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The Effect Of Hospital Engagement Network Participation On Central Line-Associated Bloodstream Infections And Readmission Rates

Tyler Wallace

THE EFFECT OF HOSPITAL ENGAGEMENT NETWORK PARTICIPATION
ON CENTRAL LINE-ASSOCIATED BLOODSTREAM INFECTIONS
AND READMISSION RATES

by

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DEDICATION

To my family - Casey, James, Andrew, Isabella, and Lucy

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by

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PREFACE

As long as I can remember, I wanted a career in the healthcare field. However, I was unsure of my specific place in the industry. All I knew is that I wanted to make healthcare better. I discovered quality improvement methodologies (Certified Six Sigma Black Belt) and project management tools (Project Management Professional). Through my experience and web-based technologies, I became proficient at implementing change across institutions in geographically disperse locations.

I took an interest in Hospital Engagement Networks during their final year of implementation, 2014. I was caught up in the debate on whether large-scale quality improvement collaborations were effective at driving large-scale change. Simultaneously, I was perplexed with the lack of technology behind the HEN program's implementation strategy and methodology.

It is now five years since the first HEN program's completion, and to my knowledge, there have been no peer-reviewed articles evaluating the effectiveness of the HEN program compared to nonparticipants. Through my dissertation research, I hoped to understand whether the HEN programs were successful and how such large-scale quality improvement collaborations might improve in the future.

ACKNOWLEDGEMENTS

It is impossible to determine how much support it took from an amazing ensemble of individuals to help me through this process. First and foremost is my wife Casey who supported me every step of this journey. Casey, you showed a tremendous amount of patience along the way. Leaning on your strength carried me through to the end. To my children, you have also demonstrated an incredible amount of grace while daddy has worked on school. I am eagerly anticipating the increased time we will have together. Also, please know that “dissertation” is not a four-letter word, and you should aspire to obtain knowledge in whatever manner you choose.

Mom, thank you for taking care of my family so well during this time. Dad, thank you for instilling in me a farmer’s work ethic. My Ph.D. isn’t a reflection of my intellect; rather, it’s a manifestation of the ability to do what needs to be done and not quit. Susan, your pitching in to love my family well during this process was invaluable.

Dr. Charles Begley, who is both my dissertation chair and academic advisory, helped me navigate the complexities of the Ph.D. program. I appreciate your support and guidance through it all. Reflecting, it is humbling to see my naiveté at the onset to where I am today. You played an instrumental role in molding me during the process.

Thank you to my dissertation committee for pushing me to deliver high-quality work. Drs. Suja Rajan and James Langabeer, thank you for your responsiveness, critical feedback, and perseverance with me through this process. Dr. Patel, thank you for your wise input.

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Gemeinhardt, thank you for graciously providing feedback on my draft dissertation and for your conversations about career and life. These off subject conversations provided a new perspective on my career and challenged me to consider how to give back.

Laurie, as my executive coach, I know you were supposed to help me figure out my goals, professional strategy, and growth plan. However, I appreciate you deviating from norm to meet me where I was. Your ability to listen and provide feedback was priceless.

Chris, thanks for being an awesome leader and boss. It’s a pleasure serving under your leadership. Danielle, I could not imagine a better teammate. For all my work colleagues, I greatly appreciate your random check-ins and sincere concern for my well-being.

Dr. Jamil, after visiting the Writing Center and incorporating your feedback, my dissertation was “immensely improved.” Thank you for the vital service that you provide the institution.

To Mark, I’ve genuinely appreciated our friendship over the past four years. Thank you for talking me out of my dissertation topic change (and nihilism). I look forward with anticipation at how you’ll change the world.

To my church family, thank you for taking up my slack over the past four years and showing me grace upon grace. Thank you for co-leading small groups, hosting and participating in my mock dissertation defense, bringing my family meals, and being awesome.

Finally, I believe the individuals listed here, as well as many others not listed, were ultimately a means of God’s grace and love toward me for which I’m forever grateful. “May He help and strengthen all men in every good endeavor.” – John Coltrane

THE EFFECT OF HOSPITAL ENGAGEMENT NETWORK PARTICIPATION ON CENTRAL LINE-ASSOCIATED BLOODSTREAM INFECTIONS AND READMISSION RATES

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In 2012, the Centers for Medicare and Medicaid Services (CMS) launched the Hospital Engagement Network (HEN) program to decrease patient harm events in United States' (US) hospitals. The HEN program became the nation's largest quality improvement collaborative (QIC) focusing on improving patient care. Results from the program's formal evaluation were inconclusive on whether the HEN program was effective. There have been no other known studies on this program's effectiveness. Even with the evidence lacking, the CMS continues to fund programs similar to the HEN program. This study's research aim was to compare patient outcomes for HEN participants to nonparticipants to evaluate the program's performance.

The sample contained US hospitals with at least 25 beds and reported outcome data to Hospital Compare. A retrospective comparative analysis was performed on central line-associated bloodstream infection (CLABSI) standardized infection ratios (SIRs) and 30-day readmission rates for heart failure (HF), acute myocardial infarction (AMI), and pneumonia.

In both articles, pre-post trends were analyzed using fixed effects regression models to control for hospital characteristics and baseline performance.

For the first study, there were a total of 7,632 hospital years of data between HEN participants (6,374) and nonparticipants (1,258). The fixed effects regression model indicated that HEN participation did not reduce the CLABSI SIR in participating hospitals (p=.816). When the sample was divided into three groups based on baseline performance, the HEN participation coefficient (-.085) was moderately significant (p=.079) for the high performing group (lowest average CLASBI SIR in 2011). For the other two groups, medium (p=.960) and low performance (p=.848), the HEN participating coefficient was not significant.

The second study was based on a total 76,900 hospital years of data with 30-day readmission rates for HF (28,280), AMI (20,936), pneumonia (27,684). The pre-post fixed effect regression coefficients for HEN participation were varied for HF (.018, p=.639), AMI (-.073, p=.032), and pneumonia (.097, p=.003). When using full panel data, the fixed effect regression coefficients were similar to the original sample with 30-day readmission rates for HF(-.032, p=.439), AMI (-.148, p=.001), and pneumonia (.103, p=.014). The sensitivity analysis determined that HEN participants achieved superior AMI readmission improvements over nonparticipants before the HEN program commenced.

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BACKGROUND

Patient Safety

Patient harm events continue to be a persistent issue in the United States (US). The Institute of Medicine (IOM), now the Health and Medicine Division of the National Academies of Sciences, stated in its ground-breaking report that 44,000-98,000 patients die every year from medical harm events.[1] More recent studies have shown the patient harm events are still prevalent with little improvement.[2] These patient harm incidents include hospital-acquired conditions and associated readmissions. A hospital-acquired condition is a condition that presents during a hospital stay that was not present on admission.[3] The total cost of patient harm events in the US ranges between $17.1 billion[4] and $19 billion.[5]

Hospital Engagement Networks

In 2001, the IOM recommended that the US should invest in a $1 billion, three-to-five-year national patient safety initiative to catalyze a national safety movement.[6] In 2010, the Patient Protection and Affordable Care Act (ACA) commissioned the Department of Health and Human Services (HHS) to develop a national strategy for improving patient outcomes.[7] In 2011, HHS launched the Partnership for Patients (PfP) initiative with a $1 billion budget to reduce preventable hospital-acquired conditions by 40% and readmissions by 20%.[8,9]

The PfP initiative allocated $218 million to develop the Hospital Engagement Network (HEN) program.[8] The HEN program designated 26 organizations as “Hospital Engagement Networks” to lead hospitals through quality improvement initiatives. These

HEN organizations ranged from state hospital associations to public, for-profit companies. They were able to recruit over 3,700 hospitals to join their programs.[10]

The HENs were responsible for improving eleven patient harm events: central line-associated bloodstream infections (CLABSIs), adverse drug events, catheter-associated urinary tract infections (CAUTIs), injuries from falls, pressure ulcers, obstetrical adverse events, surgical site infections, venous thromboembolism, ventilator-associated pneumonia, preventable readmissions, and early elective deliveries.[8] In addition to focusing on these patient harm areas, the HENs were tasked with decreasing 30-day all-cause readmission rates by 20%.

While implementation models varied across the HENs, the American Hospital Association (AHA) recommended four improvement tactics:

> 1. Facilitate training through a combination of face-to-face meetings and webinars (with replay opportunities), monthly coaching calls, and hold quarterly individual calls with each participating hospital to provide assistance gauge implementation process, identify barriers and successes and to direct development of additional supporting resources
> 2. Require hospitals to report process measures to assure implementation of key process changes, and benchmark progress
> 3. Provide technical assistance when triggers are hit (outliers based on data)
> 4. Leadership Engagement and support of unit-level activities and needs to include rounding, understanding of data and regular reporting to Board and hospital staff.[11]

Between 2010-2014, the Agency for Healthcare Research and Quality (AHRQ) reported a 17-percent drop in hospital-acquired conditions (HACs) in the United States.[12] That same report stated the United States saved approximately $19.9 billion due to the reduction in HACs.[12] AHRQ could not directly credit the HENs with the improvements. However, the report mentioned the effects of the HEN’s catalytic effect on national patient safety improvements.[12] Several articles were published on the HEN programs' improvement effects on a smaller, localized scales.[13-17] The AHRQ report and additional published articles suggested that the HEN program was having a substantial effect. However, not all patient safety professionals were convinced about the program's effectiveness.

Several patient safety researchers have openly criticized the HEN program with three primary critiques.[18] The first criticism is that the HENs did not standardize outcome metrics, which would have allowed for standardized research across HENs. Second, all of the studies conducted on the effectiveness of HENs were lacking a control group. Finally, the data, methods, and research were not available for peer review.[18] The CMS's formal evaluation of the HEN program addressed the latter two concerns.

