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Effect of Clinical Trial Participation on Patient Experience and Overall Hospital Scores

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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Walden University
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Abstract

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MS, Walden University, 2012

BS, Saint Petersburg College, 2010

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Healthcare Administration

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Abstract

Despite groundbreaking advances in technology and medicine in the United States and intensive examination of health services quality initiatives, issues of quality and patient-reported experience measures in the hospital sector remain unimproved. Although evidence-based medicine has improved through innovation in clinical research, healthcare systems have reportedly struggled to implement advances in medicine and lack the skill sets to become learning health systems. As clinical practice and clinical trials (CTs) have rarely intersected in the past, a significant lack of quantitative research has been dedicated to correlate improved patient outcomes with participation in CTs. The analysis sought a correlation, if any, between the dependent variables of linear mean patient experience scores and overall star ratings with the independent variable of hospital participation in CTs. The key research question was to what extent, if at all, are any of the 10 HCAHPS hospital quality indicators related to the type of hospital (CT versus non-CT). The Mann-Whitney test was used to determine with 95% confidence, an alpha level of 0.05, as well as a Pearson's correlation coefficient to show that participation in CTs increased patient experience metrics and linear mean scores in 7 out of 10 HCAHPS domains, with 5 out of 10 domains showing moderate correlations in hospital participation in CTs with higher HCAHPS scores. Given the findings of this study, it is reasonable to assert that increased participation in CTs may have a positive impact not only on the health of our population, but also on the health of our organizations as a whole resulting in positive social change.

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Dedication

This is in dedication to my family, both here and watching from above.

Acknowledgments

This is an opportunity for me to express my gratitude to all the individuals who both indirectly and directly helped contribute to this body of work. I would specifically like to thank my dissertation committee: Dr. Cheryl B. Cullen, Dr. Lloyd K. Ford, and Dr. Ronald Hudak, as well as Dr. Tom Granoff and Gina Gillum. Without your guidance and wisdom, this would not have been possible.

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Section 1: Foundation of the Study and Literature Review

Introduction

Despite innovative advances in technology and medicine and the intense scrutiny of health services quality initiatives, the U.S. healthcare system has continued to experience issues of quality and low scores on patient-reported experience measures (Bindman, 2017). Although continuous quality improvement (CQI) methods have been used and evidence-based medicine has improved through innovation in clinical research, healthcare systems have failed to become learning health systems (LHSs) that quickly integrate these methods and improve the patient experience (Bindman, 2017). Patient experience scores have become quickly recognized as determinants for healthcare reimbursement. In fact, Medicare derived the overall Medicare star rating system to ensure that patients have a straightforward way to compare hospitals on a one-to-five-star scale (Centers for Medicaid and Medicare [CMS], 2017a). Cyclical imminent policy changes and burgeoning patient populations increase the requirement for hospitals to remain competitive in quality and experience metrics (Bindman, 2017; CMS, 2017a). Although typical healthcare models have segregated clinical practice (CP) and clinical trials (CTs), in this study, I sought to determine whether hospitals that participate in CTs have better patient experience ratings than those that do not (CMS, 2017a).

Patient-reported outcomes have quickly become imperative to CP and clinical research initiatives. Healthcare administrators must continue to ensure best practices in clinical care, ensure high quality outcomes, and analyze and drive above-average reporting metrics to remain fiscally viable (CMS, 2017a). As hospital recruitment into

CTs has shown to be difficult for the research industry, perhaps integrating CTs into nonparticipating hospitals would benefit both hospitals and patients alike (Johnson et al., 2018). In this study, I sought to examine the difference, if any, in the mean of overall hospital star ratings, as determined by CMS, to determine if a correlation exists in linear mean Hospital Comparison Assessment of Healthcare Providers and Systems (HCAHPS) scores in participating and nonparticipating CT hospitals (Denburg et al., 2016; Johnson et al., 2018).

Problem Statement

Current advances in medical innovation and information technology have afforded the U.S. healthcare system the ability to quantify, visualize and analyze empirical data for the betterment of society and the overall patient experience (Ross, 2014). However, regardless of tireless examination and the continued identification of trends and forecasted quality issues that administrators review daily, the medical community has historically struggled with the implementation of quality care and the facilitation of improved patient outcomes and experiences (Bindman, 2017; Ross, 2014). Regardless of notable medical innovation and lifesaving methodologies that have come to fruition and are marketed to the U.S. public, many healthcare facilities have lagged in improving patient outcomes and satisfaction scores, a trend referred to as the *17-year gap* by experts in the field of public health (Bindman, 2017; CMS, 2017a). Experts have contended that healthcare delivery systems are weighted down by the many advances in medical technology and scientific innovation and are not able to assimilate this knowledge with enough speed to become learning organizations (National Academies

Press, 2013). Leveraging the multidisciplinary efforts that created these innovations may help organizations better achieve higher quality scores and better patient experiences, thereby embodying the true spirit of a LHS (Bindman, 2017; National Academies Press, 2013).

The move toward value-based care models, as mandated by the Affordable Care Act (ACA, 2010) may soon become mandatory, which would have devastating impacts on the bottom lines of hospitals nationwide (Martin, 2017). As quality indicators are a mainstay of the trend toward shared responsibility, patient ratings have been gaining significant attention from leaders in healthcare quality (Martin, 2017; National Academies Press, 2013; Ross, 2014). In fact, over 4,000 hospitals have been participating in a reimbursement strategy known as the Inpatient Prospective Payment System (IPPS), which includes providing patients with subjective questionnaires to assess patient–provider relationships, communicative performance, medication management and instruction, and myriad additional provider performance queries (CMS, 2017b). These surveys are scored, and hospitals are compensated based on these subjective patient ratings (CMS, 2017a). These overall Medicare star ratings incorporate seven groups of measures found within the HCAHPS survey as well as variables not reviewed in this case study, such as (a) safety of care, (b) readmission and mortality rates, (c) efficiencies in medical imaging, (d) and timeliness and effectiveness of care (Medicare, n.d.). As consumers of healthcare, members of the baby boomer generation have begun to represent the largest population demographic using Medicare as their third-party payer (World Population Review, 2019). Given the burgeoning patient population, value-based

purchasing (VBP) legislation, and ever-increasing transparency initiatives aimed at hospital quality, perhaps in order to improve HCAHPS survey scores, healthcare administrators should consider a LHS approach (Bindman, 2017) and use patient-centric methods employed in the recruitment and retention of voluntary subjects in CTs (Denburg et al., 2016; Johnson et al., 2018).

Patient-Centric Clinical Trials

CTs have long been scrutinized for the utmost quality and have been founded on patient trust and satisfaction (Calvert et al., 2018). Many research organizations have used patient-reported outcome (PRO) surveys to ascertain the degree of satisfaction of study subjects, ensure the quality of CTs, and further bolster the protection of voluntary subjects (Calvert et al., 2018). Experts have contended that CTs are the foundation for many approved chemotherapy and immunological therapies aimed at cancer in adults and children, yet a significant lack of patient participation causes delays in new drug application approvals (Johnson et al., 2018; Miller, 2016). This has indicated an increasing need for multidisciplinary efforts aimed at simultaneously improving the overall quality in hospitals and increasing patient enrollment in CTs (Miller, 2016). However, regardless of the many studies in which researchers have examined quality in patient outcomes in hospitals or quality in CTs, it seems the two sectors of clinical care have rarely crossed the quality chasm together in academia (Denburg et al., 2016).

