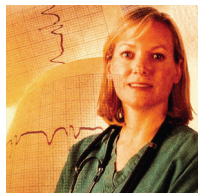
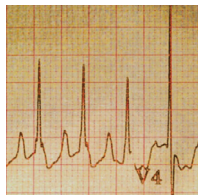


# Remote Physiological Monitoring: Innovation in the Management of Heart Failure



New England Healthcare Institute



NEHI Innovation Series

July 2004

## ABOUT

Founded in 2002, the New England Healthcare Institute (NEHI) specializes in identifying innovative strategies for improving health care quality and reducing health care costs. NEHI conducts independent, high quality research that supports evidence-based health policy recommendations at the regional and national levels. Member representatives from the academic health center, biotechnology, employer, medical device, payer, pharmaceutical, provider, and research communities bring an unusual diversity of talent to bear on NEHI's work. We collectively address critical health issues through our action-oriented research, education, and policy initiatives.

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# **Remote Physiological Monitoring:**

## **Innovation in the Management of Heart Failure**

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 **NEHI** New England Healthcare Institute

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**NEHI Innovation Series**

**July 2004**

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## Acknowledgements

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This report would not have been possible without the following individuals, who so generously offered their time and expertise to support this project.

Burt Adelman, M.D., *Executive Vice President of Development, Biogen Idec, Inc.*

Michael Azrin, M.D., *Director, Cardiac Catheterization Laboratory, University of Connecticut Health Center*

Michael Dalby, Ph.D., *Managing Director, Dalby & Dalby, LLC*

Jennifer Foley, *Vice President, Cardiovascular Clinical Sciences, Boston Scientific Corporation*

Beverly Lorell, M.D., *Vice President, Chief Medical and Technology Officer, Guidant Corporation*

Milton Weinstein, Ph.D., *Professor of Health Policy and Management and Biostatistics, Harvard School of Public Health*







NEHI would also like to thank *Innovus Research* for its contributions to this project.

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## Preface

This report is the second in a series, the *Innovation Series*, published by the New England Healthcare Institute (NEHI). The goal of the *Innovation Series* is to identify opportunities to accelerate the adoption of highly valuable innovations that will benefit patients and help contain overall health care costs. Focusing on emerging innovations for the treatment of major diseases such as cancer, cardiovascular disease and diabetes, these reports analyze specific classes of innovation to identify their value, drivers, and barriers to adoption as they move from initial concept into accepted clinical practice. NEHI draws upon its industry-wide membership to guide the development of actions that will drive change and facilitate the adoption of beneficial innovations.

### **Previous NEHI Innovation Series Reports:**

Targeting Cancer: Innovation in the Treatment of Chronic Myelogenous Leukemia (March 2004)







## Executive Summary

### OVERVIEW

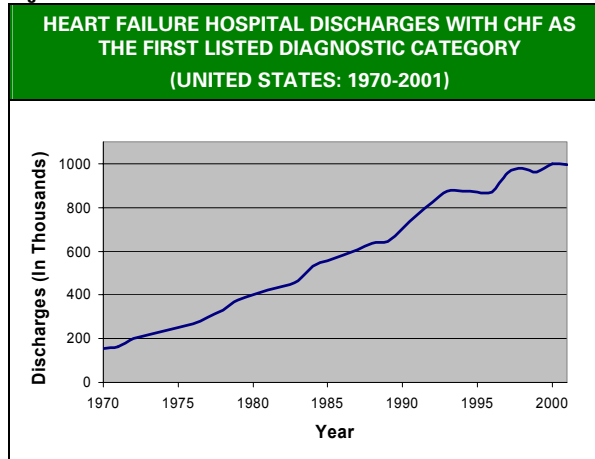
Heart disease may well be known as the leading cause of death in the United States. But perhaps less well known is the fact that heart failure itself is a primary reason for those fatalities (approximately 20 percent of heart failure patients die within one year of diagnosis and 50 percent die within five years).<sup>1</sup> In fact, there are a range of factors that make heart failure one of the most costly, debilitating and deadly chronic diseases.

*The prevalence of heart failure has grown by 500 percent over the past 30 years.*

#### High and Growing Prevalence in the U.S.

There are five million Americans currently living with heart failure in this country. The number of patients is growing, with approximately 550,000 new cases reported each year. The prevalence of heart failure has grown by 500 percent over the past 30 years.<sup>2</sup> As the massive baby boom generation continues to age, and as patients with heart disease are living longer, it seems clear that the cost and burden to society could become catastrophic over the next decade (Figure 1-1).

Figure 1-1



Sources: Centers for Disease Control and Prevention/National Center for Health Statistics; American Heart Association

#### High Cost to the Health Care System

Heart failure's annual direct costs to the U.S. health care system are approximately \$26.7 billion, with hospital costs representing over 50 percent of total heart failure direct costs, or \$13.6 billion, annually.<sup>3</sup> The average hospital stay for a heart failure patient costs \$6,000 to \$12,000.<sup>4</sup> At least 20 percent of these hospitalizations – representing \$2.72 billion in total costs – are considered to be preventable through adherence to medication and lifestyle changes.<sup>5</sup>

#### Difficult to Manage

However, heart failure is an exceedingly difficult disease to manage. Doing so requires patients to keep track of a large number of factors, from medication and diet, to weight, blood pressure and a variety of symptoms that are often difficult to gauge and monitor on a daily basis without help. Most heart failure patients are over 65 years old, 50 percent have three or more other medical conditions and



many are living alone, factors which only exacerbate the difficulty of managing the disease. The combination of all these elements results in frequent hospitalizations and impaired quality of life for most heart failure patients. In fact, 44 percent of patients are readmitted to the hospital within six-months of discharge and 17 percent of patients will be readmitted two or more times in that same time period.<sup>6</sup>

### HEART FAILURE DISEASE MANAGEMENT

Researchers have demonstrated that intensive, nurse-driven disease management programs can improve the health outcomes and decrease the costs of caring for heart failure patients, compared to standard care.<sup>7,8</sup> Although data about the value of structured disease management programs for heart failure patients have been available for nearly a decade, only approximately 10 percent of patients in this country are enrolled in these programs, leaving the majority with no intensive care management at all. This has created a critical problem for our society, given the financial and human costs associated with the disease.

### REMOTE PHYSIOLOGICAL MONITORING: A DEVICE, TECHNOLOGY AND CARE DELIVERY SERVICE ALL IN ONE

Remote physiological monitoring (RPM) consists of an electronic device in the patient's home that collects data on the patient's condition, technology that enables transmission and analysis of those data, and most importantly a care delivery service that uses those data to communicate with and monitor the patient. It is the coordination of these three elements – the device, technology and care delivery service – that is essential to this innovative tool for disease management. Patients typically use electronic home monitoring devices once a day to collect basic physiological data and to answer specific questions about their condition. The patients' data are electronically transmitted to a central monitoring station where the data are analyzed by nurses and care managers. These care managers can track early warning signs and symptoms and contact patients, providing feedback, education and medication changes long before they need to be hospitalized.

#### Reduced Hospitalizations and Costs

NEHI's analysis found that using RPM for heart failure reduces rehospitalization rates by 32 percent, compared to standard outpatient care for the six-months following a heart failure hospitalization. Applying this reduction to a population of 100 Class III, or advanced heart failure, patients results in an average of 24 fewer hospitalizations, each of which costs, on average \$9,700 and involves 5.5 days in the hospital. That results in a total reduction of 132 patient days per 100 patients. In addition, RPM can produce net cost savings of 25 percent when compared to standard care. On a per patient basis, this cost reduction amounts to net savings of \$1,861 per patient, or in our 100-patient group, a total of \$186,165. RPM use also has demonstrated a statistically significant improvement in heart failure patients' quality of life as measured in Quality Adjusted Life Years (QALYs), as well as high levels of patient satisfaction (Figure 1-2).



Figure 1-2

HEART FAILURE CARE COMPARISON – RPM VS. STANDARD CARE TREATMENT OF 100 PATIENTS FOR SIX-MONTHS FOLLOWING HOSPITAL DISCHARGE				
Study Measure	Standard Care	RPM	Difference	Percent Difference
Rehospitalizations per 100 Patients	75.3 (414 Days)	51.4 (247 Days)	-24.0 (132 Days)	-32%
Health Care Costs per 100 Patients	\$759,249	\$573,084	-\$186,165	-25%
QALYs per 100 Patients	282.0	288.5	+6.4	+2%

Source: NEHI

### Potential Impact Is Large

Based on NEHI's analysis of RPM's net cost savings per six-month period post-discharge, achieving a 25 percent adoption rate by Class III patients who are only receiving standard care today could generate net cost savings of \$500 million nationwide. In the New England region alone (NEHI's geographic focus), net savings at the 25 percent adoption rate could be as high as \$25 million.

### SIGNIFICANT BARRIERS TO ADOPTION REMAIN

Despite the potential for RPM to improve heart failure care as compared to standard treatment, its adoption by the health care system has been extremely slow. The most significant barriers to adoption of RPM are payment shortfalls, clinician concerns and low patient awareness of the technology.

#### Lack of Medicare Payment to Date

With over 70 percent of heart failure patients enrolled in Medicare, insurance coverage is vital to the adoption of any new treatment for the disease.<sup>9</sup> However, Medicare does not cover the purchase of RPM devices, nor does it reimburse care managers, nurses, and physicians for their time spent monitoring and responding to remotely monitored data.

#### Clinician Concerns

Payment problems and a scarcity of outcomes from large, randomized, controlled trials have fueled skepticism among some clinicians, discouraging them from implementing the technology. This skepticism tends to trump the common-sense view that RPM for heart failure has little clinical downside compared to its significant cost savings and quality of care advantages over the standard care that the majority of patients receive today. Moreover, the prospect of physicians and nurses having to change practice patterns to accommodate RPM, and the perceived loss of control over patient management through RPM have also been barriers to the adoption of this innovation.



### Low Patient Awareness

A third major barrier to the adoption of RPM is its low public profile. The public has relatively little awareness both about heart failure as a serious, costly disease and the opportunity for disease management tools like RPM to mitigate the impact of the disease. Lack of awareness about RPM's utility for heart failure patients extends across the board, from patients and their families and friends, to clinicians, health care leaders, policy makers and government officials, who might otherwise be instrumental in extending its use.

### THE NEXT STEPS

These three major barriers to widespread adoption of remote physiological monitoring as a disease management tool for heart failure patients are highly interdependent. That is, a turning point in one could have a domino effect on the others. For example, should Medicare opt to embrace RPM for heart failure patients, it is easy to imagine private payers following suit. Similarly, when significant outcomes data are available from classically modeled, large, randomized controlled trials that demonstrate RPM's incremental value versus intensive disease management, clinicians and payers can be expected to take a fresh look at this innovation.

The barriers notwithstanding, RPM has the potential to benefit large numbers of advanced heart failure patients who are currently receiving only standard care. The technology is available now and has been demonstrated to reduce hospitalizations, decrease health care costs, and improve quality of life as compared to standard care. Given that RPM has been shown to meet the urgent need for better management of the majority of heart failure patients who are not currently enrolled in intensive disease management programs, we recommend moving forward with an initial policy action plan for those patients at a minimum, while additional studies are in process.

Accordingly, it is important that we prepare now to confront financing/payment issues and clinicians' concerns, while raising patient awareness about access to this innovation. Specifically, we recommend the following course of action:

- Prepare to move quickly on emerging clinical trial data.
- Work with public and private payers to begin addressing issues in the coverage of and payment for RPM technology and disease management programs in general.
- Collaborate with other organizations to better understand and address physicians' and nurses' practical concerns about RPM.
- Raise patient awareness of RPM's benefits over standard care through targeted educational campaigns.



## CONCLUSION

Determining the value of health care technologies requires evidence of their impact on quality and cost of care, a thorough analysis of the factors influencing their adoption and implementation in practice, and an examination of their benefits relative to other forms of care. Our findings indicate that RPM for heart failure is clearly a valuable technology for patients who are not in an intensive disease management program. In those cases, it produces cost savings, improved outcomes, and increased quality of life relative to standard care.

With the majority of heart failure patients receiving standard care today, RPM represents a significant innovation in the treatment of heart failure. However, to fully assess the value of RPM, further evidence of its incremental value relative to other forms of disease management needs to be better understood. NEHI will support the rapid utilization of the earliest findings of these studies and will work aggressively to implement policies that are derived from their outcomes. In the interval, we will continue to advocate for policies and programs that prepare patients, providers, and payers for greater adoption of RPM technologies.





## Introduction: A Patient's Story

*It's only September and Bob Smith is scared to death. This is the third time since his sixtieth birthday that he's been admitted to the hospital and the second time since his heart attack. He is trying to speak, but his breathing is labored, and the oxygen flow makes his mouth quite dry. "I'm never getting out of here, am I?" he barely manages to whisper to the night nurse who is giving him his medication.*

*"Did you say something?" the nurse replies, bending her head close to his face.*

Mr. Smith's predicament is all too familiar to millions of heart failure patients. He is not only scared of dying, but in a state of utter bewilderment. He keeps going over and over it in his mind – the heart attack, his two years of recovery. He had tried so hard to do everything right. He keeps wondering how things could have gone so wrong so fast.

***Mr. Smith's predicament is all too familiar to millions of heart failure patients.***

The downward spiral in Mr. Smith's condition has been rapid. Just six-months ago and two years after his heart attack Mr. Smith – an overweight non-smoker with a family history of high cholesterol and heart problems – had recovered to the point of being able to do vigorous physical exercise.

### MR. SMITH BEGINS TO SLIP

But not long after that he started experiencing shortness of breath when he was on the treadmill. Within a few weeks, exercise having fallen by the wayside, he found himself breathing hard just going through his daily activities. An echocardiogram during a visit to his cardiologist's office showed that his left ventricle was pumping out only 35 percent of the blood from its chamber – an ejection fraction far below the .55 to .75 considered normal.<sup>10</sup> Mr. Smith was shocked when his cardiologist explained that he was experiencing heart failure.

Mr. Smith's cardiologist reviewed with him again how the attack had damaged his heart and carefully described what heart failure is all about. She prescribed a number of pharmaceuticals shown to be useful in managing heart failure, including diuretics, beta-blockers, ACE inhibitors and digitalis. She also instructed him to limit his salt intake to fewer than 2,400 mg of salt each day and put him on a low-fat diet that also restricted his caloric intake.<sup>11</sup> Finally, the cardiologist pulled no punches in warning him that if he didn't adhere to his medication, exercise program, and diet restrictions, his condition would likely worsen—with dire consequences.

Shaken, Mr. Smith took her instructions seriously. He did everything by the book – for a number of weeks. And each day he felt better. Then, one night, feeling hungry, he went to the kitchen where he downed a ham sandwich and some potato chips. "Just this once," he thought, "I've been so good." The next night he was back in the kitchen where he made himself another sandwich with chips.



### ADMISSION TO THE HOSPITAL

Within just a few days, Mr. Smith's weight had shot up six pounds. And in addition to his shortness of breath having returned with a vengeance, his lungs were filling up with fluid. How could that happen so quickly? It doesn't take all that much for a man in his condition. In addition to a few nightly raids on his refrigerator, Mr. Smith had skipped his exercise those same days and forgotten to take his diuretic pills. Now, alone and frightened, he literally felt like he was drowning. He called his cardiologist and was admitted to the hospital.

Upon discharge, Mr. Smith's condition continued to stabilize with the help of nurses who called to check on him during his first weeks out of the hospital. In addition, follow-up visits to his physician two weeks after discharge, and then two months out, were providing Mr. Smith with a thorough education on his condition. With these frequent contacts, he also developed strategies to remind himself to take his medications, remove all high-sodium foods from his home, and record his weight regularly in order to monitor changes.

### SELF-MANAGEMENT FAILS AGAIN

A month later, Mr. Smith once again ran into problems managing his own condition. With twelve pills to take each morning and four to five pills every night (many with side effects) not to mention the continuing food restrictions and exercise requirements, his regimen was once more getting the best of him.

For one thing, he didn't always take his diuretics – not because he forgot, but because they caused him to wake up in the middle of the night to go to the bathroom, which, in turn, made him feel too tired to exercise the next day.

*Mr. Smith once again ran into problems managing his own condition...his regimen was getting the best of him.*

Following his physician's instructions, Mr. Smith tried to monitor his weight and any new symptoms – such as persistent coughing, dizziness, or increasing shortness of breath. But he found it very difficult to gauge from day to day whether he was coughing more often. And he was never quite sure if his shortness of breath was any different during a given day, much less from one day to the next.

The same with his weight. Even when he weighed himself regularly, his weight fluctuated, and it was hard to determine whether there was cause for concern. In fact, living alone, without anyone to encourage him to adhere to his doctors' orders, Mr. Smith found it especially difficult to manage all of this on his own.

Not surprisingly, Bob Smith's condition worsened, but only subtly at first. So he failed to call his physician until he felt dramatically worse. A month before his next appointment, feeling significant congestion in his chest, experiencing shortness of breath at rest, and having noticed substantial swelling in his lower legs and feet, Mr. Smith called his physician to ask for advice. Fearing correctly that Bob Smith's condition was deteriorating, his cardiologist promptly readmitted him





into the hospital, which is where we find him tonight. When he is released tomorrow, he will have been there a full five days.