In 2015, Health Services Advisory Group, Inc (HSAG) and Mathematica Policy Research formally evaluated the HEN program's impact on patient harm events. These two research organizations used 2011-2014 data from Medicare claims, the Medicare Patient Safety Monitoring System, the National Healthcare Safety Network, the National Database of Nursing Quality Indicators, and the National Vital Statistics System.[19] The researchers utilized interrupted time series (ITS) analysis for detecting national trends in the HENs' eleven targeted patient harm areas and difference-in-difference (DID) regression analysis to estimate the HEN program's effectiveness compared to nonparticipants. Of all the HEN-targeted patient outcomes, the ITS analysis determined that only readmissions experienced a positive trend change.[19]

The evaluators performed a DID regression analysis on six of the eleven targeted patient outcomes. The DID analysis determined that the HEN hospitals performed better in three of the six patient outcomes with moderate probability, which was defined as 60% - 80% likelihood of cause. The three outcomes with a moderate probability of HEN's impact were venous thromboembolism (2-5%), pressure ulcers (25%), and central-line associated bloodstream infections (5-10%).[19] Ultimately, the formal evaluation concluded that the HEN program's "impact on outcomes and costs is inconclusive."[19]

While it appears that the formal evaluation supports the HEN critics, the HEN supporters countered back stating the lack of empirical evidence does not justify the HENs ineffectiveness at driving change.[20,21] These supporters argue that setting up robust process improvement metrics, running randomized control trials, and executing intricate research designs were not the intention of the HEN program. Indeed, the CMS intended the HEN program to drive rapid improvements in patient outcomes not serve as an academic model for robust research design.[20] Another prominent population health researcher stated that while quality improvement collaboration is laudable, the model needs additional peer review so decisions moving forward can be based on data.[22]

Despite the lack of evidence, the CMS continues forward with quality improvement collaborations similar to the HENs. The HEN program was followed by the Hospital Engagement Network Round 2 program, which launched in September 2015. In Round 2, CMS distributed $110 million for one year to 17 quality improvement organizations to continue HENs' original work.[23] In 2016, CMS announced a further continuation of the program with the Hospital Improvement and Innovation Networks (HIIN). CMS awarded $347 million to 16 organizations to improve on the work started by the HEN program. This program was funded from the end of 2016 through 2019.[24] The HIIN program combined the

HENs with the Quality Improvement Organizations (QIOs). One complaint of the HEN program was that its improvement effort was redundant because CMS had already established QIOs to assist with quality improvement efforts. The HIIN program brought together these two programs.

Literature Review

This literature review section is focused on quality improvement collaborations (QICs), specifically the HEN program. Due to the large number of studies on QICs, there was a strategic focus only to obtain systematic reviews. For the HEN program search, a more granular approach was needed, and all available published articles on HENs were reviewed.

Quality Improvement Collaboration Review

The search for QIC systematic reviews was through PubMed, Ovid Medline, and Primo. Systematic reviews are summary articles on a particular topic that use rigorous selection criteria. There were three known systematic reviews performed on QICs in the past decade. These reviews were published in BMJ (2008),[25] Milbank Quarterly (2013),[26] and BMJ Quality & Safety (2018).[27]

2008 Systematic Review

Schouten et al published their 2008 QIC systematic review, *Evidence for the impact of quality improvement collaboratives: systematic review*, in BMJ.[25] The review started with over 1,000 articles and concluded with nine studies that met the inclusion criteria. From those nine studies, two showed positive QIC effects, five showed mixed effects, and two showed no effect. The authors concluded that the impact of the QICs was positive but limited.[25]

2013 Systematic Review

Nadeem et al's systematic review, *Understanding the Components of Quality Improvement Collaboratives: A Systematic Literature Review*, was published in 2013 in Milbank Quarterly. This systematic review's purpose was to determine what implementation methods were consistent across QICs. Then the authors tied those components to improvements in provider-level behavioral change and patient-level outcomes. The authors only included articles with randomized controlled trials (RCTs) or observational studies that were quasi-experimental (i.e., controls included).[26]

For provider-level outcomes, there were nine studies with positive effects, eight with mixed effects, and two with no effect. For patient-level outcomes, there were three studies with positive effects, six with mixed effects, and four with no effects. These authors concluded that there was limited evidence for QICs overall effectiveness, especially for patient outcomes.[26]

2018 Systematic Review

Wells et al published their 2018 QIC systematic review in BMJ Quality & Safety.[27] The authors used the search methodology from Schouten et al's 2008 systematic review. The systematic review contained 64 studies with 39 in hospital settings. CLABSI was the outcome variable for over 20% of the hospital-based studies.[27]

There was a statistically significant improvement in at least one of the targeted outcomes in 83% of the hospital studies. The authors suggested that while the QICs appear mostly successful in achieving their aims, there was the possibility for multiple biases in those studies.[27] Upon reviewing all US-based studies included in this systematic review, there were no studies that mentioned the HEN program.

Hospital Engagement Network Review

A search was performed in Ovid Medline and Google Scholar for articles with "Hospital Engagement Network*" in the full text of articles (excluding citations).

General Descriptions of HEN Program

In the HEN program's first couple of years, several journals published articles about the HEN program as a potential way to improve.[28-30] These articles merely described the program and were not scientific.

Research Development

Several HEN organizations enabled research studies on qualitative research, observational studies, dissemination efforts, and best practices. HEN programs funded research indirectly or directly to provide HEN participants with evidence-based practices. One such program was a 10-year follow up study to Dr. Pronovost's foundational CLABSI study.[31] Also, HEN program staff also assisted with research studies, such as a review on regional variation in CAUTI rates.[32] One HEN reached out to its hospital members to have them identify research priorities and developed its research agenda accordingly.[33]

One of the ways HENs disseminated information was through published studies. Studies were published on patient and family engagement,[34,35] lean practices,[36] estimating costs of harm events,[37] ADE reductions,[38,39] CAUTI improvements,[40] maternal care best practices,[41] and readmission rates.[42]

Defining Terms and Metrics

HENs also served the purpose of performing research to solidify definitions of terms and validate quality improvement metrics. One HEN conducted an observational study to ensure the correct definition for the diagnosis of CAUTIs.[43] Another study validated outcome metrics for anticoagulant-associated hemorrhages.[44]

Protocols

Two research protocols were developed to utilize the HEN program to deliver interventions. However, no studies or results could be found from either protocol. One protocol proposed to evaluate transitional care effectiveness using mixed methods.[45] Another protocol was a prospective research study with 800 hospitals targeting CAUTI reductions.[46]

Outcomes

Published articles and studies with patient outcomes are listed in this section. These outcome studies were categorized into four study settings: 1) single hospital or unit 2) health system 3) HEN 4) state or national. As expected, the smaller, more focused studies generated more accurate data. As discussed in the background section, no studies used a control group.

Unit and Hospital

Three published studies documented HEN participating hospitals having an impact at the unit level. Warner et al documented the decrease of pressure ulcers in a hospital's burn unit.[17] Rhone et al recorded improvements in catheter insertion techniques in a 1,000+ bed hospital's emergency department.[47] Rosenberg et al reported CLABSI reductions in an academic medical center's large pediatric unit.[48]

Six published research articles on HEN improvement efforts came from individual hospital settings. Tuttle reported a CAUTI reduction in a 600-bed hospital's critical care units.[49] Story documented a 500-bed hospital decreasing overall CLABSIs.[50] Francis recorded a 230-bed hospital's reduction in Clostridium difficile infections.[51] Philips et al reported a 145-bed pediatric hospital's decline in the number of hospital-acquired conditions through the HEN program.[52] Adams et al documented a rural hospital's reduced readmission rates.[14] Kles et al recorded a 350-bed hospital's decreased surgical site infections.[53]

System

There were four studies at the system level, and these studies did not have the methodological rigor as the hospital and unit studies. Fakih et al documented catheter placement improvement in 18 emergency departments.[54] Frush et al recorded two health systems that showed overall safety culture improvements attributed to HEN participation.[55] Eugene A. Woods, president of then Carolinas HealthCare System, stated that HEN participation helped them to prevent over 13,000 patient harm events resulting in $80 million in cost savings.[56] Hendrich and Haydar reported how one health system used the HEN program as a step on its official high-reliability journey.[57]

Hospital Engagement Network

At the HEN level, twelve studies, including a mix of qualitative and quantitative methods, were published on HEN participation and outcomes achieved. One HEN decreased falls by almost 40% across 23 hospitals.[58] Two reports stated that rural hospitals, in particular, achieved broad performance improvement gains through the HENs.[59,60] Other studies at the HEN level included opioid awareness interventions,[61] decreasing patient falls,[62] and reducing early elective deliveries.[63] Two studies evaluated the effect of hospital leadership engagement within the HEN program.[64,65]

The Children's Hospitals' Solutions for Patient Safety (SPS) HEN had the most publications of all the HENs. The SPS HEN started with 33 hospitals and has since expanded. This HEN published improvement studies on surgical site infection reductions,[66] pressure injury declines,[67] and overall improvement gains.[68,69]

State/Nation

Only one study was published evaluating the HEN's impact on patient outcomes at the state level. California developed and sustained better maternal outcomes as a state compared to other states. The researchers cited the HEN program as one of the many programs that contributed to better outcomes.[70] One possible reason for the lack of HEN research at the state level is because HENs did not always operate within state boundaries. An Iowa-based qualitative study researched how the state attempted to increase cohesiveness between all the state-level quality improvement programs.[71]

On the national level, over a dozen publsiehd articles declared the HEN program's impact on improving patient outcomes. A report in the American Journal of Health-System Pharmacy stated that HENs had decreased adverse drug events by more than 40% across the nation.[13] In a 2018 Health Affairs article, Donald Berwick, former CMS administrator, cited the HENs as a success and an improvement model to be emulated.[21] Eleven articles mentioned that the HEN program played a role in improving patient care, but these articles did not provide any evidence of the program's effectiveness.[72-82]

Criticisms

Pronovost and Jha expressed three criticisms with the HEN program. The first criticism is that the HENs did not standardize outcome metrics, which would have allowed for standardized research across HENs. Second, all of the studies conducted on the effectiveness of HENs were lacking a control group. Finally, the data, methods, and research were not available for peer review.[18] Mendel et al published an article emphasizing the risk change fatigue brought about by a large number of national and regional quality improvement initiatives.[83]

Confounding Other Research

Ryan et al's article on readmissions and federal government interventions described how participating in value-based payment programs decreased readmissions. Their study's first limitation was that they could not control for all improvement activities underway at that time and explicitly cited the HEN program.[84]

Public Health Significance

The $212 million HEN program has yet to be proven effective at implementing large-scale change. The CMS's $9 million formal evaluation stated that the HEN program's "impact on outcomes and costs is inconclusive."[19] No known published studies have compared HEN participation to nonparticipation. The federal government continues to spend millions of dollars on QICs (e.g., HEN program), yet, there is no empirical evidence that hospitals participating in these programs achieve better outcomes than nonparticipants. This research study was the first known study to have evaluated patient care outcomes between

HEN participants and nonparticipants. The results from this study add to the discussion on whether national QIC programs should continue.

Conceptual Framework

Based on Donabedian's model, researchers at the University of Wisconsin-Madison developed an improvement model titled the Systems Engineering Initiative for Patient Safety (SEIPS).[85,86] The SEIPS model separated Donabedian's structural component into five areas within the work system: 1) the person 2) physical environment 3) organization 4) technology and tools 5) tasks.[86] At the center of the work system was the person who influences, changes, and improves the other structural components. These structural modifications influenced the care provided and ultimately, patient outcomes.