CTs rely on voluntary subject participation and are vetted by intense global and national regulatory frameworks (Moss & Harvrilesky, 2017). The clinical data or results of CTs undergo intensive evaluation by federal bodies to determine the safety and

efficacy of innovative therapies for real-world CP (Johnson et al., 2018). Principle investigators and clinical research teams carefully and diligently record, review, and analyze all patient experiences, adverse events, medical history, and concomitant medications as well as continuously follow up with patient phone calls and administer repeated laboratory tests with constant physician oversight and communication, as directed by clinical protocols, to be successful; these processes have spilled over into their daily practice patterns (Moss & Harvrilesky, 2017). The notion that these practice patterns will increase patient satisfaction and improve the patient experience has been seen in the HCAHPS survey data analyzed in this doctoral study.

Purpose of the Study

As healthcare reimbursement models move away from fee for service and toward shared responsibility and value-based reimbursement, it is imperative for healthcare administrators to understand patient perceptions that have been shown to drive clinical outcomes and compensation. In this study, I examined the difference, if any, in the mean of overall hospital star ratings as determined by CMS to determine if a correlation existed in linear mean HCAHPS scores in participating and nonparticipating CT hospitals. The analysis sought a correlation, if any, between the dependent variables of linear mean patient experience scores and overall star ratings with the independent variable of hospital participation in CTs. This exploration will inform healthcare administrators that CT participation inherently improved CP patterns and the patient experience (Denburg et al., 2016).

Research Question and Hypotheses

RQ: To what extent, if at all, are any of the 10 HCAHPS hospital quality indicators related to the type of hospital (CT versus non-CT)?

H_0: None of HCAHPS indicators are related to type of hospital.

H_1: At least one of the 10 HCAHPS indicators is related to type of hospital.

Theoretical Foundation

The theory driving this quantitative study was the LHS theory as defined by the Institute of Medicine (IOM) and the National Academies of Science (National Academies Press, 2013). The LHS theory is used to continuously improve healthcare through the alignment of science, informatics, and principles that inherently augment the practice of healthcare delivery (National Academies Press, 2013). The need for LHS was established by the IOM's findings on poor quality in healthcare delivery systems nationwide, as outlined in several now famous reports such as *To Err Is Human* and *Crossing the Quality Chasm* (National Academies Press, 2013). Simultaneous advances in clinical technology have created the landmark ability for healthcare administrators and support staff to quantitatively analyze trends in healthcare quality and best practices with real-time data (National Academies Press, 2013). These two capabilities led to a conceptual framework that could revolutionize healthcare (National Academies Press, 2013). Although LHS is far more complex than synthesized above, the mainstay of the theory rests in healthcare's recent ability to create a continuous cycle of feedback, which allows scientific evidence to bolster CP via data-driven analytical techniques (National Academies Press, 2013).

The recent trend toward CT use of the electronic data capture system, which can now be integrated directly with hospital electronic medical records provides an even more powerful capability for capturing real-time data, providing administrators the ability to analyze patient metrics and improve CT subject safety, and may speed the process of innovation through data-driven analytics (Gupta, 2015). These two data capture techniques may be the key to fostering the LHS approach to healthcare delivery and furthering the ability of CTs and CP to coincide and drive empirical knowledge on best practices and innovative medical technologies. The express intent of this doctoral study is to suggest that clinical research is an imperative foundation of the LHS and should be undertaken in a more active manner in national hospital systems to further bolster improved patient experience and outcomes, thereby improving healthcare quality and costs and hospital reimbursements. To do so, I sought to determine a link between improved clinical outcomes and patient experience scores at hospitals that participate in CTs compared to hospitals that do not (Denburg et al., 2016; National Academies Press, 2013).

Nature of the Study

A quantitative analysis of secondary data obtained through HCAHPS survey scores was used to determine the degree of correlation between improved patient outcomes and higher patient experience ratings and the participation in CTs in hospitals around the country. A subset of 522 hospitals was expected to be chosen in a nonrandom fashion, as I planned to select every third hospital from a listing supplied by the CMS (2019) hospital compare data set and corresponding code book by OmniComm Systems,

Inc. (OmniComm, 2018). The one-way analysis of variance (ANOVA) test was expected to be used to determine a correlation that hospitals that actively participated in CTs would show improved performance related to patient experience and health outcomes compared to those hospitals that do not participate in CTs (Denburg et al., 2016; Green & Salkind, 2014).

One-way ANOVA was selected as it is a well-known method for simple correlational analysis as it tests for statistical significance of differences between the means of samples with only one factor in the experiment (Green & Salkind, 2014). As the one-way ANOVA is designed to focus on sample variances, it may have been particularly useful in determining which of the hypotheses, if any, had the highest degree of correlation with participation in CTs (Green & Salkind, 2014).

Secondary Data Set Key Variables

The HCAHPS survey is given in over 4,000 national hospitals participating in the IPPS program (CMS, 2019). The HCAHPS survey is given to patients who consent to its completion, and hospital data are obtained from those hospitals having at least 300 respondents (CMS, 2019). The survey asks specific questions about patient experiences and includes questions about whether a patient would refer another patient to said hospital or whether the patient understood the home care instructions they received, if they had received any at all (CMS, 2019). For this specific study, the following HCAHPS linear mean scores were analyzed:

- Care transition, linear mean score
- Cleanliness, linear mean score

- Communication about medicines, linear mean score
- Discharge information, linear mean score
- Doctor communication, linear mean score
- Nurse communication, linear mean score
- Overall hospital rating, linear mean score
- Quietness, linear mean score
- Recommend hospital, linear mean score
- Staff responsiveness, linear mean score

The given answers are then recorded and analyzed to determine whether a hospital is meeting or exceeding national standards (CMS, 2019). These surveys were analyzed at a total of 522 national hospitals that participate in CMS's IPPS program (CMS, 2019). The hospitals were grouped by participation in CTs or nonparticipation in CTs in a 50/50 ratio of 261 hospitals that do not participate in CTs and 261 that do. The CT participation in this design is the independent variable, and the linear mean scoring of the survey instruments is the dependent variable.

Literature Search Strategy

The initial step used in the literature search strategy was to search Google and Google Scholar as well as the Walden University library for terms related to the hypothesis, including *clinical trials, quality, quality improvement, hospital reimbursement, value-based purchasing, shared responsibility,* and *patient-reported outcomes*. Once I retrieved search results, I read the online abstracts and then, if applicable, I chose the source for further review using the Walden University library link

within the Walden University Blackboard. I searched two databases—Medline and CINAHL—both peer reviewed with full text. I also searched the bibliographies of my cited sources and reviewed relevant literature on the topics discussed. The articles by Denburg et al., (2016) and Johnson et al. (2018) provided four additional articles that were analyzed and cited as sources: Moss and Harvrilesky (2017), Fernandez et al. (2014), Clarke and Louden (2011), and Karjalainen and Palva (1989). Google was used to look up CMS data and related reports and articles. Additional sources used were required course textbooks. As Table 1 shows, it was difficult it to find recent relevant peer-reviewed literature on my topic of study. This truly highlights the importance of understanding whether a correlation exists between performance and participation in CTs and increased patient experience measures in the hospital environment. Many of my sources were found in the references lists of dated, but groundbreaking, studies. I intended to cite articles published from 2013 to 2018, but also included older findings from 1989 to 2011, as this germinal literature formed the basis of the given hypothesis.

