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Using Innovative Methodologies From Technology and Manufacturing Companies to Reduce Heart Failure Readmissions

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Abstract

Heart failure (HF) patients have high 30-day readmission rates with high costs and poor quality of life. This study investigated the impact of a framework blending Lean Sigma, design thinking, and Lean Startup on 30-day all-cause readmissions among HF patients. This was a prospective study in an academic hospital in Baltimore, Maryland. Thirty-day all-cause readmission was assessed using the hospital's electronic medical record. The baseline readmission rate for HF was 28.4% in 2010 with 690 discharges. The framework was developed and interventions implemented in the second half of 2011. The impact of the interventions was evaluated through 2012. The rate declined to 18.9% among 703 discharges ($P < .01$). There was no significant change for non-HF readmissions. This study concluded that methodologies from technology and manufacturing companies can reduce 30-day readmissions in HF, demonstrating the potential of this innovations framework to improve chronic disease care.

Keywords

readmissions, heart failure, quality improvement, Lean Sigma, multidisciplinary

Heart failure (HF) affects 6.6 million people in the United States, accounting for almost 1 million admissions annually and contributing to 1 in 9 deaths.[1] High readmission rates, between 20% and 30%, have contributed to health care costs that exceed $35 billion each year.[2] Although HF management and lower readmissions have been a major priority among health care administrators and providers,[3] a national survey found that most strategies have not lowered readmission rates, and it is thought that most of the readmissions are preventable.[4] Common contributors to HF readmissions include the presence of diabetes, older age, having had prior hospitalizations, male sex, and other comorbid conditions such as depression, chronic lung disease, chronic kidney disease, and anemia.[5]

As a result of rising costs, payors have begun developing quality improvement initiatives such as value-based purchasing or pay for performance (P4P), which have become central to the reimbursement structure. For example, the Centers for Medicare & Medicaid Services has described measures that determine a hospital's performance. These include timely management of acute myocardial infarction, appropriate treatment of pneumonia with antibiotics, and discharge instructions for patients with HF. The emphasis on discharge instructions highlights one of the challenges of HF management and the importance of vigilance during transitions from inpatient to outpatient HF care.

The US health care industry is resource constrained, not unlike fledgling start-up companies in the business world where innovation is a necessity for entrepreneurs to keep their companies afloat. To provide quality, evidence-based, cost-effective care for patients, health care leaders also must innovate. Clinician innovators must work with a structured, iterative approach by first identifying problems, then developing small-scale solutions via

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early-stage prototyping. As a whole, the health care industry is still only beginning to understand how best to harness the transformative promise of innovation.[6] Industry leaders have employed many quality improvement techniques, some of which have had substantial success in creating value, improving customer satisfaction, and eliminating waste. Three of these methods are Lean Sigma, design thinking, and Lean Startup.

Lean Sigma is a combination of lean and Six Sigma. In the 1980s, the Toyota Production System developed the lean methodology to eliminate waste and create efficient processes.[7] It was unique in its emphasis on the frontline production worker's involvement in problem solving to completely understand the workflow. There also was a focus on creating value for customers. Health care leaders have been adopting lean principles for their quality initiatives in an attempt to achieve care that is high quality, safe, efficient, and appropriate.[8] Also in the 1980s, Motorola was facing increasing competition in the technological industry. This sparked the development of a formal process improvement structure that was customer centered, financially driven, and aimed for superlative quality or Six Sigma. The central goal was to minimize variance and reduce manufacturing defects to 3.4 defects per million opportunities.[8-13] Both lean and Six Sigma emphasize the use of a formalized approach to problems within an organization. These 2 strategies have been combined because of the overlap between some of the ideals and the synergy that results when they are applied together.[12-14] Both methodologies insist that before launching any process improvement initiatives, the process must be fully understood and the problem(s) clearly defined.[11]