Figure 1 displays this study's conceptual framework which is built on Donabedian's model and the SEIPS model. When hospitals chose to participate in the HEN program, access to coaching, best practices, webinars, and other resources became available. A person at the hospital consumed this content improved work systems. As previously noted, changes to these work systems eventually improved patient outcomes. However, there were additional hospital characteristics which are also structural components, but these characteristics were not easily changed (bed size, disproportionate share (DSH), and case mix index (CMI). These structural attributes also influence care processes which affect patient outcomes (CLABSIs and readmissions for this study).

Figure 1: Conceptual Framework

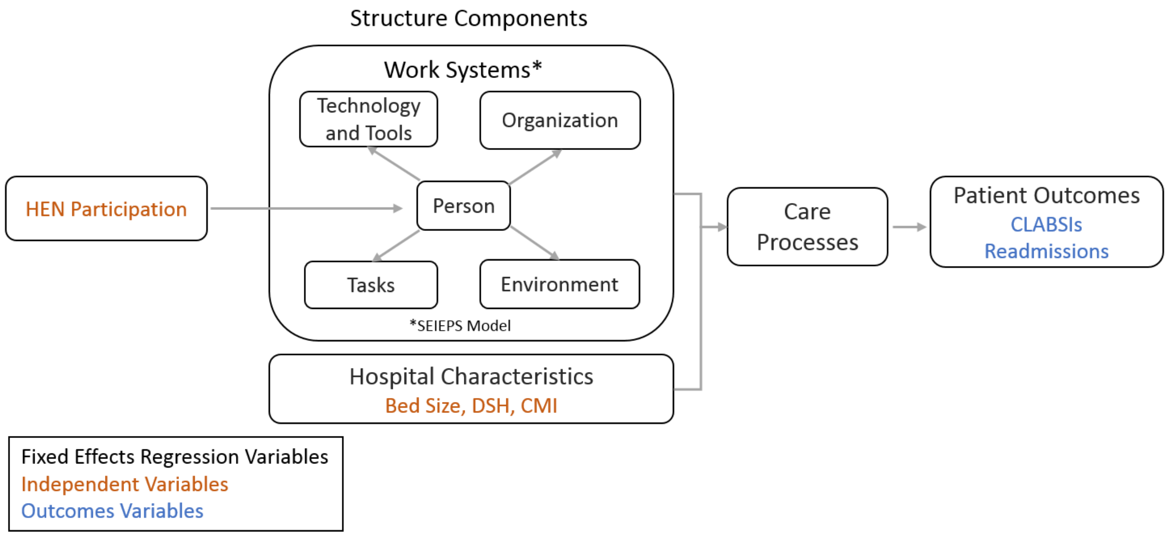

Figure 2 displays the HEN program's implementation overview from policy development through improved patient care outcomes. The ACA provisioned funding for Patient-Centered Outcomes Research Trust Fund (PCORTF) and Centers for Medicare and Medicaid Innovation (CMMI). The PCORTF endowed PCORI and AHRQ to fund research organizations to develop evidence-based practices (EBPs). The HENs disseminated EBPs through hospital quality improvement (QI) leads. The QI leads subsequently worked with multidisciplinary teams to change the hospitals' work system elements, as discussed previously in the conceptual framework. Again, using Donabedian's approach, the improved structural components facilitated better processes and ultimately improved outcomes.

Figure 2: Implementation Overview

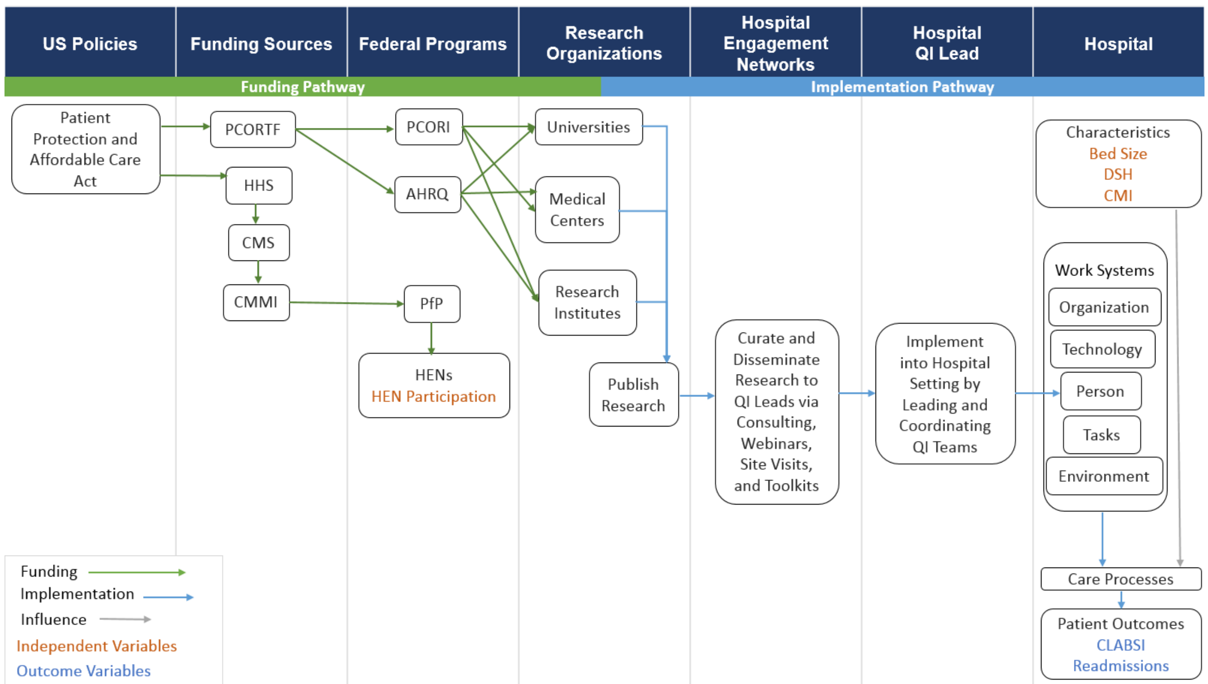

Table 1: Conceptual Framework Abbreviations

Conceptual Framework Abbreviations

Abbreviation	Term	Abbreviation	Term
AHRQ	Agency for Healthcare Research and Quality	HEN	Hospital Engagement Network
CLABSI	Central Line-associated Bloodstream Infection	HHS	Department of Health and Human Services
CMMI	Center for Medicare and Medicaid Innovation	PCORI	Patient-Centered Outcome Research Institute
CMI	Case Mix Index	PCORTF	Patient-Centered Outcomes Research Trust Fund
CMS	Centers for Medicare & Medicaid Services	PfP	Partnership for Patients
DSH	Disproportionate Share	QI	Quality Improvement

Aim and Research Questions

This study aimed to evaluate whether hospitals participating in a HEN obtained superior patient outcomes compared to hospitals that did not participate. This aim was achieved by answering two research questions: 1) Did HEN participation lead to decreased central line-associated bloodstream infections (CLABSIs)? 2) Did HEN participation lead to reductions in 30-day readmission rates for heart failure (HF), acute myocardial infarction (AMI), and pneumonia?

METHODS

Study Design

A retrospective comparative analysis was completed between HEN participants and nonparticipants with CLABSI SIRs and 30-day readmission rates (HF, AMI, pneumonia) as outcome variables. In the first article, CLABSI SIRs were compared between HEN participants and nonparticipants using a fixed effects regression model with annual data from 2011 through 2014. Similarly, in the second article, 30-day readmission rates were compared using a fixed effects regression model with 36-month rolling average data from 2008 through 2017. In both articles, pre-post trends were analyzed while controlling for hospital characteristics.

Data Collection

The research database consisted of data from several different public-use data files that linked individual hospitals using the Medicare Provider Identification Number. The outcomes (for CLABSIs and 30-day readmissions) were collected from the CMS's Hospital Compare archived data repository for a national sample of hospitals identified as general acute care with at least 25 inpatient beds.[87] Veterans Affairs (VA) hospitals, rehabilitation hospitals, dedicated cancer centers, children's hospitals, mental health facilities, psychiatric hospitals, and long-term care facilities were excluded. HEN participation was determined for the hospital sample from the "HEN Round 1 hospitals 2015" spreadsheet on the CMS Achieved Materials for the Partnership for Patients website.[88]

CMS annual impact files were used to determine core-based statistical areas (CBSA), US regional location, teaching hospital status, and disproportionate share (DSH) ratio. When available, the correction notice data was used instead of the final rule data. Ownership and state variables were obtained from the Hospital Compare's archived flat file "Hospital General Information." Hospital Compare's FY12 and FY18 files were used for the first and second article, respectively.

Data Variables

For article 1, the outcome variable, CLABSI SIR, was a ratio between observed and expected CLABSIs. Observed CLABSIs was the numerator, and the denominator was expected CLABSIs. Expected CLABSIs are adjusted based on the type of patients that the facility treats (e.g., patient care location, bed size of patient care location, and association with a medical school).[89] The SIR is interpreted similarly to an odds ratio (i.e., a SIR of below one represents the hospital had a fewer CLABSIs than expected).

For article 2, each hospital's HF, AMI, and pneumonia 30-day readmission rates were obtained for each year. The rates represent the moving average of 36-months of data. For instance, the fiscal year (FY) 2013 file contained data from July 2009 to June 2012. For the final year of the regression analysis, 2012, the readmission data from the FY13 file were used. The final year of the three-year moving average period was used for each study year. For example, 2010 through 2013 data were used for 2013. This method is commonly used when the three-year readmission rate is substituted for annual data.[84]

Time-invariant variables (US region, state, CBSAs, teaching designation, and ownership) were used as controls in the descriptive analyses and the ordinary least squares (OLS) regression models. The CMS impact file used the US Census Bureau's classification for regions: New England, Mid Atlantic, South Atlantic, East North Central, East South

Central, West North Central, West South Central, Mountain, and Pacific. The CBSA variable was categorized as large urban, other urban, or rural. The ownership variable was categorized into government-owned, private nonprofit, and for profit. To address skewness, the disproportion share ratio and the number of staffed beds variables were log-transformed.

Statistical Analysis

For both articles, the variables were categorized into time-invariant and time-varying for the descriptive analysis. The Hausman test was used to determine if a fixed effects or random effects regression model was best for the data. Hospital-level data were analyzed using several different multivariate fixed effects regression models with CLABSI SIR and 30-day readmissions as the dependent variables. The fixed effects regression model uses panel data to measure variation within a single hospital over time. In other words, this model uses each hospital as its own control.[90] The fixed effects model includes time-varying, independent variables for the number of staffed beds and the disproportionate share ratio. Case mix index (CMI) was included in the first article.

Article 1

For 2011 data, all hospitals were assigned to the control group since the HEN program did not commence until 2012. Then for 2012 through 2014 data, the HEN participants were assigned to the intervention group while keeping nonparticipants in the control group. This binary change from 0 to 1 for HEN participation enabled the capturing of a HEN participation coefficient.