Table 1

Literature Search

Data source	Boolean phrase	# of results	# of references used in the study
Medline with full text	*Clinical trials* AND *patient reported outcomes* AND *quality*	967	4
Cinahl Plus with full text	*Clinical trials* AND *quality improvement*	1,338	4
Cinahl Plus with full text	*Clinical trials* AND *hospital* AND *recruitment*	314	4
Google	*Learning Health System* AND *AHRQ*	1,240,000	2
Google	*CMS* and *HCAHPS*	1,900	4

Literature Review

The hypothesis that CTs provide medical benefit to participants has been widely debated and researched by the medical community for decades without any indication correlating CTs with positive or negative patient outcomes (Clarke & Louden, 2011; Denburg et al., 2016; Fernandes et al., 2014; Rennie, 2016). Historically, many academics focused on the ethical implications of conducting CTs, and due to the history of CTs, this was well founded (Rennie, 2016). This history has led to intensive scrutiny and rigor of national and global regulatory oversight that guide CTs today, but there is a distinct gap in the literature surrounding the benefits on clinical and patient perceptions of care in hospital systems participating in CTs. The negative paradigms of the past seem to have persisted, which may have stymied the potential for CTs and CP to work in

tandem to improve patient experiences and outcomes or to allow for unbiased examinations (Rennie, 2016).

The Need for Quantitative Analysis

Denburg et al., (2016) discussed the theory that clinical research initiatives improve institutional quality through the integration of CTs and CP, discussing many older case studies that sought to empirically show that hospitals that participate in CTs have better patient mortality rates (Denburg et al., 2016; Karjalainen & Palva, 1989). Despite assertions that this hypothesis was derived from fiscal or immoral constructs aiming to increase CTs in economically depressed nations (Rennie 2016), Denburg et al., (2016) cited some instances where this theory was examined and, in some cases, proven. Karjalainen and Palva's (1989) findings were particularly interesting; they uncovered a 10% increase in life span for those multiple myeloma patients enrolled in CTs compared to patients receiving standard of care in Finland (as cited in Denburg et al., 2016). However, Clarke and Louden (2011) performed a systematic review of the Cochrane Methodology Register searching for evidence of a trial effect, that patients in CTs demonstrated better health outcomes than nonparticipating patients receiving the same or similar treatments, but results were inconclusive (as cited in Denburg et al., 2016). When determining whether a trail effect may exist in providers and institutions, Clark and Louden (2011) returned mixed results. In a study completed from 1989 to 1993, Jha et al. (1996) examined five groups of Canadian hospitals for a CT effect (as cited in Clarke and Louden, 2011). Findings indicated with 95% confidence that nontrial hospitals had higher mortality rates (17.4%) than CT subjects at trial hospitals (6.9% and 6.6%) and that

survival for patients in hospitals participating in clinical research was, in fact, improved (Jha et al., 1996, as cited in Clarke and Louden, 2011). Additional findings indicated that in participating hospitals, adherence to CP guidelines was improved, mean length of stay was significantly decreased, and in one case specifically testing for incidence of death, treatment in hospitals that did not participate in CTs was associated with significant risk of death (Jha et al., 1996, as cited in Clarke and Louden, 2011). Clarke and Louden (2011) indicated that a more rigorous examination of CTs or infrastructure effects is warranted, an assertion mirrored by Denburg et al. (2016).

Denburg et al., (2016) found that hospital systems reacted to the rigors of CTs and sought to prove that the intensity of regulatory oversight, coupled with the CT care model, created an infrastructure effect leading to improved health quality and healthier patients. This article and the studies cited within helped to form the basic theory that institutions undergo improved practices due to organizational scrutiny derived from CT participation (Denburg et al., 2016). In short, the practical application of clinical protocols in a hospital, or in a geographical location, improve CP and therefore improve patient outcomes (Denburg et al., 2016). Nonetheless, the authors did specify a lack of empirical data on CTs and their effect on hospitals and provider behaviors, which pointed to the need for further research. Further, Denburg et al. (2016) hypothesized that institutions participating in CTs have better patient outcomes based on several cited case studies, and their theory relied on the notion that an infrastructure effect existed, yet they never tested the theory through quantitative methods. In this study, I sought to

quantitatively fill the gap in the literature, and the results show that an infrastructure effect exists in patient experiences and outcomes via secondary data analysis.

Patient experience metrics are not mutually exclusive to CP. In fact, Calvert et al. (2018) discussed the importance of understanding subject satisfaction for increasing subject recruitment and ensuring subject retention and follow up in CTs. The importance of understanding subject satisfaction and health outcomes in CTs pertains not only to conducting clinical research and informing clinical protocols, but also to informing policy and practice (Calvert et al., 2018). This notion is imperative because healthcare reimbursement policies have been moving away from fee-for-service models toward value-based structures, a construct discussed in depth by Martin (2017). Martin (2017) discussed the transition from fee for service, or volume-based, reimbursement policies to VBP.

Calvert et al. (2018) also discussed the limitations inherent in conducting subjective patient analyses and defined specific guidance for PRO scoring systems to improve the design of CTs and further inform patient-centric care often found in clinical research initiatives, which is a notion that could be applied to hospital systems in an effort toward becoming learning organizations (Bindman, 2017; Calvert et al., 2018). Calvert et al. highlighted the nature of clinical research as a patient-centric model of care and underscored the importance of continuous quality improvement ideals found within the CT model itself—a methodology that would serve hospital systems well, specifically in times where patient subjective scoring determines hospital reimbursement (Martin, 2017). The notion that subjective reported outcomes in this scenario were voluntarily

prescribed in the CT framework, yet incentivized by governmental reimbursement at the hospital level, shows the variance of paradigms between CP and trial and highlights the need for change.

Value Based Purchasing and HCAHPS

CMS (2017b) defined the hospital VBP program and its effect on hospital reimbursement using domain scores calculated via clinical outcomes and patient-experience measures. CMS described the processes by which reimbursement is withheld or incentivized for participating IPPS hospitals throughout the U.S. CMS also provided the scores for the HCAHPS survey, which represented the linear mean score data sets used in this doctoral study.

As per the ACA, hospital VBP programs directly link Medicare incentivization based on the domain scores presented in the HCAHPS survey in 4,000 national hospitals participating in the IPPS program (CMS, 2017a). Participating hospitals were evaluated using clinical process and patient experience domain scores at 70% and 30%, respectively, to derive a total performance score metric (CMS, 2017a). This metric is used to determine a 2% diagnosis-related group incentive that also is withheld for hospitals that did not meet or exceed minimum thresholds for patient experience and clinical care domains (CMS, 2017a; Martin, 2017).

The HCAHPS survey is given to patients who consent to its completion and hospital data are obtained from those hospitals having at least 300 respondents over a 12-month period (CMS, 2017a). The survey asks specific questions about patient experiences and includes questions about whether a patient would refer another patient to

said hospital or whether the patient understood the home care instructions they received, if they received any (CMS, 2017b). The given answers are then recorded and analyzed to determine whether the hospital is meeting or exceeding national standards (CMS, 2017b). As payment structures move away from fee-for-service toward patient-centric models aimed at quality and efficiency based on data analytics, hospital administrators must find innovative ways to ensure reimbursement for continued sustainability (CMS, 2017b; Martin, 2017).

