Grant Final Report

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Home Heart Failure (HF) Care Comparing Patient-Driven Technology Models

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Abstract

Purpose: To assess the impact of health information technologies on clinical and financial outcomes for patients with symptomatic (NYHA Class II – IV) heart failure (HF).

Scope: To demonstrate that telemonitoring combined with Case and Self Management would improve outcomes for patients and reduce the overall cost of care over time and to provide a delivery model that could be replicated on a broad scale, in a variety of health care settings.

Methods: We evaluated two different configurations of health information technologies: 1) Technology Supported Case Management, a combination of telemonitoring and telephone nurse case management and 2) Technology Supported Self Management, which combines telemonitoring with an expert clinical decision support system that assesses vital signs and symptoms for risk of decompensation and guides patients through an individually tailored self-care algorithm.

Results: This study was closed to enrollment May 2007 and the last subject was dis-enrolled in March 2008. Final data was collected and entered May through June. Dr. Hornung is working on the final data stastical analysis which is expected to be completed by March 32, 2009.

Key Words: telemonitoring, technology supported case management, technology supported self management. cost reduction care management

Final Report

Purpose

The objective of this study was to assess the impact of health information technologies on clinical and financial outcomes for patients with symptomatic (NYHA Class II – IV) heart failure (HF). The information technologies included in this study included remote monitoring (telemonitoring) of vital signs and symptoms, an electronic health record system and clinical decision support systems. This study tested a scalable, reproducible model for technology-supported HF management, which we believed would assist purchasers, payers and policy makers in selecting health information technologies to improve clinical and financial outcomes.

Patients were recruited from geographically, socially and ethnically diverse settings: remote and rural areas of southern Montana and Northern Wyoming, including a Native American population, and African American, Caucasian and Hispanic patients in urban and suburban Philadelphia, and in 2005 patients were recruited in Charleston, South Carolina. Patients from all three geographic areas engaged in the study receive heart failure care in urban and rural primary care practices; the types of health care settings in which a large proportion of heart failure patients are treated nationwide.

We evaluated two different configurations of health information technologies. One was *Technology Supported Case Management*, a combination of telemonitoring and telephone nurse case management. The other was *Technology Supported Self Management*, which combined telemonitoring with an expert clinical decision support system that assessed vital signs and symptoms for risk of decompensation and guided patients through an individually tailored self-care algorithm. These two interventions had many features in common; for clarity, we referred to them as Case Management and Self Management throughout the study.

Scope

We chose this study because an estimated 4.8 million Americans have heart failure. Increasing prevalence, hospitalizations, and deaths have made heart failure a major chronic condition in the United States. Each year, there are an estimated 400,000 new cases. The annual number of deaths directly from heart failure increased from 10,000 in 1968 to 42,000 in 1993, with another 219,000 related to the condition. Heart failure is the leading primary admission DRG in the U.S., with nearly 900,000 admissions annually; an additional 1.8 million hospitalized patients have heart failure as a secondary diagnosis. Heart failure is the most common diagnosis in hospital patients age 65 years and older. During the past decade, hospitalizations for heart failure have increased among Medicare beneficiaries, and they are expected to increase with progressive aging of the U.S. population. In the 65+ group, one fifth of all hospitalizations have a primary or secondary diagnosis of heart failure. Heart failure patients are high users of nursing, home healthcare, physician services and hospitalization. In 2004 when this study began, the annual cost of caring for patients with heart failure was estimated to be approximately $40

billion. Although *mortality* for heart failure is declining, the growing number of older adults who require heart failure treatment will have a substantial impact on national health-care resources and expenditures. (Graves EJ. (1992); CDC/MMWR (1998))

As a result of complex clinical management problems, elders with heart failure have the highest hospital readmission rates, ranging from 29% to 47%. (Meinert 1986, Keogh 1987, Brest 1981, Poole-Wilson 1988) With more effective management, an estimated 1/3 to 1/2 of heart failure readmissions are preventable. (Keogh 1987, Poole-Wilson 1988, Benetar 2002.) Most episodes of decompensation are preceded by one or more days of changes in vital signs and symptoms. Our study proposed that daily telemonitoring would give clinicians an opportunity to make simple interventions while the patient is at home, avoiding the need for urgent care and hospitalization. We believed that the information technologies in the study we implemented could be easily integrated with existing electronic medical records and disease and case management programs.

