Clinical Resource Utilization Assessment of Device Follow-up Clinic's Remote Monitoring Service of Cardiovascular Implantable Electronic Devices

by

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Supervisory Committee

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Abstract

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Background: With the maturity and wide availability of the telecommunication technology, the remote interrogation or remote monitoring of a cardiovascular implantable electronic device (CIED) has become an increasingly common and reliable form of telecardiology or telemonitoring in enabling patient and device follow-up remotely.

Research Aim: From the perspective of a device follow-up clinic, the aim of this research is to assess if the integration of the remote monitoring technology to the standard healthcare service model of the implanted patient and device care through remote follow-up service and remote data transmission could be instrumental to the service supply of a device follow-up clinic in timely response to the variation of the service demand while sustaining the quality of patient service.

Study Design: The study setting of the research is a single-site, single-vendor time-to-event study in serving implanted patients with on the regular follow-up service. This prospective, observational, post-test only design study consists of a control group whose patients attended all follow-up services at the conventional on-site setting, and an intervention group whose patients newly enrolled the remote monitoring services for remote follow-up service and other pertaining services. This study uses system dynamics modelling to depict the workload assessment impact by the remote monitoring technology.

Results: In the specification to the research setting, the remote monitoring services indeed created more apparent upfront variety of workload for patient starting up with the services. It may recommend that the clinic and possibly the vendor could be more involved in the early stage of patient adoption with the education and system setup to manage the learning curve of the technology. One future study could be to continue observing the intervention group for a longer period of time for any changes to the clinical resources utilization associated with the remote monitoring services.

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Dedication

I would like to dedicate this research to my father, who dedicates his life to the well-being of the whole family with greater possibility for us to choose how we live our lives.

Glossary and Abbreviation

Abbreviation	Description
AF	atrial fibrillation
AP	allied professional
BC	British Columbia
CBT	cognitive behavioral therapy
CEAP	clinically employed allied professional
CFU	conventional follow-up
CI	confidence interval
CIED	cardiovascular implantable electronic device
CLD	causal loop diagram
CRT	cardiac resynchronization therapy
CRT-PPM or CRT-P	CRT with pacemaker
CRT-ICD or CRT-D	CRT with defibrillator
CSV	comma-separated values
DFC	device follow-up clinic
DRG	diagnosis-related group
ECG	electrocardiogram
ECOST	Effectiveness and Cost of ICD Follow-up Schedule with Telecardiology
EHRA	European Heart Rhythm Association
EVOLVO	Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators
EP	cardiac electrophysiologist
ER	emergency room
FHA	Fraser Health Authority
HDO	health delivery organization
HF	heart failure
HRQoL	health-related quality of life
HRS	Heart Rhythm Society
ISHNE	International Society for Holter and Noninvasive Electrocardiology
IC	in-clinic
ICD	implantable cardioverter defibrillator
ILR	implantable loop recorder
IM/IT	information management/information technology
IO	in-office
IPE	in-person evaluation
IR	incident rate
IRR	incident rate ratio
MAE	major adverse event
MD	physician

MORE-CARE	Monitoring Resynchronization Devices and Cardiac Patients
NP	nurse practitioner
NYHA	New York Heart Association
QALY	quality-adjusted life year
QoL	quality of life
PM or PPM	pacemaker
RCH	Royal Columbian Hospital
RCT	randomized controlled trial
RI	remote interrogation
RM	remote monitoring
RMS	remote monitoring system remote monitoring service
RN	registered nurse
RR	relative risk
SC	standard of care
SCA	sudden cardiac arrest
TARIFF	Health Economics Evaluation Registry for Remote Follow-up
TM	telemonitoring

Chapter 1. Introduction

1.1 Research Setting and Motivation

A cardiovascular implantable electronic device (CIED) is a medical device implanted in the chest of a patient diagnosed with irregular heartbeat or cardiac arrhythmias. It is an electrical intervention for the monitoring, diagnosis, and treatment of bradycardia, tachycardia and heart failure (Wilkoff, et al., 2008). With the maturity and wide availability of the telecommunication technology, the remote interrogation or remote monitoring of a CIED has become an increasingly common and reliable form of telecardiology or telemonitoring in enabling patient and device follow-up remotely. The intervention of the RM technology gradually becomes a crucial data collection engine of the cardiology information system when the patient is physically outside of the clinical care setting. A follow-up service model integrating with the remote monitoring technology for remote cardiac disease management has received considerable attention as an acceptable method of care delivery in the past decade (Ricci, Morichelli, & Varma, Remote Monitoring for Follow-up of Patients with Cardiac Implantable Electronic Devices, 2014). The question of how effective the remote monitoring technology to the service delivery for the implanted patient and device remains contextual of how the health care setting integrates with it.

In a research study of the dynamic analysis of healthcare service delivery, it highlights one of the unique characteristics of health care service in comparison with common business service – the criticality of quality service in providing the right care to the right patient at the right time. (Rust, 2013). From the perspective of a device follow-up clinic (DFC) of a health delivery organization, the aim of this research is to assess if the integration of the remote monitoring technology to the standard healthcare service model of the patient and device care through remote follow-up service and remote data transmission could be instrumental to the service supply of a DFC in timely response to the variation of the service demand while sustaining the quality of patient service. The impact of the clinical resource utilization by the remote monitoring technology of the implanted patient and the device is the subject evaluation of the research.

1.2 Literature Review

The literature review on the research aim examines the published evidence on what a DFC or a health delivery organization (HDO) has experienced with the impact of the remote monitoring of CIED in utilizing the clinical resource for the routine patient and device follow-up. Consistent evidence shows the general trend of positive impact on the primary outcome of interest in the immediate clinical workload and resource consumption of a DFC or a HDO by the remote follow-up service and the remote monitoring technology. In general, it is instrumental in reducing the overall workload and clinical resource consumption than the in-clinic follow-up service only for implanted patients. On the other hand, a mixture of evidence can found in the analysis on the secondary outcomes in the changes in HDO's overall clinical resource utilization by the RM follow-up service, such as cardiac-related hospitalization, emergency visits, scheduled and unscheduled on-site visit. Some of the gaps from the literature review relevant to the research aim include the upfront workload to a DFC when the remote follow-up service was first introduced was not articulated. The workload contributed by the patient education and support and by the unscheduled remote transmission were also to be explored in the research.

1.3 Research Question and Objectives

With the motivation of the RCH cardiac clinic as the research setting and with the foundation from the literature review, the research question of the study is to evaluate the workload impact on the clinical resource of a DFC for the regular patient and device follow-up by the remote follow-up service. To address the question, the research objectives are broken down followed:

1. To identify the workload of the in-clinic only follow-up clinical protocol and in the hybrid follow-up clinical protocol with both the in-clinic and remote follow-up at a DFC;
2. To depict the relationship and interaction of the clinical resource consumption in supporting the workload of the in-clinic only follow-up clinical protocol and the hybrid follow-up clinical protocol of a DFC in a conceptual model; and
3. To project and compare if the clinical resource would be capable in serving the implanted patients in one-year and three-year periods after the study horizon in both the follow-up clinical protocols using a conceptual model.

1.4 Study Design and Methodology

The study setting of the research is a single-site, single-vendor time-to-event study on the operation of the RCH cardiac clinic as the DFC in serving implanted patients with on the regular follow-up service. This prospective, observational, post-test only design study consists of two groups. The control group, or the in-clinic (IC) group, is the implanted patients who strictly attend all follow-up services at the conventional on-site setting at RCH cardiac clinic. These patients typically adhere to the clinic's standard IC follow-up clinical protocol. The intervention group, or the remote monitoring (RM) group, is implanted patients who enroll in the remote follow-up service using the remote monitoring system. These patients typically adhere to the clinic's standard hybrid follow-up clinical protocol which consists of rotating IO follow-up and RM follow-up. In the evaluation of the impact of the remote monitoring service as the intervention, the control group acts as the baseline in demonstrating the workload difference between the two follow-up clinical protocols.

This study uses system dynamics modelling to depict the workload assessment impact by the remote monitoring technology. This application of the system dynamics in the research is broken down into three major steps. In the first step, a casual loop diagram is developed as qualitative analysis to depict the relationship between the parameters of the clinical resource utilization of the RCH cardiac clinic in service delivery for each of the IO follow-up and hybrid follow-up clinical protocols. The parameters of clinical resource utilization in serving the implanted patients are identified. In the second step, the casual loop diagram is translated into a stock and flow diagram for quantitative analysis on the workload management in demonstrating the difference between the two follow-up clinical protocols in the service volume provision by the cardiac clinic team. Based on the statistical analysis of the data collection, each parameter is converted to either a stock, for observing the dynamics behaviour over time, or a flow, for recording the behaviour in a time period, and is then assigned with a numeric value. In the final step, the stock and flow diagram is then used for running to simulation of the clinical resource utilization in projecting the service volume of the cardiac patients in one-year and in three-years of time after the study horizon for the two follow-up clinical protocols.

The study duration is approximately one year with patient enrollment from July 2017 to June 2018. Convenience sample is used on patient enrollment to the research, hence the RCH cardiac clinic's patient assignment to the control and intervention groups is independent of the

research study. A patient who is implanted with Medtronic ICD or CRT-D and eighteen years of age and older is enrolled to the research when the patient attended an in-clinic follow-up service at the RCH cardiac clinic during the study duration. The intervention of the research is Medtronic Carelink, the remote monitoring system for the Medtronic ICD and CRT.

1.5 Report Structure

This report comprises of the following chapters in presenting how this research was performed to address the research aim of the impact of the clinical resource utilization by the remote monitoring technology of the implanted patient and the device. Each chapter is summarized as follows:

- Chapter 2 provides the background information on the research setting and the motivation. It includes what a cardiovascular implantable electronic device is, how the remote monitoring technology is applied with CIED, the description of the RCH cardiac clinic which is the subject DFC of the research, and the explanation of the motivation;
- Chapter 3 describes the process of how the literature review was done on the research aim by illustrating the search strategy and selection criteria of the literature, and by presenting the consideration in contextually interpretation the outcome of the literature review;
- Chapter 4 details how the research was done through the study protocol and methodology using system dynamics as well as the data collection and processing at the RCH cardiac clinic and the statistical analysis;
- Chapter 5 presents the finding of the results to respond to each of the research objectives, and includes the patient and workload statistics of the control group and the intervention group. Then the construction of the causal loop diagram and the stock and flow diagram is described. The outcome of the simulation run using the stock and flow diagram is then discussed;
- Chapter 6 presents the discussion of the results of the research, the strengths and the limitation of the research, as well as the suggested future study of the research; and
- Chapter 7 presents the conclusion of the research by summarizing the research aim, the study design, the results of the finding, and by the implication of the finding on the remote monitoring technology to the future study.

Chapter 2. Research Setting and Motivation

This chapter introduces the setting and the motivation of the research by first providing foundational context of the subject – the remote monitoring of the cardiovascular implantable electronic device. Then the international and Canadian context of the remote monitoring is summarized. The setting of the research site, the cardiac clinic of the Royal Columbian Hospital, is described. This chapter is concluded by presenting the motivation and the aim of the research.

2.1 Cardiovascular Implantable Electronic Device and Follow-Up Service

A cardiovascular implantable electronic device (CIED) is a medical device that implanted in the chest of a patient diagnosed with irregular heartbeat or cardiac arrhythmias. It is an electrical intervention for the monitoring, diagnosis, and treatment of bradycardia, tachycardia and heart failure (Wilkoff, et al., 2008). Cardiac Services BC describes cardiac electrophysiology (EP) as "a subspecialty of cardiology that focuses on the heart's electrical system and the management of the heart rhythm disorders, or arrhythmias. The physiological burden of arrhythmias is significant as they can place an individual at an increased risk for sudden cardiac death (SCD) and are associated with significant adverse outcomes and detrimental impacts on quality of life" (Cardiac Services BC, 2011). A CIED is considered one of the diagnostic and therapeutic interventions in the management of heart rhythm and arrhythmias. It has to be complemented with long-term patient follow-up and involves the primary care provider and cardiology specialists, including cardiac EPs (Cardiac Services BC, 2011).

Four common types of CIEDs are cardiac resynchronization therapy (CRT), implantable cardioverter defibrillator (ICD), permanent pacemaker (PPM), and implantable loop recorder (ILR). Each device type features various monitoring and therapeutic functionalities to manage the patient's symptoms depending on the cardiac severity and conditions. For example, ICD and CRT with defibrillators (CRT-D), which are the subject CIED of the research, are used to monitor the cardiac rhythm and treat potentially fatal ventricular arrhythmias with pacing therapies and/or electric shocks. It may be clinically instrumental in preventing the patient suffering from sudden cardiac arrest (SCA) and heart failure (HF) (Pron, G; Ieraci, L; Kaulback, K; Health Quality Ontario, 2012). Please refer to Appendix A. Functional Description and

Component of Cardiac Implantable Electrical Device for more information on each type of CIED and its clinical application.

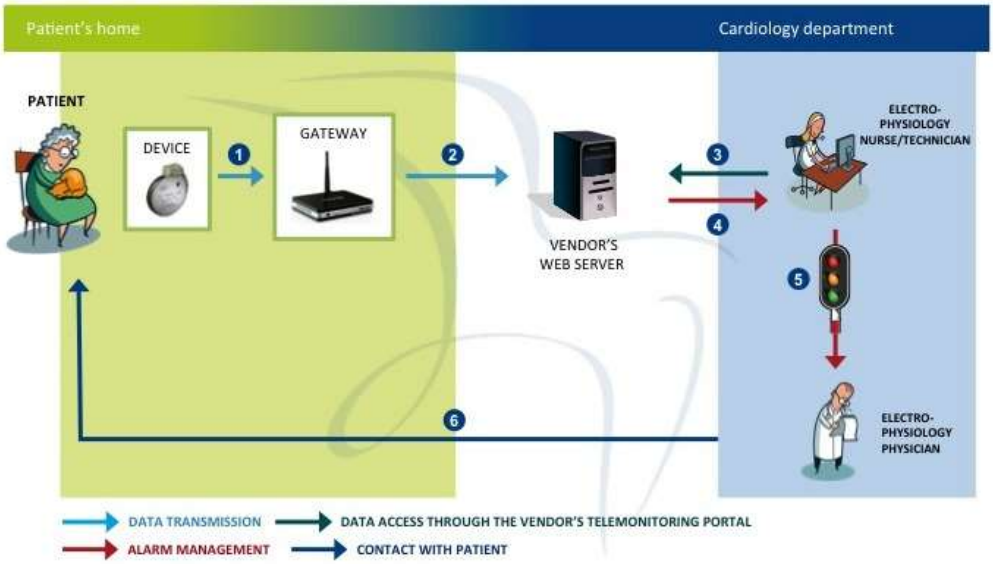
It is critical to perform regular follow-up on an implanted patient during the life of the device. It is generally the responsibility of the health delivery organization (HDO) to ensure the wellness of the patient and the implanted device by providing the patient and device follow-up service. A follow-up service consists of a clinical review of the patient's cardiac conditions and a technical assessment of the implanted device's functionalities, and may prompt the reconfiguration of the device's reprogramming and additional clinical treatment as necessary (Mabo, et al., 2012). Professional practice guidelines, such as the Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices by the European Heart Rhythm Association (Wilkoff, et al., 2008), recommend the general frequency of follow-up based on the device type. For a pacemaker and CRT with pacemaker (CRT-P), it is about every three to twelve months; and for ICD and CRT with defibrillator (CRT-D) it is about every three to six months. Other factors contribute to the frequency of the follow-up are patients' dependency on the device, patients' cardiac severity and conditions, and the device's years in use and its battery depletion rate (Wilkoff, et al., 2008). The Canadian Cardiovascular Society and Canadian Heart Rhythm Society jointly recommend a similar follow-up frequency based on device type and the contributing factors (Yee, et al., 2013).

Conventionally a follow-up is performed in an in-clinic (IC) or in-office (IO) setting, which a patient must attend in-person at a hospital ambulatory clinic or at an electrophysiologist's office, where it is equipped with the specific manufacturer's device programmer and staffed with CIED-trained clinicians. Depending on the staffing of a clinical care team, a clinician (either a cardiac technologist or a device registered nurse (RN)) performs the device interrogation on the patient and stores the device's data in a cardiology information system developed by the device's manufacturer. The clinician analyzes the data for any abnormality in the system while conducting a regular cardiac assessment with the patient. A cardiac electrophysiologist (EP) reviews the patient's overall health condition and signs off the assessment report. The follow-up assessment report is then filed on the patient's electronic medical record.

2.2 Integrating of Remote Monitoring Technology in Patient Care

With the maturity and wide availability of the telecommunication technology, the remote interrogation or remote monitoring (RM) of a CIED has become an increasingly common and reliable form of telecardiology or telemonitoring in enabling patient and device follow-up remotely. The RM technology gradually becomes a crucial data collection engine of the cardiology information system when the patient is physically outside of the clinical care setting. The data of the patient's general physiological statuses and specific cardiac alerts as well as the data of the device's functionality can be transmitted via an installed gateway or transmitter connected to a cellular network at anytime and anywhere off-site, for example at the patient's home, to an internet-based portal for review by the clinical care team. Depending on the type of device and the device's manufacture-supplied remote monitoring system, the data transmission may include battery voltage, lead characteristics, and arrhythmias history (Lopez-Villegas, Catalan-Matamoros, Robles-Musso, & Peiro, 2015) . The remote data transmission may be automatic by a scheduled time, ad-hoc as needed by patient's manual submission, or real-time. When an abnormality is discovered from the data analysis of a remote transmission, the clinical care team can further discuss with the patient, either over the phone or arrange an in-clinic or in-office follow-up for a more in-depth assessment. Figure 1 illustrates a basic technological and data workflow of a remote transmission (Dario, et al., 2016).

Figure 1 – An illustration of a basic technological workflow of a remote transmission



Although the regular follow-up service is critical to device maintain and patient care, it also puts pressure on the resources of the clinical care team in performing the service, as well as in accommodating the patients and the caregivers who have to physically travel to and wait at the clinic to attend the follow-up appointment. Furthermore, the increasing number and technical complexity of the implanted device coupled with the increasing clinical complexity of the patient population also enhances the challenge to the HDO in finding ways to modernize and improve a sustainable clinical workflow and service delivery for the implanted patients. Hence the remote monitoring technology is becoming one popular way to address the challenge – a follow-up service model integrated with the remote monitoring technology for remote cardiac disease management have received considerable attention as an acceptable method of care delivery in the past decade (Ricci, Morichelli, & Varma, Remote Monitoring for Follow-up of Patients with Cardiac Implantable Electronic Devices, 2014)

2.3 Integrating Remote Monitoring Technology in Patient Care – International and Canada Context

In the international setting of cardiac implanted patient care, professional bodies around the world have published position papers with the recommendation in integrating the RM technology to the follow-up service and the general patient and device care. Some of the major position papers are listed as follows:

- "HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDS): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations" by the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) (Wilkoff, et al., 2008);
- "ISNE/EHRA Expert Consensus on Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIEDS)" by the International Society for Holter and Noninvasive Electrocardiology (ISHNE) and EHRA (Dubner, et al., 2012); and
- "HRS Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Implantable Electronic Devices" by HRS (Slotwiner, et al., 2015).

One recommendation is on the clinical standard of the follow-up frequency and protocol of the follow-up service on patient and device using the RM technology, as presented in Table 1 (Wilkoff, et al., 2008).

Table 1 – Recommended follow-up frequency of each type of CIED

Type of Device	Event/Frequency	Follow-up Protocol
All CIED	Within 72 hours of implantation	In-Person
All CIED	2-12 weeks post implantation	In-Person
Pacemaker/CRT-P	Every 3 – 12 months	In-Person or Remote
ICD/CRT-D	Every 3 – 6 months	In-Person or Remote
All CIED	Annual until battery depletion	In-Person
All CIED	Every 1 – 3 month at signs of battery depletion	In-Person or Remote

Another recommendation is on the roles and responsibilities of the clinical resources in delivery the follow-up service. HRS recommends that physicians who prescribe RM have the overarching responsibility for patient monitoring, for "RM should be considered as an extension of the CIED diagnostic capabilities" (Slotwiner, et al., 2015). The allied professional has the pivotal role of conducting the timely and complete review of remotely transmitted information. A dedicated resource staff with clear responsibility for RM data review is strongly advised, for this ensures urgent alert information is managed with felicitous verification and appropriate intervention. For an institution or a clinic, key responsibilities include a clear communication strategy for patient on the RM policies and realistic service expectation; and a guideline on responsibilities of the care team member and the patient in overseeing the timely response of the remote data transmission and alert notification and working with patient on remote connectivity issues (Slotwiner, et al., 2015).

These position papers also define the terminology in various application of the RM technology in the patient and device care. Table 2 presents a comparison table of the definitions between the ISNE/EHRA Expert Consensus on Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs) paper (Dubner, et al., 2012) and the HRS Expert Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Implantable Electronic Devices (Slotwiner, et al., 2015). For the purpose of this research, the remote monitoring covers all the activities defined these two papers.

Table 2 – Definition Comparison of the Remote Monitoring Technology

HRS Expert Consensus Paper (Slotwiner, et al., 2015)	ISNE/EHRA Expert Consensus Paper (Dubner, et al., 2012)
Remote monitoring (RM) refers to the automated transmission of data based on the pre-specified alerts related to device functionality and clinical events. This provides the ability for rapid detection	Remote monitoring refers to data acquired automatically with unscheduled transmissions of any pre-specified alerts related to device functioning or to clinical events. The

of abnormal device function and/or arrhythmia events.	latter adds a new functionality to implanted devices, opening a new era of potentially beneficial preemptive interventions that may alter the natural history of a particular disease or condition.
Remote interrogation (RI) refers to routine, scheduled, remote device interrogation structured to mirror in-office checkups. This literally means conducting the device and patient follow-up remotely through data transmission. This is very similar to what a clinician collects when the patient is physically at the clinic.	Remote follow-up refers to programmable scheduled transmissions in which routine CIED parameters are collected remotely in a format similar to that obtained during a routine clinic visit. This information obtained by the caregiver from the data repository (usually via the internet) is encoded in such a way that could be interfaced with commercially available PMs and ICD follow-up software (i.e. Carelink with Paceart by Medtronic).
N/A	Patient-initiated interrogation refers to non-scheduled follow-up interrogations as a result of a patient experiencing a real or perceived clinical event, for which the patient is seeking expert evaluation.

The Canadian Cardiovascular Society and Canadian Heart Rhythm Society also jointly published a position statement on the Use of Remote Monitoring for Cardiovascular Implantable Electronic Device Follow-up (Yee, et al., 2013). The Position Statement recommends that remote monitoring be available at all device follow-up clinics (DFCs) "as an integral part of standard of care of device patients" (Yee, et al., 2013) and provides advice for proper design, implementation, and integration of a remote monitoring system into the clinic. The recommendations of the roles and responsibilities of the clinical resources in supporting the remote monitoring of a CIED in the position statement is practically identical as those made in the international position papers. Here are a few highlights from the position statement relevant to the research:

1) RM transmission are categorized in three types:
    a. Routine or prescheduled transmissions scheduled by the DFC staff to occur on a particular date

b. CIED alert events, when CIED data are automatically transmitted when they fall outside a value are automatically transmitted when they fall outside a value range preprogrammed for the patient's CIED
c. Patient-initiated transmissions

2) A device follow-up clinic (DFC) should identify "the needs, challenges, and risks such as staff education, privacy, security, workflow, and staff roles and responsibilities involved in the RM" (Yee, et al., 2013). Then the centre should develop the corresponding policies and procedures that guide the RM program management and support staff in the delivery of quality patient care using RM. The roles and responsibilities of each staff in the development of an RM program are described, and a proposed RM organization or workflow is presented as shown in Table 3 below.

Table 3 – Proposed Remote Monitoring Organization or Workflow (Yee, et al., 2013)

Roles: AP – allied professional; NP – nurse practitioner; MD – physician	
Event: Initiation	
Responsibility	Role
Pre-implant education includes RM discussion	AP
Remote monitoring initiated at the initial post-implant assessment	
• Patient education & consent discussion about RM use and responsibilities Patient agreement to comply with RM rules and provides explicit consent	AP
• Device programming to optimize alerts according to patient needs and/or clinic protocol	AP
• Patient registration on RM server	Clerical
• Patient education about RM hardware, set-up and operation	AP/clerical
Schedule of follow-up is determined • Schedule for in-clinic assessment • Schedule for remote assessment	AP/NP/Physician
Follow-up scheduled in RM system ± in-clinic appointment schedule (depending on clinic practice)	Clerical
Patient notified of date, time and method of next follow-up (clinic or remote)	Clerical
Event: Transmission Review	
Responsibility	Role
Scheduled or unscheduled RM transmission is received and reviewed, issues identified and forwarded to the appropriate provider for review and clinical decision	AP/NP/Physician
Documentation of the remote monitoring transmission is completed and entered into patient health record	AP

The patient is contacted in accordance with clinic policies & procedures. DFC should decide if policy will be to contact all patients who transmit or only those with abnormalities requiring intervention	If no action needed, clerical/AP; If actions needed, NP/MD
The transmission is processed – archived or closed once all activity related to the interaction is complete	AP
The next follow-up appointment is scheduled and the patient is notified	Clerical
Any other administrative processing completed (billing, etc.)	Clerical
A weekly review to identify patients who have failed to transmit. Patients are contacted, new appointments scheduled and documented in the in-clinic scheduler and the manufacturer's schedule (the one that created the automatic transmission)	Clerical

Health Quality Ontario, an independent body funded by Ministry of Health and Long-Term Care in the Canadian province of Ontario, conducted a systematic review in 2012 on the Internet-based RM of CIED for an evidence-based analysis to support the public financing decisions. The focus of the systematic review was on the safety, effectiveness, and cost-effectiveness of the RM system for therapeutic CIEDs such as PMs, ICDs, and CRTs. The systematic review presented that the RM of ICD devices demonstrated feasibility and significant reduction in-office clinic follow-up in the first year of post implantation. The substitution of almost all the first year in-office clinic follow-ups with RM was also "not associated with an increased health care utilization such as emergency department visits or hospitalizations" (Pron, G; Ieraci, L; Kaulback, K; Health Quality Ontario, 2012) On the other hand, the review also highlighted the downside of the available evidence that there were insufficient evidence on the effectiveness of RM for PM, and the follow-up in the trials was generally short-term within one year. There was also insufficient information to evaluate the overall impact to the health care system, although the time saving and convenience to patients and physicians associated with a substitution of in-office follow-up by RM is more certain. It concludes that for Ontario to invest into the RM technology for patient with CIED, "the boarder issues surrounding infrastructure, impacts on existing clinical care systems, and regulatory concerns need to be considered for the implantation of Internet-based [RM technology] in jurisdictions involving different clinical practices" (Pron, G; Ieraci, L; Kaulback, K; Health Quality Ontario, 2012)

In the Canadian province of British Columbia (BC), although cardiac remote monitoring is yet formally specified as a strategic initiative at the time of this report, it is generally considered a tool of telehealth as a form of telecardiology and telemonitoring. In 2015 the Ministry of Health published a policy discussion paper titled "Rural Health Services in BC: A

Policy Framework to Provide A System of Quality Care" which focuses on a wide variety of challenges and strategies in improving service access to health care in rural and remote communities in BC (British Columbia Ministry of Health, 2015). The challenges in providing the appropriate health care access to these communities stem from factors such as geographic remoteness, long distance, low population densities, less availability of other providers and inclement weather conditions. One category of the policy directions is enabling the IM/IT tools and processes in supporting innovation and flexibility in health access across the province. Within the area of IM/IT, telehealth in general is a strategic direction moving forward. As defined in the policy, telehealth is an overarching term used to describe information and communication technologies used to connect health care providers, patients, and educators over distance, to enable clinical consultation and health care management; general health promotion; and continuing professional education. Three broad categories of telehealth technologies are store-and-forward, remote monitoring, and (real-time) interactive services. The overall utilization of cardiac remote monitoring as a telehealth tool is aligned with the policy discussion paper. The quote below illustrates the Ministry in the wide spreading of telehealth:

> "A key direction going forward is to both set out a system wide approach and go forward plan to using telehealth in rural and remote areas and then standardize its usage across rural areas. The policy direction arising from this paper will be to build and efficient and agile provincial program integrating telehealth across the continuum of care" (British Columbia Ministry of Health, 2015)

Table 4 provides the volume of patients who received cardiac implants from Year 2010-2011 to 2014-2015 in Canada and in the province of British Columbia as recorded by Canadian Institute for Health Information (CIHI) in its Discharge Abstract Database (DAD) and National Ambulatory Care Reporting System (NACRS) (CIHI, 2016). The volumes were calculated by counting the number of unique patients having each of four cardiac implant category types in each fiscal year. A growing trend of volume can be observed for all four types of CIED. With the growing number of new implants in Canada and having its universal health care system be accountable with the responsibility of overseeing the wellness of the implanted patients and the device, Canada also faces the similar challenge as the rest of the world in managing the increasing workload. Remote monitoring may also be considered as an alternative in coping with the workload increase.

Table 4 – Volume of Cardiac Implants in Canada and in BC

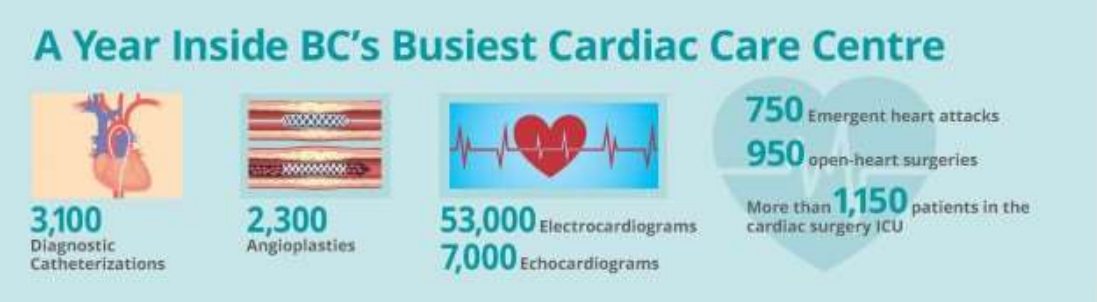
Patient province/ Fiscal year	Pacemaker	Temporary Pacemaker	CRT–Pacemaker (CRT-P)	Cardioverter/defibrillator (AICD, CRT-D, BiV-ICD)
Canada				
2010–2011	13,534	1,726	117	3,563
2011–2012	13,964	1,826	171	3,833
2012–2013	14,461	1,690	186	3,744
2013–2014	14,122	1,663	217	3,829
2014–2015	14,786	1,782	336	4,079
BC				
2010–2011	2,882	246	10	590
2011–2012	3,045	304	20	633
2012–2013	3,120	280	13	658
2013–2014	2,992	271	43	652
2014–2015	3,071	324	85	640

2.4 Cardiac Clinic at Royal Columbian Hospital

Fraser Health Authority (FHA) is one of the six regional health authorities in the province of BC in Canada. It provides a wide range of health care services to more than 1.7 million people living the geographic region from Burnaby to White Rock to Hope and Boston Bar. It is the largest health authority in BC in terms of the size of serving population. It covers the City of Surrey which is one of the fastest growing cities in Canada in terms of population (Fraser Health Authority, 2016). Royal Columbian Hospital (RCH) is one of the thirteen acute and outpatient sites and one of the busiest tertiary hospitals in FHA (Royal Columbian Hospital Foundation, 2016).

The cardiac care centre at RCH is one of the five centres in the province. It is also the province's busiest cardiac care centre. The department delivers cardiac services and programs for inpatient and outpatient in Fraser Health Authority including the intake of patient referrals from the other acute and community sites (Royal Columbian Hospital Foundation, 2016). Please see Figure 2 for a summary of the services offered by RCH Cardiac Services in Year 2015 (Fraser Health Authority, 2011).

Figure 2 – Service delivery by RCH Cardiac Services in 2015



In 2010, FHA Cardiac Services began to conduct ICD and CRT insertion, hence it is responsible to provide regular follow-up service on patients with implanted devices during in the lifetime of the device. It adheres to the recommended clinical protocol by the Canadian Cardiovascular Society and Canadian Heart Rhythm Society (Yee, et al., 2013) and advises patients for regular in-office follow-up. Depending on the type and the battery lifetime of the device, along the severity of a patient's health and cardiac condition, an ICD patient in FHA requires a follow-up generally every six months, while a CRT patient requires a follow-up every three to six months. Although all FHA thirteen acute or outpatient sites are equipped with the device interrogation and device programmer for the implanted patient follow-up service, only the cardiac clinic at RCH can offer the formal follow-up service as this is the only FHA site that a cardiac electrophysiologist (EP) is physically working on-site to attend patients. Therefore, for an implanted patient that resides in the geographic area of FHA, one has to travel to RCH for in-office follow-up. As one of the five cardiac care centres in the province, the RCH cardiac clinic also attends to implanted patients from anywhere across the province.

The RCH cardiac clinic runs as an ambulatory device follow-up clinic every Fridays in a month. Sometimes it has to run the device clinic on the weekend to keep up with the follow-up appointments. Although it provides patient support during the business hours, the RCH cardiac clinic provides other diagnostic cardiac services, such as stress test and ECG test.

As a device follow-up clinic, the RCH cardiac clinic team comprises the following groups of staff in delivery the follow-up service:

- Cardiac electrophysiologists (EP) is a physician who is specialized in treating heart's electrical system and on diagnosing and treating irregular heartbeats or arrhythmias;

- Cardiac technologists are allied health professionals who provides clinical support to the patients and the EP in the follow-up services; and
- Booking clerks and administrators are administrative support staff: who coordinate patient appointment booking and patient's cardiac health records.

Their general responsibilities for a follow-up service is listed in Table 5.