The data were further analyzed to determine if the starting performance affected the HENs' impact on CLABSIs. The sample was divided into thirds based on 2011 CLABSI

SIRs, and a fixed effects regression model was conducted. Since there was only one period of pre-intervention data (2011), separating the sample this way controlled for possible bias. Hospitals were categorized as high performing (SIR <.25), average (SIR between .25-.69), or low performing (SIR >.7) with a third of the sample in each category.

Finally, the CLABSI SIR variable was zero in 16% of the observations. The CLABSI SIR was converted into a binary variable by coding hospitals that experienced a CLABSI as one and non-CLABSI hospitals as zero. The binary CLABSI SIR was regressed on time-varying, independent variables previously listed by using a logit fixed effects model. The statistical analyses were completed using Stata v14.2, College Station, Texas. [91]

Article 2

30-day readmission rates were graphed for ten periods and categorized by HEN participation and nonparticipation. An ordinary least squares (OLS) regression model of readmissions was estimated for 2008 through 2011 using a binary variable for HEN participation as a way to compare HEN participant to nonparticipant performance before the program started.

For the fixed effects model, a binary variable for HEN participation was zero for all hospitals through five periods (2008 through 2012). Starting in the sixth period (ending in June 2013), HEN participation was labeled as one and nonparticipation as zero. This variable allowed for testing the effect of HEN participation on the readmission rate while controlling for other time-invariant and time-varying variables. Hospitals with missing outcome data were removed, and the fixed effects regression model was executed again to determine if strongly balanced panels achieved the same results.

To check the validity of the model, two sensitivity analyses were performed. The first analysis determined the effect of changing the intervention period in the fixed effects model. In the original fixed effects regression, the HEN coefficient was assigned to the start of period six (July 2010 through June 2013). The HEN coefficient variable was then assigned to the start of periods four, five, and seven. The second analysis was to determine the HEN program's effect during and after the intervention. Periods nine (July 2013 through June 2016) and ten (July 2014 through June 2017) were omitted, and the fixed effects regression model was executed again.

Human Subjects, Animal Subjects, or Safety Considerations

The University of Texas School of Public Health's Institutional Review Board determined this study was exempt from human subjects' protection (HSC-SPH-18-0470, HSC-SPH-0376).

JOURNAL ARTICLE #1

Hospital Engagement Network Participation and Central Line-associated Bloodstream Infections

Journal of Patient Safety

Abstract

Objective

In 2012, the Partnership for Patients program launched the Hospital Engagement Network (HEN) program to reduce eleven types of patient harm events in United States hospitals. Evaluation research on the HEN program and other national quality improvement collaborations has yet to show definitive results. A formal evaluation of the HEN program determined that HEN participations probably outperformed nonparticipating in reducing three types of patient harm events, one of which was central-line associated bloodstream infections (CLABSIs). The effectiveness analysis was ultimately inconclusive.

Despite the lack of empirical evidence, the collaboration improvement model continued. There was a divide between individuals who believe the model should be continued and others who want the model to be further validated as effective. The purpose of this study was to provide further evidence of the impact of the HEN program by replicating the findings of the formal evaluation regarding HEN-attributable CLABSI improvement in participating hospitals using a national dataset and multiple regression analyses.

Methods

We completed a comparative retrospective analysis of the CLABSI standardized infection ratio (SIR) from 2011 through 2014 in 1,650 HEN hospitals and 329 control hospitals. The CLABSI SIR was regressed on time-varying, independent variables using a fixed effects model. The regression model was reestimated separately for hospitals categorized as high, medium, and low performers based on 2011 CLASBI SIR data. In addition, a logit fixed effects regression model was used to test the relationship by converting the CLABSI SIR into a binary dependent variable for CLABSI occurrence.

Results

The fixed effects regression model indicated that HEN participation did not reduce the CLABSI SIR in participating hospitals (p=.816). When the sample was divided into three groups based on baseline performance, the HEN participation coefficient (-.085) was significant at the 10% confidence level only for the high performing group (lowest average CLASBI SIR in 2011, p=.079). For the other two groups, medium SIR (p=.960) and low SIR (p=.848), the HEN participating coefficient was not significantly better than controls. The logit model also produced a nonsignificant HEN coefficient (p=.786).

Conclusions

This study was unable to show that HEN participation generated CLABSI improvement over the study period using a national hospital database and different regression models. However, there was a slight improvement in high performing hospitals. Additional research is needed to determine if the program may have improved other patient harm events targeted by the HEN program.

Introduction

In 2001, the Institute of Medicine (IOM) recommended that the United States (US) invest in a $1 billion, three- to five-year national patient safety initiative to catalyze a national safety movement.[1] Nearly a decade later, the Patient Protection and Affordable Care Act (ACA) commissioned the Department of Health and Human Services (HHS) to develop a national strategy for improving patient outcomes.[2] In 2011, HHS launched the Partnership for Patients (PfP) initiative with a $1 billion budget to reduce preventable hospital-acquired conditions by 40% and readmissions by 20%.[3,4]

The PfP initiative allocated $218 million to develop the Hospital Engagement Network (HEN) program.[3] The HEN program designated 26 organizations as "Hospital Engagement Networks" to lead hospitals through quality improvement initiatives. These HEN organizations ranged from state hospital associations to for-profit companies. The HENs were able to recruit over 3,700 hospitals to join their programs (roughly 72% of all US hospitals).[5]

The HENs were responsible for improving eleven patient harm events: central line-associated bloodstream infections (CLABSIs), adverse drug events, catheter-associated urinary tract infections, injuries from falls, pressure ulcers, obstetrical adverse events, surgical site infections, venous thromboembolism, ventilator-associated pneumonia, preventable readmissions, and early elective deliveries.[3]

Implementation models varied across the HENs, but all followed the four American Hospital Association (AHA) recommended improvement tactics:

> “1. Facilitate training through a combination of face-to-face meetings and webinars (with replay opportunities), monthly coaching calls, and hold quarterly individual calls with each participating hospital to provide assistance gauge implementation process, identify barriers and successes and to direct development of additional supporting resources
>
> 2. Require hospitals to report process measures to assure implementation of key process changes, and benchmark progress
>
> 3. Provide technical assistance when triggers are hit (outliers based on data)
>
> 4. Leadership Engagement and support of unit-level activities and needs to include rounding, understanding of data and regular reporting to Board and hospital staff.” [6]

Initial reports appeared that the HENs achieved significant patient harm improvements. Between 2010 through 2014, AHRQ reported a 17 percent drop in hospital-acquired conditions (HACs) in the US.[7] That same report stated the US saved approximately $19.9 billion due to the reduction in HACs.[7] AHRQ could not directly credit the HENs with the improvements. However, the report mentioned the HENs catalytic efforts on reducing patient harm.[7] Numerous studies were published suggesting HEN participants had decreased patient harm events, but none of these studies used control groups.[8-12] While the HEN outcomes appeared promising, not all patient safety professionals were convinced.

Several patient safety researchers have openly criticized the HEN program with three primary critiques.[13] The first is that the HENs did not standardize outcomes metrics which would have allowed for standardized research across HENs. Second, all research studies conducted on the effectiveness of HENs before 2014 were lacking a control group. Finally, the data, methods, and research were not available for peer review.[13] CMS commissioned a formal evaluation of the HEN program to address the latter two concerns.

In 2015, Health Services Advisory Group, Inc (HSAG) and Mathematica Policy Research formally evaluated the HEN program’s impact on patient harm events. These two research organizations used 2011 through 2014 data from Medicare claims, the Medicare Patient Safety Monitoring System, the National Healthcare Safety Network, the National Database of Nursing Quality Indicators, and the National Vital Statistics System.[14] The researchers utilized interrupted time series (ITS) analysis for detecting national trends in the HENs' eleven targeted patient harm areas difference-in-difference (DID) regression analysis to estimate the HEN program's effectiveness compared to nonparticipants. The ITS analysis determined that none of the patient harm areas experienced a national positive trend change.[14] The DID analysis determined that the HEN hospitals performed better in three of the six patient outcomes with moderate probability, defined as 60% to 80% likelihood of causality. The three outcomes with a moderate probability of the HEN's impact were venous thromboembolism (2-5%), pressure ulcers (25%), and CLABSIs (5-10%).[14]

Ultimately, the formal evaluation concluded that the HEN program's "impact on outcomes and costs is inconclusive."[14] While it appeared that the formal evaluation did not validate the HEN program's effectiveness, HEN supporters countered by stating the lack of empirical evidence did not justify concluding that the HEN program was ineffective in driving change.[15,16]

One leader in population health stated that while quality improvement collaboration is laudable from a theoretical perspective, the industry needs empirical evidence for decisions.[17] Despite the lack of evidence, CMS continued with quality improvement collaborations similar to the HENs.

The purpose of this study was to contribute to the HEN discussion by evaluating the effectiveness of the HENs in decreasing CLABSIs compared to nonparticipants. It is the first known study to examine the HEN program's outcomes with a nonparticipating control group. The outcome variable was the CLABSI standardized infection ratio (SIR) as documented in Hospital Compare. The focus on CLABSIs was because the formal evaluation found a moderate probability of likelihood of HEN hospitals outperforming nonparticipants on this particular measure, and CLABSI data were publicly available.

Methods

Study Design

We compared CLABSI SIRs between HEN participants and nonparticipants using a fixed effects regression model with annual data for 2011 through 2014. Pre-post trends were analyzed while controlling for hospital characteristics. The University of Texas School of Public Health's Institutional Review Board determined this study was exempt from human subjects' protection.

Data Collection

The research database consisted of data from several different public-use data files that linked individual hospitals using the Medicare Provider Identification Number. We collected CLABSI outcome from the CMS's Hospital Compare archived data repository for a national sample of hospitals identified as general acute care with at least 25 inpatient beds.[18] Veterans Affairs (VA) hospitals, rehabilitation hospitals, dedicated cancer centers, children's hospitals, mental health facilities, psychiatric hospitals, and long-term care facilities were excluded. HEN participation was determined for the hospital sample from the "HEN Round 1 hospitals 2015" spreadsheet on the CMS Achieved Materials for the PfP website.[19] CMS annual impact files for fiscal years (FY) 2012 through 2015 were used to determine core-based statistical areas (CBSA), US regional location, teaching hospital status, and disproportionate share (DSH) ratio. When available, the correction notice data was used instead of the final rule data. Ownership and state variables were obtained from the Hospital Compare's FY12 archived flat file "Hospital General Information."