The long-term goals of this project were to demonstrate, in real-world clinical settings, that telemonitoring combined with Case and Self Management would improve outcomes for patients and reduce the overall cost of care over time (including the cost of the interventions,) and to provide a delivery model that could be replicated on a broad scale, in a variety or urban and rural health care settings. Additionally, we hoped to demonstrate additional benefits of technology-supported Self Management that were unknown to the researchers at the implementation of this study four years ago.

The Self Management intervention was a unique feature of this study. It used information technology to perform many of the services of a case manager, including data surveillance, education and coaching. We believed that if Self Management can be shown to be better than Standard Care and equivalent to Case Management, we would have a technology system that can be used by small and large healthcare providers in a variety of settings: rural and urban, managed care, individual and group practice, home health and disease management, with consistent results across sites. Little specialized training would be needed, and no added personnel would be required.

We proposed that Self Management would also address the problem of specificity versus sensitivity inherent in most remote monitoring systems. Existing systems usually have single hard endpoints for alerts. If alert levels are set very close to normal, few if any serious situations will be missed (high sensitivity) but clinicians will respond to a lot of false alarms (low specificity.) If the alert levels are loosened, the rate of false alarms goes down, but the risk that a serious condition will not be flagged goes up. The expert clinical decision support system we proposed to test in the Self Management group included looking at trends and clusters of low- and medium-level conditions in addition to high-level alert conditions. This supports high levels of sensitivity and specificity.

We monitored progress toward these goals throughout the study, including daily review of new telemonitoring data, scheduled interviews with patients and regularly scheduled discussions with key personnel. Data collection, monitoring, coordination and analysis are described in detail in the study design section.

The specific goals of this project were as follows:

1. improvements in access to care,

2. improvements in quality of care;

3. reduction in costs (hospital, ambulance, home nursing); and/.or

4. improved patient involvement and satisfaction.

The proposed study was to assess the value of Health Information Technology (HIT) in diverse health care settings (e.g. outpatient clinics, home health, and community care), consider the perspective of various stakeholders (e.g., patients, providers and health care organizations), and include priority populations (e.g., low income groups; minority groups) the elderly; and individuals with special health care needs, including individuals who need chronic care or end-of-life health care.

Methods

The following hypotheses were tested:

Primary.

1. Case Management and Self Management will improve clinical outcomes, as evidenced by decreased heart failure related hospital and emergency room (ER) utilization and improved functionality.

2. Case Management and Self Management will reduce the cost of heart failure care by reducing ER, and hospital admissions and by reducing the need for coronary interventions including the use of ventricular pacing, ventricular assist devises and implantation or transplantation.

3. Management and Case Management will lead to equivalent improvements in heart failure related clinical outcomes.

Secondary.

4. Self Management will reduce the cost of heart failure care more than Case Management by eliminating the cost of nursing case management.

5. Assessment of Self Management patients' vital signs and symptoms by the expert clinical decision support system, coupled with tailored self-care algorithms, will improve patients' Self Efficacy in the management of their disease more so than in patients in the Case Management group.

6. Self Management and Case Management patients will have greater satisfaction with care than Standard care patients.

7. Physician's satisfaction will be higher with Self Management and Case management approaches to patient management than Standard care.

The outcomes that we measured included the following:

1. hospitalizations for Heart failure, cardiovascular and all causes;
2. hospital length of stay (LOS);
3. ER visits for heart failure, cardiovascular and all causes;
4. survival, mortality and fatal and nonfatal myocardial infarctions;
5. self-efficacy in management of heart failure as well as HRQoL and its dimensions assessed by the Kansas City Cardiomyopathy Questionnaire;
6. acute care visits to physicians; and
7. satisfaction with care

The system did not appear to have been tested by actual vendor staff from their homes and offices or it appears that some of the delays would have been identified early on; such as firewall issues to gain access to the existing system, the routing or hunts for the expert system, the faxed reports and printing of Alerts for the expert system and the headings as well as information documented on the reports for ease of reading by the clinician (physician, NP or nurse) in the practices. The researchers would not permit study arm II or III devices and modems to be placed in subject/patient homes until it had been well tested under various scenarios by the study team.

