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Barriers To Remote Monitoring In Patients With Implantable Cardioverter Defibrillators

Elise Liu

Barriers to Remote Monitoring in Patients with Implantable Cardioverter Defibrillators

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Elise Gao Liu

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Abstract

BARRIERS TO REMOTE MONITORING IN PATIENTS WITH IMPLANTABLE CARDIOVERTER DEFIBRILLATORS.

Elise Liu, Kristin Mattocks, Lynda Rosenfeld, and Rachel Lampert. Section of Cardiology, Department of Internal Medicine, Yale University, School of Medicine, New Haven, CT.

Background: Remote monitors are machines that allow patients with implantable cardioverter-defibrillators (ICDs) to transtelephonically send data to their physicians. Remote monitors have been associated with increased survival and faster recognition of clinical events. Despite the benefits of using remote monitors, they are highly underused. We aimed to better understand barriers to the usage of remote monitors.

Methods: Mixed methods interview was used, with both quantitative questions and qualitative in-depth interview. Patients who had Medtronic ICDs placed at either Yale Electrophysiology or Cardiology Associates of New Haven were invited to participate. 82 patients consented to participate.

Results: Quantitative data showed that compared to people who do not use remote monitors, people who transmit are more likely to own a landline, use computers regularly, have non-government health insurance, and believe there is a benefit to using the monitor. Qualitative data showed that there are several categories of reasons that patient do not use remote monitors including a belief that transmissions are being sent, a belief that there is no benefit to monitoring,

problems with set up, problems with phone lines, financial limitations, and low strength of physician recommendation.

Conclusions: This study has identified several potential barriers to remote monitoring that should be confirmed with quantitative methods. To increase remote monitor usage, physicians ought to educate patients about the benefits of monitoring and explicitly recommend the use of monitors. In addition, device manufacturers should provide feedback from monitors and consider ways to make monitoring more accessible to patients, both financially and technologically.

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I. Introduction

Sudden Cardiac Death Background

Sudden cardiac arrest is defined as an episode of cessation of cardiac activity resulting in unresponsiveness with no signs of breathing or circulation. Sudden cardiac arrest may be reversed with CPR, defibrillation, or cardiac pacing. Alternatively, it may lead to sudden cardiac death [1].

Sudden cardiac death is a major cause of death in the United States. Annually, roughly 450,000 people succumb to sudden cardiac death. [2, 3] Various studies estimate that sudden cardiac death causes between 5.6 percent and 15 percent of all deaths. [3, 4]

Sudden cardiac death can affect anyone, but it is more common with underlying heart disease, male gender, and increasing age. [5] In a 1999 Center for Disease Control and Prevention (CDC) report of United States mortality data, about 70% of sudden cardiac death is due to underlying coronary heart disease. In the same report, roughly 10% of sudden cardiac death was due to underlying non-ischemic structural heart disease, such as myocarditis, dilated cardiomyopathy, hypertrophic cardiomyopathy, and congenital abnormalities. Another 5% of sudden cardiac deaths were due to arrhythmias without underlying structural disease, such as hereditary channelopathies. Older patients were disproportionately affected by coronary heart disease, and patients younger than 40 were more likely to have non-ischemic disease. [6]

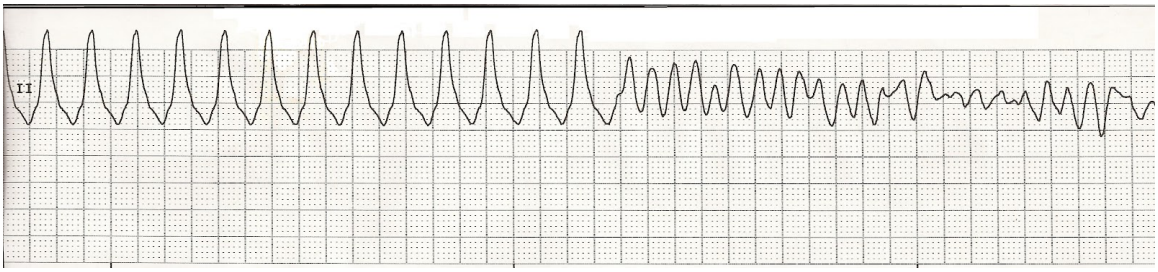
Of note, the presence of heart failure increases the risk of sudden cardiac death. One prospective cohort of 2,873 Framingham Study participants found that

having heart failure from any cause increased the risk of sudden death 5-fold. [5] On a similar note, another study found that 39% of deaths in heart failure patients were due to sudden cardiac death. [7]

Mechanism of Sudden Cardiac Death

Sudden cardiac death is most often due to ventricular fibrillation. This is illustrated by one case series of 157 patients who suffered sudden cardiac death while wearing Holter devices, which allowed their fatal arrhythmias to be analyzed. In this study, 84% of patients had a tachyarrhythmia that lead to their death. The vast majority of the patients dying from a tachyarrythmia had a terminal run of ventricular fibrillation, preceded by ventricular tachycardia (Figure 1). The remaining 16% of patients in this study died of bradyarrhythmias, most often due to slow sinus node pacing. [8]

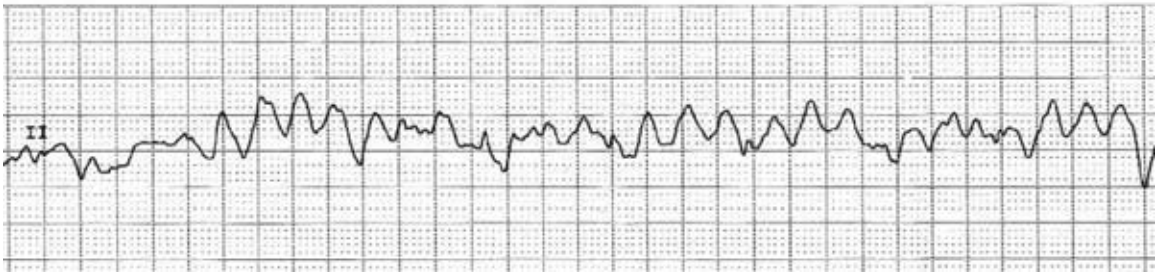
Figure 1. Rhythm strip of ventricular tachycardia progressing to ventricular fibrillation



Ventricular fibrillation is a tachyarrhythmia that results in uncoordinated contraction of the myocardium. The most likely underlying mechanism is spiral waves, which are small, three-dimensional patterns of electrical activity in the myocardium that interact with each other and propagate to involve large areas of

the heart. This disorganized electrical activity leads to uncoordinated, fibrillating movement of the myocardium, which is seen on EKG as irregular waveforms with constantly changing amplitude and frequency (Figure 2). This fibrillation leads to cessation of cardiac contraction, which prevents oxygenation of the myocardium. The resulting myocardial ischemia reduces excitability of the heart and over a few minutes leads to longer periods of time between fibrillation waves and lower amplitudes of waves. At this point, ventricular fibrillation becomes more difficult to terminate than at the onset of the arrhythmia. The fibrillation waves continue to become finer and sparser, eventually leading to the cessation of observable electrical activity. [9],[10]

Figure 2. Rhythm strip of ventricular fibrillation.



Treatment of Ventricular Fibrillation

Ventricular fibrillation is a rapidly fatal arrhythmia. In the past, anti-arrhythmic drugs such as quinidine or procainamide were used in an attempt to prevent ventricular fibrillation, but this approach was not very effective. [11] A breakthrough came when surgeons found that patients who developed ventricular

fibrillation intraoperatively could sometimes be saved by opening up the chest and providing a defibrillating countershock applied directly to the heart. This idea evolved into the development of external defibrillation; reports of successful defibrillation using an external alternating current shock were first published in 1956. [12] In 1962, another advance was made when a research group found that direct current shocks to the heart were effective and much safer than alternating current shocks, which often lead to arrhythmia and mortality. [11] Throughout the early 1960's, research on direct current defibrillation proved its safety and efficacy. As a result, external defibrillation quickly became known as an effective means to terminate ventricular fibrillation.

History and Development of the Implantable Cardioverter Defibrillator

By the 1960's, it had long been recognized that ventricular fibrillation caused a large proportion of out of hospital sudden cardiac death. With the advent of the external defibrillator, patients suffering from ventricular fibrillation in the hospital could be promptly saved. However, most people who developed sudden cardiac arrest did so outside the hospital. In the late 1960's, Dr. Michel Mirowski began working on an implantable device that could potentially prevent these out of hospital sudden cardiac deaths by sensing ventricular fibrillation and promptly delivering a shock to abort the arrhythmia.

