boyd's OODA may address these issues (Von Lubitz & Wickramasinghe, 2006a; Von Lubitz, Beakley, & Patricelli, 2008).

Boyd's OODA "loop" provides an effective framework based on four components of observe, orient, decide and act, for developing creativity and initiative throughout an organization and harmonizing them to achieve the organization's goals, in competitive environments (Angerman, 2004; Richards, 2001). The foundation of network-centric philosophy is the OODA loop while Boyd's OODA loop governs the process of information extraction, development of competitive thrust and also generation of germane knowledge (Von Lubitz & Wickramasinghe, 2006a). Boyd's OODA loop also incorporates both people- and technology-centric concepts (Boyd, 1987; Von Lubitz & Wickramasinghe, 2006a).

The dynamic aspects of the OODA loop have seen it recently rapidly adapted by unpredictable changes within the theatre of operations (Knoll et al., 2000; Richards, 2004; Von Lubitz et al., 2008). Hence, in this research case, it is found that adapting the OODA loop provides an effective technique to integrate healthcare research with clinical practice. This is because applying the OODA loop involves the research case in the process of observation, orientation, decision making and tacking action while this process is already confirmed by the IRD initial framework and the study findings. In fact, the OODA strategy can be integrated with the IRD process. The steps of the IRD initial framework, as demonstrated in figure 11, include a cycle of risk assessment, risk detection, parental/personal decision making, analytical report and evaluation.

Risk assessment is involved in the observing of data and information to assess surgical risk factors and forward them to the risk detection process. This information should be integrated into the orientation step to detect hidden risk factors and predict the surgical outcomes through the historical data and to introduce these hidden risk factors and predictions of outcomes to patients' parents, cardiologists, surgeons and clinicians in intensive care. Based on the IRD initial framework, parents and clinicians should make a decision regarding the surgery. However, the study findings show that in the research case study there is no parental decision making process, in this step. The next process is taking action. This means developing an analytical report to apply decision results to action and to evaluating the IRD Model by comparing actual and anticipated results.

Therefore, the OODA loop can be adapted by the IRD solution as an intelligent tool to facilitate rapid responses to outcome data in the research case. It follows, that based on the analysed data and research findings, the key components of the IRD framework can be observe, orient, decide and act in a real time environment, to detect surgical risk factors by intelligent techniques and tools (figure 19).

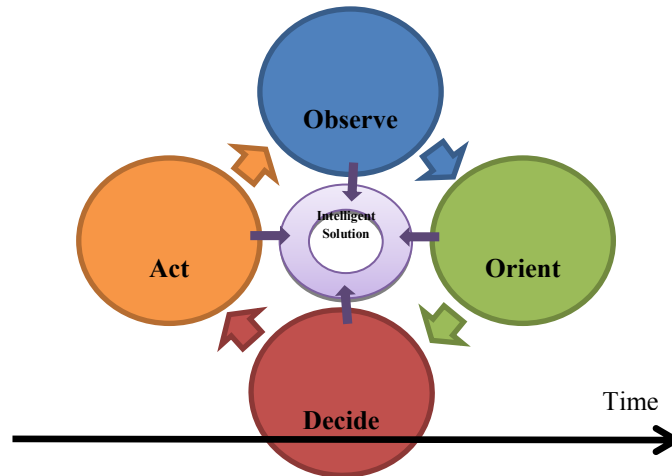


Figure 19. The IRD Framework

## 9.2 Implications and Recommendations for Practice

The discussions with the expert groups by interviews showed that Norwood surgery is much more risky than other surgical procedures for CHD repair and treatment. This is because the mortality and the morbidity rate is more than that found with other CHD surgical techniques. Hence, applying a solution such as the IRD application within the Norwood surgical process, particularly during the pre-operation and post-operation stages, would improve the surgical outcomes significantly. Based on the analysis of collected data, surgical decisions are often made based on doctors' intuition and experience rather than on the knowledge-rich data hidden in the database. However, based on presented results there are numerous risk factors, and possible cardiac conditions and diagnoses across CHD spectrum of surgery which makes surgical decision making and the knowledge sharing process complex for all involved healthcare parties. Thematic analysis of qualitative data through several data sources used in this study, proved the importance of discovering hidden patterns in data to assist in the development of data and attributes for a data mining model to facilitate surgical risk detection and surgical outcome prediction. To develop an IRD Model, this research suggests using data mining techniques - namely decision trees, artificial neural networks and data classification to



prepare the IRD Model for use in practice. Based on the research findings, the significant roles of data mining in the IRD Model are addressing the following key requirements:

- Given a patients' medical profile, predict the surgical outcomes (Mortality, Morbidity and Success)
- Identify the significant impact and relationships in the surgical risk factors with the predictable states (Mortality, Morbidity and Success).
- Identify the surgical risk factors through the medical profile.

The role of domain experts is important during the design phase of the data mining solution to allow the extraction of specific knowledge by considering the user's requirements.

The study has identified that there is no decision sharing or parental decision making process in children with CHD as there is no decision alternative for parents other than surgery. Hence, this study recommends a knowledge sharing process, rather than a decision sharing process between clinicians and parents in the CHD surgical decision making process, particularly post surgery. The study defines this recommendation as an important component of IRD Model.

In summary, the findings related to practice include:

1. The importance of knowledge sharing between clinicians as well as between clinicians and patients through an on-line application;
2. The clinicians' involvement during systems development;
3. The acceptability and capability of the system and high demand of outcome predictions to improve decision efficiency.

This study highlighted the role of parent's income and the quality of their social life with respect to their intention to understand and monitor post-operative risk factors. In the case of CHD, post-operative home care is very important to assist in avoiding any side effects or sudden death. Hence, a solution such as IRD can be effective to monitor parent's quality of social life and their income to provide them with training or special services in order to assist them to improve their knowledge and information towards post-operative home care.

The logical next step of this research is to design and develop an appropriate prototype of IRD solution in order to identify and address issues associated with usability and acceptability of the proposed IRD model for use in paediatric cardiac surgery.

### **9.3 Implications and Recommendations for Theory**

In this research three strong theories User Centred Design (UCD), Network-Centric Health Care Operations (NHCO) and Intelligence Continuum (IC) Model, were applied to create a comprehensive body of knowledge that was used to develop the IRD Model. The study findings make a significant contribution to theory by proving the importance of the principals of the three theories as well as proposing new elements contributing to them.

#### **9.3.1 User Centred Design (UCD)**

UCD guidelines can be applied in the design and development of the IRD framework in order to explore the explicit understanding the of users' tasks and environments with the users' multidisciplinary skills and perspectives.

The exploration of clinicians' perspectives and patients'/parents' perspectives informs the design phase about their collective attitudes towards the IRD's potential as an enabler to applying intelligent solutions in the healthcare context.

This exploratory research also reveals various social-technical concerns about the potential impacts of the IRD solution on clinical knowledge sharing, critical thinking and complex decision making processes.

This research reaffirms the importance of UCD principles and clinician participation in the subsequent design process used to evaluate the solution acceptability.

#### **➤ Implications and recommendations for theory**

One of the principals of UCD is defined as “The design is based upon an explicit understanding of users, tasks and environments” (Norman & Draper 1986; Gulliksen, Göransson et al. 2003; Avison & Fitzgerald 2008). The study findings emphasise the significant role of patients' parents in the design of healthcare solutions, the parents being “information receivers”, a component of the system users. In this study “information receivers” are patients/patients' parents who need to receive understandable information pertaining to different treatment processes. The parent's point of view is important to improve the capability and acceptability of the designed solution, and is due to patient/parents empowerment role in the care process.

### **9.3.2 Networkcentric Healthcare Operations (NHCO)**

In order to perform knowledge transferring and information sharing among clinicians and between clinicians and patients/parents, the application of NHCO allows full, unhindered sharing of information in the treatment of CHD.

As NHCO is employed as a source of information superiority necessary to gain competitive advantage (Von Lubitz and Wickramasinghe 2006a), it allows for the exploration of all of the characteristics of the operational environment of the IRD solution, such as diversity of infrastructure, security, social structure, policies, and economy (Von Lubitz and Wickramasinghe 2006b).

The doctrine of networkcentric operations finds its origins in the pioneering work of Boyd (1987), and it allows analysis of the process of decision-making, interaction with and control of a fast-paced and unpredictably changing environment, NHCO can be adapted to explore process components of the IRD Model to address complex sets of decisions in real-time.

#### **➤ Implications and recommendations for theory**

This study confirms the importance of “the information domain” of the NHCO approach in order to facilitate knowledge and information sharing between care parties, as a significant issue in developing the IRD Model. By adapting Boyd’ OODA loop as the foundation of the NHCO (Von Lubitz & Wickramasinghe, 2006a) to incorporate both people- and technology-centric concepts in order to design the IRD Model is the other contribution of this study to theory.

### **9.3.3 The Intelligence Continuum (IC) Model**

This study supports the importance of IC Model components in clinical complex decision making processes, in order to maximize the value of the data and use the data to improve processes through the techniques and tools of data mining, BI/BA and KM (Wickramasinghe and Schaffer 2006).