The study was placed on hold under Investigational Review Board (IRB) direction and approval in late March 2005. A pilot study was developed by the researchers and implemented on fourteen healthy human subjects under IRB approval in April 2005 utilizing the device and IVR to be utilized on subjects with HF, study arm III. The key researchers were then over six months behind in initiating and implementing enrollment.

The clinical site study teams then had to re-introduce the team and study to all participating practices. Full IRB approval of each clinical site was obtained to implement the primary study in mid- June 2005. The first subject was voluntarily consented and enrolled in the study on or about 6/22/2005. The actively participating clinical sites as of that time were University of Pennsylvania and St. Vincent Healthcare.

There were multiple ongoing administrative challenges that delayed the implementation of the study. Several of the primary challenges are outlined below:

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There were multiple ongoing administrative challenges that delayed the implementation of the study. Several of the primary challenges are outlined below:

1. Key Researchers were informed that enrollment was ready to begin as far as LifeLink Monitoring's prospective (vendor) as of early March 2005.

2. As of March, 2005, the key researchers had not been provided the vendors equipment, online access or paper documents for pilot testing to ensure accuracy prior to fully implementing the study on subjects/patients.

3. The researchers were provided by LifeLink the study arm II equipment for testing from the researchers home in early March; the following challenges/potential issues were identified:

    a. The researchers missed the initial introduction when picking up the phone to hear the introduction to LifeLink and the short sequence of questions.

    b. The researchers could not log on to see the reports on LifeLink's website; this was critical as this is the arm in which the Call Center case managers at St. Vincent Healthcare are managing the subject/patient population.

    c. Firewall Challenges: The IS department at St. Vincent worked over a week reconfiguring and providing additional access for the researchers at St. Vincent.

    d. This created additional delays as the research team could not complete online training on LifeLink Monitoring website until 3/21/05.

The researchers were provided the equipment on 3/18/05 in Philadelphia and 3/21 in Billings, to test the "expert" system (study arm III) and informed by the vendor that the system, equipment and reports had been "checked and validated" on multiple occasions.

a. Philadelphia team, began testing "expert" system over the weekend of 3/19/05.

b. Fax's of all reports were to be sent to B. Farberow, Project Director.

c. Project Director began receiving reports, though the "mock" patient had weight gains and losses of over 18 to 20 lbs, the reports came through documenting "no alerts". In a real life scenario, if this subject/patient had not contacted their physician and/or the physician was not in the office to receive and actually review the details, this would have been a hospital admission.

The research team was then requested to "stop" testing as they worked on the issues at LifeLink Monitoring. The key researchers were then informed mid-week of 3/21 that there was a problem with the "hunt" and routing to Arm II versus expert system by Verizon. Which was fixed, and the researchers were requested on 3/23 to begin another round of testing of the expert system.

There were additional administrative challenges that were encountered during the first year and several of those challenges extended well into year two of the award. The approval and implementation process of the Native American population in Montana and Northern Wyoming was one of the primary challenges identified. There were changes in tribal leadership during the first several months of full study implementation. In order for documents to be submitted on the reservation for IRB review and approval there had to be tribal signatures and approvals. This process was delayed until the last quarter of 2005. The tribe then assigned a nurse as the designated Clinical Research Coordinator (CRC). This CRC was trained by the St. Vincent and University of Pennsylvania research team. Dr. Goldberg made a site visit to the reservation clinic to meet the physicians onsite. January of 2006, this CRC resigned her position in the study and from the clinic on the reservation. March 2006, the CRC for St. Vincent Healthcare (also of native american descent) was approved to assume this role.

Amendments to the Protocol

December, 2005. The protocol inclusion criteria was amended to include cardiologist co-management of the patient population due to the early finding which supports the key researchers previous study outcomes; that the majority of the heart failure patients in the Philadelphia and Southern New Jersey region are not primarily managed by the PCP.

November, 2005. The protocol was amended to lift the criteria that a patient must have a documented heart failure admission or two emergency room admissions within the past 12 months, to "any documented heart failure admission or emergency room visit".