Paradigms and the Learning Healthcare System

Healthcare delivery providers may be resistant to the rigors of not only understanding the CT process but fulfilling its requirements (Johnson et al., 2018). The case study completed by Johnson et al. (2018) showed evidence that many institutions lack the administrative support required to recruit participating hospitals regardless of the proposed potential benefits to stroke victims. The Comprehensive Post-Acute Stroke Services study was designed to evaluate the effectiveness of standard follow-up care versus a more intensive follow-up regimen involving early supportive discharge preparation, nurse-led follow-up calls, and translational care management and ensured follow-up visits involving patient subjective functional assessments and neurological examination (Johnson et al., 2018). The intent of the study was to decrease caregiver burnout rates, improve functional outcomes, and reduce readmissions. The research team struggled with hospital participation due to lack of health system support in staffing and monetary capabilities as the primary deterrent, which was cited as the main reason for nonparticipation in the Comprehensive Post-Acute Stroke Services study in 61% of the

nonparticipating hospitals surveyed for nonparticipation (Johnson et al., 2018). Regardless of the lack of investigational medication in the study design, Johnson et al. successfully recruited only 43% of previously supportive prospective state stroke centers and hospitals, which took excessive time (15 months instead of the proposed 4 months) and was espoused to be unnecessarily complicated (Johnson et al., 2018). Additional perceived barriers to participation were cited as healthcare administrative determinations based on political and fiscal constraints as well as perceived lack of value (Johnson et al., 2018).

Provider buy-in has been shown to be the cornerstone of all treatment methodologies; albeit investigational, or standard of care (Bindman, 2017). Bindman (2017) discussed the development of the LHS and the importance of nurse buy-in to achieve a robust healthcare delivery system aimed at continuous quality improvement. Bindman expounded upon the need for evidence-based practice garnered through multidisciplinary efforts, inclusive of research initiatives, utilizing data driven analytic techniques and information sharing across facilities, which is inherently true to the Agency for Healthcare Research and Quality's (AHRQ) initiative to move toward LHS (Bindman, 2017). Bindman also delved into the barriers to achieving the LHS, specifically the 17-year gap; a trend in medical innovation that allows a distinct lag from discovery to clinical implementation which promotes health disparities for at risk patient populations (Bindman, 2017).

To overcome the delay between scientific discovery and implementation, Bindman encouraged providers to seek medical knowledge from sources outside of the

typical continuing education units and journal articles. Bindman further asserted that the generation of evidence from internal data analysis coupled with the implementation of external evidence of scientific discovery and healthcare delivery improvements would shrink the 17-year gap and ensure an LHS approach to healthcare delivery (Bindman, 2017).

The utilization of information technology to improve healthcare delivery was at the core of this quantitative data analysis. As Bindman contended, healthcare organizations that applied tools of population management to maximize patient outcomes can be shown to be one of the causes associated with achieving a higher value of care. One such tool has been represented in survey instruments obtaining data on PROs. Bindman further asserted that engaging patients in decision making increased value (Bindman, 2017). Clinical research subjects were actively engaged as volunteers and informed carefully and thoroughly to ensure the ethical tenets espoused by the Declaration of Helsinki (World Medical Association, 2018). It can be shown that the influence of CT participation ensured improved patient experience and satisfaction and may have the ability to provide a bridge for patients and providers to shorten the duration from innovation to implementation (Bindman, 2017).

Definitions

Care transition: The movement of a patient from one healthcare facility or setting to another; this represents an important component of healthcare as patients are at increased risk of experiencing adverse events due to lack of provider communication

and/or lack of patient and/or alternative provider understanding of discharge instructions (AHRQ, 2016).

Clinical practice (CP) patterns: The preferred method, or standard method of clinical care; specifically, one in which experts in the field agree upon, in general (Medical dictionary.com, n.d.)

Clinical trial (CT): A research-based study prospectively requesting voluntarily assigned human subjects and/or groups of human beings to participate in one or more investigational interventions based on disease stratification. These interventions may or may not be given as placebo or actual investigational product with the express intent of evaluating the effects on the condition of the disease in question (National Institutes of Health, 2017).

Discharge instructions: Written instructions or additional documentation of educational instructions and material give to caregivers and patients which encompass all discharge medications and instructions for use, such as known side effects, dosages and frequency of dosing schedule (Joint Commission for National Quality Core Measures, 2010).

Diagnosis related group (DRG): A classification system for categorizing patients based on diagnoses, both primary and secondary, comorbidities, patient demographics and medical history. The DRG standardizes prospective payment to hospitals based on these categories and encourages cost containment initiatives. DRG payments are expected to cover charges related to an inpatient stay from the time of admission to discharge (CMS, 2019).

Federal regulations for clinical trials: As federal regulations pertain to CTs; the FDA creates rules intended to be followed in the performance of CTs with voluntary subjects; which are referred to as Good Clinical Practice (GCP) Guidelines (U.S. Food and Drug Administration, 2015).

Federal regulations for healthcare: As federal regulations pertain to healthcare; agencies create rules that govern public health policy under the authority of the United States Congress (U.S. Department of Health & Human Services, n.d.).

Good clinical practice (GCP): FDA mandated rules and laws enforced by the FDA governing the processes of Performing and volunteering for CTs (U.S. Food and Drug Administration, 2015).

Healthcare provider: Any organization, company, or association formed by or at the behest of a healthcare provider; any person with an interest of control over the provider; an employee, child, parent, sibling or spouse or individual with ownership or control interest in a provider; suppliers of healthcare services, or items; an individual or organization receiving payment for healthcare and services provided therein (Cornell Law School, n.d.)

Health Insurance Portability and Accountability Act (HIPAA): A legislative enactment which established national privacy standards with the intent of protecting the American public's private health information. HIPAA regulations dictate that providers of care protect all information related to patients regardless of medium and disallow providers from sharing patient information without the express consent of the patient or legally authorized representative (U.S. Department of Health & Human Services, n.d.).

Hospital Consumer Assessment of HealthCare Providers and Systems (HCAHPS): A healthcare quality survey given to patients that are hospitalized and consent to participation, with multiple questions used to measure the quality of healthcare in hospitals nationwide. This survey instrument includes one to five-point Likert type questions that assess patient experience via subjective reporting measures. Types of questions asked include categories relating to patient experiences in the hospital itself, with their providers of care, the environment, home care instructions, medication management and overall patient rating of the hospital (CMS, 2019).

HCAHPS linear mean score: A given score from 0 to 100% derived by collecting patient HCAHPS survey data on each survey question and averaging each respondent survey questions derived from the top, middle and bottom box scores for each composite domain (CMS, 2019).

HCAHPS bottom box score: The "bottom-box" is the least positive response category for HCAHPS Survey items. The "bottom-box" response is "Sometimes or Never" for the HCAHPS composite regarding Communication about Medicines "No" for the Discharge Information composite, "'6' or lower (low)" for the Overall Hospital Rating item, "'Definitely No' and 'Probably No'" for the Recommend the Hospital item, and "'Strongly disagree' and 'Disagree'" for the Care Transition composite (CMS, 2019).