The IC Model components make a suitable foundation for the IRD model by applying socio-technical components as well as new IT based techniques and tools such as data mining followed by knowledge discovery, as the IRD model is a powerful composite model presenting all of these components together.

### ➤ **Implications and recommendations for theory**

This research has found the “time” and “real-time” processing also plays a significant role in developing intelligent solutions in the healthcare context, and time and real-time processing are used in conjunction with the other elements of IC Model, such as data, people, technology, process and environment. This is because in clinical contexts, particularly during the surgical phases, receiving the last available information and keeping information up to date is important. Hence, real-time data process is a significant requested component, as suggested by participating clinicians.

## **9.4 The IRD Model**

The functionality of the proposed IRD Model is further enhanced by drawing from the concepts of User Centred Design (UCD), Network-Centric Health Care Operations (NHCO) and Intelligence Continuum (IC), for example, specifically applying the three domains of NHCO (physical; domain, information domain and cognitive domain (Von Lubitz & Wickramasinghe, 2006b). In the context of network-centricity, healthcare operations must be conducted within the three functionally related domains of physical domain, information domain and cognitive domain. To develop a powerful and well-structured network, which facilitates information sharing among all participants within the operational continuum space (Wickramasinghe & Bali, 2008), these three domains are applied in the IRD Model.

In accordance with the importance of rapid decision making and knowledge generation necessary to support decision making in complex healthcare operations, Boyd’s OODA Loop (Von Lubitz, et al., 2008) is applied. The socio-technical and analytic nodes (integral to the IC Model) are included into the IRD framework to support both people and technology perspectives and to highlight the need for key analytics at various points throughout the decision making process. To facilitate capturing the significant input of users (clinical and non-clinical) to design and develop the IRD framework the principles of UCD (User-Centred Design and CC (co-creation) are incorporated. The IRD main components and contexts are presented in figure 20. Followed sub-sections present the main components of the IRD Model designed in three domains of physical, information and cognitive.

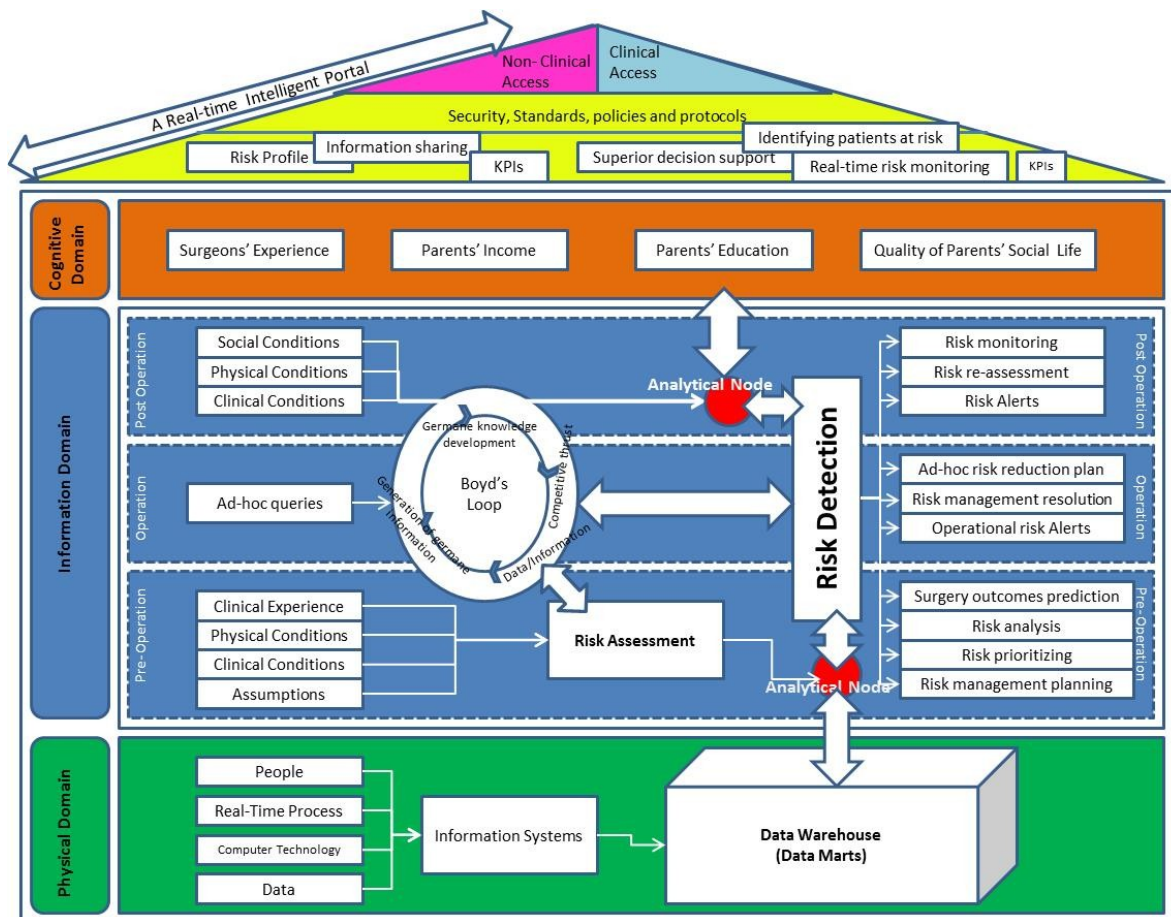


Figure 20. Main components of the IRD framework

### 9.4.1 Physical Domain

Considering the theory of healthcare network-centric operations, the IRD Model is founded on three domains of physical, information and cognitive. Through the NHCO theory, the physical domain is the collection of all physical assets (platforms) such as data management facilities, hospitals or clinics facilities and activities, administrative entities, as well as all other physical subcomponents (Von Lubitz & Wickramasinghe, 2006c).

Therefore, to design the physical domain of the IRD Model, physical components of the study findings are explored in the research case. These components are people, real-time processes, computer technology, data, information systems and data warehousing.

*People* in the research case, are all clinical and non-clinical actors such as patients' parents, cardiologists, surgeons, clinicians in intensive care, nurses and administrators. These people have clinical or administrative inputs to the current information systems available in the hospital.

*Real-time processes* are an attribute explored through the clinical experts' interviews, as one of the main components of the IRD solution.

*Computer technologies* are also identified as one of the important components of the IRD Model by interviewed clinical experts. Also, the literature reveals that IT infrastructure and IT hardware both have significant roles in the design, development and implementation a computer based solution. Types of the technology (i.e., desktop, laptop or iPad), type of the computer OS, CPU model and the other functionalities of the IT infrastructure and hardware are important to improve the performance of the IRD solution.

*Data* includes both clinical and administrative data that is regarded as the most important input of the current systems in the hospital. Although some hospitals still collect this data by hard copy, in our research case study all patients' records were collected from 2001 as soft copies through electronic health records systems.

*Information systems* are used in many hospitals around the world. Recently there has been a remarkable upsurge in activity surrounding the adoption of personal health record (PHR) systems for patients and consumers (Tang et al., 2006). At the hospital in this study, patients' records are collected through computer based record systems.

*Data warehouse or integrated data marts* are other important components of the IRD Model explored through analysis of the literature. To discover hidden knowledge and patterns through the analysis of historical data, it is necessary to have real-time data storage with the capability of dimensional relationships between data. Hence developing a real time data warehouse is recommended for the IRD Model. This is because, a wide range of business operations in healthcare have shown that a data warehouse can provide accurate and timely information together with suitable business analysis tools that may offer key competitive advantage (Von Lubitz & Patricelli, 2007).

#### **9.4.2 Information Domain**

The Information domain contains all the elements required for generation, storage, manipulation, dissemination/sharing of information, and its transformation and sharing as knowledge in all its forms (Von Lubitz & Wickramasinghe, 2006c). All communications about the state of healthcare take place through interactions within this domain (Von Lubitz & Wickramasinghe, 2006c).

As already discussed in this study, the dynamics of Boyd's OODA loop are integrated with proposed technologies, such as business analytics to design the IRD Model as a real time intelligent solution. As a consequence, the information domain is included in the OODA loop as are the risk detection and risk assessment components to make a strong process to assess, produce and share knowledge in order to capture surgical risk factors to facilitate complex clinical decision making. The Information domain is included in the three phases of pre-operation, operation and post operation.

*In the pre-operation phase*, risk assessment provides inputs to the risk detection process via analytical nodes. Analytical nodes in this phase are classification techniques which are followed by the application of data mining tools. Based on the interview findings, the inputs of risk assessment phase in CHD surgery are clinical experience, physical conditions, clinical conditions and assumptions. The observed strategies via the OODA loop are the other important inputs of the risk assessment process and they are designed to insert all captured surgical risk factors to the risk assessment process and vice versa. Outputs of risk assessment should be applied to the risk detection process.

Considering the study findings, it is expected to have surgical outcome prediction, risk analysis, risk prioritizing and risk management planning, as outputs of the risk detection process in pre-operative phase.