Design thinking, also called human-centered design, is another process improvement methodology that has garnered recent success. Technology companies like Apple Inc. and IDEO have created successful customer-centered products by using design thinking concepts. The methodology attempts to understand people's needs and wants, often through direct observation, to power innovation.[15] IDEO, a not-for-profit design firm, has used design thinking tools to develop successful health care initiatives around the world.[16]

Lean Startup, used by Silicon Valley technology companies, relies on rapid and repeated experimentation with "validated learning" to achieve product–market fit.[17] Essential to the Lean Startup methodology is an entrepreneurial pursuit of solutions that are trialed and revised based on customer preferences. Of the methodologies described, Lean Startup is the newest and currently has the least data in the health care arena; however, biotechnology companies have begun to employ Lean Startup methods to improve health care products.[18]

Each technique has demonstrated ways to improve health processes,[1-4,6,8,12,19] but their combined impact on outcomes has not yet been validated in the health care arena. This study blended Lean Sigma, design thinking, and Lean Startup innovation techniques to redesign the care delivery service for adult HF patients. The study sought to assess the impact of the innovations framework on 30-day all-cause readmissions among HF patients.

Methods

Study Design

This prospective, pre-and-post intervention study was conducted at the Johns Hopkins Bayview Medical Center, an academic urban community hospital in Baltimore, Maryland, that admits 20 000 patients annually, approximately 700 of whom have HF as the primary reason for admission. A collaborative team of Johns Hopkins Lean Sigma experts was engaged as part of a 7-hospital system Joint Commission Center for Transforming Healthcare project for reducing readmissions among adult HF patients. Index HF admission and 30-day all-cause readmissions were determined using the hospital's electronic medical record (Meditech, version 5.6, data repository; Medical Information Technology, Inc., Westwood, Massachusetts). The Johns Hopkins institutional review board approved the study.

Interventions

A multidisciplinary team, including physicians, pharmacists, physiatrists, behavioral specialists, dietitians, and nurses, was convened to first identify problems, needs, and barriers to HF care. The goal was to develop patient-centered solutions for improving quality HF care that would reduce readmissions. The group employed the Lean Sigma Define-Measure-Analyze-Improve-Control (DMAIC) framework, process maps, and fishbone diagrams (Figure 1) to define the scope of the readmission problem, measure key determinants of readmission, and analyze root causes of readmissions. A fishbone diagram is one way to define a problem because it helps the user understand the various underlying contributors to a problem. Similarly, a root cause analysis delineates the factors integral to a problem and often uses a fishbone diagram and other tools during the analysis. Process maps help outline the steps of a process such that each can be parsimoniously interpreted and examined for its potential improvements. Lean Sigma emphasizes this structured approach to process improvement with objective measurements along the way.

After the problem of HF readmissions was better understood, the group began to develop solutions. Two of