Data Variables

The outcome variable, CLABSI SIR, is a ratio between observed and expected CLABSIs. The numerator was observed CLABSIs with the denominator as expected CLABSIs. Expected CLABSIs are adjusted based on the type of patients that the facility treats (e.g., patient care location, bed size of patient care location, and association with a medical school).[20] The SIR is interpreted similarly to an odds ratio (i.e., a SIR of below one represented the hospital had a fewer CLABSIs than expected).

Time-invariant variables (US region, state, CBSAs, teaching designation, and ownership) were used as controls in the descriptive analyses and the ordinary least squares (OLS) regression models. The CMS impact file used the US Census's classification for regions: New England, Mid Atlantic, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific. The CBSA variable was categorized as large urban, other urban, or rural. We categorized the ownership variable into government-owned, private nonprofit, and for profit. We log-transformed the disproportion share ratio and the number of staffed beds variables to address skewness.

Statistical Analysis

The variables were categorized into time-invariant and time-varying for the descriptive analysis. The Hausman test was used to determine if a fixed effects or random effects regression model was best for the data. We analyzed hospital-level data using several different multivariate fixed effects regression models with CLABSI SIR as the dependent variable. The fixed effects regression model uses panel data to measure variation within a single hospital over time. In other words, this model uses each hospital as its own control.[21] The fixed effects model includes time-varying, independent variables for the number of staffed beds, DSH ratio, and case mix index (CMI).

To capture HEN participation, we assigned the binary variable of 0 for nonparticipation and 1 for participation. This change from 0 to 1 in HEN participation enabled us to capture a coefficient for HEN participation. For 2011 data, we assigned all hospitals with a variable of 0 since the HEN program did not commence until 2012. Then for 2012 through 2014 data, we assigned HEN participants with a 1 for the HEN participation variable.

We further analyzed the data to determine if the starting performance affected the HENs' impact on CLABSIs. We divided the sample into thirds based on 2011 CLABSI SIRs and conducted a fixed effects regression model. Since there was only one period of pre-intervention data (2011), separating the sample this way controlled for possible bias. We categorized hospitals as high performing (SIR <.25), average (SIR between .25-.69), or low performing (SIR >.7) with a third of the sample in each category.

Finally, the CLABSI SIR variable was zero in 16% of our observations. We converted the CLABSI SIR into a binary variable by coding hospitals that experienced a CLABSI as one and non-CLABSI hospitals as zero. We then regressed the binary CLABSI

SIR on time-varying, independent variables previously listed by using a logit fixed effects model. The statistical analyses were completed using Stata v14.2, College Station, TX. [22]

Results

Descriptive Statistics

Our sample contained 1650 HEN participating hospitals from each of the 26 HENs and 329 nonparticipating hospitals. Our sample's HEN participation rate of 83% was well above the national average of 72%. We addressed this disparity as a limitation in the discussion section.

Table 1 displays the time-invariant characteristics of the hospitals. HEN participation was disproportionately smaller in the West South Central Region (Oklahoma, Arkansas, Texas, Louisiana) and South Atlantic Region (Maryland, Delaware, West Virginia, Virginia, North Carolina, South Carolina, Georgia, Florida, District of Columbia). Another difference between the two groups was the high proportion of for-profit hospitals in the nonparticipation group. Finally, while the majority of HEN participants were teaching hospitals, this was only true for a third of the nonparticipants.

Table 1: Descriptive Statistics for Time-invariant Variables

Descriptive Statistics for Time-invariant Variables

Variables	HEN Participants *n (% of sample)*	Nonparticipants *n (% of sample)*
Region		
New England	66 (4.04%)	25 (7.67%)
Mid Atlantic	251 (15.35%)	7 (2.15%)
South Atlantic	285 (17.43%)	97 (29.75)
East North Central	263 (16.09%)	48 (14.72%)
East South Central	110 (6.73%)	19 (5.83%)
West North Central	111 (6.79%)	8 (2.45%)
West South Central	167 (10.21%)	65 (19.94%)
Mountain	115 (7.03%)	18 (5.52%)
Pacific	267 (16.33%)	39 (11.96%)
Geography		
Rural	139 (8.5%)	14 (4.29%)
Small Urban	627 (38.35%)	133 (40.8%)
Large Urban	869 (53.15%)	179 (54.91%)
Teaching		
Yes	832 (50.89%)	121 (37.12%)
No	803 (49.11%)	205 (62.88%)
Ownership		
Government	222 (13.72%)	22 (6.92%)
Private Nonprofit	1,170 (72.31%)	148 (46.54%)
For Profit	226 (19.32%)	148 (46.54%)

Table 2 displays the time-varying hospital characteristics from the 2011 data that were used in the fixed effects regression model and the CLABSI SIR by year. On average, nonparticipants had a lower case mix index, fewer beds, and higher disproportionate share ratio than the HEN participants. The CLABSI SIR was lower for HEN participants than nonparticipants in each of the four years. Moreover, the average CLABSI SIRs decreased every year for both HEN participants and nonparticipants.

Table 2: Descriptive Statistics for Time-varying Variables in 2011

Time-varying Hospital Characteristics in 2011

	HEN Participants	Nonparticipants	
Variables	*Mean (sd)*	*Mean (sd)*	*P-value (t-test)*
Fixed Effect Variables			
Case Mix Index (2011)	1.59 (.226)	1.54 (.253)	<.001
Beds (2011)	284.7 (191.4)	242.0 (179.8)	<.001
DSH Ratio (2011)	.285 (.17)	.312 (.20)	<.02
CLABSI SIRs by Year			
2011	.549 (.604)	.661 (.689)	<.001
2012	.559 (.526)	.648 (.640)	<.001
2013	.512 (.479)	.583 (.591)	<.03
2014	.454 (.442)	.569 (.697)	<.001

Fixed-effects Results

The Hausman test (p<.01) confirmed that only the fixed effects regression model should be estimated for both the fixed effects regression and logit regression with fixed effects.

Table 3 displays the results of our first fixed effects regression model. The HEN participation coefficient was .007 (p=.816). The only independent variable with a statistically coefficient was 2014. On average, all hospitals had lower CLABSI SIRs in 2014 compared to 2011, with a statistically significant coefficient of -.089 (p=.005).

Table 3: CLABSI SIR Fixed-effects Regression

CLABSI SIR Fixed-effects Regression

Variables	*Coefficient*	*P-value*	*95% C.I.*	
In Hen				
No (reference)				
Yes	.007	.816	-.056	.071
Beds (log)	-.076	.379	-.247	.094
DSH (log)	-.003	.940	-.093	.086
CMI	-.010	.374	-.319	.120
Year				
2011 (reference)				
2012	.003	.918	-.058	.064
2013	-.046	.138	-.108	.015
2014*	-.089	.005	-.152	-.027

* Statistically significant at p < .05

Table 4 summarizes the results of the fixed effect regression model when the sample was divided into thirds based on 2011 CLABSI SIRs. Based on the baseline year of 2011, hospitals were categorized as high performing (SIR score <.25), average (.25-.69), or low performing (>.7). The only group with a significant HEN participation coefficient was the high performing group (-.085, p=.079). Both high performing and low performing groups experienced a regression to the mean by having three statistically significant years (2012, 2013, 2014) compared to their 2011 baselines (p<.001).

Table 4: Fixed Effects Regression with SIR Score Grouped by 2011 Baseline

Fixed Effects Regression with SIR Score Grouped by 2011 Baseline

Variables	**High Performing** *Coefficient*	*P-value*	**Average** *Coefficient*	*P-value*	**Low Performing** *Coefficient*	*P-value*
In Hen						
No (reference)						
Yes	-.085	.079	.002	.960	-.011	.848
Beds (log)	-.021	.863	-.123	.302	-.049	.779
DSH(log)	-.033	.651	-.131	.085	-.002	.976
CMI	.195	.257	-.108	.478	-.185	.360
Year						
2011(reference)						
2012	.417*	.001	.095*	.028	-.404*	.001
2013	.434*	.001	.057	.192	-.533*	.001
2014	.382*	.001	.035	.425	-.591*	.001

* Statistically significant at p < .05

Finally, we converted the CLABSI SIR into a binary variable by coding hospitals that experienced one or more CLABSI cases during the year as one and hospitals with no CLABSI cases as zero. We then regressed the binary CLABSI SIR on time-varying, independent variables by using a logit fixed effects regression model. The results of this regression are summarized in Table 5. As indicated in the table, there was no significant relationship between HEN participation and CLABSI events (p=.786).

Table 5: Logit Fixed Effects Regression

CLABSI SIR Logit Fixed Effects Regression

Variables	*Coefficient*	*P-value*	*95% C.I.*	
In Hen				
No (reference)				
Yes	-.051	.786	-.418	.316
Beds (log)	-.360	.484	-1.369	.648
DSH (log)	.063	.833	-.524	.650
CMI	.404	.555	-.940	1.749
Year				
2011 (reference)				
2012	.142	.423	-.058	.064
2013	.176	.324	-.108	.015
2014*	.125	.488	-.152	-.027

* Statistically significant at p < .05

Conclusions

Our study added further empirical evidence to the ongoing debate on whether large-scale quality improvement collaborations, such as the HEN program, have been effective. We were unable to corroborate the formal HEN evaluation that HEN hospitals decreased CLABSI rates with HEN participation. The one exception is that high performing hospitals experienced a moderate improvement from HEN participation (-.085, p=.079). Both HEN hospitals and nonparticipants decreased their CLABSI SIR over four years, 17% and 14% respectively.

It is unknown what precisely was driving the CLABSI improvements at this time. Additionally, it is unknown how nonparticipants were able to achieve similar improvement results to the HEN participants.

One possibility is that the nonparticipating hospitals gained quality improvement knowledge through "spillover."[14] For instance, the nonparticipating hospitals may have experienced some benefits (e.g., receiving toolkits, attending conferences, viewing webinars) without participating in time-intensive tasks such as regular reporting of process measures and attending mandatory meetings.

Increasing healthcare market pressures such as value-based purchasing, increased consumer demands, mandated reporting requirements, and reimbursement withheld for poor quality may have contributed to CLABSI declines.

The final interpretation of the insufficient findings was that the HENs were not effective in delivering quality improvement interventions. This study is consistent with the existing QIC studies that suggested these types of collaborations have generated minimal sustained improvements. Additionally, the HENs, as QICs, might have experienced diminishing returns on their efforts. On the national level, new quality improvement models may be needed to scale future interventions.

Limitations

This study has several limitations for consideration. The first limitation is that critical access hospitals (CAHs) were omitted because CMS did not report CAH CLABSI data in 2011. Omitting these hospitals likely created sampling bias. For instance, in our study, we had a HEN participation rate of 83%. However, the national average HEN participation rate was approximately 72%. Due to the CAH omissions, our study was missing the proportionate amount of controls.