October, 2006. The protocol was amended to decrease data collection from 15 to 12 months to permit the CRC's primary focus to be on enrollment. The subjects/patients continue to have 9 months of active participation with 90 days or 3 months follow-up data collection.

Enrollment Challenges Prioritized

- Patients just do not want to be bothered or are overwhelmed
- Patients denial of the severity of disease process
- Refusal to participate in research
- Lack of physician support to discuss with patients during office visits primarily due to extremely busy practices
- Skilled Nursing Facility (SNF)
- Dementia
- Renal Failure

- Trying to reach patients (disconnected phones, changed numbers)

- Identification upon chart review or call initiated to subject/patient that they expired

Charleston Area Medical Center (CAMC) was added as an additional site to increase enrollment into this study July 2005 with full IRB approval.

CROW Indian Health Service center had an enrollment of only four subjects/patients and has been placed on hold for "active" screening as of October 2006 due to the following:

1. Direct conflict which was discovered only through chart review of a contract with CROW and Deaconess Hospital; also based in Billings, MT for cardiology care. This patient population is being enrolled in a CMS heart failure demonstration project, which is a exclusion criteria for this study.

2. Yield of enrollment for initial potential population with HF from initial list of >350 is less than .01%.

Results

Due to the delays in the technology development, development of the pilot study, completion and obtaining full IRB approval to proceed with the primary study, healthcare professional recruited and trained in the early part of year one had to be re-educated to the study to increase participation, support and identification of potential patients.

Challenges Encountered

1. Recruitment and Enrollment:

    a. Primary exclusion factors were; once potential patient was identified and then upon screening the medical record - skilled nursing facility (SNF), death (findings even after physicians have signed off that the patient maybe a good candidate for participation), renal disease (Creat. >3.0), end stage (hospice care or other terminal illness

    b. Primary factors for "hold or watch list"; patient did not have a qualifying event within the protocol required time period or patient has not had an Echo within the past 12-18 months or has had a CABG or Valvular replacement without a repeat Echo within 60-90 days post surgical event.

2. Patients refusal to participate or lack of interest due to the following reasons impacted target enrollment:

    a. Patient felt that they were doing OK with managing their heart failure

b. Patient was “too” ill

c. Patient “did not have the time and was not interested”

d. Patient was “traveling too much or has a winter and summer home not within the research area and does not want to take equipment”.

e. Physicians did not want patient to participate

f. Family did not want to help patient

3. Device Challenges:

   a. There were software challenges

   b. Challenges with devices (collectively or individually)

   c. LifeLink Monitoring team was inconsistent with responses to potential issues and attempts to correct any potential issue throughout the study.

4. Clinical Practice Challenges:

   a. Healthcare professionals did not review written reports

   b. Healthcare professionals did not file reports on medical record

   c. Healthcare professionals felt that there was too much documentation being faxed

   d. Healthcare professionals did not log onto LifeLink website to utilize the online software and report reviewing

   e. When asked to complete the final physician survey, there were physicians that refused to complete the survey stating on the document “that they did not actively participate through review of any reports or intervene due to the device.”

This study was closed to enrollment May 2007. The last subject was dis-enrolled in March 2008 from active study participation or intervention. Final data was collected and entered May through June on the last group of subjects. Dr. Hornung has utilized a student to work on the set-up of the final statistical analysis program over the last quarter of year 4.

Study Update (Challenges/Issues/Complaints)

Dr. Hornung’s team at the University of Louisville continues to work on the final data analysis which is expected to be completed by the end of March 2009. As requested by R. Mutter, Project Officer, he was notified that there were delays in the final data analysis. The final data analysis will be submitted to Mr. Mutter upon completion. However, due to the

continued delays, the final progress report is being submitted prior to completion of the final data analysis.

Incident Report

There have not been any significant incidents or patient complaints since the last report.

Monitoring Reports

The final dataset was locked by July 20th, 2008.

Regulatory

All clinical sites and the DCC have continued IRB approval for data collection and analysis until completion of the study.

List of Publications and Products

The first manuscript, Caveat Emptor: The Need for Evidence, Regulation, and Certification of Home Telehealth Systems for the Management of Chronic Conditions was published in the May/June edition of *The American Journal of Quality Medicine.*