HCAHPS middle box score: The "middle-box" captures intermediate responses to HCAHPS Survey items. The "middle-box" response is "Usually" for the HCAHPS composite Communication about Medicines, represents the numeric value of '7' or '8' (medium)" for the Overall Hospital Rating item, "Probably yes" for the Recommend the

Hospital item, and “Agree” for the Care Transition composite. There is no “middle-box” response in the Discharge Information composite as these questions represent yes no answers (CMS, 2019).

HCAHPS top box score: The “top-box” is the most positive response to HCAHPS Survey items. The “top-box” response is “Always” for the HCAHPS composite Communication about Medicines, represents “Yes” for the Discharge Information composite, “‘9’ or ‘10’ (high)” for the Overall Hospital Rating item, “Definitely yes” for the Recommend the Hospital item, and “Strongly agree” for the Care Transition composite.

Hospital participation in clinical trials: Hospital staff and administration agrees to follow GCP guidelines in order to successfully provide clinical research services to any patient that wishes to voluntarily participate in the administration of investigational clinical protocols (Johnson et al., 2018).

Inpatient Prospective Payment System (IPPS): A reimbursement strategy in which each clinical case is categorized into a DRG. Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients (CMS, 2019).

Medication management communication: Communicative methodologies aimed at the optimization of therapeutic results meant to ensure patient safety, prevent and detect medication errors and make sure patients receive the utmost benefit from prescription medicines (ACCP, 2018).

Patient experience: HCAHPS patient experience surveys focus on patient perceptions of care and the key aspects of their experiences, including the frequency with which they encountered critical aspects of their care, inclusive of communication with providers, the coordination of their transitions of care and comprehension of medication mandates and instructions given when being discharged (CMS, 2019).

Value-based purchasing (VBP): A CMS healthcare reimbursement model that aims to improve the quality of healthcare by assessing PRO measures and linking reimbursement with quality scores. The VBP program functions by either revoking or providing incentive-based payments linked to DRG's to hospitals that participate in the IPPS based on the metric data relating to patient mortality and complications, patient experience, safety and nosocomial infection rates. VBP also assesses hospital performance in process, efficiency, and cost reduction (CMS, 2019).

Assumptions

The first assumption was that the instrumentation was reliable and valid given the subjective nature of patient perceptions of clinical care (CMS, 2019). The survey administrators assumed that patients would give honest answers to questions without bias; however, it was cost and resource prohibitive to validate every response by survey respondents (CMS, 2019). In order to ensure validity, HCAHPS surveys undergo intensive quality control and amending on a regular basis to ensure accurate and complete data capture and reduction of erroneous results (CMS, 2019). Another related assumption was that the four modes by which subjects received the survey maintained the validity and reliability of the respondent's answers (CMS, 2019). HCAHPS surveys were given

via four methods: by mail only, telephone call only, a mixed method of mail with a telephone follow-up call, or by Interactive Voice Response, (IVR) methods (CMS, 2019). CMS admittedly reported that patients were more likely to give positive answers via telephonic methods, inclusive of the IVR mode and have addressed that finding (CMS, 2019). CMS built in an adjustment to the scoring of the survey to correct the mode effect that was identified in a nationwide study of 27,229 randomly sampled respondents (CMS, 2019). The final assumption was that the secondary data set referenced would provide an accurate listing of hospital sites.

Scope and Delimitations

The scope of this study was aimed at uncovering whether a positive correlation could be made between improved HCAHPS scores in hospitals that participate in CTs in comparison to those that do not. The hypothesis that hospitals participating in CTs would inherently receive better HCAHPS scores in the domains of Medicare overall star ratings per hospital, and linear mean scores per hospital for medication management and discharge instructions and likelihood of recommendation to family and friends was studied (CMS, 2019). The overall Medicare hospital rating was proposed to be the key indicator to test the remaining research questions and was thought to highlight the need for further study into the uninvestigated HCAHPS survey questions (CMS, 2019). The linear mean scores for the variables, medication management and discharge instructions received and understood were important components of improved health outcomes and would test research questions three and four. Delimitations to this study were based on the analysis of specific questions derived from the HCAHPS survey itself. It was not

possible to obtain the raw data sets for each actual survey given as per CMS, as this would be in violation of Health Information Act regulations (personal email received from HOSPITALCAHPS@cms.hhs.gov on October 7, 2019). Therefore, the publicly reported linear mean scores per each survey question was studied.

The study addressed all HCAHPS domains regarding room cleanliness, subjective pain reporting, patient ratings on perceived feelings of emotional wellbeing, readmissions, reinfections, or hospital acquired infections as part of the Medicare overall star ratings. However, it should be noted that room cleanliness and hospital quietness could vary depending on multiple factors that were outside the scope of this study as many rooms could have been shared or may have been on varying floors which could have been more active than others. Pain reporting and feelings of wellbeing were problematic variables to solely identify as a specified research question on the linear mean analysis for this study and have been amended by CMS in the survey instrument due to the confounding likelihood of patient subjectivity. Infection, readmission and hospital acquired infection rates are not a PRO of satisfaction, but a quality issue that may be considered in a study by itself. However, were included in the Medicare overall star ratings and therefore included in the research questions herein as important indications of hospital quality (CMS, 2019).

Significance, Summary, and Conclusions

As per the Patient Protection and Affordable Care Act, (ACA) (2010) value-based models have continued to determine hospital reimbursement with patient experience and outcomes being the largest determinant of either shared profits, or depleted compensation

(Martin, 2017). The future patient population demographic has been shifting as baby boomers begin to turn 65 and qualify for Medicare (Martin, 2017). With Medicare as the largest third-party payer of that generation, this informed population will determine hospital compensation via Medicare overall star ratings and quality metrics (CMS, 2019). This factor, coupled with the potential for increased ACA repeal highlights the need for healthcare leaders to ensure that their delivery systems quickly become learning organizations and find innovative ways to improve patient satisfaction and quality scores (Martin, 2017). As both CTs and CP rely heavily on understanding patient perceptions on health and healthcare delivery, healthcare administrators must make the best determinations on evidence-based practice and find the best way forward to ensure the highest quality of care and experience for patients (Ross, 2014). This study shows that applying the principles of clinical research to everyday care not only improve the patient experience. Further analyses may also seek to show improved clinical outcomes (Denburg et al., 2016).

Clinical research initiatives have been the cornerstone of medical innovation, yet recruitment efforts at the hospital level have been shown to be stymied by insufficient staffing and lack of health system support (Johnson et al., 2018). In order to achieve continued clinical innovation and improved health outcomes for a growing population, there is a need for both CTs and CP to align to create symbiosis via utilizing a LHS ideology (National Academies Press, 2013). This approach would help improve the patient experience, could show improved patient outcomes and at best, speed the process of life saving medical advances, or at the very least, improve the daily lives of patients

(Moss, and Harvrilesky, 2017; National Academies Press, 2013). The proceeding section will describe the research design and variables of the study as well as provide an in-depth review of the design methodology for purposes of replication. Section two will also include information regarding the statistical validity and reliability of the HCAHPS survey instrument itself (CMS, 2017a).

Section 2: Research Design and Data Collection

Introduction

Regardless of notable medical innovation and lifesaving methodologies that came to fruition and have been marketed to the U.S. public, many healthcare facilities lag in improving patient outcomes and experience scores, a trend referred to as the *17-year gap* by experts in the field of public health (Bindman, 2017; CMS, 2017a). Experts contend that healthcare delivery systems have been weighed down by the many advances in medical technology and scientific innovation and cannot assimilate this knowledge with enough speed to become learning organizations (National Academies Press, 2013). Leveraging the multidisciplinary efforts that create these innovations could have been helping organizations better achieve higher quality scores and better patient experience metrics, thereby embodying the true spirit of a LHS (Bindman, 2017; National Academies Press, 2013).