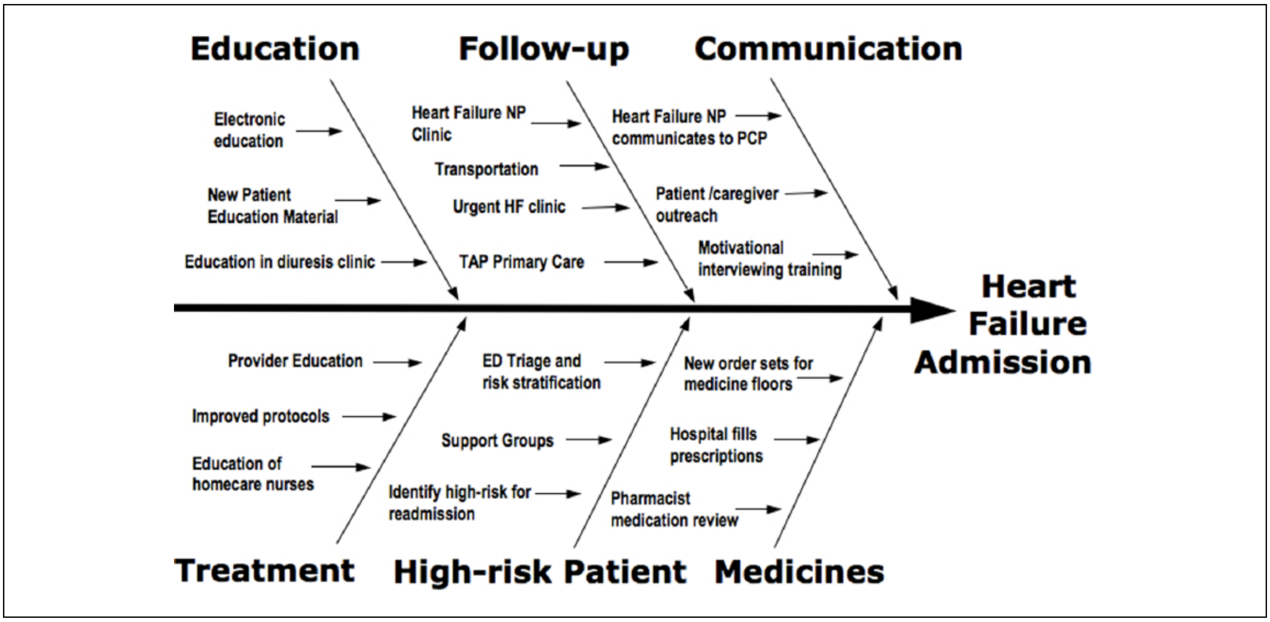

Figure 1. Fishbone diagram of root cause analysis.
Abbreviations: ED, emergency department; HF, heart failure; NP, nurse practitioner; PCP, primary care provider; TAP, The Access Partnership (an insurance program for low-income patients).

Table 1. Characteristics for 30-Day All-Cause Readmission Among Heart Failure Patients.

	Baseline (n = 690)	After Innovations Framework (n = 704)	*P* Value
Age, (mean years ± SD)	70.8 ± 14.5	69.3 ± 14.8	.06
Women, n (%)	352 (51)	345 (49)	.6
Diabetes, n (%)	338 (49)	373 (53)	.1
Length of stay (days ± SD)	5.4 ± 5.5	5.5 ± 5.1	.7

Abbreviation: SD, standard deviation.

the group members participated in a design thinking training with IDEO. The workshops inspired several hundred ideas, which were shared with the working group. Based on an understanding of the root causes, available resources, and institutional wisdom, the group began to develop solutions to be tested on a small scale. Minimum viable products are early-stage prototypes of interventions, which are developed rapidly, integrating careful observations from design thinking. Using continuous feedback in real time, the efficacy and uptake of these small-scale prototypes was observed. The most promising pilot interventions were expanded or modified and the least promising were abandoned.[17]

Concurrent to these efforts, a separate hospital-wide initiative had been undertaken in an effort to reduce readmissions for all patients using P4P measures. The hospital activities included screening patients for risk of readmission, interdisciplinary care planning, encouraging patient/family self-management, providing medications in hand at discharge, making follow-up appointments within 7 to 10 days, completing discharge summaries in 48 hours, and providing transition guides and/or home care for high-risk patients.

Data Analysis

Demographic data were collected using the hospital's electronic medical record. Age, sex, presence of comorbid diabetes, and length of stay were the baseline characteristics included in the data set (Table 1). These are among the factors that previously have been shown to affect readmissions.[5] There were no significant differences before or after implementation of the interventions.

The primary outcome was 30-day all-cause readmission rates among adult HF patients, with either systolic or diastolic dysfunction at baseline (calendar year 2010), compared to a one-year exposure period after the innovation interventions were implemented (calendar year

2012). Secondary outcomes included 30-day all-cause readmission rate comparisons between HF patients exposed to the innovation interventions and non-HF patients exposed to conventional quality improvement interventions. The avoided hospital charges were estimated using the average hospital charges at the Johns Hopkins Bayview Medical Center during the study period for a HF patient admission ($14 736).