*In the operation phase*, based on the findings of observation and document reviewing, the most important issue is that of ad-hoc queries that need ad-hoc decision making. These queries should be processed by the OODA loop to convert them to the decision making process and also to make an actionable strategy. The output of the OODA loop should then be applied to the risk detection process to identify risk factors involved in these ad-hoc decisions. Interview findings show that clinical experts believe they cannot use any computer based solution such as IRD in the operating room. Therefore IRD Model has no analytical node for the operation phase.

Based on this study's findings, it is expected to have an ad-hoc reduction plan, risk management resolution and operational risk alerts through the operative risk detection process.

*In the post-operation phase*, as explored through interview analysis, the three functional groups of social components, physical components and clinical conditions should be applied

to the risk detection process via an analytical node. The analytical node in the post-operative phase is a neural network technique followed by the application of data mining tools.

Based on the study findings, it is expected to have risk monitoring, risk re-assessment and risk alerts as the main outputs of post-operative risk detection.

### **9.4.3 Cognitive Domain**

The cognitive domain contains all human factors that affect operations, such as experience, training, personal engagement or even the intuition of individuals involved in the relevant activities (Von Lubitz & Wickramasinghe, 2006b). The cognitive domain also comprises elements of social attributes (i.e., behaviours, peer interactions).

Hence, the cognitive domain in the IRD Model includes in human related components, explored through the study questionnaires and interviews. These components are:

#### *Surgeons' experience:*

Interview analysis shows that surgeons' experience is one of the most important components of outcomes of CHD surgery. In fact, surgeons' experience is a risk factor affecting the CHD surgery results.

#### *Parents' income:*

Questionnaire analysis explored the postulate that parents' income is directly related to the parents' ability to understand surgical risk factors. It was found by the study that parents with high income (i.e more than \$AUD80K annually) are more interested to know about the surgery risks and are more interested and able to use a solution such as the IRD to contribute in their children's treatment process via knowledge sharing and information transferring with clinician as well as the other parents.

#### *Parents' education:*

Analysis of the literature (Anderson & Minke, 2007; Jackson et al., 2008; Kilicarslan-Toruner & Akgun-Citak, 2013) shows that parents' education has an important influence on parents' ability to participate in the decision making process in their children's health related issues.



### *Quality of parents' social life:*

Questionnaire analysis showed that the quality of the parents' social life has a significant role in the parents' ability in managing their children's post-operation treatment. Due to the long term post-operative treatment for children affected by CHD, assessing parents' quality of life by IRD can be beneficial for patients' parents.

#### **9.4.4 A Real Time Intelligent Portal**

The interview & observation analysis showed that the IRD solution should be accessible through a real time portal for both clinicians and patients' parents with different level of access and security. A real time intelligent portal with capability of identifying patients at risk, sharing information and knowledge between clinicians and parents as well as monitoring KPIs and patients' risk profile would be required. These components are already explored through the study data analysis.

### **9.5 Clinical Scenarios**

To illustrate benefits of the IRD Model, some clinical scenarios are examined. These scenarios are developed based on actual patients' records and clinical reports in the hospital. Due to the ethical issues, patients' name and their identifiable information are deleted.

The aim of these scenarios is to present the complexity of surgical decision making during the CHD operations and to explore how the IRD solution can be beneficial in the three phases of pre-operation, at-operation and post-operation.

#### **9.5.1 First Scenario**

The first scenario is related to a patient with followed information:

SEX: Female

Date of first operation: \*\*/\*\*/2010, 1 day after birth)

Diagnosis: HLHS

Operation: Norwood Operation

Patient's post-surgery status: Diseased

- **Indications and findings:**

The 1<sup>st</sup> patient in our scenario was born in the afternoon, a very small baby, 2.1 kg from very young parents. The cardiac surgeon and cardiac consultant spent two and a half hours discussing with baby's parents and the grandmother trying to convince the parents not to proceed with surgery. The main reason for this discussion was because of the prematurity of the baby and the extremely poor result encountered in that situation with the Norwood technique. They notified the parents that the likelihood of survival is extremely small with a birthweight below 2.5 kg and it would put an extreme burden upon the parents at their very young age. Despite all of these attempts to dissuade them, the parents were adamant that they wanted to proceed with the surgery because of their religious beliefs. Because the baby presents with a restrictive atrial septum, it was decided to proceed with surgery as quickly as possible in order to give the baby a chance at survival. Therefore the operation started around 2am the next morning.

- **Procedure**

Midline sternotomy, removal of the thymus, the head vessels were dissected, the innominate artery was clamped, a size 3 mm shunt was implanted at this level and a size 10 cannula was inserted and was used as the aortic cannula. Cannulation of the SVC via the right atrium and the IVC. Cardiopulmonary bypass was instituted, cooling to 25°C. During cooling, the descending thoracic aorta was dissected, the first three pairs of intercostal arteries were cauterised and divided. Once cooling was obtained, the ductus was divided between two sutures, the head vessels were snared, the ascending aorta was transected, a size 3 mm olive tip catheter was then snared into the ascending aorta and cardioplegia was given at this level. Right atriotomy, atrial septectomy, a size 4mm olive tip catheter was then snared into the descending aorta and regional perfusion was maintained at this level and at the level of the aortic cannula. The entirety of the concavity of the arch was then opened, the aortic arch reconstruction was performed as continuous blood infusion was maintained into the ascending aorta. A patch of glutaraldehyde preserved homograft pericardium was used in order to reconstruct the concavity of the arch. The main pulmonary artery was then separated from the pulmonary artery bifurcation. The orifice of the pulmonary artery bifurcation was anastomosed through an obliquely cut size 3 mm shunt. The Damus part of the procedure

was then performed, this Damus root was then implanted to the reconstructed arch. A punch hole of 3.5 mm was then used to make the hole into the right ventricular free wall and the proximal anastomosis of this RV-PA conduit of a size 3 mm was then performed. The patient was re-warmed, the atrial opening was closed, the heart was deaired, all the head vessels were un-snared and the descending aorta was un-snared. Full re-warming. Once the patient was re-warmed, an attempt of weaning of cardiopulmonary bypass was made. Unfortunately, the patient remained a too desaturated and surgeon decided to increase the size of the shunt. The head vessels were snared again, cardioplegia was given into the Damus root, the proximal part of the shunt was taken down, a size 3.5 mm shunt was then used to create an RV-PA conduit. The distal part of the anastomosis which was very oblique was kept and the obliquely cut 3.5 mm shunt was sutured to this opening. The proximal anastomosis was then performed following the Laks technique. Deairing of the heart, removal of the snare and the cross clamp. Weaning of cardiopulmonary bypass, the haemodynamics and the equilibrium between the two circulations now seems to be good. The chest was left open on one silastic membrane, one silastic chest drain, four pacemaker wires, one Tenckhoff catheter. Although the surgery was successful, the patient suddenly was diseased 3 months after the surgery.

#### ***9.5.1.1 IRD Benefits to the surgery process***

In the first scenario, the patients' parents had to make a decision whether to allow the Norwood surgery to proceed. The cardiologists and surgeons didn't recommend the surgery in this case but they couldn't dissuade the patients' parents from proceeding with the surgery. However, by using the IRD solution, clinicians could develop an accurate analytical report to predict the surgery results prior to doing the surgery rather than spending two hours trying to explain the surgical consequences to the parents.

Non-clinical access in the real-time portal makes an opportunity for parents to identify and access similar cases through the hospital data warehouse to understand on the clinical state and ramifications for their baby. In this study, parents mentioned that they are interested to know about similar cases, their post-operative conditions and their surgical outcomes to assist them cope with any possible risks more easily. The functionality of information sharing in the portal makes it possible to identify similar cases and review their conditions and their surgical outcomes by patients' parents. This information can be shared by patients' parents.

The other benefit of the IRD is pre-operative risk management planning and risk prioritizing to find out which size of shunt is suitable for this patient. As explained in the scenario, surgeons during the surgery made an ad-hoc decision to change the size shunt. The interview analysis shows that there are lots of ad-hoc decisions during the surgery while in the operating theatre it is not possible to detect all consequences and risks of these decisions. Hence, clinical experts in this study stated that risk management planning and risk prioritizing can be beneficial components of the IRD solution in the pre-operative phase. In fact, by using the IRD solution, surgeons could predict which sizes of shunts might be effective in the operation and what are the risk factors followed by each shunt size. For example in this scenario, the IRD could present an opportunity for surgeons to detect risk factors of each possible shunt size, compare and prioritize them, prior to surgery.

This patient suffered sudden death 3 months after Norwood surgery. Although she was under clinical care of the parents and clinicians, post-operative risk alert and risk monitoring of the IRD solution might be helpful to detect any post-operative risks at an earlier stage. In this study parents mentioned that sometimes they are faced with some reactions or signs in their sick children and they don't know what they should do. The parents also mentioned that access to cardiologists is not easy and sometimes to make an appointment or even speak with them on the phone is not easy and time-efficient. Hence, the IRD would be a good solution to share patients' post-operative conditions with clinicians on-line via the real time intelligent portal to receive clinicians' advice as soon as possible. It is a safe, efficient and cost efficient solution to reduce post-operative sudden death and its burdens for patients.