Table 5 –Responsibilities of the RCH cardiac clinic team for a follow-up service

RCH Cardiac Clinic Team	General Responsibilities
One cardiac EP	• Attend patient's IC follow-up with patient examination and clinical consultation • Diagnose and sign-off the unscheduled (ad hoc) and scheduled RM transmission by the technologist's report • Recommend and change patient's follow-up protocol
Three full-time and one part-time cardiac technologists	• Provide phone support to patient upon inquiry on the device, the cardiac condition, and the remote monitoring technology • Coordinate test transmission during initial RM enrollment • Contact patient who did not send scheduled transmission for RM follow-up appointment, and rebook a RM follow-up appointment • Analyze and annotate unscheduled (patient-triggered , ad hoc) and scheduled RM transmissions • Produce IO and RM follow-up report for cardiac EP's review and sign-off • Manage and synchronize patient information and follow-up report in Meditech, Medtronic Carelink, and Medtronic Paceart • Attend patient's IC follow-up with the device interrogation, device programming, and patient examination • Refer patient to contact Medtronic for technical support of the remote monitoring technology • Arrange patient an in-office appointment if abnormality is detected in the RM transmission • Support at Emergency Department on admitted implanted patience (during cardiac clinic hours only) • Maintain patient's complete medical record on follow-up report and additional diagnosis or intervention

Various booking clerks and administrators	• Book IO and RM follow-up appointment with patient • Follow-up with patient who did not show up for IC follow-up appointment at the cardiac clinic, and rebook an IC follow-up appointment • Coordinate patient with IC follow-up at the clinic with the cardiac technologist

In 2016, FHA Cardiac Services rolled out the RM follow-up service with Medtronic Carelink as the remote monitoring system at RCH. The goals of the RM follow-up service by the RCH cardiac clinic are summarized as follows:

1. To sustain and improve the service quality and satisfaction of patient care by easing patient to attend follow-up appointment through reducing travel by patient and caregiver for on-site follow-up, while ensuring the clinical safety of the patient and device;
2. To offer the RCH cardiac clinic team with more flexibility to optimize workload;
3. To enable more responsive and frequent follow-up in timely and cost-effectively manner for early detection of cardiac/medical adverse events and technical issues upon patient's report, thus saving the patient's life and cost of unexpected hospital visit and more complicated and resource-intensive treatment;
4. To be more resource-efficient in complying with the recommended clinical protocol of the patient and device follow-up frequency with the current clinical resource. This includes the reduction of patient in-clinic follow-up at the already overcrowded cardiac clinic across the health authority, as well as the staff availability with the clinical proper training; and
5. To prepare for serving the anticipated growing number of insertion procedures in the health authority with the current clinical resource as projected by the population and patient growth.

With the roll-out of the RM follow-up service, a patient with a newly implanted or a replacement Medtronic ICD or CRT-D can have the follow-up options of the in-clinic (IC) only follow-up and the recommended hybrid of IC and RM follow-up. The cardiac EP would also recommend certain patients to enroll the RM follow-up service – patients who live far from RCH that it requires more than half hour of driving, or who have difficulty in travelling to RCH; and patients who are determined to be advisory and require more readily medical attention. Based on the clinical protocol, the recommended frequency of the two follow-up options is typically

indifferent, although each patient may uniquely incur more or less follow-up service depending on the cardiac health and the device condition. Table 6 compares the clinical protocols of the IC-only follow-up and the hybrid of IC and RM follow-up of ICD and CRT-D patients.

Table 6 – Standard clinical protocol of IC follow-up and hybrid follow-up for patient at RCH Cardiac Clinic

Duration of follow-up since implant	IC Follow-up	Hybrid Follow-Up
4 to 6 weeks – this is when the patient is offered with the follow-up option	In-clinic	In-clinic
6 months	In-clinic	Remote monitoring
12 months (1 year)	In-clinic	In-clinic
18 months (1½year)	In-clinic	Remote monitoring

The RCH cardiac clinic provides implanted patient with supplementary information in managing the shocks from its device in between the regular follow-up services. One source of the supplementary information is a brochure which is included in Appendix B. RCH Cardiac Clinic Supplementary Information in Device Shock Management. In essence, an implanted patient with a cardiac or device condition can reach out to the RCH cardiac clinic during its service hours from 8AM to 4PM Monday to Friday. The clinic is staffed with cardiac technologists and cardiac EP on-site during the hours to provide the patient care regardless if one enrolled to any particular follow-up clinical protocol, or one was physically at the clinic, called in over the phone, or sent in scheduled or unscheduled remote transmission. Also a patient can visit any one of the FHA thirteen acute sites for emergency services at any time.

2.5 Motivation and Aim

In a research of the dynamic analysis of healthcare service delivery, it highlights one of the unique characteristics of health care service in comparison with common business service – the criticality of quality service in providing the right care to the right patient at the right time. (Rust, 2013). From the perspective of a device follow-up clinic of a health delivery organization, the aim of this research is to assess if the integration of the remote monitoring technology to the standard healthcare service model of the implanted patient and device care through remote follow-up service and remote data transmission could be instrumental to the service supply of a device follow-up clinic in timely response to the variation of the service demand while sustaining the quality of patient service. The remote monitoring service offered by the technology can be considered as a new touchpoint or communication channel between the clinic and the implanted patient in delivery healthcare service. On one hand, the effectiveness of cardiac clinic resource

may be strengthened by this new touchpoint, for the care team can consult the patient's condition remotely at a convenient time for both ends. On the other hand, clinical resources should be prepared in supporting this touchpoint to ensure that the patient experience and outcome is as seamlessly as it would be in the in-clinic setting. The impact of the clinical resource utilization by the remote monitoring technology of the implanted patient and the device is the subject evaluation of the research.

This research is motivated by the various workload challenges faced by the RCH cardiac clinic, as a DFC and as a part of FHA as a HDO, in utilizing the clinical sources to sustain its general service demand by the implanted patients with ICD or CRT-D, particularly since the recent roll-out of the remote follow-up service by FHA Cardiac Services. For the purpose of this research, the clinical resource comprises of the cardiac technologists and the cardiac EP as they provision the follow-up service to the patient.

As supplied by FHA Cardiac Services, Table 7 shows the number of device implant procedures are accumulating in the past few years and will continue to be performed at FHA. This indicates that the demand of the regular follow-up service is growing too. The number of the total follow-up services is calculated based on the standard clinical protocol of two follow-up services per year for both ICD and CRT patients. FHA Cardiac Services indicates that the actual number of implant procedure have likely exceeded the estimated number for the reported years. In addition, the RCH cardiac clinic attends some of the implanted patients more frequently as medically required than what the clinic has planned for with its staffing based on the standard clinical protocol. Under the capacity pressure of the fixed physical space at the clinic and the limitation of the available cardiac technologists and cardiac EP resources, the clinic would like to evaluate if the RM follow-up service could mitigate the follow-up service workload from the growing number of patient, in order for the clinic to sustain the follow-up service so that the patient demand can be timely served by the clinic resources.

Table 7 – Resource planning on annual new cardiac implants at Fraser Health Authority

Fiscal Year	Estimated Number of ICD and CRT Implant	Device Follow-ups for Fiscal Year	Total Follow-ups for Fiscal Year
2013-14	200	400	400
2014-15	205	410	810
2015-16	287	574	1384
2016-17	325 – 335	Up to 670	2054

In addition, the RCH cardiac clinic also experiences its workload rising from the remote monitoring technology since its roll-out of the remote follow-up service. The clinic would like to assess how much of the clinic's workload change is introduced by the remote monitoring technology. One possible source of the workload is the continual patient support in managing the technology that enables the remote follow-up service. During remote service enrollment, a cardiac technologist provides a patient with supplementary information in clinical management of device shock, and refers a patient to contact Medtronic for the technical support on the remote technology and the Carelink system. Some patients insist of contacting the cardiac clinic for the technical support as they weigh on the trust and familiar relationship with the technologists. As a result, the technologists have to conduct extra education sessions to enhance the patient's user experience and confidence in using the technology. How much the patient support and education on the remote technology has contributed to the workload of the team is a question to the clinic.

Another possible source of workload from the remote monitoring technology comes from having to respond timely to the unscheduled remote transmissions are that are outside the regular remote follow-up services. As per the standard clinical protocol, the response time is defined as the time to respond a patient with the appropriate consultation and treatment upon the clinic receiving a remote transmission with a medically significant adverse event of the patient or the device. The standard response time at the RCH cardiac clinic is within the business day that the clinic receives the remote transmission. Normally a remote follow-up service is achieved by an automatic remote transmission at a scheduled time booked by the patient appointment. A remote transmission can also be triggered manually by the patient, automatically by device alert (lead alert or battery alert) configured by the cardiac EP, or automatically by device shock. The clinic seeks to understand how much of the clinic's workload is contributed by these unscheduled remote transmissions.

Another challenge faced by the RCH Cardiac Clinic is the inability to deliver the in-clinic follow-up service to patients who are incapable to attend in-person. In particular, some patients who are implanted may not always be capable to adhere to the clinical protocol. They are commonly part of the older demographic who suffer mobility issues. The travelling cost and time as well as the waiting time at the clinic can be quite demanding and inconvenient for a patient physically and mentally. The cost of attending a follow-up service may also be increased

if a patient were escorted by a family member, a friend or a caregiver. This intensifies one's unwillingness to attend an in-clinic follow-up appointment.

In the next chapter, the literature review presents the published evidence on the research aim of how the remote monitoring technology impacts the clinical resource utilization of a DFC or a HDO serving the cardiac patients with CIED.

Chapter 3. Literature Review

This chapter presents the literature review on the research aim to examine the published evidence on what a device follow-up clinic (DFC) or a health delivery organization (HDO) has experienced with the impact of the remote monitoring of cardiovascular implantable electronic device (CIED) in utilizing the clinical resource for the routine patient and device follow-up. The search strategy and the selection criteria of the studies are first described in this chapter. Then the data extraction of the literature review is presented. The outcome of the literature review as well as the outstanding questions of the research aim are discussed at the end of the chapter.

3.1 Search Strategy

The literature search began in June 2015 and was complete in August 2018. To scrutinize the published evidence to the research aim, the search targets on the evaluation of the remote follow-up services and pertaining medical and device support towards the impact on the clinical resource utilization. The primary outcomes of interest of the literature search include immediate impact to the upfront clinical workload and resource consumption of a DFC by the remote follow-up service and the remote monitoring technology, such as the type of supports or services and the staff workload by frequency or time per service or patient encounter. The secondary outcomes of the literature search include changes in HDO's overall clinical resource utilization by the RM follow-up service, such as cardiac-related hospitalization, emergency visits, scheduled and unscheduled on-site visit.

The literature search was performed using three sources. The first source was to use the main search engines of PubMed, Google Scholar, and the University of Victoria Library Summon 2.0. The second source was to review the studies referenced in the position papers published by the international and Canadian professional cardiac care bodies. The third source was the automatic search generated by Mendeley based on its engine in matching up the theme from the studies from the first and the second source. The search keywords included the various combination of these phrases – "clinical remote monitoring", "cardiac remote monitoring", "cardiac remote monitoring device", "cardiac remote monitoring implanted device", and "cardiac remote monitoring device", "resource", "capacity", "capacity", "clinical", "regular follow-up", "follow-up", "clinical resource", "clinical capacity", "economic analysis", and "cost analysis".

3.2 Selection Criteria

To focus on the research aim, the inclusion and exclusion criteria are applied to the search result from the strategy to narrow down the relevant studies from the search result.

3.2.1 Inclusion Criteria

The inclusion criteria of the evaluation of the studies are as follows:

- Literature published since 2007 in the English language;
- Completed human studies with full reports available, or with a description of study method on how the study and the analysis is done to draw the result and conclusion;
- Randomized controlled trials (RCTs), systematic review and meta-analysis, cohort and controlled clinical studies, and economic evaluation;
- Use of CIED including CRT, ICD, and pacemaker;
- Use of remote monitoring system (RMS) as the telehealth/telemedicine/telecardiology intervention of cardiac care in evaluation against no RMS use in clinical setting;
- All forms of telecommunication protocol that enables the remote monitoring technology such as Internet-based and trans-telephonic;
- All modes of remote transmission: manual transmission and automatic transmission including timed transmission and continuous real-time transmission;
- All modes of remote transmission trigger: patient triggered, alert triggered, time triggered
- DFC's or HDO's perspective of the evaluation in the effectiveness of RM follow-up as alternative to IO follow-up in serving the general wellness of device and patient;
- Regular patient and device follow-up as HDO's service delivery is one of the use case in the RMS evaluation;
- Study design that includes the workflow with HDO delivering patient education on device management and RMS;

3.2.2 Exclusion Criteria

The exclusion criteria of the evaluation of the studies are as follows:

- Remote monitoring system is used with no CIED (Upatising, et al., 2015);
- Regular patient and device follow-up is not in scope of the study design – an example study is the HomeGuide Registry which specified that the workflow model did not include setting up subsequent scheduled remote follow-up services (Ricci, et al., 2014);

- The evaluation is not against a clinical setting with no RMS use. An example is a study in the validation of an organization management model with alerts from remote monitoring of CIED (Guédon-Moreau, et al., 2015);
- Non-HDO's perspective of the evaluation in the effectiveness of remote follow-up – an example study is the REMOTE-CIED study as the evaluation is from patient's perspective (Versteeg, et al., 2014); and
- Evaluating the remote monitoring technology solely on cardiac outcome such as the atrial fibrillation detection (Zoppo, et al., 2014).

3.3 Data Extraction

To evaluate each study for the selection criteria of the literature review, the abstract or the executive summary of each literature was first perused to determine if the study is relevant to the research aim, particularly the primary and secondary outcome of interest on the clinical resource utilization by the remote monitoring technology. The whole literature was then read and analyzed. Then the study design with the data collection and analysis process on how the outcomes were generated is assessed against the inclusion and exclusion criteria of this literature search. The discussion and the limitation of each study on how the outcome concluded the study objectives was then assessed for the validity of the evidence to finalize the inclusion of a study. As a result, the total of fifteen studies which met the inclusion criteria of the research aim are included in the literature review. The summary of each literature is in Appendix C. Summary of Literature Review.

To organize the findings from these fifteen studies for the literature review, the data is extracted and organized in the following Table 8 using the PICO framework (PubMed Health, n.d.), with the **C**omparison as the implanted patient with no access to remote monitoring services (RMS) as the control group. The data of the study methodology and the result of the outcome is extracted from each individual study from both the Abstract section and the respective section within the main body of the literature. As each study uses its own terminology to describe the evaluation of the CIED remote monitoring, the labelling of the remote monitoring setting or the intervention group as RM (remote monitoring) and the in-clinic/in-office setting or the control group as IC (in-clinic) is added to each study in the table for clarity and consistency.

Table 8 – Data Extraction of Literature Review

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
1	A randomized trial of long-term remote monitoring of	Randomized, multi-centre, non-inferiority study	248 in RM group; 246 in IC group	18.3 ± 3.3 months	Biotronik Home Monitoring	1) After the last scheduled follow-up, the between-groups decrease was 36% decrease in the number of in-office follow-

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
	pacemaker recipients (the COMPAS trial) (Mabo, et al., 2012)		PPM			ups conferred by remote monitoring. 2) At the 18-month scheduled follow-ups, 79% were non-contributory in the IC group and 73% in the RM group.
2	Remote monitoring of cardiovascular devices: a time and activity analysis (Cronin, et al., 2012)	Time and activity analysis with workflow analysis	434 in RM group; 82 in IC group ICD, PPM, ILR	6 – 12 weeks	Biotronik Home Monitoring, Boston Scientific Lattitude, Medtronic Carelink, and St. Jude Merlin.net.	1) For a follow-up with no finding, it took 11.5 ± 7.7 minutes for remote follow-up and 27.7 ± 9.9 minutes for IO follow-up. For a follow-up with clinically significant finding it took 21.0 ± 7.4 minutes for the remote follow-up and 10.1 ± 2.1 minutes for IO follow-up 2) 135 (27.0%) of the 500 remote transmissions demonstrated a total of 172 clinically important events. And only 41 events of the 172 events required physician notification as per the predefined protocols, hence the remaining transmissions are indeed non-actionable.
3	Large Controlled Observational Study on Remote Monitoring of	Multi-centre, multi-vendor, controlled, observational,	230 (192 PM and 38 ICD) in the RM group; 1871 (with 979	12 months	Biotronik Home Monitoring, Medtronic Carelink, Boston	1) Except with a nurse having to arrange an in-office follow-up with a PM patient, physician and nurse time spent were

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
	Pacemakers and Implantable Cardiac Defibrillators: A Clinical, Economic, and Organizational Evaluation (Dario, et al., 2016)	prospective study	PM and 892 ICD) in the IC group		Scientific Latitude, and Sorin SmartView	reduced by at least four minutes by for both ICD and PM patients. 2) Cost savings of $803.41for remote PM follow-up and $306.08 for remote ICD follow-up were reported. 3) Statistically significant difference was measured for the ICD U-group to have more number of cardiology visits and in-clinic follow-up than the ICD I-group.
4	Effectiveness of pacemaker tele-monitoring on quality of life, functional capacity, event detection and workload: The PONIENTE trial (Lopez-Villegas, Catalan-Matamoros, Robles-Musso, & Peiro, 2015)	Controlled, non-randomized, non-blinded single-centre study	30 in the RM group; 52 in the IC group PPM	12 months	Medtronic Carelink	1) Four in-hospital follow-up visits per patient were calculated in the HM group, while five follow-ups per patient were calculated in the RM group, with two of them done via remote transmissions. 2) 71% of all patients had experienced at least one cardiovascular events, with 67% of the patients in the RM group and 73% of the patients in the HM group.
5	Remote monitoring of implantable cardioverter defibrillator patients:	Prospective, non-randomized, single centre	41 ICD	9 months	Medtronic Carelink	1) The time needed by the patients for remote data transmission (6.9 ± 3.7 min, range 2.3–17.5 min) was

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
	a safe, time-saving, and cost-effective means for follow-up (Raatikainen, Uusimaa, van Ginneken, Janssen, & Linnaluoto, 2008)	study with intervention group only with pre-test and post-test design				significantly shorter than the duration (travel time + time in the hospital) of an in-clinic visit 391 ± 282 min (range 41–1346 min), P < 0.001 2) The time needed by the physician for reviewing device data on the secured website (8.4 ± 4.5 min, range 2–30 min) was significantly shorter than the time needed for completing an in-clinic follow-up (25.8 ± 17.0 min, range 5–90 min), P < 0.001.
6	Cost-utility analysis of the EVOLVO study on remote monitoring for heart failure patients with implantable defibrillators: randomized controlled trial (Zanaboni, et al., 2013) Remote monitoring reduces healthcare use and improves quality of care in	Prospective, randomized, open, multi-centre with cost-utility analysis	89 in the RM group; 87 in the IC group ICD and CRT-D	16 months	Medtronic Carelink	1) Average cost of a protocol-defined clinic visits was €90.29 (±38.58) in the IC group and €56.63 (±38.64) in the remote group at P < 0.001. 2) Cost saving was reported from using remote monitoring technology by comparing the average annual cost per patient of €1962.78 in the RM group from €2130.01 in the standard arm. 3) The total health care visits were 21% less frequent in the remote arm than the standard arm.

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
	heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study (Landolina, et al., 2012)					
7	Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK (Burri, et al., 2013)	Cost-consequence analysis with Markov cohort model	1000 on IC (CFU) group and 1000 RM (HM) group ICD and CRT-D	10 years	Biotronik Home Monitoring	1) RM is predicted to be cost neutral at about GBP 11,500 per patient in either treatment arm, with all costs for the initial investment in RM and fees for on-going remote monitoring included. 2) If the remote monitoring technology were used for more than ten years or longer, then RM becomes increasingly cost saving.
8	Effect of telemonitoring of cardiac implantable electronic devices on healthcare utilization: a meta-analysis of	Systematic review and meta-analysis	11 RCTs	N/A	Did not specify	The study of relative risk (RR) for each clinical outcome of health care utilization shows that between the RM arm and the IC groups that the rates of cardiac hospitalizations and the

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
	randomized controlled trials in patients with heart failure (Klersy, et al., 2016)					composite rates of unplanned hospital visits, ER attendances, and hospitalizations for cardiovascular events were very similar.
9	Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association (Mairesse, Braunschweig, Klersy, Cowie, & Leyva, 2015)	Survey studies with online questionnaire	43 centres PM, ICD, CRT-P and CRT-D	N/A	Did not specify	The number of PM follow-up was reduced by RM at 61% of the centres, the number of ICD follow-up was reduced 62% of the centres, and the number of CRT-P and CRT-D follow-up was reduced at 54% of the centres.
10	Impact of remote monitoring on clinical events and associated health care utilization: A nationwide assessment (Piccini, et al., 2016)	Retrospective, nationwide, observational cohort study with data mining of the Truven Health Analytics MarketScan	34,259 in the RM group; 58,307 in the IC group PM, ICD, CRT-P or CRT-D	3 years	Did not specify	1) Patients in the RM group experienced with the lower adjusted risk of all-cause hospitalization, including all cardiovascular and non-cardiovascular events and shorter mean length of hospitalization

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
		Commercial and Medicare Supplemental Claims databases				2) The hospitalization cost per patient in the RM group with all device types were also lower than cost per patient in the non-RM group 3) Patients with CIEDs in the RM group are generally associated with lower health care utilization in all the clinical events.
11	Health Care Utilization and Expenditures Associated With Remote Monitoring in Patients With Implantable Cardiac Devices (Ladapo, Turakhia, Ryan, Mollenkopf, & Reynolds, 2016)	Retrospective, nationwide, observational cohort study with data mining of the Truven Health Analytics MarketScan Commercial and Medicare Supplemental Claims databases	1.127 pairs of ICD patients, 427 pairs of CRT-D patients, and 1,295 pairs of PPM patients PPM, ICD, CRT-D	2 years	Did not specify	1) ICD patients enrolled in RM had fewer emergency department visit resulting in discharge ($p = 0.050$) and had fewer hospital stays ($p = 0.057$) than its counterpart of patients with in-clinic follow-up 2) PPM patients ($p = 0.025$) and CRT-D patients ($p = 0.006$) patients enrolled in RM associated with lower health care expenditures 3) ICD patients enrolled in RM associated with lower total inpatient and outpatient expenditures ($p < 0.0001$)
12	Economic analysis of remote monitoring of cardiac implantable electronic devices:	Observational, prospective, non-randomized,	102 in the RM group; 107 in the IC group	12 months	St. Jude Merlin.net	From the health care system perspective, IO patients reported more hospitalizations for cardiovascular reasons,

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
	Results of the Health Economics Evaluation Registry for Remote Follow-up (TARIFF) study (Ricci, et al., 2017)	multi-centre study with cost effectiveness analysis	ICD and CRT-D			more emergency department visits, more outpatient diagnostic tests, and more outpatient visits than RM patients did. From the hospital's perspective, the total number of in-hospital device follow-up visits was reduced by 58.78% in the RM group.
13	Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the randomized ECOST study (Guédon-Moreau, et al., 2014)	Prospective, randomized study with cost analysis	158 in the RM group, 152 in the IC group ICD	27 months	Biotronik Home Monitoring	1) The average non-hospital costs, related to device management and other non-hospital costs is €257 more for IC group than the RM group. 2) The hospitalization costs per patient-year were €2829 ± 6382 and €3549 ± 9714 in the RM and IC groups respectively (P = 0.46).
14	Economic impact of remote monitoring on ordinary follow-up of implantable cardioverter defibrillators as compared with conventional in-hospital visits. A single-center	Prospective, randomized single-centre study with cost analysis	117 in RM group; 116 in the IC group ICD	12 months	Biotronik Home Monitoring, Medtronic Carelink, Boston Latitude, and St. Jude Merlin.Net	Physician's time and nurse's time required for follow-up is less for the RM group than the IC group. Overall, the costs associated with RM and standard follow-up were USD 103 ± 27 and 154 ± 21 per patient/year, respectively (p = 0.01).

No.	Study Title	Type of study	**P**atient Size and CIED Type	Duration	RMS as **I**ntervention	**O**utcome
	prospective and randomized study (Calò, et al., 2013)					
15	Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial. (Boriani, et al., 2017)	Prospective, multicentre, RCT	437 in RM group; 428 in the IC group De novo (new implant) of CRT-D	2 years	Medtronic Carelink	In general the healthcare resource utilization for cardiovascular reasons was 38% lower in the RM group than the IC group. The two-year cost saving of €2899 per 100 would be possible if the remote device check were reimbursed as half of the cost of in-clinic device check.

3.4 Outcomes and Considerations

Some of the significant study outcomes from the analysis of the data extraction of the literature review are discussed in this section. Consistent evidence shows the general trend of positive impact on the primary outcome of interest in the immediate clinical workload and resource consumption of a DFC or a HDO by the remote follow-up service and the remote monitoring technology. In general, it is instrumental in reducing the overall workload and clinical resource consumption than the in-clinic follow-up service only for implanted patients. In the COMPAS study (Study 1 in Table 8) (Mabo, et al., 2012), the decrease of 36% between the RM group and the IC group was reported in the number of pacemaker follow-up services per patient after the last scheduled follow-up Next, a time and activity analysis is performed at the Cleveland Clinic in United States (Study 2 in Table 8) to compare the time taken to complete a remote monitoring (RM) follow-up and an in-person follow-up, the frequency of the clinically actionable events detected in the remote transmission, and how the remote monitoring affects the overall devices clinic workflow (Cronin, et al., 2012) for patients with ICD, PPM or ILR. For a follow-up service with no finding, the processing time of the remote interrogation (monitoring) transmissions, with 11.5 ± 7.7 minutes, was faster than in-person programming evaluation, with 27.7 ± 9.9 minutes ($P < .01$). Remote interrogation evaluations that reveal clinically important findings, with 21.0 ± 7.4 minutes, and took longer to process than those that did not revealed, with 10.1 ± 2.1 minutes ($P < .01$). Although it took longer to process the clinically important findings, the nonactionable transmissions could be more rapidly processed to allow clinicians to focus on clinically important findings. It concluded that poor patient compliance complicates the workflow efficiency of currently available systems, with the measure that a total of 5.8% of the transmissions were duplicate. In a clinical, economic, and organizational evaluation of the remote monitoring of pacemakers and ICDs at the Veneto region in Italy (Study 3 in Table 8), it reported that on average, the time spent by the physician and the nurse on the PPM and ICD follow-up service is shorter for the remote follow-up service than in the in-clinic follow-up service (Dario, et al., 2016) as presented in Table 9.

Table 9 – Mean time (minutes) spent by physicians and nurses – usual care (the IC group) versus intervention (the remote group) (Dario, et al., 2016)

Type of resource	Mean time (min) – IC group	Mean time with telemedicine only (min) – RM group	Mean time (telemedicine + in clinic follow-up performed) (min) – RM group	Difference (IC-group - RM-group) (min)
Physician PM	13.1	4.7	9.0	4.1
Nurse PM	18.1	11.2	18.3	-0.2
Physician ICD	32.8	7.5	19.1	13.7
Nurse ICD	44.2	19.6	36.1	8.1

In Study 4 of Table 8, the study of the effectiveness of the pacemaker telemonitoring at a hospital in Spain concluded that over the twelve-month study period the remote monitoring technology had significantly reduced the number of in-hospital visits – on average four in-hospital follow-up visits per patient was calculated in the IC group, while five follow-ups per patient were calculated in the RM group, with two of them done via remote transmissions (Lopez-Villegas, Catalan-Matamoros, Robles-Musso, & Peiro, 2015). The similar result is drawn in the EVOLVO study on the ICD and CRT-D patients in the Italian hospitals (Zanaboni, et al., 2013), where the total health care visits were 21% less frequent in the patients in the remote monitoring group than the standard care group (Study 6 of Table 8). Next, in the Finland study investigating if internet-based remote monitoring offers "safe, practical, and cost-effective alternative" to the in-clinic follow-up visits of patients with ICD (Study 5 of Table 8), it reported that the time needed by the physician for reviewing device data on the secured website (8.4 ± 4.5 min, range 2–30 min) was significantly shorter than the time needed for completing an in-clinic follow-up (25.8 ± 17.0 min, range 5–90 min), $P < 0.001$ (Raatikainen, Uusimaa, van Ginneken, Janssen, & Linnaluoto, 2008). Finally, in Study 14 of Table 8, the aim of the randomized single-centre study at an Italian hospital study is to assess the costs of one-year ICD follow-up (Calò, et al., 2013). Table 10 below shows one of the outcome of the study, the measurement of the time spent per patient per the clinical staff member of the hospital. The total time spent by each staff member is less in the RM group than the in-hospital group in a follow-up service.

Table 10 – Time spent per patient by the hospital staff for activities concerning RM and in-hospital follow-ups in a year (Calò, et al., 2013)

	RM group – Mean time per patient in a year (min)	Control group – Mean time per patient in a year (min)	p value
Responsible physician			
RM follow-ups	22.0 ± 11.5	N/A	N/A
In-hospital visits	24.8 ± 7.6	74.1 ± 22.8	0.001
Administrative activities	N/A	12.0 ± 6.7	N/A
Total responsible physician	46.8 ± 19.1	86.1 ± 29.5	0.03
Responsible nurse			
RM follow-ups	15.5 ± 3.6	N/A	N/A
In-hospital visits	24.8 ± 7.6	74.1 ± 22.8	0.006
Administrative activities	35.2 ± 15.2	18.0 ± 5.1	0.07
Total responsible nurse	75.5 ± 26.2	92.1 ± 27.9	0.41
Total	122.3 ± 45.3	178.2 ± 57.3	0.02

On the other hand, a mixture of evidence can found in the analysis on the secondary outcomes in the changes in HDO's overall clinical resource utilization by the RM follow-up service, such as cardiac-related hospitalization, emergency visits, scheduled and unscheduled on-site visit. To begin, the abovementioned Study 3 (Dario, et al., 2016) showed no statistical significance on the impact of the remote monitoring technology on the HDO's clinical resource utilization in cardiac-related hospitalization, emergency visits, scheduled and unscheduled on-site visit by remote monitoring of ICD and PPM patients. The exception was analyzed in the ICD-implanted patient RM group, which incurred more cardiology visit and in-clinic follow-up than its counterpart group on conventional follow-up group. In the (MORE-CARE) trial (Study 15 of Table 8) in 61 cardiology centres in nine countries from Europe and Israel, the remote monitoring technology of the CRT-D patients contributed to 38% lower healthcare resource utilization for cardiovascular reasons by less hospitalizations for cardiovascular reasons, emergency department admissions, and in total outpatient visits than the standard care group of in-clinic service only (Boriani, et al., 2017). In the United Kingdom, the National Health Service assessed the long-term cost and consequences of using the remote monitoring system daily on ICD and CRT-D over conventional follow-up with the understanding that remote CIED

management has been established as a safe alternative (Burri, et al., 2013). As summarized in Study 7 in Table 8, with the sample size of 1000 patients was chosen, the result of the Markov cohort model simulation indicated that in over ten years, the remote monitoring technology is predicted to be cost neutral at about GBP 11,500 per patient in either the remote and standard care arm, with all costs for the initial investment in RM and fees for on-going remote monitoring included. Furthermore, the remote monitoring technology was used for more than ten years or longer, then the remote monitoring technology can become increasingly cost saving. In the United States, a retrospective observational nationwide study was conducted using the Truven Health Analytics MarketScan database to evaluate if the remote monitoring of clinical events of the patients with CIEDs (PM, ICD, CRT-P or CRT-D) could reduce health care utilization and costs in clinical practice. As summarized in Study 10 in Table 8, patients in the remote monitoring group experienced with the lower adjusted risk of all-cause hospitalization. The hospitalization cost per patient in the remote monitoring group is also lower than the standard care group (Piccini, et al., 2016). Next, from the abovementioned EVOLVO study on the ICD and CRT-D patients in the Italian hospitals, the average health care system cost for each type of implanted patient service is tabulated in Table 11. For the patients in the remote monitoring group, the cost is usually cheaper to the health care system unless the patient required in-clinic follow-up services outside of the standard protocol (Zanaboni, et al., 2013).

Table 11 – Comparison of health care system costs (Zanaboni, et al., 2013)

Health care system costs Costs (€), mean (SD)	Standard arm (n=101)	Remote arm (n=99)	Mean difference (95% CI)	P value
Protocol-defined clinic visits	90.29 (38.58)	56.63 (38.64)	33.66 (22.89, 44.43)	<.001
ED visits and urgent in-office visits	23.60 (33.68)	14.80 (24.71)	8.81 (0.56, 17.06)	.04
Non-urgent in-office visits	20.13 (38.71)	30.81 (72.13)	–10.68 (–26.78, 5.42)	.19
Scheduled remote follow-ups	0.00 (0.00)	32.50 (9.20)	–32.50 (–34.34, –30.67)	<.001
Unscheduled remote follow-ups	0.00 (0.00)	56.42 (58.95)	–56.42 (–68.18, 44.67)	<.001
Hospitalizations	1945.82 (5247.62)	1722.02 (4106.00)	223.80 (–1091.83, 1539.44)	.74
Mean annual cost per patient	2130.01 (5251.33)	1962.78 (4185.61)	167.23 (–1158.61, 1493.06)	.80

Finally, the Health Economics Evaluation Registry for Remote Follow-up study, or the TARIFF study, investigated the impact on the ICD and CRT-D patients from the perspective of costs and benefits of the remote care services in comparison of the standard care (Ricci, et al., 2017). From the perspectives of both the hospital and the health care system, the remote care service shows less healthcare resources consumption by less in-hospital follow-up visits, emergency department visits, diagnostic tests, and outpatient visits. It can discreetly note that how the remote monitoring of CIED influences the HDO's overall clinical resource utilization may be driven by other environmental and clinical factors.

The research field of the clinical resource utilization of CIED remote monitoring is richly diversified with study designs and methodologies as well as perspectives in how the results of the common outcomes are delivered. Furthermore, environmental and clinical factors must be considered in the interpretation the evidence in concluding the outcomes. Some of the variations are discussed as follows.