The inability to quantify motivation is a common limitation of quality improvement observational studies. As such, this study does not have a variable to capture a hospital's willingness to improve. Hospitals with a high motivation to improve might have been more likely to join a HEN. Therefore, it was the desire to improve that led to better outcomes, not necessarily HEN program participation. [23]

The CLABSI SIR data were only available from 2011 through 2014, which resulted in a short time-series panel. CLABSI SIR data before 2011 was not available in the Hospital Compare data archive. In 2015, the National Healthcare Safety Network (NHSN) updated how the CLABSI SIR was calculated.[24] Therefore, we were unable to directly compare 2015 CLABSI SIR data with the other years in our panel.

Omitted variable bias was a concern with this study. Several quality improvement efforts were ongoing at this time, such as Meaningful Use, accountable care organizations, and bundled payments.[25] Our research did not control for other improvement efforts in which hospitals could have participated.

Additional Research

Our study reviewed one of the 11 patient harm outcomes targeted by the HEN program. Further research is needed on other outcomes to determine if the results are similar. Additional research is needed to understand why there was such a reduction in CLABSIs between 2011 and 2014. Several policy changes, improvement efforts, and technology enhancements were underway during this time. Therefore, it will be challenging to find the primary source of improvement. Recent research states it was most likely a combination of events working in tandem.[25]

In the future, quality improvement research should also consider conducting prospective cost-effectiveness analyses of QICs interventions. The cost-effectiveness perspective is essential if QICs were effective but started to experience diminishing returns. Understanding the actual cost of these national QIC interventions is necessary to determine the cost per outcome gained is justified.

Finally, the HEN program's new iterations should be researched and evaluated. Launched in 2015, HEN 2.0 followed in the footsteps of the original HEN program. In version 2.0, CMS distributed $110 million for one year to 17 quality improvement organizations to continue the HENs' original work.[26] In 2016, CMS announced a further continuation of the program with the Hospital Improvement and Innovation Networks (HIIN). CMS awarded $347 million through 2019 to 16 organizations to improve on the work started by the HEN program. [27] However, there have been no studies reviewing the effectiveness of these programs, and we are unaware of any future evaluations.

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JOURNAL ARTICLE #2

Hospital Engagement Network Participation and 30-day Readmission Rates

Journal of Patient Safety

Abstract

Objective

This study evaluated the impact of Hospital Engagement Network (HEN) participation on 30-day readmission rates for heart failure (HF), acute myocardial infarction (AMI), and pneumonia.

Method

We completed a comparative retrospective analysis of HEN hospitals and control hospitals utilizing Hospital Compare's 30-day readmission data from 2005-2017. We regressed changes in 30-day readmission rates for HF, AMI, and pneumonia on time-varying, independent variables using a fixed effects regression model and conducted multiple sensitivity analyses.

Results

There were a total of 76,900 hospital years of data with 30-day readmission rates for HF (28,280), AMI (20,936), pneumonia (27,684). The pre-post fixed effect regression coefficients for HEN participation were varied for HF (.018, p=.639), AMI (-.073, p=.032), and pneumonia (.097, p=.003). When using full panel data, the fixed effect regression coefficients were similar to the original sample with 30-day readmission rates for HF(-.032, p=.439), AMI (-.148, p=.001), and pneumonia (.103, p=.014). The sensitivity analysis

determined that HEN participants achieved superior AMI readmission improvements over nonparticipants before the HEN program commenced.

Conclusions

In this study, we determined that there is little evidence that HEN participation in reducing 30-day readmissions. Policymakers should consider the lack of improvement evidence in contemplating the future of the national quality improvement collaborations.

Introduction

In 2001, the Institute of Medicine (IOM) recommended that the United States should invest in a $1 billion, three-to-five-year national patient safety initiative to catalyze a national safety movement.[1] In 2010, the Patient Protection and Affordable Care Act (ACA) commissioned the Department of Health and Human Services (HHS) to develop a national strategy for improving patient outcomes.[2] In 2011, HHS launched the Partnership for Patients (PfP) initiative with a $1 billion budget to reduce preventable hospital-acquired conditions by 40% and readmissions by 20%.[3,4] A 20% reduction in readmissions would have resulted in a decline of 1.6 million readmissions.[3]

The PfP initiative allocated $218 million to develop the Hospital Engagement Network (HEN) program.[3] The HEN program designated 26 organizations as "Hospital Engagement Networks" to lead hospitals through quality improvement initiatives. These HEN organizations ranged from state hospital associations to for-profit companies. The HENs were able to recruit over 3,700 hospitals to join their programs.[5]

The HEN program was a result of the federal government's increasing reliance on Quality Improvement Collaborations (QICs) to implement large-scale change. QICs were defined as multiorganizational systems striving together to improve patient outcomes.[6] The Institute for Healthcare Improvement's (IHI) Breakthrough Series formalized and codified the modern QIC structure.[7] Effectiveness studies on QICs have been mixed.[6-8]

A 2014 QIC systematic review identified standard components of collaboratives. The HEN organizations utilized these components, which included expert panels synthesizing research, Plan-Do-Study-Act (PDSA) cycles, in-person learning sessions, multidisciplinary quality improvement teams, conference calls, and email support.[8] The American Hospital Association recommended four improvement tactics: 1) clear, regular communications between HEN organization and hospitals 2) hospitals should report process measures 3) HEN should intervene when process measures are out of alignment with goal 4) hospitals' leadership engagement.[9]

Several patient safety researchers have openly criticized the design of the HEN program and studies of its impact. The criticisms focus primarily on three areas.[10] First, the HENs did not standardize outcomes metrics which would have allowed for standardized research across HENs. Second, all of the studies conducted on the effectiveness of HENs were lacking a control group. Finally, the data, methods, and research were not available for peer review.[10]

The Centers for Medicare & Medicaid's (CMS) sponsored evaluation, conducted by the Health Services Advisory Group, Inc. and Mathematica Policy Research in 2015, addressed the latter two concerns. This study used 2011 through 2014 Medicare claims data, the Medicare Patient Safety Monitoring System data, the National Healthcare Safety Network data, the National Database of Nursing Quality Indicators, and the National Vital Statistics System data.[11] The researchers conducted an interrupted time series (ITS) analysis to detect national trends in the HENs' eleven targeted patient harm areas and difference-in-difference (DID) regression analysis to estimate the HEN program's impact on participants compared to nonparticipants. Of the eleven HEN-targeted patient harm events, the ITS analysis determined only one area, readmission rates, were significantly impacted.[11] The evaluation detected a 5.6% decline in 30-day all-cause readmissions from 2010 through

2014.[11] This decline fell short of the 20% goal established by CMS. In the DID regression, HEN participants and nonparticipants performed the same for 30-day all-cause readmissions. Ultimately, the formal evaluation concluded that the HEN program's "impact on outcomes and costs is inconclusive."[11]

While the formal evaluation supported HEN critics, HEN supporters countered that the lack of empirical evidence did not justify a conclusion of ineffectiveness.[12,13] They argued that setting up robust collaborative processes and metrics to drive improvements in patient outcomes were significant accomplishments with the potential for future improvement.[12] One leader in population health stated that while quality improvement collaboration is laudable, the industry needs additional peer review for decisions based on data.[14] Currently, CMS continues to support quality improvement collaborations similar to the HENs.

The purpose of this study was to contribute to the HEN evidence base in several ways. First, by comparing the HEN program's outcomes with a nonparticipating control group. Second, by using three distinct readmissions outcome variables (HF, AMI, and pneumonia) instead of 30-day all-cause readmissions. Finally, by using readmission data through 2017 to evaluate if improvements continued after the HEN program ended.

Methods

Study Design

We compared changes in readmission rates between HEN participants and nonparticipants using a fixed effects regression model with 36-month moving average data for 2008 through 2017. Pre-post trends were analyzed while controlling for hospital characteristics. The University of Texas School of Public Health's Institutional Review Board determined this study was exempt from human subjects' protection.

Data Collection

The research database consisted of public-use data files linked to individual hospitals by using the Medicare Provider Identification Number. We collected readmission data from the CMS's Hospital Compare archived data repository for a national sample of hospitals identified as general acute care with at least 25 inpatient beds.[15] Veterans Affairs (VA) hospitals, rehabilitation hospitals, dedicated cancer centers, exclusive children's hospitals, mental health facilities, psychiatric hospitals, and long-term care facilities were excluded. HEN participation was determined for the hospital sample from the "HEN Round 1 hospitals 2015" spreadsheet on the CMS Achieved Materials for the Partnership for Patients website.[16] CMS annual impact files for fiscal year (FY) 2009 through 2018 were used to determine core-based statistical areas (CBSA), US regional locations, and the disproportionate share (DSH) ratio. When available, the correction notice data were used instead of the final rule data. Ownership and state variables were obtained from the Hospital Compare's FY18 archived flat file "Hospital General Information." Teaching hospital designation was based on CMS's "2018 Reporting Cycle: Teaching Hospital List."

Variables and Measures

Each hospital's HF, AMI, and pneumonia 30-day readmission rates were obtained for each year. The rates represent the moving average of 36-months of data. For instance, the FY2013 file contains data from July 2009 through June 2012. For the final year of the regression analysis, 2012, the readmission data from the FY13 file were used. The final year of the three-year moving average period was used for each study year. For example, 2010 through 2013 data were used for 2013. This method was used in other studies when the three-year readmission rate was substituted for annual data.[17]

Time-invariant variables (US region, state, CBSAs, teaching designation, and ownership) were used as controls in the descriptive analyses and the ordinary least squares (OLS) regression model. The CMS impact file used the US Census Bureau's classification for regions: New England, Mid Atlantic, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific. The CBSA variable was categorized as large urban, other urban, or rural. We categorized the ownership variable into government-owned, private nonprofit, and for profit. We log-transformed the disproportionate share ratio and the number of staffed beds variables to address skewness.

Analysis

The variables were time-invariant and time-varying. The 2012 data from the FY 2013 impact file was analyzed to develop graphs of the average 30-day readmission rates throughout the ten periods categorized by HEN participation and nonparticipation. An ordinary least squares (OLS) regression model of readmissions was estimated for 2008 through 2011 using a binary variable to compare HEN participant-nonparticipant rates before the program started.

The Hausman test was used to determine if a fixed effects or random effects regression model was best for the data. The fixed effects regression model used panel data to measure variation within a single hospital over time, using each hospital as its own control.[18] The model included categorical independent variables for the number of staffed beds, operating margin, DSH ratio, and case mix index. A binary variable for HEN participation was zero for all hospitals through five periods (2008 through 2012) and one for HEN participants starting in the sixth period, July 2012. This variable allowed us to test the effect of HEN participation on the readmission rate while controlling for other time-invariant and time-varying variables.