#### **THE REMOTE PHYSIOLOGICAL MONITORING ALTERNATIVE**

Try to imagine the same scenario unfolding for millions of heart failure patients across the country, and one begins to have a sense of the magnitude of how costly and difficult it is to manage this disease.

Now, try to imagine a technology that would overcome most of the problems that led to Bob Smith's readmission to the hospital – an event that costs on the order of \$6,000 to \$12,000, not to mention the discomfort of being in the hospital for five days at a stretch. Try to picture a remote monitoring system that is so easy to use that Mr. Smith can weigh himself, take his own blood pressure, and not only check his compliance with his prescribed regimen, but get feedback and warnings if anything goes wrong. Imagine that he can do all of that using a special scale, pressure cuff, and screen that is part of a simple-to-use question and answer device that can sit on a countertop or table anywhere in his house where there's a telephone jack.

Imagine further that this system streams daily data on Mr. Smith's condition to a monitoring station where trained nurses are automatically alerted when something's amiss. When that happens, according to the cardiologist's protocols, they either call Mr. Smith with specific instructions, or call his doctor, who determines what to do next.

It would probably come as a surprise to most heart failure patients and their loved ones, not to mention clinicians, payers, and government officials that this system is already on the market and – in small numbers – in use and producing dramatic results. In fact, remote physiological monitoring (RPM) for heart failure patients is ready for wider use today, needing only greater awareness of its potential, better documented and designed studies, and a properly readied market.

*Accordingly, this report documents RPM's potential for improving the care of advanced heart failure patients, along with the barriers to its broader use. It concludes by presenting recommendations, driven by upcoming data, on addressing these barriers to adoption.*





## Remote Physiological Monitoring for Heart Failure: A Valuable Innovation

To understand the potential value that broader adoption of remote physiological monitoring (RPM) for heart failure can offer, it is important to consider

- The growing burden that heart failure is placing upon society.
- The many ways in which RPM can mitigate this burden.
- How RPM delivers demonstrable value compared to today's standard care.
- The growing foundation for wider adoption.

The remainder of this section explores each of these topics in detail.

### HEART FAILURE: A HEAVY BURDEN TO SOCIETY

It may well be known that heart disease is the leading cause of death in the United States. But perhaps less well known is the fact that heart failure is a primary reason for those fatalities. In fact, there are a range of factors that make heart failure a costly, debilitating, and deadly, chronic disease.<sup>12</sup>

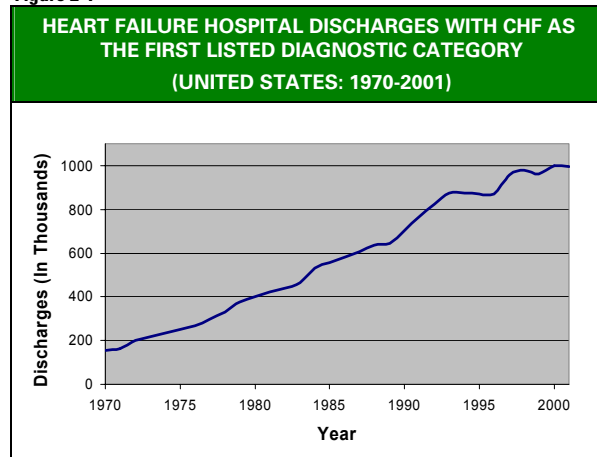
*There are five million Americans currently living with heart failure, 53,000 of them dying each year.*

First, prevalence is high and rising at alarming rates (Figure 2-1). Second, there is the cost to the U.S. health care system, which can be measured in billions of dollars, as well as many hundreds of thousands of hospitalizations and deaths each year. Moreover, the complexity of managing heart failure effectively hinders our ability to care for heart failure patients. All told, heart failure is placing a heavy burden on our health care system and on our society.

#### A High and Growing Prevalence in the U.S.

Heart failure is already a pervasive disease in the United States. There are five million Americans currently living with heart failure, 53,000 of them dying each year. Every year, an estimated 550,000 new cases are

Figure 2-1



Sources: Centers for Disease Control and Prevention/National Center for Health Statistics; American Heart Association



diagnosed in the United States, representing 10 percent of the entire heart failure population.<sup>13</sup>

The prevalence of heart failure has grown rapidly, with heart failure hospital discharges increasing by 500 percent over the past 30 years.<sup>14</sup>

As lives have lengthened due to successful treatment of and declining mortality from other forms of cardiovascular disease, the chances for cardiac patients to develop heart failure have increased proportionately.

Heart failure's prevalence in society will only continue to grow (Figure 2-2). The annual incidence of heart failure is projected to

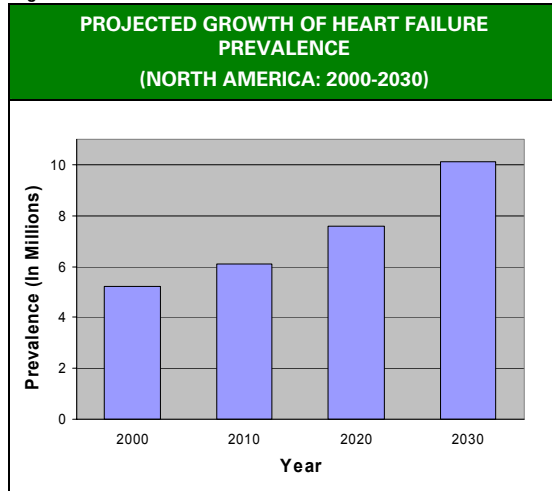
double in the next 40 years, due to our aging population.<sup>15</sup> Approximately 75 percent of heart failure patients are over the age of 65.<sup>16</sup> And the number of Americans over that age is expected to increase to 55 million by 2020.<sup>17</sup>

**Costs Our Health Care System Billions of Dollars Annually**

Besides being deadly, heart failure is extremely expensive. Heart failure patients like Bob Smith require numerous prescription medications, frequent high-cost hospitalizations, ER visits, and costly life-saving devices and surgeries in the latter stages of the disease. Heart failure's annual direct costs to the U.S. health care system are approximately \$26.7 billion.<sup>18</sup>

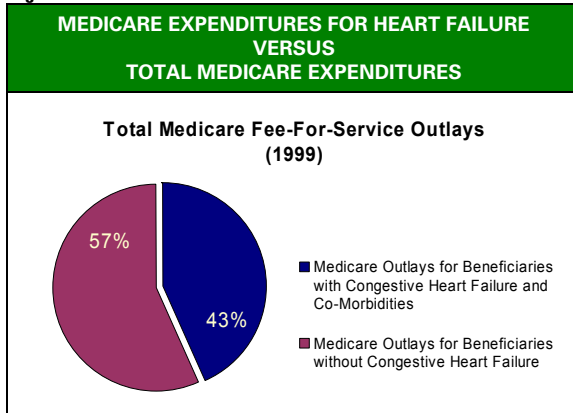
Heart failure is also responsible for a dramatically disproportionate share of Medicare costs. Although heart failure patients represent 14 percent of Medicare beneficiaries, the disease, including co-morbidities, accounts for 43 percent of Medicare program expenditures (Figure 2-3).<sup>19</sup>

Figure 2-2



Source: American Heart Association

Figure 2-3



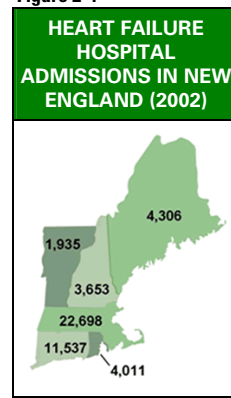
Sources: Health Affairs; 1999 Medicare Current Beneficiary Survey Cost and Use Files



Similarly, heart failure hospitalizations alone are responsible for over 50 percent of total heart failure direct costs, with annual expenditures of \$13.6 billion.<sup>20</sup> This is because heart failure hospitalizations are particularly costly and protracted, with an average duration of 5-6 days<sup>21</sup> and costs ranging from \$6,000 to \$12,000 per hospitalization.<sup>22</sup> Given the benefits of RPM described in detail below, it is important to note that at least 20 percent of these hospitalizations – representing \$2.72 billion in total costs – are considered to be preventable through adherence to medication and lifestyle changes.<sup>23</sup>

Heart failure is also the first-listed diagnosis for 995,000 hospitalizations annually and the leading cause of hospitalizations for patients age 65 years and older.<sup>24</sup> It ranks as one of the major diseases responsible for hospital admissions in the United States. About five percent of all heart failure hospitalizations occurred in New England (NEHI’s geographic focus) in 2002, which is consistent with the five percent of the U.S. population residing in the region (Figure 2-4).<sup>25</sup>

Figure 2-4



Sources: Health Technology Center; Solucent

### Debilitating and Deadly

As Bob Smith’s story demonstrates, heart failure is a highly debilitating disease that incapacitates patients with a range of symptoms, including fatigue, shortness of breath and difficulty breathing, swelling of the ankles and lower legs, loss of appetite, abdominal discomfort, and weight gain from fluid retention.<sup>26</sup> As the disease progresses, patients experience these symptoms during almost any form of physical activity. The functional symptoms associated with the advancement of heart failure have been classified by the New York Heart Association (NYHA) (Figure 2-5).

Figure 2-5

NEW YORK HEART ASSOCIATION (NYHA) CLASSIFICATION OF HEART FAILURE				
NHYA Class	Population Frequency	Symptoms	Primary Source of Cardiac Care	Mortality Rates
Class I	40%	Patients with no limitation of activities; they suffer no symptoms from ordinary activities	<ul style="list-style-type: none"> <li>• 100% Primary Care Physician</li> </ul>	<10% per year
Class II	30%	Patients with slight, mild limitation of activity; they are comfortable with rest or with mild exertion	<ul style="list-style-type: none"> <li>• 60% Primary Care Physician</li> <li>• 35% Shared</li> <li>• 5% Cardiologists</li> </ul>	10% per year
Class III	20%	Patients with marked limitation of activity; they are comfortable only at rest	<ul style="list-style-type: none"> <li>• 10% Primary Care Physician</li> <li>• 60% Shared</li> <li>• 30% Cardiologists</li> </ul>	20-30% per year
Class IV	10%	Patients who should be at complete rest, confined to bed or chair; any physical activity brings on discomfort and symptoms occur at rest	<ul style="list-style-type: none"> <li>• 15% Primary Care Physician</li> <li>• 70% Shared</li> <li>• 15% Cardiologists</li> </ul>	50-60% per year

Sources: New York Heart Association; Huffington Center on Aging; Guidant Corporation; Expert Interviews



In addition, the American Heart Association and the American College of Cardiology recently developed stages of heart failure that emphasize its evolution, progression, and potential for treatment at each stage (Figure 2-6).<sup>27</sup>

**Figure 2-6**

AMERICAN HEART ASSOCIATION AND AMERICAN COLLEGE OF CARDIOLOGY RECOMMENDED THERAPY FOR HEART FAILURE		
AHA/ACC Stage	Description of Stage	Recommended Treatment
Stage A	<ul style="list-style-type: none"> <li>• High risk for congestive heart failure (CHF)</li> <li>• Without structural heart disease</li> <li>• Without CHF symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• Treat high blood pressure</li> <li>• Quit smoking</li> <li>• Treat lipid disorders</li> <li>• Refrain from alcohol and illegal drug use</li> <li>• Regularly exercise</li> <li>• ACE inhibition in appropriate patients</li> </ul>
Stage B	<ul style="list-style-type: none"> <li>• Structural heart disease</li> <li>• Without CHF symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• All of the measures listed for stage A</li> <li>• Beta-blockers in appropriate patients</li> </ul>
Stage C	<ul style="list-style-type: none"> <li>• Structural heart disease</li> <li>• With prior or current CHF symptoms</li> </ul>	<ul style="list-style-type: none"> <li>• All of the measures listed for stage A</li> <li>• Drugs for routine use:                             <ul style="list-style-type: none"> <li>○ Diuretics</li> <li>○ ACE Inhibitors</li> <li>○ Beta-blockers</li> <li>○ Digoxin</li> </ul> </li> <li>• Restriction of dietary salt intake</li> </ul>
Stage D	<ul style="list-style-type: none"> <li>• End-stage of disease</li> <li>• Marked symptoms of CHF at rest</li> <li>• Requires specialized intervention</li> </ul>	<ul style="list-style-type: none"> <li>• All of the measures listed for stage A</li> <li>• Mechanical assist devices</li> <li>• Heart transplant</li> <li>• Continuous IV inotropic infusions for palliation</li> <li>• Hospice care</li> </ul>

Source: American Heart Association/American College of Cardiology

Heart failure is also a progressive condition. In approximately 50 percent of patients, the heart muscle gradually weakens and loses its pumping power. In the other 50 percent, the heart muscle stiffens while pumping power remains nearly normal. Approximately 20 percent of heart failure patients die within one year of diagnosis and 50 percent die within five years.<sup>28</sup> About half of these patients die from sudden cardiac death, and the rest from mechanical heart failure and organ failure.<sup>29</sup> As the incidence of heart failure has grown, the number of heart failure deaths increased 155 percent from 1979 to 2001.<sup>30</sup> (See Appendix 1 for additional information about heart failure.)

### Difficult to Manage

Some of the reasons that the increases in these dire statistics seem so unstoppable have to do with the challenging nature of heart failure management and how few innovations have been developed to help patients control this chronic disease.

### *Self Management Is Challenging*

Remember how Bob Smith’s best efforts at managing his own condition fell apart? This is a major reason that heart failure has such a devastating impact. Just like it is for Mr. Smith, it is very difficult for most patients to manage their own condition, even though doing so could yield significant improvements. This fact greatly exacerbates the costs, morbidity and mortality associated with the disease.



Although some patients are better able to live with chronic heart failure through dietary modification (e.g., avoidance of salt) and drug therapy, in general, standard outpatient management is frequently interrupted or undermined. These debilitating periods (known as “decompensation”, or more rapid deterioration involving fluid retention, weight gain and changes in blood pressure) often lead to hospitalization.

According to American College of Cardiology and American Heart Association Guidelines, an effective, evidence-based regimen of heart failure management involves a combination of diet, medication and exercise.<sup>31</sup> Typically, heart failure patients are instructed to lower their sodium intake, take an average of six prescription medications daily, and exercise regularly if they are capable.<sup>32</sup> As long as their condition is stable and they have not been recently hospitalized, they normally visit their physicians every three to six-months.<sup>33</sup>

*Most heart failure patients’ difficulties in self-managing their conditions result in frequent hospitalizations, along with recurring symptoms and impaired quality of life.*

However, a variety of factors impair patients’ ability to self-manage their condition. For example, most heart failure patients are elderly and relatively inactive, 50 percent have three or more other medical problems, and many – as is the case for Mr. Smith – are living alone.<sup>34</sup> This combination of factors makes it difficult for the majority of

heart failure patients to monitor their diets, remember to take multiple medications and exercise regularly.

All this is further complicated by the fact that weight and vital signs vary among patients, even by time of day for a given patient. As a result, patients commonly under- or overdose themselves with medications to which they are highly sensitive. Moreover, due to factors such as affordability, side-effects, cultural issue, and depression, patients may simply fail to adhere to recommended treatments. Studies have found, for example, that only 10 percent of heart failure patients complete their annual drug regimens, notwithstanding the severity and risk of their conditions.<sup>35</sup>

As is the case for Bob Smith, most heart failure patients’ difficulties in self-managing their conditions result in frequent hospitalizations, along with recurring symptoms and impaired quality of life. In fact, just like Bob Smith, 44 percent of hospitalized heart failure patients are readmitted to hospitals within six-months. And one in six patients will be rehospitalized two or more times during this time frame.<sup>36</sup> Studies have found that many of these rehospitalizations are preventable; at least 1 in 5 heart failure hospitalizations are considered unnecessary and result from lack of adherence to national guidelines.<sup>37</sup>

#### **Low Penetration of Disease Management to Date**

Heart failure is, by its nature, a prime candidate for more focused and direct intervention by clinical professionals operating in payer-supported disease



management programs. These programs have become increasingly beneficial to patients as heart failure treatment itself has become more effective.

Although they can take many forms, disease management programs often refer to “multidisciplinary efforts to improve the quality and cost-effectiveness of care for select patients with chronic illness.”<sup>38</sup> They may include home health care visits, nurse phone calls, educational materials, dietary counseling, social services, as well as exercise and stress management. By design, disease management interventions often incorporate several approaches to addressing the various factors that exacerbate heart failure.<sup>39</sup>

To date, however, disease management programs for managing heart failure patients have been implemented very selectively. For at least 10 years, disease management has been shown to be more effective than standard care, but its adoption is still extremely low.<sup>40</sup> Despite a variety of approaches, it is our estimate that fewer than 10 percent of heart failure patients are currently enrolled in these programs, leaving the majority to face the self-management challenges experienced by Bob Smith.<sup>41</sup>

#### **Prognosis: Innovative Approach Needed**

It’s clear that heart failure patients need help to live with this chronic condition. In particular, in order to reduce costly, unnecessary hospitalizations, heart failure patients require assistance with managing their condition in the home. Furthermore, any innovative solutions that prove valuable must also be scalable to a wide patient population. Hence, to have an impact, new approaches will need to be relatively simple to implement, cost-effective, and lend themselves to distribution among heart failure patients across the country.