- The environmental factor of the health care system should be noted. Every clinic is bound to its local health care system. Each local health care system commonly dictates how a patient and device follow-up service is provided and charged, and how a cardiac device clinic operates and manages the reimbursement model on the follow-up service as well as the professional fee to the clinician such as the cardiac EP. The reimbursement model for the RM follow-up service and the IO follow-up service can be different. In the United States, insurance reimbursement codes are set up the RM follow-up service by device type identified with Current Procedural Terminology (Piccini, et al., 2016). During the EVOLVO study, remote follow-ups were not covered by the official reimbursement scheme in Italy (Zanaboni, et al., 2013). The health care system may indeed change over time in updating its patient service and corresponding reimbursement model. It may affect how the clinic would adopt the remote monitoring service into its standard clinical protocol for patient care.
- The clinical factor of the follow-up service workflow and other clinical support by the remote monitoring of technology should be noted. Although a standard follow-up protocol exists for each type of the cardiac device, variances in the clinical workflow and the team structure at a device clinic impacts the resource utilization in patient care. The roles and responsibilities may be slightly different as well between physician, nurse, and technologists. For example, in one setting a nurse would bear more follow-up workload in one context (Dario, et al.,

2016), while in another setting the administrative personnel leverages most of the follow-up workload (Calò, et al., 2013). While the Cleveland Clinic in United States designates one nurse per day to be responsible for processing all remote transmissions (Cronin, et al., 2012), in Japan a RM care team is designated to provide RM follow-up service (Nishii, 2014).

- The economic factor of the cost definition should be noted. It is typical in health economic analysis where the definition and criteria of cost (resource input) and outcome (service output) can vary depending on the context. Factors that deviates the definition may include the reimbursement model in the local health care system and the clinical resource of a cardiac device clinic. Hence not every health care system or cardiac device clinic can enjoy the benefits and cost savings from the remote monitoring technology similarly as how some of the studies reported. For example, travel costs of patient and caregiver are generally covered by the Social Insurance Institution of Finland (Raatikainen, Uusimaa, van Ginneken, Janssen, & Linnaluoto, 2008) thus it can be considered an indirect cost to the health care system. But in Italy under the Public National Health Services the travel cost is considered a patient's cost (Calò, et al., 2013).

Although the outcomes of the literature review provided some foundation that the remote monitoring of CIED could be beneficial to a DFC or a HDO in mitigating the follow-up service workload within the capacity of the clinical resources, some of the other gaps of the research aim were to be yet addressed. Specifically, the upfront workload to a DFC when the remote follow-up service was first introduced was not articulated. The workload contributed by the patient education and support and by the unscheduled remote transmission were also to be explored in the research. In the next chapter, the study design is detailed in response to the research aim.

Chapter 4. Study Design

This chapter details the study design of the research to address the research question – to evaluate the workload impact on the clinical resource of a device follow-up clinic (DFC) for the regular patient and device follow-up by the remote follow-up service. This chapter begins with the research question and objectives. The study protocol is then described. The justification and the workflow of System Dynamics as the study methodology is explained. The workflow analysis of the on-site and remote monitoring service are discussed and compared. The data collection and management of the workload assessment in the clinical resource utilization is then described. Finally, the ethics requirement and approvals by both Fraser Health Authority and University of Victoria are presented in completing the chapter.

4.1 Research Question and Objectives

The study design aims to address the research aim of the impact of the clinical resource utilization by the remote monitoring technology of the implanted patient and the device as the subject evaluation. With the motivation of the RCH cardiac clinic as the research setting and with the foundation from the literature review, the research question of the study is to evaluate the workload impact on the clinical resource of a device follow-up clinic (DFC) for the regular patient and device follow-up by the remote follow-up service. To address the question, the research objectives are broken down followed:

1. To identify the workload of the in-clinic only follow-up clinical protocol and in the hybrid follow-up clinical protocol with both the in-clinic and remote follow-up at a DFC;
2. To depict the relationship and interaction of the clinical resource consumption in supporting the workload of the in-clinic only follow-up clinical protocol and the hybrid follow-up clinical protocol of a DFC in a conceptual model; and
3. To project and compare if the clinical resource would be capable in serving the implanted patients in one-year and three-year periods after the study horizon in both the follow-up clinical protocols using a conceptual model.

Please refer to Table 6 in 2.4 Cardiac Clinic at Royal Columbian Hospital for the tabulated comparison of the in-clinic only follow-up clinical protocol and in the hybrid follow-up clinical protocol

4.2 Protocol

The study setting of the research is a single-site, single-vendor time-to-event study on the operation of the RCH cardiac clinic as the DFC in serving implanted patients with on the regular follow-up service. This prospective, observational, post-test only study design consists of two groups. The control group, or the in-clinic (IC) group, is the implanted patients who strictly attend all follow-up services at the conventional on-site setting at RCH cardiac clinic. These patients typically adhere to the clinic's standard IC follow-up clinical protocol. The intervention group, or the remote monitoring (RM) group, is implanted patients who enroll in the remote follow-up service using the remote monitoring system to send transmission. These patients typically adhere to the clinic's standard hybrid follow-up clinical protocol which consists of rotating IO follow-up and RM follow-up. In the evaluation of the impact of the remote monitoring service as the intervention, the control group acts as the baseline in demonstrating the workload difference between the two follow-up clinical protocols.

As discussed in the Research Setting and Motivation chapter of this report, for the purpose of this research the clinical resources are the RCH cardiac clinic team who provide the direct service to implanted patient. At any business day of the device follow-up clinic at RCH cardiac clinic, the team comprises of one cardiac electrophysiologist (EP) and three Medtronic-trained/certified cardiac technologists for ICD and CRT-D. In the assessment of the clinical resource utilization in the research study, the workload of the cardiac clinic team is with respect to the service delivery to the enrolled Medtronic ICD and CRT-D patients, and the service may include regular follow-up and any additional consultation or treatment as needed, either remotely or in-clinic as necessary. The workload measurement is in terms of the type and the volume of service delivered by the cardiac clinic team to the implanted patients. A service or a patient encounter is a basic unit of workload measurement. The workload of a service of patient encounter is measured by time in minutes based on the approximation by the cardiac clinic team. For example, on average each patient encounter for a typical in-clinic follow-up would be allocated the workload of fifteen minutes regardless if this is an IC or a RM follow-up. Yet the workload may also depend other factors, such as the patient's age and health condition, as well as the functional status of the implanted device.

4.3 Methodology and Deliverables with System Dynamics

This study uses system dynamics modelling to depict the workload assessment impact by the remote monitoring technology. System dynamics is a methodological approach to mathematically and graphically structure and understand a complex, dynamic problem in an environment which is "characterized by interdependence, mutual interaction, information feedback, and circular causality" (System Dynamics Society, 2016). This type of modelling does not produce precise numerical forecasts, but is an investigative tool allowing comparison of the relative benefits, and potential consequences, of various changing options (Lattimer, et al., 2004). The system dynamics modelling is chosen as the study methodology because in a health care system a clinical service demand is naturally complex as it would involve many interdependent resources and parameters. To ensure that the impact of a change to a clinical service is examined holistically in the health care system, such as the introduction of the remote monitoring technology, all the relevant parameters are appropriately captured in this model depending of the size of scope of interest. In addition, some of the resources and parameters may not have direct associable relationships that can be easily comprehensible, thus having a visual model to depict such non-linear, intermingled relationships is instrumental in assessing the impact of the change, for example the workload and the clinical resource consumption by the remote monitoring service.

System dynamics regular follow-up modelling enables both qualitative analysis and quantitative analysis of the complex problem. Qualitative analysis involves identifying and depicting all the parameters and their relationship relevant to the problem of clinical resource utilization on patient's service demand in a causal loop diagram. Quantitative analysis involves measuring how each parameter affects the patient's service demand and thus the workload of the cardiac clinic team with a stock and flow diagram. Through running simulations, this diagram can be used to project dynamically the care team's workload by the patient's service demand over a period of time, thus identify any possible bottlenecks and room for improvements with a holistic view of the clinical environment at the RCH cardiac clinic. These two diagrams and the model simulation may be preserved for future research, with the adjustment to the individual parameters or changes to existing and new parameters are applied to update the context of the evaluation.

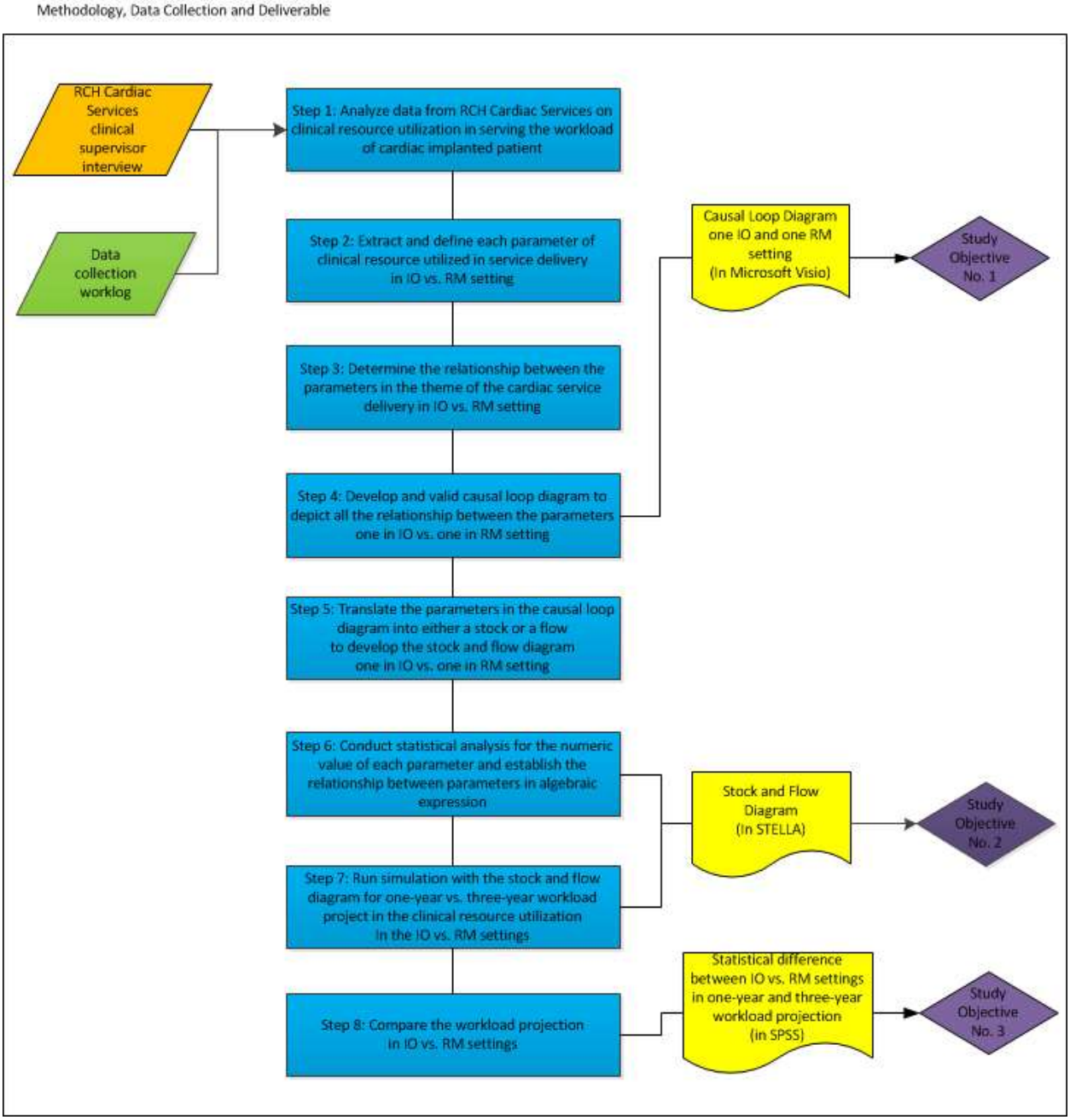
This application of the system dynamics in the research is broken down into three major steps. In the first step, a casual loop diagram is developed as qualitative analysis to depict the relationship between the parameters of the clinical resource utilization of the RCH cardiac clinic in service delivery for each of the IO follow-up and hybrid follow-up clinical protocols. The parameters of clinical resource utilization in serving the implanted patients are identified. The casual loop diagram is the deliverable that corresponds to the first research objective – to identify the workload of the in-clinic only follow-up clinical protocol and in the hybrid follow-up clinical protocol with both the in-clinic and remote follow-up at a DFC. Microsoft Visio 2010 is used for the casual loop diagram.

In the second step, the casual loop diagram is translated into a stock and flow diagram for quantitative analysis on the workload management in demonstrating the difference between the two follow-up clinical protocols in the service volume provision by the cardiac clinic team. Based on the statistical analysis of the data collection, each parameter is converted to either a stock, for observing the dynamics behaviour over time, or a flow, for recording the behaviour in a time period, and is then assigned with a numeric value. The relationships between parameters is also established with algebraic expressions. The stock and flow diagram is the deliverable that corresponds to the second research objective – to depict the relationship and interaction of the clinical resource consumption in supporting the workload of the in-clinic only follow-up clinical protocol and the hybrid follow-up clinical protocol of a DFC in a conceptual model.

In the final step, the stock and flow diagram is then used for running to simulation of the clinical resource utilization in projecting the service volume of the cardiac patients in one-year and in three-years of time after the study horizon for the two follow-up clinical protocols. The numerical outcome of the simulation are the deliverable that corresponds to the third research objective – to project and compare if the clinical resource would be capable in serving the implanted patients in one-year and three-year periods after the study horizon in both the follow-up clinical protocols using a conceptual model. STELLA Architect V10.0.3 is used as the simulation modelling software for constructing the stock and flow diagram and running the simulation.

The workflow of the research with the study methodology, the data collection, and the deliverables for the research objectives is depicted in Figure 3.

Figure 3 –Workflow of study methodology, data collection and deliverable



4.4 Duration, Patient Selection, Intervention

The study duration is approximately one year with patient enrollment from July 2017 to June 2018. This is chosen to mirror the average workload of the RCH cardiac clinic within one year of time for serving existing and newly implanted patients including patients with replacement device. Based on the standard clinic protocol, a patient should have attended a minimum of two follow-up services regardless of the in-clinic or the remote mode of the service delivery during the year.

Convenience sampling is used on patient enrollment to the research, hence the RCH cardiac clinic's patient assignment to the control and intervention groups is independent of the research study. A patient who is implanted with Medtronic ICD or CRT-D and eighteen years of age or older is enrolled to the research when the patient attended an in-clinic follow-up service at the RCH cardiac clinic during the study duration. A patient is assigned to the IC group when a newly implanted patient or a device replacement patient is medically advised to the standard IC follow-up clinical protocol, or the existing implanted patient is to continue with the standard IC follow-up clinical protocol. A patient is assigned to the RM group when a newly implanted patient or a device replacement patient is medically advised to the hybrid follow-up clinical protocol, or an existing patient is advised to change to the hybrid follow-up clinical protocol. The RCH cardiac clinic employs a general convention on that a patient who either lives more than an hour away from the clinic based on the registered home address on the health record, or who is medically sensitive and may require more frequent monitoring would be recommended to the remote monitoring service. The purpose of the guideline is the clinic to prioritize the distribution of the remote monitor to the patients who need better access to the follow-up service and the consultation service, as the Medtronic contract with FHA covers the cost of a fixed number of remote monitors per year as patient safety.

The intervention of the research is Medtronic Carelink, the remote monitoring system for the Medtronic ICD and CRT. It is the natural selection of the remote monitoring system because at the time of the research project proposal was submitted in February 2017, Medtronic Carelink is the only FHA-approved remote monitoring system. In addition, because Medtronic Carelink is only compatible with the Medtronic devices, RCH cardiac clinic can only enroll patients with Medtronic ICD and CRT-D to the remote follow-up service. Medtronic ICDs indeed account for generally 50 – 60% of all the ICDs implanted at FHA as of 2011. At RCH cardiac clinic,

Medtronic Carelink is primarily responsible to receive remote transmissions sent from the patient at any time. A remote transmission contains the device's historical data including detected patient's cardiac abnormality and arrhythmias, as well as device status and activity such as battery depletion and in some cases a triggered shock. Then a cardiac technologist downloads all of the remote transmissions for each patient from Medtronic Carelink to Medtronic Paceart for further data analysis, regardless if a remote transmission is sent automatically for a scheduled remote follow, or is alert-triggered by the implanted device, or is sent manually by the patient. For a remote transmission that is a regular follow-up service or is clinically significant to the patient care, a report is generated in Medtronic Paceart, is signed by a cardiac EP, and is filed electronically in Meditech the electronic medical record.

4.5 Data Collection and Follow-up Service Workflow Analysis

The data requirement of the clinical resource utilization assessment is based on the literature review as well as a preliminary research discussion with FHA Cardiac Services and the RCH cardiac clinic. Three types of data are deemed to be crucial to the workload measurement of a regular patient and device follow-up service: patient demographic and device status, and the resource consumption of the RCH cardiac clinic team by the patient encounter or service workload. The list of the data collection is as follows:

- Patient demographic data: age, gender, vital status, NYHA (New York Heart Association) Functional Classification. A patient who previously had a heart failure is assigned with a NYHA functional classification based on how much one is limited during physical activity (American Heart Association, 2017). Please note that the data collection did not include the reason of the implant such as for primary or secondary prevention;
- Patient's device implant data: a new device or a replacement device. Please note that the data collection did not include the reason for device replacement. It could be for a generator change, a lead change, or a battery change. It could also be a device function upgrade from ICD to CRT-D or pacemaker to CRT-D;
- Workload of the RCH cardiac clinic to the implanted patients: type and volume of scheduled and unscheduled patient encounter including regular follow-up service at RCH cardiac clinic; mode of the patient encounter provided by the clinic (in-clinic, phone, remote service etc.); and time spent in each patient encounter by each clinic team

member at the RCH cardiac clinic. Please note that the event of the remote transmission is not included in the data collection. A remote transmission could be alert-triggered, shock-triggered automatically, or patient-triggered; and

- Patient's other cardiac-related clinical resource consumption at FHA: number of implanted patient's cardiac-related hospitalizations, emergency services, and scheduled and unscheduled hospital or clinic visits.

The RCH cardiac clinic initially confirmed that the data collection could be available in Meditech, Medtronic Paceart, and Medtronic Carelink. Shortly after the data collection began in June 2017, the clinic advised that some of the ad hoc services that it provided to the patients would not be recorded in any of these clinical information systems. This included phone support on the remote monitoring technology and on following up on missed scheduled remote follow-up services. The clinic argued that the pertaining workload could be comparably substantial to its overall workload, and hence should be in the scope of the study. Hence a work log was created to centrally record all the patient and patient encounters data collection for the study. Most of the patient encounters in the data collection can be cross-referenced back to a record in one of the three systems. The cardiac technologist of each patient encounter was responsible to record the workload details into the work log. Please see the work log in Appendix D. Data Collection and Processing. The Word document contains the printable version of the work log for a cardiac technologist to complete during a patient encounter. The data is transposed to the Excel document which manages the electronic format of the work log as the central data storage for data analysis. The data is anonymized in the same manner as the data in Meditech and Medtronic Paceart for analysis. RCH cardiac clinic shred all paper work with patient information produced by the study securely according to the standard clinical protocol

Before the data collection began, the workflows of the in-clinic follow-up service and the remote follow-up service were analyzed to understand the workload difference between the two types of services at RCH cardiac clinic. The workflow documentation can be found in Appendix E. Workflow Analysis on Patient and Device Follow-up Service. The workflow documentation was based on several iterative discussions with the cardiac technologists. Figure 4 and Figure 5 below are the workflow diagram that depicts the summary of the IO follow-up and RM follow-up services described in the workflow analysis. In comparing the workflows of the remote monitoring follow-up and the in-clinic follow-up, a few differences are worth highlighting in the

clinical resource utilization. First, for a remote monitoring follow-up service, only a cardiac device technologist is mandatory in attending the service to the patient. For an in-clinic follow-up service, the booking clerk has to admit the patient, and the cardiac device technologist and the cardiac EP are mandatory to attend the patient. Next, for a patient attending the remote follow-up service, the patient is responsible to interact with the remote monitoring technology for the transmission. On the other hand, although the patient is responsible to be physically present at the clinic for the on-site follow-up, the cardiac device technology is responsible to interrogate the device data to the cardiology information system. Finally, a cardiac device technologist adheres to a regular routine to adhere remote transmission processing at 8AM of the following business day. This routine can be adjustable to any time during the day, as long as the processing is within the clinical protocol. However, the cardiac device technology must be present at the patient's appointment to process the device interrogation. Hence the remote monitoring technology offers some flexibility for the cardiac technologists to prioritize the workload during the business day.

Figure 4 – Workflow diagram of in-clinic follow-up service

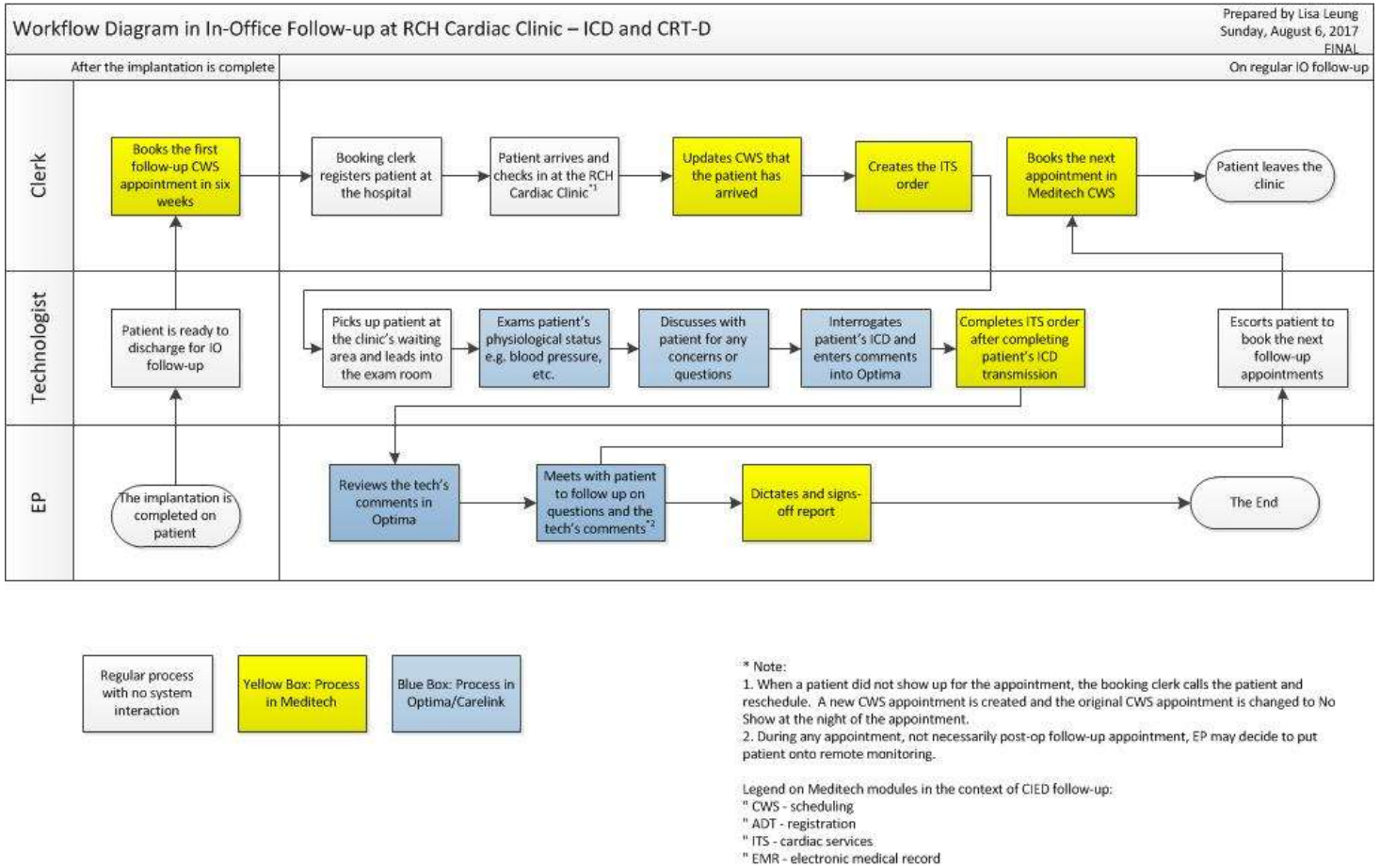
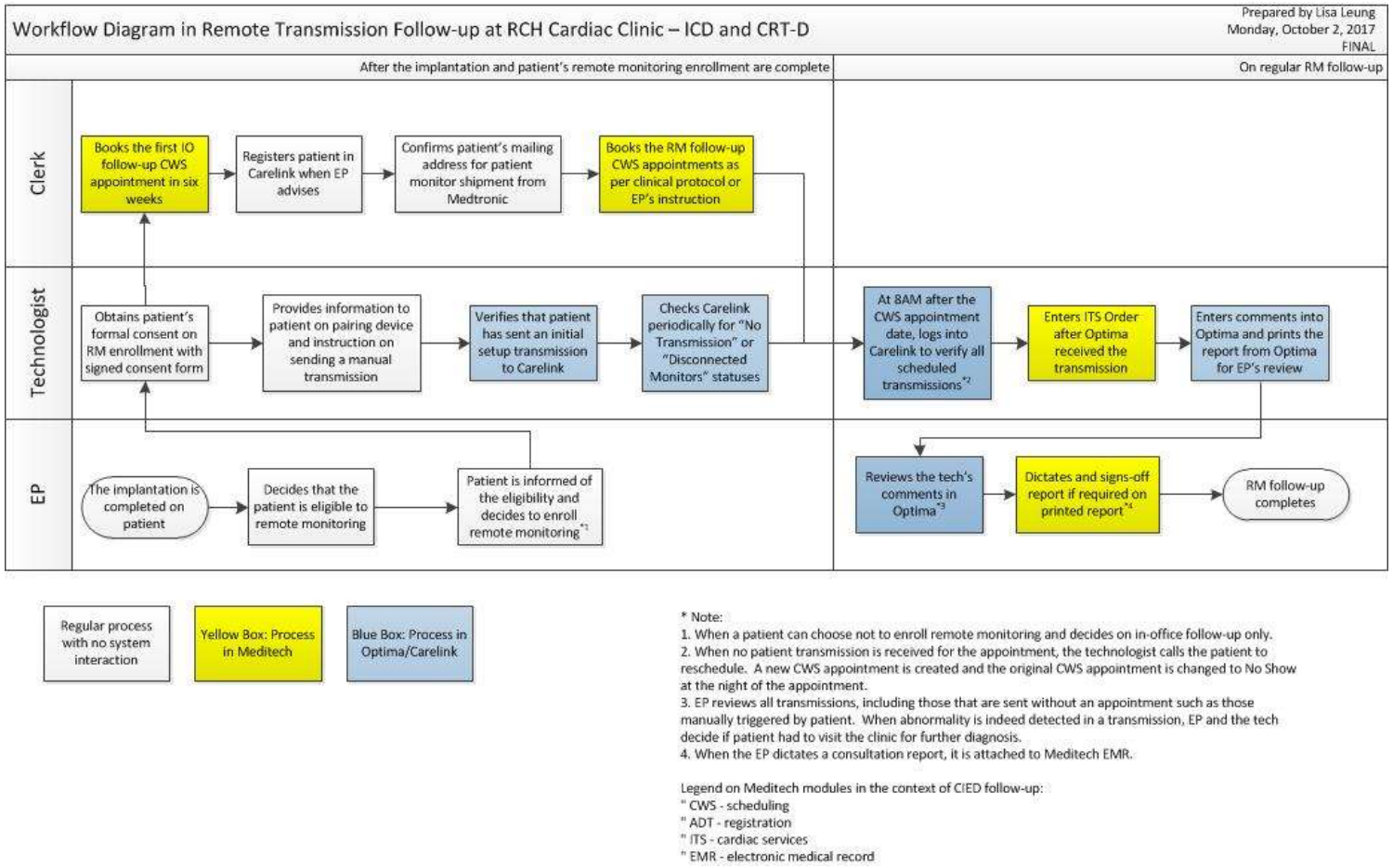


Figure 5 – Workflow diagram of remote follow-up service



The data collection began at July 2017 when the RCH Cardiac Clinic started to enroll patients for the research study and ended at June 2018. These enrolled patients were scheduled to attend its in-clinic follow-up appointment during the data collection period. The data collection represents the workload of the cardiac clinic for the study protocol of the control group (the IC follow-up clinical protocol) and the intervention group (the hybrid follow-up clinical protocol). Each study group aimed to enroll the sample size of 20 to 25 patients depending on the implant schedule at RCH Cardiac Services. From the data analysis perspective, the sample size is chosen to allow for enough dispersing power to compare the control group and the intervention group. During data collection, discussions took place at the RCH cardiac clinic approximately every six weeks to follow-up any update, feedback and questions on the research and the data collection with the clinic team.

To anonymize the data collection for research, each enrolled subject patient is assigned with a study identification number. Each patient encounter data is labelled by the patient's study identification number and the date of the record entry by the RCH cardiac clinic. Before receiving the data collection from RCH cardiac clinic, the Excel work log was final-anonymized by the FHA Cardiac Services application coordinator. The data was temporarily stored on an encrypted USB drive and transferred onto a personal laptop installed with TrueCrypt as encryption solution. The data remained on both the encrypted USB drive and the personal laptop while utilizing STELLA on a workstation at University of Victoria for data analysis.

When the data collection was received, the data of the patient and the workload of the patient encounter were reviewed with the cardiac clinic. To verify the completeness, missing data or patient encounter were investigated and backfilled as medically justified. Data was crossed checked as needed with Meditech, Medtronic Paceart, and Medtronic Carelink for clinical interpretation. Then the data processing and statistical analysis were performed on the data collection, so that the data can be applied in system dynamics in response to the research objectives.

4.6 Data Processing and Statistical Analysis

To process the workload data for system dynamics, each patient encounter was analyzed and categorized with the RCH cardiac clinic team based on how the clinic is responsible for the patient service demand in relation to the clinical protocol of the standard follow-up service and the other timely service to the implanted patient and device. Each service category becomes a parameter of the clinical resource consumption at RCH cardiac clinic in the causal loop diagram of the respective study group. The diagram incorporated the service categories and other parameters that were crucial in the research scope of serving the implanted patients and devices. The causal loop diagram was then translated symbolically into a stock and flow diagram. The diagram was prepared using Microsoft Visio.

After the service categorization was complete for all patient encounters, the total workload of the clinic was summed by time in minutes and by each service category within each study group. The workload included the cardiac technologist's time and the cardiac EP's time in each patient encounter. The total frequency of the service demand and the number of patients demanded the service by each service category were counted. Then three numbers were calculated and assigned to each service category in the stock and flow diagram – the average service demand in the patient group (total number of patient demanded the service by total patient), the average service demand per patient (total frequency of the service by total number of patient demanded the service, for some patient demands the same service more than once), and the average clinical workload per each service category (total workload by total frequency of the service). Other parameters in the stock and flow diagram were also assigned with a numerical value, so that the diagram can be utilized to run as a simulation model for one-year and three-year projection period. The diagram and its simulation model was prepared using STELLA.

To evaluate the statistical difference of the hybrid (intervention) group with the remote monitoring service from the in-clinic (control) group as the baseline, descriptive statistics were performed on both the patients and the workload by patient encounters with 95% confidence interval. For testing the independency of the control group and the intervention group, Student's t-test would be used for the small sample size on continuous data, for each study group was not

expected to have more than thirty enrolled patients. For categorical data, chi-squared (χ^2) test would be used. SPSS and Microsoft Excel were utilized on the descriptive statistics.

The projected workload in one-year and three-year of study periods from the simulation model in each study group would be used in the analysis of the H_0 hypothesis that each clinical protocol can sustain the service demand. This determined that the projected workload would be within 10% of the baseline clinical resource in the specific clinical protocol, for the clinic is assumed to have the threshold to buffer limited resource to address the unplanned patient's service demand. For the purpose of the research, the baseline clinical resource is defined as the availability of the cardiac technologists and the EP planned in the operation of the cardiac clinic. Its numerical definition will be articulated with the workload analysis in the next chapter. Microsoft Excel was utilized on the statistical analysis of the service sustainability hypothesis.

Sensitivity analysis were be performed on the workload projection in the one-year and three-year of study periods based on the variations of the baseline clinical resource and the rate of change in the number implanted patients.

4.7 Out of Scope and Assumptions

A number of areas in the remote monitoring of CIED are out of scope based on the research aim. The aim of this research is to assess if the integration of the remote monitoring technology to the standard healthcare service model of the implanted patient and device care could be instrumental to the service supply of a device follow-up clinic from the perspective a device follow-up clinic of a health delivery organization. Hence the patient's perspective on the impact of the technology towards the accessibility of clinical service and the medical outcomes of cardiac health are out of scope. Next, to focus the research on the clinical resource utilization by the impact of the remote monitoring technology, the cost of the RCH cardiac clinic's service delivery is also not in the scope. The main reason for the exclusion is that the reimbursement of the remote monitoring service requires further medical analysis. According to the RCH cardiac clinic, the BC Medical Service Plan reimburses up to two remote follow-up services per patient per year. For any additional remote transmissions, the reimbursement may vary depending if the transmission would turned into a clinical or device-technical event that required more service, from an in-clinic visit or a medical intervention or treatment. Measuring tangible and intangible benefits of the remote monitoring to the clinic are also not in scope in the research because the

definition of benefit by the remote monitoring technology has yet been defined and measured in this research.

Assumptions are drawn to ensure that the research focuses reasonably to the research objectives. They are described as follows:

- The number of working hours is capped for the cardiac team members;
- No cap is imposed on the number of implanted patients to the RCH cardiac clinic and the cardiac EP can take;
- The biomedical equipment, the IT infrastructure, and the operation of the physical space and the fixture of the cardiac clinic are capital resources that would remain relatively stable throughout the study period, thus they are not factored in the evaluation;
- The workload on the system maintenance of Medtronic Carelink the remote monitoring system is not included in the evaluation. Medtronic and the FHA Cardiac Services application coordinators are assigned the responsibility of the daily operation of the system. In reality the clinical care team is be involved in user acceptance testing and system troubleshooting on the regular system upgrade and maintenance;
- For an EP must attend during the operation of the device follow-up clinic, the workload of a service is the summation of the time spent by both the cardiac technologist and EP, even though EP may not be engaged in every patient encounter; and
- The in-clinic and the hybrid follow-up clinical protocols are considered to be two different service options for the patient. Having a remote follow-up service for the hybrid patient implies that the implanted patient has one more interaction channel or touchpoint with the cardiac clinic in receiving the service. Hence they are not directly comparable in evaluating the impact of the respective service model to the patient.