Dr. Mirowski and his collaborators tested the prototype of an implantable defibrillating device in dogs with great success, leading to the publication of a landmark paper in 1970 detailing the initial design and application of the

"automatic defibrillator" in dogs. [13] This work attracted the attention of Medrad Inc., a medical device company. Over the next decade, Dr. Mirowski and a team at Medrad continued to refine the defibrillator until they achieved a model that could be chronically implanted and was suitable in size to be used with a human. The team successfully implanted this improved device in dogs, and Dr. Mirowski published the results of the long-term dog studies and the design of this updated defibrillator in 1978. After more extensive testing and development, the implantable defibrillator was first implanted in a human in 1980. [14]

This early model of the implantable defibrillator weighed half a pound and comprised electrodes protruding from a hermetically sealed box containing the defibrillator (**Figure 3**). Thoracotomy was required for placement of the two electrodes, which were attached to heart via epicardial patches. All the materials in the defibrillator were chosen to be compatible with human tissues. This model also improved several parameters of the previous automatic defibrillator, including the sensing mechanism. Ventricular fibrillation was identified by the absence of an isoelectric segment in the cardiac cycle, a more direct measure than the pressure changes measured in the prototype. Also improved in the new model was the shock delivery mechanism, which allowed for up to 4 shocks to be delivered after the onset of an arrhythmia. [15]

Figure 3. A figure excerpted from Mirowsky's 1978 paper, showing a photo of the implantable cardioverter-defibrillator. [15]

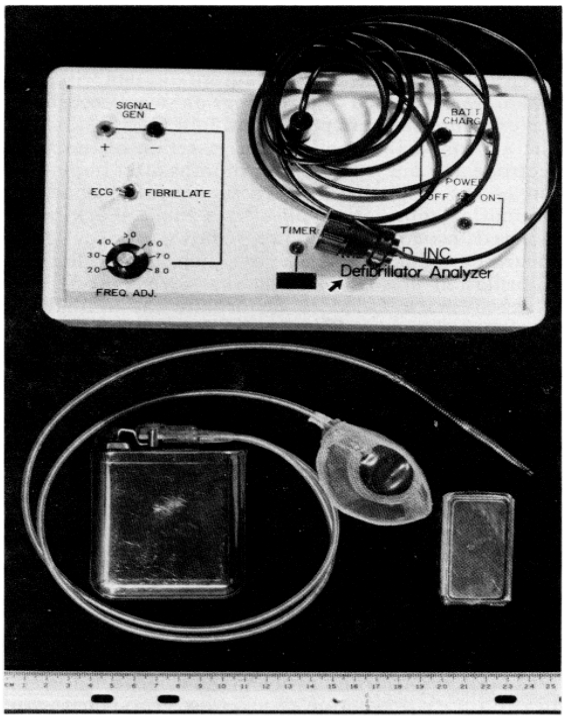


FIGURE 1. *The automatic defibrillating system. The implantable defibrillator with apex and superior vena cava electrodes appears at the bottom left, the fibrillator at the bottom right, and the defibrillator analyzer in the upper half of the photograph. The arrow points toward the electromagnetic transducer.*

After the success of the initial human implantations, Medrad sponsored further clinical trials of the device. [16] These clinical trials culminated in 1985, with the United States Food and Drug Administration (FDA) approval of the use of ICDs for secondary prevention of sudden cardiac death in patients who had a previous sudden cardiac arrest and in patients who had ventricular arrhythmias that could not be medically suppressed. [17]

Since the initial FDA approval of the ICD, the device has undergone numerous improvements. The generator became smaller, with modern versions weighing about 3 ounces (Figure 4). This size reduction allowed for implantation over the

chest instead of over the abdomen. Lead technology also improved, leading to the first completely transvenous lead placement in 1988. This system involved leads with shocking coils that attached to the myocardium (Figure 5). Sensing technology progressed, leading to drastically reduced incidence of inappropriate shocks. Finally, defibrillating technology improved. Especially important was the 1993 development of the biphasic defibrillation waveform, which lowered the amount of energy necessary to defibrillate an arrhythmia and reduced the risk of myocardial injury from the shock. The above improvements helped make ICDs more acceptable to patients and played a part in the acceptance of wider indications for ICDs. Indeed, ICDs are implanted today in routine, minimally invasive procedures, and they are indicated for prevention of sudden cardiac death from a wide variety of conditions. [16, 18]

Figure 4. A photo of a modern implantable cardioverter-defibrillator.

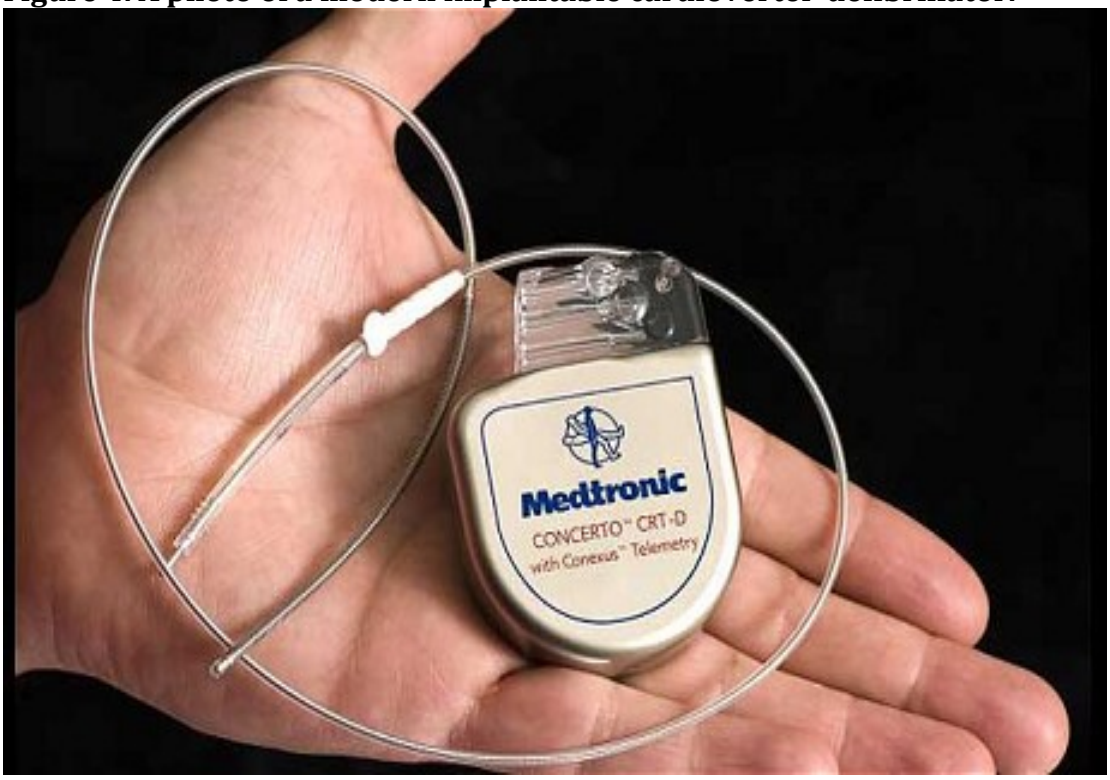
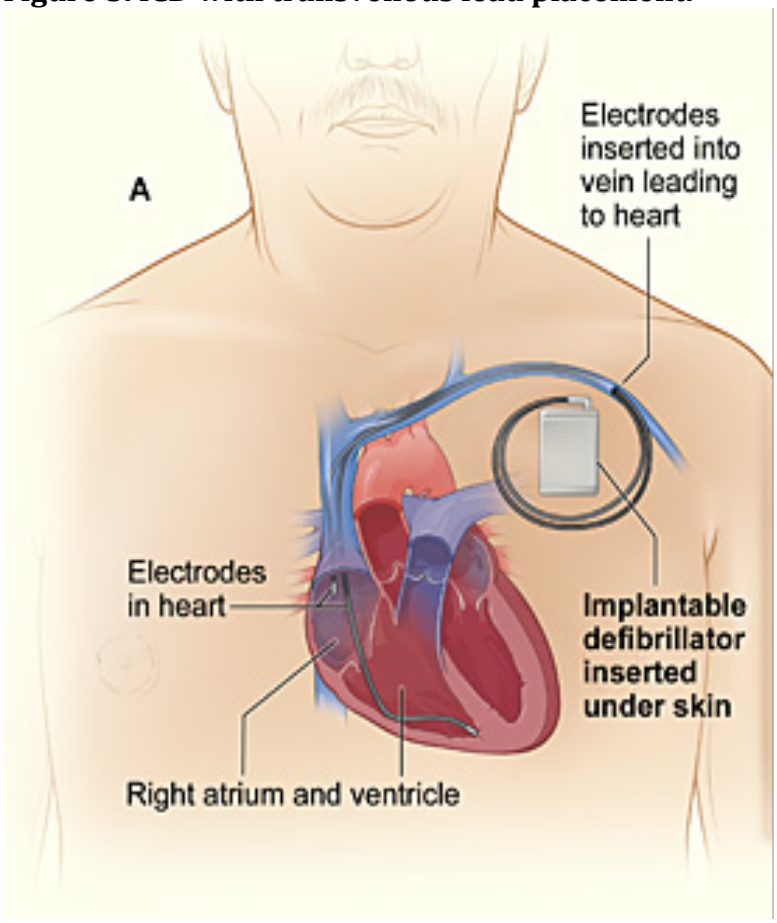


Figure 5. ICD with transvenous lead placement.



ICDs for Secondary Prevention

ICDs were first used for secondary prevention, the prevention of sudden cardiac death in people who have a history of previous sudden cardiac arrest or underlying heart disease with sustained ventricular tachycardia.