As healthcare reimbursement models have been moving away from fee for service toward shared responsibility and value-based reimbursement, it is imperative for healthcare administrators to understand patient perceptions that drive clinical outcomes and compensation. The purpose of this quantitative secondary data research study was to determine if hospitals that actively participate in CTs inherently receive better HCAHPS scores than hospitals that do not participate in CTs. The analysis found correlations between the dependent variable of linear mean patient experience scores and overall Medicare hospital ratings with the independent variable of hospital participation in CTs. This exploration could inform healthcare administrators that CT participation may

inherently improve CP patterns and patient experience (Denburg et al., 2016). Understanding whether participation in CTs effects patient perceptions of care and quality is imperative to the discipline and the current gap in the literature regarding a quantitative analysis of the infrastructure effect of participation in CTs must be further addressed (Denburg et al., 2016).

In Section 2, I review the linear mean scores for each variable in question for every hospital, both participating and nonparticipating in CTs, to determine if any correlation exists relating higher Medicare overall star ratings and mean scores for patient experience variables found in the HCAHPS survey questions with CT participation at the hospital level. The survey questions were broken down into patient survey variables relating to care from nurses, care from doctors, experiences in the hospital, the hospital environment, medication management, medication instructions received and understood, likelihood to recommend the hospital to friends and family, and overall Medicare star ratings on a scale of 1 to 5.

The research question and hypotheses to investigate if a correlation exists between the independent and dependent variables are as follows:

RQ: To what extent, if at all, are any of the 10 HCAHPS hospital quality indicators related to the type of hospital (CT versus non-CT)?

H_0: None of HCAHPS indicators are related to type of hospital.

H_1: At least one of the 10 HCAHPS indicators is related to type of hospital.

Research Design and Rationale

The independent variable in this analysis was hospital participation in CTs, and the dependent variables were Medicare overall star ratings and linear mean patient experience scores as defined in the RQ (CMS, 2019). This study aims to examine the difference, if any, in the mean of overall hospital star ratings as determined by CMS to determine if a correlation exists in linear mean HCAHPS scores in participating and nonparticipating CT hospitals. In my analysis I sought to find a correlation, if any, between the dependent variables of linear mean patient experience scores and overall star ratings with the independent variable of hospital participation in CTs. This exploration should inform healthcare administrators that CT participation could inherently improve CP patterns and the patient experience (Denburg et al., 2016).

The Likert-type scale of HCAHPS survey questions of medication management and discharge instructions between CT and non-CT hospitals, patient experience variables that link medication management and discharge instructions received and understood, and the patient experience survey mean score of recommending hospital to friends and family were analyzed using IBM's SPSS statistical tool to calculate the differences between the means of participating and nonparticipating hospitals with 95% confidence and a 0.5 alpha level (Green and Salkind, 2014).

The data sets to the corresponding hospitals, both participating and non-participating were linked with the linear mean scores per RQ and corresponding variables for each HCAHPS survey question, which will be discussed further below. The mean scores per each survey question related to the RQ for participating hospitals were

matched to the list of participating hospitals that could not be obtained from OmniComm systems, which will be discussed in the following sections. The non-participating hospitals were identified by me and then scored similarly, in Excel per CMS HCAHPS ratings and mean scores. I avoided including hospitals that had dissimilar numbers of respondents and selected hospitals nationwide to ensure generalizability (CMS, 2017a).

The association between participation in CTs with regards to patients' understanding of medications and discharge instruction variables were essential to the study. As previously stated, CTs rely heavily on patient–provider interaction and communication about voluntary participation with investigational products. As there was a statistically meaningful difference in the mean scores per variable in these composite domains, a positive correlation empirically showed that the null hypothesis can be rejected. In addition, the association of improved linear scores for these variables with participation in CTs could eventually further explain improved patient outcomes, lead respondents to be more likely to recommend others to the facility and give higher overall Medicare HCAHPS ratings, which could also point to an infrastructure effect as espoused by Denburg et al. (2016).

Methodology

Population

The data needed for this analysis were obtained from the actual HCAHPS data sets from each specific hospital with an expected sample size of 522 hospitals participating in the IPPS framework, with 261 participating in CTs and 261 nonparticipating hospitals (Creative Research Systems, 2012). According to CMS, for

hospitals to participate in the IPPS program, they must have had at least 300 survey respondents (CMS, 2017b). This research design sought to analyze all linear mean scores for each survey question per hospital, as well as the Medicare overall star rating, and compare the mean scores to determine if a correlation exists between higher mean scores and hospital participation in CTs based on the survey variables as defined in the questions.

Sampling and Sampling Procedures

The analysis of the HCAHPS survey instrument from volunteer respondents was completed by accessing the HCAHPS survey database, also known as the hospital compare data sets website and collecting the mean scores per question related to (a) care transition, (b) discharge medications, (c) discharge instructions received and understood, and (d) likelihood to recommend friends and family (Data.Medicare.gov, n.d.). The non-participating hospitals were chosen by reviewing the data export file that was obtained on the CMS (2019) HCAHPS website. My initial sampling procedure was conducted to filter for hospitals in the five most populated states: California, Texas, Florida, New York, and Pennsylvania. Every third hospital was then randomly chosen per state until the 261-sample size was reached for nonparticipating hospitals. Each hospital must have had at least 300 respondents to be included in the analysis completed by CMS. The participating hospitals would be obtained from a listing of clinical research sites both collected over the years from my experience with working in CT sites as a site coordinator and as a project manager and a listing of hospitals extracted from the OmniComm Systems databases. If this listing was not available, I planned to manually

compile a listing of CT sites at the hospital level in the above-mentioned states. The actual survey questions were as follows:

Nurse Communication:

During your hospital stay, how often did nurses treat you with courtesy and respect?

Never Sometimes Usually Always

During your hospital stay, how often did nurse listen carefully to you?

Never Sometimes Usually Always

During this hospital stay, how often did nurses explain things in a way you could understand?

Never Sometimes Usually Always

During this hospital stay, after you pressed the call button, how often did you get help as soon as you wanted it?

Never Sometimes Usually Always

Doctor Communication:

During this hospital stay, how often did doctors treat you with courtesy and respect?

Never Sometimes Usually Always

During this hospital stay, how often did doctors listen carefully to you?

Never Sometimes Usually Always

During this hospital stay, how often did doctors explain things in a way you could understand?

Never Sometimes Usually Always

Hospital Environment:

During this hospital stay, how often were your room and bathroom kept clean?

Never Sometimes Usually Always

During this hospital stay, how often was the area around your room quiet at night?

Never Sometimes Usually Always

During this hospital stay, did you need help from nurses or other hospital staff in getting to the bathroom or in using a bedpan?

Never Sometimes Usually Always

How often did you get help in getting to the bathroom or in using a bedpan as soon as you wanted?

Never Sometimes Usually Always

Overall Medicare Star Ratings

Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?

How often did staff explain about medications before giving them to patients?

Before giving you any new medicine…

How often did hospital staff tell you what the medicine was for?

Never Sometimes Usually Always

How often did hospital staff describe possible side effects in a way you could understand?