#### **RPM IS A VALUABLE TOOL FOR MANAGING HEART FAILURE**

Over the past three to five years, RPM has emerged as an important innovation for improving heart failure care in the patient’s home. The technology is simple, available today, and has the potential to significantly improve patients’ quality of life, while reducing both hospitalizations and costs, especially for patients who do not have access to intensive disease management programs.

#### **RPM: A Device, Technology, and Care Delivery Service All in One**

RPM is a disease management tool that improves the care of heart failure patients in their homes. While there are many other forms of disease management, RPM is a novel technology that can be used both as an educational tool to help patients self-manage their condition and to identify early warning signs and symptoms, enabling care providers to intervene before a patient might need to be hospitalized. In addition, it allows more frequent and timely patient contact with health care providers.

RPM consists of an electronic device in the patient’s home that collects data on the patient’s condition, technology that enables transmission and analysis of that data, and most importantly, a care delivery service that uses that data to communicate with and monitor the patient. The coordination of these three factors – the device,



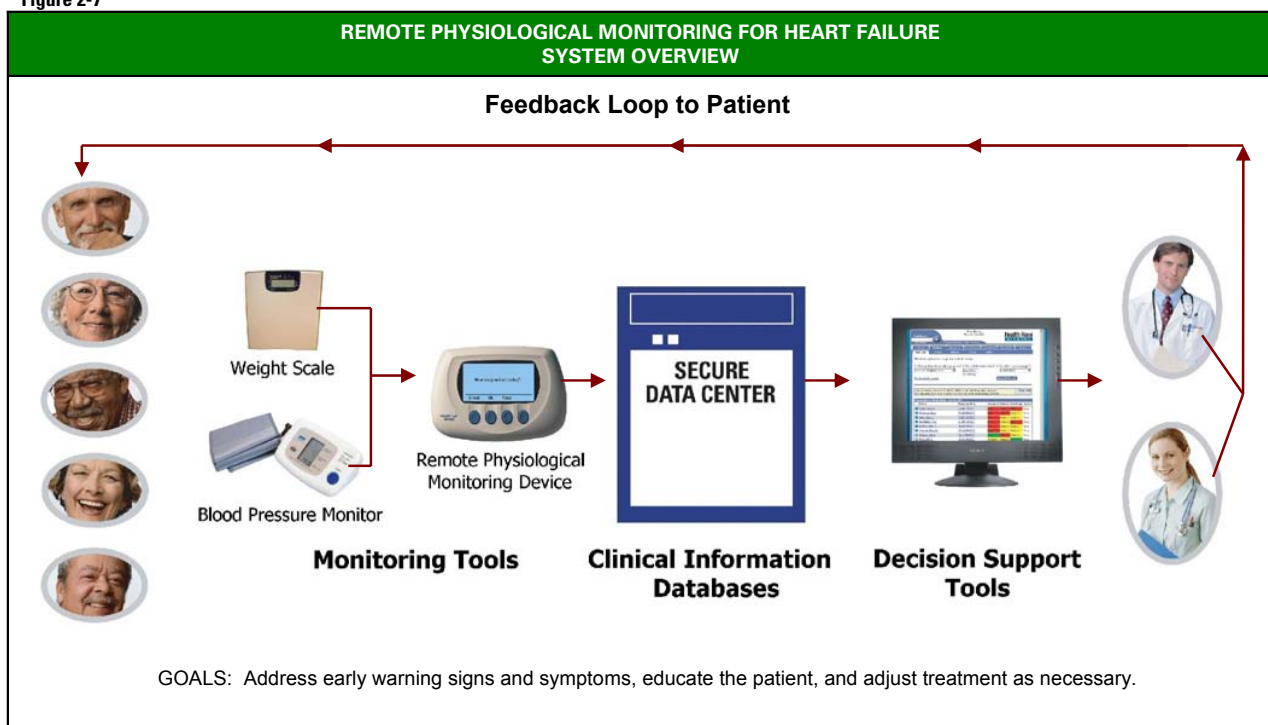


technology, and care delivery service – is essential to this innovative tool for disease management.

#### *How RPM Works*

With RPM, patients typically use electronic home monitoring devices once a day to collect basic physiological data – most commonly weight, and sometimes blood pressure, heart rate, and blood oxygen levels. The patients' data are automatically transmitted to a database at a central monitoring station via a home phone line (Figures 2-7 and 2-8).

Figure 2-7

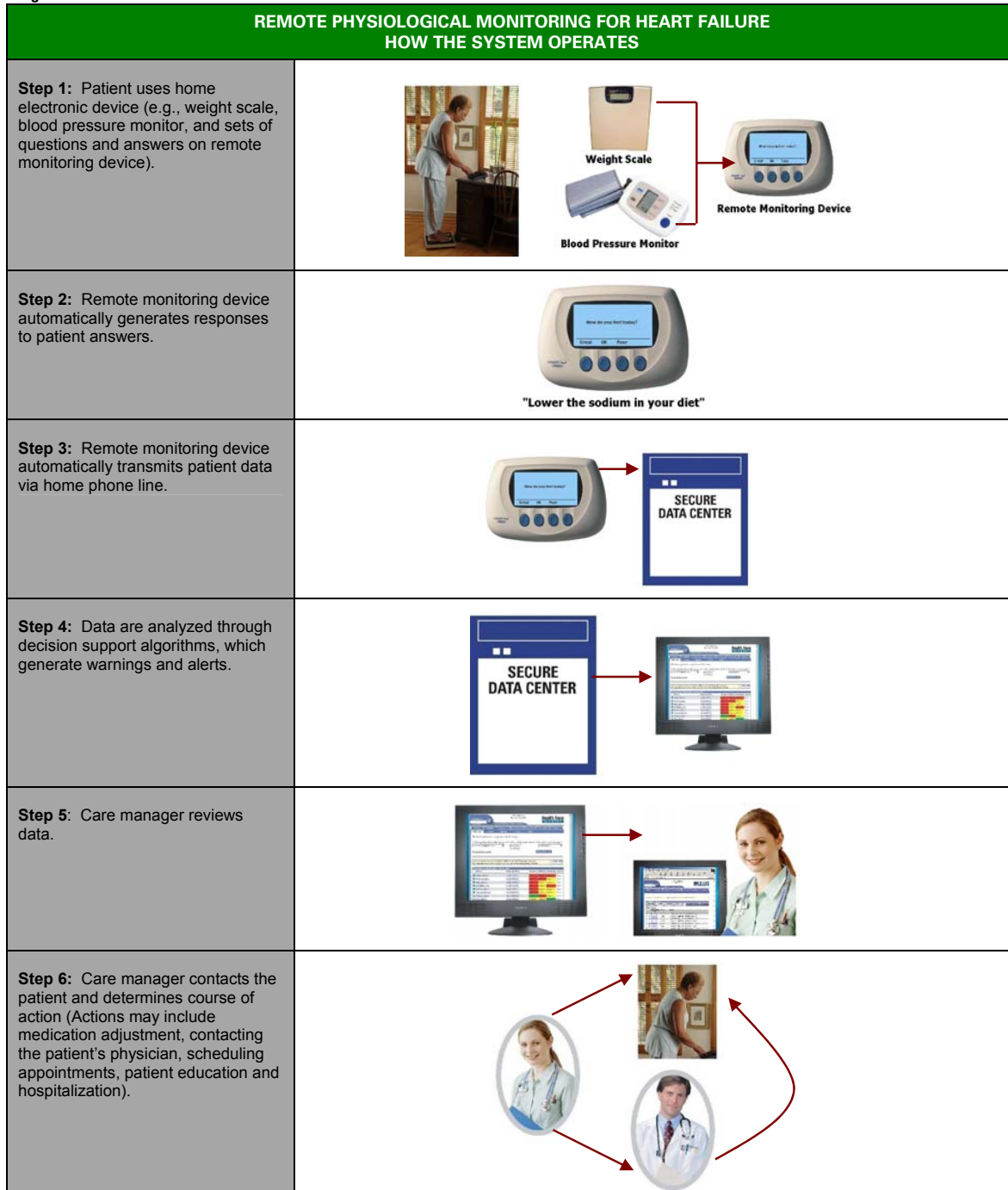


Source: Health Hero Network, Inc.

In addition to collecting physiological data, some devices ask patients specific questions about their daily condition. Patients can enter their yes/no or multiple choice answers and receive immediate and automatic on-screen feedback and advice. For example, an RPM device might ask patients whether they have been experiencing shortness of breath, and patients might reply yes or no. Depending on the answer, the device asks follow-up questions. It then automatically provides education on adhering to medications, modifying behavior, and improving self-management.



Figure 2-8



Sources: Health Hero Network, Inc.; Expert Interviews



Devices available to date vary in size, but most are smaller than a child's lunch box. Unlike a computer keyboard, they only have a few buttons to operate, and therefore are about as easy to operate as a radio or telephone.<sup>42</sup>

#### *Feedback Loop to Patients*

At the central station – typically a call center at a disease management company, heart failure clinic, or home health agency – a software application analyzes all patients' data, identifies trends in the data and generates on-screen warnings and alerts when a patient's condition is abnormal. A cardiac nurse or care manager monitors patient data and responds to warnings and alerts by contacting the patient and, if necessary, his/her physician.

To respond to an alert, for example, the care manager calls the patient to collect direct information about the patient's condition and educates the patient as needed. The care manager then forwards the patient's data to his/her physician. Depending on the situation and the protocols established by the physician, the care manager either intervenes in the patient's care directly, or if it's an emergency and/or the situation calls for a major change in strategy, determines how to respond in consultation with a physician. The care manager and/or physician may elect to adjust that patient's medications, schedule an office visit, recommend that the patient be hospitalized or simply educate the patient about medications and diet. After this determination has been made, the care manager or physician contacts the patient with instructions.

Our research indicates that had Bob Smith been connected to a system of this type, he may have avoided his rehospitalization, not to mention the fear, discomfort and deterioration that brought him to his episode.

#### *Purchasers and Users of RPM*

In today's environment, purchasers and users of RPM typically include health plans, that purchase/lease the devices and monitor patients themselves, or that have contracted with third-party disease management companies to provide both the device and the monitoring services; third-party disease management companies, that purchase/lease the devices and monitor patients through contracts with health plans and other payers; and finally home health agencies and heart failure clinics, that purchase/lease the devices and use their own nurses to monitor patients.

Health plans and other purchasers of RPM typically use RPM as a disease management tool to control costs and improve quality of care for a select portion of their heart failure population whose records indicate they are the most costly and difficult to manage. Cost savings derive from reduced hospitalizations, shorter lengths of stay and staffing efficiencies.

#### **Target Population: Class III, Post-Discharge Patients**

RPM is currently employed for a particularly high-risk segment of the heart failure population. These patients – like Bob Smith – are at an advanced stage of heart failure and are typically classified as NYHA Class III, but the technology may also be valuable for some Class II and Class IV patients.



Whatever their classification, patients typically receive the devices following their initial discharge from the hospital – when they face the highest risk of rehospitalization.<sup>43</sup> To qualify, they must be well enough to use the remote monitoring devices regularly. RPM is then used as an adjunct to – rather than a complete substitute for – standard nurse and physician follow-up care.

#### **RPM DELIVERS DEMONSTRABLE VALUE COMPARED TO STANDARD CARE METHODS**

NEHI's findings indicate that RPM is a valuable innovation because it provides a wide range of benefits when compared to the standard outpatient care that most patients receive today. These benefits include reducing overall health care costs, improving quality of life, reducing nurse workloads and delivering value to multiple stakeholders in the health care system.

*NEHI's analysis found that using RPM for heart failure patients reduces rehospitalization rates by 32 percent compared to standard care.*

#### **A Comparison to Standard Care...**

NEHI's value analysis utilized the best available evidence-based data to assess the impact of RPM on heart failure outcomes. We then developed a traditional cost-effectiveness analysis and used this to compare the value of RPM relative to standard heart failure care.

Our analysis compared RPM and standard care for Class III and IV heart failure patients for the six-months following hospital discharge, when they are most vulnerable to being rehospitalized.<sup>44</sup> Standard care for heart failure patients following a hospitalization includes patient education about medication, diet and exercise and about symptoms and signs of decompensation, all given prior to hospital discharge. It also typically includes three physician visits in the first six-months after discharge and may include follow-up nurse phone calls during the first two weeks after hospitalization.<sup>45</sup>

#### **...not to Intensive Disease Management Programs**

To date, no published studies have demonstrated the benefits of RPM over other forms of intensive disease management in the U.S., so our analysis was limited to a comparison of RPM against standard care. However, given the low adoption of disease management today and the fact that the majority of heart failure patients are receiving standard care, our analysis compared RPM to the care that most heart failure patients are currently receiving. Moreover, most studies have focused only on short-term, six-month results, so our analysis considers the benefits of using RPM for six-months, but it remains unclear what the longer term benefits may be.

#### **Reduced Hospitalizations and Costs**

NEHI's analysis found that using RPM for heart failure reduces rehospitalization rates by 32 percent, compared to standard care (Figure 2-9). Applying this reduction to a population of 100 patients results in an average of 24 fewer hospitalizations, each of which costs on average \$9,700 and involves 5.5 days in



the hospital.<sup>46</sup> That makes for a total reduction of 132 patient days per 100 patients. The reduction in rehospitalizations results from recognition of early warning signs and corresponding medication and behavioral adjustments that prevent acute patient decompensation and decrease the costs associated with unnecessary hospitalizations.

RPM also results in net cost savings of 25 percent over standard outpatient care. On a per patient basis, this cost reduction amounts to net savings of \$1,861 per patient, or in our 100-patient group, a total of \$186,165 over a six-month post-discharge period. These savings can be attributed to fewer hospitalizations as well as shorter lengths of stay when using RPM. (See Appendix 2 for further detail.)

Figure 2-9

HEART FAILURE CARE COMPARISON – RPM VS. STANDARD CARE TREATMENT OF 100 PATIENTS FOR SIX-MONTHS FOLLOWING HOSPITAL DISCHARGE				
Study Measure	Standard Care	RPM	Difference	Percent Difference
Rehospitalizations per 100 Patients	75.3 (414 Days)	51.4 (247 Days)	-24.0 (132 Days)	-32%
Health Care Costs per 100 Patients	\$759,249	\$573,084	-\$186,165	-25%
QALYs per 100 Patients	282.0	288.5	+6.4	+2%

Source: NEHI

### Quality of Life

NEHI's analysis also finds that RPM results in a statistically significant, though relatively small, improvement in heart failure patients' quality of life as measured in Quality Adjusted Life Years (QALYs).<sup>47</sup> This measurable improvement most likely results from patients remaining healthier and avoiding additional hospitalizations.

But these numbers do not tell the full story because it is difficult to quantify the true magnitude of how RPM can improve the quality of life for heart failure patients. Going back to our patient Bob Smith, the impact of RPM for heart failure becomes apparent. His ability to understand his own body, more easily follow physicians' instructions, get instant feedback and warnings, feel a greater sense of security, and have a structure provided by a system are all things that would enhance daily living, improved health notwithstanding.

### Reduced Nurses' Workload/Staffing Problems

At the same time, RPM has been shown to reduce nurses' workloads and alleviate staffing difficulties resulting from nursing shortages. For example, the technology increases nurses' productivity by allowing a single nurse or care manager to effectively monitor more than 150 patients' data – something that is not practical through more traditional methods of disease management such as daily phone calls and frequent home visits.<sup>48</sup> In addition, by facilitating more frequent interaction



between caregivers and patients, home health agencies that have implemented RPM have been able to reduce the total number of nurse visits required to manage patients effectively.<sup>49</sup>

#### **Value to Multiple Stakeholders**

Multiple health care constituencies stand to benefit from RPM. As noted above, patients enjoy improved satisfaction and more frequent contact with health care providers. This benefit may be even greater for patients living in rural areas who may have difficulty accessing or visiting their cardiologist on a regular basis. Nurses and care managers are empowered by increased efficiency in providing care. At the same time, health plans and insurers save money by reducing their costs associated with heart failure, and they gain increased ability to manage the care provided to their patients. Finally, physicians can utilize this new tool to enhance patient outcomes and improve practice efficiencies.

#### **Potential Impact Is Large**

Based on our findings, increased adoption of RPM for heart failure could result in significant savings on both a national and a regional level. On a national level, a 25 percent adoption rate among eligible patients who are only receiving standard care today could achieve cost savings of \$500 million.<sup>50</sup> The New England region alone (NEHI's geographic focus) could realize cost savings of \$25 million with a 25 percent adoption rate. Our analysis suggests that expanding RPM to a wider population of eligible heart failure patients, particularly to those patients not currently enrolled in an intensive disease management program, has the potential to save the health care system millions of dollars.