### **9.5.2 Second Scenario**

The second scenario is for a patient with followed information:

SEX: Male

Date of first operation: \*\*/\*\*/2007

Diagnosis: HLHS

Operation: Norwood Operation

Patient's post-surgery status: Diseased

- **Indications and findings**

The 2<sup>nd</sup> patient was one day old and had an antenatal diagnosis dating from the 20th week of gestation. He was born premature at 35 weeks of gestation with a history of breaking of the membrane. The patients' parents moved to Melbourne from NSW before child birth. There has always been significant doubt on a restrictive PFO from the time of the diagnosis and after birth a completely intact inter atrial septum was diagnosed with derivation of the blood from the left atrium into systemic veins from an ascending collector as would be seen in a TAPVD. However, there was a significant pulmonary venous obstruction on the chest X Ray and dilation of the pulmonary veins on echocardiographic study. On the morphology the HLHS was typical with very severe mitral hypoplasia and complete aortic atresia. The ascending aorta is miniscule, probably less than 1 mm. Because of his size, only 2 kg, his prematurity and the obstruction of the interatrial septum, doctors have elected to do an RV-PA conduit and used a 4 mm Goretex conduit. They have slightly modified their protocol and did the surgery at 18°C with several short periods of circulatory arrest.

#### Procedure:

Supine decubitus, vertical sternotomy, sub-total ablation of both thymic lobes, vertical opening of the pericardium. Dissection of the head vessel and the aortic arch. Cardiopulmonary bypass between the body of the right atrium and the pulmonary artery bifurcation using an ECMO cannula. When full flow was reached the duct was snugged down, excluding flow to the pulmonary arteries. Dissection of the aortic arch, of the right pulmonary artery, separation from the ascending aorta from the main PA. The ascending aorta was miniscule. Early into the bypass, surgeons divide the ascending aorta and cannulate the approximate ascending aorta with a 2 mm olive tip catheter. This was quite difficult as the tip of the catheter was greater than twice the size of the lumen. Continued perfusion in the ascending aorta was maintained at 20°C with continuous infusion of GTN at 1 mcg/kg/min. After surgeons cannot further dissect the descending aorta, the aortic cannula was removed and a short period of circulatory arrest was applied. The heart continues being perfused. The aortic arch was incised longitudinally. Excision of all ductal tissue. A 4 mm olive tip catheter is inserted into the descending thoracic aorta and a 3 mm olive tip catheter inserted into the right innominate artery. Continuous perfusion was resumed in both cannulae. Excision of the posterior aspect of the isthmus. Resection of all ductal tissue. The continuity between the posterior aspect of the aortic arch and the descending thoracic aorta was reconstructed by end to end anastomosis. The anterior aspect of the reconstruction of the isthmus, the lower part of

the descending thoracic aorta and the aortic arch were enlarged with a patch of homologous pericardium treated with glutaraldehyde. The patch was tailored as to allow for a 7 mm probe.

When this was done, the perfusion to the ascending aorta was switched to cardioplegia. After arrest, the ascending aorta was decannulated and the Damus anastomosis was performed. Side to side anastomosis between the main PA and the ascending aorta using two counter incisions facing one another, immediately posterior to the rightward commissure of the pulmonary root. The anastomosis was done very carefully using 8/0 running suture. When this was done, the opening to the ascending aorta seems to be very satisfactory. Then the defect in the PA bifurcation was anastomosed end to side with a bevelled 4 mm conduit. The pulmonary end of the duct was ligated with one 6/0 purse string. When this was done, a right atriotomy was performed and the interatrial septum was resected. The anatomy was quite complex, and needs a total circulatory arrest to be appropriately assessed. The resection was performed and circulation was resumed. The Damus anastomosis was anastomosed end to side into the anterior aspect of the reconstructed aortic arch. A clamp was applied on the ascending aorta, and the cannulation site was inserted into the distal ascending aorta. The aortic arch was deaired and circulation was resumed in the whole body. Then the right ventriculotomy was performed in a wedge of avascular myocardium between the LAD and the inferior aspect of the pulmonary annulus. A 6 mm hole was excised and the anastomosis with the trimmed conduit was performed with 6/0 Goretex suture. When this was done, the heart was deaired and the cross clamp was removed. The heart starts beating immediately. During re-warming a triple lumen catheter was inserted into the right atrium and a dobutamine infusion was initiated. First attempt at bypass was unsuccessful after five minutes and doctors gave more assistance, secure the inotrope infusion and remove a small pulmonary band that was applied onto the conduit. At that time with continuous atrial pacing at the rate of 150, bypass can be stopped with good haemodynamic condition and a saturation consistently above 70%. The haemostasis was secured and the chest was closed on one silicone membrane, one chest drain, two A wires, two V wires, one Tenckhoff catheter, one direct RA line.

In ICU, the chest was thoroughly prepped, the ECMO cannulae were thoroughly prepped, draping was installed, the silicone membrane was removed and the chest was washed extensively with warm saline. The ECMO cannulae were clamped and the haemodynamics

are observed for 10 minutes. ECMO cannulae were removed and the purse strings were tied. The chest was washed again and closed on one silicone membrane.

#### ***9.5.2.1 IRD Benefits to the surgery process***

Due to the patients' size, weight and pre-maturity in this scenario, the surgical procedure was complicated for this patient. For example, choosing an RV-PA conduit and used a 4 mm Goretex conduit in the Norwood technique was a critical decision that the cardiologist and surgeons had to make during the operation. However, the IRD solution gives an opportunity for clinicians to detect risk factors and allows for this decision and the chance to compare this option with other possibilities prior to surgery. Then, IRD can prioritize possible risk factors and after that suggest the best decision to the cardiologist in pre-operative phase.

The other benefits of the IRD solution include providing on-line access to patients' clinical information and risk monitoring and information sharing via the IRD real-time portal. For instance, in scenario 2, the patients' parents had to move to Victoria from NSW to receive the best care for their baby. However, they cannot stay in Victoria for a long time and they have to go back to NSW after the post-operative phase. Hence, the IRD real time portal can be an effective, efficient and fast way to receive relevant knowledge and information and also to monitor any possible post-operative risk factors on-line.

### **9.5.3 Third Scenario**

SEX: Female

Date of first operation: \*\*/\*\*/2006, 4 days after birth)

Diagnosis: HLHS

Operation: Norwood Operation, BCPS, Fonton

Patient's post-surgery status: Alive

#### **Indications**

The 3<sup>rd</sup> patient was born with an antenatal diagnosis of Hypoplastic Left Heart Syndrome. She has been very stable for the first three days of life.

#### **Procedure 1: Norwood**

Midline sternotomy, removal of the thymus, dissection of the head vessels, the PA branches and the ductus and the initial portion of the descending aorta. A C clamp was applied on the right carotid artery, a size 3.5 mm shunt was inserted at this level. A size 10 argyle cannula was inserted into the shunt, cannulation of the SVC via the right atrium and the IVC. Cardiopulmonary bypass was instituted. Cannulation of the ductus with a size 8 femoral cannula. The size 8 femoral cannula was placed in a Y fashion on the aortic side of the circuit in order to perfuse the lower part of the body adequately because of the presence of this abhorrent right subclavian artery. The body temperature was progressively cooled down to 24°C. A C clamp was applied on the ductus, the ductus was divided, the pulmonary artery side of the ductus was closed directly with a continuous prolene suture. A C clamp was applied on the PA root. The PA bifurcation was divided from the PA root, a size 5 mm Goretex shunt was implanted on the PA bifurcation. This shunt was cut obliquely and orientated as going from right to left. The descending aorta was dissected and the first three pairs of intercostal arteries were cauterised and divided. The head vessels were snared, the transverse arch was clamped, the ascending aorta was divided. A size 2 mm olive tip catheter arising from the cardioplegic cannula was inserted in the ascending aorta and snared into position. Continuous perfusion of blood was given through this cannula in order to keep the heart beating. The ductal cannula was clamped and removed. All the ductal tissue was resected, the transverse arch was widely opened. Surgeon hesitated to separate the transverse arch from the descending aorta, but the two subclavian vessels were extremely close to the previous area of the coarctation and he was scared that he would lose both these vessels, or one of them if he separated the two and re-did the suture. The four vessels and the arch were extremely small and so was the ascending aorta. A size 3 mm olive tip catheter was introduced and snared into position into the ascending aorta and continuous perfusion was ensured at this level. A patch of glutaraldehyde preserved homograft pericardium was sutured to enlarge the area of the arch. Cardioplegia was then given into the aortic root, right atriotomy, the atrial septum was removed. An opening was made in the right ventricular free wall. The Damus part of the anastomosis was performed and this double barrel opening sutured to the opening of the reconstructed aortic arch. The proximal anastomosis of the RV-PA conduit was performed, the heart was deaired. Closure of the right atriotomy, un-snaring of the head vessels. The descending aorta was un-snared, deairing of the transverse arch and the Damus. Removal of all clamps, sinus rhythm resumed immediately. The pulmonary valve was competent, the heart does not dilate, very good haemodynamics were obtained after a very short period of time. The baby was weaned off cardiopulmonary bypass easily. Modified



ultra-filtration was performed, protamine and blood products were administered. There was absolutely no bleeding. The chest was left open with a silastic membrane, one silastic chest drain, four pacemaker wires and one Tenckhoff catheter.