4.8 Ethics Consideration and Approval

The ethics requirement of this research was reviewed by both Fraser Health Authority and University of Victoria, specifically on the data collection on the implanted patient. Fraser Health Department of Research and Evaluation Services had determined that the study does not require ethics approval by Fraser Health Research Ethics Board. This decision was made based on the study is “a quality improvement and evaluation” with no direct use of patient’s personal identifying information. In addition, no on-site patient interview was conducted. The data

access request is also approved by Fraser Heath Information Privacy Office by email for the compliance of the BC provincial data access. Furthermore, the University of Victoria Office of Research Services has granted the necessary research approvals on the research, the use of the data collection tool, the extension of the research, and the extension of the data collection. All approvals issued by Fraser Health Authority and by University of Victoria can also be found in Appendix F. Research Ethics Approvals by University of Victoria and Fraser Health Authority.

Chapter 5. Results

This chapter reports the results of the research for the research question by responding to each of the three research objectives. The chapter begins by presenting the patient statistics of the enrolled patient in the IC group and the RM group. Then the service types from the service categorization are defined based on the input from the RCH cardiac clinic team. Then the construction of the causal loop diagram is described to depict the interrelationship of the parameters of the direct service delivery operation of the RCH cardiac clinic for the implanted patients and device. Next, the construction of the stock and flow diagram is presented with the mathematical relationship explained for each parameter in the diagram. The outcome of the projected workload produced by the simulation run is discussed on the service sustainability analysis with the use of remote monitoring technology. Finally, sensitivity analysis is conducted on the service sustainability with a change of the new implant rate per year and a change of the planned clinical resource as the baseline for the RM group.

5.1 Patient Statistics

From July 2017 to June 2018, the RCH cardiac clinic enrolled a total of forty two ICD and CRT-D patients to the research, with twenty one patients were enrolled to the control group, or the in-clinic (IC) group and twenty one patients were enrolled to the intervention group, or the remote monitoring (RM) group. One patient in the RM group was deceased before the study began, and one patient in the RM group was deceased during the study. At the end of the study, twenty one patients in the IC group and twenty patients in the RM group were included in the study. The average age of all forty one included patients is 64.44 years old. The study included five female patients and thirty six male patients. A total of sixteen patients were newly implanted patients who never had a CIED before, and twenty five patients were receiving a replacement device. The device replacement could be either a pulse generator change, a battery change, a lead change, or a device change or upgrade from an ICD to a CRT-D or a pacemaker to a CRT-D. Please refer to Appendix A. Components and Functional Description of Cardiac Implantable Electrical Device for the graphical representation of an implant procedure with the various component of the device replacement.

On NYHA Classification, the overall calculation is performed by assigning a numerical value to each classification, with I is 1, II is 2, III is 3, and IV is 4. For patients who are not

classified for no history of heart failure, they are assigned with 0 for calculation purpose. For simplicity, for the patient that has more than one classification, for example I-II, the higher classification (II) is selected in representing the patient. In the RM group, four patients are not assigned with a NYHA classification. Eight patients are NYHA Classification I, seven patients are classified as II, one patient is classified as III, and one is classified as IV. In the IO group, two patients are not assigned with a NYHA classification. Seven patients are NYHA Classification I, four patients are classified as II, and seven patient is classified as III. The average NYHA functional classification for all enrolled patients is 1.58.

The summary of the descriptive statistics of the enrolled patients in the IO group and the RM group is presented in Table 12. SPSS and Microsoft Excel were used in the statistical analysis. Please note that the rounding rule in the patient statistics is that the calculation of the age and overall NHYA classification is round to the nearest two decimal places.

Table 12 – Summary of Descriptive Patient Statistics

Patient Analysis	IC	RM	All
Sample Size	20	21	41
Age			
Mean	66.00	62.95	64.44
Std Dev	13.99	13.18	13.50
Gender			
Female	2	3	5
Male	18	18	36
Type of ICD/CRT-D Implant			
New Implant	10	6	16
Replacement	10	15	25
NYHA Classification			
Overall mean	1.80 Between I and II	1.38 Between I and II	1.58 Between I and II
I	7	8	15
II	4	7	11
III	7	1	8
IV	0	1	1
N/A	2	4	6

In testing the independency of the IC group and the RM group, the Student's t-test value 0.718 is greater than the p-value of 0.477 for age concludes that they are independent by age. For gender, the χ^2 test value 0.176 is less than the p-value of 0.675 concludes that they are not independent. As observed in Table 12, both the IC group and the RM group are dominated by

male patients. For NYHA classification, the χ^2 test value 7.031 is greater than the p-value of 0.134 conclude that they are independent. This conveys that the patient enrollment to the IC group and the RM group of the research is statistically independent by age and NYHA classification.

5.2 Service Categorization and Workload Statistics

The RCH cardiac clinic workload as the clinical resource utilization is recorded as patient encounter by the cardiac technologist. In the data processing, each patient encounter is categorized by service type for workload statistical analysis. This is to respond to the first research objective – to identify the workload of the IC-only follow-up clinical protocol and in the hybrid of clinical protocol with the IC and RM follow-up to the RCH cardiac clinic. The service categorization assigns a service type to each patient encounter by understanding the service nature of each patient encounter in the medical implication to the RCH cardiac clinic in assuming its responsibility as a device follow-up clinic for the implanted patient and the device. As a patient encounter may involve more than one medical or device event, it is categorized by the most dominating service type that occupied more than 80% of the entire patient encounter. Each service type is assigned with a number for numerical analysis in Microsoft Excel. The workload measurement is the time spent by the cardiac clinic team and is summed by each service type in the workload statistical analysis.

Through the service categorization of the IC group patient encounters, the cardiac clinic acknowledges that it also provides two more type of services for the implanted patients on top of the IC follow-up service. After the service categorization was complete, three types of services were reported to the IC group and are described as follows:

- Service 1 – In-clinic regular follow-up service: the standard follow-up service that is scheduled as per the clinical protocol. The service involves a cardiac technologist and a cardiac EP to conduct the regular follow-up check-up on the implanted patient and the device physically in the clinic.
- Service 2 – Scheduled insignificant service: a service that the clinic scheduled for the patient to attend at the clinic. It would often be initiated by the patient phoning a cardiac technologist with concerns of suspected device or medical issues during the office hours of the clinic. The technologist would schedule an appointment for the patient at the clinic

so the cardiac technologist can examine the patient physically to verify the issues, similar to a regular follow-up service, and engage the cardiac EP as needed. This service type is insignificant because no medical adverse event were found on the patient and the device. If an issue were indeed found, then the patient encounter is instead assigned as schedule significant service.

- Service 3 – Scheduled significant service: a service that the clinic scheduled for the patient to attend at the clinic. Very similar to a scheduled insignificant service, it would often be initiated by the patient phoning a cardiac technologist that one has experienced with an actual device (such as therapeutic shocks) or medical issues (such as dizziness or chest pain) during the office hours of the clinic. The technologist would schedule an appointment for the patient at the clinic so the cardiac technologist can further examine the patient physically to verify the issues, similar to a regular follow-up service, and engage the cardiac EP as needed. This service type is significant because the clinic is medically responsible to the medical adverse event of the device and the patient once the patient reaches out to the clinic.

From the workload statistical analysis, a cardiac technologist spent approximately1320 minutes and the cardiac EP spent approximately 225 minutes in the forty one patient encounters delivered to the twenty one IC group patients between July 2017 and June 2018. The time spent is to measure when the cardiac technologist or the cardiac EP interacted with the patient in a patient encounter regardless of the mode of the interaction– either in-clinic or over the phone. Both the cardiac technologists and the cardiac EP were involved in all the patient encounters. In calculating the workload based on the average time spent on each service type, a cardiac technologist spent 29.27 minutes in an in-clinic regular follow-up service, 30 minutes in a scheduled insignificant service, and 30 minutes in a scheduled significant service. And a cardiac EP spent approximately five minutes in all the three services. Table 13 provides the summary of the workload statistics of the IC group patients. Please note that the rounding rule in the workload statistics is that the calculation of the time spent and the patient encounter is round to the nearest two decimal places.

Table 13 – Workload Statistics of the IC Group by Service Type

Service Type	Total Service	No. Patient of Service	Average Service/ Patient (min)	Total Tech Workload (min)	Average Tech Workload (min)	Total EP Workload (min)	Average EP Workload (min)	% of Workload
1 - Regular follow-up – in-clinic follow-up	41	20	2.05	1200	29.27	205	5.00	90.94%
2 - Scheduled Insignificant	1	1	1.00	30	30.00	5	5.00	2.27%
3 - Scheduled Significant	3	2	1.50	90	30.00	15	5.00	6.80%
Total Services Delivered	45			1320		225		100.00%

Through the service categorization of the RM group patient encounters, the cardiac clinic realized that it also provided far more variety of services for the implanted patients on top of the IC follow-up service and the RM follow-up service. After the service categorization was complete, eight types of services were reported to the RM group and are described as follows:

- Service 1 – In-clinic regular follow-up service: the standard follow-up service that was scheduled as per the clinical protocol, and that was essentially the same service as for the IC group patients. The service involved the cardiac technologists and the cardiac EP to conduct the regular follow-up check-up on the implanted patient and the device physically in the clinic. It may also include the remote follow-up service enrollment.
- Service 1 – Remote regular follow-up service: the standard follow-up service that was scheduled as per the clinical protocol. The service involved Medtronic Carelink received the automatic remote transmission from the patient at a scheduled time. The cardiac technologists reviewed the remote transmission in Carelink as the regular follow-up check-up on the implanted patient and the device, and recorded the analysis for reporting, and engaged the cardiac EP as abnormality is detected for further medical consultation.
- Service 3 – Scheduled significant service: a service that the clinic scheduled for the patient to attend at the clinic. Very similar to its kind in the IC group, it would often be initiated by the patient phoning a cardiac technologist that one has experienced with actual device (such as therapeutic shocks) or medical issues (such as dizziness or chest pain) during the office hours of the clinic. With the remote follow-up service, the cardiac

technologist can then schedule the patient to manually send a remote transmission to examine if further medical attention would be required. If so, the technologist would then schedule an appointment for the patient so the cardiac technologist can further examine the patient physically to verify the issues at the clinic, and engage the cardiac EP as needed.

- Service 4 – Patient education: specific to the remote follow-up service, all the remote monitoring related support that the cardiac technologist provided to educate a patient for the correct use of the technology for medical service, such as under what circumstance a patient should send a remote transmission to the RCH cardiac clinic. This had also involved some technical support with the physical connection of the remote monitor, how to send or re-send the first test remote transmission, and re-educate the remote follow-up service all together. Some of the support should be provided by Medtronic. Hence the cardiac technologist often would explain and refer the patient to Medtronic for further technical support.
- Service 5 – Remote service enrollment and start-up: specific to the remote follow-up service, all the support the cardiac technologist provided to patient enrollment to the remote follow-up service. This is comprised of the remote follow-up service enrollment that the cardiac technologist had to organize or repeat that is not part of a follow-up service, as well as coordinate the test remote transmission to complete the remote follow-up service enrollment.
- Service 6 – Other Service: all the other services that the cardiac clinic offered to the implanted patients. Based on the data collection, this included the cardiac technologist followed up patient who missed the remote follow-up service, and attended the patient at the emergency room due to cardiac issue.
- Service 7 – Unscheduled insignificant: specific to the remote follow-up service, this is all the unscheduled remote transmission that the cardiac clinic received and were accountable to review to clear out any medical issues with the implanted patients or the device. They are mostly unintentional or duplicated transmission manually triggered by the patients. This service type is insignificant because no medical adverse event were found on the patient and the device, however the clinic had to thoroughly review it as a regular remote transmission in case of any unreported medical adverse event.

- Service 8 – Unscheduled significant: specific to the remote follow-up service, this is all the unscheduled remote transmission that the cardiac clinic received and were accountable to review. The remote transmission could be manually triggered by a patient upon the experience of a medical condition. It could also be automatically triggered by device alert (lead alert or battery alert) configured by the cardiac EP, or by device shock. This service type is significant because the clinic is medically responsible to the medical adverse event of the device and the patient as programmed by the device.

In total, the cardiac technologist spent approximately1805 minutes and the cardiac EP spent approximately 425 minutes in eighty seven patient encounters or services delivered to the twenty RM group patients between July 2017 and June 2018. The cardiac technologists were involved in all the patient encounters while the cardiac EP were involved eight two of all the patient encounters. As per the standard clinical protocol and the workflow analysis, the cardiac technologists are the primary and the first point of contact with the patient, and the cardiac EP is involved most of the time as engaged by the cardio technologists. On calculating the workload based on the average time spent on each service type a cardiac technologist spent 29.81 minutes in an in-clinic regular follow-up service and 17.22 minutes in a remote regular follow-up service. For these two follow-up services, the cardiac EP spent 5.58 minutes and 5 minutes respectively. Table 14 provides the summary of the workload statistics of the RM group patients. Please note that the rounding rule in the workload statistics is that the calculation of the time spent and the patient encounter is round to the nearest two decimal places.

Table 14 – Workload Statistics of the RM Group by Service Type

Note:
Average EP Workload[*1] – The total service demand is used to calculate the average as the cardiac EP still had to stand by for the service. This is used for the stock and flow diagram to average out that some of the services would not require the EP's resource.
Average EP Workload[*2] – The total service demand where the cardiac EP is involved is used to calculate the average.

Service Type	Total Service Tech:EP	No. Patient of Service	Average Service/ Patient (min)	Total Tech Workload (min)	Average Tech Workload (min)	Total EP Workload (min)	Average EP Workload (min)[*1]	Average EP Workload (min)[*2]	% of Workload
1 - Regular follow-up – in-clinic follow-up	26:26	21	1.24	775	29.81	145	5.58	5.58	41.26%
1 - Regular follow-up - remote follow-up	9:9	8	1.13	155	17.22	45	5.00	5.00	8.97%
3 - Scheduled Significant	7:7	5	1.40	125	17.86	35	5.00	5.00	7.17%
4 - Patient Education	5:4	3	1.67	85	17.00	20	4.00	5.00	4.71%
5 - Remote Service enrollment and start-up	20:19	18	1.11	330	16.50	95	4.75	5.00	19.06%
7 - Unscheduled insignificant	9:8	5	1.80	110	12.22	40	4.44	5.00	6.73%
8 - Unscheduled significant	8:7	5	1.60	175	21.88	35	4.38	5.00	9.42%
6 - Other Service	3:2	3	1.00	50	16.67	10	3.33	5.00	2.69%
Total Services Delivered	87:82			1805		425			100.00%

A few observations are made in the service categorization of the RM group and the IC group patient encounters. The first observation is that scheduled insignificant service demanded by the IC group patients is not applicable to the RM group patients, as the cardiac clinic team can utilize the remote follow-up service to examine the medical issue for the necessity of an in-clinic visit, and can consult the patient over the phone without a patient's physical visit to the clinic. The second observation is that the average time spent on each RM group patient (106.19 minutes per patient per year) is more than on each IC group patient (77.25 minutes per patient per year). The third observation is most of the service types in the RM group is associated to the remote monitoring technology as an additional touchpoint of the service between clinic and the patient. Although in the IC group, the scheduled insignificant service and scheduled significant are associated with phone support, another touchpoint, the remote monitoring technology is relatively new to both the implanted patient and the cardiac clinic in comparison with the phone technology for patient support. There may be room for improvement in the remote monitoring technology use by the RCH cardiac clinic for the clinical resource utilization as well as patient care and support in workload management. The fourth observation is that within the RM group, the average workload of a remote follow-up service 32.55 minutes (17.22 + 5 minutes) is less than the average workload of an in-clinic regular follow-up service of 35.39 minutes (29.81 +

5.58 minutes), and is also less than an in-clinic regular follow-up service in the IC group of 34.27 minutes (29.27+5 minutes). Table 15 summarizes the average workload by each service type in comparison of the IC group and the RM group. The average workload would then be used for simulation in the stock and flow diagram.

Table 15 – Summary of Average Workload by Service Type

	IC Group			RM Group		
Service Type	Total Service	Average Tech Workload (min)	Average EP Workload (min)	Total Service Tech:EP	Average Tech Workload (min)	Average EP Workload (min)
1 - Regular follow-up – in-clinic follow-up	41	29.27	5.00	26:26	29.81	5.58
1 - Regular follow-up - remote follow-up	N/A	N/A	N/A	9:9	17.22	5.00
2 - Scheduled Insignificant	1	30.00	5.00	N/A	N/A	N/A
3 - Scheduled Significant	3	30.00	5.00	7:7	17.86	5.00
4 - Patient Education	N/A	N/A	N/A	5:4	17.00	4.00
5 - Remote Service enrollment and start-up	N/A	N/A	N/A	20:19	16.50	4.75
7 - Unscheduled insignificant	N/A	N/A	N/A	9:8	12.22	4.44
8 - Unscheduled significant	N/A	N/A	N/A	8:7	21.88	4.38
6 - Other Service	N/A	N/A	N/A	3:2	16.67	3.33
Total IC/RM Group	20 patients with 1,545 minutes total workload = 77.25 minutes per patient			21 patients with 2,230 minutes total workload = 106.19 minutes per patient		

The service categorization and the workload statistics in the clinical resource consumption at the RCH cardiac clinic is instrumental to the analysis of clinical resource consumption by the service workload in responding to the last two study objectives, respectively to depict the relationship and interaction of the clinical resource utilized at the RCH cardiac clinic to support the workload of the IC-only follow-up clinical protocol and the hybrid of

clinical protocol with the IC and RM follow-up in a conceptual model; and to project and compare if the clinical resource would be capable to serve the patients in one-year and three-year periods after the study horizon in both follow-up settings using a conceptual model. They are illustrated in the following sections.

5.3 Relationship of Clinical Resource Utilization

To symmetrically depict the parameters of the clinical resource utilization, the causal loop diagram (CLD) is adapted as per the system dynamics methodology to model the service delivery operation at the RCH cardiac clinic. The CLD is instrumental for the qualitative analysis of the interrelationship between the parameters that impact the clinical resources of the cardiac technologist and the cardiac EP in the service demand by the ICD and CRT-D patients and the service supply available by the clinic. The construction of the CLD is to respond to the second research objective – to depict the relationship and interaction of the clinical resource utilized at the RCH cardiac clinic to support the workload of the IC-only follow-up clinical protocol and the hybrid of clinical protocol with the IC and RM follow-up in a conceptual model. Microsoft Visio 2010 is used for building the casual loop diagram.

The research scope of the CLD is the direct service delivery operation of the RCH cardiac clinic in the respective clinical protocol for the follow-up implanted patient and device. To visualize the difference by the impact of the remote monitoring technology in the clinical resource utilization, one CLD is developed for the IC follow-up protocol (the control group) as shown in Figure 6, and one CLD is developed for the hybrid follow-up protocol (the intervention group) as shown in Figure 7. The CLD stages the clinical setting of the research scope to illustrate the parameters and their interrelationships. The parameters and their interrelationships were first hypothesized based on the workflow analysis and were confirmed through the various discussions with the RCH cardiac clinic team. The parameters include the service categorization which is central to the CLS in the clinical resource utilization.

Figure 6 – CLD of the IC follow-up protocol

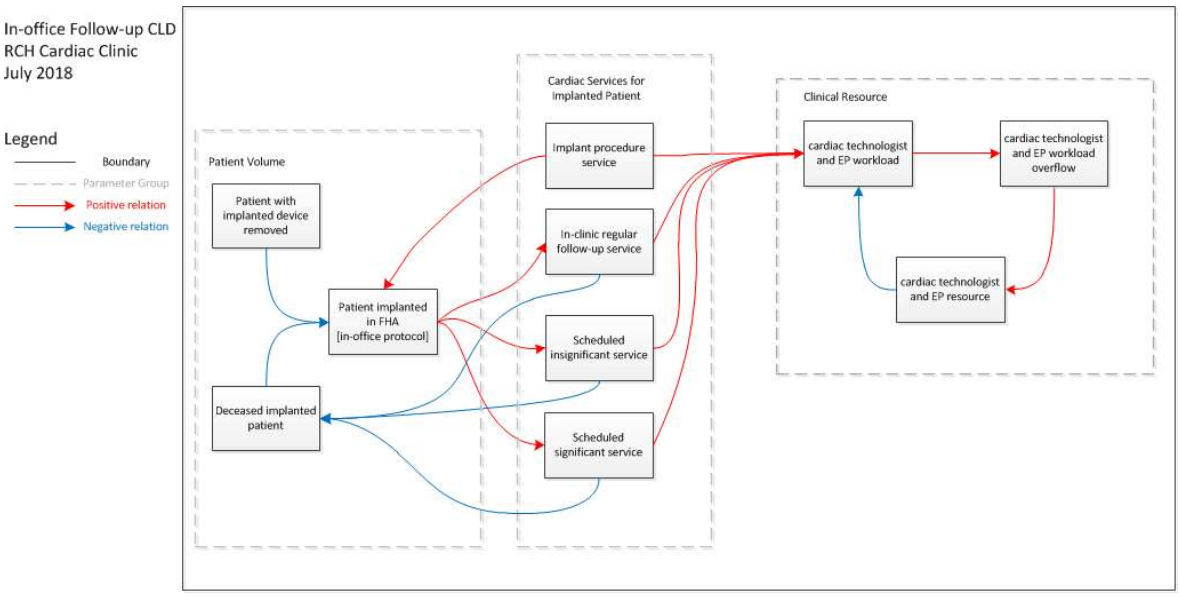
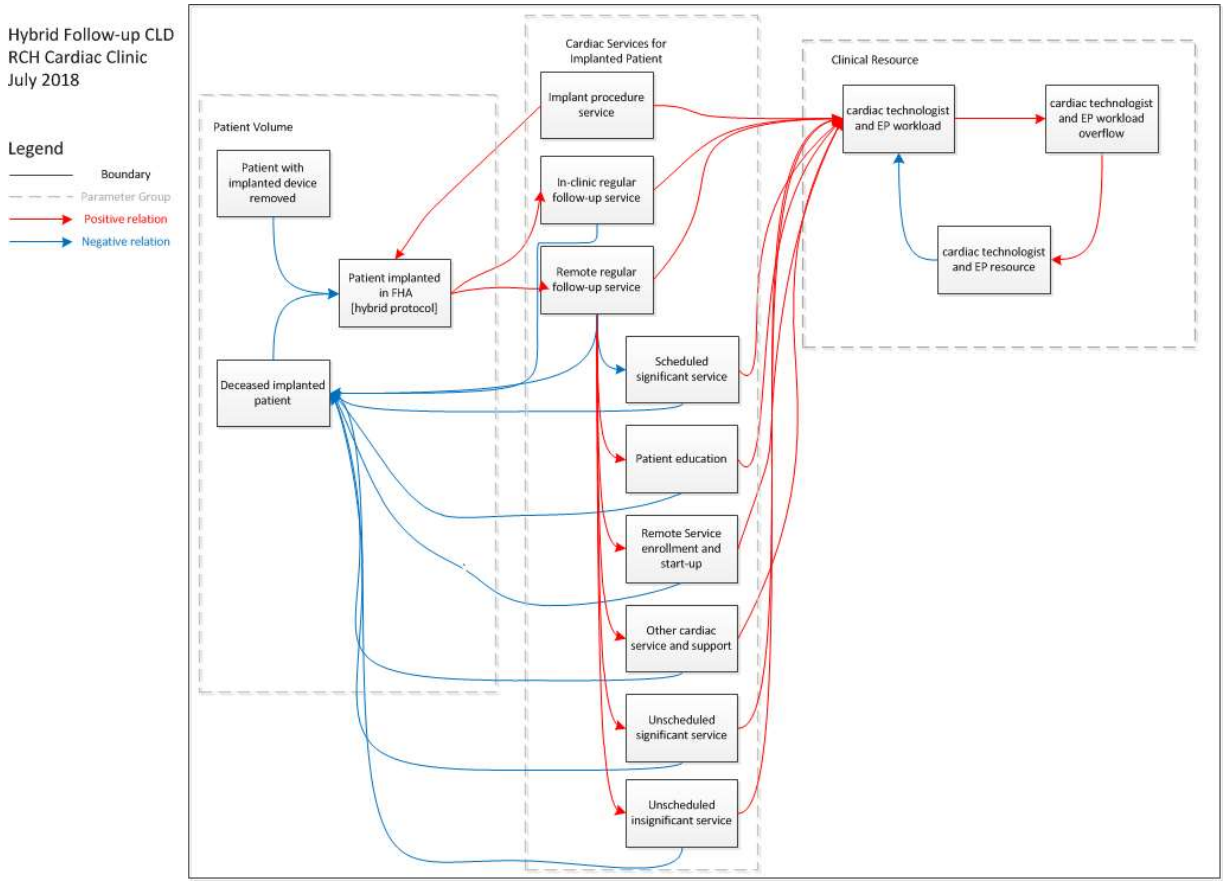


Figure 7 – CLD of the hybrid follow-up protocol



The black line is the boundary of the CLD that encapsulates the service delivery for the implanted patients including the regular follow-up service in the research study. And inside the boundary each box represents a parameter. The structure of the CLD with the organization of the parameters for both clinical follow-up protocols is essentially identical. The parameters are organized in three groups as bordered by the grey dash lines. Each group with the pertaining parameters is described as follows:

1) Patient volume: the implanted patient's service demand to the RCH cardiac clinic, which includes the following parameters:
    - Patient implanted with ICD in FHA: the pool of the implanted patients and their devices that FHA is responsible for as the study subject of the research. They can be implanted in FHA or implanted anywhere in BC. The pool includes the new implanted patients and patients with a replacement or change of device of ICD and CRT-D. Please note that patients who are due for a replacement device are included as they continue to receive the follow-up services after being implanted with a new device;
    - Deceased implanted patient: patients who no longer require follow-up service and support from the clinic. These patients have since passed away between the regular follow-up services from all cardiac and non-cardiac related causes; and
    - Patient with implanted device removed: patients who no longer require follow-up services and support from the clinic. These patients who have an implanted device but de-activated or removed since the previous follow-up service for personal or clinical reasons, for example because they are in palliative care.
2) Cardiac services for implanted patients: all the services that the cardiac clinic delivers to the implanted patients by their demand and patients who is prescribed with an implant procedure of either an ICD or a CRT-D by the clinic. The parameters in this group are already described in the previous section under Service Categorization for each protocol. An exception is the Implant procedure service, which is the service that the cardiac EP implants patients with devices at FHA. After the implant procedure is complete, FHA begins to be responsible to provide follow-up service on the device and the patient.
3) Clinical resource: the cardiac technologists and the cardiac EP as the staff capacity of at the clinic in delivery the cardiac services to the implanted patients.

- Cardiac technologist and EP workload: their time spent as the clinical resources utilized by all the cardiac services delivered to the implanted patients;
- Cardiac technologist and EP resource: the availability of their time as the clinical resources or the staff capacity of the clinic. This includes all the full-time and part-time cardiac technologists and EPs that the RCH cardiac service can readily arrange them to work at the clinic;
- Cardiac technologist and EP workload overflow: their time spent as the clinical resource utilized beyond the staff capacity of the clinic during the business hours from 8AM to 4PM Monday to Friday. Currently the RCH cardiac clinic runs during lunch hours or as overtime during regular clinic days to catch up with the services. It also runs on the weekends to keep up the service demands.

The type of relationship between the parameters are labelled by the colour of the connector in the CLD. Two colours are used in the CLD – a red connector indicates that the two parameters have a same or positive relationship. For example, a red line is linked from a patient implanted with ICD in FHA to the regular in-clinic follow-up service. This means that when the total number of the implanted patients grows, then the number of in-clinic office follow-ups also grows proportionally. And a blue connector indicates that the two parameters have an opposite or negative relationship. In the case of a blue connector linking from Scheduled significant service to Deceased implanted patient, it symbolizes that when more scheduled significant service is delivered to the patient, there will be less in the implanted deceased patient.

The assumptions and constraints were made in the construction of the CLDs are as follows:

- The diagram reflects the general trend of the demand and supply of the follow-up service and other cardiac services by the patient volume over an individual patient;
- The amount of clinical resource of the cardiac technologist and EP available is fixed and remain the same over a short term (such as within the year). The clinic team indeed operates only the business hours five days a week. Hence the number of the cardiac service supply is limited. Training of the staff also takes some time if the clinic were planned to expand. The clinic implements measures to accommodate the scheduled regular follow-up services as well as other cardiac services and patient support from the patient demand. Interim measures by the clinic include working

overtime and weekends, and the creation of the wait list for cardiac services to fulfill the demand.

- No limit is capped on the number of patients by the cardiac clinic. In fact every year the province funds the projected number of implant procedures at each health authority. The funding covers the staff and the surgery room of a cardiac centre. And;
- The current clinical protocol and how the cardiac clinic delivers patient service would remain the same. This includes the clinical workflow of the follow-up service, the off-hour support by the emergency room, and the communication channel on patient support. There may be room for change in the service delivery for the implanted patient.

Overall, both CLDs depict that as the volume of the implanted patient grows, the demand of the cardiac services by the cardiac clinic also grows (the red lines in between), and hence the workload of the cardiac technologists and EP also grow (also the red lines in between). With the services delivered by the clinic to the patients, the number of deceased implanted patients decrease (the blue lines in between), or the mortality rate of the implanted patient improve, and hence the volume of the implanted patient does not decrease (the blue lines in between). This reinforcing loop portrays the notional challenge that the RCH cardiac clinic could face in service delivery to the potentially growing implanted patient on its clinical resource capacity, depending on the number of implant services performed and the mortality rate of the implanted patients. Furthermore, no relationship can be linked from any parameter in the clinical resource parameter group. The diagram conveys a tacit question that how the service delivery to the implanted patient can be sustained so that a balance loop can be constructed. The concept of service sustainability in this research is that an equilibrium point can closely be emerged by the service demand by the patient and the service delivery by the clinic's resource capacity. In its current operation, the clinic also determines and plans how much of its current workload that it could support to the implanted patients. What the RCH cardiac clinic can do in the immediate short time as interim measure is to arrange more weekend clinic service that may eventually jeopardizing other services that the cardiac clinic offers as trade-off.

Observations are made in comparing the CLDs of the IC group and the RM group on the remote monitoring technology. Most of the cardiac services patient demand naturally drive up the workload of the cardiac technologists and EP, as shown in the red lines indicating a positive

relationship in between. Note that the CLD of the RM group illustrates that the remote follow-up service indeed lowers the demand of the scheduled significant services as opposed to the IC group in its respective CLD. This is based the RCH cardiac clinic agrees that some of the patient's medical or device issues can be assessed and resolved over the phone as the patient and device data is available via remote transmission. Another observation is carried from the service categorization that the RM group patients generally demand more variety of the services from the cardiac clinic, particularly from the cardiac technologist. In essence the diagrams may be valuable for the clinic to explore how the remote follow-up could be instrumental to sustain the follow-up service using the remote monitoring technology.

To continue with the research, the CLD is then be transformed into a stock and flow diagram for each study group. The transformation process plus the integration of the service categorization and workload statistical analysis in the construction of the stock and flow diagram and the simulation model will be described next section.

5.4 Dynamics Behaviour of Service Delivery Impact to Clinical Resource Utilization

A stock and flow diagram is built on the service delivery of the RCH cardiac clinic to the implanted patient based on the service categorization and the causal loop diagram, with one diagram for each of the IC (control) group and the RM (interventional) group. The stock and flow diagram encapsulates the dynamics behavior of the clinic's operation by the patient's service demand and the workload of the clinical resources in the service delivery. In the evaluation of the impact by the remote monitoring technology between the study groups, the purpose of the diagram is to simulate the dynamics behaviour of the RCH cardiac clinic's operation so that the changes to the clinical resource utilization can be projected numerically. This is to address the third research objective and the third research objective and the final one of this research – to project and compare if the clinical resource would be capable to serve the patients in one-year and three-year periods after the study horizon in both follow-up settings using a conceptual model. This section illustrates the construction of the stock and flow diagram and explains of the mathematical relationship programmed in the diagram for each study group. The numerical outcome of the simulation run for one-year and three-year periods is presented for statistical analysis to evaluate the difference in clinical resource consumption between the in-clinic and the hybrid clinical follow-up protocols. The models are built using STELLA V10.0.6.

The source files of the STELLA model can be found in Appendix G. Stock and Flow Diagram and Simulation Model Source File.

Figure 8 and Figure 9 are the stock and flow diagrams for the IC follow-up protocol and the hybrid follow-up protocol respectively. Their structure is similar in that three type of dynamics behaviours are observed. They are described in three parts as follows with each main parameter in the diagram is underlined:

1. Patient flow is the stock-flow process that trace down the dynamic of the volume of implanted patients (the Implanted Patient stock) through the growth rate (the New Implant converter and the Implanting flow) and the decline rate (the Mortality Rate converter and the Dying flow);
2. Service demand is all the services that the RCH cardiac clinic provides to the implanted patients from the service categorization. Each follow-up service converter is a group of the respective patient encounters. Each service converter is associated with three converters – a Workload per service converter (measured in minutes), a Probability of service converter (measured by the number of patients in the implanted patient group that statistically demands the service), and a Frequency per service converter (measured by the frequency of the service demand by each patient); and
3. Workload sustainability (service supply) measures how RCH cardiac clinic manages the patient workload with its clinical resources.
    - The Planned Resource converter is the service supply that RCH cardiac clinic can provide. This is based on the resource availability of the cardiac technologist and EP reflected and is measured in minutes.
    - The total workload by all the services are summed up in the Total Workload converter and is measured in minutes. A converter is used over a stock because the service demand are served to the patient during the period due to the clinical protocol. The workload of the cardiac technologists and the EP are added together in the model because although the cardiac technologist is the first point of contact in the assessment and the triage of the patient and device services, the clinical protocol indicates that an EP is mandatory to medically standby at the clinic. In reality all services would require an EP's engagement.

- The Workload Overflow is the services that the cardiac clinic has to somehow provide to the patient beyond its planned resources if the service demand by the patient surpassed the service supply by the clinic. Similar to the Service Demand, a converter is used over a stock because the service supply is delivered by the cardiac clinic during the period in response to the patient demand.