### **THERE IS A BASIC FOUNDATION FOR THE GROWTH OF RPM**

RPM for heart failure has been an emerging innovation for several years. The system was developed in the mid to late 1990s by start-up companies in conjunction with advances in technology and the introduction of patient-friendly diagnostic equipment. As RPM has become more established, there are a number of forces at work that are promoting its wider adoption in the health care system. These developments provide a basic foundation for the future expansion of RPM.

#### **Successful Implementation by the VHA and Home Health Organizations**

RPM for heart failure has recently gained significant traction from its highly visible, successful implementation by the Veterans Health Administration (VHA) in the Department of Veterans' Affairs (VA). To date, the VHA's Office of Care Coordination has reached 3,150 patients with its care coordination model, which utilizes RPM for heart failure as part of its larger care coordination program. The VHA intends to expand its care coordination program to 25,000 patients by 2006. The program has demonstrated clear value, measured in terms of lower costs and increased efficiency, and has achieved patient satisfaction rates of over 95 percent.<sup>51</sup> (See Sidebar: The VHA Success Story.)



## THE VHA SUCCESS STORY

### THE CHALLENGE

The Veterans Health Administration (VHA) in the Department of Veterans Affairs (VA) provides medical care and support services to more than 6.8 million enrolled patients. Like all health care systems, the VHA faces a challenge from changing demographics. Patients are living longer and frequently prefer home to institutional care. Patients in the VHA are also older, sicker, and poorer than the general population, with 49 percent of them over the age of 65.<sup>52</sup>

### REMOTE MONITORING SOLUTION

The VHA believes it can improve quality of care and reduce overall spending by delivering the right care in the right place at the right time. To this end, the Office of Care Coordination (OCC) was established in 2003 to support these efforts. Remote monitoring technology is an important example of a care transformation tool the OCC is using for patients with chronic conditions who are at high risk of hospitalization.<sup>53</sup>

Unlike traditional care administered episodically in clinic, hospital, or homecare settings, the VHA's use of interactive technology enables it to maintain continuous, ongoing contact with patients in their homes. VHA nurse care managers use a web-based application to review monitored patients' data.<sup>54</sup>

Dr. Robert Roswell, former Under Secretary for Health at the VA, explains that this "shift from 'just in case' care to 'just in time' care is a profound and fundamental change in how we view health care."<sup>55</sup> Adam Darkins, the OCC's Chief Consultant, elaborates:

*"Just in time" means being able to intervene in the deterioration of a person with congestive heart failure at home when they are initially symptomatic and have a slight weight gain rather than receiving them in the hospital in crashing heart failure that may necessitate an intensive care unit admission.*<sup>56</sup>

### RESULTS HAVE BEEN DRAMATIC

The VHA has already implemented care coordination programs in a number of Veterans

Integrated Service Networks (VISNs) with a strong showing of positive outcomes.<sup>57</sup> Results from one such pilot program revealed that:

*Care coordination resulted in dramatic reductions in outpatient clinic visits, hospital admissions and prescription medications. Outcomes analyses showed a 40 percent reduction in emergency room visits, 63 percent reduction in hospital admissions, 60 percent reduction in bed days of care, 63 percent reduction in VHA nursing home admissions and an 88 percent reduction in nursing home bed days of care when care coordination was used.*<sup>58</sup>

The VHA has also achieved strong patient satisfaction associated with these radical changes in care. According to Dr. Adam Darkins, the VHA's care coordination programs are associated with patient satisfaction rates of 95 percent and above.<sup>59</sup> A VHA patient using remote physiological monitoring for heart failure describes the experience this way:

*"[Remote physiological monitoring] is good because it's a daily reminder of things you're supposed to do and not supposed to do... The doctors know about me at home – that I've got a problem – and immediately they can respond to it. This is going to be a massive improvement in the VA system for the patient and doctor relationship."*<sup>60</sup>

### VHA MODEL PROVIDES PLATFORM FOR GENERAL USE

Because of its success, the OCC is rapidly expanding the scope of its care coordination programs to a much larger veteran population. It projects an increase in enrollees from 3,150 patients currently to 7,500 by October 2004 and to 25,000 by May 2006.

The VHA is a unique example of an integrated delivery system that has embraced the use of information and telehealth technologies, and specifically remote physiological monitoring. As the VHA expands its care coordination programs and continues to achieve positive outcomes and high patient satisfaction, it can serve as model for the health care system at large.



Additionally, organizations involved in home health services have effectively used Medicare's Prospective Payment System (PPS) 60-day payments as a means to utilize RPM for their heart failure patients. Examples include Partners HealthCare, which is piloting RPM through its Partners Telemedicine division, and the Visiting Nurses Associations (VNAs) of Houston and Southeast Michigan.

The two regional VNAs, for example, have each completed studies revealing that RPM and patient education successfully reduced hospitalizations and ER visits, improved patient satisfaction and quality of life and decreased the number of required home nurse visits.<sup>61</sup>

#### **Medicare Chronic Care Improvement Programs**

Medicare also shows signs of moving forward on the issue of coverage for RPM. This developing situation is critical to widespread adoption of RPM, since over 70 percent of the heart failure population is enrolled in Medicare, and heart failure patients including co-morbidities account for over 43 percent of fee-for-service Medicare expenditures.<sup>62</sup> The greatest potential lies in Medicare's Chronic Care Improvement Programs (CCIPs), which were recently established in the Medicare Prescription Drug, Improvement and Modernization Act that was passed in December 2003. (See Sidebar: Medicare Chronic Care Improvement Programs Enable Remote Physiological Monitoring.)

These programs, which will enroll between 150,000 and 300,000 fee-for-service Medicare beneficiaries over the next three years, are required by law to incorporate "monitoring technologies" in managing the care of their enrollees.<sup>63</sup> It is expected that the programs will indirectly cover various forms of RPM for heart failure as well as other chronic diseases. If the CCIPs demonstrate value, they will be expanded to a wider Medicare population, and the private sector will likely follow their lead and implement new RPM programs as well.

#### **The Growth of Disease Management**

RPM is one of a variety of disease management tools that can be used to manage the care of patients with chronic diseases. Estimates suggest, however, that fewer than 10 percent of heart failure patients currently participate in intensive disease management programs.<sup>64</sup> The value of heart failure disease management programs has recently been demonstrated in a number of clinical studies which have found that increased patient contact and education can significantly reduce hospitalizations and costs as well as improve quality of life.<sup>65</sup> As heart failure disease management continues to be adopted and its evidence base grows, standard use of RPM would appear to be an important adjunct to those programs.

#### **Product Advancements and the Entrance of More Established Manufacturers**

Improvements in the design of RPM devices are also supporting wider adoption. Product advancements have made devices more convenient for patients to use, and technological enhancements have made their data more reliable.





## MEDICARE CHRONIC CARE IMPROVEMENT PROGRAMS ENABLE REMOTE PHYSIOLOGICAL MONITORING

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 legislates the implementation of a series of Chronic Care Improvement Programs (CCIPs). The goal of the CCIPs is to improve chronic care for Medicare beneficiaries and to provide evidence of the cost-effectiveness of various disease management programs for major chronic diseases, including remote monitoring for heart failure.<sup>66</sup> These CCIPs represent an important step by Medicare in recognizing the need for disease management and the value of specific management tools, such as RPM.

The CCIP legislation (Section 721) appropriates up to \$100 million for Medicare to enter into three-year agreements with approximately ten pilot programs, the first of which will begin in December 2004. These CCIPs must include geographic areas that represent, in aggregate, at least 10 percent of Medicare beneficiaries. In total, 150,000 to 300,000 Medicare beneficiaries are expected to be enrolled in these programs.<sup>67</sup>

According to the legislation, the CCIPs may be implemented through “a disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program.”<sup>68</sup> Thus, many

models are possible. But, due to the size and scope of the program, disease management companies and health plans are the most likely organizations to implement the CCIPs.<sup>69</sup>

As a specific component, each of these programs is required to include remote monitoring technology, according to the following guidelines:

*A care management plan for a targeted beneficiary...shall, to the extent appropriate, include...the use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information and health assessment.*<sup>70</sup>

RPM for heart failure patients meets these criteria.

In April 2004, the Centers for Medicare and Medicaid Services published a request for CCIP proposals in the Federal Register, and Administrator Mark McClellan expects the agency to sign its first service agreements in December.<sup>71</sup> Further, CMS is required to report regularly to Congress on the CCIPs and will evaluate the entire program in a final report to be published in 2008.<sup>72</sup>

If the programs meet the conditions of being budget-neutral, improving quality of care and health outcomes, and enhancing patient satisfaction, the legislation mandates that CMS expand the programs to additional geographic areas beyond those included in the initial contracts.



For instance, scales have been designed using multiple sensors that account for imbalances in a patient's weight distribution. In addition, video capabilities can be incorporated into the devices, and RPM equipment is increasingly wireless.<sup>73</sup>

Advances like these are likely to continue as remote monitoring product manufacturers mature and as more established medical device companies enter the market. The first manufacturers of RPM products, such as Alere and Health Hero, began as small, start-up companies. Recently, they have been joined by major industry players such as Philips Medical Systems and a partnership between Bayer and Panasonic known as Viterion Telehealthcare. The entrance of these more established manufacturers, with greater experience and resources to bring to bear on new product development, promises to further expand the market for RPM products in the future.

#### **Expansion of RPM Technology**

As RPM technology becomes more sophisticated, the market for these products is expected to increase. Due to advances in the evolution of sensor technology, future remote monitoring devices will be capable of measuring additional types of physiological information, and they will become increasingly mobile. RPM will be used to manage heart failure patients with other diseases such as diabetes and COPD. It will also be incorporated into other medical and non-medical products, such as implantable heart devices and wearable, sensor-embedded "smart shirts". The potential for expanded uses of RPM both helps to drive and is driven by the adoption of current RPM technology for heart failure. (See Sidebar: Advances in Remote Physiological Monitoring.)

#### **CONCLUSION**

Collectively, these forces have created a basic foundation for RPM for heart failure to expand. Given the immense promise of RPM, particularly for the majority of patients whom are currently receiving standard care, its spread to a wider population of heart failure patients would be beneficial to patients, as well as for multiple stakeholders in the health care system.

However, RPM currently suffers from very low adoption, and the expansion of its use faces a number of significant barriers. The following section of this report examines the barriers to adoption that have limited the current use of RPM and could restrain its future growth.



## ADVANCES IN REMOTE PHYSIOLOGICAL MONITORING

Remote physiological monitoring technology already exists for managing later-stage heart failure patients. But even more advanced monitoring technologies are in development and rapidly becoming available. A few significant examples are highlighted below.

### RPM FOR CO-MORBIDITIES

Many of the standard RPM devices available today may also be used to manage heart failure patients with multiple chronic conditions, including asthma, chronic obstructive pulmonary disease (COPD), and diabetes. These devices can measure blood sugar as well as peak flow oxygen levels to determine whether a patient's air passages are free or partially narrowed or blocked.

They may also measure additional patient information, such as temperature and heart and lung sounds. Some incorporate a digital video camera to allow for real-time remote patient teleconferencing.<sup>74</sup>

### WEARABLE CARDIAC MONITORING DEVICES

"Smart shirts" are a mobile form of RPM that incorporate monitoring technology into a patient's clothing.<sup>75</sup> These wearable shirts have tiny sensors woven into the fabric that constantly monitor patients' heart rate, blood pressure and other biometric data.<sup>76</sup> Wearable defibrillator vests are also available for patients with a high short-term risk of sudden cardiac death.<sup>77</sup> These vests continuously monitor a patient's heart rate and provide immediate, automatic defibrillation when an irregular heart beat is detected.

### IMPLANTABLE CARDIAC MONITORING DEVICES

The most mobile remote physiological monitors will be implantable heart devices, such as pacemakers and implantable cardioverter defibrillators (ICDs) that are designed to regularly measure and transmit patient data.

In fact, medical device companies have already developed a remote monitoring service for patients

with ICDs.<sup>78</sup> Patients wave a portable monitor over their implanted devices to download data – such as electrocardiogram readings and information about how the devices are functioning – and then transmit the information to their physicians over a telephone line. The Food and Drug Administration (FDA) has recently approved heart devices that are compatible with this system<sup>79</sup>, and the Department of Veterans Affairs is providing patients with the devices and monitoring service.<sup>80</sup>

Future implantable devices may measure new forms of patient data, including pulmonary artery pressure as well as cardiac biomarker proteins released into the bloodstream when the heart muscle is damaged.<sup>81</sup>

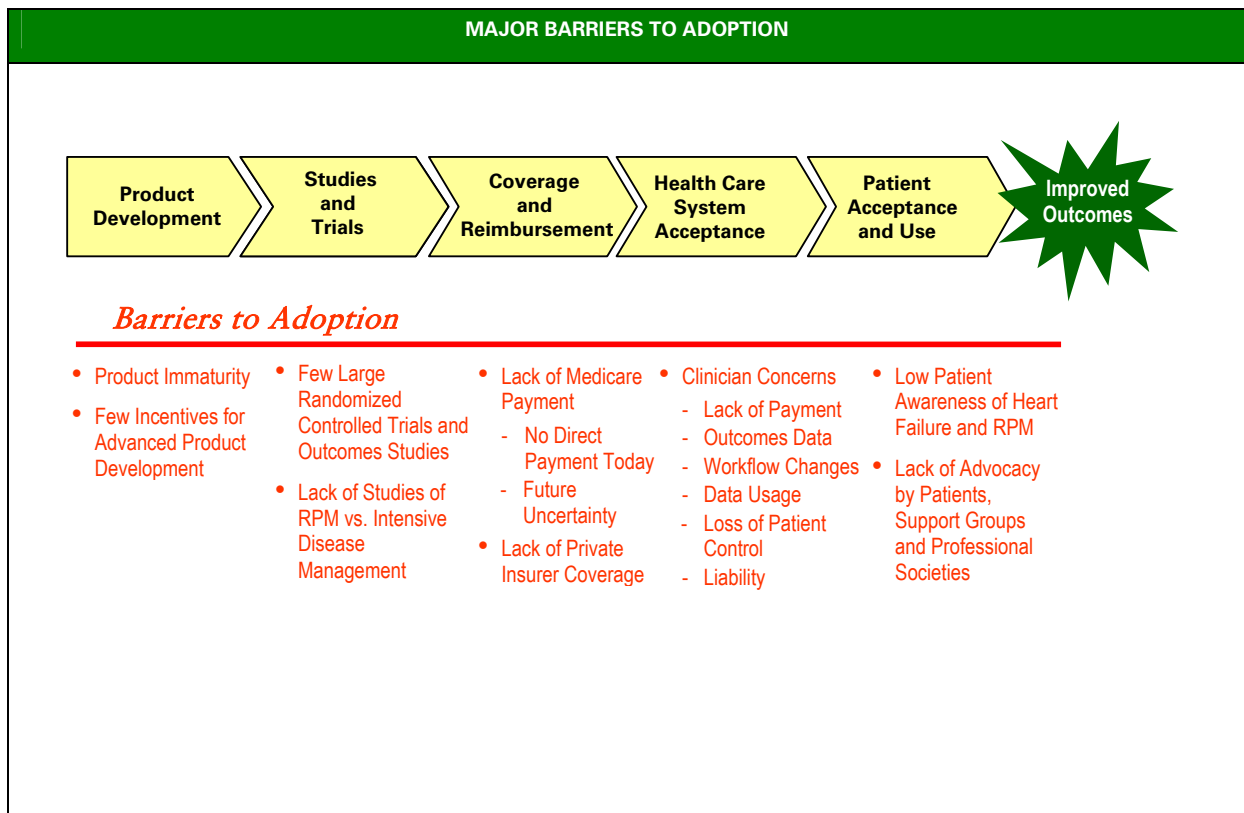
### SUMMARY

Advances in RPM technology are likely to expand its use to a wider range of applications and larger patient populations. As the use of RPM increases, it is likely to continue to add value in terms of both cost savings and quality of care. However, it will also raise a number of additional challenges for clinicians who use the data it generates, for patients seeking to protect their privacy and for health plans and the Centers for Medicare and Medicaid Services which must weigh the relative costs and benefits of new devices. The lessons learned from adopting current forms of RPM for heart failure will help health care stakeholders prepare to address these and other future challenges.



# Barriers to Adoption

Figure 3-1



Source: NEHI



## Barriers to Adoption

Despite the potential for RPM to improve heart failure care, its adoption in the health care system has been extremely slow. Fewer than five percent of eligible heart failure patients are using RPM devices today.<sup>82</sup>

*Fewer than five percent of eligible heart failure patients are using RPM devices today.*

Why? Our study indicates that there are a number of barriers ranging from product development to patient acceptance and use (Figure 3-1). However, the most significant barriers to adoption of RPM are payment shortfalls, clinician concerns and lack of patient

awareness. In particular, these three factors, unless addressed, will continue to restrain widespread use.

### **PAYMENT INSUFFICIENT, FUTURE REIMBURSEMENT UNCERTAIN**

Reimbursement gaps have severely limited the spread of this technology. The new Medicare Chronic Care Improvement Programs do offer considerable hope for progress. Still, unless uncertainty surrounding the structure of future reimbursement is decisively eliminated, it will likely continue to inhibit widespread use.