The evidence supporting ICDs in secondary prevention came from three large randomized controlled trials from the 1990s, the AVID, CASH, and CIDS studies (**Figure 6**). The largest of these trials, AVID, was a randomized trial comparing ICD to antiarrhythmic therapy in 1,016 patients with either prior sudden cardiac arrest or sustained ventricular tachycardia and ejection fraction<40%. ICDs were found to

reduce mortality by 31% compared to antiarrhythmics at three years of follow up. [19]

Figure 6. Randomized clinical trials of ICDs for secondary prevention [18]

Trial Name	Number of Patients	Patient Inclusion Criteria	Study Arms	Outcome
AVID	1016	Prior SCA, VT with syncope, or VT with EF<40%	ICD vs anti-arrhythmic	ICDs decrease mortality by 31% at 3 years
CASH	288	Prior SCA	ICD vs anti-arrhythmic	ICDs decrease mortality by 28% at 3 years
CIDS	659	Prior SCA, VT with syncope, or VT with EF<35%	ICD vs anti-arrhythmic	ICDs decrease mortality by 20% at 3 years

AVID=Antiarrhythmics Versus Implantable Defibrillators; CASH=Cardiac Arrest Study Hamburg; CIDS=Canadian Implantable Defibrillator Study; EF=Ejection fraction; SCA=Sudden cardiac arrest; VT=Ventricular tachycardia

ICDs for Primary Prevention

There are many randomized clinical trials that define the indications for ICDs for primary prevention (Figure 7), defined as preventing sudden cardiac death in patients who have not yet suffered from sudden cardiac arrest. MADIT-II is an important trial that demonstrated that ICDs are useful for primary prevention in patients with ischemic heart disease. The MADIT-II was a randomized study examining conventional medical therapy versus ICD therapy that enrolled 1232 patients who had a previous myocardial infarction and a left ventricular ejection fraction of less than 30%. The MADIT II study was terminated early when a striking difference between the medication and ICD groups emerged by 20 months of follow up. The mortality rate was 19.8% in the medication group and 14.2% in the ICD group. [20]

Figure 7. Randomized clinical trials of ICDs for primary prevention. [21]

Trial Name	Number of Patients	Patient Inclusion Criteria	Study Arms	Outcome
MADIT	196	Prior MI with EF<35%, NSVT, and inducible VT on EPS	ICD vs medical therapy	ICD decreases mortality
CABG Patch	900	CABG with EF<36% and +signal-avg EKG	ICD vs control	No benefit to ICD
MUSTT	704	Prior MI with EF<40%, NSVT, and inducible VT	EPS guided therapy with ICD or meds vs no therapy	ICD decreases mortality
MADIT II	1232	Prior MI, EF<30%	ICD vs medical therapy	ICD decreases mortality
SCD-HeFT	2521	NYHA Class II or III HF with EF<35%	ICD vs amiodarone vs placebo	ICD decreases mortality
IRIS	898	Recent MI (within 31 days) and EF<40 with HR>90 or NSVT	ICD vs medical therapy	No benefit to ICD
DINAMIT	674	Recent MI (within 40 days), EF<35%, and low HRV or high RHR	ICD vs control	No benefit to ICD
DEFINITE	458	DCM, EF<35%, and VPB or NSVT	ICD+medical therapy vs medical therapy	Trend for ICD to decrease mortality
CAT	104	DCM with EF<30%	ICD vs control	No benefit to ICD
AMIOVIRT	103	DCM with EF<35 and NSVT	ICD±amiodarone vs amiodarone	No benefit to ICD

CABG=coronary artery bypass grafting; DCM=dilated cardiomyopathy; EF=ejection fraction; EPS=electrophysiology study; HF=heart failure; RHR=resting heart rate; HRV=heart rate variability; MI=myocardial infarction; NSVT=non-sustained ventricular tachycardia; NYHA=New York Heart Association; VPB=ventricular premature beat; VT=ventricular tachycardia

Several studies have defined the limits of ICD therapy in ischemic heart disease. The IRIS and DINAMIT studies aimed to determine if immediate implantation after a myocardial infarction (MI) would be beneficial. Both studies enrolled patients with recent MI, within the past 31 and 40 days, respectively, and randomized the patients to ICD therapy or control. Both studies concluded that

immediate post-MI implantation does not improve survival and play a large part in why immediate post-MI implantation is not recommended today. Another large study, CABG-Patch, found that ICD implantation at the time of bypass surgery did not improve survival.

ICDs have also been shown to be useful in both non-ischemic and ischemic heart failure. Published in 2005, SCD-HeFT was a randomized trial of 2,521 New York Heart Association (NYHA) Class II or Class III heart failure patients with ejection fraction less than 35%. The patients in this study all received conventional medical therapy and were randomized to receive one of three additional treatments: amiodarone, ICD, or placebo. This study found that ICD decreased mortality by 23% compared to placebo and was effective in both ischemic and non-ischemic heart failure. Amiodarone did not decrease mortality. [22, 23] As a result of SCD-HeFT, indications for ICD were widened to include patients with heart failure with ejection fraction less than 35%.

Current Guidelines for Implantable Cardioverter Defibrillators

The indications for ICD have rapidly expanded in the past 15 years. As a result, ICD implantation has increased dramatically as well. Today, there are hundreds of thousands of people in the United States living with ICDs, with approximately 150,000 patients receiving ICDs each year. [24]

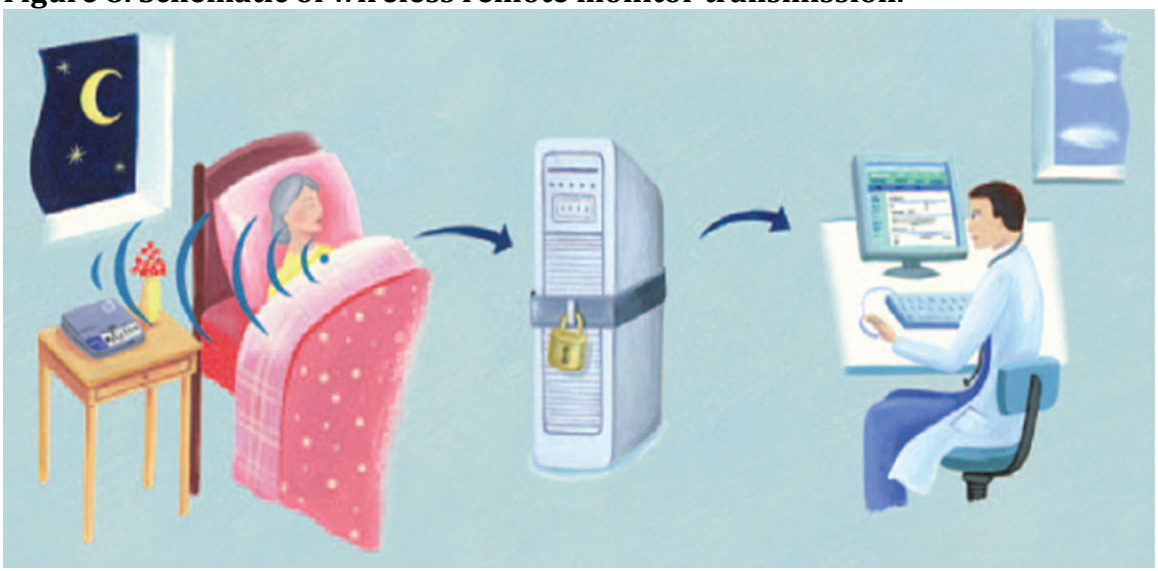
ICDs are indicated as first-line treatment in many heart conditions. The 2008 American College of Cardiology/American Heart Association/Heart Rhythm Society joint guidelines outlined the current indications for ICD implantation. Per the

guidelines, ICDs should be used for secondary prevention of sudden cardiac death in patients who have suffered a previous episode of sudden cardiac arrest with no identifiable reversible cause and in patients with episodes of sustained ventricular tachycardia with underlying heart disease. ICDs should be implanted for primary prevention in patients with a history of myocardial infarction and a left ventricular ejection fraction of less than 30%. ICDs should also be used for primary prevention in patients with ischemic or nonischemic cardiomyopathy, with a left ventricular ejection fraction of less than 35% NYHA Class II or III heart failure. [25] ICDs are also implanted for primary prevention in certain patients with genetic or idiopathic heart conditions predisposing to ventricular tachycardia/fibrillation, such as Brugada syndrome, long QT syndrome, hypertrophic cardiomyopathy, or arrhythmogenic right ventricular cardiomyopathy. [25]

Remote Monitor Background

Remote monitors, first introduced to the market in 2002, are devices that enable ICD patients to follow up and diagnosis problems from home. Remote monitors gather information like heart rhythms, lead performance, shocks delivered, and battery life from patients' ICDs and send it over a standard telephone line to a server that physicians can access via a secure website (Figure 8). All ICDs today are compatible with remote monitoring systems. [26, 27]

Figure 8. Schematic of wireless remote monitor transmission.



Overview of Remote Monitors Recommendations

There is significant evidence that remote monitoring has benefits in terms of survival, hospitalization, safety, cost, and ease of use. In light of the available evidence, both the 2009 Heart Rhythm Society/American College of Cardiology (ACC)/American Heart Association (AHA) and the 2012 European Heart Rhythm Association (EHRA)/Heart Rhythm Society (HRS) task forces released consensus guidelines that recognize the benefits of remote monitoring and acknowledge remote monitors as an appropriate choice for post-ICD implantation follow up. [28],[29] The available evidence has led the 2013 Canadian Cardiovascular Society/Canadian Heart Rhythm Society task force to go one step further and recommend the universal use of remote monitors as a part of standard care of ICD patients. [30]

Remote Monitors May Improve Survival

The most compelling argument for remote monitor usage is the survival benefit associated with their use. The survival benefit is best demonstrated in the ALTITUDE Survival Study. This study, the largest of its kind, examines survival in a prospective cohort of 185,778 patients up to five years after ICD implantation. In the cohort, 69,556 patients used a remote monitor and 116222 patients did not. At five years from implantation, the patients using remote monitors had a 50% relative reduction in the risk of death ($p<0.0001$) compared to the patients being followed in clinic only. This survival benefit persisted even after adjusting for age, gender, device type, and year of implantation. [31]

This survival benefit is likely due to earlier detection of events that lead to faster diagnosis and treatment. Also, patients may be more motivated to manage their health after making transmissions with the monitor. [31]

One limitation of the ALTITUDE study is that it is not randomized. Because of this, it is possible that the survival benefit seen in remote monitor users is a reflection of the "healthy-adherer effect." [32] Another limitation of the ALTITUDE study is a lack of detailed clinical information about the patients, which could lead to confounding. However, the authors demonstrated that patients using standard follow up would have to have 5 times more baseline risk factors than the remote monitoring group to be able to account for the difference in mortality. [31]