We removed hospitals that were missing outcome data and ran the fixed effects regression model again to determine if strongly balanced panels achieved the same results. We performed two sensitivity analyses. The first analysis determined the effect of changing the original intervention period in the fixed effects model from period six to periods four, five, and seven. The second analysis was to determine if there were differences in the HEN program's effect during and after the intervention. We eliminated periods that contained 18 months and 30 months of data after the HEN program completion in December 2014. The statistical analyses were completed using Stata v14.2, College Station, Texas.[19]

Results

Descriptive Statistics

The sample contained 3,275 HEN participating hospitals from all 26 HENs and 1,164 nonparticipating hospitals from throughout the United States who reported readmission outcome data. The sample's HEN participation rate of 73% was in line with the national average of 72%. Hospitals with full panels of all three segments of outcome data were 1,083 HEN participants and 192 nonparticipants.

Table 1 displays the descriptive statistics for 2012, the year with most details on the hospitals. HEN participation was disproportionately smaller in the West South Central Region (Oklahoma, Arkansas, Texas, and Louisiana). The urban/rural geographic distribution was similar for the two groups. HEN participants had twice the percentage of teaching hospitals as nonparticipants. Finally, the nonparticipating cohort had twice the percentage of for profit hospitals compared to the HEN participation cohort.

Table 1: Descriptive Statistics for Time-invariant Variables

Descriptive Statistics for Time-invariant Variables

	HEN Participants	Nonparticipants
Variables	*% of sample*	*% of sample*
Region		
New England	3.5%	7.21%
Mid Atlantic	13.6%	3.21%
South Atlantic	17.3%	20.35
East North Central	16.1%	14.42%
East South Central	9.2%	10.42%
West North Central	8.7%	4.49%
West South Central	11.6%	23.72%
Mountain	6.5%	7.37%
Pacific	13.5%	8.81%
Geography		
Rural	24.4%	25.66%
Small Urban	34.6%	33.33%
Large Urban	41.0%	41.0%
Teaching		
Yes	28.4%	13.75%
No	71.6%	86.25%
Ownership		
Government	22.1%	26.03%
Private Nonprofit	65.8%	45.62%
For Profit	12.1%	28.35%

Table 2 displays the time-varying variables for our fixed effects regression model. On average, nonparticipants had a lower case mix index, fewer beds, and higher disproportionate share ratio than the HEN participants. Figure 1 displays the 30-day readmission rate for AMI, HF, and pneumonia by HEN participation.

Table 2: Descriptive Statistics for Time-varying Variables

Descriptive Statics for Time-varying Variables

	HEN Participants	Nonparticipants	
Variables	*Mean (sd)*	*Mean (sd)*	*P-value (t-test)*
Fixed Effect Variables			
Case Mix Index	1.51 (.290)	1.42 (.363)	<.001
Beds	218.6 (188.5)	156.4 (160.4)	<.001
DSH Ratio	.287 (.164)	.300 (.203)	<.001

Figure 1: 30-day Readmission Rates between HEN Participants and Nonparticipants

OLS Regression Model

Table 3 displays the OLS regression results for HF, AMI, and pneumonia 30-day readmission rates from the four periods ending in 2008 through 2011. The HEN coefficients for HF (-.163, p<.001), AMI (-.106, p=.008), and pneumonia (-.253, p<.001) indicated that

HEN hospitals were obtaining superior results before the HEN program began in 2012. The coefficients for bed size, DSH, geographic location, were statistically significant (p<.001) across all three readmission outcomes.

When the state was used as an independent variable compared to the region, it yielded a higher adjusted R-squared, and many states were statistically significantly related to the outcomes. However, state information was not relevant to our study. Therefore, we did not list this information in Table 2.

Table 3: OLS Regression for Readmissions in 2008-2011

OLS Regression for Readmissions in 2008-2011

	HF		**AMI**		**Pneumonia**	
Variables	*Coefficient*	*P-value*	*Coefficient*	*P-value*	*Coefficient*	*P-value*
In Hen						
No (reference)						
Yes	-.163*	<.001	-.106*	.008	-.253*	<.001
Beds (log)	-.212*	<.001	-.115*	<.001	.049*	<.001
DSH Ratio (log)	.729*	<.001	.475*	<.001	.433*	<.001
Teaching						
No (reference)						
Yes	-.164	<.001	.003	.938	.007	.852
Hospital Type (omitted)						
Geography						
Rural (reference)						
Small Urban	-.413*	<.001	-.080*	<.001	-.143*	.001
Large Urban	.386*	<.001	.357*	<.001	.403*	<.001
State (not listed)						
Year						
2005-2008 (reference)						
2006-2009	.200*	<.001	.032	.398	.141*	.002
2007-2010	.294*	<.001	-.093*	.014	.198*	<.001
2008-2011	.193*	<.001	-.270*	<.001	.275	<.001

* Statistically significant at p < .05

Fixed-effects Model

We analyzed hospital-level data using a multivariate fixed effects regression model of the readmission outcomes (HF, AMI, and pneumonia). Both multivariate fixed effects and random effects regressions were estimated using Stata. The Hausman test ($p<.01$) confirmed that the fixed effects regression model was the best fit for the data.

Table 4 below shows the fixed effects result with all observations included in the sample. There were a total of 76,900 hospital years in the data for HF (28,280), AMI (20,936), and pneumonia (27,684). The HEN coefficients for AMI (-.073, $p=.032$) and PN (.097, $p=.003$) were both statistically significant but in opposite directions. On average, HEN participation decreased AMI readmission rates by .073 percentage points. However, HEN participation was associated with a .097 percentage point increase in pneumonia readmission rates. The HF readmission rate was not affected by HEN participation (.018, $p=.639$). The disproportionate share ratio was statistically significant ($p<.05$) across all three outcome measures.

Table 4: Fixed Effects Model of Readmissions in 2008-2017

Fixed Effects Model of Readmissions in 2008-2017

	HF		**AMI**		**Pneumonia**	
Variables	*Coefficient*	*P-value*	*Coefficient*	*P-value*	*Coefficient*	*P-value*
In Hen						
No (reference)						
Yes	.018	.639	-.073*	.032	.097*	.003
Beds (log)	.030	.526	-.062	.165	-.105*	.007
DSH Ratio (log)	.234*	.002	.278*	<.001	.134*	.035
Year						
2005-2008 (reference)						
2006-2009	.210*	<.001	.032	.224	.147*	<.001
2007-2010	.320*	<.001	-.078*	.004	.224*	<.001
2008-2011	.235*	<.001	-.239*	<.001	.318*	<.001
2009-2012	-1.46*	<.001	-1.60*	<.001	-.582*	<.001
2010-2013	-1.81*	<.001	-2.01*	<.001	-.933*	<.001
2011-2014	-2.50*	<.001	-2.85*	<.001	-1.33*	<.001
2012-2015	-2.55*	<.001	-2.95*	<.001	-1.13*	<.001
2013-2016	-2.87*	<.001	-3.54*	<.001	-1.30*	<.001
2014-2017	-2.88*	<.001	-3.86*	<.001	-1.54*	<.001

* Statistically significant at $p < .05$

Table 5 displays the fixed effects results for hospitals with full panels (i.e., hospitals with readmission rates reported for all ten study years). There were a total of 58,530 hospital years in the data for HF (26,650), AMI (12,810), and pneumonia (19,070).

The HEN coefficients for the full sample mirrored those of the original sample. The HEN participation coefficients for AMI (-.148, p=.001) and pneumonia (.103, p=.014) were again significant in opposite directions. For HF, the HEN participation coefficient was not significant (-.032, p=.439).

Table 5: Fixed Effects Regression Results for Readmissions in 2008-2017 for Full Panels

Fixed Effects Regression Results for Readmissions in 2008-2017 for Full Panels

	HF		**AMI**		**Pneumonia**	
Variables	*Coefficient*	*P-value*	*Coefficient*	*P-value*	*Coefficient*	*P-value*
In Hen						
No (reference)						
Yes	-.032	.439	-.148*	.001	.103*	.014
Beds (log)	.063	.228	-.056	.359	-.102*	.048
DSH Ratio (log)	.185*	.016	.232*	.010	.048	.554
Year						
2005-2008 (reference)						
2006-2009	.206*	<.001	.027	.465	.144*	<.001
2007-2010	.315*	<.001	.090*	.015	.215*	<.001
2008-2011	.245*	<.001	-.243*	<.001	.312*	<.001
2009-2012	-1.45*	<.001	-1.63*	<.001	-.598*	<.001
2010-2013	-1.76*	<.001	-1.98*	<.001	-.949*	<.001
2011-2014	-2.45*	<.001	-2.83*	<.001	-1.37*	<.001
2012-2015	-2.51*	<.001	-2.91*	<.001	-1.09*	<.001
2013-2016	-2.81*	<.001	-3.51*	<.001	-1.27*	<.001
2014-2017	-2.82*	<.001	-3.81*	<.001	-1.51*	<.001

* Statistically significant at $p < .05$

Sensitivity Analysis

Table 6 displays the results of the first sensitivity analysis performed with the fixed effects model with the HEN coefficient starting in periods four (July 2008 through June 2011), five (July 2009 through June 2012), and seven (July 2011 through June 2014).

Table 6: Sensitivity Analysis for the Start of the HEN Program

Sensitivity Analysis for the Start of the HEN Program

	HF		**AMI**		**Pneumonia**	
HEN Coefficient	*Coefficient*	*P-value*	*Coefficient*	*P-value*	*Coefficient*	*P-value*
Period 4 (July 08-June 11)	.008	.854	-.094*	.011	.049	.180
Period 5 (July 09-June 12)	.001	.972	-.072*	.039	.064	.056
Period 6 (July 10-June 13)	.018	.693	-.073*	.032	.097*	.003
Period 7 (July 11-June 14)	.013	.732	-.074*	.035	.089*	.007

* Statistically significant at $p < .05$

The HF HEN coefficient was not significant for each of the four periods. Therefore, no matter the timing of the HEN intervention in the statistical analysis, there was no effect of HEN participation on the HF readmission rate.

The HEN coefficient for AMI was significant for each of the fixed effects regressions, including period four, which was before the HEN program commenced. Therefore, HEN participants started experiencing improved AMI readmission rates before the program began.

Finally, HEN participants experienced worse pneumonia readmission rates during the program. The HEN coefficient was not statistically significant until measured starting in the sixth period.

A second sensitivity analysis was performed to eliminate the last two periods of this study. Periods nine (July 2013 through July 2016) and ten (July 2014 through June 2017) contained observations after the HEN program ended in December 2014. Table 7 displays the results of dropping the last period and the last two periods from our analyses. When these periods were dropped, there was not a significant change in the HEN participation coefficients.