### **Procedure 2: BCPS**

The patient has had a Norwood stage 1 and initially did extremely well. She had a course that was impeded by supra ventricular tachycardia needing at least two ICU admissions. She had continuous feeding difficulties. Cardiac MRI identified no obstruction on the aortic arch. There was a kink in the left pulmonary artery, but both pulmonary arteries appeared to be very good.

Re-do sternotomy, removal of the Goretex membrane, dissection of the heart, the aortic arch, the SVC and both PAs. The conduit was easily identified by the surgeon. Cardiopulmonary bypass was instituted between the innominate vein, the right atrium and the aorta. The RV-PA conduit was divided between clips. The distal portion of the RV-PA conduit was resected and the opening was sutured to itself with continuous suture. The SVC was separated from its connection to the right atrium. An opening was made in the right PA and the SVC was sutured at this level. Both vessels were of good size and quality. She was weaned off cardiopulmonary bypass without difficulties and the PA pressures were never higher than 14. Classical closure of the chest on a Goretex membrane and two redivac drains.

### **Procedure 3: Fontan**

Midline sternotomy, removal of the goretex membrane, dissection of all the adhesions, cardiopulmonary bypass was instituted between both the innominate vein, the inferior vena cava and the aorta. Dissection of the pulmonary arteries, verifying the hilum, surgeon found that there was a bit of tension, especially in the left hilum and it was difficult for me to obtain a good mobility of the pulmonary vessel. On the beating heart, the underside of the left pulmonary artery up to the hilum was open and this incision was extended towards the right pulmonary artery. This long incision was sutured to an obliquely cut goretex tube of 18 mm. Cardioplegia was then given into the Damus root, the IVC was separated from the right atrium, the lower anastomosis of the Fontan was performed, a size 4 mm fenestration was performed on the side of the goretex tube, the whole opening of the aorta was sutured around this fenestration. The heart was deaired, removal of the cross clamp and first weaning of

cardiopulmonary bypass. At this stage, the saturation is extremely low and persistently in the low 60's at best. There had been some suggestion in the past that there was some pulmonary AV malformation, especially in the right upper lobe and therefore surgeon decided to close the fenestration. 5/0 prolene suture was used to close the atrial tissue covering the fenestration of the goretex. After this manoeuvre, this saturation goes up to 80-90%. At this stage, surgeon was a little unhappy about the goretex conduit, which he thought may be pressing the right pulmonary artery a somewhat upward. The goretex conduit was clamped, it was divided and a bit of resection of this goretex conduit was performed. End to end anastomosis of these two portions of the goretex conduit. The second weaning attempt of cardiopulmonary bypass clearly the haemodynamics were not acceptable, the block pressure was low, the saturation remains low, the SVC pressure was in the low 20's, the surgeon decided to go back on bypass to revise the goretex anastomosis, especially on the left pulmonary artery. On bypass on the beating heart, the anterior portion of the left pulmonary artery was opened, it was very clear at that time that there was a thrombus occluding the whole left pulmonary artery and in particular the area that was previously narrow that did not seem to have been enlarged enough by this long anastomosis. The incision was prolonged into the lobar branch and prolonged back on the right side onto the level of the anastomosis between the SVC and the right pulmonary artery. A long patch of goretex was sutured at this level. By inspecting it the surgeon was not completely happy with the size of the pulmonary artery. He extended the patch. The goretex tube itself was divided again and further shortened. The Fontan circuit seems to be better at this stage. Weaning of cardiopulmonary bypass, the haemo dynamics seems to be satisfactory with the SVC pressure in the high teens, they decided to leave it as it was for the time being. The chest was left open on a silastic membrane, three silastic chest drains, two pacemaker wires, one Tenckhoff catheter.

### ***9.5.3.1 IRD Benefits to the surgery process***

In the 3rd scenario, three types of CHD surgery were presented for the patient who was affected by HLHS. Although the patient could cope with all surgeries very well, the IRD solution could bring some advantages to the patients, patients' parents and clinicians.

By using the IRD solution in the pre-operative phase, cardiologists can have access to previous clinicians' relevant experience as well as the patient's physical and clinical condition through the IRD real time portal. Moreover, based on their experience, the cardiologists and surgeons can make some assumptions related to the surgical procedures. Then, by using the risk assessment function, they can assess some common risks of the

surgery for the patient. However, in this case, due to the complexity of the surgery, there are several hidden risk factors resulting in semi-structured and ad-hoc decisions during the surgery, such as choosing suitable shunt size and femoral cannula size, modifying ultra filtration or even choosing the surgery date. Hence, to capture hidden risk factors, risk detection component of the IRD will assist cardiologists and surgeons during all three phases of pre-operation, operation and post operation:

- To predict the surgical outcomes in the pre-operation phase, analyses possible risks and prioritize them and also plan the risk management process for the patient, prior to the surgery.
- To develop an ad-hoc risk reduction plan, provide risk management resolution and setting operational alerts.
- To monitor post-operation risk factors, re-assess possible risk and provide risk alerts through capturing patients' clinical and physical conditions as well as their parents' social issues and concerns.

Furthermore, patients' parents can have access to the patients' risk profile and treatment key performance indicators to monitor any possible risk factors in each stage. Patient's parents are able to share their questions or issues with clinicians during the post-operation phase, to find any possible risks as soon as possible.

## **9.6 Model Verification and Validation**

Model verification and validation are essential parts of the model development process if models to be accepted and used to support decision making (Macal 2005). Validation ensures that the model meets its intended requirements in terms of the methods employed and the results obtained. The ultimate goal of model validation is to make the model useful in the sense that the model addresses the right problem, provides accurate information about the system being modelled, and to make the model able to be actually used (Sargent 2012). Considering Sargent's (2012) approach, I applied the subject matter experts' techniques in the research case study and also in the contexts of Total Hip and Knee Arthroplasty (THA and TKA) to validate the IRD model. Considering that both THA and TKA involve complex surgical decision making processes, I found that THA and TKA were appropriate surgical case studies to verify and validate the IRD model. Hence, an expert group of Orthopaedic

surgeons at one of the biggest private hospitals in Melbourne were asked to validate the IRD Model as applied to their surgical specialities. After conducting several expert focus groups, the IRD Model has been validated by CHD and THA/ TKA surgical experts.

### **9.7 Lessons Learnt From the Hospital**

Due to this research being centred on human subjects, mandatory ethics approval was obtained to allow investigators to conduct data collection in the hospital. Although this study was classified as a low risk research study by the ethics committee of the hospital, obtaining ethics approval took approximately one year. Getting ethics approval was subject to two relevant clinicians conducting at least two peer reviews of ethics application and relevant documents, as a prelude to making an ethics submission to the hospital ethics committee. During ethics approval process, a number of the information statements and questionnaires were revised six or seven times. The main reasons for these revisions were lack of information about clinical contexts and explaining these contexts through the plain language.

After obtaining ethics approval, the researcher commenced data collection through the stated techniques. However, during document and report reviewing, it was found that locating information of past patients through the hard copy of their folder was too difficult. Although the hospital is converting all hard copies to a computer based system, there are many documents and reports in patient folders that there are not scanned yet, one reason being that the template and structure of the reports for patients with similar clinical conditions is not consistent as yet. Developing a data base or data warehouse for this clinical information is challenging, particularly for some non-clinical people who are experts in IT or software engineering.

Through observations made attending clinical meetings relating to planning future CHD surgery, it was noted that there are some international and interstate patients and there is no official and continuous procedures for clinicians to communicate with these patients' parents or doctors regularly, before admitting patients in the hospital or during the surgical phases. The IRD model provides enhanced clinical communication which facilitates an improvement in outcomes in the surgical decision making process.

## 9.8 Lessons Learnt From This Study

This study has outlined an exploratory research program to examine the potential benefits of combining a real time intelligent risk detection solution with decision support in a healthcare context. The proposed IRD model has an advantage in its continuous nature. By comparing anticipated results and actual outcomes and performing risk auditing, the important task of amending risk factors to improve future predictions will be achieved. A further important feature of the proposed IRD model is the integration of the three IT solutions, risk detection, knowledge discovery and clinical decision support systems, to solve the clinical issue of the definition and assessment of outcomes in patients with CHD. The next stage in this research is prototyping the solution to undertake a clinical trial.

This research program has a strong contribution to practice by emphasizing the importance of:

- Knowledge sharing between clinicians as well as between clinicians and patients
- Clinicians' involvement during systems development
- Acceptability and capability of the system
- High demand of outcome predictions to improve decision efficiency.

This study makes a contribution to theory and the body of knowledge by proving the importance of IC, NHCO and UCD theory to assist in developing a solution such as the IRD in healthcare context. The study findings have indicated new elements in the ICM and in UCD theory. This study has identified that *time* can be an important element within the ICM. *Information receivers* in the healthcare context are understood to have a significant role in the design of clinical solutions. *Information receivers* therefore should be involved in the design process for the IRD.

However, discovering & capturing operational risk factors is quite difficult, due to the lack of interaction between healthcare industry practitioners and academic researchers. This situation would therefore contribute to limited opportunities for the application of predictive analysis techniques in the healthcare context.