Overall, the ALTITUDE study provides good evidence that there is likely a survival benefit to using remote monitors, and there are currently randomized

controlled trials underway to determine the effect of remote monitors on survival. [33, 34]

Other Health-Related Benefits of Remote Monitors

Survival is not the only benefit of remote monitors. One study demonstrating the safety and faster recognition of clinical events provided by remote monitoring is the Lumos-T Safely Reduces Routine Office Device Follow-Up (TRUST) Trial, a randomized study of 1,339 patients comparing remote follow up to standard follow up. The remote follow up group had continuous remote monitoring with in office visits at 3 and 15 months post-ICD, whereas the standard follow up group had office visits every 3 months post-ICD. At one year post-implantation, there was no difference in morbidity between the two groups. In addition, the number of in-hospital device evaluations was reduced by 45% in the remote monitoring group because the vast majority of follow up could be completed with the remote monitor. Finally, this study strikingly found that the time elapsed between onset of a clinically significant arrhythmia (atrial fibrillation, ventricular tachycardia, or ventricular fibrillation) and evaluation by a physician was significantly reduced from an average of 36 days in the standard follow up group to less than two days in the remote monitoring group. [35]

Another study that demonstrates the safety and reduction of shocks administered associated with remote monitoring is the ECOST trial, a study of 433 ICD patients who were randomized 1:1 to either remote follow up or outpatient follow up. Over a 24.2-month follow up period, 38.5% of remote follow up patients

and 41.5% of standard follow up patients experienced a major adverse event, defined as death or a major cardiovascular event. This rate was not significantly different between the two groups. Interestingly, the ECOST study also found that the remote follow up group received 71% fewer appropriate and inappropriate shocks than the standard follow up group. The reduced number of shocks in the remote group was likely due to early recognition and treatment of inappropriate shocks and by prevention of appropriate shocks with early implementation of antiarrhythmic treatments. [36]

Remote monitoring may also decrease the length of hospital stay after a cardiovascular event. The "Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision (CONNECT)" study is a randomized trial of 1,997 patients examining the effect of remote monitoring on response time to a clinical event. Like the TRUST trial above, the CONNECT trial found that remote monitoring significantly reduced the time from clinical event to clinical decision, from 22 days in the standard follow up group to 4.6 days in the remote follow up group ($p<0.001$). Importantly, this faster response time seems to be clinically meaningful; the remotely monitored group had a shorter length of stay for cardiovascular hospitalizations, 3.3 days versus the control group's 4.0 days ($p=0.002$). [37]

Due to the TRUST, ECOST, and CONNECT trials, as well as several other trials, remote monitors are now generally recognized as being a safe alternative to office visits. As a result, many centers, including Yale's, have implemented remote monitoring follow up schedules that can replace office visits.

Remote Monitors are Cost Effective

Remote monitors have been shown to reduce healthcare costs. The CONNECT trial, discussed above, found that the reduction in length of hospital stay lead to a savings of $1,793 per cardiovascular hospital stay. [37]

Remote monitors may also reduce costs by reducing the number of in-office visits. This makes sense because as described above, patients can be safely followed with fewer in-office visits if they are using a remote monitor. One prospective study of 41 patients being followed with remote monitors found that substitution of two in-office visits with remote monitoring over the 9-month follow up period reduced the cost of ICD follow up by a average of 524 euros per patient, a cost reduction of 41%. This reduction in cost was due to several factors, including lower physician evaluation cost for remote transmissions, avoidance of travelling costs for the patient, and decreased need for taking sick days for in-office visits. [38]

Remote Monitors are Easy to Use

Several small studies have found that both patients and doctors have high levels of satisfaction with remote monitors. In one prospective study of 41 patients using remote monitors, 94% of patients felt that overall, the remote monitor either met or exceeded their expectations. Almost all patients in this study found the monitor easy to set up and use. This study also examined physicians' thoughts about the remote monitoring system. Notably, it found that 97% of transmissions were either 'easy' or 'very easy' to access by physicians. [38] A more recent survey of 288 remote monitoring patients reinforced that remote monitors were easy to

use by both patients and physicians and in addition showed that half of patients felt that remote monitor usage led to improved communication with their doctor. [39]

Details of Remote Monitor Usage

Remote monitors remain plugged into a power source and landline phone jack. The monitor is compatible with most landlines, but sometimes a phone adaptor is needed. If patients do not have access to a landline, cellular adapters that allow transmission through a company-issued device can be rented for a monthly fee of between $10 and $20. Remote monitors come packaged with written instructions and a DVD explaining the set up and usage of the monitor. The monitor has lights that indicate the status of the monitor (Figure 9). It also has toggle buttons (Figure 10) that allow the user to configure the monitor to the specific type of phone line (tone versus pulse) and to add a prefix number for phone lines that require it to dial out.

Figure 9. Explanation of the lights on the remote monitor.

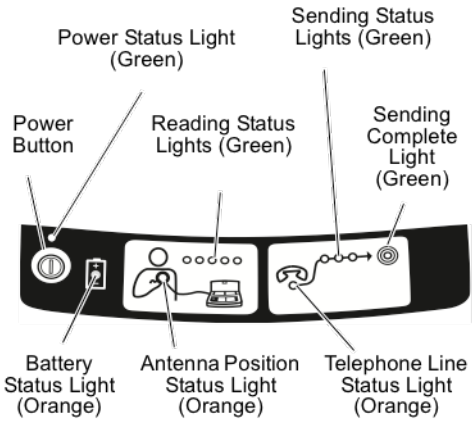
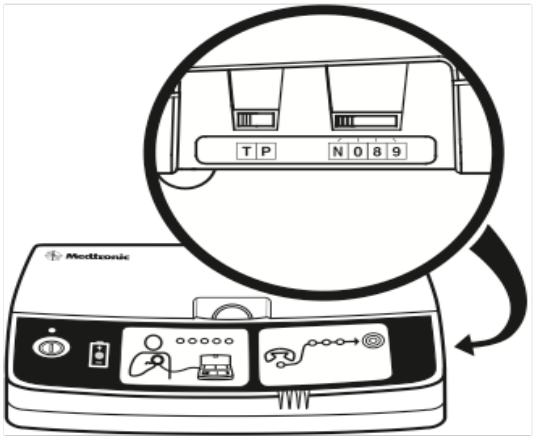


Figure 10. Diagrams of the toggle buttons on the remote monitor.



Remote monitors can be either manual or wireless. Manual monitors require the patient to place a sensor over their ICD and press a button to manually initiate the interrogation. Wireless monitors can continuously interrogate a patient's ICD without any action by the patient, after an initial set up. A patient needs to be within about a 10-foot radius of the automatic monitor in order for the monitor to detect the patient's ICD, so most patients choose to place the monitor in the bedroom. [40]

Remote Monitor Usage is Low

Despite the survival benefit, safety, cost effectiveness, and ease of use of remote monitors, many people still do not use remote monitors. Institutional data from Yale shows that about 54% of patients who receive a Medtronic ICD and are eligible to receive a remote monitor actually choose to sign up for the monitor.

Of the patients who receive the monitor, roughly 80% use the monitor consistently. This leads to an overall remote monitor usage rate of only 43%.

Co-author Dr. Lynda Rosenfeld has conducted studies now in press that indicate that 21% of people who have Medtronic remote monitors nationwide do not use them. Female gender, age less than 40, smaller clinics, and certain geographic areas (the Medicare Census Mountain Region) were found to predict non-transmission. This study recommended further research in these populations in order to develop strategies to improve monitor usage. [41]

In addition, a recent, large prospective cohort study of 40,000 patients that analyzed data from in the National Cardiovascular Data Registry (NCDR) ICD Registry and from Boston Scientific, an ICD manufacturer, has also shown that remote monitors are used in only 47% of eligible patients. This low usage was due to a combination of not signing up for the monitor and not using the monitor once signed up. The authors suggest further study on how the elucidated factors relate to enrollment and activation of the monitor. [42]

Despite interest in the reasons that people do not use remote monitors, there is a dearth of data in the literature about the reasons people do not transmit. These reasons need to be elucidated so that remote monitor usage can be increased.

II. Aims

The aims of this study are two-fold. First, quantitative factors that may affect remote monitor usage will be examined for correlations with monitor usage. It is hypothesized that increased age, lower socio-economic status, government health

insurance, lack of a landline, lower technology usage, and increased disease severity will correlate with non-usage. Second, qualitative methods will be used to generate hypotheses about patient-centered factors that impact remote monitor usage.

III. Methods

Mixed Methods

Convergent parallel mixed-methods, meaning concurrent collection and analysis of qualitative and quantitative data, were used in this study. [43] Quantitative data can elicit relationships between factors known to affect access and usage of healthcare and remote monitor usage. Qualitative data can be used to generate theories about the barriers to remote monitoring. The two types of data compliment each other and can be used to gain a more thorough understanding of factors that affect the usage of remote monitors.

The qualitative portion of this study was based on the principles of grounded theory. Grounded theory, first introduced by Glauser and Strauss in 1967, is a method of generating theories based on observations. In this method, the process of data gathering is open and iterative. No preconceived notions are brought into the study, and questions are designed to be open-ended to generate theories. As data is collected, patients' responses are continuously analyzed to generate tentative theories that are flexible and can be refined with further data collection. Through this analysis, general themes emerge. Data collection continues until there is thematic saturation, defined as the cessation of emergence of new themes with subsequent interviews. [44]

Patient Selection

Patients who received a Medtronic ICD compatible with remote monitoring at Yale Electrophysiology or at the Cardiology Associates of New Haven between January 2007 and June 2012 were eligible to participate in this study. Patients who did not speak English, were under the age of 18, or did not have capacity were excluded.