#### **Historical Lack of Medicare Payment**

With over 70 percent of heart failure patients enrolled in Medicare, this coverage is vital to the adoption of any new treatment for the disease.<sup>83</sup> However, Medicare does not cover the purchase of RPM devices, nor does it reimburse care managers, nurses, or physicians for their time spent monitoring and responding to remotely monitored data.

Historically, this lack of Medicare coverage has had repercussions for multiple sectors of the health care system's use of RPM to manage heart failure. For example,

- Hospitals and specialty heart failure clinics have been reluctant to make independent investments in RPM, because they have not been reimbursed for either capital investment or operating expense.
- Physicians are reluctant to provide monitoring services and phone calls for which they will not be reimbursed. In fact, clinician time spent monitoring patient data, or responding to alerts is often considered lost time that could have been spent on revenue generating activities.
- Taking their lead from Medicare, private insurers have been slow to examine and adopt this technology for their patient populations.

Nevertheless, some home health care organizations have managed to leverage Medicare's Prospective Payment System (PPS) for home health services to offset the cost of purchasing RPM for heart failure patients. The set 60-day PPS payments



may be used at the discretion of the home health care agency, and some organizations have chosen to use these payments for RPM within the first 60 days of treatment.

These home health care organizations hope to enjoy a return from lower total costs, and some organizations have found that implementing RPM for as little as 60 days reduces net costs.<sup>84</sup> But the obvious downside of this indirect form of coverage and use is that home health care providers have a disincentive to continue using RPM once the 60 days are up. This means that a substantial portion of the full health benefit and economic value of using RPM – which may be realized over the course of six-months or longer – is not being captured.

#### **Future Payment Uncertain Despite New Chronic Care Improvement Programs**

As previously noted, legislation passed in 2003 appropriates up to \$100 million over five years to the Centers for Medicare and Medicaid Services (CMS) for contracting with Chronic Care Improvement Programs (CCIPs). While the program and its outcome could stimulate more aggressive demands for the inclusion of heart failure RPM in Medicare coverage, there are no guarantees that a major change in Medicare policy on RPM for heart failure patients will occur.

First, reimbursement procedures will not be transparent. This is because while CCIPs will generally be funded to provide chronic care services to fee-for-service Medicare patients, they will not provide *direct* reimbursement specifically for devices or monitoring services. As a result, each individual CCIP will have discretion over its level of investment in monitoring technologies.

Second, reimbursement policy is still vague. CCIPs are, after all, intended to be experiments, not full-fledged financing programs. Moreover, the timing is also unclear, in that the agency has not yet indicated when it might consider providing broader direct or indirect reimbursement for remote monitoring of any type, outside the CCIP test environment. So far, it has only said that if the program is successful it would be rolled out more broadly by 2008.

Third, because CMS is evaluating the impact of each program in total, the results will most likely not be broken down to a level that can discern the impact of RPM over other components of disease management.

Consequently, based on the high proportion of the Medicare population represented by heart failure patients, its high visibility, and the tremendous influence Medicare tends to exert on payers and providers across the industry, the lack of Medicare coverage for RPM strongly limits its adoption.

#### **CLINICIAN CONCERNS IMPEDE ADOPTION**

Beyond the issues raised by Medicare's failure to cover RPM, a second set of barriers arises from other practical concerns. While a growing number of clinicians have adopted RPM for heart failure and are optimistic about its impact on patient care, many are still concerned about limited outcomes data, lack of



reimbursement, perceived clinical workflow changes, loss of control over patient care, hazards in data usage and potential malpractice liability.

Obviously, the support of clinicians (physicians, nurses, care managers, and other health care providers) is essential to the adoption of health care innovations. So, unless a number of these objections are addressed in detail, clinician's concerns are likely to remain a key impediment.

#### **Few Randomized, Controlled Trials and Outcomes Studies**

Many clinicians are concerned because there have been only a limited number of rigorous outcomes studies analyzing the clinical benefits of RPM, and no studies in the U.S. have been completed comparing RPM to other forms of intensive disease management.<sup>85</sup> Consequently, clinicians often view the existing body of data as incomplete.

Historically, clinicians have relied heavily on traditional trial protocols to demonstrate the effectiveness of one treatment approach over another. Furthermore, they also tend to rely on findings from large randomized, controlled trials before making their treatment decisions for their patients. But to date there have been relatively few such studies of RPM's impact on heart failure patients.

Although there have been many other types of studies supporting the value of RPM technology, most have either

- Been sponsored by device manufacturers – perceived to be self-interested parties, or
- Emerged from small pilot programs run by a diverse group of institutions lacking the clout of the premier heart failure centers, or
- Not followed the protocols of randomized, controlled trials and/or did not publish results.

The main hurdles for these studies have been the high cost required to run clinical trials on RPM devices without the benefit of Medicare coverage, the minimal interest among investigators who have typically leaned toward other avenues of research, and the challenge of recruiting advanced heart failure patients to a trial.

The limited amount of outcomes data has fueled sufficient skepticism among some clinicians as to dissuade them from implementing the technology. In many professional quarters, this skepticism continues to trump the more intuitive or common-sense view of heart failure RPM as yielding significant clinical benefits and cost savings over the standard care that most patients receive today.

#### **Payment Problems for Clinicians**

Clinicians' payment concerns stem from uncertainties associated with patient communication and care that is not provided face-to-face. In today's health care system, clinicians are not typically paid for any sort of monitoring of patients in



the home, nor are they paid for routine phone calls with patients, so most physicians avoid frequent use of these out-of-office processes.

RPM, however, requires clinicians to review patient data received electronically and to act on alerts by contacting patients and deciding how to treat them, mostly over the telephone. Lack of payment for these services has offset the attractiveness of the potential benefits.

### **Workflow and Practice Pattern Changes**

Another notable concern of clinicians has to do with how RPM use affects the day-to-day flow of activities in clinical practice. To be effective, RPM does require some proactive changes in practice patterns. And although the net result may be greater efficiency and leveraging of current staff, incorporating some fundamental changes into the workflow routine tends to be a daunting prospect to the physicians and nurses who have to implement them.

One challenge is the fact that RPM requires physicians to adjust to receiving patient alerts at any time and responding to them efficiently. This concept is the opposite of what clinicians are typically used to, which is: short, intermittent periods of doctor-patient interaction in the office, with physicians controlling the timing and frequency and where decisions are made and then carried out largely “off-line” by the patient.

Thus, RPM places new and different demands on the traditional practice model. For example,

- Nurses and care managers must train to use computer software to absorb and synthesize the meaning of a daily, continuous stream of patient data coming up on-screen, either in addition to or in lieu of more conventional but intermittent patient phone calls and visits.
- Physicians must be prepared to recognize, evaluate and respond to patient alerts.
- Each clinician must work collaboratively with the other participants in the system to manage patients effectively.
- Beyond daily workflow, these changes also imply more frequent communication among physicians, nurses, and care managers.
- Adjustments must also be made to provide 24-hour coverage.

But the magnitude of change actually required is probably more moderate than it might appear to clinicians. Many aspects have already been anticipated and are being addressed by monitoring companies and technology providers who are highly motivated to ease the practice pattern transition as much as possible.

Nevertheless, in reality, changing clinician practice patterns is rarely an easy process. It can produce considerable friction, particularly in the absence of





convincing, standard evidence accompanied by a favorable cost/reimbursement incentive.

### **Loss of Control over Patient Care**

In addition to concerns about workload and practice pattern changes, some physicians also express concern that they will lose control over the care of their patients if they are not actively and personally involved in implementing RPM for heart failure. As health plans continue to outsource disease management and remote monitoring to third-party disease management companies – which use their own care managers to monitor heart failure patients – physicians worry that the doctor-patient relationship may move away from its current central role in patient care.

On the one hand, with RPM doctors can gain access to far more data about patients' daily lives, which – if recognized and acted upon – will have great positive clinical and financial impact. Moreover, physicians will ultimately determine the protocols for when they need to be involved in an alert and what should be done subsequently. On the other hand, disease managers will also have access to the data flow and may be better positioned to focus on the need for intervention. For physicians, the question ultimately boils down to, who is in charge?

RPM changes the game to a real-time, data-driven environment where responsiveness becomes a major factor affecting physicians, and in which third-party care managers are likely needed to triage patient care and alerts. At its extreme, their concern is that they may find themselves on the periphery of patient care and may ultimately lose control of the process of patient management.

The history of managed-care processes to date indicates that physicians are – and will continue to be – in charge. But in order to ensure this, it is vital to effectively integrate physicians into the RPM system.

### **Using Data Effectively**

A further substantive concern for clinicians springs from the same source – how to effectively and efficiently use the potentially voluminous data generated by RPM for heart failure. That is, how will they be able to separate the “noise” from the salient facts they need in order to size up the situation quickly and make a judgment call on what should be done?

As noted, when a heart failure alert is transmitted from the monitoring center, the physician may have an enormous amount of data available regarding the patient experiencing a potentially critical episode. In fact, s/he may have all the data that has been generated daily since inception of the monitoring up to that moment. It may not be clear to every physician or to an on-duty nurse just how to translate into action the last 24 hours worth of data, let alone how to compare that information to the data generated over the days, weeks or months preceding an episode.



As clinicians receive “noisy” data through RPM, they will need to gain experience using it effectively. Eventually, they might need help developing their own customized systems for coordinating data to provide efficient, well-designed decision support.

#### **Fear of Liability**

Finally, some clinicians are concerned that they will be subject to increased liability for their use of RPM data – in some cases, for simply being the primary point of responsibility for disposition of the data RPM generates. Since RPM gives physicians access to a constant stream of patient data and also sends them patient alerts, they are concerned that they may be held liable for negligence in how they use and respond to this data.

Moreover, this type of data is not only new to the daily care environment, but it is also a matter of record, generating an electronic “paper trail” as it emerges. While most RPM vendors include language in their patient contracts that aims to reduce this concern and legal challenges have not yet been brought against clinicians using RPM for heart failure, anxiety about liability has both a real and a powerful psychological basis.

#### **LOW PATIENT AWARENESS**

The third major barrier to the adoption of RPM for heart failure is its low public profile. The public has relatively little awareness both about heart failure as a serious, costly disease and about the opportunity for tools like RPM to mitigate the impact of the disease.

#### **Low Awareness of Heart Failure**

Given the severity and prevalence of heart failure, its low profile may be surprising. However, heart failure receives significantly less popular media attention and research funding than better known diseases, such as breast cancer or diabetes, or even as compared to other cardiovascular diseases, such as stroke or acute myocardial infarction.<sup>86</sup>

The lack of public awareness of heart failure may stem from the stigma that is often attached to the disease – i.e., perceptions about patients’ frail condition and highly publicized data linking heart failure to undesirable behavioral and lifestyle factors such as smoking, lack of physical activity and overeating.

Importantly, heart failure lacks a champion from among the organizations that typically advocate initiatives that drive research funding, legislative action, and public education. The American Heart Association (AHA) has made great strides in generating support for cardiovascular disease in general, but to date it has not placed a strong focus specifically on heart failure. The Heart Failure Society of America (HFSA), in contrast, has provided a forum for health care professionals interested in improving heart failure care, but currently has a limited public presence.



There may be an answer to this particular challenge in the very size of the heart failure patient population, since their caregivers, friends and family constitute a de facto advocacy group with sufficient numbers to put the disease in the spotlight. Aside from their sheer numbers, these stakeholders, if mobilized, could be a powerful force in advocating for improved management of the disease.

#### Low Awareness of RPM for Heart Failure

Compounding the low visibility of the disease itself is the even lower level of general awareness among heart failure patients about the availability and promise of RPM technology. Because of its current level of penetration in the care delivery system, most patients are not even aware that the technology exists. Moreover, industry players have not yet chosen to advertise the technology and its benefits directly to patients and/or their caregivers.

*Most patients are not even aware that RPM technology exists.*

The irony is that studies find that those patients who have used RPM have indicated high levels of satisfaction. But because most patients and their caregivers are unaware of the technology, many patients who might benefit from this technology do not even know to advocate for access or for its adoption in the health care system.

Moreover, heart failure patients are frequently in such poor health throughout the course of the disease that they have been only marginally effective in being their own advocates. Not surprisingly, they have neither mobilized themselves, nor exerted much influence through advocacy or lobbying initiatives. This sets them apart from most other patients with chronic illnesses whose conditions remain relatively stable until the final stages of their diseases, and who have thus had the ability to form effective collective patient interest groups.<sup>87</sup>

#### CONCLUSION

The most significant barriers to the adoption of RPM for heart failure fall into each of three categories: payment issues, clinician concerns and lack of patient awareness. These categories represent opportunities where innovative solutions and effective action could drive expanded usage. There are a number of steps that can and should be taken to speed appropriate adoption of this technology, particularly for eligible patients who do not have access to intensive disease management programs. The final section of this report presents recommendations for addressing barriers to adoption and strategies that will enable wider patient access to RPM for heart failure in the future.





## Policy Action Plan

### MOVING AHEAD

As indicated previously, the three major barriers to widespread adoption of remote physiological monitoring as a disease management tool for heart failure patients are highly interdependent. That is, a turning point in one could have a domino effect on the others. For example, should Medicare opt to embrace RPM for heart failure patients, it is easy to imagine private payers following suit. Similarly, when significant outcomes data are available from classically modeled, large, randomized controlled trials that demonstrate RPM's value versus intensive disease management, clinicians and payers can be expected to take a fresh look at this alternative.

The barriers notwithstanding, RPM has the potential to benefit large numbers of advanced heart failure patients who are currently receiving only standard care. The technology is available now and has been demonstrated to reduce hospitalizations, decrease health care costs and improve quality of life as compared to standard care. Given that RPM has been shown to meet the urgent need for better management of the majority of heart failure patients who are not currently enrolled in intensive disease management programs, we recommend moving forward with a policy action plan for those patients at a minimum, while additional studies are in process.

Accordingly, we recommend the following course of action:

- Prepare to move quickly on emerging clinical trial data.
- Work with public and private payers to begin to address issues in the coverage of and payment for RPM technology and disease management programs in general.
- Collaborate with other organizations to better understand and address physicians' and nurses' concerns about RPM.
- Raise patient awareness of RPM's benefits over standard care through targeted educational campaigns.

### PREPARE TO MOVE QUICKLY ON EMERGING CLINICAL TRIAL DATA

As noted, limitations in the data produced by completed studies of RPM in the treatment of heart failure have, to date, precluded an unqualified policy recommendation for its adoption. What do we know today?

There are a variety of data that demonstrate that RPM can improve the quality of life and decrease the number of hospitalizations for the most high-risk patient populations, but only as compared to patients who are receiving standard outpatient care. We also know that intensive, nurse-driven disease management programs can improve the health outcomes and decrease the costs of caring for heart failure patients, compared to standard outpatient care.



What we are missing are data that demonstrate the relative effectiveness of RPM as compared to other, non-automated, intensive, disease management programs. Fortunately, it turns out that one study currently in progress holds potential for increasing our knowledge about such a comparison. Results from this research are not yet available, but they are expected in early to mid-2005.

Hence, we recommend that stakeholders who have an interest in achieving wide adoption of RPM for heart failure prepare to utilize and capitalize on these results and other potential findings as soon as they are available.

#### **SPAN-CHF Study Currently Underway**

The Specialized Primary and Networked Care in Heart Failure Study (SPAN-CHF) at the Tufts-New England Medical Center is in the process of generating results from a randomized, controlled trial of approximately 200 heart failure patients examining “the degree to which automated home monitoring improves upon a more standard non-automated disease management program.”<sup>88</sup>

This multi-center study in Massachusetts and Rhode Island compares two groups of patients, each receiving conventional disease management (including an education visit, weekly phone calls, medication checks and access to heart failure clinicians at all times). However, one treatment group is also monitored with RPM, using a scale and a blood pressure monitor at the patient’s home.

The research team will measure 90-day hospital utilization rates for heart failure and compliance to ACE inhibitor and Beta-blocker prescriptions. The results from the SPAN-CHF project may build a base of evidence about the benefit of RPM relative to an intensive, but non-automated heart failure disease management program.

Assuming that the results of this study, and possibly others, turn out to be an endorsement of RPM, our analysis of the remaining barriers to the adoption of RPM for heart failure indicates that the best and fastest way to prepare for widespread adoption is to directly confront financing/payment issues and clinicians’ concerns now, while continuing to raise patient awareness about access to this innovation.

If the outcomes from the SPAN-CHF and other trials do not demonstrate incremental value of RPM over disease management, RPM would be understood as providing value relative to standard care, but not necessarily relative to other forms of disease management. In that case, we would adjust our policy recommendations to reflect these findings.

#### **Prepare to Support Payment for RPM Technology**

In the near future, we would work with both the public and the private sectors to understand the coverage and payment issues related to implementing RPM technology and to formulate policy recommendations for its potential adoption.



### **Collaborate with CMS and Forthcoming CCIPs**

To further enhance the value of the findings from this study and other trials, we would seek to establish a liaison with key decision-makers at CMS. We would encourage and support CMS in incorporating these results into their analyses of heart failure disease management in the Chronic Care Improvement Programs. These findings would complement Medicare's results, expand them significantly, and speak directly to issues of practicality and financing in a wider sphere.