The assumptions and constraints drawn in the construction of the causal loop diagram are also applicable to the construction of the stock and flow diagram. In addition, the diagram is built with the assumption that the current operation and the dynamics behaviours of the RCH cardiac clinic would remain the same over the simulation period. Another key assumption is that the clinic allocates resources to suffice the changing in the number of patients. The resources of the cardiac technologist and EP should be fixed as a constraint in short term is not programmed in the diagram. Also no constraints are built in the model on the number of the Implanted Patients, the Total Workload, and the Workload Overflow.

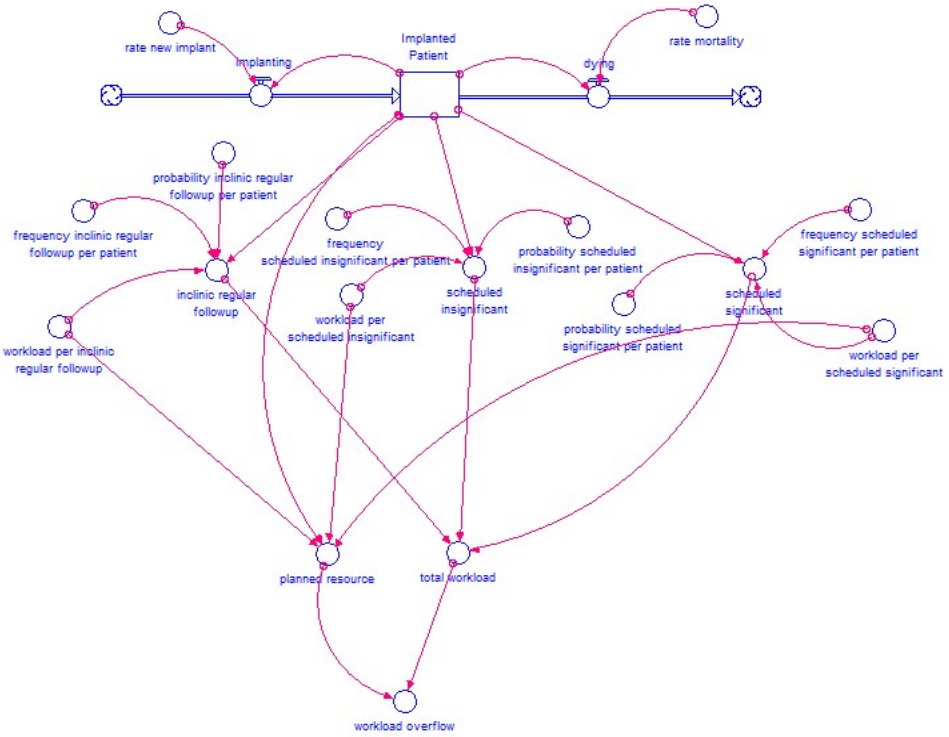
Each simulation run represents one year for the data collection covers the clinic's one year of operation from July 2017 to June 2018. Please note the rounding rules of each parameter in the calculation of the simulation run is as follows:

- Patient count is around to the nearest decimal place;
- Rates and probabilities are round to the nearest four decimals for calculation unless the whole fraction is available for calculation; and
- Workload is measured in minutes and round to the nearest two decimals.

5.4.1 Stock Flow Diagram of the Control Group

This section details the description and the mathematical relationship of the stock flow diagram of the control group, or the IC group representing the standard in-clinic follow-up standard protocol. Figure 8 is the stock and flow diagram of the IC group.

Figure 8 – Stock and flow diagram of the IC follow-up protocol



Each parameter in the IC stock and flow diagram is described as follows:

Part 1 – Patient flow

- `Implanted_Patient(t) = Implanted_Patient(t - dt) + (implanting - dying) * dt`

  The mathematical relationship of the volume of the Implanted Patient in each simulation run.

- `INIT Implanted_Patient = 20`

  The initial value of the volume of Implanted Patient. This is the sample size of the IC group patients.

- `INFLOWS:`
  - `rate_new_implant = 335/1027`

    The original intention is to assign the rate of the new implant patient per a year with the number of new implanted patient added to the IC group in the data collection, in this case 10 patients. This number comes from the number of the new implanted patient of the IC patient group. In running the simulation this converter would result a rate of 10/20 or 50% growth of implanted patient. The reality of the clinical setting that the number of new implant for FHA is a decision made by the provincial funding as reflected in Table 7 of 2.5 Motivation and Aim, and is independent from the number of FHA's original

implanted patients. Hence the rate is calculated as 335 implanted patients in the year 2016/17 over the total 1027 implanted patients as per the projection (200 + 205 + 287 + 335), or 32.62% of the total implanted patients. This rate is used in the hybrid protocol simulation as well. It assumes that the rate remains constant over the simulation period; however the observation from Table 7 shows a growing trend of the number of new implant procedures over the years.

Please note that the replacement does not count towards the implanted patients because as they are already implanted, they would not create any new workload to the clinic's overall workload.

- `implanting = round(Implanted_Patient*rate_new_implant)`

The mathematical relationship of the implanted patient added to the volume of the implanted patient during a simulation. This is essentially the number of new implanted patient. This number is normally independent from the volume implanted patient because it simulates the reality is that the number of implant procedures depends on the provincial funding of the staff and surgical space resources.

- `OUTFLOWS:`
  - `rate_mortality = 0.0697`

Because the vital status of the implanted patients at RCH cardiac clinic is not regularly updated, the mortality rate is not available for the research. Hence the calculation of the mortality rate is chosen from an Ontario study on the mortality rate of the ICD patients (Yung, et al., 2013). This is chosen as the demographic composition of the province of Ontario could be presumed to be comparable with the province of British Columbia, although further analysis would be required to validate this presumption. Please refer to Appendix H. Mortality Rate Calculation for Simulation for the calculation. In general, the mortality rate of implanted patient is lower than the mortality rate of general cardiac patient because the ICD or CRT-D is a therapeutic measure.

- `dying = round(Implanted_Patient*rate_mortality)`

The mathematical relationship of the implanted patient reduced from the volume of the implanted patient in the simulation.

Part 2 – Service demand

Service 1 – In-clinic regular follow-up service

- `inclinic_regular_followup = round(Implanted_Patient*probability_inclinic_regular_followup_per_patient*frequency_inclinic_regular_followup_per_patient)*workload_per_inclinic_regular_followup`

  This is the total workload of the in-clinic regular follow-up services demand by all the implanted patients of the measured by minutes.

- `probability_inclinic_regular_followup_per_patient = 20/20`

  This is the number of patients who are probable to attend the in-clinic regular follow-up service out of the total patients in the group. From the workload statistics, it shows that all the IC patients had attended at least one regular follow-up service.

- `frequency_inclinic_regular_followup_per_patient = 41/20`

  This is the average number of in-clinic regular follow-up service demand per implanted patient in the IC group by the number of patient encounter. From the workload statistics, it shows that the IC patients have attended more than one in-clinic regular follow-up during one-year of the data collection period.

- `workload_per_inclinic_regular_followup = 29.27+5`

  This is the average workload of the cardiac technologist and EP of each patient encounter of in-clinic regular follow-up service.

Service 2 – Scheduled insignificant service

- `scheduled_insignificant = round(Implanted_Patient*probability_scheduled_insignificant_per_patient*frequency_scheduled_insignificant_per_patient)*workload_per_scheduled_insignificant`

  This is the total workload of the scheduled insignificant services demand by all the implanted patients of the measured by minutes. The number of patients is first round to the nearest decimal place, and then is used to calculate the workload that rounds the minutes to the two decimal places.

- `probability_scheduled_insignificant_per_patient = 1/20`

  This is the number of patients who are probable to ask for the scheduled insignificant service from the cardiac clinic in the IC group. From the workload statistics, only one patient asked for the scheduled insignificant service in the IC group.

- `frequency_scheduled_insignificant_per_patient = 1/1`

  This is the average number of scheduled insignificant service demand per implanted patient in the IC group by the number of patient encounter. Based on the workload statistics, one of the twenty one patients demanded the service in a year. And the patient demanded only one patient encounter.

- `workload_per_scheduled_insignificant = 30+5`

This is the average workload of the cardiac technologist and EP per each patient encounter of scheduled insignificant service.

Service 3 – Scheduled significant service

- `scheduled_significant = round(Implanted_Patient*probability_scheduled_significant_per_patient*frequency_scheduled_significant_per_patient)*workload_per_scheduled_significant`

  This is the total workload of the scheduled significant services demand by all the implanted patients of the measured by minutes. The number of patients is first rounded to the nearest decimal place, and then is used to calculate the workload that rounds the minutes to the two decimal places.

- `probability_scheduled_significant_per_patient = 2/20`

  This is the number of patients who are probable to ask for the scheduled significant service from the cardiac clinic in the IC group. From the workload statistics, twos patients asked for the scheduled significant service in the IC group.

- `frequency_scheduled_significant_per_patient = 3/2`

  This is the average number of scheduled significant service demand per implanted patient in the IC group by the number of patient encounter. Based on the workload statistics, two of the twenty one patients demanded the service in a year with the total of three patient encounters. Hence on average each patient demands 1.5 services.

- `workload_per_scheduled_significant = 30+5`

  This is the average workload of the cardiac technologist and EP of each patient encounter of scheduled significant service.

3. Workload sustainability

- `planned_resource = Implanted_Patient*((2*workload_per_inclinic_regular_followup) + (1*workload_per_scheduled_insignificant) + (1*workload_per_scheduled_significant))`

  This converter is the resources that RCH cardiac clinic plans for all its implanted patients in the IC group, or the clinical resource capacity of the clinic. In reality, the clinic does not plan its resources based on the number of patients. Therefore a bold assumption is made for the research that each IC patient in one year would demand two in-clinic regular follow-up services as per the clinical protocol. In addition, it is assumed that on average each IC patient would demand one patient encounter of the scheduled significant service and one patient encounter of the scheduled insignificant service. A patient may require more or less frequent of the service depends on its cardiac health condition and device functional status.

- `total_workload = inclinic_regular_followup+scheduled_significant+scheduled_insignificant`

This converter is the total workload of all the services by the IC group implanted patients. This is the summation of the workload of all three IC group services: in-clinic regular follow-up services, scheduled significant service, and the scheduled insignificant service.

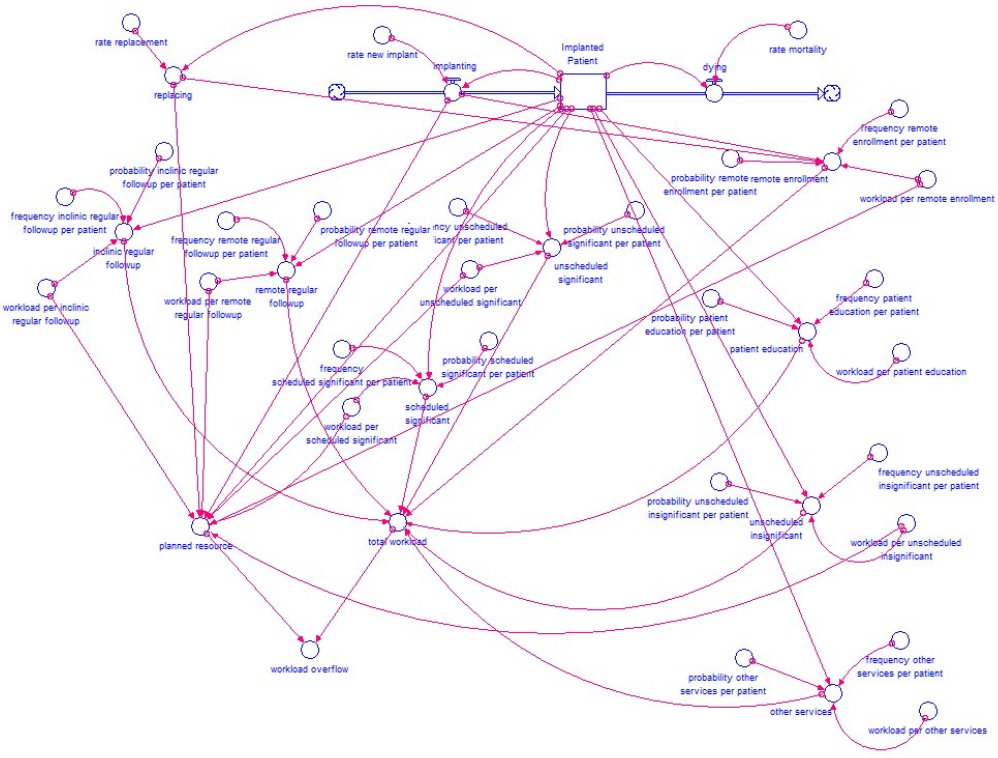
- `workload_overflow = if (total_workload > planned_resource) then (total_workload - planned_resource) else 0`

  This converter is any workload overflow that the clinic provides on top of its capacity. This is the difference of the total workload by all patient service demand minus the planned resources by the clinic.

5.4.2 Stock Flow Diagram of the Intervention Group

This section details the description and the mathematical relationship of the stock flow diagram of the intervention group, or the RM group representing the standard hybrid follow-up protocol with both the IC and the RM follow-up service. Figure 9 is the stock and flow diagram of the RM group.

Figure 9 – Stock and flow diagram of the hybrid follow-up protocol



Each parameter in the RM stock and flow diagram is described as follows:

Part 1 – Patient flow

- `Implanted_Patient(t) = Implanted_Patient(t - dt) + (implanting - dying) * dt`

  The mathematical relationship of the volume of the Implanted Patient in each simulation run.

- `INIT Implanted_Patient = 21`

  The initial value of the Implanted Patient of the first simulation run. This is the sample size of the hybrid patient group.

- `INFLOWS:`
  - `rate_new_implant = 335/1027`

    The rate of the new implant patients per a year is the same calculated rate as it is in the IC group.
  - `implanting = round(Implanted_Patient*rate_new_implant)`

    This is the same mathematical relationship as it is in the IC group.

- `OUTFLOWS:`
  - `rate_mortality = 0.0620`

    Similar to the IC group, the calculation of the mortality rate is chosen from an Ontario study (Yung, et al., 2013). Please refer to Appendix H. Mortality Rate Calculation for Simulation for the calculation.
  - `dying = round(Implanted_Patient*mortality_rate)`

    The mathematical relationship of the implanted patient reduced from the volume of the implanted patient in the simulation.

Unique to the hybrid clinical protocol, the number of the replacement patients who are new to enroll the remote follow-up services is calculated it creates new workload to the RCH cardiac clinic.

- `rate_replacement = 0.3`

  This is an estimated rate of the replacement patient per year of all the FHA implanted patients who would enroll to the remote follow-up service. A device has an estimated lifetime of five to ten years. It may require replacement soon depending on various medical and technical issues.
- `replacing = round(Implanted_Patient*rate_replacement)`

  The mathematical relationship of the replacement patients who enroll to the remote follow-up service in the simulation.

Part 2 – Service demand

Service 1 – In-clinic regular follow-up service

- `inclinic_regular_followup = round(Implanted_Patient*probability_inclinic_regular_followup_per_patient*frequency_inclinic_regular_followup_per_patient)*workload_per_inclinic_regular_followup`

  Same as it is in the IC group, this is the total workload of the in-clinic regular follow-up services demand by all the implanted patients of the measured by minute.

- `probability_inclinic_regular_followup_per_patient = 21/21`

  This is the number of patients who are probable to attend the in-clinic regular follow-up service out of the total patients in the group. From the workload statistics, it shows that all the RM patients had attended at least one regular follow-up service.

- `frequency_inclinic_regular_followup_per_patient = 26/21`

  Same as it is in the IC group, this is the average number of in-clinic regular follow-up service demand per implanted patient in the IC group by the number of patient encounter.

- `workload_per_inclinic_regular_followup = 29.81+5.58`

  Same as it is in the IC group, this is the average workload of the cardiac technologist and EP of each patient encounter of in-clinic regular follow-up service.

Service 1 – Remote regular follow-up service

- `remote_regular_followup = round(Implanted_Patient*probability_remote_regular_followup_per_patient*frequency_remote_regular_followup_per_patient)*workload_per_remote_regular_followup`

  This is the total workload of the remote regular follow-up services demand by all the implanted patients of the measured by minutes.

- `probability_remote_regular_followup_per_patient = 8/21`

  This is the number of patients who are probable to utilize the remote follow-up service after the enrollment service. From the workload statistics, only eight out of the twenty patients utilized the remote follow-up service in the RM group, although each patient is projected to have at least one service in one year as per the clinical protocol.

- `frequency_remote_regular_followup_per_patient = 9/8`

  This is the average number of in-clinic regular follow-up service demand per implanted patient in the RM group by the number of patient encounter.

- `workload_per_remote_regular_followup = 17.22+5`

  This is the average workload of the cardiac technologist and EP of each patient encounter of remote regular follow-up service.

Service 3 – Scheduled significant service

- `scheduled_significant = round(Implanted_Patient*probability_scheduled_significant_per_patient*frequency_scheduled_significant_per_patient)*workload_per_scheduled_significant`

Same as it is in the IC group, this is the total workload of the scheduled significant services demand by all the implanted patients of the measured by minutes. The number of patients is first round to the nearest decimal place, and then is used to calculate the workload that rounds the minutes to the two decimal places.

- `probability_scheduled_significant_per_patient = 5/21`

  This is the number of patients who are probable to ask for the scheduled significant service from the cardiac clinic in the RM group. From the workload statistics, five patient asked for the scheduled significant service in the RM group.

- `frequency_scheduled_significant_per_patient = 7/5`

  Same as it is in the IC group, this is the average number of scheduled significant service demand per implanted patient in the RM group by the number of patient encounter. Based on the workload statistics, five of the twenty one patients demanded the service in a year with the total of seven patient encounters. Hence on average each RM patient demands 1.4 services per year.

- `workload_per_scheduled_significant = 17.86+5`

  Same as it is in the IC group, this is the average workload of the cardiac technologist and EP per each patient encounter of scheduled significant service.

Service 4 – Patient education

- `patient_education = round(Implanted_Patient*probability_patient_education_per_patient*frequency_patient_education_per_patient)*workload_per_patient_education`

  This is the total workload of the patient education and support of the remote follow-up service demand by all the implanted patients of the measured by minutes.

- `probability_patient_education_per_patient = 3/21`

  This is the number of patients who are probable to ask for education and support on the remote follow-up service from the cardiac clinic in the RM group.

- `frequency_patient_education_per_patient = 5/3`

  This is the average number of patient education per implanted patient in the RM group.

- `workload_per_patient_education = 17+4`

  This is the average workload of the cardiac technologist and EP of each patient encounter for patient education and support.

Service 5 – Remote service enrollment and start-up

- `remote_enrollment = round((replacing+implanting)*probability_remote_enrollment_per_patient*frequency_remote_enrollment_per_patient)*workload_per_remote_enrollment`

This is the total workload of the remote service enrollment and start-up required by all the new and replacement implanted patients of the measured by minutes.

- `probability_remote_enrollment_per_patient = 18/21`

  This is the number of patients who are probable to ask for the remote service enrollment and the start-up in the RM group. Please note that three patients out of the twenty one RM patients were enrolled in the remote follow-up service but did not utilize it.

- `frequency_remote_enrollment_per_patient = 20/18`

  This is the average number of remote service enrollment and start-up per implanted patient in the RM group. Some of the patients required more than one patient encounter to complete the remote enrollment.

- `workload_per_remote_enrollment = 16.5+4.75`

  This is the average workload of the cardiac technologist and EP of each patient encounter for the remote service enrollment and the start-up.

Service 6 – Other Service

- `other_services = round(Implanted_Patient*probability_other_services_per_patient*frequency_other_services_per_patient)*workload_per_other_services`

  This is the total workload of the other services the clinic provided to the implanted patients in the RM group measured by minutes.

- `probability_other_services_per_patient = 3/21`

  This is the number of patients who are probable to ask for the other service in the RM group.

- `frequency_other_services_per_patient = 3/3`

  This is the average number of the other services per implanted patient in the RM group.

- `workload_per_other_services = 16.67+3.33`

  This is the average workload of the cardiac technologist and EP of each patient encounter for the other services.

Service 7 – Unscheduled insignificant

- `unscheduled_insignificant = round(Implanted_Patient*probability_unscheduled_insignificant_per_patient*frequency_unscheduled_insignificant_per_patient)*workload_per_unscheduled_insignificant`

  This is the total workload of the unscheduled insignificant services the clinic provided to the implanted patients in the RM group measured by minutes.

- `probability_unscheduled_insignificant_per_patient = 5/21`

  This is the number of patients out of the hybrid patient group who may request for the unscheduled insignificant services with the remote follow-up service in the RM group.

- `frequency_unscheduled_insignificant_per_patient = 9/5`

  This is the average number of the unscheduled insignificant services per implanted patient in the RM group.

- `workload_per_unscheduled_insignificant = 12.22+4.44`

  This is the average workload of the cardiac technologist and EP of each patient encounter for the unscheduled insignificant services.

Service 8 – Unscheduled significant:

- `unscheduled_significant = round(Implanted_Patient*probability_unscheduled_significant_per_patient*frequency_unscheduled_significant_per_patient)*workload_per_unscheduled_significant`

  This is the total workload of the unscheduled significant services the clinic provided to the implanted patients in the RM group measured by minutes.

- `probability_unscheduled_significant_per_patient = 5/21`

  This is the number of patients out of the hybrid patient group who may request for the unscheduled significant services with the remote follow-up service in the RM group.

- `frequency_unscheduled_significant_per_patient = 8/5`

  This is the average number of the unscheduled significant services per implanted patient in the RM group.

- `workload_per_unscheduled_significant = 21.88+4.38`

  This is the average workload of the cardiac technologist and EP of each patient encounter for the unscheduled significant services.

3. Workload sustainability

- ```
  planned_resource = Implanted_Patient*((1*workload_per_inclinic_regular_followup)
     + (1*workload_per_remote_regular_followup)
     + (1*workload_per_scheduled_significant)
     + (1*workload_per_unscheduled_significant)
     + (1*workload_per_unscheduled_insignificant))
  + ((implanting+replacing)*(workload_per_remote_enrollment))
  ```