Never Sometimes Usually Always

During this hospital stay...

Did hospital staff talk with you about whether you would have the help you needed when you left the hospital?

Yes No

Did you get information in writing about what symptoms or health problems to look out for after you left the hospital?

Yes No

How well did patients understand the type of care they would need after leaving the hospital?

During this hospital stay...

Did hospital staff consider your health care options and wishes when deciding what kind of care you would need after leaving the hospital?

Strongly disagree Disagree Agree Strongly agree

Did you and/or your caregivers understand what you would have to do to take care of yourself after leaving the hospital?

Strongly disagree Disagree Agree Strongly agree

Did you know what medications you would be taking and why you would be taking them after leaving the hospital?

Strongly disagree Disagree Agree Strongly agree

I was not given any medication when I left the hospital

Yes No

Would you recommend this hospital to your friends and family?

Definitely no Probably no Probably yes Definitely yes

Were patients given information about what to do during their recovery at home?

During this hospital stay...

Did hospital staff talk with you about whether you would have the help you needed when you left the hospital?

Yes No

Did you get information in writing about what symptoms or health problems to look out for after you left the hospital?

Yes No

How well did patients understand the type of care they would need after leaving the hospital?

During this hospital stay...

Did hospital staff consider your health care options and wishes when deciding what kind of care you would need after leaving the hospital?

Never Sometimes Usually Always

Did you and/or your caregivers understand what you would have to do to take care of yourself after leaving the hospital?

Never Sometimes Usually Always

Did you know what medications you would be taking and why you would be taking them after leaving the hospital?

Never Sometimes Usually Always

How often did staff explain about medicines before giving them to patients?

Never Sometimes Usually Always

Before giving you any new medicine…

How often did hospital staff tell you what the medicine was for?

Never Sometimes Usually Always

How often did hospital staff describe possible side effects in a way you could understand?

Never Sometimes Usually Always

Would you recommend this hospital to your friends and family?

Yes No

The determination to use nonprobability sampling in this quantitative study was due to the fact that the actual individual survey respondent data were unavailable due to regulatory constraints; hence performing a randomization would have been excessively time consuming and improbable. Additionally, due to the lack of quantitative study on this particular subject, this analysis was initially thought to require a nonrandom sampling strategy based on convenience and purposeful selection of hospitals that do and do not participate in CTs (Laerd.com, 2012).

Classification of hospitals was to be completed utilizing a list of CT hospitals provided by OmniComm Systems as permitted to determine those hospitals that do participate in CTs. In order to fully ensure that 261 hospitals were found from each cohort of participating and non-participating hospitals within the IPPS reimbursement strata, the researcher was potentially going to utilize hospital listings from CMS to identify hospitals that do and do not participate in CTs (Medicare.gov, n.d.). The hospital patient satisfaction scoring codebooks were obtained from CMS and the instructions on how to analyze HCAHPS surveys were published online as the HCAHPS linear means scores and Medicare overall star ratings are published for the sole purpose of allowing the public to compare hospitals based on voluntary patient perceptions of care and additional domain found within the overall start ratings (CMS, 2019). Personal communications with the HCAHPS help desk agent assisted me to ensure I was able to obtain the correct data sets. Linear mean scores were available, and the actual number of surveys completed. The individual HCHAPS survey was not available due to HIPPA regulations.

Calculating the HCAHPS Sample Size

According to the HCAHPS Quality Assurance Guidelines, Centers for Medicare and Medicaid services specified that each hospital participating in the IPPS program must collect a minimum of 300 surveys and aim for a targeted sample size (n) of 335 completed surveys over a 12-month period (hcahpsonline.org., 2018). The second step in the process required the hospital, or survey vendor to estimate the proportion of patients expected to complete the survey, those who may have been ineligible to complete the survey and the expected survey response rate. The calculation was $P = (1-1) \times R$

(hcahpsonline.org., 2018). CMS required that the proportional estimate be determined on an as needed basis depending on the number of admitted patients. The expected response rate was thirty two percent, and the expected rate of ineligible respondents was seventeen percent (hcahpsonline.org., 2018). Utilizing the proportionate calculation, the number of hospital discharges needed to produce a minimum of 300 viable surveys over the 12-month reporting period was approximately 1,259 discharges with 105 completed respondents per reporting period (hcahpsonline.org., 2018).

HCAHPS Sampling Procedure

CMS ensured that the respondents and survey data were representative to the population under study by drawing an equiprobable simple, proportionate stratified random sample, or a disproportionate stratified random sampling procedure for all surveys given to eligible discharges monthly (hcahpsonline.org., 2018). Hospitals were given the choice to sample continuously throughout each month, or at the end of the month if the sampling method remained the same throughout the quarter. Additionally, if a continuous sample was drawn, the ratio and sampling timeframe must have remained consistent throughout the quarter (hcahpsonline.org., 2018). Hospitals and/or survey vendors were required to maintain a monthly sampling strategy even if the sample size (n=300) requirement had been reached (hcahpsonline.org., 2018).

Sample Size

To perform the quantitative analysis for all research questions, the sample size of 522 out of 4,000 US hospitals was initially chosen, which would represent 261 participating and 261 non-participating hospitals. This sample size was chosen utilizing

the sample size calculator from Creative Research Systems (2012). The research questions would have been analyzed with 95% confidence and a confidence interval of 4.0 with an alpha level of 0.05 and 1.96 z-score that the null hypotheses would be rejected for research questions. The overall Medicare star ratings were collected from the hospital compare website (Medicare.gov, n.d.).

As per the sample size calculator tool utilized, the first research question (RQ) RQ1: overall Medicare star ratings would have been analyzed to determine with 95% confidence that between 56-64% of respondents will rate hospitals participating in CTs with at least 3 out of 5 stars. For RQ2, each survey question would have been analyzed to determine with 95% confidence that 56-64% of hospitals participating in CTs would receive a linear mean score that was 20% or higher on each survey variable. For RQ3, each survey question would have been analyzed to determine with 95% confidence that 56-64% of hospitals participating in CTs would have received a linear mean score that was 20% or higher on each survey variable. For RQ4, the survey question of will recommend friends and family to hospital would have been to determine with 95% confidence that 56-64% of respondents at participating hospitals would have answered with a Yes response (Creative Research Systems, 2012).

Instrumentation and Operationalization of Constructs

The HCAHPS survey was tested and created by center for Medicare and Medicaid Services Quality Improvement Organization (CMS, 2003). As the HCAHPS scores are published online on a quarterly basis, the latest annual survey data by hospital was expected to be analyzed. If the 2019 annual data set was available representing all 12

months in the reporting period by the time of data collection, the 2019 data set would have been utilized. The HCAHPS survey instrument is the best secondary data source for determining if a correlation existed between patient experience and overall outcomes with participation in CTs as the hypotheses being tested. The data is published in a public domain for the sole purpose of allowing consumers of care to make the best determinations when choosing a hospital, therefore, no permissions were necessary to obtain the data set (Medicare.gov, n.d.).