### **Work with Private Payers to Potentially Expand Coverage and Access**

At the same time, we would educate private payers about findings from existing studies and work with them to construct policies for access to, and payment for, RPM for heart failure patients.

## **COLLABORATE WITH OTHER ORGANIZATIONS TO ADDRESS PRACTICAL CLINICIAN CONCERNS**

Understanding that there is considerable provider concern regarding the adoption of intensive disease management programs, including RPM, we would collaborate with professional organizations, heart disease associations, and health plans to better understand and address practical concerns about the use of RPM in daily clinical practice. These working sessions would highlight findings from studies of RPM, as well as the experiences of clinicians, disease management companies and RPM vendors who have had success in implementing actual RPM programs.

The sessions would also bring clinicians face-to-face with RPM experts, vendors, and health plans to hammer out the most difficult questions about reimbursement, clinical practice, and liability. Physicians and nurses would be encouraged to voice their concerns about issues, such as payment, outcomes data, workflow changes, physician-patient relations, data usage and liability.

Importantly, the sessions would differentiate between real and perceived barriers and develop strategies for clinicians to bring RPM to their heart failure patients, if appropriate. We would recommend that these working sessions be incorporated into existing clinician gatherings, such as meetings of regional medical societies, or symposia. The workshops would specifically convene heart failure experts alongside community cardiologists in order to get their practical perspectives on how to overcome the barriers to adopting RPM.

### **White Paper with Blueprint**

On completion of these working sessions, the project leadership would publish and strategically distribute a white paper to publicize the sessions' outcomes and lessons learned. In this way, a wide audience of clinicians across the country would be reached. Moreover, the white paper could serve as a blueprint that physicians and nurses could use to incorporate RPM into their respective systems of care for heart failure patients.



### **RAISE PATIENT AWARENESS THROUGH TARGETED CAMPAIGNS**

We would also recommend that national organizations develop campaigns to raise awareness of RPM and the importance of improving heart failure care. Since lack of patient awareness is a barrier to adoption, these initiatives could help turn that around. As noted, our study indicates that better-informed patients who tend to be more highly motivated to manage their heart failure more effectively than those less informed could drive demand for RPM and other care management programs.

#### **Key Role for National Patient Support Organizations**

We would recommend that national organizations such as the American Heart Association (AHA), the Heart Failure Society of America (HFSA), the American Associations of Retired Persons (AARP), and the Business Round Table be enlisted to develop campaigns about the significance of heart failure in American society. As noted in our findings, this important information is severely lacking in this country.

One way to do this, and spread the word on the value of RPM technology at the same time, is for these organizations to use the introduction to RPM as an avenue for education. Because RPM is a novel disease management tool that is cost-effective and could significantly improve the lives of millions of patients when compared to the standard care that they receive today, we believe it can be a “hook” to get them interested in learning more about their disease and how to take better care of themselves.

In addition, we would recommend that these organizations follow the model of successful education campaigns that have worked very effectively for other diseases, such as colorectal cancer and breast cancer. Similarly, we urge them to develop strategies that simplify RPM technology and make it easy for their audiences to recognize how it is used and its impact on patient care and quality of life.

Finally, we would recommend that they also tailor their campaigns for different audiences, including heart failure patients, their caregivers, and clinicians, in order to raise awareness among all of these key constituencies.

### **CONCLUSION**

Determining the value of health care technologies requires evidence of their impact on quality and cost of care, a thorough analysis of the factors influencing their adoption and implementation in practice, and an examination of their benefits relative to other forms of care. Our findings indicate that RPM for heart failure is clearly a valuable technology for patients who are not already in an intensive disease management program. In those cases, it produces cost savings, improved outcomes, and increased quality of life relative to standard care.

With the majority of advanced heart failure patients receiving standard care today, RPM represents a significant innovation in the treatment of heart failure. However, to fully assess the value of RPM, further evidence of its incremental value relative to other forms of disease management needs to be better understood.





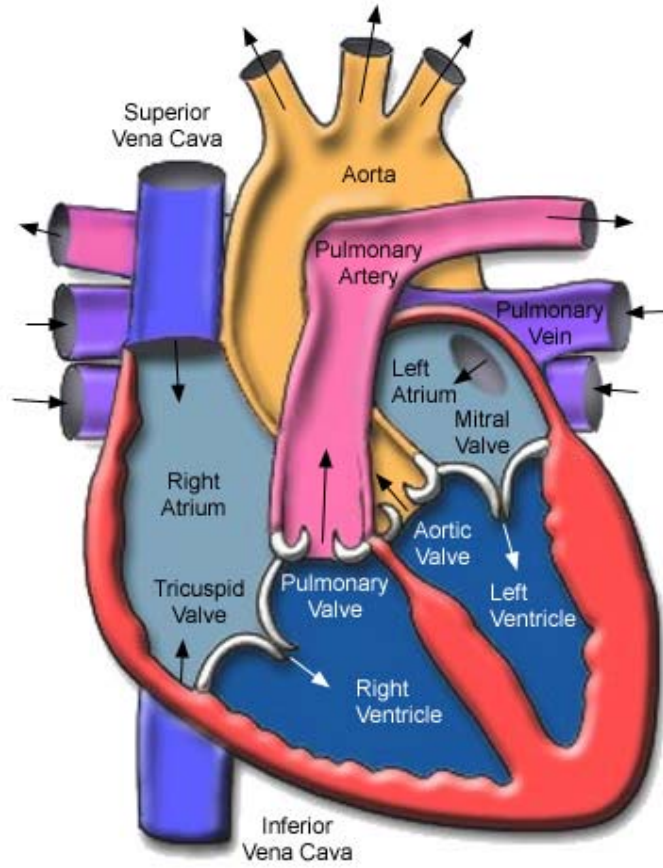
NEHI will support the rapid utilization of the earliest findings of these studies and work aggressively to implement policies that are derived from their outcomes. In the interim, we will continue to advocate for policies and programs that prepare patients, providers, and payers for greater adoption of RPM technologies.



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## APPENDICES

## THE ANATOMY OF THE HEART



Source: Texas Heart® Institute

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## Appendix 1: Overview of Heart Failure

Heart failure is a progressive condition that results from damage to the heart muscle, or the mechanisms that control the heart's inflow and outflow of blood. As a result, the heart is unable to pump blood, fill with blood at low pressure at its usual capacity, or both. As the disease progresses, in what is referred to as heart failure, circulatory blood returning to the heart "backs up" and the lungs and other tissues become congested from the accumulation of excess fluid.

There are a number of risk factors for heart failure, the most significant of which is age. A number of others, such as smoking, hypertension, and high cholesterol, are associated with cardiovascular disease in general. Heart failure may be diagnosed in a routine office exam using an echocardiogram to determine the heart's pumping ability.

The progression of heart failure can be slowed or partially reversed, and treatment consists of medication, lifestyle modification, devices such as pacemakers and implantable cardiac defibrillators, and, in some cases, surgery.<sup>89</sup>

### **RISK FACTORS**

Age is the strongest risk factor for heart failure, since aging is frequently associated with damage to the heart muscle and a natural decline in the heart's pumping ability.<sup>90</sup> In fact, heart failure affects as many as one in ten persons aged 70 and older.<sup>91</sup> In addition, anything that damages the heart muscle can be a risk factor for heart failure, including the major risk factors for coronary heart disease. These include smoking, hypertension, high cholesterol, drug use and excessive alcohol consumption, as well as previous heart attacks, diabetes, arrhythmias, chronic lung diseases, viral infections, heart valve problems, chemotherapeutic agents and a family history of heart disease or heart failure.<sup>92</sup> Antecedent hypertension or a previous heart attack are present in 50 and 75 percent of newly diagnosed heart failure cases, and each increases the incidence of heart failure by factors of two and five, respectively.<sup>93</sup>

### **DIAGNOSIS**

Heart failure can be diagnosed in a routine office exam and through a variety of laboratory tests. In some cases, a physician may make a diagnosis of heart failure based on a patient's symptoms and medical history and by listening for the sound of congestion in a patient's lungs using a stethoscope.

If heart failure is suspected but not confirmed, an echocardiogram (ECG) can be used to easily diagnose the type of heart failure that has low ejection fraction (EF) – a measure of the fraction of blood pumped out of the heart's left ventricle during each heartbeat. An echocardiogram (ECG) is an ultrasound of the heart and uses the heart's electrical activity to measure its size, shape, rhythm and thickness. Chest x-rays may also be used to diagnose heart failure by revealing the enlarged size of the heart and the presence of fluid in the lungs.

## TREATMENT

The goal of heart failure treatment is to manage the disease to prevent patients' progression from New York Heart Association (NYHA) Classes I and II to Classes III and IV. This is because the prognosis for heart failure patients is that their health will gradually decline. Twenty percent of heart failure patients will survive less than one year and 50 percent will survive less than five years. Fewer than 10 percent of patients survive longer than 10 years.<sup>94</sup>

Treatment for heart failure mainly consists of lifestyle changes and medications. Lifestyle changes include reducing sodium intake, exercising, monitoring daily fluid intake, monitoring symptoms, avoiding alcohol, limiting or avoiding caffeine, eating a low-fat diet and reducing stress.<sup>95</sup>

Medications include ACE inhibitors to dilate the blood vessels, beta-blocking agents to slow the heart's rhythm, diuretics to help reduce fluid retention, and digoxin to improve pumping function. Episodes of decompensation require inpatient hospital stays for the administration of oxygen, intravenous diuretics, vasodilators and nitroglycerin or inotropes.<sup>96</sup>

Surgery or invasive procedures are less common forms of treatment. Surgery is used only when a patient has a specific, correctable problem that is causing heart failure – such as a leaky valve, blockages in the coronary arteries or an arrhythmia – or in the very advanced stages of heart failure when medications and lifestyle changes can no longer improve the patient's condition.<sup>97</sup> The most common procedures include: valve replacement, angioplasty, coronary artery bypass, defibrillator implantation, heart transplant and the implantation of a left ventricular assistance device (LVAD).<sup>98</sup>

Patients with end-stage heart failure may need heart transplants, but only about 2,200 heart transplant surgeries are performed each year due to long waiting lists and the limited availability of donor hearts that match recipients.<sup>99</sup>

A number of alternative surgical interventions are under investigation, including artificial, mechanical hearts and LVADs that can be implanted on a permanent basis.<sup>100</sup> These surgical interventions are showing promise in investigations, but they are not yet available for most heart failure patients.

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## Appendix 2: Value Analysis

### I. METHODS

- We used a Markov model of heart failure management to examine the cost-effectiveness of RPM for heart failure patients.
- The target population for the model is patients with Class III or IV heart failure (as defined by the New York Heart Association) who have been recently discharged from the hospital.
- The time horizon of the model is 180 days, or about 6 months, since patients are typically at greatest risk of rehospitalization during this time. As patients using RPM are at risk of experiencing a reportable event on a daily basis, the cycle length of the model is one day.
- The model was estimated using data from expert interviews and the following published literature: Benatar et al. 2003<sup>101</sup>, Goldberg et al. 2003<sup>102</sup>, Knox et al. 1999<sup>103</sup>, Heidenreich et al. 1999<sup>104</sup>, Nanevicz et al. 2000<sup>105</sup>, 2003 Physician's Fee and Coding Guide<sup>106</sup>, Agency for Healthcare Research and Quality HCUP Nationwide Inpatient Sample (NIS) 2001<sup>107</sup>, Bureau of Labor Statistics Consumer Price Index for Medical Care Services<sup>108</sup> and unpublished data from the EPHEBUS trial.<sup>109</sup>
- We used the model to estimate the total costs, total number of rehospitalizations and total quality-adjusted life years (QALYs) for patients receiving RPM and standard care, respectively.

#### Model Structure

To examine the cost-effectiveness of remote physiological monitoring (RPM) of patients with heart failure, we developed a Markov model of the management of this condition with and without the use of RPM.

#### Monitoring Strategies for Heart Failure

*Remote physiological monitoring.* Patients in the RPM group are assumed to have a device installed in their home that permits them to weigh themselves on a daily basis and transmit results to a care management center via a telephone line. (Although remote monitors may measure other vital signs in addition to weight, the efficacy trials of remote monitoring employed in this analysis used devices that measure weight only). If the data received by nurses in the care management center indicate a weight gain above some pre-specified amount, the nurse contacts the patient and the patient's physician. This "reportable event" triggers a response from the patient's physician, such as a phone call to alter the patient's medication regimen. Patients on remote monitoring are assumed to have two routine visits with their physician during the six-month follow-up period. Patients who do not comply with remote monitoring are assumed to have the device removed from their home after two months; they are assumed to have risks of rehospitalization and death equal to those of patients receiving standard care throughout the six-month period.

*Standard care.* Patients in the standard care arm receive education prior to discharge from the hospital, may receive nurse follow-up phone calls in the two weeks following discharge and have three physician visits over the six-month study period for the treatment and monitoring of heart failure.

### Model Estimation

The base-case model parameter estimates and the data sources used in their estimation are summarized below.

Key Base-Case Model Parameters

Model Parameter	Estimate	Data Sources
<b>Remote Physiological Monitoring</b>		
Monthly rate of rehospitalization for heart failure	0.09	Goldberg et al., 2003; Benatar et al., 2003; Knox et al., 1999
Annual death rate	20%	National Heart, Lung and Blood Institute, National Institutes of Health, 2003
Number of routine physician visits over 6 months	2	Expert Opinion
Average length of stay for heart failure admission	4.8	Benatar et al., 2003; Agency for Health Care Research and Quality, HCUP Nationwide Inpatient Sample (NIS), 2001 (ICD-9-CM 428.0, 428.1, 428.9)
<b>Standard Care</b>		
Monthly rate of rehospitalization for heart failure	.133	Knox et al., 1999
Annual death rate	20%	National Heart, Lung and Blood Institute, National Institutes of Health, 2003
Number of routine physician visits over 6 months	3	Expert Opinion
Average length of stay for heart failure admission	5.5	Agency for Health Care Research and Quality, HCUP Nationwide Inpatient Sample (NIS), 2001 (ICD-9-CM 428.0, 428.1, 428.9)

*Likelihood of a patient complying with the remote monitoring program.* Data on compliance with the monitoring system were obtained from a randomized, controlled trial of remote monitoring in which noncompliance was defined as patient measurements not received for two or more consecutive days for reasons other than hospitalization, vacation, a physical condition that does not allow for weighing, or technical difficulties.<sup>110</sup>

*Monthly rate of a reportable event.* Data on the frequency with which patients on remote monitoring experience a reportable event (i.e., weight gain) were obtained from three studies of remote monitoring.<sup>111</sup> Rates reported in these studies were converted to monthly rates and weighted by the respective sample size to estimate a weighted average monthly rate of a reportable event. In the model, numbers of events per month are transformed to daily rates by dividing by 30; this assumes that the daily probability of a reportable event is conditionally independent of prior events.



*Likelihood of physician action following a reportable event.* Data on the probabilities of a physician calling the patient, recommending an office visit, suggesting an ER visit, and taking no action following a reportable event could not be found in the published literature. Data obtained from clinical experts indicate that the physician action following a reportable event typically consists of a phone call to the patient to alter the patient's medication, provide dietary advice, or both. As such, it was assumed in base-case analyses that physicians always place a phone call to the patient following a reportable event.

*Rates of rehospitalization.* The baseline rate of rehospitalization for heart failure among patients receiving standard care was estimated from national benchmark data.<sup>112</sup> Data on the rate of rehospitalization for heart failure among patients on remote monitoring were obtained from two randomized, controlled trials of remote monitoring.<sup>113</sup> We calculated the risk of rehospitalization for the monitored patients as a weighted average of these two studies, where the weights were the number of patient-months of follow-up in each respective study. In the model, the numbers of rehospitalizations per month among remote monitoring and standard care patients are converted to daily rates by dividing by 30; this assumes that the risk of rehospitalization is conditionally independent of prior events.

*Likelihood of death.* The annual probability of death among patients with heart failure was obtained from the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health.<sup>114</sup> In base-case analyses, the risk of death was assumed to be the same for patients in the remote monitoring and standard care groups. In a sensitivity analysis, differential mortality risks as reported in a randomized, controlled trial of remote monitoring were employed (18.4 percent and 8.0 percent over six-months for the control and remote monitoring groups, respectively).<sup>115</sup> In this analysis, the mortality rate for the standard care group was set equal to the base-case estimate. The relative risk of death for monitored versus control group patients was estimated by first converting the probabilities of death reported in the trial to rates, and then dividing the six-month death rate for monitored patients by the six-month rate for the control group patients. The relative risk was multiplied by the base-case death rate to obtain a six-month death rate for remote monitored patients. Rates were converted to daily probabilities in the model.

*Utility weights associated with heart failure and rehospitalization for heart failure.* The number of QALYs gained among patients on remote monitoring was estimated using utility weight estimates from a study of the impact of hospitalization on utility scores in patients with heart failure complicating acute myocardial infarction (AMI).<sup>116</sup> In the model, patients are assigned a utility over the entire six-month period based on whether they experience 0, 1, or 2 or more rehospitalizations.