Table 7: Sensitivity Analysis for when the HEN Program Ended

Sensitivity Analysis for when the HEN Program Ended

	HF		**AMI**		**Pneumonia**	
HEN Coefficient	*Coefficient*	*P-value*	*Coefficient*	*P-value*	*Coefficient*	*P-value*
All Ten Periods (original model)	.018	.693	-.073*	.032	.097*	.007
Drop Period 10 (June 14-July 17)	.039	.334	-.061*	.085	.096*	.005
Drop Periods 9 (June 13-June16) and 10	.032	.467	-.071*	.063	.093*	.011

* Statistically significant at $p < .05$

Conclusions

Our study added further empirical evidence to the ongoing debate on whether large-scale quality improvement collaborations, such as the HEN program, have been effective. Our study expanded on previous HEN research on readmissions by breaking out 30-day readmissions into HF, AMI, and pneumonia. Also, our study sample contained years beyond on the HEN program's conclusion, allowing us to review sustainability after the HEN program concluded.

In our sample, we were unable to show that HEN participation lead to declined readmission rates. Only one HEN coefficient, AMI showed statistically significant improvements for HEN participation (-.073, p=.032). However, a sensitivity analysis determined that HEN participants started reducing readmission rates compared to the nonparticipants before the HEN program commencing. The HEN participation coefficient for HF was not significant (.018, p=.693). The pneumonia HEN coefficient determined that HEN participation was associated with a statistically significant decline (.097, p=.007). The statistically significant results from AMI and pneumonia were still less than one-tenth of a percentage point resulting in a small effect size.

There are a few reasons as to why the HEN participants did not outperform nonparticipants. Since HEN participating hospitals achieved better readmission rates before the HEN program, it might have been difficult to accelerate improvements over the nonparticipants further. Another possibility is that the nonparticipating hospitals gained quality improvement knowledge through "spillover."[11] For instance, the nonparticipating hospitals may have experienced some benefits (e.g., receiving toolkits, attending conferences, viewing webinars) without participating in time-intensive tasks such as regular reporting of process measures and attending mandatory meetings.

Limitations

Our study had a few limitations. The first limitation was that we did not control for mortality rates, which were possibly correlated with readmission rates.[20]

Next, we did not know which hospitals dropped out of the HEN program. Some research shows that up to 30% of QIC participants drop out.[21] Similarly, this study did not have a variable to capture a hospital's willingness to improve. The inability to quantify motivation is a common limitation of quality improvement observational studies. Hospitals with a high motivation to improve might have been more likely to join a HEN. Therefore, a hospital's desire to improve leads to better outcomes not necessarily the HEN program.[22]

Omitted variable bias was also a concern with this study. Several quality improvement efforts were ongoing at this time. These efforts included Meaningful Use, accountable care organizations, and bundled payments.[17] Our study does not control for when hospitals joined these other programs or even the next round of HEN programs.

Additional Research

This study was the first known study that evaluated HEN participation with nonparticipation on reducing hospital readmissions. Since this study was modeled after Ryan et al's readmission study,[17] further research should combine their data with this study's HEN data. Combining the data sets would determine if HEN participation is significant while controlling for value-based program participation.

Also, additional research could determine the effect of programs such as the Hospital to Home initiative or the American Heart Association's Get with the Guidelines impact in reducing cardiovascular readmission rates.[23,24] Since HEN participants achieved better outcomes for AMI readmissions before the HEN program, one possibility is that HEN participants previously participated in one of these other programs.

Future QICs studies should evaluate using technology as a means to drive effectiveness. The QIC systematic review on methods did not mention the use of implementation software as a popular implementation tool. Using updated technologies may lead to superior outcomes.

Additional research should focus on penalties and participation in QICs. In the past decade, large QICs were preceded by policy developed penalties. For instance, Meaningful Use threated penalties if providers did not adopt electronic health record (EHRs). However, simultaneously, the federal government created Regional Extension Centers (RECs) to aid EHR adoption. In 2012, the Hospital Readmissions Reduction Program began penalizing hospitals for readmissions. While at the same time, the HENs assisted hospitals with decreasing readmission rates. For example in one qualitative study, several interviewees cited policy changes as a reason for joining a HEN.[25] There were several studies published on policy changes improving patient outcomes;[26-28] however, to our knowledge no articles are exploring how penalty enacting policies drive QIC participation.

The HEN program's new iterations should be researched as well. Launched in 2015, HEN 2.0 followed in the footsteps of the original HEN program. In version 2.0, CMS distributed $110 million for one year to 17 quality improvement organizations to continue the

HENs' original work.[29] In 2016, CMS announced a further continuation of the program with the Hospital Improvement and Innovation Networks (HIIN). CMS awarded $347 million through 2019 to 16 organizations to improve on the work started by the HEN program.[30] However, there have been no known studies reviewing the effectiveness of these programs, and we are unaware of any future evaluations.

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CONCLUSION

This study was the first known assessment of the HEN program since CMS's inconclusive formal evaluation in 2014. There were several significant findings in this study. First, HEN participants had superior outcomes for CLABSIs and 30-day readmissions compared to nonparticipants before the HEN program commenced. Next, there was no evidence of the HEN participation's effect on CLABSIs (p=.816). For 30-day readmission rates, the pre-post fixed effect regression coefficients for HEN participants were varied for HF (.018, p=.639), AMI (-.073, p=.032), and pneumonia (.097, p=.003).

Limitations

This study has several limitations for consideration. The first limitation is that critical access hospitals (CAHs) were omitted because CMS did not report the CLABSI data in 2011. Also, the readmission data were lacking for CAHs. Omitting these hospitals may have created sampling bias. CAHs may have experienced a more significant benefit in participating in the HEN program compared to larger hospitals.

Next, it is not known which hospitals dropped out of the HEN program. Some research shows that up to 30% of QIC participants drop out of similar programs.[92] Similarly, this study did not have a variable to capture a hospital's willingness to improve. The inability to quantify motivation is a standard limitation of quality improvement observational studies. Hospitals with a high motivation to improve might have been more likely to join a HEN. Therefore, a hospital's desire to improve that leads to better outcomes, not necessarily the HEN program.[65]

Omitted variable bias was also a concern with this study. Several quality improvement efforts were ongoing at the same time as the HEN program. These efforts included Meaningful Use, accountable care organizations, and bundled payments.[84] Initiatives focusing on cardiovascular readmissions started a few years before the HEN program.[93,94] This study did not control for when hospitals joined these other programs.

For the first study, the CLABSI SIR data were available only from 2011 through 2014, which resulted in a short time-series panel. CLABSI SIR data before 2011 were not available in the Hospital Compare data archive. In 2015, the National Healthcare Safety Network updated how the CLABSI SIR was calculated.[95] Therefore, we were unable to directly compare 2015 CLABSI SIR data with the other years in our panel. In the second study, the unique limitation was that we did not control for mortality rates, which were possibly correlated with readmission rates.[96]

Future Research

This study is the first known study to evaluate the HEN program apart from CMS's formal evaluation. The study focused on two (CLABSIs and 30-day readmission rates) of the 12 outcomes targeted by the HEN program. These two outcomes were chosen because the data were publicly available. Further research is needed on the other ten outcomes to determine if the results are similar to this study.

Future QICs studies should evaluate using technology as a means to drive effectiveness. The QIC systematic review with a focus on methods did not mention the use of implementation software as an implementation tool. Using updated technologies may lead to superior outcomes.

Additional studies should also research monetary penalties for poor performance and participation QICs. For the past decade in the US, large QICs were preceded by penalties developed by policies. For instance, Meaningful Use issued penalties if providers did not adopt electronic health record (EHRs). However, simultaneously, the federal government created Regional Extension Centers (RECs) to aid EHR adoption. In 2012, the Hospital Readmissions Reduction Program began penalizing hospitals for readmissions. While at the same time, the HENs assisted hospitals with decreasing readmission rates. For example, in one qualitative study, several interviewees cited policy changes for joining a HEN.[71] There were several studies on policy changes improving patient outcomes.[97-99] However, no known articles are exploring how penalty enacting policies drive QIC participation.

The HEN program's new iterations should be researched and evaluated. Launched in 2015, HEN 2.0 followed in the footsteps of the original HEN program. In version 2.0, CMS distributed $110 million for one year to 17 quality improvement organizations to continue the HENs' original work.[23] In 2016, CMS announced a further continuation of the program with the Hospital Improvement and Innovation Networks (HIIN). CMS awarded $347 million through 2019 to 16 organizations to improve on the work started by the HEN program.[24] However, there have been no known studies reviewing the effectiveness of these programs.

APPENDICES

Appendix A: The University of Texas School of Public Health IRB Exemption Letter for Article 1

UTHealth
The University of Texas
Health Science Center at Houston

Committee for the Protection of Human Subjects
[illegible]
[illegible]

Tyler Wallace
UT-H - SPH - Student

June 25, 2018

HSC-SPH-18-0470 - *Did Hospital Engagement Networks Improve the Quality of Patient Care Delivered in General Acute Care Hospitals?*

The above named project is determined to qualify for exempt status according to 45 CFR 46.101(b)

CATEGORY #4 *: Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.*

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via iRIS to the Committee for the Protection of Human Subjects for review.

INFORMED CONSENT DETERMINATION:
Waiver of Consent Granted

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):
Exempt from HIPAA

STUDY CLOSURES: Upon completion of your project, submission of a study closure report is required. The study closure report should be submitted once all data has been collected and analyzed.

Should you have any questions, please contact the Office of Research Support Committees at 713-500-7943.

Appendix B: The University of Texas School of Public Health IRB Exemption Letter for Article 2

UTHealth
The University of Texas
Health Science Center at Houston

Committee for the Protection of Human Subjects

Tyler Wallace
UT-H - SPH - Phd In Public Health (Management & Policy Sciences)

NOTICE OF APPROVAL TO BEGIN RESEARCH **May 09, 2019**

HSC-SPH-19-0376 - Hospital Engagement Networks Impact on 30-day Readmission Rates in United States Hospitals

PROVISIONS: This approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered by the Committee for the Protection of Human Subjects, e.g. study documents, informed consent, etc.

APPROVED: By Expedited Review and Approval

REVIEW DATE: May 9, 2019

APPROVAL DATE: 05/09/2019

CHAIRPERSON: L. Maximilian Buja, MD L. Maximilian Buja

Subject to any provisions noted above, you may now begin this research.

PLEASE NOTE: Due to revisions to the common rule that went into effect July 19, 2018, this study that was approved under expedited approval no longer needs to submit for continuing review. Changes to the study, adverse events, protocol deviations, personnel changes, and all other types of reporting must still be submitted to CPHS for review and approval. When this study is complete, the PI must submit a study closure report to CPHS.

CHANGES: The principal investigator (PI) must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. **ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.**

INFORMED CONSENT DETERMINATION:

Waiver of Consent Granted

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