This study proffers a suitable solution which combines the application of ANNs (Artificial Neural Networks) and Knowledge Discovery (KD) techniques to identify key clinical and surgical decision milestones and participating relevant actors and parties. This then provides

assistance to medical professionals to embrace appropriate knowledge sharing to facilitate the decision making process.

The benefit of knowledge sharing is that it allows doctors to clarify and contribute to patients or patients' families' understanding of key facts and relevant values, and to highlight the unique circumstances that might alter the decision for any individual by adding a considered perspective on the decision (Sheridan et al. 2004).

This study confirms that the selection of a risk detection method, prediction by data mining tools and then decision support are very important for decision making in complex surgical procedures, in particular CHD. In closing, the researcher contends that real time intelligent risk detection appears to be critical for many areas in healthcare where complex and high risk decisions must be made. The researcher acknowledges that more research is required for full and complete elucidation of real time IRD application use in the healthcare context.

### **9.9 Study Limitations and Recommendations**

This research cannot attempt to determine all actual risk versus actual benefit. This is because long term risks and rare occurrences are not currently possible to identify using randomized controlled trials, these risks and occurrences can only be identified by using methods that were specifically developed for large, observational and longitudinal data sets. This study therefore can only explore the main components of a surgical intelligent risk detection framework to improve clinical decision efficiency.

Although this study supports the benefits of such an intelligent application for healthcare contexts, many issues regarding its implementation into specific healthcare contexts such as Congenital Heart Disease (CHD) remain to be examined. Therefore, the next phase for this research is prototyping and simulation of the solution to trial the model in a selected clinical environment.

### **9.10 Summary**

This chapter has attempted to discuss the main components required for an intelligent surgical knowledge sharing framework to improve clinical decision making efficiency. This integrative framework has been developed by combining findings from this exploratory research study that focused on the application of intelligent solutions to the context of

paediatric CHD. Although this chapter discusses the benefits of such an intelligent application for healthcare contexts, many issues regarding its implementation into specific healthcare contexts such as CHD remain to be examined. Therefore, developing and prototyping the Model and simulation of the solution are the next steps for this research in future. The following sections discuss the study limitations, implications to theory, implications to practice and contribution to the body of knowledge.

Emphasizing the importance of knowledge sharing between clinicians as well as between clinicians and patients; clinicians' involvement during systems development; acceptability and capability of the system and high demand of outcome predictions to improve decision efficiency are the major contribution to practice. This study also contributes to theory by highlighting the importance of IC, NHCO and UCD theories in developing and designing knowledge sharing solutions for healthcare contexts. In closing, the researcher contends that real time intelligent knowledge sharing between clinical professionals and patients or their families appears to be critical for many areas in healthcare where complex and high risk decisions must be made. Real time intelligent knowledge sharing will only become more significant as healthcare reforms continue, the myriad of proposed e-health solutions fail to deliver their promises (Kavousi, et al., 2012; Rozenblum et al., 2011) and healthcare challenges of access, cost and quality continue to intensify exponentially.

## CHAPTER 6

### Conclusion

This report has outlined an exploratory research study undertaken to examine the potential benefits of combining a real time intelligent risk detection Model with decision support in a healthcare context, that being surgical intervention in CHD. This research study has aimed to answer the research question:

*“How can an intelligent risk detection (IRD) Model be developed in the healthcare context?”*

The emergent themes from this exploratory research include:

- 1) Early identification of patients at risk
- 2) Providing superior decision support to clinical staff
- 3) Developing key performance indicators to detect surgical risk factors
- 4) Predicting possible surgical results to identify patients at risk during surgery
- 5) Standardizing clinical risk assessment and management processes to facilitate superior health care and outcomes.

An advantage of the proposed IRD model that should be noted is its continuous nature. By comparing anticipated results and actual outcomes and performing risk auditing, the important facility of amending risk factors to improve future predictions will be achieved. A further important feature of the proposed IRD Model is the integration of the three IT solutions of risk detection, clinical decision support systems and knowledge discovery. This integration, combined with assessment measures, assists in solving the clinical issue of the definition and assessment of outcomes in patients with CHD. The next step for this research is prototyping the solution in a clinical trial environment.

This research makes a contribution to practice by emphasizing the importance of knowledge sharing between clinicians as well as between clinicians and patients, clinicians' involvement during systems development, acceptability and capability of the system and the high demand for outcome predictions to improve decision efficiency. This study has contributed to theory



and the knowledge base by proving the importance of IC, NHCO and UCD theory to developing a Model, such as the IRD, in healthcare context. The study identifies new elements within the IC Model and UCD theory. The study has identified that time is an important element to IC Model. And those information receivers in the healthcare context have a significant role in the design of clinical support solutions. Therefore, information receivers should be involved within the design process.

However, discovering and capturing surgical risk factors is quite difficult, due to the lack of interaction between healthcare industry practitioners and academic researchers. This fact was found to compromise the opportunities for the application of predictive analysis techniques in the healthcare context, namely surgical intervention of CHD. This research confirms that the selection of the risk detection, prediction by data mining tools and then clinical decision support systems are very important for decision making in the complex surgeries. In this chapter, section 6.1 provides answers to the main research question, and sections 6.2 addresses the importance of intelligent risk detection (IRD) Model and section 6.3 presents the research framework. Sections 6.4 & 6.5 examine the research contributions in theory and practice. Sections 6.6 & 6.7 describe the study limitations and further studies.

### **10.1 How Can the Intelligent Risk Detection (IRD) Model Be Developed in a Healthcare Context?**

Healthcare is an information rich industry where successful outcomes require the continual processing of multi-spectral data and sound decision making. In order to ensure superior decision making and successful healthcare outcomes, it is imperative to utilize the knowledge and information hidden in these data elements. While other industries have benefited from the use of intelligent solutions, healthcare delivery has been noted to lag behind in this area. This study addresses the void thus created by investigating the benefits of using an intelligent risk detection (IRD) Model to support surgical decision making and to answer the research question:

*How can the intelligent risk detection (IRD) Model be developed in the healthcare context?*

Answering the research question has been achieved by integrating the three key domains of knowledge discovery, decision support and risk detection, within the design and clinical application of information systems. This study explored main the components and elements to design and develop the IRD framework. The study outcomes have identified key essential

processes that contribute to the successful development of the IRD framework. The key essential processes are detailed as follows:

- Understanding the clinical domain

The study findings emphasize that to develop the IRD framework in a healthcare context, the clinical domain should be identified together with its procedures and policies to allow significant observations to be captured in depth.

- Identifying all decision makers in the clinical domain

The primary role of the IRD framework is to support the making of clinical decisions. Based on the content and outcomes of the study interviews, it is critical to identify all clinical and non-clinical decision makers related to any clinical decisions to successfully develop the IRD framework.

- Mapping of patient's management and treatment processes in the clinical domain

Due to a lack of understanding of the patient's management and treatment processes, designing and developing computer based solutions in the healthcare context is challenging. The observation results in this study show that mapping the patient's management and treatment processes in the clinical domain would be helpful to develop the IRD framework.

- Exploring benefits, barriers and requirements in both clinical and non-clinical point of views

## **10.2 Why the Intelligent Risk Detection (IRD) Model Is Important?**

This study serves to demonstrate that a risk detection approach enhanced by the prediction provided by knowledge discovery and further developed by decision making has the potential to provide significant benefits for healthcare. I have given insight into the provided benefits within the context of hip and knee replacement surgery in orthopaedic medicine. The next phase for this research is to trial the IRD model in an appropriate clinical setting. It should be noted that other factors, such as individual surgeon complication rate and/or facility complication rate must be considered.

Leading healthcare organizations are recognizing the need to incorporate the power of a decision efficiency approach, driven by intelligent solutions (Wickramasinghe et al., 2008).

The primary drivers for this include the time pressures faced by healthcare professionals coupled with the need to process voluminous and growing amounts of disparate data and information in shorter and shorter time frames and yet make accurate and suitable treatment decisions which have a critical impact on successful healthcare outcomes and far reaching implications for the lives of their patients (Wickramasinghe et al., 2008). This research directly examines the benefits of real-time risk detection and outcome prediction in order to support and facilitate superior decision making in the context of CHD for children.

An important, unique feature of the proposed IRD Model is the integration of the three well established IT solutions (knowledge discovery, decision support systems & risk detection), which have proved to be very successful in providing decision support in complex, high risk decision making scenarios in various business contexts (including the military and banking and finance sectors) (Porter & Tiesberg, 2006; Wickramasinghe, et al., 2008).

In this research, an intelligence risk detection model using knowledge discovery methods is proposed. Intelligent risk detection is a particularly challenging area for the healthcare industry while relatively common for fraud detection in finance, diagnosis in industry, and affect analysis in chemistry. This is not only because building cases for training sets is difficult, but also because the cases may have many forms, causes, and unknown relationships. I propose the application of knowledge discovery techniques to high-level surgical risk detection and outcome prediction. The IRD model designed is based on two steps in the decision making process (surgical and personal) and includes a decision support system which is suitable for high concentration prediction. The facility for continual model update that is inherent in the proposed IRD system results in adaptive and more accurate risk detection and outcome prediction capabilities compared to previous models.