  This converter is the resources that RCH cardiac clinic plans for all its implanted patients in the RM group, or the clinical resource capacity of the clinic. In reality, the clinic does not plan its resources based on the number of patients. Therefore a bold assumption is made for the research that each hybrid patient in one year would demand one in-clinic regular follow-up services and one remote regular follow-up as per the clinical protocol. In addition, it is assumed that on average each hybrid patient would demand one patient encounter of the scheduled significant service and one patient encounter of the unscheduled significant
  ```

service. For both the new implanted and replacement patients, one remote enrollment would be reasonably required as well. A patient may require more or less frequent of the service depends on its cardiac health condition and device functional status, plus its adoption of the remote follow-up service and technology.

- `total_workload = inclinic_regular_followup+remote_regular_followup+scheduled_significant+unscheduled_significant+unscheduled_insignificant+patient_education+remote_enrollment+other_services`

  This converter is the total workload of all the services by the RM group implanted patients. This is the summation of the workload of all eight hybrid group services: in-clinic regular follow-up services, remote regular follow-up services, scheduled significant service, unscheduled significant service, unscheduled insignificant service, patient education, remote service enrollment and start-up, and other services.

- `workload_overflow = if (total_workload > planned_resource) then (total_workload - planned_resource) else 0`

  Similar to the IC group, this converter is any workload overflow that the clinic provides on top of its capacity. This is the difference of the total workload by all patient service demand minus the planned resources by the clinic.

5.4.3 Workload Projection with Remote Monitoring Technology

The stock and flow diagram with the assigned numerical value from the workload statistics was used in STELLA to run the simulation for the IC group and the RM group. As the data collection at the RCH cardiac clinic simulates one year of its workload, each simulation represents one year of workload. The numerical outcome of the simulation run represents the workload projection of the clinic in the one-year and the three-year periods in the respective in-clinic or the hybrid follow-up clinical protocol. For the purpose of the research in response to the third objective, the analysis of the service sustainability between the service demand by the patient (Total Workload in the diagram) and the service supply by the clinic (Planned Resource in the diagram) defines that it would be sustainable if the Total Workload were within the 10% range of the Planned Resources. This implies that 10% of the workload overflow could be acceptable by the clinic as it would responsibly prepare with some threshold resources for the changing service demand by the implanted patients as required medically. The following assumptions are made in the construction of the stock and flow diagram and would affect in interpretation simulation outcome and the analysis of the follow-up service sustainability:

- the behaviour of the patients in service demand is reasonably consistent and stable over the projection periods in the simulation model;
- the change of the Planned Resources is related to the change in the number of implanted patients in the diagram;
- the Planned Resources defined in the IC group is the clinic's planned workload of two in-clinic regular follow-up services, one scheduled insignificant service, and one scheduled significant service for all implanted patients;
- the Planned Resources defined in the RM group is the clinic's planned workload of one in-clinic regular follow-up service, one remote regular follow-up service, one scheduled insignificant service, and one scheduled significant service for all implanted patients. In addition, the clinic adds one remote enrollment service for all the newly implant patients and replacement patients in the planned workload; and
- the Planned Resources in the initial year is used as the baseline for analysis. This is to reflect that the clinic has no plan yet in the upcoming year in expanding its current capacity of the staffing resources of the cardiac technologists and the cardiac EP.

The numerical outcome of the simulation run for the IC group is summarized in Table 16. The calculated baseline of the Planned Resource in the initial year of the simulation run is 2,770.80 minutes. The Total Workload after Year 1 is 1,991.31 minutes and is less than the baseline Planned Resources by 28.13%. Hence at Year 1 the clinic's follow-up service for the implanted patient and device is sustainable. The Total Workload after Year 3 is 3,090.14 minutes and is greater than the Planned Resources by the difference of 11.53%. Hence at Year 3 the clinic's follow-up service is not sustainable.

Table 16 – Workload Simulation on the IC Follow-up Protocol

	Patient Flow			Workload by Service Type (in minutes)			Workload Analysis		
Years	Implanted Patient	New Implant	Deceased	In-clinic regular follow-up	scheduled insignificant	scheduled significant	planned resource	total workload	workload overflow
Initial	20	N/A	N/A	1,405.07	35.00	105.00	2,770.80	1,545.07	0.00
1	26	7	1	1,816.31	35.00	140.00	3,602.04	1,991.31	0.00
2	32	8	2	2,261.82	70.00	175.00	4,433.28	2,506.82	0.00
3	40	10	2	2,810.14	70.00	210.00	5,541.60	3,090.14	0.00
4	50	13	3	3,495.54	105.00	280.00	6,927.00	3,880.54	0.00
5	63	16	3	4,420.83	105.00	315.00	8,728.02	4,840.83	0.00

Both Figure 10 and Figure 11 present the upward line graphs of the simulation run for the patient flow, the planned resource, the total workload, and the workload by the service types for the IC group, indicating a steadily growth of workload to the RCH cardiac clinic over time. The breakeven point between the planned resources and the total workload appears to be in between Year 2 and Year 3. And the in-clinic follow-up service is visually growing the fastest out of all the IC patient service demand over the projection period.

Figure 10 – IC Simulation Run Graph on Patient Flow, Planned Resources, and Total Workload

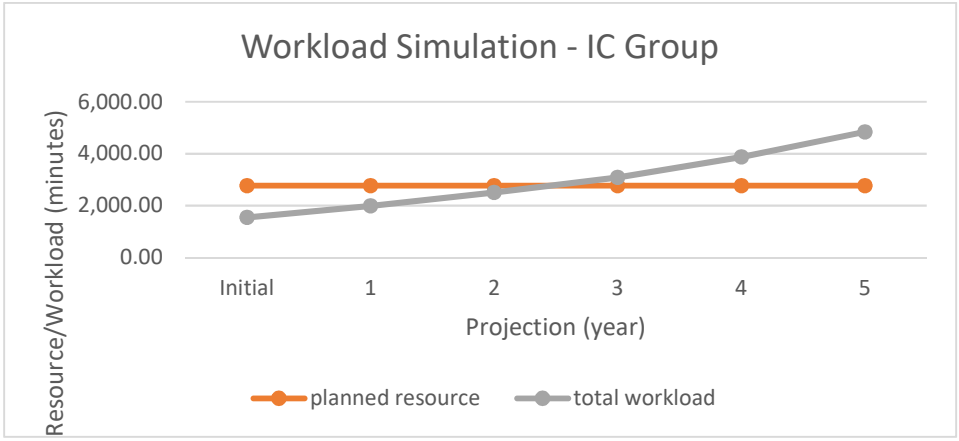
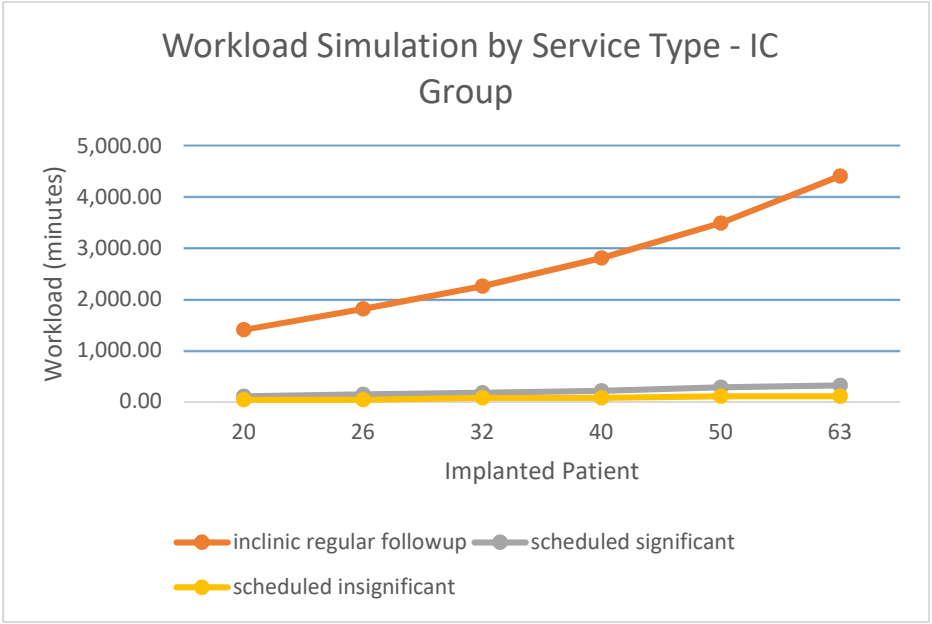


Figure 11 – IC Simulation Run Graph on Patient Flow and Workload by Service Type



The numerical outcome of the simulation run for the RM group is summarized in Table 17. The calculated baseline of the Planned Resource in the initial year of the simulation run is 2,867.44 minutes. The Total Workload after Year 1 is 2,648.77 minutes and is less than the baseline Planned Resources by 7.63%. Hence at Year 1 the clinic's follow-up service with the remote follow-up service for the implanted patient and device is sustainable. The Total Workload after Year 3 is 4,198.21 minutes and is greater than the Planned Resources by the difference of 46.41%. Hence at Year 3 the clinic's follow-up service is not sustainable even with the remote follow-up service.

Table 17 – Workload Simulation on the Hybrid Follow-up Protocol

	Patient Flow				Workload by Service Type (in minutes)								Workload Analysis		
Years	Implanted Patient	New Implant	Replacement	Deceased	in-clinic regular follow-up	remote regular follow-up	scheduled significant	patient education	remote enrollment	other services	unscheduled insignificant	unscheduled significant	planned resource	total workload	workload overflow
Initial	21		6		920.14	199.98	160.02	105.00		60.00	149.94	210.08	2,867.44	2,060.16	0
1	27	7	8	1	1,167.87	266.64	205.74	126.00	255.00	80.00	199.92	262.60	3,692.78	2,648.77	0
2	34	9	10	2	1,486.38	333.30	251.46	168.00	340.00	100.00	249.90	341.38	4,641.51	3,355.42	0
3	43	11	13	2	1,875.67	399.96	320.04	210.00	425.00	120.00	299.88	420.16	5,879.52	4,198.21	0
4	54	14	16	3	2,371.13	511.06	411.48	273.00	552.50	160.00	383.18	551.46	7,385.56	5,341.31	0
5	69	18	21	3	3,008.15	666.60	525.78	336.00	680.00	200.00	499.80	682.76	9,448.91	6,811.59	0

All Figure 12 and Figure 13 also present the upward line graphs of the simulation run for the patient flow, the planned resource, the total workload, and the workload by the service types for the RM group, indicating a steadily growth of workload to the RCH cardiac clinic over time. The breakeven point between the planned resources and the total workload appears to be in between Year 1 and Year 2. And the in-clinic follow-up service is also visually growing the fastest out of all the RM patient service demand over the projection period.

Figure 12 – RM Simulation Run Graph on Patient Flow, Planned Resources, and Total Workload

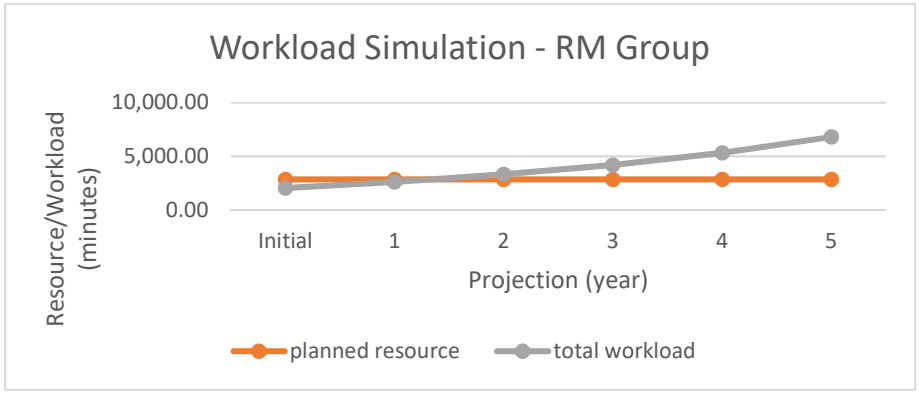
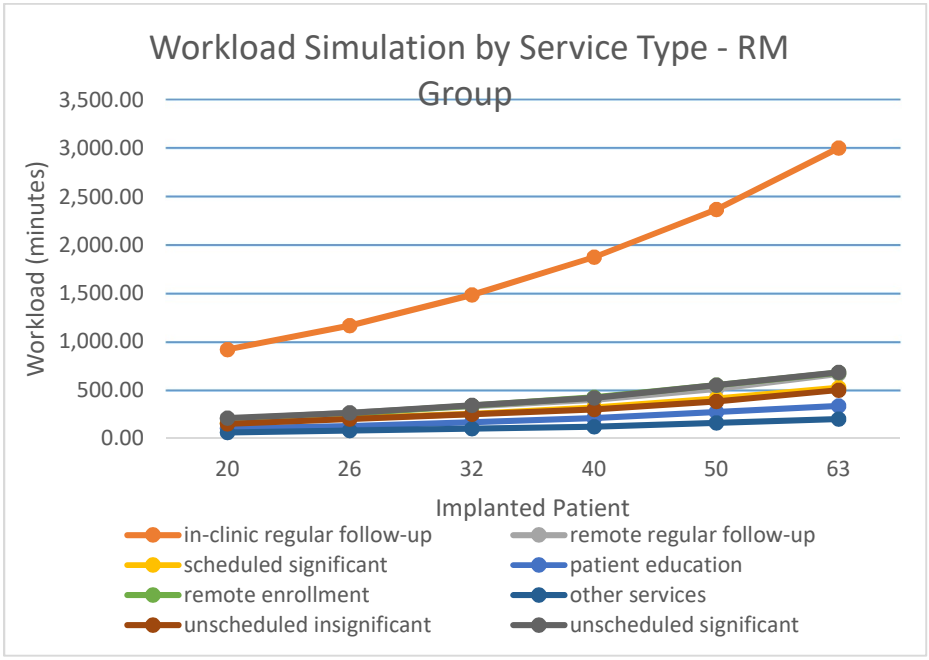


Figure 13 – RM Simulation Run Graph on Patient Flow by Workload by Service Type



5.5 Sensitivity Analysis on New Implant Rate and Planned Resources

Sensitivity analysis was lastly conducted to explore on the service sustainability of RCH cardiac clinic by the impact of the two parameters using the simulation model in the workload projection in the one-year and the three-year periods. The first parameter is on the annual rate of the new implant patient. The general impact to the clinic would be that the growing number of implanted patients would increase the service demand for follow-up services and all the associated services. The second parameter is the definition of the planned resources. The general impact would be that the increased planned resources would increase the availability of the clinical resource and service supply for the patients so that the clinic would be more capable to provide to patient's service demand. Both of these two parameters would influence how the RCH cardiac clinic would plan and manage its capacity of clinical resources. Sensitivity analysis was conducted using both STELLA for simulation and Microsoft Excel for data organization.

In the first scenario of the sensitivity analysis, the annual rate of the new implant patient is set from the original rate of 33% (from 335/1027 which is 32.62%) to 15% (more than half of the original rate) and 40% (a contextually realistic increase from the original rate at the RCH cardiac clinic). Although both of these alternative rates are higher than the mortality rate of 6.97% for the IC group and 6.20% for the RM group, they represent various degree in the growth of the implanted patient thus the potential growth of workload to the clinic to cope with. As shown in the sensitivity analysis table in Table 18, both the planned resources for the IC group and the RM group in Year 1 would be both under-utilized under all the three new implant rates. On the other hand, when the new implant rate is at 40% in Year 3, the clinic would be over-utilized by 30.10% and 72.79% to the IC group and the RM group respectively. Furthermore, the RM group would be more than doubled the overutilization of the clinic than the IC group.

Table 18 – Sensitivity Analysis on New Implant Rate

	IC Group				RM Group			
	Implanted Patient	planned resource	total workload	difference	Implanted Patient	planned resource	total workload	difference
Years	rate new implant = 15%				rate new implant = 15%			
Initial	20	2,770.80	1,545.07	-44.24%	21	2,782.44	1,996.41	-28.25%
1	22	2,770.80	1,682.15	-39.29%	23	2,782.44	2,176.44	-21.78%
3	24	2,770.80	1,854.23	-33.08%	27	2,782.44	2,542.52	-8.62%
Years	rate new implant = 33% (original)				rate new implant = 33% (original)			
Initial	20	2,770.80	1,545.07	-44.24%	21	2,867.44	2,060.16	-28.15%
1	26	2,770.80	1,991.31	-28.13%	27	2,867.44	2,648.77	-7.63%
3	40	2,770.80	3,090.14	11.53%	43	2,867.44	4,198.21	46.41%
Years	rate new implant = 40%				rate new implant = 40%			
Initial	20	2,770.80	1,545.07	-44.24%	21	2,888.69	2,081.41	-27.95%
1	27	2,770.80	2,059.85	-25.66%	28	2,888.69	2,809.31	-2.75%
3	47	2,770.80	3,604.92	30.10%	50	2,888.69	4,991.47	72.79%

In the second scenario of the sensitivity analysis, the definition of the planned resources is adjusted. This is to conduct on the RM group only as it provides a lot more variety of services for the patients as enabled by the remote monitoring technology as one additional touchpoint than for the patients in the IC group, hence the RM group patients can access more services from the clinic. The base definition of the planned resource comprises the workload of one in-clinic follow-up, one remote follow-up, one scheduled significant service, one unscheduled significant service, and one unscheduled insignificant service for all patients in the group, plus one remote enrollment service only for the new implant patients and the replacement patients. The two alternative definitions of the planned resources for the analysis are to include one more scheduled significant service and one more unscheduled significant service, and to include two scheduled significant services and two more unscheduled significant services respectively. This is for the clinic to buffer more resources to timely action on patient's medical adverse events that could be detected by remote transmissions. As shown in the sensitivity analysis table in Table 19, in Year 3, the clinic's service sustainability would be improved from 46.41% over-utilized, to 7.68% over-utilized in the first alternative planned resources, to 14.85% under-utilized in the second alternative planned resources.

On the other hand, it would imply an increase of 35.97% and 71.95% in planned resources from the original planned resources over the three-year period.

Table 19 – Sensitivity Analysis on Planned Resources

	RM Group			
	Implanted Patient	planned resource	total workload	Difference
Years	original planned resource			
Initial	21	2,867.44	2,060.16	-28.15%
1	27	2,867.44	2,648.77	-7.63%
3	43	2,867.44	4,198.21	46.41%
Years	alternative planned resource def 1			
Initial	21	3,898.96	2,060.16	-47.16%
1	27	3,898.96	2,648.77	-32.06%
3	43	3,898.96	4,198.21	7.68%
Years	alternative planned resource def 2			
Initial	21	4,930.48	2,060.16	-58.22%
1	27	4,930.48	2,648.77	-46.28%
3	43	4,930.48	4,198.21	-14.85%

Chapter 6. Discussion

This chapter presents the discussion of the results of the research for the research aim. It begins with the association of the results with the published evidence, as well as the interpretation of the results to the RCH cardiac clinic. The strengths and the weakness of the study design of the research is analyzed. The chapter wraps up by suggesting the future study of the research aim based on the current setting at RCH cardiac clinic

6.1 Implication of the Remote Monitoring Technology on Workload Management

The result of the research on the impact of the clinical resource utilization by the remote monitoring technology of CIED to a DFC is first discussed in the generalization of the published evidence, and then in the specification to the research setting at the RCH cardiac clinic.

Some of the results of this research may be associated with the published evidence on the impact of the remote monitoring services. First, the scheduled and unscheduled services from the service categorization of the RM group workload appear to be in common with the scheduled remote follow-up and unscheduled remote follow-up services in the EVOLVO study as the type of health care system costs for comparison (Zanaboni, et al., 2013). The costs for comparison are between the standard arm of in-clinic follow-up only and the remote arm with the remote monitoring services. The local health care system can differentiate the implication of the service to the workload of a DFC and also the clinical resource utilization of the health delivery organization. Next, the workload statistics demonstrated that on average each in-clinic follow-up service is 32.27 minutes (29.27 minutes of the cardiac technologist's resource plus 5 minutes of the cardiac EP's resource) for the IC group, and 35.39 minutes (29.81 minutes of the cardiac technologist's resource plus 5.58 minutes of the cardiac EP's resource) for the RM group, while the remote follow-up service is 22.22 minutes (17.22 minutes of the cardiac technologist's resource plus 5 minutes of the cardiac EP's resource). The result of the workload that a remote follow-up service is less an in-clinic follow-up service is consistent with the Finnish study that the time needed by the physician for reviewing device data on the secured website (8.4 ± 4.5 min, range 2–30 min) was significantly

shorter than the time needed for completing an in-clinic follow-up (25.8 ± 17.0 min, range 5–90 min), $P < 0.001$. This study also confirms that it was more time-consuming also for the additional hospital staff to complete an in-clinic visit than remote monitoring (45.3 ± 30.6 min vs.9.3 ± 15.9 min, $P < 0.001$) (Raatikainen, Uusimaa, van Ginneken, Janssen, & Linnaluoto, 2008). The study of the Veneto region in Italy (Dario, et al., 2016) also demonstrated the similar result where both the ICD physician (7.5 minutes only with the system, 19.1 minutes with the system and an in-clinic follow-up as medically necessary) and the ICD nurse (19.6 minutes only with the system, 36.1 minutes with the system and an in-clinic follow-up as medically necessary) spent less time with the remote monitoring system than they would with the in-clinic setting for a follow-up service (33.8 minutes and 44.2 minutes respectively).

In the specification to the research setting at the RCH cardiac clinic, the remote monitoring services indeed created more apparent variety of start-up workload, with the average workload per IC patient is 77.25 minutes and per RM patient is 106.19 minutes. Given the variation of the device and patient condition, the hybrid follow-up protocol would have driven the workload ratio of the two follow-up services roughly close to 1 for the RM group. Yet 41.26% of the total workload is for the in-clinic follow-up services while only 8.97% is for the remote follow-up services. Furthermore, patient education comprises of 4.51% of the workload, remote service enrollment and start-up comprises of 19.06% of the workload, and some of the 6.73% unscheduled insignificant services are also contributed to the patient education of the remote monitoring service. Consider that the RCH cardiac clinic offers the remote monitoring services in 2016, all the RM patients enrolled in the study are the first time users of the technology. It may recommend that the clinic and possibly Medtronic the vendor could be more involved in the early stage of patient adoption with the education and system setup to manage the learning curve of the technology, so that in the long term the workload pertaining to the remote monitoring technology may be reduced. The rationale and the benefit of the remote follow-up service as integrated to the hybrid follow-up clinical protocol may also better be materialized by both the clinic and the patient, such as reduced workload and improve workload flexibility by the clinical resources of a DFC, and the reduced stress in travelling to and waiting at the clinic for the patient. In turn, the remote monitoring

service may indeed improve the effectiveness of the clinical resource utilization, yet it would require a longer term study of the RM patients after they become mature with the technology to build up the relevant evidence.

The service categorization of the remote monitoring services breaks down the variety type of workload contributed by the service. It also highlights the needs of resource planning for this additional touchpoint for patient interaction and care services. Out of the eight type of services provided to the RM group patients, four of them are specific to the remote follow-up services (patient education, remote service enrollment and start-up, unscheduled insignificant services, and unscheduled significant services). In the long term, their service demand should be reduced as the patients become more adroit to the medical application of the technology. On the other hand, the service demand may also increase for the remote monitoring services could become an easier channel by sending in remote transmissions for medical attention, hence creating the probable increase of both the unscheduled insignificant services and unscheduled significant services. Appropriate resources should be planned around supporting this touchpoint as RCH cardiac clinic is responsible for all the remote transmissions.

The research focuses on the clinical resource utilization at RCH cardiac clinic as a device follow-up clinic, and did not go into depth with the overall FHA resource utilization as a health delivery organization. One emergency service is indeed recorded in the data collection for an RM patient. With the remote monitoring service as an additional touchpoint on receiving real-time device and medical remote data transmission of the implanted patients, overall it should reduce clinical resource utilization in other part of the health delivery organization, for example emergency services and hospitalization. The scheduled significant and unscheduled significant services in the RM group had presented evidence where during the business hours that the cardiac technologist and the cardiac EP can deliver medical consultation and treatment to patient, remotely interacting with the patient using the combination of the remote transmission and the phone discussion, so the clinic can timely increase the service supply through remote transmission while improve the timeliness of the response, and reduce the patient's service demand to the other part of health delivery organization. The clinic should build up its knowledge and experience in streamlining the workflow process and

standard clinical operating procedure in utilizing the remote monitoring technology. The implanted patient should also comprehend one's responsibilities of using the service with the clinic.

6.2 Strength and Limitation of Study

The study design has both the strengths and limitations to the research of the impact of the CIED remote monitoring technology on a device follow-up clinic. This section reviews the four areas of the study design – patient selection, scope, data collection on workload measurement, data processing in service categorization, the application of the system dynamics, and the support of operation resource management.

Convenience sampling is used in the patient selection of the study based on the patients having its follow-up appointment scheduled at the RCH cardiac clinic during the data collection period. The RCH cardiac clinic has the convention of recommending the patient who live far from the clinic, many live more than one hour of driving distance from RCH, or who presents more sensitivity to the device or the cardiac condition to enroll in the remote follow-up service. Although there may be patient selection bias from this convention of remote follow-up services, but as shown in the patient statistics, the NYHA classification between the IC group and the RM group show no significant difference with the small sampling of less than thirty patient samples.

The data collection of the workload as the clinical resource utilization is a time-to-event study is based on the cardiac technologist's assessment on the time spent on each patient encounter of the service delivery by oneself and the cardiac EP. The self-reporting mechanism is based on the honour system of the technologist in self-entering the workload to the data collection work log. As a limitation, all the technologists were fully informed on the context of the research aim but also leverage their knowledge of the standard clinical protocol of the follow-up service in justifying the time measurement entered, thus may balance the performance bias on the data collection and comply with the internal validity of the study. On the other hand, this workload entry is the least invasive approach for the clinic's service delivery for both the patient and the cardiac clinic team. Patient anonymity remains in the study because the technologists captures most of the information without the researcher's involvement. Furthermore, the one-year

study period on the data collection is valuable to average the workload of the new and replacement patients enrolling to the control group and the interventional group at different time of the year. It also helps to average the seasonable workload change throughout the year so that it is reflective of the annual cardiac clinic operation to existing and new patients.

The decision to exclude cost and clinical outcome of the remote monitoring services in the analysis of the clinical resource utilization is to limit the scope of the research to effectively simplify focus on the daily operation of the RCH cardiac clinic and its main manageable resources – the clinical resource of the cardiac technologists and the cardiac EP. Hence the research can address the clinic's motivation of the research to evaluating if the research monitoring services could solely mitigate its workload for the patient growth.

The data processing in service categorization breaks down the variety of workload to the IC group and the RM group at the RCH cardiac clinic. The data processing was performed with a cardiac technologist provided the clinical validity of the workload at the clinic. The service types of the IC group becomes a referential baseline to put a perspective of the more variety of the service types of the RM group to demonstrate the different services provided for each clinical protocol of the follow-up service. Although some of the services may be common for all device follow-up clinic, the outcome of the service types is contextual to the RCH cardiac clinic and may not be fully generalizable to the other similar ambulatory device follow-up clinic, particularly the staffing structure as the clinical resources in delivery the service. Also, the service categorization has addressed the gap that patient education is a contributing workload for the new implanted or replacement patients on enrolling the remote follow-up services. From the literature review, many of the device follow-up clinics are staffed with dedicated device nurses, whereas the cardiac technologists at the clinic provides implant procedure services and other diagnostic services.

This research applies the system dynamics to assess the clinical resource utilization of a device follow-up clinic for the remote follow-up service and pertaining services. Both the causal loop diagram and the stock and flow diagram for the simulation model have been instrumental to focus on the scope of impact by the remote monitoring

technology to the clinic's overall workload management and resource planning, while strategically narrowing down to the boundary of the research scope, and leaving out the other less relevant factors. The causal loop diagram creates a backbone of a basic service supply-and-demand model of the implanted patients that can be generalized to the other device clinic follow-up without having to bound to the specific environmental factors of the clinic such as the type of remote monitoring technology, the device type, the clinical standard protocol, the clinical workflow, the type of clinical resources of the clinic, as well as the local health care system (on patient service accessibility, reimbursement model, and service resource planning and funding). The diagram can show the specific challenge that the RCH cardiac clinic could face on how the clinical resources can meet up with the service demands by the growing volume of new implanted and replacement patients. With a small sample size of about twenty patients per control and interventional group, the simulation model assists the impact analysis of the clinic's capacity to manage the service supply by the various factors, such as the annual implant rate and the planned resources as presented in the research. This is tailored-made for the RCH cardiac clinic using its data collection hence the external validity is poor in the generalization. One limitation of the simulation model is the assumption is built that the same dynamics behaviour of the service demand by the sample patients in each of the control and intervention groups would repeat every simulation run. The reality is that the dynamics behaviour of the service demand can be random by the patient's cardiac health and device status. In addition, in three years of time the clinic could implement program and workflow change that could improve the overall clinical resource management in the follow-up service delivery. The interpretation of the three-year projection in the workload simulation hence should be made reasonably cautious with the assumption. On the other hand, the simulation model can be reused for sensitivity analysis when the change of a parameter is under investigation.

Lastly, another limitation of the research is that the research is driven by the volume of patient on the clinical resource utilization. The data collection and the workload analysis of the research is based on patient as the basic unit of measurement. Yet when the RCH cardiac clinic conduct its resource planning for the daily operation, the planning is per business day of the cardiac EP or per shift of the cardiac technologists.

The clinic does not plan its resources based on how many patients and how many remote transmission that it would receive, for the staff is responsible for all the patient workload during the day. Although the research provides a solid breakdown of the workload types and the service sustainability, an outstanding question is how the research would address the clinical resource planning and workload projection between patient volume and the operation of the clinic is still to be determined as the patient service demand requires timely respond during the business hours of the clinic. This question should be addressed by both the clinic team and the FHA Cardiac Services management team on the clinic's overall resource planning.

6.3 Future Study

Based on the research setting at RCH cardiac clinic, a few areas should be further research for future study in evaluating the impact of the remote monitoring technology of CIED to a device follow-up clinic.

The study period of the research could extend beyond one year and ideally to three years on the same patients in the RM group. This is to investigate if the remote monitoring services can be better utilized after the patient has become mature with the technology. The time in between the patient enrolls to the remote monitoring service and to attend the first remote follow-up service can be captured to measure the patient's duration and the clinic's workload to be sufficiently support the patient's learning curve. Hence the ratio of the in-clinic follow-up service and the remote follow-up service may be changed over time, along with the workload associated with the patient education and unscheduled insignificant services due to duplicated transmission may be expected to dwindle over time. The longer study period may also demonstrate the reduction of the service demand to the FHA as the health delivery organization, for example emergency services and hospitalization. This could also capture any change in the clinical workflow in streamlining the respond to patient's service demand related to the remote monitoring services

The research captures the workload of the patients implanted with ICD and CRT-D devices. They are generally considered as the interventional treatment to the cardiac patient with arrhythmia or had previously heart failure. These patients are implanted

because they have already been diagnosed. The research can expand to the other types of CIED such as pacemakers and ILR, which the diagnostic device. It may be worth the research on the impact of the workload by remote monitoring to the RCH cardiac for different clinical nature including finding the cause of the medical issue and determining the appropriate treatment.

The scope of the research should also expand beyond the fundamental service demand and supply at the RCH cardiac clinic. For example, in the future study, the broader scope of the RCH cardiac clinic's causal loop diagram should include the waiting list of the implant procedure services and the follow-up services at RCH. Also, the clinic also provides other diagnostic services, and the cardiac clinic team also offers other medical services within FHA Cardiac Services. The diagram should also depict the resource management in the trade-off service between serving these implanted patients including the regular follow-up services and the other services the clinic provides to the general cardiac patients. The RCH cardiac clinic may consider associating the relationship of the clinical resources and the patient growth to the clinic as shown in the causal loop diagram. Other factors that should be included in the future study on workload and resource management for the clinic includes the replacement schedule, implanted patients leaving FHA or joining FHA for follow-up services, annual provincial funding of the new FHA implant patients, as well as the training resources for recruiting additional cardiac technologists and cardiac EP.

Chapter 7. Conclusion

A cardiovascular implantable electronic device (CIED) is a medical device that implanted in the chest of a patient diagnosed with irregular heartbeat or cardiac arrhythmias. It is an electrical intervention for the monitoring, diagnosis, and treatment of bradycardia, tachycardia and heart failure (Wilkoff, et al., 2008). It is critical to perform regular follow-up on an implanted patient during the life of the device. The impact of the clinical resource utilization of a device follow-up clinic by the remote monitoring technology of the implanted patient and the CIED is the subject evaluation of the research. The research is motivated by the RCH cardiac clinic for the challenge of serving the growing number of the implanted patients as well as the workload associated with the technology from patient education and ad hoc remote transmissions. From the literature review, the remote monitoring services consistently showed positive effect to the mitigation of the workload from the follow-up service. The research objectives are broken down as followed:

1. To identify the workload of the in-clinic only follow-up clinical protocol and in the hybrid follow-up clinical protocol with both the in-clinic and remote follow-up at a DFC;
2. To depict the relationship and interaction of the clinical resource consumption in supporting the workload of the in-clinic only follow-up clinical protocol and the hybrid follow-up clinical protocol of a DFC in a conceptual model; and
3. To project and compare if the clinical resource would be capable in serving the implanted patients in one-year and three-year periods after the study horizon in both the follow-up clinical protocols using a conceptual model.

This prospective, observational, post-test only study design at RCH cardiac clinic consists of two groups. The control group, or the in-clinic (IC) group, is the implanted patients who strictly attend all follow-up services at the conventional on-site setting at RCH cardiac clinic. These patients typically adhere to the clinic's standard IC follow-up clinical protocol. The intervention group, or the remote monitoring (RM) group, is implanted patients who enroll in the remote follow-up service using the remote monitoring system to send transmission. This study uses system dynamics modelling to

depict the workload assessment impact by the remote monitoring technology using one-year of data collection from the clinic's implanted patient encounters.

At the end of the data collection from July 2017 to June 2018, twenty one patients in the IC group and twenty patients in the RM group were included in the study. The average age of all forty one included patients is 64.44 years old. In response to the first research objective, three types of services were delivered to the IC group including the in-clinic follow-up service. Eight types of services were delivered to the RM group including the in-clinic follow-up service and the remote follow-up services. Four of the eight types of services were associated with the remote monitoring services. In response to the second research objective, the causal loop diagram and the stock and flow diagram are structured so that three types of parameters are identified: patient volume is the implanted patient's service demand to the RCH cardiac clinic; cardiac services for implanted patients are the types of services demanded from the clinic; and clinical resources are the cardiac technologists and the cardiac EP as the staff capacity of at the clinic in delivery the cardiac services to the implanted patients. Lastly, in response to the third research objective using the stock and flow diagram as the simulation model, the research demonstrates that for the IC group, the workload projection at Year 1 is sustainable by the clinic being 28.13% under-utilized, but the workload projection at Year 3 is not sustainable by the clinic being 11.53% over-utilized. For the RM group, the workload projection at Year 1 is sustainable by the clinic being 7.63% under-utilized, but the workload projection at Year 3 is not sustainable by the clinic being 46.41% over-utilized.

Although the research shows that the workload of a remote follow-up service is indeed less than an in-clinic follow-up service, the workload associated with supporting the patient in the adopting of the remote monitoring services is also fairly substantial, with over 30% of the total workload for the RM group with the summation of remote service enrollment and start-up, patient education, and unscheduled insignificant services. To leverage these RM patients who may become more mature with the use of the technology, one recommended future study is to continue investigate the workload by these patients at the clinic to evaluate if the remote follow-up service can be better

utilized while the workload with the remote monitoring services may be dwindled over time.

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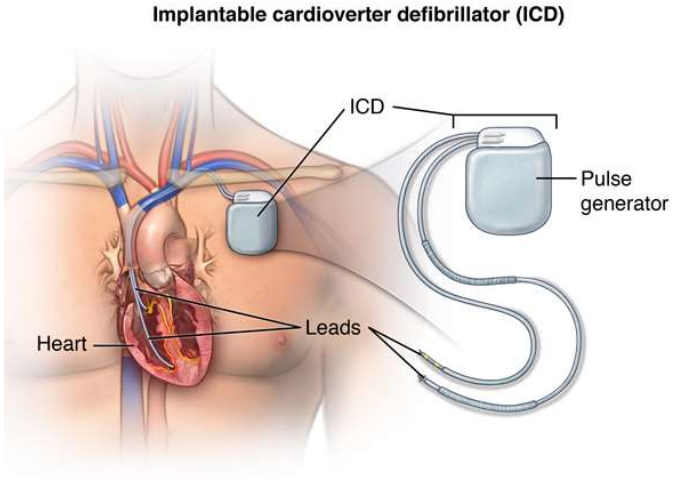
Appendix A.
Components and Functional Description of Cardiac Implantable Electrical Device

Cardiovascular implantable electronic device (CIED) is a medical device that acts as an interventional electric treatment to the medical conditions of irregular heartbeat or cardiac arrhythmias. A device is commonly made up of a pulse generator and a pacing lead. The pulse generator stores a battery and built-in programs to manage the artificial electric conduction system in the device. It enables the device for a life of five to ten years. The pacing lead is an insulated wire that carries the electric impulse generated by the artificial electric conduction system in the pulse generator from the device to the heart. Figure 14 illustrates the components of an implantable cardioverter defibrillator (ICD).

Figure 14 – Components of Implantable Defibrillator Implant



In general, a CIED provides one or more of the following functions:

- Monitoring – a function that checks and records the regularity and pattern of heartbeat
- Pacing – a function that uses electrical impulses to regulate the beating of the heart.
- Defibrillation – a function that delivers therapeutic dosage of electric shock to the heart