*Physician visits for heart failure patients.* In the model, it is assumed that patients receiving standard care for heart failure have three routine visits with their physician over the six-month period; patients on remote monitoring are assumed to have two visits over the same time period. These estimates were obtained from clinical experts. Patients on remote monitoring who do not comply with monitoring are assumed to have the visit schedule of remote monitoring patients

for the first two months of the study period and the visit schedule of standard care patients thereafter.

*Costs associated with remote monitoring.* Data from RPM manufacturing companies indicate that per patient costs of RPM include a one-time initiation fee as well as a monthly monitoring fee.<sup>117</sup> Patients who do not comply with monitoring are assumed have the device removed from their home after two months; consequently, they do not incur monthly costs of monitoring after that time.

*Costs of physician services.* The costs of a physician phone call to a patient and a physician visit were obtained from the *2003 Physicians Fee and Coding Guide*.<sup>118</sup>

*Hospitalization costs.* To estimate the cost per day for heart failure hospitalizations, the cost of an inpatient hospitalization for heart failure and the corresponding average length of stay were obtained from the 2001 Healthcare Cost and Utilization Project Nationwide Inpatient Sample (HCUP NIS).<sup>119</sup> The cost of a hospitalization was estimated as the mean total charge for patients with principal diagnoses of heart failure *not otherwise specified*, *left heart failure*, and *heart failure not otherwise specified* (ICD-9-CM 428.0, 428.1, 428.9), weighted by the total number of discharges for each diagnosis. We then adjusted the weighted average charge by the average cost-to-charge ratio for US acute-care hospitals in 2001 (0.531). We adjusted this cost to 2003 dollars using the Consumer Price Index for medical care services.<sup>120</sup> The cost of a hospitalization was divided by the average length of stay to arrive at a cost per inpatient day.

The average length of stay for standard care patients was assumed to be equal to the estimate obtained from HCUP NIS. Data from a randomized, controlled trial of remote monitoring suggest a significant reduction in length of stay for patients in the remote monitoring group relative to patients in the control group (3.8 versus 4.4 days, respectively).<sup>121</sup> To estimate the length of stay for remote monitoring patients, we applied the percentage risk reduction from the trial to the length of stay for standard care patients.

## II. RESULTS

- Base-case analyses suggest that RPM reduces rehospitalizations (by 32 percent), yields more QALYs (two percent increase), and reduces health-care costs (by 25 percent) relative to standard care.
- When differential mortality rates are assumed, RPM yields a substantial increase in QALYs gained (112 percent increase).
- Sensitivity analyses suggest that results of the analysis are robust to reasonable alternative assumptions regarding parameter values.

We used modeling techniques and data from various secondary sources to assess the cost-effectiveness of remote physiological monitoring for patients with heart failure. The model estimates the number of rehospitalizations, QALYs and total

health-care costs incurred for patients with Class III or IV heart failure who are initiated on either remote monitoring or standard care. Rehospitalizations and health-care costs were estimated for a six-month period of follow-up; QALYs were estimated for the remainder of the patient's lifetime. Cost-effectiveness was estimated in terms of the cost per rehospitalization averted and cost per QALY gained; when remote monitoring resulted in net cost savings, the number of rehospitalizations averted, QALYs gained and net savings were reported.

In the base-case analysis, remote monitoring of heart failure patients was found to result in fewer rehospitalizations, more QALYs, and lower health-care costs than standard care. In the parlance of cost-effectiveness analysis, it meets the criteria for being a "dominant" strategy. Results are even more favorable with respect to QALYs gained when it is assumed that remote monitoring is associated with a lower mortality rate than standard care. When the assumption of equal rehospitalization rates is added to the latter scenario, remote monitoring becomes more costly than standard care. Sensitivity analyses revealed that results of the analysis are not very sensitive to changes in assumptions regarding the cost of hospitalization and the monthly cost of remote monitoring; remote monitoring is more costly than standard care when the rate of rehospitalization is assumed to be equal between the groups, as well as when the costs for remote monitoring are set to their maximum likely values. However, even in the latter scenario, the incremental cost-effectiveness ratios for remote monitoring relative to standard care are well within the range of what is commonly accepted for medical interventions.

### III. SUMMARY AND CONCLUSIONS

- In the base-case analysis, RPM results in fewer rehospitalizations, more QALYs and lower net health-care costs than standard care.
- Even when the costs of RPM are set at their maximum likely values or when the rate of rehospitalization and length of stay are assumed to be equal for patients receiving RPM and standard care, the incremental cost-effectiveness ratios for RPM relative to standard care are well within the range of what is commonly accepted for medical interventions.
- Currently available evidence suggests that the adoption of RPM could save money and improve patient outcomes when compared to standard outpatient care.

Results from this analysis are consistent with other studies that have reported decreased costs among patients initiated on remote monitoring. For example, Heindenreich et al. reported that annual medical-care claims decreased among a group of patients initiated on home monitoring relative to pre-intervention claims.<sup>122</sup> Nobel et al. reported that initiation of a remote monitoring program reduced per member per year costs by 55 percent among a Medicare population over one year.<sup>123</sup> Pearson et al. reported that combined hospitalization and monitoring costs were 52 percent lower than pre-intervention costs over a 90-day period.<sup>124</sup> Ertle et al. reported that inpatient costs for heart failure admissions were

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reduced by 73 percent with monitoring over a six-month period.<sup>125</sup> Kohlrus et al. reported savings per patient of \$10,525 in a six-month period relative to pre-intervention.<sup>126</sup> Weiss et al. reported annual savings of \$8,189 per patient associated with remote monitoring.<sup>127</sup> These studies were all observational studies in which patients served as their own controls. In contrast, our study is the first to employ data from randomized, controlled trials to estimate the cost-effectiveness of remote physiological monitoring.

While the conduct of additional randomized, controlled trials are warranted to validate the efficacy data reported in the two studies published to date, currently-available evidence suggests that the adoption of remote monitoring for the treatment of heart failure could save money and improve patient outcomes when compared to standard outpatient care.

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## Appendix 3: Experts Interviewed

NEHI is very grateful to each of the experts who generously gave us their time and provided us with valuable input into our research and analyses.

### ALERE MEDICAL INC.

Ron Geraty, M.D., Chief Executive Officer

Timothy Moore, M.D., Chief Medical Officer and Senior Vice President

### AMERICAN HEALTHWAYS

Michael Montijo, MD, Vice President and Medical Director for Business Development

Jim Pope, M.D., Executive Vice President and Chief Medical Officer

### BERLEX LABORATORIES

Michael Collins, M.D., Director, Corporate Business Development

### BETH ISRAEL DEACONESS MEDICAL CENTER

David Cohen, M.D., Director, Interventional Cardiology Research

### BETTER HEALTH TECHNOLOGIES

Vince Kuraitis, Principal

### BIOGEN IDEC

Burt Adelman, M.D., Executive Vice President, Development

### BOSTON SCIENTIFIC CORPORATION

Amy Charette, Corporate Director, Customer Market Development

Jennifer Foley, Vice President, Cardiovascular Clinical Sciences

### BLUE CROSS BLUE SHIELD OF MASSACHUSETTS

Peter Goldbach, M.D., Medical Director

### BRIGHAM AND WOMEN'S HOSPITAL

Donald Baim, M.D., Director, Center for Innovative Minimally Invasive Therapy (CIMIT)

Kenneth Baughman, M.D., Director, Advanced Heart Disease Section

Jim Fang, M.D., Associate Physician

Michael Givertz, M.D., Co-Director, Cardiomyopathy and Heart Failure Program

Richard Kuntz, M.D., Associate Physician

Lynne Warner Stevenson, M.D., Co-Director, Cardiomyopathy and Heart Failure Program

Peter Stone, M.D., Co-Director, Cardiac Care Unit

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**CENTER FOR THE INTEGRATION OF MEDICINE AND INNOVATIVE TECHNOLOGY (CIMIT)**

Jonathan Rosen, M.D., Director, CIMIT Office of Technology Implementation

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Renee Mentnech, Director, Division of Beneficiary Research, Office of Research, Development and Information

William Taylor, M.D., Associate Regional Administrator

**CONNECTICARE**

Paul Bluestein, M.D., Senior Vice President, Chief Medical Officer

**CORDIS CORPORATION**

Stephen Davis, M.D., Business Development

**DISEASE MANAGEMENT ASSOCIATION OF AMERICA (DMAA)**

Warren Todd, Executive Director

**DISEASE MANAGEMENT PURCHASING CONSORTIUM**

Al Lewis, Executive Director

**GUIDANT CORPORATION**

Beverly Lorell, M.D., Vice President, Chief Medical and Technology Officer

Milton Morris, Ph.D., Director, Research and Technology

**HARVARD SCHOOL OF PUBLIC HEALTH**

Jeremy Nobel, M.D., Adjunct Lecturer on Health Policy and Management

**HEALTH DIALOG DATA SERVICE**

David Wennberg, M.D., President and Chief Operating Officer

**HEALTH HERO**

Julie Cherry, Medical Director

**HEALTH TECHNOLOGY CENTER**

Ravi Nemana, Senior Advisor

**HOMMED**

Kate Fruth, Director of Training and Communications

**INDIANA UNIVERSITY SCHOOL OF NURSING**

Susan Bennett, DNS, Professor

**INSTITUTE FOR HEALTHCARE ADVANCEMENT**

Gloria Mayer, President and Chief Executive Officer

**INSTITUTE FOR SOCIAL, BEHAVIORAL, AND ECONOMIC RESEARCH AT SANTA BARBARA**

Debra Lieberman, Ed.M., Ph.D., Lecturer and Researcher

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**INTERMOUNTAIN HEALTH CARE**

Kismet Rasmusson, Nurse Practitioner, Heart Failure Prevention and Treatment Program at Latter-Day Saints Hospital

**JOHNSON AND JOHNSON**

Youseph Yazdi, M.D., Corporate Director, Science and Technology

**KAISER PERMANENTE CARE MANAGEMENT INSTITUTE**

William Caplan, M.D., Director of Clinical Development

Paul Wallace, M.D., Executive Director

**LIFEMASTERS SUPPORTED SELFCARE, INC.**

Jeffrey Davis, M.D., Vice President for Medical Affairs

Chris Selecky, Chief Executive Officer

**LINDEN CONSULTING GROUP**

Ariel Linden, DrPH., President

**MASSACHUSETTS GENERAL HOSPITAL**

Jeremy Ruskin, M.D., Director, Cardiac Arrhythmia Service

**MAYO CLINIC, ROCHESTER, MINNESOTA**

Douglas Wood, M.D., Physician, Cardiovascular Diseases

**MEDICAL CARE DEVELOPMENT, INC.**

Richard Wexler, M.D., Medical Director

**MILLENNIUM PHARMACEUTICALS**

Fred Paster, Director of Strategic Marketing, Inflammation

**NORTHERN CALIFORNIA KAISER PERMANENTE**

Warren Taylor, M.D., Medical Director for Chronic Conditions Management

**PARTNERS HEALTHCARE**

Thomas Elliott, M.D., Director, Business Development

Joe Kvedar, M.D., Director, Partners Telemedicine

Nancy Lugn, Corporate Manager, Clinical Services, Partners Telemedicine

Beth Holbert, Nurse Practitioner

**PHILIPS MEDICAL SYSTEMS**

Dan Barton, Director, Marketing for E-Care Systems

David Freeman, Vice President, Cardiology Marketing

Philip Prather, Marketing Director, Cardiovascular CT

David Rollo, M.D., Ph.D., Chief Medical Officer, Nuclear Medicine

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**STONY BROOK UNIVERSITY SCHOOL OF HEALTH TECHNOLOGY AND MANAGEMENT**

Craig Lehmann, Ph.D., Professor and Dean

**TUFTS HEALTH PLAN**

Leslie Sebba, M.D., Medical Director of Secure Horizons

Robert LoNigro, M.D., Medical Director for Care Management

**TUFTS-NEW ENGLAND MEDICAL CENTER**

Christine Delano, Nurse Coordinator, SPAN-CHF

Marvin Konstam, M.D., Chief of Cardiology

**UNIVERSITY OF CALIFORNIA, DAVIS HEALTH SYSTEM**

Jana Katz-Bell, Chief Administrative Officer, Center for Health and Technology

**UNIVERSITY OF CONNECTICUT HEALTH CENTER**

Michael Azrin, M.D. Director, Cardiac Catheterization Laboratory

**UNIVERSITY OF MARYLAND MEDICAL SYSTEM**

Stephen Gottlieb, M.D., Director, Heart Failure and Transplantation

**UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM**

Lee Goldberg, M.D., Medical Director, Heart Failure Disease Management Program

**VERTEX PHARMACEUTICALS**

Tony Coles, M.D., Senior Vice President, Commercial Operations

**VETERANS HEALTH ADMINISTRATION**

Adam Darkins, M.D., Chief Consultant for Care Coordination

**VISITING NURSE ASSOCIATIONS OF AMERICA**

Michelle Kur, Nurse Practitioner, Visiting Nurses Association of Cleveland

Paula Wehrman, President and Chief Executive Officer, Visiting Nurses Association of Houston

**VITERION TELEHEALTHCARE**

Pramod Gaur, Ph.D., President and Chief Executive Officer



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## Appendix 4: Expert Panelists

On May 4, 2004 the New England Healthcare Institute's (NEHI) panel discussion of the value of emerging health care innovations brought together a range of experts to discuss the value and impact of RPM for heart failure.

NEHI would like to offer special thanks to all participants in our Expert Panel who so generously gave us their time, feedback and valuable input in our research and analysis.

*Dan Barton, M.B.A., M.S.*

Mr. Barton is the Director of Marketing for Philips Telemonitoring Services. Part of the New Ventures group within Philips Medical Systems, this division was formed to develop and promote innovation within the remote patient monitoring arena. Prior to launching Philips' Interactive Healthcare Services in 1999, Barton held a number of marketing management positions, including Product Manager for the Patient Monitoring Division's flagship product – Philips CMS, an acute-care patient monitoring system. Mr. Barton is a frequent speaker and advocate for the role of technology as a key enabler for the Disease Management industry. He sits on the National Advisory Board for the Rehabilitation Engineering Research Center on Technology for Successful Aging and participated in the White House Forum on Technologies for Successful Aging in 2000.

*Jeffrey M. Davis, M.D., M.P.H.*

Dr. Davis is the Vice President for Medical Affairs at LifeMasters Supported Care Inc. He brings in-depth experience in managed health care and in medical management to LifeMasters. Dr. Davis was formerly a senior medical director at FHP and the MetLife Healthcare Network of California/MetraHealth and, prior to joining LifeMasters, was the Senior Vice President and Chief Medical Officer of the San Jose Medical Group in Northern California. Dr. Davis has also served as an assistant professor at the University of Wisconsin School of Medicine and as an associate clinical professor at both the University of New Mexico and the University of California, Irvine Medical Centers. He is certified by the American Board of Pediatrics and also holds subspecialty board certification in Medical Genetics. He also has extensive experience in the medical informatics arena.

*Michael M. Givertz, M.D.*

Dr. Givertz is Co-Director of the Cardiomyopathy and Heart Failure Program at the Brigham and Women's Hospital and Assistant Professor of Medicine at Harvard Medical School. Dr. Givertz directs a comprehensive disease management program in heart failure and cardiomyopathy, with a focus on the management of acute decompensated heart failure. His research interests include the role of oxidative stress in myocardial failure, secondary pulmonary hypertension, and novel tools to assess hemodynamics. Dr. Givertz is a past research fellow of the American Heart Association and a current recipient of a career development award from the National Institutes of Health.

*Peter D. Goldbach, M.D.*

Dr. Goldbach is a Medical Director at Blue Cross Blue Shield of Massachusetts (BCBSMA). His major responsibilities include developing and maintaining successful relationships with providers; and assisting BCBSMA in developing and deploying successful programs in medical and pharmacy management, quality improvement and prevention, medical and payment policy, provider contracting, and peer review and credentialing. Dr. Goldbach's background includes 15

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years experience in medical administration, serving as a community hospital chief executive officer, medical director, trustee, and physician hospital organization (PHO) president as well as a medical director for a rehabilitation hospital, a transitional care unit, and a national home care business.

*Lee R. Goldberg, M.D., M.P.H., FACC*

Dr. Goldberg is Assistant Professor of Medicine at the University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania. He is also Medical Director of the Heart-Lung Transplantation Program at the Hospital of the University of Pennsylvania and is Medical Director of the Heart Failure Disease Management Program of the University of Pennsylvania Health System. Dr. Goldberg is board certified in internal medicine and cardiovascular disease. The author of numerous journal articles, abstracts and reviews, Dr. Goldberg's work has been published in the Journal of Clinical Epidemiology, Cardiovascular Drugs and Therapy, American Journal of Cardiology and The American Heart Journal. Dr. Goldberg is a Fellow of the American College of Cardiology, and a member of the American Heart Association, the International Society of Heart and Lung Transplantation, and the American Medical Association.