Statistical Analysis

Comparisons of baseline and postintervention groups were conducted using *t* test for normally distributed continuous variables, Wilcoxon rank sum test for nonnormally distributed continuous variables, and χ^2 test for dichotomous variables. Chi-square tested the statistical significance between baseline and postintervention groups relative to 30-day all-cause readmissions; a *P* value of <.05 was considered statistically significant. All analyses were completed using Stata for Windows version 8.2 (StataCorp LP, College Station, Texas).

Results

Results of Quality Improvement Initiatives

A root cause analysis featured interviews with a number of stakeholders including randomly selected patients and a variety of providers. The root causes of HF readmissions included deficiencies in 6 areas (Figure 1). (1) Patient education was identified as a major barrier. Most patients in the hospital's catchment area had a third-grade reading level and a low health literacy level. The multidisciplinary team identified that the lack of health literacy created a barrier to care. (2) Heart failure medication regimens are complicated and require different medications to be taken several times throughout the day. Medication self-management including polypharmacy, medication changes, and cost of medications all contributed to readmissions. HF medication management was not optimized for patients. This sometimes occurred because providers were unclear of the recommended, evidence-based regimens. (3) Patient access to follow-up emerged as another cause of HF readmissions. Patients often did not have a follow-up appointment scheduled at the time of discharge. In the event of poor HF control, patients often would depend on the emergency department for access to care. (4) The multidisciplinary team also found that communication with providers was lacking. Inpatient and outpatient providers were not communicating at the time of discharge. Patients would receive differing and inconsistent messages from their providers. (5) Patient characteristics created a major problem for readmissions. Unfortunately, patients with HF have comorbid conditions that put them at risk for hospitalization. Additionally, a growing number of patients did not speak English as their native language. Ultimately, the most tenuous patients were not being adequately identified and risk stratified. (6) Furthermore, many patients were alone on returning home after discharge and lacked the adequate social support required to navigate the health care system. Self-care was identified as being a challenge for many of these patients.

Many different solutions were developed to address these deficiencies. As has been described, the interventions were intentionally small, "minimum viable products" during the initial stages. Low health literacy patient education materials were developed to address patient education. These were written by the providers who often cared for these patients and translated into several languages. An urgent HF clinic was established to address challenges with access and follow-up. A diuresis clinic was developed to aid patients who were not getting adequate diuresis with oral medications. This work has been described elsewhere.[20] For inpatient management, evidence-based order sets were incorporated into the computerized order entry system; these were designed to meet the needs of both trainees and hospitalists.[21] The order sets were implemented in April 2012 and have been used consistently by providers over time. Providers (physicians, midlevel providers, and nurses) also were educated about caring for HF patients. To aid with the transition between hospital and home, a nurse practitioner was hired, first on a part-time basis, to arrange postdischarge outreach to HF patients and their caregivers. This was done in collaboration with home care. Addressing patient characteristics was a major challenge that the multidisciplinary team attempted to solve with the development of a HF support program.

The HF patient support program serves as an example of rapid iteration using the Lean Startup methodology. Lack of patient support, particularly involving self-care, had been identified as a major contributor to readmissions in the root cause analysis. To improve this, a support program was created and pilot tested with a small group of volunteers recruited from the hospital's chaplain training program. The chaplain program was chosen based on their availability and willingness to help with the project. The chaplain trainees underwent 2 weeks of HF teaching. Compared with baseline, the pilot group of volunteers showed an increase in HF knowledge scores on the Dutch Heart Failure Knowledge Scale[22] and the Atlanta Heart Failure Knowledge Test Version 2.[23] HF advocates were then paired with patients to whom they would provide support. The initial response to this pilot intervention was unanimously positive. Both the patients and the advocates enjoyed the program. Therefore, the