A list of patients meeting the inclusion criteria was generated from a Medtronic database. The patients were divided into three groups as defined below:

1. "Transmitters"- patients who were enrolled in Medtronic's remote monitoring system, Carelink, and had made at least 2 transmissions with their monitor over the past year.
2. "Non-transmitters"- patients who were enrolled in Carelink, and had made one or zero transmissions with their monitor over the past year.
3. "Not enrolled"- patients who were not enrolled in Carelink and thus did not have a remote monitor.

Medical record review was then performed to identify each patient's address and telephone number. Also, information such as birthdate, gender, date of ICD implantation, and ICD serial number was collected from patients' charts.

Patient Recruitment

Recruitment letters describing the study and notifying patients of their eligibility to participate were sent, starting with those patients who received their

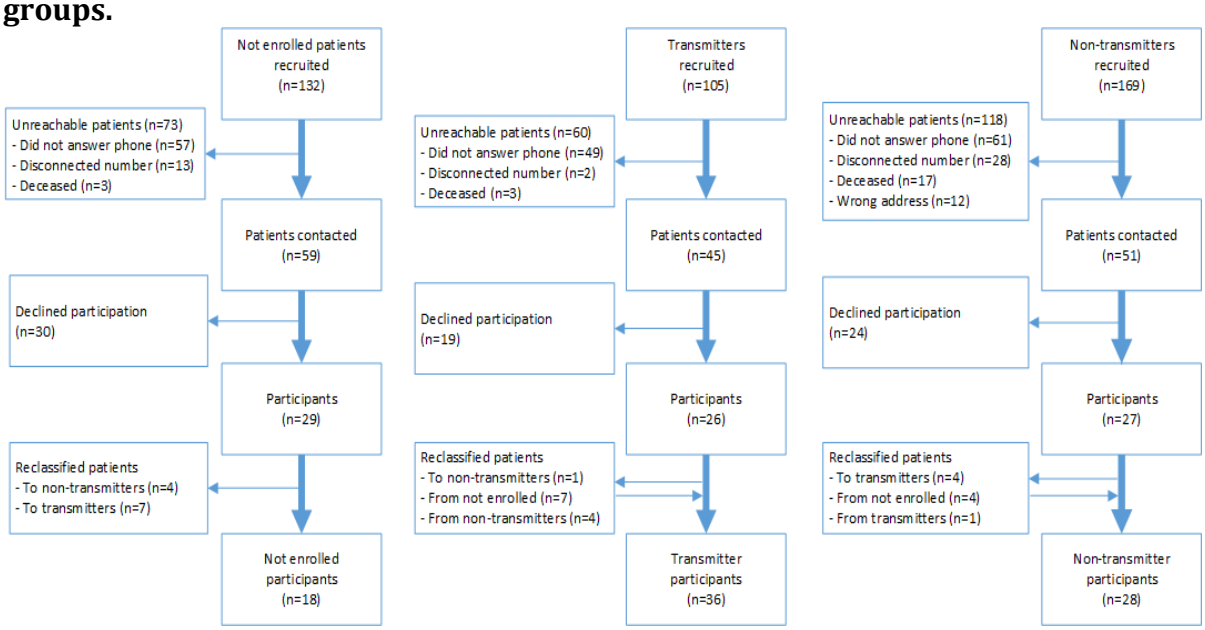
ICD most recently and proceeding in backward chronological order. Patients were informed that study personnel would be contacting them and were given the opportunity to "opt-out" of the study by leaving a message at a phone number given in the letter. Patients who left a message were not contacted. Attempts were then made to contact the remaining patients by telephone. Patients were contacted by phone and asked if they wanted to participate. Those who chose to participate were consented over the phone.

Patients were offered compensation for their participation in this study. "Non-Transmitters" and "Not Enrolled" patients were offered $60 for participation, and "Transmitter" patients were offered $25 for participation.

In the non-transmitters group, 169 recruitment letters were sent, 51 patients were reached by telephone, and 27 agreed to participate in the study. In the not enrolled group, 132 recruitment letters were sent, 59 patients were reached by telephone, and 29 agreed to participate in the study. In the transmitters group, 105 recruitment letters were sent, 45 patients were reached by telephone, and 26 agreed to participate in the study. Of note, patients were sometimes misclassified initially; transmission status was reassigned in these patients after patient interview. (Figure 11)

Overall, 82 patients participated in this study. The participants comprised 28 non-transmitters, 36 transmitters, and 18 not enrolled patients. One transmitter and one non-transmitter completed only the qualitative section of the interview, citing time limitations and difficulty hearing, respectively.

Figure 11. Enrollment data for not enrolled, transmitter and non-transmitter groups.



Quantitative Methods

All quantitative questions were administered over the telephone by E.L., and data was entered in an Excel spreadsheet, in real time. Patients' responses were also recorded so that data could be reviewed for accuracy.

The quantitative section of this study was designed to gather data about factors that may influence remote monitor usage. Factors that typically affect access and usage of healthcare, such as age, gender, and socioeconomic status (household size, occupation and education level [45]) were collected. Patients' occupations were classified into one of two groups, manual/clerical or professional/managerial based on Hollingshead criteria [45]. In addition, the Yale electrophysiology nurses

were consulted about the types of issues they thought affected remote monitor usage. These factors included type of phone service, whether the phone service was bundled, and the type of health insurance coverage. The quantitative section also included the Brief Illness Perception Questionnaire.

Quantitative Data- The Brief Illness Perception Questionnaire

The Brief Illness Perception Questionnaire is a 9-question instrument that probes a patient's ideas about his or her illness (Figure). There are 8 LIkert-scale questions, each about how a patient feels about a facet of their disease. There is also one free response question about why the patient thinks they have developed their disease. The free response answers in the Brief Perception of Illness Questionnaire were coded into two different categories for analysis: controllable factors, like diet or smoking, and uncontrollable factors, like genetics.

Figure 12. The items of the brief perception of illness questionnaire.

Theme Probed	**Question**
Consequences	How much does your illness affect your life?
Timeline	How long do you think your illness will continue?
Personal control	How much control do you feel you have over your illness?
Treatment control	How much do you think your treatment can help your illness?
Identity	How much do you experience symptoms from your illness?
Concern	How concerned are you about your illness?
Understanding	How well do you feel you understand your illness?
Emotional representation	How much does your illness affect you emotionally?
Causation	Please list the three most important factors that you believe caused your illness.

The first 8 questions below are answered on an 11-point Likert Scale, from 0-10. The last question is free-response.

The Brief Illness Perception Questionnaire has been internally and externally validated in patients with several acute and chronic conditions, including diabetes, asthma, colds, and myocardial infarction. The scores on the questionnaire have been shown to correlate with outcomes in several conditions as well. [46]

Quantitative Data Analysis

Data analysis was completed by R.L. and E.L. An Excel spreadsheet containing all the quantitative data was imported into JMP 9 statistical software for data analysis. ANOVA and t-test were used to compare continuous variables between three and two groups, respectively. Post-hoc t-test analysis was performed when ANOVA indicated significance. Continuous variables included age, means household size, and all the Likert scale questions and on the Brief Illness Perception Questionnaire.

Categorical variables, including gender, education level, employment status, health insurance status, telephone type, computer usage, and the coded free response question on the Brief Illness Perception Questionnaire, were analyzed using chi-squared analysis. Multivariate analysis was conducted to control for variables.

Qualitative Methods and Grounded Theory

The qualitative interview was designed to probe patients' perceptions of their remote monitors. In-depth interviews were conducted with very general questions exploring topics such as patients' feelings and experiences with their

remote monitors, and their experiences with other aspects of their heart disease, including experiences with their ICD and with managing multiple conditions. The questions were designed to probe for specific barriers to using remote monitors as well as related topics such as patients' overall attitudes toward their remote monitor, ICD, and heart disease. While there was an interview guide for the overall structure of the interview (Figure 13), the interviewee directed the course of the discussion so that rich data could be collected.

Figure 13. The qualitative in-depth interview guide.

Interview Prompt Outline
Perception of heart disease
What has it been like to manage your heart condition?
How do you cope with your illness?
Percepetion of multiple conditions
Besides your heart condition, are there any other conditions you're dealing with?
Are there any specific things that you do to manage these other conditions?
Perception of ICD
What has it been like to manage your ICD?
Perception of remote monitor
What has your experience been with your remote monitor?
What do you think are the benefits of your remote monitor?
General probe of barriers to remote monitor use
What are some things that would make your remote monitor easier to use? (Specific probes about set up, training, awareness of transmission dates, location of monitor, toggle buttons, and confirmation of transmission were used accordingly)
Interest in Remote Monitoring Data
Would you like to have access to your own remote monitor data?
What types of information would you like to see from your remote monitor?

Interview Procedure

Interviews were conducted over the telephone. The first two interviews were conducted by K.M. while being observed by E.L. K.M. then observed E.L. conducting the next two interviews and gave feedback. E.L. proceeded to complete the rest of the interviews. Interviews continued until thematic saturation occurred. The conversations were recorded and then sent to various transcription services to be transcribed.

Qualitative Data Analysis

The interview transcriptions were verified for accuracy of content. All members of the research team (E.L., K.M., R.L.) reviewed a portion of the interviews transcriptions line by line. Each team member independently coded these transcripts using the principles of grounded theory, as described above. The coding was reviewed jointly to ensure inter-rater reliability.

Once a coding framework was developed jointly, E.L. completed coding for the rest of the transcripts. R.L. also coded a portion of the subsequent interviews and met regularly with E.L. to ensure continued inter-rater reliability. Codes were modified throughout the process as needed to ensure that the analysis remained grounded in the patients' beliefs.

IV. Results

Quantitative Data

The participants in the three groups, transmitters, non-transmitters, and not enrolled, did not differ significantly in gender or age (Table 14).

Table 14: Characteristics of non-transmitters and transmitters.