- Cardioversion – a function that converts an abnormally fast heart rate or cardiac arrhythmia to a normal rhythm
- Resynchronization – a function that resynchronizes the heartbeat consistently across the four heart chambers

Here is a list of the common types of CIED. These devices function differently to address and treat the specific cardiac conditions.

- **Permanent pacemaker (PPM)**

  A type of interventional device that monitors the heartbeat and to regulate the beating of the heart. When it detects that the heartbeat rate is too fast, too slow or irregular, the device uses therapeutic electric pulses to prompt the heart to resume back to a normal regular rhythm.

  Function: monitoring and pacing
- **Implantable cardioverter defibrillator (ICD)**

  A type of interventional device that is used by patients with irregular heartbeats or at risk of sudden cardiac arrest (SCA). It provides the same function as the pacemaker; in addition it delivers electric shock to the heart to prevent possible cardiac death.

  Function: monitoring, pacing, defibrillation, and cardioversion
- **Cardiac resynchronization therapy (CRT)**

  A type of interventional device that is used by for patients with moderate and severe heart failure. The device specifically addresses the issue of the contraction inconsistency of the heart's ventricles. It sends electrical pulses to pace both ventricles in a more coordinated rhythm. This coordinating therapy improves the heart's ability to pump blood and oxygen more efficiently to the body. CRT pacemaker (CRT-PPM or CRT-P) and CRT defibrillator (CRT-ICD or CRT-D) are two common types of a CRT. CRT-D devices, like all defibrillators, have a pacemaker function in them. Both devices help to coordinate the heart's pumping action and deliver pacing therapy for a slow heart rate. However, a CRT-D can also treat fast heart rhythms.

  Function: monitoring, pacing, defibrillation, cardioversion, and resynchronization

- **Implantable loop recorder (ILR)**

  It is also known as insertable cardiac monitor (ICM). If a patient is experiencing recurring fainting spells, a physician may recommend an ICM that continuously records a patient's heart rhythm over long periods of time. The information is downloaded from the monitor which can help diagnose if the fainting spells are caused by a heart-related problem.

  Function: monitoring

Reference:

Implantable Defibrillator Insertion. (n.d.). In *Lifebridge Health Cardiovascular Institute*. Retrieved from http://www.lifebridgehealth.org/Cardiovascular/ImplantableDefibrillatorInsertion.aspx.

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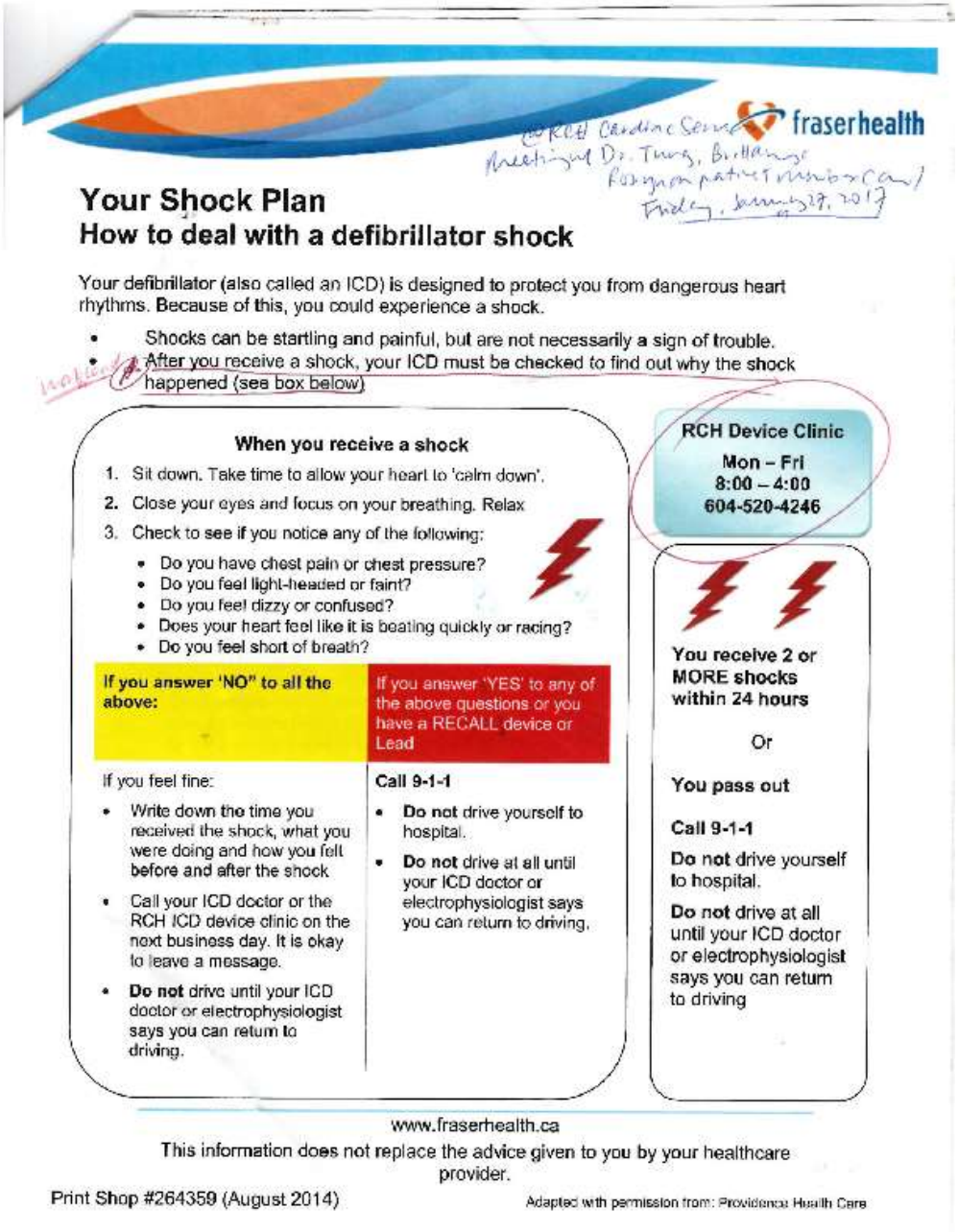
Appendix B.
RCH Cardiac Clinic Supplementary Information in Device Shock Management

The RCH cardiac clinic prepares this supplementary information titled "Your Shock Plan – How to Deal with a Defibrillator Shock" for patient to take the appropriate measure when experiencing and managing the shocks from the ICD or CRT-D.



fraserhealth

Your Shock Plan
How to deal with a defibrillator shock

Your defibrillator (also called an ICD) is designed to protect you from dangerous heart rhythms. Because of this, you could experience a shock.

- Shocks can be startling and painful, but are not necessarily a sign of trouble.
- After you receive a shock, your ICD must be checked to find out why the shock happened (see box below)

When you receive a shock

1. Sit down. Take time to allow your heart to 'calm down'.
2. Close your eyes and focus on your breathing. Relax
3. Check to see if you notice any of the following:
   - Do you have chest pain or chest pressure?
   - Do you feel light-headed or faint?
   - Do you feel dizzy or confused?
   - Does your heart feel like it is beating quickly or racing?
   - Do you feel short of breath?

If you answer 'NO" to all the above:	If you answer 'YES' to any of the above questions or you have a RECALL device or Lead
If you feel fine: • Write down the time you received the shock, what you were doing and how you felt before and after the shock • Call your ICD doctor or the RCH ICD device clinic on the next business day. It is okay to leave a message. • **Do not** drive until your ICD doctor or electrophysiologist says you can return to driving.	**Call 9-1-1** • **Do not** drive yourself to hospital. • **Do not** drive at all until your ICD doctor or electrophysiologist says you can return to driving.

RCH Device Clinic
Mon – Fri
8:00 – 4:00
604-520-4246

You receive 2 or MORE shocks within 24 hours

Or

You pass out

Call 9-1-1

Do not drive yourself to hospital.

Do not drive at all until your ICD doctor or electrophysiologist says you can return to driving

www.fraserhealth.ca

This information does not replace the advice given to you by your healthcare provider.

Print Shop #264359 (August 2014)

Adapted with permission from: Providence Health Care

Appendix C.
Summary of Literature Review

This Appendix presents the summary of each literature reviewed. The reference number of each summary can be found in Table 8 of 3.3 Data Extraction of Chapter 3. Literature Review.

1) The COMPAS study (Mabo, et al., 2012) a randomized, multi-centre, non-inferiority trial that examined the safety of long-term remote monitoring of pacemakers. The study took place at 43 French medical centres including 30 public and 13 private institutions. The primary objective of the trial was to confirm that the proportion of the patients who experienced at least one major adverse event (MAE) was not higher in the remote follow-up (active or RM) than in the standard care (control or IO) group. Relevant to this principle research study are two of its five secondary objectives of the trial, (1) to measure the decrease in the number of in-office follow-ups conferred by remote monitoring, and (2) to compare the contribution of the follow-ups in both groups. The study uses Biotronik Home Monitoring system as the remote monitoring/telecardiology solution to monitor the patients in the active group daily. The daily monitored data is managed by either a physician or an allied professional during office hours. No interim visit was scheduled for the active group, unless the cardiologist investigator was notified by email regarding a device technical issue or medical issue detected. Patients assigned to the control group were managed by the usual practice of standard care follow-up at each medical centre. Between December 2005 and January 2008, 248 patients were assigned to the active group and 246 patients were assigned to the control group. The mean study duration of the follow-up was 18.3 ± 3.3 months.

In response to the first secondary objective, a 56% decrease (95% CI: −61 to −48; $P < 0.001$) in the number of interim follow-ups per patient was measured between the RM group, with the mean number of 0.51 ± 0.71 (95% CI: 0.43–0.59), and the IO group, with mean number of 1.15 ± 1.07 (95% CI: 1.03–1.27). After the last scheduled follow-up, the between-groups decrease was 36% (95% CI: −43 to −28; $P < 0.001$), with the mean number of follow-ups per patient-year was 1.04 ± 1.02 (95% CI: 0.94–1.14) in the RM group and 1.63 ± 1.28 (95% CI: 1.50–1.76) in the IO group. It was demonstrated based on the statistical analysis that each patient in the control group were usually followed every six months. On the other hand, 126 patients (50.8%) in the active group needed no interim follow-up throughout the 18-month follow-up study. Furthermore, out of the 167 interim follow-ups in the active (RM) group, 73 follow-up were prompted by remote monitoring which 34 were clinical events and 39 technical events. In response to the second secondary objective, 71% of the interim follow-ups in the control (IO) group were non-contributory while only 38% of the interim follow-ups in the active (RM) group ($P < 0.001$). Limiting the analysis to the interim follow-ups prompted by remote monitoring, only 26% were non-contributory. At the 18-month scheduled follow-ups, 79% were non-contributory in the control (IO) group and 73% in the active (RM) group ($P = 0.13$). This study result provides numerical evidence that the remote monitoring follow-up can reduce the necessity for on-site follow-up, hence reserving the clinical resources readily for patients who truly required the appropriate clinical care. Specifically, as a straightforward example, the 126 patients in the active group with no

interim follow-up is the saving of the clinical resources from three on-site visits per person, or total of 378 on-site visits at the medical centres during the 18-month follow-up study.

2) A time and activity analysis is performed at the Cleveland Clinic in United States to compare the time taken to complete a remote monitoring (RM) follow-up and an in-person follow-up, the frequency of the clinically actionable events detected in the remote transmission, and how the remote monitoring affects the overall devices clinic workflow (Cronin, et al., 2012). The clinic uses four remote monitoring systems or network– Biotronik Home Monitoring, Boston Scientific Lattitude, Medtronic Carelink, and St. Jude Merlin.net. The clinical protocol is each patient is scheduled 6-week post-implant office in-person visit and one annual in-person visit with additional unscheduled visits as necessary. Patients that accept enrollment in an RM network are enrolled at the 6 – 12-week follow-up programming evaluation visit. All evaluations, either by remote or in-person, are ultimately reviewed by physician. For study comparison, during the study period between March 1 and March 16, 2011 the time taken to complete an in-person follow-up were collected on 82 consecutive follow-ups over 2 days. Definitions also were delineated for the study, including (1) the time to process an RM transmission "as the time taken by the device nurse from accessing the patient's transmission on the RM system Web site to closing the encounter, which included reviewing all received RM data and all data export, comments, billing and rescheduling, and patient and physician phone calls or emails, if applicable"; and (2) time to complete an in-person evaluation as "the time from when the patient entered the room to the time the patient left the room, with all the above tasks also completed". The physician time, either face to face or subsequent to the visit, was not included in this definition.

500 remote transmissions were received from 434 patients during the study period, with 346 from ICD, 84 PPM, and 70 ILR. After analysis of the result remote transmission and the in-person follow-up, the processing of the remote interrogation (monitoring) transmissions, with 11.5 ± 7.7 minutes, was faster than in-person programming evaluation, with 27.7 ± 9.9 minutes ($P < .01$). Remote interrogation evaluations that reveal clinically important findings, with 21.0 ± 7.4 minutes, and took longer to process than those that did not revealed, with 10.1 ± 2.1 minutes ($P < .01$). Next, 135 (27.0%) of the 500 transmissions demonstrated a total of 172 clinically important events. Only 41 events of the 172 events required physician notification as per the predefined protocols, hence the remaining transmissions are indeed non-actionable. Lastly, a total of 49.2% scheduled remote transmissions were missed initially owing to patient noncompliance. An average of 21 patients/day was performed on telephone follow-up of patients who missed the scheduled remote remissions, with an average of 55.1 minutes per day (range of 20 – 98) was spent. In conclusion, the study provides numerical evidence that the remote monitoring follow-up can directly free up the clinical resources for patients who actually require medical attention based on evidence of the remote data available to the clinical care team ahead of time before the patients arriving at the clinic.

3) A clinical, economic, and organizational evaluation was done on remote monitoring of pacemakers and ICDs at the Veneto region in Italy (Dario, et al., 2016). This study is a multi-centre, multi-vendor, controlled, observational, prospective study to evaluate the impact of the service delivery of the RM follow-up compared with the in-clinic follow-up in terms of the effectiveness and efficiency to the cardiology department, the local health authorities, and the health system. The outcomes from the study relevant to this principle research study are (1) the workload from the organizational evaluation; (2) hospitalization and other special visits from the clinical evaluation; (3) the direct costs of each follow-up from the economic evaluation. The cardiology department of six local health authorities in the Veneto region assigned eligible patients into two groups – the intervention group (the I group or the RM group) which were followed up with a RM system, and the control group (the U group or the IO group) which were followed up as routine in-clinic follow-up. Follow-up routine were performed every 12 months for PM and every 6 months for ICDs, and additional in-clinic visits as required. The remote monitoring systems used were Biotronik Home Monitoring, Medtronic Carelink, Boston Scientific Latitude, and Sorin SmartView. They all support both wireless (automatic) and manual remote monitoring of the implanted device. In the twelve-month study between October 2011 and November 2012, 1871 patients (with 979 PM and 892 ICD patients) were enrolled in the I-group (the IO group) and 230 patients (192 PM and 38 ICD patients) were enrolled in the U-group (the RM group).

In response to the first research question of the study, the organizational evaluation based on the clinical workflow evaluates clinical resources required for patient follow-up by the time spent to each patient in the I-group and the U-group. Table 9 of 3.4 Outcomes and Considerations summarizes how much time spent in minutes by a physician and a nurse in each study group per device. Generally if no intervention in the form of an in-clinic follow-up was not required, then generally it required less physician and nurse time to complete a regular follow-up for both types of devices. More nurse time was spent only when a PM patient in the I-group requires clinical follow-up. Indeed, in the U-group 74.8% of the in-clinic follow-ups resulted in no clinical intervention nor device reprogramming. In fact, some portion of the nurse time spent in the I-group was instead in data entry, for no integration of the remote monitoring system was established with the electronic medical record, and time was also spent in contacting patients to clarify the legitimacy of the remote transmissions and alerts.

In response to the second research question of the study, the economic analysis from the health care system's perspective was based to quantify the service delivery based on the market value of the services and the diagnosis related group payment rates. Some of the total costs included project start-up costs (including education of clinical professional), travel costs, staffing cots, changes in the use of health care resources, and medication costs. Table 20 presents the summary of the calculation of the cost saving.

Table 20 – Mean direct costs of care per patient per year (€, 2011 prices) (Dario, et al., 2016)

Patient Group	Total Cost	Confidence Interval	Difference	Confidence Interval
PM U-group	1775.83	41545.41-2007.28		(P < .001)
PM I-group	972.42	938.15-1009.12	-803.41	-1036.32 to -569.11

ICD U-group	2119.19	1428.01-2812.16		(P = .37)
ICD I-group	1813.11	1706.12-1908.35	-306.08	-1011.68 to 385.98

In response to the third research question of the study, additional in-clinic follow-up, hospitalization, cardiology visit, and emergency department visits per patient-year were compared between the two studies groups are summarized in Table 21. Statistically significant difference was measured for the ICD U-group to have more number of cardiology visits and in-clinic follow-up than the ICD I-group.

Table 21 – Hospital Visit per Patient-Year (Dario, et al., 2016).

Patient Group	Hospitalization	In-clinic follow-up	Cardiology Visit	Emergency Department
PM U-group	0.50	1.07	0.85	0.67
PM I-group	0.37	0.43	0.37	0.64
ICD U-group	2.14	0.67	1.69	0.67
ICD I-group	0.98	0.60	1.58	0.80

Overall, the study builds foundational evidence regarding the usefulness of RM in reducing the amount of physician and nurse time for the follow-up, and the cost saving from conducting RM follow-up over an IO follow-up in patient and device management.

4) A study was performed on the effectiveness of the pacemaker telemonitoring at the Poniente Hospital in Almeria, Spain (Lopez-Villegas, Catalan-Matamoros, Robles-Musso, & Peiro, 2015). The primary objective of the study was to assess potential differences between the remote monitoring (RM) and hospital monitoring (HM or IO) groups in terms of the health-related quality of life (HRQoL) during the year after the implantation of the pacemaker. The two secondary objectives of the study relevant to the principal research study were to assess the difference between the two groups in (1) workload pertaining to regular follow-up; and (2) proportion of adverse events (AE), including death, hospitalization and fibrillation episodes. The remote monitoring system used the study is Medtronic Carelink. In this controlled, non-randomized, non-blinded single-centre study, patients assigned to the RM group were not scheduled with on-site visits during the 12-month study period, unless patients were phoned for a hospital visit if the data received detected a technical or cardiac event; while patients assigned to the HM group were managed according to the standard practices of the hospital, with follow-up visit scheduled according to physician's criteria. Patients were interviewed on the date of implantation, and at the 1-, 6-, and 12-month visits. At each scheduled visit and on the completion of the study, the research team revised the medical record for identifying adverse events, changes in patient management and pacemaker reprogramming. Between October 2012 and November 2013, 30 patients were enrolled in the RM group and 52 were enrolled in the HM group. In response to the first secondary objectives, four in-hospital follow-up visits per patient were calculated in the HM group during the study period, while five follow-ups per patient were calculated in the RM group. Note that the two of these five follow-ups were conducted via remote transmissions, hence three follow-ups were done in-hospital. In response to the second secondary objectives, 71% of all patients had experienced at least one cardiovascular events, with 67% of the patients in the RM group and 73% of the patients in the HM group. One patient from the HM group was hospitalized from a cardiovascular event that was unrelated to the pacing systems. Two patients, one from each study group, died of non-cardiovascular causes.

5) A Finland study investigated if internet-based remote monitoring offers "safe, practical, and cost-effective alternative" to the in-office setup to the in-office follow-up visits of patients with ICD (Raatikainen, Uusimaa, van Ginneken, Janssen, & Linnaluoto, 2008). The prospective, non-randomized, single centre study pre-test and post-test design was conducted between May 2006 and October 2006. The study was a single-group with study with patients with a previously implanted ICD that was supported by the Medtronic Carelink remote monitoring services were asked to particulate in the study. Then the participating patient sent the first remote data transmission one to two weeks after being included in the study. Then the 2nd and 3rd remote transmissions were sent at 3- and 6-month period following the first data transmission to substitute for the recommended in-office ICD follow-up. Then a regular follow-up visit was performed in the hospital at 9-month period. More remote transmission or in-office follow-up may be arranged as required by patient or the study nurse or doctor. The primary objective of the study was to assess the safety of the system, in terms of the percentage of successful transmissions that did not require a troubleshooting phone call was calculated for all data transmissions. One of the three secondary objectives of the study that is of interest to the principal research study was to assess the travel burden on the patients and the workload on the clinic in order to calculate the economic impact of remote ICD monitoring. Both the direct and indirect expenditures of ICD follow-up were analyzed. The indirect cost by the Social Insurance Institution of Finland consisted of travel and accommodation costs and sickness allowance for the patients and accompanying persons. Overall 41 patients were included in the study with page of the patients was 62±10 years. In response to the primary objective, over 90% (with 85 – 95 at 90% CI) of the data transmissions were performed without troubleshooting phone call. Here is the outcome from the description statistics analysis in response to the second objective:

- The time needed by the patients for remote data transmission (6.9 ± 3.7 min, range 2.3–17.5 min) was significantly shorter than the duration (travel time + time in the hospital) of an in-office visit 391 ± 282 min (range 41–1346 min), $P < 0.001$
- The average one-way distance and travel time to the hospital were 130 ± 95 km (range 3–350) and 182 ± 148 min (range 10–670 min), respectively
- The time needed by the physician for reviewing device data on the secured website (8.4 ± 4.5 min, range 2–30 min) was significantly shorter than the time needed for completing an in-office follow-up (25.8 ± 17.0 min, range 5–90 min), $P < 0.001$.
- In keeping with this, it was more time-consuming also for the additional hospital staff to complete an in-clinic visit than remote monitoring (45.3 ± 30.6 min vs.9.3 ± 15.9 min, $P < 0.001$).

The economic evaluation concluded that with the cost and reimbursement model in Finland, substitution of the two in-office visits during the 9-month follow-up period by remote monitoring accounted for a total cost savings of €21,468 (41%). Hence the study concluded that remote monitoring offers s safe, feasible, time-saving, and cost-effective solution to ICD follow-up.

6) The Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators (EVOLVO) study is a prospective, randomized, open, multi-centre clinical trial to compare chronic HF patients with ICD/CRT-D between the remote monitoring care (remote arm) and the current standard of care (standard arm). The study was performed at six Italian hospitals (four in Milan, one in Pavia, and one in Brescia) using Medtronic Carelink as the remote monitoring system. Over the 16-month of the study period, patients assigned to the standard arm were scheduled with in-office follow-up at fourth, eighth, twelfth, and 16th months. Patients assigned to the remote arm were scheduled with in-office follow-up at eighth and 16th months, and were scheduled instead with remote transmissions instead in the fourth and twelfth months. The study analyzed the comparison with various aspects, with one aspect aimed at measuring remote monitoring as a cost-effective intervention in an economic evaluation from the perspectives of the health care system and patient (Zanaboni, et al., 2013). A cost-utility analysis is a type of health economic analysis that evaluates the cost as input to the intervention against the changes to health and well-being as output (U.S. National Library of Medicine, 2016; University of Victoria, 2016) .It was carried out in the study to measure the potential benefit of remote monitoring, with the outcome presented in terms of cost per quality-adjusted life year (QALY). Costs from the health care system perspective included urgent and non-urgent in-office visits, scheduled and unscheduled remote follow-ups, emergency department visits, hospitalizations, and diagnostic examinations. The costs generally correspond to the specific public tariffs from the diagnosis-related group (DRG) system offered by the regional health care authority. Costs from patient's perspective included was related to out-of-pocket expenses, including transportation, room and board, and wages lost by patients and family caregivers. Pre-specified rates were used for calculating the patient's main expenses. After calculating all the costs, QALYs, and utility values, the cost-utility ratio was computed as differential costs between the remote arm and standard arm over 16 months and differential QALYs.

The study ended with 89 patients in the remote arm from 99 patients assigned and with 87 patients in the standard arm from 101 patients assigned. Relevant to the principal research study is the costs from the health care system perspective, and the result of caring an chronic HF patient with ICD or CRT-D with remote monitoring did not show statistically significant annual cost savings than with standard care, although some saving did incurred – the average annual cost per patient in the standard arm is €2130.01 (±5251.33) and the cost per patient in the remote arm is €1962.78 (±4185.61) at $P = 0.80$. As summarized in Table 11 of 3.4 Outcomes and Considerations below, the average cost of a protocol-defined clinic visits was €90.29 (±38.58) in the standard arm and €56.63 (±38.64) in the remote arm at $P < 0.001$. In the remote arm, the average cost of schedule remote follow-up was €32.50 (±9.20) and unscheduled remote follow-up was 56.42 (±58.95). Note that cost saving occurred with two of the four follow-up over the study period were replaced from the protocol-defined clinic visits by the schedule remote follow-up in the remote arm. Furthermore, although statistically significant cost saving in the remote arm incurred from having lower costs in ED visits and urgent in-office visits and hospitalization, non-urgent in-office visits is more expensive than it is in the standard arm. Cost saving was reported from using remote monitoring technology by

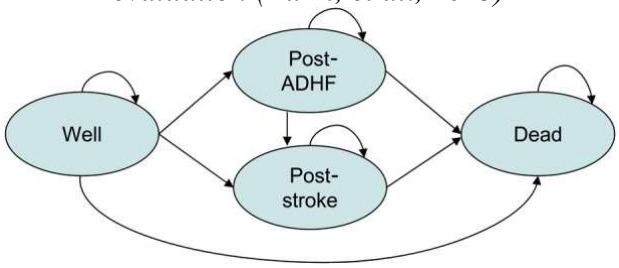
comparing the average annual cost per patient of €1962.78 in the RM group from €2130.01 in the standard arm.

Another aspect of the EVOLO study assessed the impact of the remote monitoring technology for heart failure, arrhythmias, or ICD-related events for the reduction in emergency healthcare visits (Landolina, et al., 2012). The primary objective of the study was to assess the rate of emergency department or urgent in-office visits between the standard arm and the remote arm. One of the three secondary objectives that is relevant to the study is the rate of the total health care use (any in-office visit, emergency department visit, and hospitalization required at least one overnight stay). In response to the primary objective, 63 emergency department and 129 urgent in-office visits for the heart failure, arrhythmias, or ICD-related events were recorded. Out of the 192 of these visits, 75 events were recorded in the remote arm and 117 events were recorded in the standard arm. In calculating the incident rate (IR) of the study, 127 person-years in the remote arm and 126 person-years in the standard arm were pre-defined. Hence the incident rate of the remote arm is 0.59 events per year, and the incident rate of the standard arm is 0.93 events per year. The incident rate ratio (IRR) is then 0.65 at 95% confidence interval (CI). Over 16 months, the visits were 35% less frequent in the remote arm than the standard arm. In response to the secondary objective, there were 1285 of total healthcare uses recorded in the study, with 559 uses recorded in the remote arm and 726 recorded in the standard arm. A statistical difference in the rates of events was noted between the two arms, with 4.4o events per year in the remote arm and 5.74 events per year in the standard arm. The incident rate ratio is 0.79 at 95% confidence interval (CI). The total health care visits was 21% less frequent in the remote arm and the standard arm. The study result fitted the expectation that the remote monitoring system allows early device data review while reducing the need for urgent hospital examinations and increasing the appropriateness of in-office visits.

7) In United Kingdom, the National Health Service assessed the long term cost and consequences of using the remote monitoring system daily on ICD and CRT-D over conventional follow-up (CFU or referred as IO in this principle research study), with the understanding that remote CIED management has been established as a safe alternative (Burri, et al., 2013). The study utilized Biotronik Home Monitoring (HM, or referred as RM in this principle research study) as the remote monitoring system. Cost-consequences analysis as health economic evaluation was performed to compare the long-term follow-up using either Home Monitoring or CFU in ICD and CRT-D patients. As defined in the study, a cost-consequence analysis is a variation of the cost-effectiveness analysis includes both costs as input and desire outcomes or consequences as output as defined by the study. A deterministic Markov cohort model was developed, with each cycle length as one year and a base case modelling period of ten years. This was ensured that the device replacement would be captured by the model, as the device would typically be replaced between every five to ten years. The model examined twelve consequences which were either clinical events or device-related technical events. Costs and outcomes were discounted at 3.5% per annum to be in line with the UK guideline. The patient population represented in the model consists of patients who have undergone an ICD or CRT-D implantation and are managed in an outpatient setting. One treatment arm represents patients managed by RM, while the other arm consists of patients

managed with CFU. In every Markov cycle and health state (except 'Dead'), the probabilities of experiencing the clinical and technical events were applied. Clinical and cost data were identified via structured searches using MEDLINE and systematic review of the identified sources. While most of the event data were taken from randomized controlled trials (RCTs) for RM; all costs were specific for the UK, data from multiple sources were pooled or meta-analysed. In building the model, the CFU model consisted of approximately three scheduled in-office follow-up per year, while the RM model consisted of one scheduled in-office follow-up per year and approximately 0.78 remote monitoring service per year. Event rates were converted into annual probabilities. Some of these probabilities remain constant, while others change over time depending on age or prior clinical events. The same model structure is applied to the CFU arm and the RM arm. Figure 15 depicts the transition diagram for the model structure of the Markoc cycle and the four main health states.

Figure 15 – Transition diagram based on the Markov cohort model for CFU and RM evaluation (Burri, et al., 2013)



With the sample size of 1000 patients was chosen, the result of the model simulation indicated that in over ten years, RM is predicted to be cost neutral at about GBP 11,500 per patient in either treatment arm, with all costs for the initial investment in RM and fees for on-going remote monitoring included. Furthermore, the remote monitoring technology was used for more than ten years or longer, then RM can become increasingly cost saving.

8) A systematic review and meta-analysis were carried out to explore whether implantable device telemonitoring (DTM or referred as RM in this principle research study) in patients reduces healthcare utilization over standard of care (SoC or referred as IO in this principle research study) without compromising patient outcomes (Klersy, et al., 2016). Endpoints with respect to health care utilization include number of hospitalizations, emergency room (ER) and/or unscheduled visits, total number of outpatient visits, and costs. A composite endpoint, consisting of the number of ER visits, unplanned hospital visits, or hospitalization, was also assessed. Based on the search strategy and study selection for randomized controlled trials (RCTs) on DTM with heart failure and mid- to long-term clinical outcomes, and taking into account of healthcare utilization data, eleven RCTs were investigated with 5702 patients were enrolled for the follow-up range between 12 and 36 months. For meta-analysis of each study, the relative risk (RR) of the DTM group and the SoC group with 95% CI for each categorical outcome was derived from the available data. Relative risk is defined as "the ratio of the risk of disease (or death) among people who are exposed to the risk factor, to the risk among people who are unexposed" (University of Ottawa, 2015). The study RRs for each

outcome were then pooled based on statistical methods. No single study influenced the overall meta-analytic estimates for any endpoint from these studies:

- Eight studies reported on cardiac hospitalization, with RR= 0.96 (CI 0.82–1.12, P = 0.60);
- Four studies reported on the composite of unplanned hospital visits, ER attendances, and hospitalizations for cardiovascular events, with RR = 0.99 (0.68–1.43, P = 0.96);
- Nine studies reported on ER and/or unplanned hospital visits, with RR = 1.37 (1.11 –1.70, P = 0.004); and
- Eleven studies reported on total number of all (planned, unplanned and ER) hospital visits, with RR 0.56 (CI 0.43– 0.73, P < 0.001).

The study of RR for each clinical outcome of health care utilization shows that between the DTM arm and the SoC groups that the rates of cardiac hospitalizations and the composite rates of unplanned hospital visits, ER attendances, and hospitalizations for cardiovascular events were very similar. While the rates of total number of all hospital visits were reduced, an increased rates in the total number of ER and/or unplanned hospital visits were reported. Note that the abovementioned EVOLVO study (Zanaboni, et al., 2013) was included as one of the RCTs in this systematic review, along with other large studies of remote monitoring and management of CIED investigated by the professional bodies as discussed in Chapter 1, such as the CONNECT study (Crossley, Boyle, Vitense, Chang, & Mead, 2011) and the TRUST study (Varma, Epstein, Irimpen, Schweikert, & Love, 2010).

9) In 2014 a survey study was conducted by the European Heart Rhythm Association (EHRA) (Mairesse, Braunschweig, Klersy, Cowie, & Leyva, 2015) on the assessment of the implementation and the funding of remote monitoring of CIEDs including PMs, ICDs and CRTs in Europe. This survey was based on an electronic questionnaire sent to 152 centres participating in the EHRA research network. The survey assessed the frequency of surveillance of RM and the effect of RM on in-office visits, with the questions focused on the perceived benefits of and constraints to the use of RM. Response was received from 43 centres (28% of response rate) in 15 European countries comprised of university hospitals (69%), regional hospitals (22%) and local hospitals (9%). During the calendar year prior to the survey in 2014, participating hospitals implanted 263 (200–372) single or dual-chamber PMs, 115 (60–150) single- or dual-chamber ICDs, and 60 (43–110) CRT devices (CRT-P or CRT-D) including both new implants and replacements. RM was set up for PMs in 63% of responding centres and adopted in 22 ± 23% of patients (range 1–80%, adoption rate 14%). For ICDs, RM was set up in 74% of the responding centres and was also adopted in 69 ± 25% of patients range (10–100, adoption rate 51%). For CRT, RM was set up in 69% of centres and adopted in 71 ± 25% of patients (range 5–100, adoption rate 49%). Table 22 below is the summary of the response to the changes in the number of follow-up by the introduction of RM by the responding centre to the questionnaire. Overall, the number of PM follow-up was reduced by RM at 61% of the centres, the number of ICD follow-up was reduced 62% of the centres, and the number of CRT-P and CRT-D follow-up was reduced at 54% of the centres.

Table 22 – Effective of remote monitoring on in-office follow-up visits as percentage of responding centres (Mairesse, Braunschweig, Klersy, Cowie, & Leyva, 2015)

Changes by RM in the year?	No – still 3 follow-ups	No – still 2 follow-ups	Yes – to less than 2 follow-up	Yes – to less than 1 follow-up
PM	4	35	39	22
ICD	14	24	52	10
CRT-P and CRT-D	19	27	46	8

10) In United States, a nationwide study was conducted using the Truven Health Analytics MarketScan database to evaluate if the remote monitoring of clinical events of the patients with CIEDs could reduce health care utilization and costs in clinical practice (Piccini, et al., 2016). According to the study, the Truven database included "integrated inpatient, outpatient, and pharmacy data from privately insured and Medicare Advantage patients throughout the United Sates" since 1995. The database has been used in nationwide health care utilization and outcome studies, in terms of hospitalization including patients "with implanted cardiac electronic devices" and patients "undergoing cardiac electrophysiological procedures." According to its website, it contains data from over 240 million de-identified patients (Truven Health Analytics, 2018). The study was a retrospective, nationwide, observational cohort study using patient data from April 1, 2008 to March 31, 2013 in the Truven Health Analytics MarketScan Commercial and Medicare Supplemental Claims databases. The patients who had PM, ICD, CRT-P or CRT-D implanted from any manufacturer between March 31, 2009 to April 1, 2012 were included in the study. Hospitalization associated major clinical events were compared between those using RM and those not using RM by using the Cox proportional hazards methods with Anderson-Gill extension and propensity scoring. Although the frequency of the follow-up was not specified, the analysis included patients maintain regular follow-up and excluded those without a clinic visit or RM follow-up within 120 days of implants. Overall, there were 92,566 patients (mean age 72 ± 13 years) with 34,259 or 37% of the total patients used RM and 58,307 did not use RM. An average of patient follow-up is 19 ± 12 months, including 54,520 (59%) pacemaker, 27,816 (30%) implantable cardioverter-defibrillator, and 10,230 (11%) cardiac resynchronization therapy patients. To respond to the primary outcome of the study, across the entire cohort of patients with all device types, patients in the RM group experienced with the lower adjusted risk of all-cause hospitalization, including all cardiovascular and non-cardiovascular events such as pneumonia, (adjusted hazard ratio 0.82; 95% confidence interval 0.80–0.84; $P < .001$) and shorter mean length of hospitalization (5.3 days vs 8.1 days; $P < .001$). The hospitalization cost per patient in the RM group with all device types were also lower than cost per patient in the non-RM group, respectively $8720 average cost per patient-year and $12,423 mean cost per patient-year. Hence for every 100,000 patient-years of follow-up, RM was associated with 9810 fewer hospitalizations, 119,000 fewer days in hospital, and $370,270,000 lower hospital payments. To respond to the secondary outcomes in health care utilization in clinical events, data was analyzed in five clinical events – cardiovascular hospitalization, heart failure (HF) hospitalizations