Currently healthcare delivery in all OECD countries is experiencing exponentially increasing costs with no likely solution to address this problem. Some of these costs are due to errors, poor decision making and poor judgment. Decision support facilitated by risk detection has been shown to lead to better decision making in many service sectors such as banking and finance.

### **10.3 The Research Framework**

The initial IRD conceptual framework included the main components of risk detection, risk assessment, anticipated results, parental decision making support, surgical decision making support, actual surgery results, and a final report of the surgery management of patients.

Seven elements were consistent between the study findings and the conceptual IRD model. These elements are:

- Business analytics tools
- Analytical reports
- Using the IRD application in the pre-operative stage
- Using the IRD application in the post-operative stage
- Knowledge sharing between parents and clinicians
- Risk detection
- Risk assessment

Considering these elements, the new IRD model framework incorporates observe, orient, decide, act and time to facilitate the IRD model success.

### **10.4 Contribution to Theory**

This study has contributed to theory and the body of knowledge by proving the importance of IC, NHCO and UCD theory in developing the IRD Model in the healthcare context. The study findings identify new elements associated with the IC Model and UCD theory. The study has identified that *time* can be an important element to IC Model., as are *information receivers* in the healthcare context and both elements have a significant role in the design clinical solutions. *Time* and *information receivers* should therefore, be involved within the design process as a matter of course.

Also, this research explored key aspects and benefits of applying NHCO to design and develop a risk detection model in order to design a sustainable solution in healthcare contexts.

### **10.5 Contribution to Practice**

While the incorporation of intelligent technology solutions has occurred in other industries such as banking and finance with great success, healthcare in general has been very slow in adopting such technology (Metaxiotis, 2011). This study represents a ground breaking endeavour to explore the potential of intelligent tools to facilitate better healthcare outcomes. The major contribution to practice is emphasizing the importance of knowledge sharing between clinicians as well as between clinicians and patients.

Also, the importance of clinicians' involvement during systems development and their role during design and develop the model is the other important contribution of this study.

Furthermore, exploring key requirements to design and develop the IRD solution in order to enhance the acceptability and capability of the system, is one the significant outcomes of this research. Moreover, this study proved the high demand of clinical risk detection and outcome predictions in healthcare contexts to improve decision making efficiency.

### **10.6 Limitations**

Discovering and capturing surgical risk factors is quite difficult due to the lack of interaction between healthcare industry practitioners and academic researchers. Hence opportunities for the application of predictive analysis techniques in the healthcare context were found by this research to be compromised. This research has three limitations pertaining to the case study:

➤ Capturing all risk factors:

The researcher acknowledges the difficulty associated with attempting to capture all risk factors. This is because always there are some hidden risks that cannot be recognise in early stages. Also, the other reason is because of the nature of CHD surgical risks, a risk factor for one patient may not be a risk factor for the other patient. Also risk factors and their effects might be changed in different ages. Hence, due to these complexities, capturing surgical risk factors to design and develop the IRD Model is challenging and addressing all possible and potential risks are not possible.

➤ No access to longitudinal data sets

The study showed that there was no access to longitudinal data sets. For this study, I had access to the hospital data sets between 2006 and 2012. This is because before 2006 there was no EHR in the hospital, for patients affected by CHD. Due to the importance of access historical data for designing accurate data mining algorithms, no access to longitudinal data sets is the other limitation of this research study.

➤ Collecting data through parents as a group of participants

There were found to be highly emotional events for parents as a group of participants, and this may have compromised this group's ability to recollect what happened during the surgical and recovery processes.

### **10.7 Further Study**

The following propositions warrant further study:

**P1:** Knowledge transferring protocols with the IRD Model can improve the surgical decision making process.

**P2:** Real time data process with the IRD Model is positively related to better surgical outcomes.

**P3:** Patients/their families' access to the IRD application can improve postoperative outcomes.

**P4:** Clinical interactions through the IRD application can improve the surgical decision making process.

**P5:** Non-clinical interactions through the IRD application can improve the surgical decision making process.

### **10.8 Summary**

This research serves to demonstrate that the selection of the risk detection, prediction by data mining tools as one of the data science techniques and then decision support are very important for decision making in the complex surgeries. IRD, in practice, can also be used as a training tool to train nurses and medical students to detect the CHD surgery risk factors and their impact on surgery outcomes. Moreover, it can also provide decision support to assist doctors to make better clinical and surgical decisions or at least provide a second opinion.

Furthermore, IRD can be used as a knowledge sharing and information transferring tools between clinicians, between clinicians and patients or their families and also between patients with the other patients. The study also has a significant contribution to practice and theory; namely confirming a role for data mining models and data science technologies in healthcare contexts.

In closing, the thesis contends that real time intelligent risk detection appears to be critical for many areas in healthcare where complex and high risk decisions must be made and thus calls for more research in this area.

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## **Appendix 1: Ethics Approval from RMIT University**

Human Research Ethics Committee (HREC)  
Research and Innovation office

**Notice**

Date: **20 December 2011**

RMIT project number: **82/11**

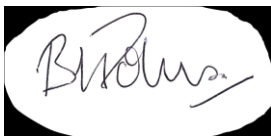
Project title: ***An intelligent risk detection framework to improve decision efficiency in healthcare contexts***

Investigator: **Ms. Fatemeh Hoda Moghimi**

The RMIT University Human Research Ethics Committee has noted that the above project, which is to be conducted by Ms Fatemeh Hoda Moghimi, a doctoral candidate at RMIT University, has been approved by the XXX Hospital Human Research Ethics Committee (HREC).

The RMIT University HREC acknowledges that the Hospital HREC is responsible for the conduct of the project and that the principal researcher shall be providing annual and final reports on the project to the RCH. Copies of these reports and any other project documentation should also be forwarded to the RMIT HREC for information.

In any future correspondence please quote the project number and project title above.



A/Prof Barbara Polus

Chairperson

RMIT HREC

cc: Dr Peter Burke (Ethics Officer/HREC secretary), Prof Nilmini Wickramasinghe (supervisor).

## **Appendix 2: Questionnaire**

## Questionnaire

### **Participants: Parent of CHD patient**

*Please, complete the questions below at best you can:*

**a. *These questions explore your family background.***

- i. Are you the child's:
- Father                       Mother                       Other..... (Please, state)
- ii. How old are you?
- Less than 20 years       20-25       25-30       30-40       Older than 40 years.
- iii. How many children do you have?
- 1       2       3       4       More than 4
- iv. We would like to ask for information on your child and his/her treatment so far.

Current age (please, state)	Current health (Please, check most correct box.)
	<input type="checkbox"/> Good <input type="checkbox"/> Mildly limited <input type="checkbox"/> Moderately limited <input type="checkbox"/> Severely limited

Other Comments:

- v. Total household income per year.
- Less than \$40,000       \$40-60,000       \$60-80,000       \$80-120,000       More than \$120,000
- vi. How has your child's health affected your family life overall?
- No effect       Positive effect       Negative impact

Can you please, explain.

**b. *These questions explore your knowledge of CHD, surgical outcome, and your general experience during your child's treatment.***

- i. When was your child's problem diagnosed?  
 Before birth     After birth: if so at what age? .....  
 If yes, at what time in pregnancy? ..... weeks
- ii. Did you have an ante natal ultra sound scan?  
 Yes     No  
 If yes, how many scans were done? .....
- iii. During your child's treatment, did you get enough information about his/her condition and treatment?  
 Yes     No

Other comments:

- iv. How would you rate your understanding of the surgery risk factors before the surgery?  
 High Level     Medium Level     Low Level

Other comments:

- v. Did the level of your understanding of the risk factors (considering the previous question) affect your decision to proceed with the surgery?  
 Yes     No

Other comments:

**c. These questions explore “quality of life” and “side effects”, and their importance in the decision making process of CHD treatment**

**Quality of life:** An important consideration in medical care, quality of life refers to the patient's ability to enjoy normal life activities.

**Side effects:** Some medical treatments can impair quality of life, while others greatly enhance quality of life. In this question the effects of these types of treatments are called “**side effects**” like shortness of breath.

i. Based on the above definition, how is your child's quality of life *after* his/her surgery?

Excellent    Good     Slightly less than normal.....    Poor

Other comments:

ii. Does your child's quality of life meet your expectation?

Yes                      No.....

please explain:

iii. Has your child suffered from any side-effects of the surgery?

Yes                      No

Other Comments:

1.                                      If yes, was this side-effect discussed with you before the surgery?

Yes                      No

2.                                      If it was not discussed before the surgery, how this would have affected your decision if you knew about it before the surgery?

Yes                      No

Please explain:



- iv. What are the 5 outcomes that are most important to you as measures of a successful operation? Please order these 1-5, with 1 being the most important, in the table below.

<b>The outcomes</b> (Please, state below)	<b>Priority (1:low - 5: high )</b> (Please rank below)

## **Appendix 3: Semi-Structured Interview Questions**

## Semi-Structured Interview Questionnaire

### Interview Questions: Expert group

- i. Do you think detecting surgical risk factors and predicting surgical results will help to improve decision making in CHD surgery?  
 Yes                       No .....