	Non-transmitter (n=28)	Transmitter (n=36)	p-value
%Male	68%	75%	0.52
Mean age (S.D.)	65 (16)	69 (14)	0.27
% with HS diploma	81%	89%	0.43
% with 4-yr degree	41%	29%	0.32
% Working	33%	37%	0.76
Mean household size (S.D.)	2.2 (1.0)	2.5 (1.4)	0.16
% with manual/clerical jobs	46%	36%	0.47
% with government health insurance	52%	20%	0.01*
% with landline	78%	100%	0.003*
% with bundled phone service	71%	67%	0.72
% owning computer	74%	86%	0.25
% using computer at least weekly	48%	76%	0.02*

Significant p-values are denoted with a "*".

Socioeconomic Status Measures

Several measures of socioeconomic status were studied. Non-transmitters had a significantly higher number of patients on government insurance (Medicaid or Medicare with no secondary insurance) than transmitters, p=0.01. Insurance type remained significant after controlling for age. Other measures of socioeconomic status, including education level, household size, and type of employment, did not differ between transmitters and non-transmitters.

Telephone and Computer Usage Results

Significantly fewer non-transmitters owned a landline compared to transmitters, 78% versus 100%, p=0.003. Non-transmitters were also significantly less likely to use a computer than transmitters; 48% of non-transmitters and 78% of transmitters used a computer at least once a week, p=0.02. There was a non-statistically significant trend for non-transmitters to be less likely to own a computer.

Brief Illness Perception Results

Table 15: Brief Illness Perception Questionnaire results

	Non-transmitters	Transmitters	Not Enrolled	p-value
Consequences	5.7 (3.2)	5.4 (3.7)	4.8 (3.4)	0.73
Timeline	9.2 (2.2)	9.4 (1.9)	9.4 (1.9)	0.86
Personal Control	6.6 (3.0)	5.9 (3.6)	4.5 (3.6)	0.14
Treatment Control - ICD	8.5 (2.5)	8.9 (1.8)	9.2 (1.4)	0.57
Treatment Control - Monitor	*6.5 (3.4)	*8.9 (1.7)	7.9 (3.3)	0.005**
Identity	3.9 (3.4)	2.7 (3.1)	2.3 (2.2)	0.18
Concern	6.4 (3.4)	5.0 (3.8)	3.9 (3.3)	0.07
Understanding	8.6 (2.4)	8.6 (2.2)	8.7 (1.7)	0.97
Emotional Response	5.5 (3.6)	4.5 (3.9)	4.9 (3.5)	0.60
Total Score	41.2 (13)	34.8 (14.7)	34.5 (10.9)	0.19

This table shows the mean response and standard deviation for each item in the Brief Illness Perception Questionnaire. P-values less than 0.05 are denoted with "". Pairs of values determined to differ significantly with paired t-test post hoc analysis are denoted with "*".**

The only significant difference between the three groups in the Brief Illness Perception Questionnaire (Table 15) was in the "Treatment Control-Monitor" item. In this question, transmitters found the remote monitor to be significantly more beneficial than the non-transmitters, with respective average helpfulness ratings of 8.9 and 6.5, p=0.005.

There was a non-significant trend for non-transmitters and transmitters to be more concerned about their heart conditions compared to the not enrolled

group, p=0.07. Post hoc analysis showed the largest difference between the non-transmitter and not enrolled groups, p=0.01.

Other results that approached significance included a trend for non-transmitters and transmitters to believe they had more control over their condition (in the "Personal Control" item) than the not enrolled patients and a trend for non-transmitters to have more symptoms (in the "Identity" item) from their heart condition than transmitters or not enrolled patients. Based on the cumulative score, there was a non-significant trend for non-transmitters to view their disease as more threatening than transmitters or not enrolled patients.

In the free response question, 54% of transmitters and 67% of non-transmitters listed at least one controllable cause for their heart disease, p=0.32.

Qualitative Data

Experiences with Health

The first domain queried during in-depth interviews was patients' experiences with their health, including experiences with heart disease, multiple conditions, and ICDs

Experiences with Heart Disease

Both transmitters and non-transmitters seemed to have similar sets of experiences with their heart disease. In both groups, negative themes such as limitations, difficult illness, and fear emerged. One transmitter said of his heart condition:

> "Oh, it's horrible, let's put it that way. I worry about doing things I probably shouldn't do. I don't want to get over-worked. I pretty much got away from a lot of my outdoor activities. A lot of walking, I don't do anymore."

A non-transmitter noted the limitations of his heart condition:

> "There's a lot of things I can't do that I used to do."

Many positive themes, such as uncomplicated disease and easy management, emerged in all three groups. One transmitter noted the minimal impact of his disease:

> "It's been good, it hasn't been bad, at all. [I] just go about my normal activities."

A non-transmitter had a similarly positive experience with his heart condition:

> "I do the regular things around the house. [My heart condition] doesn't bother me a bit."

One not enrolled patient said of his heart condition:

> "It just has become a way of life. I think I adapted fairly well. It's not difficult to eat right and exercise. That's part of my regime, now. I don't feel like it's any type of handicap or anything like that."

Of note, the not enrolled patients tended to have more positive experiences with their heart conditions compared to the transmitters and non-transmitters.

Experiences with Multiple Conditions

Patients in all three groups had similar comorbidities, with diabetes, back conditions, lung disease, hypertension, and kidney disease commonly occurring in all three groups.

Management of the multiple conditions was also similar between the three groups, with all three groups citing diet and other lifestyle changes as management strategies. Of note, the non-transmitters seemed to use more mobility aids, like canes, walkers, or wheelchairs.

Despite the similarities in types and management of comorbidities, non-transmitting patients seemed to have a slightly more negative overall experience with their multiple conditions compared to the two other groups. Though all three groups had mixed experiences with comorbidities, more negative themes, such as difficult management, symptoms, and confusion, occurred in the non-transmitter group. One non-transmitter expressed the difficulty of managing multiple conditions:

> "I've had some difficulty with my lungs… And then from the radiation I developed some gastrointestinal problems… [The heart condition is] just one more thing, you know? It just adds to it all. Cumulatively, it kind of gets to you, you know?"

Experiences with ICD

Patients in all three groups were able to appreciate the benefits of ICDs, citing the ICD's ability to save lives and the sense of security the device offered. For example, a patient said:

> "So, it's also a comfort to know that I don't have to worry. It's just been like having an insurance policy on you."

All three groups also had similar ranges of experiences with their ICDs. A large number of patients in all three groups found their ICDs to be unobtrusive and easy to manage. A patient voiced this sentiment:

> "I don't worry much about [my ICD], it's just there. It doesn't seem to require management on my part."

There were also patients in each of the three groups that had negative experiences with the ICD. Some patients were scared of the defibrillator firing:

> "It's scary, the defibrillator firing and knocking you on your butt. It's just always on my mind, like worrying about getting a cold if you go outside, or something."

Other patients had experiences with recalled leads:

> "The first one I had was … defective. So, it was shocking me. So they had to take that one out of me."

Despite largely positive experiences, many patients in all three groups were able to identify minor disadvantages of the ICD, such as aesthetic faults and minor discomfort. Many patients noted the protrusion of the device and the scar from implantation:

> "I don't really like [the ICD] totally, because you can see it through my skin, the lump."

> "I was aware of wearing low scoop-neck shirts, because you see the scar."

Some patients had discomfort during driving or sleeping:

> "I think the only negative I can say about the defibrillator is that when I wear a seatbelt, it's very uncomfortable."

> "I have one minor problem with [the ICD]. If I lie on my right side in bed at night, the pacemaker throbs a little bit, which keeps me awake. So, I have to sleep on my left side."

Experiences with Remote Monitors

The next domain queried during the in-depth interview was patients' experiences with their remote monitors. This included thoughts about benefits of monitors, experiences with setup and usage of monitors, and other factors influencing transmission.

Transmitters Identify More Benefits to Monitor Usage

Transmitters were better able to identify the benefits of the remote monitor compared to non-transmitters and not enrolled patients. Many transmitters noted the ability of the monitor to diagnose problems:

> "[The remote monitor] picks up things that you don't even realize are happening. Some of the times that my heart got out of rhythm there, I didn't even know it. [The doctor's office] called me to come in there and shock it back into rhythm again.

Some transmitters also recognized that monitors led to more prompt evaluation of problems:

> "If I have an episode, then the doctor can just tell me to go ahead and send him the information rather than wait to go to the office and get it checked. It's just a lot more convenient, and a lot quicker."

Many transmitters also noted that the monitor gave them a sense of security:

> "[The remote monitor] gives you a feeling of comfortableness in that somebody's looking at it to make sure things are working alright."

Many transmitters also appreciated that remote monitors reduced clinic visits:

> "It's a great benefit. You don't have to see the doctor as often because it's transmitted. Yes, and it helps me as far as transportation."

In contrast to transmitters, non-transmitters tended to identify the secondary benefits of the monitor, such as convenience and reduced clinic visits:

The non-transmitters tended to not recognize the primary benefits of the monitor, namely improved diagnosis and evaluation of events.

Not enrolled patients were generally not familiar with any of the benefits of the remote monitor. Some not enrolled patients did not know whether there were benefits to the monitor, and others believed that there was no reason to use the remote monitor:

> "I really don't think it's going to help me at all because when I go to [my doctor] every 3rd month and all they say is, "You're doing fine and nothing happened," I'd be carrying that goddamn thing around for nothing. I'm not going to do that."

<u>Reasons for Not Enrolling in Carelink</u>

Patients who chose to not enroll in Carelink cited three major categories of reasons:

1. Remote monitor not offered.
2. Perceived lack of benefit to the monitor
3. Lack of a landline.

Each category is discussed below.