in patient with a previous diagnosis of HF, readmission for HF, stroke hospitalizations in patients with a previous diagnosis of atrial fibrillation (AF), and stroke hospitalizations in patients with new-onset AF within 1 year after CIED implants. Patients with CIEDs in the RM group are generally associated with lower health care utilization in all the clinical events. As discussed in the study, RM provides several potential advantages in managing patient with arrhythmias, including earlier detection, lead malfunction, or device failure. The benefits of RM may potentially reach beyond efficiencies in outpatient care, since the technology may enable early intervention to present patient morbidity and potentially avoid reduce hospitalization, hence may bring profound implication for cost reduction.

11) Next, another United States study also used the data from the same Truven Health Analytics MarketScan Commercial and Medicare Supplemental Claims databases as the above study (Ladapo, Turakhia, Ryan, Mollenkopf, & Reynolds, 2016). The focus was to assess episodes of care and associated expenditures for office visits, remote monitoring claims, emergency visits, and hospitalizations in the 12-month follow-up on newly implanted CIED including PPM, ICD, and CRT-D in RM and in-office regular follow-up. The associated expenditures assessed included ambulatory care, hospital care, radiologic testing and procedures, laboratory testing, and other services. Because the analysis is based on medical claims, only the expenditures associated with the structured billing practices allotted for continued access to the remote monitoring system and did not capture the actual intensity of the utilization by the patient. Patient were selected from 2009 who had continuous health plan environment two years after implantation. The data analysis methodology used was the generalized linear models and propensity score matching to adjust for confounders and estimate differences in in patients with remote or in-office monitoring. From January 2009 to December 2011, 400,464 patients were identified with medical claims for follow-up of a CIED. Based on the selection criteria and the matching process, 1.127 pairs of ICD patients, 427 pairs of CRT-D patients, and 1,295 pairs of PPM patients are identified who had a similar propensity score. The outcome of the analysis included:

- ICD patients enrolled in RM had fewer emergency department visit resulting in discharge ($p = 0.050$) and had fewer hospital stays ($p = 0.057$) than its counterpart of patients with in-office follow-up
- PPM patients ($p = 0.025$) and CRT-D patients ($p = 0.006$) patients enrolled in RM associated with lower health care expenditures
- ICD patients enrolled in RM associated with lower total impatient and outpatient expenditures ($p < 0.0001$)

Otherwise, no statistical difference was reported from the data analysis between the two groups of patients in health care utilization by clinical events. The study concluded that remote monitoring of patients with CIEDs may associate with reductions in health care utilization and expenditures compared with in-office care only.

12) Health Economics Evaluation Registry for Remote Follow-up, or TARIFF, is an observational, prospective, non-randomized, multi-centre study designed to quantify and compare the direct and indirect costs and benefits of on-site standard of care (SC or IO as referred in the principle research study) and remote (RM) ICD and CRT-D patient follow-ups from the perspectives of the hospital, the health care system (HCS), and the

patients by one-year economic evaluation in cost effectiveness analysis (Ricci, et al., 2012). Costs from the perspective of HCS were the health care services used were assessed, such include hospitalizations, visits, and examinations. Costs from the patient's perspective were the out-of-pocket expenses such as travel, informal care as time spent by the caregiver, and the time spent by the patient for follow-up were assessed. The study was conducted at six Italian medical centres. The study consists of two phases. For the in-clinic group as the first phase, a patient was followed-up at a clinic upon two to eight weeks of enrollment, then followed-up at a clinic at 3-month, 6-month, 9-month and 12-month from enrollment. For the remote monitoring group as the second phase, a patient was followed-up at a clinic upon two to eight weeks of enrollment and 12-month from enrollment, and then followed-up remotely at 3-month, 6-month, and 9-month via the St. Jude Merlin.net remote monitoring system. Continuous monitoring was configured according to predefined technical and clinical alerts.

The result of the study was based on the SC group comprised of 107 patients with 89 patients completed the 12-month study, and the RM group comprised of 102 patient with 86 patients completed the study. From the HCS perspective, the overall mean annual cost per patient in the SC group (€1044.89 ± €1990.47) was significantly higher than in the RM group (€482.87 ± €2488.10) ($P < .0001$), with a reduction of 53.87% being achieved in the RM group. The primary driver of cost reduction was the cost of cardiovascular hospitalizations (SC: €`886.67 ± €1979.13 vs RM: €432.34 ± €2488.10; $P = .0030$). The analysis indicated that SC patients reported more hospitalizations for cardiovascular reasons, more emergency department visits, more outpatient diagnostic tests, and more outpatient visits than RM patients did. No statistically significant difference was measured in the length of hospital stay between the two groups of patients and between the types of device. From the hospital's perspective, the total number of in-hospital device follow-up visits was reduced by 58.78% in the RM group. In managing the remote transmission review, the time spent reviewing scheduled remote follow-up data and alert-triggered transmissions was, on average, 4.46 ± 3.35 and 5.89 ± 8.58 minutes, respectively (Ricci, et al., 2017).

13) The Effectiveness and Cost of ICD follow-up Schedule with Telecardiology (ECOST) trial is a French study that evaluated prospectively the economic impact of long-term remote monitoring of ICD in terms of the safety and the costs from the standard ambulatory care (Guédon-Moreau, et al., 2014). The study was conducted from the perspective of the French national insurance perspective using Biotronik Home Monitoring as the remote monitoring system. The costs of each follow-up strategy included (i) (a) ICD-related ambulatory visits and transportation, (b) other ambulatory visits, (c) cardiovascular treatments and procedures, and (ii) hospitalizations for the management of cardiovascular events. Over the study period of 27 months, patients assigned to the active (RM) group were followed with HM and were seen by a cardiac electrophysiologist in the ambulatory department within 1–3 months of ICD implantation, and then followed up in 15-month and 27-month from the first follow-up. Patients assigned to the control group were also were seen by a cardiac electrophysiologist in the ambulatory department within 1–3 months of ICD implantation, then be followed up every six months in 9-, 15-, 21- and 27-month.

The study was carried on 310 patients were randomly assigned, which 158 patients to RM (active or RM group) and 152 patients to ambulatory (control or IO group) follow-ups. Over a follow-up of 27 months, the average non-hospital costs, related to device management and other non-hospital costs such as ICD-related ambulatory visits and associated transportation , per patient-year were €1695 ± 1131 in the active group in comparison with €1952 ± 1023 in the control group (P = 0.04), a €257 difference. The difference is mainly due to the cost saving from device management which brought €74 difference at P = 0.001. The hospitalization costs per patient-year were €2829 ± 6382 and €3549 ± 9714 in the active and control groups, respectively (P = 0.46). The conclusion is that from the French national health insurance perspective, the remote monitoring of ICD patients incurred cost saving.

14) A single-centre prospective, randomized study was conducted at an Italian hospital on the economic impact by remote monitoring. The aim of the study is assessing the costs of one-year ICD follow-up, with costs distinguished between direct cost by hospital costs and social costs incurred by patients (Calò, et al., 2013). All four remote monitoring systems used at the site were included in the study – Biotronik Home Monitoring, Medtronic Carelink, Boston Latitude, and St. Jude Merlin.Net. Patient is randomized to the control arm and the remote arm with a standard schedule of quarterly follow-up. Patient in the control arm had all four follow-up at the hospital, while one in the remote arm had three remote follow-ups and a 12-month in-hospital follow-up. With the focus of the hospital cost as the principal research study of focus, the costs were taken from its regular Diagnosis-Related Group coded reimbursements for the care and health services provided. The cost model of the clinic has the following significant items:

- Costs of medical and nursing hospital staff for standard and RM follow-up for each single patient expressed as amount of USD per minute;
- Depreciation costs of hospital machinery, instruments, and equipment used during in-hospital visits;
- Cost increase due to RM service; and
- Costs for implant surgical procedures and related hospitalization were neglected since they were considered equal in both arms.

The working time of the clinic's personnel was manually recorded both for RM and for standard in-hospital follow-up strategies and tracked on log sheets grouping activities as follows:

- RM follow-up time: time spent by the physician/nurse to perform each remote follow-up, including website access, data review, and decision if required. Tracking of this time component was automatically performed by custom software.
- In-hospital follow-up visit time: time spent by the physician and the nurse for each in-hospital follow-up from the patient's entrance to exit from ambulatory.
- Time for administrative activities: these include patient file archiving and management, training, phone calls and contacts with patients as well as the administrative work related to the calendar management for scheduled remote follow-ups and medical report relative to the remote follow-ups performed to be prepared and mailed on patient's demand.

For all these activities, a distinction was made between medical and nursing personnel, timed and recorded for 1 year for all the patients included in this investigation.

The study included the total of 117 patients in the RM group and 116 in the control group. There were 520 follow-ups, done in both remote or in-hospital, and 489 follow-up in the control group. As per Table 10 in 3.4 Outcomes and Considerations summarized, the average time required by a physician or a nurse is less for the RM group than the control group based on the analysis of these follow-ups. Follow-up required 47 minutes per patient/year in the RM arm versus 86 minutes per patient/year in the control arm ($p = 0.03$) for involved physicians, generating cost estimates for the provider of USD 45 and USD 83 per patient/year, respectively when the average rate applied at USB 0.97 per working minute. Follow-up required 76 minutes per patient/year in the RM arm versus 91 minutes in the control arm ($p = 0.03$) for involved nurses, generating cost estimates for the provider of USD 59 and USD 70 per patient/year, respectively when the average rate applied at USB 0.77 per working minute. Overall, the costs associated with RM and standard follow-up were USD 103 ± 27 and 154 ± 21 per patient/year, respectively ($p = 0.01$). The study demonstrated that the remote monitoring could save cost by USD 51 per patient/year.

15) The randomized MORE-CARE (MOnitoring Resynchronization dEvices and CARdiac patiEnts) (MORE-CARE) trial is an international, prospective, multicentre, randomized controlled trial involving 61 cardiology centres in nine countries overall, from Europe and Israel (Boriani, et al., 2017). The aim of this study was to evaluate the clinical efficacy and safety of remote monitoring in CRT-D patients with heart failure implanted with a biventricular defibrillator (CRT-D) with advanced diagnostics. The trial was designed in two phases: in Phase 1 it is to demonstrate that RM reduces the time from the onset of a clinically relevant event to clinical decision; an in Phase 2 it is to demonstrate that RM reduces the incidence of all-cause deaths and major cardiovascular (CV) and device-related hospitalizations. Patients newly implanted with Medtronic CRT-D within the last eight weeks before the enrolment were included in the study. Patients were randomized 1:1 to the remote arm of alternating in-office follow-ups and remote checks, and to the standard arm of the in-office follow-ups only. Patients in these two arms were followed up in every four months. At the end of the patient enrollment from May 2009 to July 2014, 437 patients were included in the remote arm (the RM group) and 428 patients in the standard arm (the IC group) for analysis. Relevant to this research is the endpoint on the use of healthcare resources for cardiovascular reasons – in general the healthcare resource utilization for cardiovascular reasons was 38% lower in the remote arm than the standard arm [incidence rate ratio (IRR) 0.62, 95% CI 0.58–0.66, $P < 0.001$], with 2-year rates of 3.7 (95% CI 3.5–3.9) and 6.0 (95% CI 5.7–6.2) per 100 patients, respectively. Some of the contribution includes the lower hospitalizations for cardiovascular reasons with 197 events (111 events due to HF) and 200 events (103 events due to HF) in the remote and standard arms, respectively. There were 40 events in the remote arms and 56 events in the standard arms in the emergency department admissions not followed by a hospitalization, with a significantly lower occurrence in the remote arm (IRR 0.72, 95% CI 0.53–0.98, $P = 0.04$). RM also led to a significant reduction in total outpatient visits (IRR 0.59, 95% CI 0.56–0.62, $P < 0.001$), with more frequent unscheduled visits compared with the Standard arm (IRR 2.80, 95% CI 2.16–

3.63, $P < 0.001$). The other endpoint relevant to the study is that the two-year cost saving of €2899 per 100 would be possible if the remote device check were reimbursed as half of the cost of in-office device check.

Appendix D. Data Collection and Processing

The work log is to record all patient encounters for the data collection of the research, including the ad hoc patient encounters which are not normally capture in the clinical information systems in FHA Cardiac Services. To ease the use by the cardiac clinic team, the work log is developed in printable form in Word document form and an electronically fillable form in Excel spreadsheet to record the data collection centrally.

This attached Excel document is the work log in the electronic format as the central data storage for data analysis.

RCH_WorkLog - Fill Form - FINAL - 2018.

This attached Word document is the work log in the printable format. A cardiac technologist completed the printed form during a patient encounter. The data in the work log was then transposed to the above Excel document. The form was then securely shredded according to FHA standard in handling patient information.

RCH_WorkLog - Print Form.docx

Appendix E.

Workflow Analysis on Patient and Device Follow-up Service

To assess the workload management of the follow-up service of the cardiac clinic, the workflow analysis at the RCH Cardiac Clinic was started in May 2017 and completed in October 2017 for the standard implanted patient follow-up services using Medtronic Paceart, Medtronic Carelink, and Meditech. The purposes of the workflow analysis are to determine the source of the workload involved by each staff in the cardiac clinic team is responsible for in the service delivery, and the steps and the timing of the tasks; to present who in the cardiac clinic team is responsible for which part of the follow-up; and to capture interaction within the team and the patient including the pertaining data and information exchange.

The workflow analysis was based on the formal interviews and informal discussions as well as email communication with the cardiac device technologists, the RCH cardiac clinic supervisor and the cardiac EP, and included the following workflows:

- Workflow 1 – Clinical protocol follow-up selection and remote monitoring enrollment
- Workflow 2 – Initial follow-up appointment booking for new or replaced device patient
- Workflow 3 – Remote monitoring setup and initial validation transmission
- Workflow 4 – Remote monitoring follow-up
- Workflow 5 – Scheduled in-clinic follow-up at RCH Cardiac Clinic
- Workflow 6 – Clinical reporting for follow-up service

This appendix presents the workflow analysis for each of the standard follow-up services.

Workflow 1 – Clinical protocol follow-up selection and remote monitoring enrollment

Participants: patient, cardiac EP, cardiac device technologist, clinical support clerk

1. After the new or replacement implant procedure is complete on the patient, the cardiac electrophysiologist (EP) explains the device management and follow-up clinical protocols to patient in the first visit or in the subsequent visit. A patient is given the

choice of the two clinical protocols – the IO follow-up protocol or the hybrid follow-up as presented in Table 8. The EP may recommend the remote follow-up service to a patient, or a patient may also seek for the service during a follow-up.

1A. If the patient would like to adopt the remote follow-up service and hence the hybrid follow-up clinical protocol, then the EP refers the patient to a cardiac device technologist to discuss the RM enrollment process. **Continue to Step 2.**

1B. If the patient declined the remote follow-up service, then the patient must accept that all follow-ups must be attended in-person in-clinic and hence accept the IO follow-up clinical protocol. **Continues to Step 5.**

2. The cardiac device technologist explains the RM enrollment process to the patient. The information includes providing the instruction of remote monitoring with the patient monitor setup at home or care home, signing the consent form to authorize patient information be stored at Medtronic Carelink hosting outside of Canada, providing Medtronic technical support contact information, verifying patient's home address in Meditech for ordering a patient monitor, etc. Patient understands the information, then signs the consent form and takes away all the information.

2A. If the patient refuses the remote enrollment process, then the tech explains **Step 1B** to the patient.

3. Once the cardiac device technologist completes the paper work of the enrollment process, the paper work is passed to a clinical support clerk. The clerk registers the patient into Medtronic Carelink website, and submits online order of a patient monitor which matches up and be compatible with the implanted device by its serial number. The device is either handed to the patient during the enrollment process, or the device will be sent to the patient's delivery address.

4. The clinical support clerk stores away the consent form and send patient's enrollment paperwork to the corresponding health record management i.e. Medtronic, RCH Cardiac Services, etc.

Workflow 2 – Initial follow-up appointment booking for new or replaced device patient

Pre-requisite: Workflow 1 is complete

Participants: patient, cardiac device technologist, booking clerk

1. The cardiac device technologist directs the patient to the booking clerk. The booking clerk sets up the first year of a patient's follow-up appointments to attend at RCH cardiac clinic.
   1A. For a patient with the hybrid follow-up clinical protocol with the RM follow-up enrollment: one RM follow-up in six months, one in-clinic follow-up in twelve months.
   1B. For a patient with the IO follow-up clinical protocol: typically one in-clinic follow-up in six months or as per EP's consult
2. The cardiac device technologist discharges the patient home.
3. The cardiac device clerk updates the patient's record information in Paceart and Meditech respectively. For patient enrolled in RM, additional information to enter into the systems includes signed consent form, patient's remote monitoring registration.

Workflow 3 – Remote monitoring setup and initial validation transmission

Pre-requisite: Workflow 1 and 2 are complete, and patient has received the instruction and patient monitor for remote monitoring connection and transmission.

Participants: patient enrolled the hybrid follow-up clinical protocol, cardiac device technologist

1. When a patient returns home from implantation procedure, he or she sets up the patient monitoring. The patient is responsible for following the instructions in setting up the device within the cellular network for connection.
   Note: Medtronic is responsible for the technical support of patient monitor and Medtronic Carelink setup. RCH cardiac clinic provides limited patient support for verifying the remote transmission and usually refers the patient to contact Medtronic for technical support when needed.
2. When the patient's implanted device is synchronized to the patient monitor, the patient monitor automatically sends an initial set-up transmission to Medtronic Carelink.

3. The patient can confirm his/her recent transmission by logging into the personal profile at the Medtronic Carelink web portal. He or she needs to create his/her personal profile at Medtronic Carelink if this is the first access.

   Note: If the initial transmission was not successful, the patient is responsible to contact Medtronic for setup support and troubleshooting. During the RM enrollment process the cardiac device technologist has provided the patient with the Medtronic contact information.

4. The cardiac device technologist logs in Medtronic Carelink and Paceart in the next morning and sees all patients' remote transmissions including any initial set-up transmissions sent in the previous business day.
5. To ensure the patient is confirmed on the Medtronic Carelink network, the cardiac device technologist marks patient with the first success remote transmission, and combines patient's and device's information in Medtronic Paceart.

Workflow 4 – Remote monitoring follow-up

Pre-requisite: Workflow 3 is complete

Participants: Patient enrolled the hybrid follow-up clinical protocol, cardiac device technologist

Conditional Participants: Cardiac EP, booking clerk

1. Patient monitor is pre-configured of automatically sending the device transmission to the Medtronic Carelink between 12AM to 3AM.
2. Between12AM and 3AM on the scheduled remote follow-up appointment, the patient must be in bed and at a location that is within 3 metres of the patient monitor, or the patient must be in a designated area for those who cannot be at home, such as night shift workers, etc.

3 The patient monitor automatically pulls the stored data from the implanted device.

4. When the patient monitor completely receives the device's transmission, it sends to the Medtronic Carelink.
5. Medtronic Carelink triggers Medtronic Paceart to download the patient' device transmission from Medtronic Carelink.

6. At approximately 8AM of the following day, the cardiac device technologist logs into the Medtronic Carelink web portal. To verify the transmission from the scheduled day, the Carelink dashboard displays the list of patients with scheduled remote follow-up appointments and status of each expected transmission.
   6A. For a successful transmission, the cardiac device technologist updates patient's remote follow-up appointment status to the status "Attended" in Meditech scheduling system (CWS). The remote follow-up appointment in Meditech cardiac service order system (ITS) is also marked as "Complete".
   6B. If the patient monitor has attempted more than three remote transmissions to the Medtronic Carelink but all unsuccessfully received, the Carelink dashboard shows the patient with no transmission. Then the cardiac device technologist updates the status of the remote follow-up appointment in Meditech to "No Show" and cancels the remote follow-up service in Meditech. The cardiac device tech contacts the patient via phone to determine the situation, and to makes the next appointment for the patient in Meditech.
7. The cardiac device technology reviews the device data in the transmission to detect for any abnormality on the patient and the device, then annotates comment/technical summary into Medtronic Paceart for the EP's review and reporting purposes. The summary includes analysis of the device data and patient's abnormality. The associated Meditech remote follow-up service order is also updated.
8. If an abnormality is observed, the cardiac device technologist consults with a cardiac EP for additional instruction.
9. The cardiac EP may decide that the patient must attend an in-clinic follow-up. Then the cardiac device technologist or the booking clerk contacts the patient to set up the appointment.

Workflow 5 – Scheduled in-clinic follow-up at RCH Cardiac Clinic

Pre-requisite: Workflow 1 and 2 are complete
Participants: patient enrolled the IO follow-up clinical protocol, cardiac device technologist, cardiac EP, booking clerk

1. The patient is physically present in the waiting area of the cardiac clinic at the scheduled time. The patient checks in with the booking clerk at the reception. The booking clerk updates patient's appointment in Meditech to admit patient's arrival.
2. Patient is escorted by a cardiac device technologist into the examination room, where the technologist interrogates patient's CIED (ICD or CRT-D) with a programmer.
3. The cardiac device technologist downloads the device data from the programmer into Medtronic Paceart.
4. The cardiac device technologist conducts device site check with patient e.g. review medication, read blood pressure, etc.
5. The cardiac device technologist reviews the device data to detect for any abnormality on the patient and the device, then logs comment/technical summary with feedback from patient and the analysis of the device data into Medtronic Paceart for the EP's review and reporting purposes. The Meditech IO follow-up service order is also updated.
6. If abnormality is observed, the cardiac device technologist consults with a cardiac EP for additional instruction.
7. The cardiac EP meets up the patient in the examination room and conducts clinical assessment.
8. If the cardiac EP determines that patient and device are good, the patient is discharged from the examination room.
9. The booking clerk sets up the patient's next appointments in the upcoming year before the patient leaving the clinic.

Workflow 6 – Clinical reporting for follow-up service

Pre-requisite: Workflow 4 or 6 is complete

Participants: cardiac EP, clinical support clerk

<u>Reporting:</u>

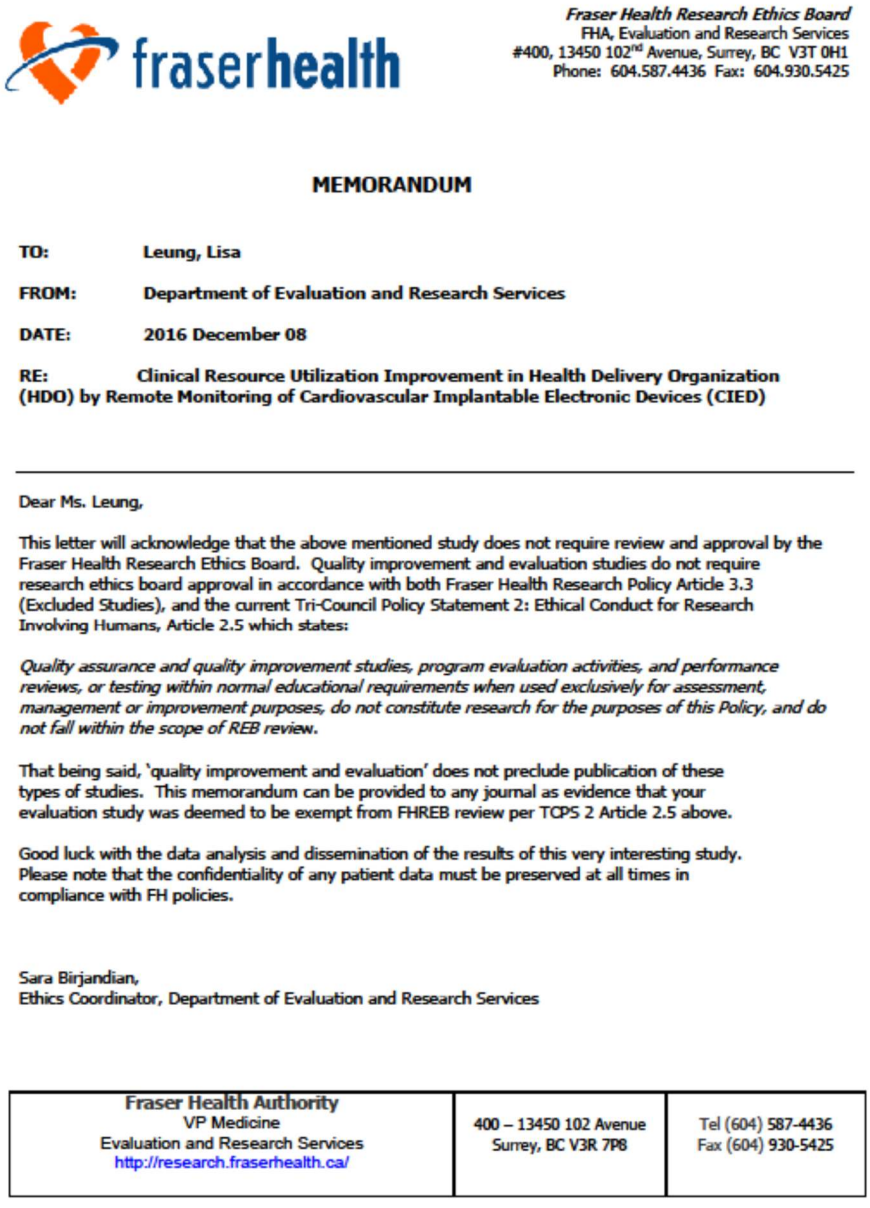
1. A cardiac EP reviews a patient's technical summary in Medtronic Paceart.
2. The cardiac EP enters his comment in the technical summary and signs the report in Medtronic Paceart. The clinical support clerk prints out the device report in

Medtronic Paceart. The device report is then scanned to Meditech-managed electronic medical record (EMR) and becomes part of patient's medical record.

3. The cardiac EP dictates his consultation report. The consultation report is then transcribed and stored in Meditech EMR, and becomes patient's medical record.

Appendix F.
Research Ethics Approvals by University of Victoria and Fraser Health Authority

Here is the memorandum by Fraser Health Research Ethics Board on the decision that the research study is exempt from the ethics review.



Fraser Health Research Ethics Board
FHA, Evaluation and Research Services
#400, 13450 102nd Avenue, Surrey, BC V3T 0H1
Phone: 604.587.4436 Fax: 604.930.5425

MEMORANDUM

TO: **Leung, Lisa**

FROM: **Department of Evaluation and Research Services**

DATE: **2016 December 08**

RE: **Clinical Resource Utilization Improvement in Health Delivery Organization (HDO) by Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIED)**

Dear Ms. Leung,

This letter will acknowledge that the above mentioned study does not require review and approval by the Fraser Health Research Ethics Board. Quality improvement and evaluation studies do not require research ethics board approval in accordance with both Fraser Health Research Policy Article 3.3 (Excluded Studies), and the current Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans, Article 2.5 which states:

Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

That being said, 'quality improvement and evaluation' does not preclude publication of these types of studies. This memorandum can be provided to any journal as evidence that your evaluation study was deemed to be exempt from FHREB review per TCPS 2 Article 2.5 above.

Good luck with the data analysis and dissemination of the results of this very interesting study. Please note that the confidentiality of any patient data must be preserved at all times in compliance with FH policies.

Sara Birjandian,
Ethics Coordinator, Department of Evaluation and Research Services

Fraser Health Authority VP Medicine Evaluation and Research Services http://research.fraserhealth.ca/	400 – 13450 102 Avenue Surrey, BC V3R 7P8	Tel (604) 587-4436 Fax (604) 930-5425

Here is the certificate of approval issued by University of Victoria Human Research Ethics Board on the research.

University of Victoria

Office of Research Services | Human Research Ethics Board
Administrative Services Building Rm B202 PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada
T 250-472-4545 | F 250-721-8960 | uvic.ca/research | ethics@uvic.ca

Certificate of Approval

PRINCIPAL INVESTIGATOR:	Lisa Leung	ETHICS PROTOCOL NUMBER Minimal Risk - Chair/Vice-chair	17-132
UVic STATUS:	Master's Student	ORIGINAL APPROVAL DATE:	30-Mar-17
UVic DEPARTMENT:	HEIS	APPROVED ON:	30-Mar-17
SUPERVISOR:	Dr. Abdul Roudsari	APPROVAL EXPIRY DATE:	29-Mar-18

PROJECT TITLE: **Clinical Resource Utilization Assessment in Health Delivery Organization (HDO) by Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIED)**

RESEARCH TEAM MEMBER **None**

DECLARED PROJECT FUNDING: **None**

CONDITIONS OF APPROVAL

This Certificate of Approval is valid for the above term provided there is no change in the protocol.

Modifications
To make any changes to the approved research procedures in your study, please submit a "Request for Modification" form. You must receive ethics approval before proceeding with your modified protocol.

Renewals
Your ethics approval must be current for the period during which you are recruiting participants or collecting data. To renew your protocol, please submit a "Request for Renewal" form before the expiry date on your certificate. You will be sent an emailed reminder prompting you to renew your protocol about six weeks before your expiry date.

Project Closures
When you have completed all data collection activities and will have no further contact with participants, please notify the Human Research Ethics Board by submitting a "Notice of Project Completion" form.

Certification

This certifies that the UVic Human Research Ethics Board has examined this research protocol and concluded that, in all respects, the proposed research meets the appropriate standards of ethics as outlined by the University of Victoria Research Regulations Involving Human Participants.

Rachael Scarth

Dr. Rachael Scarth
Associate Vice-President Research Operations

Certificate Issued On: 30-Mar-17

17-132 Leung, Lisa

Here is the modification of an approved protocol issued by University of Victoria Human Research Ethics Board on authorizing the use of a work log for data collection.

University of Victoria
Office of Research Services | Human Research Ethics Board
Michael Williams Building Rm B202 PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada
T 250-472-4545 | F 250-721-8960 | ethics@uvic.ca | uvic.ca/research |

Modification of an Approved Protocol

PRINCIPAL INVESTIGATOR:	Lisa Leung	ETHICS PROTOCOL NUMBER: Minimal Risk - Chair/Vice-chair	17-132
UVic STATUS:	Master's Student	ORIGINAL APPROVAL DATE:	30-Mar-17
UVic DEPARTMENT:	HEIS	MODIFIED ON:	19-Jul-17
SUPERVISOR:	Dr. Abdul Roudsari	APPROVAL EXPIRY DATE:	29-Mar-18

PROJECT TITLE: **Clinical Resource Utilization Assessment in Health Delivery Organization (HDO) by Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIED)**

RESEARCH TEAM MEMBER None

DECLARED PROJECT FUNDING: None

CONDITIONS OF APPROVAL

This Certificate of Approval is valid for the above term provided there is no change in the protocol.

Modifications
To make any changes to the approved research procedures in your study, please submit a "Request for Modification" form. You must receive ethics approval before proceeding with your modified protocol.

Renewals
Your ethics approval must be current for the period during which you are recruiting participants or collecting data. To renew your protocol, please submit a "Request for Renewal" form before the expiry date on your certificate. You will be sent an emailed reminder prompting you to renew your protocol about six weeks before your expiry date.

Project Closures
When you have completed all data collection activities and will have no further contact with participants, please notify the Human Research Ethics Board by submitting a "Notice of Project Completion" form.

Certification

This certifies that the UVic Human Research Ethics Board has examined this research protocol and concluded that, in all respects, the proposed research meets the appropriate standards of ethics as outlined by the University of Victoria Research Regulations Involving Human Participants.

Rachael Scarth

Dr. Rachael Scarth
Associate Vice-President Research Operations

17-132 Leung, Lisa

Certificate Issued On: 19-Jul-17

Here is the certificate of the renewed approval issued by University of Victoria Human Research Ethics Board.

University of Victoria

Office of Research Services | Human Research Ethics Board
Administrative Services Building Rm B202 PO Box 1700 STN CSC Victoria BC V8W 2Y2 Canada
T 250-472-4545 | F 250-721-8960 | uvic.ca/research | ethics@uvic.ca

Certificate of Renewed Approval

PRINCIPAL INVESTIGATOR:	Lisa Leung	ETHICS PROTOCOL NUMBER: Minimal Risk - Chair/Vice-chair	17-132
UVic STATUS:	Master's Student	ORIGINAL APPROVAL DATE:	30-Mar-17
UVic DEPARTMENT:	HEIS	RENEWED ON:	23-Feb-18
SUPERVISOR:	Dr. Abdul Roudsari	APPROVAL EXPIRY DATE:	29-Mar-19

PROJECT TITLE: Clinical Resource Utilization Assessment in Health Delivery Organization (HDO) by Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIED)

RESEARCH TEAM MEMBER None

DECLARED PROJECT FUNDING: None

CONDITIONS OF APPROVAL

This Certificate of Approval is valid for the above term provided there is no change in the protocol.

Modifications
To make any changes to the approved research procedures in your study, please submit a "Request for Modification" form. You must receive ethics approval before proceeding with your modified protocol.

Renewals
Your ethics approval must be current for the period during which you are recruiting participants or collecting data. To renew your protocol, please submit a "Request for Renewal" form before the expiry date on your certificate. You will be sent an emailed reminder prompting you to renew your protocol about six weeks before your expiry date.

Project Closures
When you have completed all data collection activities and will have no further contact with participants, please notify the Human Research Ethics Board by submitting a "Notice of Project Completion" form.

Certification

This certifies that the UVic Human Research Ethics Board has examined this research protocol and concluded that, in all respects, the proposed research meets the appropriate standards of ethics as outlined by the University of Victoria Research Regulations Involving Human Participants.

Rachael Scarth

Dr. Rachael Scarth
Associate Vice-President Research Operations

Certificate Issued On: 23-Feb-18

17-132 Leung, Lisa

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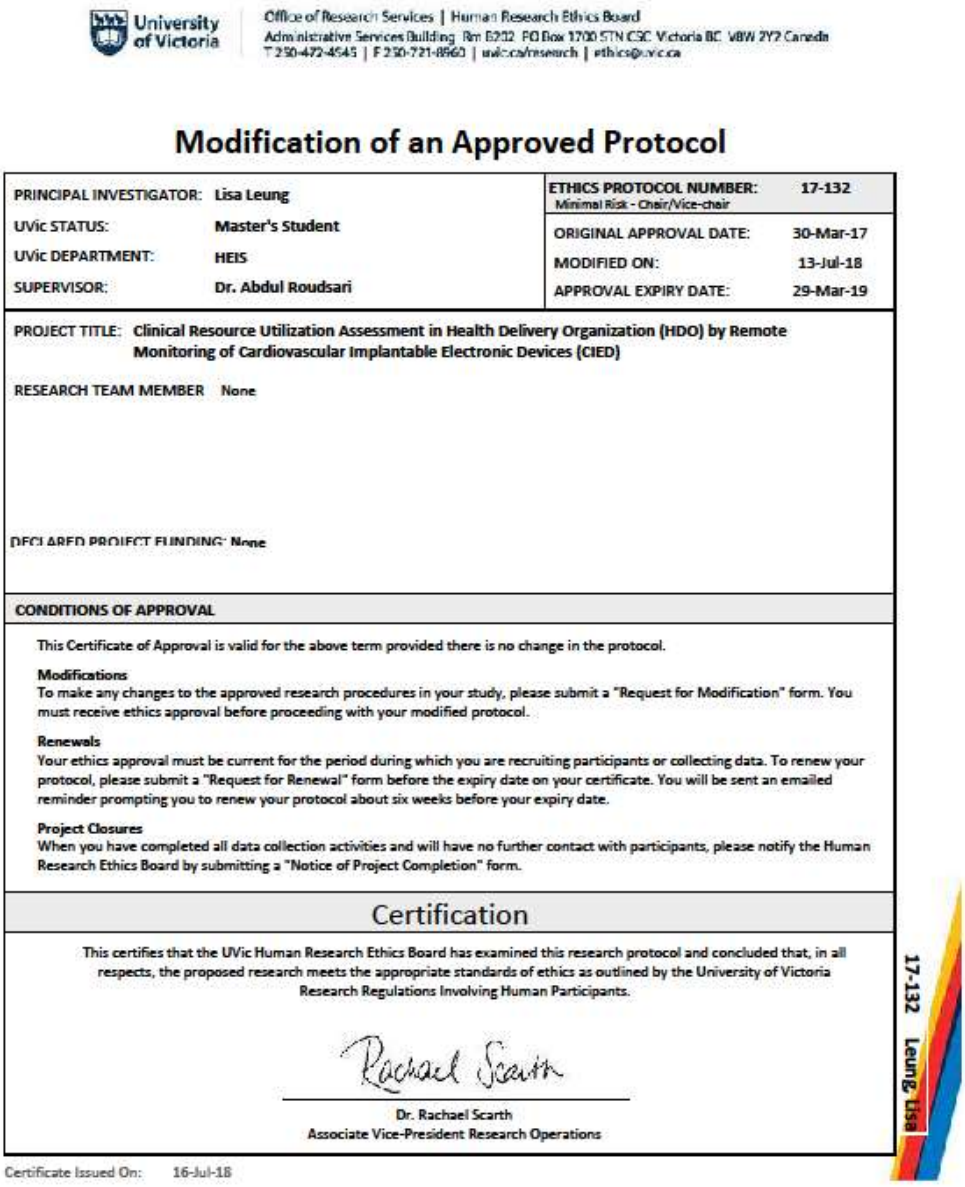
Here is the modification of an approved protocol issued by University of Victoria Human Research Ethics Board on authorizing the extension of the data collection timeline from six months to one year.



University of Victoria

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T 250-472-4545 | F 250-721-8960 | uvic.ca/research | ethics@uvic.ca

Modification of an Approved Protocol

PRINCIPAL INVESTIGATOR:	Lisa Leung	ETHICS PROTOCOL NUMBER: Minimal Risk - Chair/Vice-chair	17-132
UVic STATUS:	Master's Student	ORIGINAL APPROVAL DATE:	30-Mar-17
UVic DEPARTMENT:	HEIS	MODIFIED ON:	13-Jul-18
SUPERVISOR:	Dr. Abdul Roudsari	APPROVAL EXPIRY DATE:	29-Mar-19

PROJECT TITLE: **Clinical Resource Utilization Assessment in Health Delivery Organization (HDO) by Remote Monitoring of Cardiovascular Implantable Electronic Devices (CIED)**

RESEARCH TEAM MEMBER None

DECLARED PROJECT FUNDING: None

CONDITIONS OF APPROVAL

This Certificate of Approval is valid for the above term provided there is no change in the protocol.

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To make any changes to the approved research procedures in your study, please submit a "Request for Modification" form. You must receive ethics approval before proceeding with your modified protocol.

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Project Closures
When you have completed all data collection activities and will have no further contact with participants, please notify the Human Research Ethics Board by submitting a "Notice of Project Completion" form.

Certification

This certifies that the UVic Human Research Ethics Board has examined this research protocol and concluded that, in all respects, the proposed research meets the appropriate standards of ethics as outlined by the University of Victoria Research Regulations Involving Human Participants.

Rachael Scarth

Dr. Rachael Scarth
Associate Vice-President Research Operations

Certificate Issued On: 16-Jul-18

17-132 Leung, Lisa

Appendix G. Stock and Flow Diagram and Simulation Model Source File

Here is the STELLA source file of the IC group or the control group.

Simulation_PatientFlow_IC_Combined_Base.STMX

Here is the STELLA source file of the RM group or the intervention group.

Simulation_PatientFlow_Hybrid_Combined_Base.STMX

Appendix H. Mortality Rate Calculation for Simulation

The calculation of the mortality rate is based on the Ontario study (Yung, et al., 2013). The weighted-average calculation uses the age of the enrolled patients in the respective control and the intervention group. Even though the reason of the device implant is not collected for the research, it can safely presume that patient with no NYHA classification is implanted as primary prevention (for no history of heart failure), and patient with a NYHA classifications is implanted as secondary prevention (for the history of heart failure).

	Deaths per 100 person-years		Patient Count			
Age Group	Primary Prevention	Secondary Prevention	RM - Primary	RM – Secondary	IO - Primary	IO - Secondary
18 to 49	2.1	2.2	0	4	0	3
50 to 59	3.0	3.8	0	4	0	3
60 to 69	5.4	6.1	2	4	0	4
70 to 79	6.9	8.7	2	3	2	6
≥80	10.2	15.5	0	2	0	2
		Total Patient	21		20	
		Weighted-average mortality rate	0.0620		0.0697	