To receive the best results from the Intelligent Risk Detection (IRD) software application, we would like to define major categories of risk as well as the factors in each of these categories at separate time points in the surgical process:

- pre-operative
- intraoperative
- post-operative

We would also like to categorise the risk factors in 3 different age ranges of:

- Less than 30 days
- Between 1 and 3 months
- Between 3 and 12 months
- 

In the table below, would you please define the major categories of risk factors and also within each category the factors which you would consider the most important ordered most important factor as F1.

*For example if you considered patient factors were an important category with patient sex as the most important factor followed by social class, fill in patient sex as F1 and social class as F2.*

		Under 1 month of age		Aged 1-3 months		Aged 3-12 months	
		Risk Category	Risk Factors (in this category)	Risk Category	Risk Factors(in this category)	Risk Category	Risk Factors(in this category)
Pre-operative	<b>G1:</b> eg: patient factors	F1: Overweight F2: F3: More:	<b>G5:</b>	F1: F2: F3: More:	<b>G9:</b>	F1: F2: F3: More:	
	<b>G2:</b>	F1: F2: F3: More:	<b>G6:</b>	F1: F2: F3: More:	<b>G10:</b>	F1: F2: F3: More:	
	<b>G3:</b>	F1: F2: F3: More:	<b>G7:</b>	F1: F2: F3: More:	<b>G11:</b>	F1: F2: F3: More:	
	<b>Additional categories?</b> <b>G4:</b>		<b>Additional categories?</b> <b>G8:</b>		<b>Additional categories?</b> <b>G12:</b>		
Intraoperative	<b>G13:</b> -	F1: F2: F3: More:	<b>G17:</b>	F1: F2: F3: More:	<b>G21:</b>	F1: F2: F3: More:	
	<b>G14:</b>	F1:	<b>G18:</b>	F1:	<b>G22:</b>	F1:	

- a. *This set of questions will explore the level at which you would consider the risk factors are likely to have an important impact on outcome and also discover what would be considered important Key Performance Indicators (KPIs) through each of these surgical phases.*

Risk factors that you have considered important, could you please estimate the level of impact that these may have on outcome (on scale of 1-10, 1 being low to 10 being high), AT also the cut off threshold that might be important to consider? (eg. Obesity can be a moderate risk factor and the threshold level may be > 30kg/m<sup>2</sup>).

*Notice: To make it easier to fill the risk factor fields in the table below, you can use such a coding system. For example use GIF1 rather than the name of risk factors (the letter of G with its number to show the category and the letter of F to show the risk factor in the mentioned category).*

Risk Factors	Level of risk (1: low - 10 high)	Threshold for Risk
-eg: Overweight or <b>GIF1</b>	-eg: 5	-eg: BMI > 30kg/m <sup>2</sup>
More:		

- i. What are the top 5 outcomes that are important to you for measuring the success of operation (5 items are enough) and also the priority? (Top priority being 1 and 5 being the least important)

Outcome	Priority (1 highest- 5 lowest importance)

## **Appendix 4: Publications**

### ❖ **Journal Papers:**

1. Moghimi, F. H., De Steiger, R., Schaffer, J., & Wickramasinghe, N. (2013). The benefits of adopting e-performance management techniques and strategies to facilitate superior healthcare delivery: the proffering of a conceptual framework for the context of Hip and Knee Arthroplasty. *Health and Technology*, 3(3), 237-247.
2. Mohammad I., Moghimi, F.H., Wickramasinghe N., Kent B., Nguyen L., Redley B., Taylor N., Stie M., and Botti M. 2013 “Using ANT to Uncover the Full Potential of an Intelligent Operational Planning Support Tool (IOPST) for Acute HealthCare Contexts”,. In press *Intl J Actor Network Theory and Technology Innovation (IJANTTI)*. 5(2), 29-49.
3. Moghimi, H., Zadeh, H., Schaffer, J., & Wickramasinghe, N. (2012). Incorporating intelligent risk detection to enable superior decision support: The example of orthopaedic surgeries. *Health and Technology*, 2(1), 33-41.

### ❖ **Conference Papers:**

1. Moghimi, F. H., and Wickramasinghe, N. 2012 “The Benefits of Adopting e-Performance Management to facilitate Superior HealthCare Delivery”, Bled 2012, Bled, Slovenia
2. Moghimi, F.H., Zadeh, H., Cheung, M.; & Wickramasinghe, N., “An Intelligent Risk Detection Framework Using Business Intelligence Tools to Improve Decision Efficiency in Healthcare Contexts" (2011). *AMCIS 2011*. Detroit, U.S.
3. Moghimi, F. H, Zadeh, H. & Wickramasinghe, N. 2011 “An Intelligent Risk Detection Framework Using Knowledge Discovery To Improve Decision Efficiency In Healthcare Contexts: The Case of Paediatric Congenital Heart Disease”, *PACIS 2011*, Brisbane, Australia.
4. Moghimi, F. H, Zadeh, H. & Wickramasinghe, N. 2011 “An Intelligence Risk Detection Framework to Improve Decision Efficiency in Healthcare Contexts: The Example of Pediatric Congenital Heart Disease”, *HICSS 2011*, Hawaii, U.S.

5. Wickramasinghe, N., Moghimi, F., & Schaffer, J. (2010). Designing an intelligent risk detection framework using knowledge discovery techniques to improve efficiency and accuracy of healthcare care decision making. *FZID Hohenheim, Discussion Papers*, 31.

❖ **Book Chapters:**

1. Moghimi F.H, and Wickramasinghe N. 2013 “Intelligent Risk Detection for HealthCare”, Encyclopaedia chapter to Encyclopaedia of Business Analytics and Optimization. IGI, pp.158-170.
2. Moghimi F.H, and Wickramasinghe N. 2013, “Artificial Neural Network Excellence to facilitate Lean Thinking Adoption in HealthCare Contexts”, In Eds Wickramasinghe et al. *Lean thinking for healthcare*, Springer, New York, 13-27.
3. Moghimi F.H, and Wickramasinghe N. 2013, “Initiatives of Service Oriented Architecture towards Performance Improvement in Healthcare”, In Eds Wickramasinghe et al. *Lean thinking for healthcare*, Springer, New York, 83-95.
4. Wickramasinghe N., Moghimi, F.H., Kent B., Nguyen L., Redley B., Taylor N., Stie M., and Botti M. 2013, “Using Technology Solutions to Streamline Healthcare Processes for Nursing: The Case of an Intelligent Operational Planning Support Tool (IOPST) Solution”, In Eds. Wickramasinghe et al. *Lean thinking for healthcare*, Springer New York, 405-430.
5. Moghimi, F. H., Goldberg, S. and Wickramasinghe N. 2012, “Applying the IPM Framework to Improve Remote Performance Management in the Contexts of Chronic Disease Care”, *Pervasive Health Knowledge Management*”, Springer, 221-239.
6. Moghimi, F.H, Zadeh, H. and Wickramasinghe, N. 2012 “An intelligence e- risk detection model to improve Decision efficiency in the context of the orthopaedic operating room”, in Eds. Wickramasinghe et al. *Critical Issues in Developing Sustainable e-Health Solutions* Springer, New York., 17-32.
7. Moghimi, F.H, and Wickramasinghe N. 2012. “Improving e-Performance Management in HealthCare Using Intelligent IT Solutions”, in Eds Wickramasinghe

et al. Critical Issues in Developing Sustainable e-Health Solutions Springer, New York., Springer, 3-15.

#### ❖ Posters

1. Moghimi, F.H., and Wickramasinghe N. 2012 “Applying Data Science Techniques to Develop an Intelligent Risk Detection Application for HealthCare Context”, MedInfo Conference, Denmark, 20-23 August 2013.
2. Moghimi, F. H., Cheung, M., De Steiger, R., Schaffer, J. and Wickramasinghe, N. 2012 “Applying Intelligent Risk Detection to Enable Superior Decision Support for HealthCare Contexts” Research week at Epworth HealthCare.
3. Wickramasinghe N., Moghimi, F.H., Kent B., Nguyen L., Redley B., Taylor N., Stie M., and Botti M. 2013 “Investigating the Efficacy of an Intelligent Operation Planning and Support Tool for Acute HealthCare Contexts”, Poster submission to MedInfo Conference, Denmark, 20-23 August
4. Wickramasinghe N., Moghimi, F.H., Kent B., Nguyen L., Redley B., Taylor N., Stie M., and Botti M. 2013 “Investigating the Efficacy of an Intelligent Operation Planning and Support Tool for Acute HealthCare Contexts”, Poster submission to Research week at Epworth HealthCare Moghimi, F.H., Cheung, M., De Steiger, R., Schaffer, J. and Wickramasinghe, N. 2012 “An Intelligent Risk Detection Framework Using Business Intelligence Tools to Improve Decision Efficiency in HealthCare Contexts”, Research Week at RMIT University.
5. Moghimi F.H., Zadeh, H., and Wickramaisnghe, N. 2011 “An Intelligent Risk Detection Framework Using Business Intelligence Tools to Improve Decision Efficiency in HealthCare Contexts”, Research week at RMIT University, Note: This poster won the best poster prize.