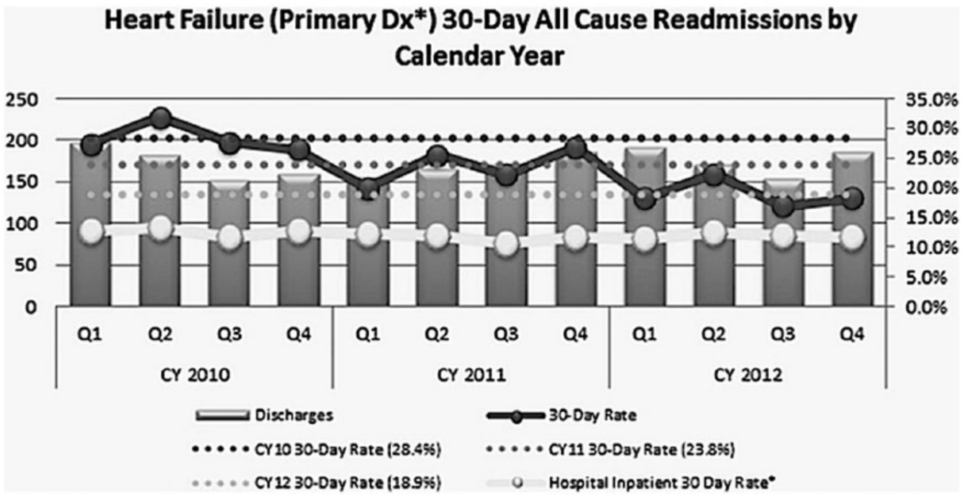

Figure 2. Impact of innovations framework on 30-day readmissions.
Abbreviations: CY, calendar year; Q, quarter.

pilot was expanded. As part of this project expansion, the limited number of chaplain trainees was replaced with more plentiful volunteers from the community. The new volunteers were trained and demonstrated improvement in HF knowledge scores similar to those of the pilot group. When the prototype was scaled up and implemented, however, the response was not as favorable as initially projected by the pilot. For example, patients expressed dislike for the intervention and did not want the volunteers to come into their homes. Feedback about the program suggested that a clinic-based approach, wherein meetings would be held at a central location (ie, the HF clinic), would be preferable. The multidisciplinary team decided to pivot away from the volunteer approach and instead developed a clinic-based support group for the HF patients.

Design thinking also was also central to the interventions. As an example, design thinking was used to develop order sets for providers caring for HF patients. Through observation of primary users of the HF order sets (interns, residents, midlevel providers, and hospitalists), it was determined that trainees wanted to reason through their own orders, while hospitalists and midlevel providers wanted a comprehensive set of all the recommended orders. Most users wanted orders to take into account HF patients who were in the hospital for non-HF reasons. To meet these needs, order sets were created that linked to evidence-based literature to facilitate resident education, included all recommended orders, and included a pared-down subset for patients for whom HF was a secondary diagnosis. After implementation, order set use gradually increased and then remained stable over the course of the intervention period.

Readmission Results After Implementation

The 30-day all-cause readmission rate was 28.4% of 690 discharges at baseline (2010) compared with 18.9% of 704 discharges after one year of exposure to the innovations interventions (2012) ($P < .01$). In contrast, the 30-day all-cause readmission rate among non-HF patients was 12.1% of 19 940 discharges at baseline and 11.6% of 19 978 discharges for the same time period ($P < .12$).

Figure 2 depicts the summative results of the interventions over time. The *y*-axis shows number of discharges on the left and the 30-day all-cause readmission rate on the right. The *x*-axis shows time, divided into quarters and calendar years. The bars represent number of HF discharges, the darker solid line shows the 30-day all-cause readmission rate of HF patients, and the lighter solid line shows the 30-day all-cause readmission rate of all patients, including those who did not have HF. The dotted lines represent average 30-day HF readmission rates for each of the calendar years studied.

There were 64 fewer HF admissions in 2012 than in 2010. In other words, 64 readmissions were prevented in 2012 compared to 2010, thus reducing the non-value-added service by an estimated $928 557. This is a 32% decrease in readmission rates. The cost of implementation included hiring a nurse practitioner and nurse, as well as the purchasing and publishing program supplies, all of which totaled $200 000.