-Remote Monitor Not Offered

Many of the not enrolled patients were never presented with the option of a remote monitor. For example, two patients shared their experiences:

"No one's ever talked about a monitor with me."

"I don't think [the remote monitor] has ever been offered to me. I don't know if they ever had a program through my doctors that offered [the monitor]. I was not even aware of [the monitor] until you mentioned it."

-Lack of Benefit of Remote Monitor

As described above, many not enrolled patients did not believe there was a benefit to using a remote monitor. One patient stated:

"The only thing [the remote monitor] really accomplished was to download what was in my chest. So, I thought that was its primary function, and that gets done at the doctor's office, so it didn't matter."

Other patients did not see a remote monitor as something necessary. For example, one patient said:

"I have not had a need for one, but if I felt I needed one I would get one."

-Lack of a Landline

Finally, some patients who did not enroll in Carelink cited the lack of a landline. For example, one patient said:

"I didn't have a home phone line. I wanted to be able to use the monitor."

Another patient said:

> "I don't have a telephone line for [the doctor] to do [remote monitoring]. I don't have a phone because I don't have a need for it. I discontinued it a while back. It was a waste of money."

Reasons for Not Transmitting in Carelink

Patients had diverse reasons for not transmitting in Carelink. There were six major categories of reasons that patients did not transmit:

1. Belief that transmissions were actually being sent.
2. Problems with set up.
3. Problems with phone line.
4. Financial barriers.
5. Low strength of recommendation from physicians.
6. Belief that transmissions were not necessary when feeling well.

Each category is discussed below.

-Belief that Transmissions are Actually Being Sent

Some non-transmitting patients mistakenly thought that they were transmitting. For example, one non-transmitter from whom no transmission had ever been received described his experiences with his monitor:

> "It's really been pretty easy. You know, the instructions were good. I would just go into my bedroom and close the door, and, you know, do what it said and it was very simple."

-Problems with Set Up of Monitor

Many non-transmitting patients cited difficulty in the set up of the monitor. Some patients did not understand how to set up the monitor. For example, one patient said:

"I tried to hook it up, but I had problems with hooking it up, like not knowing how to hook it up. Nobody ever taught me how to hook it up."

Another patient said:

"I've had trouble setting it up. Yeah, the directions were not very clear."

Other patients found the set up difficult because of physical limitations. For example, one elderly, frail patient said:

"They gave me a new [remote monitor]. Where the jack is located, behind my bed, I can't put it back there."

In contrast, transmitters almost universally believed that remote monitors were easy to set up. One transmitter said:

"Piece of cake. [The set up] was so easy, it wasn't funny."

Of note, despite differences in perceived difficulty of set up, both transmitters and non-transmitters learned how to set up the remote monitor in similar ways. Patients in both groups referenced the Medtronic pamphlet and what they were taught by their doctors.

Though transmitters and non-transmitters had differing experiences with the set up of the monitor, both groups overwhelmingly believed that remote monitors were easy to use once set up. For example, one transmitter said:

"I think [the monitor] is easy to use."

A non-transmitter had a similar sentiment:

> "[The monitor's] pretty easy to use and there's no effort at all on my part."

-Problems with Phone Line

Another common cause of technical difficulty was problems with the phone line. Some non-transmitters also did not transmit because they did not have landlines. For example, one non-transmitter said:

> "I don't use the remote monitor because all I have is a cell phone. And, I'm surprised that in this day of technology, there isn't a technology that allows me to use that monitor with my cell phone."

Several patients also noted that their landlines were not compatible with the monitor. For example, one patient said:

> "The only difficulty I have is that I can't send my report because my system is a digital system and not an analogue system."

Some patients also noted that they did not have phone jacks in the bedroom, making it difficult to use automatic monitors. One patient explained:

> "There's no phone jack in my room where I sleep. The kitchen has the only phone jack."

-Financial Barriers

Some non-transmitter patients described financial barriers to transmitting. These financial issues included the cost of the phone line and problems with insurance coverage for remote monitor transmissions. One patient with out a phone line explained:

> "I'm strictly cellular. It's a convenience. I don't need another phone and don't want to pay another $20 for another phone."

Another patient described his prohibitive insurance situation:

> "I belong to a labor union and we're self-funded, our insurance, and our board of trustees doesn't believe that that's absolutely medically necessary to remote monitor. They consider [the transmission] a diagnostic charge, and they don't want to pay it."

-Low Strength of Recommendation from Physician

Several non-transmitters cited the strength of their doctor's recommendation in their decision to not use the remote monitor. One patient said of his doctors:

> "They don't think [remote monitoring] is all that important. They never said to me that it's really important that you transmit this on time. I never had that kind of a conversation with anybody. The level of the conversation hasn't dictated that I create this as a priority."

Another patient felt that his doctors presented the remote monitor as optional:

> "They say, "You could hook this up" but they didn't say I had to. If the doctors insisted upon it, I would."

A few non-transmitters were also directly advised to stop using the monitor by their doctors. One patient who was told by her doctor to stop transmitting said:

> "I stopped using [the monitor] because the doctor said no problem or anything, said don't even use it. He said, "Your heart is stronger than before, you don't have to use it."

In contrast to the non-transmitters, transmitters often cited their physician's high strength of recommendation in their decision to use the monitor. For example, one transmitter said of his decision to use the monitor:

"I want to do what the doctor ordered."

One former non-transmitter who had recently decided to start transmitting said:

"I had seen [my doctor] and then the nurses started questioning me about the monitor. They told me it was pretty easy and not a problem so I thought I better get cracking and start [transmitting]."

-Belief that Transmissions are Unnecessary when Feeling Well

Many non-transmitters also believed that they did not need to transmit because they were feeling well. For example, one non-transmitter said:

"I just don't feel like I have to [transmit]. I mean, if I'm uncomfortable, if I felt there was something that had to be monitored, I would probably hook it up."

Another non-transmitter said:

"I'm not too concerned about [not being able to transmit] because I have fewer events. I don't have an urgency to send [transmissions] because my heart rhythms are so good and I very rarely feel any kind of palpitation."

Transmitters Tend to Troubleshoot Problems

Of note, transmitters also commonly faced problems with transmission. Most commonly, these problems involved the phone line. Several transmitters required an adaptor in order to transmit through their phone lines, and others rented the Medtronic cellular adapter. Some transmitters also faced problems involving the toggle buttons on the monitor. For example, one transmitter said:

> "When I dusted the machine, because it's on my nightstand, I hit one of the buttons in the back that set it into a different mode. So, they went to do a download and it didn't go through. So, I got a letter, I called them, and they told me what to do and it was fixed."

Many transmitters were able to troubleshoot and solve problems they had with transmission. Transmitters and non-transmitters were both able to list their doctor's office and Medtronic as where they would theoretically turn to for help, but transmitters tended to actually seek help for problems.

Suggested Improvements to Remote Monitors

The final domain addressed was patients' desire for feedback from the monitor and improvements to the monitor.

Feedback from Clinic

Many patients in both the transmitters and non-transmitters groups expected communication from the clinic about the remote monitor transmissions.

Many patients from both the transmitters and non-transmitters groups also thought that the clinic should let them know when a transmission was received. For example, one transmitter said:

> "[After the scheduled transmission], they didn't call, they didn't do anything. Even with the [manual monitor] before, when I'd do it myself once a month, I'd get a letter back."

Another non-transmitter had a similar experience:

> "I never received a call, never received any information anywhere."

Many patients also expected that the clinic would inform them if something were wrong with their transmission. For example, one patient said:

> "The doctor's office call[s] me if there's anything wrong. If I don't hear from them, then, everything's fine."

Feedback from Monitor

Many transmitters and non-transmitters also noted that the monitor did not give feedback about whether transmissions had completed. A transmitter said:

> "You know, the patient actually doesn't know if [the doctor] got the results."

One non-transmitter similarly noted:

> "[The monitor] never gave me back any information, it never, like told me what's going on, or what the doctors are saying."

Desire for Confirmation of Transmission

Given that many patients noted the lack of feedback after transmission, it is not surprising that both transmitters and non-transmitters almost universally thought that it would be useful to receive confirmation that transmissions had gone through. For example, one transmitter suggested:

> "If the machine had a light that was like an indicator that it did work, [that] would help."

Access to Data

In addition to wanting confirmation, most transmitting and non-transmitting patients also wanted access to data from their remote monitors. One patient suggested:

> "It would be great to know what's going on. Even if it's like an online picture. Like if I call the doctor and he says, "Hey, go to this website." And you will see what I'm seeing. That would be great."

Another patient said:

> "I want to know everything that's going on. Sometimes I get the heart palpitations, and it goes up a little high - and I think, "Hm, what was I doing at that time?"

All smaller subset of both groups did not want access to the data from remote monitors. These patients tended to feel that they would not understand or be able to apply the information from the remote monitor. For example, one non-transmitter said:

> "I don't think I need to see it, because I wouldn't know what I'm looking at."

<u>Desire for Cellular Capability</u>

Many patients across the three groups also suggested that the monitor be improved to allow for cellular transmission. For example, one patient said:

> "The point is [the remote monitor] should be cell phone capable and it's not, and that is, in my opinion, unacceptable and a disgrace that it isn't."

Another patient said:

> "Obviously if it was wireless and didn't have to be connected to a phone outlet it could go anywhere … that would make it easier."

V. Discussion

Quantitative analysis showed that transmitters and non-transmitters did not differ significantly in gender, age, or socioeconomic status. Transmitters are significantly more likely to own a landline, use computers regularly, have non-government health insurance, and believe there is a benefit to using the monitor. Qualitative analysis revealed six major categories of reasons that non-transmitters do not use their remote monitors: belief that transmissions are actually being sent, problems with set up, problems with telephone landline, low strength of recommendation from physicians, financial barriers, and the belief that transmissions aren't necessary when feeling well. This study also found three categories of reasons that patients do not enroll for a remote monitor, including no knowledge of remote monitors, a perceived lack of benefit to remote monitors, and not having a landline telephone.