*Craig Lehmann, Ph.D., CC (NRCC), FACB*

Dr. Lehmann is Professor and Dean of Stony Brook University School of Health Technology and Management. During his tenure in the School of Health Technology and Management, Dr. Lehmann has held two administrative positions; Chair of the Department of Clinical Laboratory Sciences and Associate Dean of the School. As a registered clinical chemist and while in the department of Clinical Laboratory Sciences he established a national and international reputation for his contributions in lipid research, clinical laboratory integration, diagnostic technology, clinical laboratory economics, telemedicine, hematology imaging, web-based informatics, integrated delivery systems, home health care and clinical laboratory science education. In addition, for over twenty years he has served as a consultant to hospitals, integrated delivery systems, physician group practices, nursing homes, home health agencies and clinical laboratory diagnostic and informatic companies both nationally and internationally.

*Ariel Linden, DrPH, M.S.*

Dr. Linden is President of Linden Consulting Group, specializing in program design and evaluation for healthcare initiatives. Dr. Linden began his healthcare career as a clinical scientist, performing research in the areas of cardiovascular and pulmonary physiology. Dr. Linden has since worked at various health plans in the area of clinical quality improvement and research. His focus in the last three years has been on Disease Management, specifically evaluation strategies for determining program effectiveness. Dr. Linden has also been quite active in the MCO accreditation process, serving as a surveyor for the Accreditation Association of Ambulatory Health Care (AAAHC), and sitting on several nationwide boards and committees to improve the quality of care delivered to managed-care members.

*Robert Mittman, M.S., M.P.P. (Moderator)*

Mr. Mittman is founder of Facilitation, Foresight, Strategy. An experienced moderator, Mr. Mittman brings a multidisciplinary perspective to emerging technology and health care forecasting and planning. Mr. Mittman specializes in developing innovative approaches to modeling and forecasting under conditions of little or conflicting data. He is co-author of The Future of the Internet in Health Care: A Five-Year Forecast. He was also a contributing author

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of IFTF's annual Health Care Outlook report and of The Future of American Health Care, Vol. IV, Transforming the System: Building a New Structure for a New Century.

*William R. Taylor, M.D., M.P.H.*

Dr. Taylor is the Associate Regional Administrator and Director of the Division of Quality Improvement in the Boston Regional Office of the Centers for Medicare and Medicaid Services. He is responsible for the Medicare Quality Improvement Program in 16 states, including the New England region. Formerly, Dr. Taylor led the Georgia Medicaid agency and oversaw the launch of the Children's Health Insurance Program, expanded fraud detection and prevention, and began to measure the quality of health services. Dr. Taylor is an epidemiologist and scientist who has worked at the Centers for Disease Control and Prevention in public health, international health, cancer prevention and control, and program evaluation.

*Paula Wehrman, R.N., M.H.A.*

Ms. Wehrman is President and Chief Executive Officer of the Visiting Nurses Association (VNA) of Houston. In addition, she is also a Vice President of the Methodist Health Care System in Houston. Ms. Wehrman has a broad range of experience in for-profit and not-for-profit, hospital-based, and freestanding agencies. She currently serves on the Board of Directors of the Visiting Nurse Associations of America. Ms. Wehrman has been utilizing telemedicine for patient care in her agency for approximately four years. The VNA of Houston has been awarded several grants for telemedicine, including two that focus on utilizing telemonitoring in the care of congestive heart failure patients.

## Endnotes

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<sup>1</sup> Heart Disease and Stroke Statistics – 2004 Update. American Heart Association and American Stroke Association, 2004.

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

<sup>4</sup> Young, JB and Mills RM. Treatment of Decompensated or Refractory Heart Failure. Clinical Management of Heart Failure. West Islip: Professional Communications, 2001: 209-232. Cited at The Cost of Heart Failure. Medtronic. (Accessed June 24, 2004, at <http://www.medtronic.com/hf/physician/cost.html>).

<sup>5</sup> Nohria A et al. Quality of Care for Patients Hospitalized with Heart Failure at Academic Medical Centers. American Heart Journal, 1999; 137(6): 1028-1034.

<sup>6</sup> Krumholz HM et al. Readmission after Hospitalization for Congestive Heart Failure Among Medicare Beneficiaries. Archives of Internal Medicine, 1997 Jan 13; 157(1): 99-1-4.

<sup>7</sup> Rich MW et al. A Multidisciplinary Intervention to Prevent the Readmission of Elderly Patients with Congestive Heart Failure. New England Journal of Medicine. 1995 Nov 2; 333(18): 1190-5.

<sup>8</sup> Standard care for heart failure patients following a hospitalization typically includes patient education about medication, diet, and exercise and about symptoms and signs of decompensation, all given prior to hospital discharge. It also normally includes three physician visits in the first six months after discharge and may include follow-up nurse phone calls during the first two weeks after hospitalization.

<sup>9</sup> Heart Failure Epidemiology. Medscape. See also, Background Information on Heart Failure. Guidant. (Accessed June 24, 2004, at

<http://www.guidant.com/webapp/emarketing/newsroom/newspg.jsp?dir=heartfailure&file=backgrounder&pdf=y>).

<sup>10</sup> NIH Update: Statement on Sodium Intake and High Blood Pressure. National Heart, Lung, and Blood Institute, 1998. (Accessed June 8, 2004, at <http://www.nhlbi.nih.gov/new/press/17-1998.htm>).

<sup>11</sup> Ibid.

<sup>12</sup> This report uses the term heart failure rather than the term congestive heart failure. Heart failure is a clinical syndrome in which the either of the heart's ventricles is unable to pump at its normal capacity. Congestive heart failure is a more specific condition involving the accumulation of fluid in the lungs resulting from the dysfunction of the heart's left ventricle. The most recent heart failure clinical guidelines from the American Heart Association and American College of Cardiology state that, "Because not all patients have volume overload at the time of initial or subsequent evaluation, the term 'heart failure' is preferred over the older term 'congestive heart failure.'" (See ACC/AHA Clinical Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult. Introduction. American College of Cardiology and American Heart Association, 2001. (Accessed June 24, 2004 at, [http://www.acc.org/clinical/guidelines/failure/I\\_introduction.htm](http://www.acc.org/clinical/guidelines/failure/I_introduction.htm)) See also, What is Heart Failure? Heart Failure Online. (Accessed December 4, 2003, at [http://heartfailure.org/eng\\_site/hf.htm](http://heartfailure.org/eng_site/hf.htm)).

<sup>13</sup> Heart Disease and Stroke Statistics – 2004 Update.

<sup>14</sup> Ibid.

<sup>15</sup> Wiseman S, LeJemtel T H, Sonnenblick E H. Congestive Heart Failure in the Elderly. In: Cardiovascular Disease in the Elderly Patient. Tresch D and Aronow WJ, Ed. New York, NY: Marcel Dekker, 1999. Cited at Tangalos, E. Congestive Heart Failure: Nutrition Management for Older Adults. American Academy of Family Physicians. (Accessed June 24, 2004, at [http://www.aafp.org/PreBuilt/NSI\\_CHE.pdf](http://www.aafp.org/PreBuilt/NSI_CHE.pdf)).

<sup>16</sup> Heart Failure Epidemiology. Medscape. See also, Background Information on Heart Failure. Guidant.

<sup>17</sup> U.S. Interim Projections by Age, Sex, Race, and Hispanic Origin. U.S. Census Bureau, 2004. (Accessed July 2, 2004, at <http://www.census.gov/ipc/www/usinterimproj>).

<sup>18</sup> Ibid.

- <sup>19</sup> Foote SM. Population-Based Disease Management under Fee-For-Service Medicare, Health Affairs, July/August 2003; 22(4). Cited at Medicare's Chronic Care Improvement Pilot Program: What Is Its Potential. National Health Policy Forum Issue Brief; 2004; 797: p. 7-8.
- <sup>20</sup> U.S. and the Americas Investment Research, Congestive Heart Failure: A Major Device Opportunity? Morgan Stanley Dean Witter, 1999. Cited at Background Information on Heart Failure. Guidant. See also, Heart Disease and Stroke Statistics – 2004 Update.
- <sup>21</sup> Expert Interviews.
- <sup>22</sup> Young, JB and Mills RM. Treatment of Decompensated or Refractory Heart Failure. Clinical Management of Heart Failure, 2001. Cited at The Cost of Heart Failure. Medtronic.
- <sup>23</sup> Nohria A et al. Quality of Care for Patients Hospitalized with Heart Failure at Academic Medical Centers. American Heart Journal, 1999.
- <sup>24</sup> Heart Disease and Stroke Statistics – 2004 Update. See also Congestive Heart Failure. Lifespan. (Accessed June 24, 2004, at <http://www.lifespan.org/SvcLines/CardiacSvcs/Cardiology/CongHtFailure.htm>).
- <sup>25</sup> Market Impact Modeler. Health Technology Center and Solucient. See also Heart Disease and Stroke Statistics – 2002 Update. American Heart Association and American Stroke Association, 2002.
- <sup>26</sup> Flavel C and Stevenson LW. Take Heart With Heart Failure. Circulation, 2001; 101; e89-e91.
- <sup>27</sup> The New York Heart Association (NYHA) has developed a functional classification of heart failure, which is widely used to categorize heart failure patients according to the advancement of their symptoms. In 2001, the American Heart Association (AHA) and the American College of Cardiology (ACC) developed an additional classification, which complements the NYHA categorization and emphasizes the evolution and progression of heart failure, highlighting its treatments, rather than its symptoms. (See AHA/ACC Clinical Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult. Introduction. See also, Chavey WE et al. Guideline for the Management of Heart Failure Caused by Systolic Dysfunction. American Family Physician. American Academy of Physicians, September 1, 2001. (Available at, <http://www.aafp.org/afp/20010901/769.html>).
- <sup>28</sup> Heart Failure Epidemiology. Medscape.
- <sup>29</sup> Background Information on Heart Failure. Guidant.
- <sup>30</sup> Heart Disease and Stroke Statistics – 2004 Update.
- <sup>31</sup> AHA/ACC Clinical Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult. Therapy.
- <sup>32</sup> English M. and Mastream M. Congestive Heart Failure: Public and Private Burden. Critical Care Nursing Quarterly, 1995; 18: 1-6.
- <sup>33</sup> Expert Interviews.
- <sup>34</sup> English M, Mastream M. Congestive Heart Failure: Public and Private Burden. Critical Care Nursing Quarterly, 1995.
- <sup>35</sup> Ibid.
- <sup>36</sup> Krumholz HM et al. Readmission after Hospitalization for Congestive Heart Failure Among Medicare Beneficiaries, 1997.
- <sup>37</sup> Nohria A et al. 1999.
- <sup>38</sup> Faxon DP et al. Improving Quality of Care Through Disease Management: Principles and Recommendations From the American Heart Association's Expert Panel on Disease Management. Circulation. 2004; 109; 2651-2654.
- <sup>39</sup> Rich MW et al. A Multidisciplinary Intervention to Prevent the Readmission of Elderly Patients with Congestive Heart Failure, 1995.
- <sup>40</sup> Ibid.
- <sup>41</sup> Expert Interviews.
- <sup>42</sup> To facilitate their use, RPM devices are also available in multiple languages and can often “speak” questions for patients who cannot see well or read. Expert Interviews.
- <sup>43</sup> Krumholz HM et al. Readmission after Hospitalization for Congestive Heart Failure Among Medicare Beneficiaries. Archives of Internal Medicine, 1997.
- <sup>44</sup> Ibid.
- <sup>45</sup> Expert Interviews.
- <sup>46</sup> Agency for Healthcare Research and Quality, HCUP Nationwide Inpatient Sample (NIS), 2001 (ICD-9-CM 428.0, 428.1, 428.9).

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<sup>47</sup> A Quality Adjusted Life Year (QALY) is a figure that quantifies patient quality of life on a scale of 0 (lowest quality) to 1 (highest quality) and uses that number to assign lower values for years spent in poor health and higher values for years spent in good health.

<sup>48</sup> Expert Interviews.

<sup>49</sup> Expert Interviews.

<sup>50</sup> To calculate the potential regional and national cost savings of implementing RPM for heart failure, we estimated the number of Class III heart failure patients capable of using RPM who are not already in an intensive disease management program. We then applied the per-patient cost savings from our analysis to that population. Finally, we calculated the potential cost savings assuming varying levels of adoption.

<sup>51</sup> Darkins A. Care Coordination. Videotape Transcript. Department of Veterans Affairs Central Office Broadcast Center. April 22, 2004.

<sup>52</sup> VHA patients typically have more mental and non-mental health diagnoses than the general population. And seventy percent of them have an annual income under \$26,000, forty percent, under \$16,000. Darkins A. Care Coordination. Videotape Transcript. Department of Veterans Affairs Central Office Broadcast Center. April 22, 2004.

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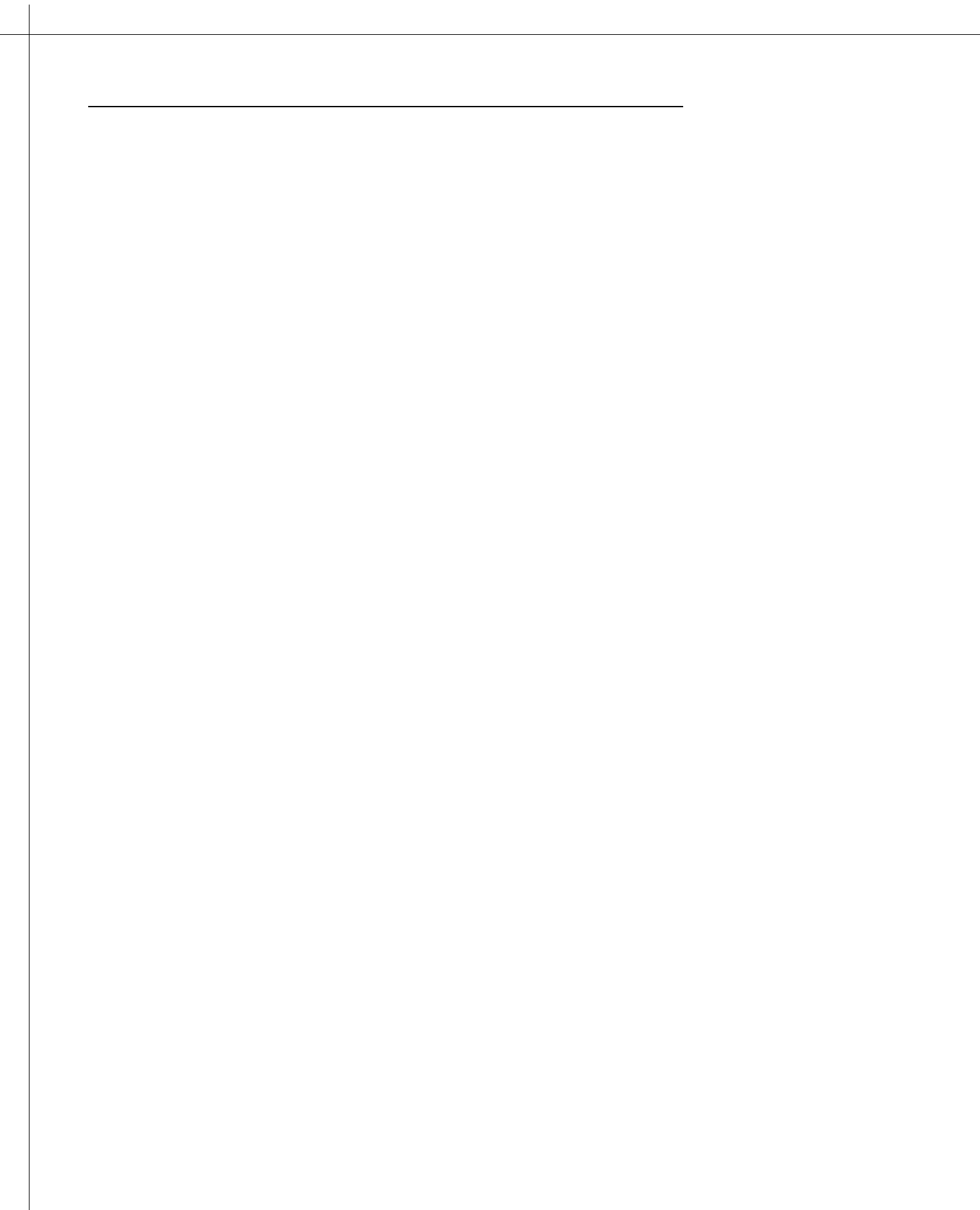
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- <sup>84</sup> Expert Interviews.
- <sup>85</sup> The SPAN-CHF project at New England Medical Center has currently enrolled 178 heart failure patients from all NYHA classes for 90 days after their heart failure hospital admission. The study compares two groups of patients both receiving standard disease management (including an education visit, weekly phone calls, medication checks, and access to heart failure clinicians at all times), in which one group also receives RPM, including a scale, blood pressure. Results from this study are not yet available, but the outcomes measured will be 90-day hospital utilization for heart failure and compliance to ACE inhibitor and Beta-blocker prescriptions. The project is titled, "Can Automated Home Monitoring Reduce Heart Failure Hospital Utilization and Augment Medication Compliance Compared with Non-Automated Standard Disease Management?"
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