Discussion

In this study, Lean Sigma, design thinking, and Lean Startup techniques were combined to improve HF care at an academic community hospital and led to a significant 32% reduction in the 30-day all-cause readmission rate for HF patients. The readmission rate decreased to less than 19% at a time when the national average readmission rate was 24.6%.[4] This is the first known study to combine these innovative methods, which saved payers almost $1056 per patient per year. If replicated nationally, this would translate to more than $1 billion in savings. Moreover, the innovation framework was more effective at decreasing 30-day all-cause readmission rates than were the baseline hospital-wide quality improvement interventions.

Lean Sigma provided a rigorous approach to root cause analysis and generated a conceptual framework around which interventions could be formulated. Design thinking allowed for reliance on the power of observation, an inherent component of health sciences training, to amplify idea generation and drive innovation. Lean Startup fostered a rapid and simultaneous experimentation process to test interventions. Together, these methods had the added benefit of taking advantage of local resources, promoting multidisciplinary teamwork, and channeling creativity—all while being technology agnostic.

When faced with unsuccessful efforts, it can be challenging to know when to pivot away. However, this is central to the iterative approach described herein and was highlighted with the advocate program example. Although the patient volunteer approach has shown success in Scotland,[24] it did not appear to have broad-based appeal in the study community and became increasingly difficult to implement. Efforts were made to alleviate social isolation among at-risk HF patients, which was initially successful in the pilot. Unfortunately, the larger scale iteration met resistance from participants who identified home visits as too intrusive for them. Instead, the participants preferred a group support meeting held at the outpatient clinic. Based on principles described in Ries' book,[17] it is important to keep your customer at the center of your actions. Iterative improvements must always be patient-centered.

The strengths of this study include evaluation of a community hospital setting. These methods had traditionally been reserved for manufacturing and non–health care service industries. Yet this study has shown that they can be applied in a hospital setting. Importantly, the study cohort demonstrated characteristics that are comparable to patients in a large national HF database, thus lending to the generalizability to the findings.[25] Furthermore, this novel intervention demonstrated success above what was achieved by a concurrent baseline intervention to reduce readmissions at the study hospital.

This study has some limitations. First, this observational study lacked randomization and creation of a control group. A group of patients from prior to the intervention served as a comparison for postintervention patients. This quasi-experimental design meant that the patients comprised a heterogeneous group for which many variables were impossible to control. Second, outcomes were tracked using the hospital's electronic medical record, which has many shortcomings in its ability to manipulate data. This rendered the multidisciplinary team incapable of selecting which comorbidities to include in the data analysis. This study was restricted to a single center and does not include data on how the present initiatives affected HF readmissions in other hospital systems. Additionally, when many interventions are implemented concurrently, it is difficult to isolate the effect of a single intervention on outcomes. Unfortunately, many details are unknown, including how 7-day follow-up changed or how much patient education improved. The implementation of standardized HF orders also was difficult to assess. The feeling is that the order sets led providers to think about the evidence-based recommendations even if they did not use the set in its entirety. These ancillary effects are difficult to assess. Nevertheless, the rate of use remained stable over the intervention period. The multidisciplinary team projected that the savings during the study would translate into even larger savings nationwide; however, there is an inherent lack of transparency in the health care financial structure, so exact figures are difficult to ascertain.

This study sought to reduce HF readmissions through multidisciplinary teamwork and innovative quality improvement. Other groups have been working to better understand and manage the cardiovascular mechanisms that comprise the complex HF disease process.[26] Similar to readmissions in HF, outcomes in chronic disease are the result of a complex interplay among patients, hospitals, and communities.[27] The methodologies in this study provided tools to understand the key determinants of HF patient readmissions. They facilitated the creation of interventions that leveraged existing resources and were tailored to meet local needs. If replicated in other centers, this innovation framework has the potential to revolutionize chronic disease care.

Declaration of Conflicting Interests

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