There are very few studies in the literature that address the reasons that patients do not use remote monitoring. A recent study of 40,000 ICD patients listed some factors that are associated with remote monitor usage. This study found that the strongest determinant of enrollment for monitoring was the prior rate of enrollment at the hospital; the type and size of hospital did not make a difference. Physician associated factors, such as being electrophysiology board certified and having a history of more ICD implantations are also significantly associated with enrollment for the monitor. Patient factors such as older age, white race, non-Medicaid health insurance, and better overall health were associated with both higher rates of enrollment and transmission. This study was not able to directly

collect landline information, but the authors postulated that availability of a landline telephone is also an important factor that is related to monitor usage. [42]

A review of the current literature also reveals a small qualitative study examining the experiences with remote monitors of 4 non-transmitters and 5 transmitters. The study identified lack of understanding of the remote monitor and lack of phone lines as possible reasons that patients do not transmit. [47]

This study expands the knowledge base of possible reasons that patients do not use remote monitors. As described below, the data suggests several ways that physicians and industry can help to increase usage of remote monitors.

Patient Characteristics

There are no significant differences in the age or gender between the groups. Prior studies of remote monitoring have found significant differences in age and gender between transmitters and non-transmitters; in this study, the age and gender trend in the directions of previous reports, but sample size was not large enough to achieve significance in these measures.

This study found no significant difference in socioeconomic status between transmitters and non-transmitters. It is commonly accepted that lower socioeconomic status is associated with less healthcare usage. [48] In this case, ICD implantation may have served as a screen for patients who are better off.

This study also found that non-transmitters were significantly more likely to have government insurance than transmitters. This finding is consistent with Akar

et al's finding that patients with commercial or HMO insurance are more likely to enroll and transmit than those with Medicaid or Medicare [42].

Recognition of Benefit

The data indicates that patients who understand the benefits of the remote monitor tend to use the monitor. Quantitative data from the Brief Illness Perception Questionnaire showed that transmitters rated the benefit of remote monitors significantly higher than non-transmitters. Transmitters were also able to identify more benefits to remote monitoring than non-transmitters and not enrolled patients. Patients in the latter two groups often cited a lack of benefit in their decision to not use the monitor.

It is generally accepted that perceived benefit of a treatment is a predictor of treatment adherence, across a wide spectrum of diseases including in heart disease. [49-51] The benefit of treatment item on the Illness Perception Questionnaire has also been shown to be associated with treatment adherence in several conditions. [52, 53] Based on the findings on this study, physicians can affect remote monitor usage by clearly communicating the benefits to patients.

Strength of Doctor's Recommendation

The strength of a doctor's recommendation to use remote monitoring appeared to be associated with monitor usage. Many transmitters received strong recommendations to use the monitor, whereas many non-transmitters and not enrolled patients felt that their physicians presented the monitor as something

unimportant or optional. These findings are consistent with findings in the literature showing that doctor's recommendations have an effect on patients' adoption of telemonitoring. [54] Physicians should consider explicitly recommending remote monitoring.

Akar et al previously reported that remote monitor enrollment and usage varies depending on physician specific factors [42]. This variation may be due in part to differing strengths of recommendation between doctors. It would be useful to conduct further study on physicians' beliefs about recommendation of remote monitoring and adoption of remote monitoring into their practices.

A perceived low strength of recommendation could also be due to a lack of communication or misunderstanding of a doctor's recommendation. This is supported by several studies that show that doctors and patients often leave shared encounters with different perceptions of the encounter. [55] Again, further research into physicians' perspectives can help clarify this issue.

Lack of Transmission Confirmation

A surprising theme that emerged in the non-transmitters was that some patients don't realize that they are not transmitting. One possible reason that patients may not know if they have transmitted is a lack of feedback from the monitor and clinic about transmission status. Patients in both the transmitters and non-transmitters groups noted this lack of feedback. Patients almost universally desired some sort of confirmation that transmissions had been received.

These data suggest ways in which device manufacturers can improve technology to increase usage of remote monitors. A system to confirm transmission, such as a clear indicator on the monitor or an automated confirmation call, should be implemented.

Problems with Phone lines

A prior small focus group study reported that problems with landlines might impede transmissions.[47] This study also found that patients commonly had problems with their phone lines. Quantitative data from this study showed that non-transmitters are significantly less likely to have a landline than transmitters. Qualitative data showed that problems with phone lines prevent non-transmitters from using their monitor and deter not enrolled patients from signing up for the monitor. This study appears to be the first to delineate the types of phone problems that patients encountered. Types of phone problems encountered included: no access to a landline, phone line incompatibility with remote monitor, and inconvenient location of phone jacks.

Device manufacturers have already recognized that problems with phone lines are common. One solution that manufacturers have introduced is the wireless adaptor. Though this seems to be a reasonable alternative to obtaining a landline, this study found that many patients do not own a landline because of the cost. Often times, patients who cannot afford landlines find the contract fee and rental fee for the wireless adaptor to be prohibitive as well.

Previous studies have shown that under-served patients are very willing to adopt technology to manage their health, if given the financial resources to be able to do so. [56] Remote monitors have been shown to reduce overall healthcare expenditure [37], [38], so providing financial help to those who cannot afford a landline or the wireless adaptor may still be cost effective in the long run.

Of note, most patients who did not own a landline did own a cell phone, and there was significant patient interest in being able to use cell phones for transmission. In a day and time where cell phone usage is drastically increasing in all age groups and more than half of young adults only use cell phones [57], it may also be worthwhile for device makers to develop monitors compatible with cell phones.

Physical limitations

A theme that emerged in the non-transmitters was physical limitations. Presence of physical limitations may be a factor that prevents use of remote monitors, as some non-transmitters reported having physical difficulty setting up the remote monitor. This study also found that non-transmitters seemed to be a group that had more physical limitations, as evidenced by a generally more negative experience with multiple conditions and higher usage of mobility aids. This is corroborated by a previous study has shown that people who do not activate their remote monitors are an overall sicker group of patients. [42] Healthcare professionals should be cognizant that complicated illness and limited mobility can

affect set up of remote monitors and work with patients and their families to arrange set up of the monitor.

Difficult Set Up and Computer Literacy

Many patients did not transmit because the set up of the remote monitor was too difficult. The perceived difficulty of set up may be related to an overall discomfort with new technology. This study found that non-transmitters had a significantly lower rate of computer usage compared to the transmitters. Computer usage has been shown to affect the adoption of telemedicine, as illustrated by a study that showed that baseline computer usage correlates with use of and satisfaction with a diabetes telemedicine program. [58]

While the healthcare system cannot impact a patient's comfort with technology, it can offer resources to patients to help work through these issues. As a future direction, the authors of this study are conducting a randomized study to determine if an over-the-telephone teaching session can help patients set up of the monitor

Troubleshooting

It is interesting to note that transmitters encountered many of the same barriers that non-transmitters and not enrolled patients did, but they were able to overcome those barriers. Transmitters were able to use clinic resources and Medtronic's helpline to solve their problems. This suggests that part of the reason people transmit is due to a determination to do so, which may in part be explained

by the transmitters' greater perceived benefit of remote monitoring. There may also be differences in unexamined baseline patient characteristics between the groups that can help explain this.

Desire for Access to Data

A majority of both transmitters and non-transmitters wanted access to their remote monitor data. Previous studies have shown that electronic feedback has already been used successfully in the management of congestive heart failure and asthma. [59],[60] Although there was a cost to implement the feedback mechanism, outcomes were improved for patients receiving the electronic feedback. Perhaps implementing a way for remote monitor users to get feedback can offer incentive for using the monitor and potentially improve patient outcomes as well. Pilot studies should be considered to examine electronic feedback for remote monitoring patients.

Future Directions

The hypotheses generated using qualitative research need to be confirmed with quantitative methods, such as surveys in large populations. If these hypotheses can be confirmed, they can guide changes to increase remote monitor usage in the future.

Limitations

This study involves a patient population from a single academic center. As geography and hospital-specific factors can affect remote monitor usage, perspectives from other centers or rural areas could vary. However, patients were recruited from both a community practice affiliated with the academic center and from the university clinic in order to increase the generalizability of this study.

This study examined barriers to remote monitoring specifically in the Medtronic Carelink system. Though the study findings are specific to Carelink, all remote monitors operate on the same basic principles with similar technology. Therefore, the findings from this study are likely applicable to the other systems as well.

The participants in this study were self-selected. Those patients who could not be contacted or chose to not participate may have differing viewpoints from those who did participate. However, this limitation is inherent to interview studies. Additionally, the rate of participation among those patients who could be reached by telephone was slightly over 50%, which is similar to rates of participation in other interview studies involving patients with ICDs or remote monitors. [47], [61]

VI. Conclusions

Quantitative analysis showed that transmitters are significantly more likely to own a landline, use computers regularly, have non-government health insurance, and believe there is a benefit to using the monitor. Qualitative analysis revealed six major categories of reasons that patients do not use their remote monitors: belief that transmissions are actually being sent, problems with set up, problems with telephone landline, low strength of recommendation from physicians, financial barriers, and a perceived lack of benefit to monitoring.

The findings of this study suggest that there are actions that physicians can take to help increase remote monitor usage, such as explicitly recommending remote monitoring, giving explanations of why monitoring is beneficial, and ensuring that patients have the help necessary to set up the monitor. ICD manufacturers can also help increase remote monitor usage by providing patients with feedback from monitors, reducing the price of cellular adapters, and developing technology that allows for cellular phones to be used for transmission.

VII. References

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