Reliability and Validity

Reliability and validity of the HCAHPS survey instrument was researched heavily in the literature on patient satisfaction scoring and then studied further for confirmation in a 2003 pilot study, testing inpatients in hospital systems in three states, New York's IPRO, Arizona's Health Services Advisory Group and Maryland's Delmarva Foundation for Medical care (DFMC) (CMS, 2003). In order to ensure reliability and validity, AHRQ solicited the submission of instruments measuring patient perceptions of care via the federal register. Out of seven submissions AHRQ compiled a draft HCAHPS survey instrument with three considerations in mind. The first that the instrument was valid in capturing perceptions of care from inpatient and acute care settings, that the instrument demonstrated validity and reliability and that the instruments had been used across multiple hospital settings (CMS, 2003). AHRQ derived sixty-six questions from the seven instruments obtained as well as a literature review and previous CAHPS documentation (CMS, 2003).

Utilizing the draft HCAHPS instrument, CMS and AHRQ conducted a pilot study (CMS, 2003). A group of 104 hospitals participated, excluding pediatric, psychiatric and OB/GYN stillborn delivery patients with a response rate of forty seven percent. The initially hypothesized questionnaire was revised post exploratory analysis completed at the hospital and patient level. As a result of a series of analyses measuring hospital-level and internal consistency reliability as well as item scale and global rating correlations, a revised HCAHPS survey was created, consisting of 32 questions which assess seven domains of care (CMS, 2003). The first domain is based on nurse communication and represents the first three questions on the survey. The second domain assesses nursing services, the third, physician communication, followed by physical environment, pain control, medication management and discharge information. Also included, are global domain questions regarding nursing, physician, and overall hospital care as well as the likelihood of a patient to recommend the facility to friends and family. The seven composite scores showed an internal consistency of .69 and median high hospital reliability score of .74 (CMS, 2003).

Prior to the HCAHPS survey draft, myriad studies were performed on the seven survey instruments used to collectively create the HCAHPS survey itself. These studies were created with the express intent of testing reliability and validity through obtaining patient experience scores to ensure consistency across time, facilities, and researchers (CMS, 2003). Further, ecological validity was analyzed to determine when and how to administer the survey to respondents to ensure a large enough response rate to maintain generalizability (CMS, 2003). Findings indicated across most studies completed, that

young single males were less likely to be respondents. Studies also showed that patients on Medicare were more likely to respond than patients on Medicaid and private insurance. Overall, patients with good self-perceptions of health, those that were hospitalized with greater frequency and those patients that were older or on Medicare were most likely to respond with greater satisfaction and frequency (CMS, 2003).

To account for the findings that specific patient subgroups may respond more positively or negatively to the HCAHPS questionnaire, CMS applies patient-mix adjustment to quarterly overall Medicare star rating scores. Further, the scores are adjusted based on the survey administration type to account for the effect mode of administering the survey via telephonic methods, interactive voice response, mail, or a mixed method administration (CMS, 2017a). Additionally, CMS rescales each adjusted linear measure and converts the scores into a 0-100 linear scaled score. Each quarterly average linear score is weighted in proportion to the number of patients seen quarterly. It is important to note that patients must be considered eligible to answer the survey instrument to count. Last, the four quarter averages are rounded to whole numbers (CMS, 2017a).

Operationalization

The dependent variables of linear mean patient experience scores per each research question and overall Medicare star ratings per hospital, both participating and non-participating (independent variables) (n = 522) would have been analyzed to determine if there was a correlation with an increased linear mean score per RQ in hospitals that participate in CTs (the IV). Linear mean scores were found by calculating

the average bottom, middle and top scores for every survey and every survey question given at each hospital (CMS, 2017a). To obtain the overall Medicare star ratings per hospital, the responses to the survey items used in each HCAHPS measure, which is obtained from each of the composite measures, individual items, and global items, are scored, rescaled, averaged across quarters, and rounded up or down to the nearest integer to yield a 0-100 linear-scaled score (CMS,2017a).

Survey Question Sample

Communication about medicines as an example, is derived from the following questions on the HCAHPS survey: How often did staff explain about medicines before giving them to patients?

Before giving you any new medicine how often did hospital staff tell you what the medicine was for?

How often did hospital staff describe possible side effects in a way you could understand? (CMS, 2017b).

Data Analysis Plan

When the data set was retrieved from the CMS hospital compare website, each hospital linear mean score for each RQ's survey variable was expected to be parsed out by hospital type, participating and non-participating, added to an excel spreadsheet and uploaded into SPSS. Hospitals were given the binary variable of "1" in IBM's SPSS statistical software program to specify a Yes value for participation in CTs while the hospitals that did not participate in CTs would be given the variable of "0' for No. Published overall Medicare star ratings for all hospitals would have been coded utilizing

an ordinal scale from 1 to 5 to represent the actual overall Medicare star rating. For the answers to RQ's 2-3, all linear mean scores would have been analyzed to determine if a correlation could be made with an increase in linear mean scores of at least 20% for hospitals participating in CTs. For the Yes No question in RQ4, *will recommend hospital to friends and family*, the variables would have been coded in an ordinal fashion as a 1 for No and a 2 for Yes, analyzed and correlated with the Yes/No variables for participating and nonparticipating hospitals as published on the Hospital Compare data site (Medicare.gov., n.d.). The linear mean scores for RQ's 2-4 were obtained from the published csv files on the CMS hospital compare website (hcahpsonline.org., 2019). The linear mean scores per HCAHPS survey variable were previously analyzed by each hospital's biostatistics department, or vendor averaging the bottom, middle and top scores for every survey respondent's answer to HCAHPS questions at each hospital (CMS, 2017b). The average linear mean scores per each RQ would have been tested using the One-Way ANOVA to see if there are differences between the independent variables, participating and non-participating hospitals, with the ten dependent variable scores from the research question as seen below:

The research question and hypotheses to investigate if a correlation exists between the independent and dependent variables are as follows:

RQ1: To what extent, if any, are any of the 10 HCAHPS hospital quality indicators related to the type of hospital, CT participant versus non-CT participant?

H_0: No relationship exists between the HCAHPS indicators and the type of hospital, CT versus non-CT participant.

H_1: A relationship exists between the HCAHPS indicators and the type of hospital, CT versus non-CT participant.

The research question will be analyzed with 95% confidence and a confidence interval of 4.0 with an alpha level of 0.05 and 1.96 z-score that the null hypotheses will be rejected for research questions (Creative Research Systems, 2012).

Threats to Validity

As CMS controlled for threats to internal and external validity, there was little evidence to support any major concerns (CMS, 2017a). However, threats to internal validity, such as history may have been a concern as questionnaires may be given via mixed method of mail and telephonic interview, for an example, which may have created a change in the subjective answers to the HCAHPS interview if patients had forgotten about a specific circumstance that previously bothered them, or conversely if they were feeling well again and in a better state of mind, or mood and feeling more grateful to the hospital than they were directly post discharge (CMS, 2017a). Instrumentation may also have been an issue as the HCAHPS survey does frequently come under review for improvement; for instance, the subjective responses to pain management were removed from the HCAHPS survey; which was not an issue as the study would not be analyzing patient perceptions of pain.

Ethical Procedures

As the HCAHPS survey instrument and all data sets are publicly shared for the purposes of public information and consumer selection of hospitals, there was no need to obtain specific permissions from hospitals (CMS, 2017a). All hospitals are listed online

with the scores per hospital for each research questions found in this study. Participating patients were volunteers and were never forced to participate; they were given the information via mail and asked to call in, or write back to the hospital, which gave respondents complete control over their participation (CMS, 2017a). All patient information was kept anonymous as each hospital collects and redacts patient identifying information prior to statistical calculation and reporting of results (CMS, 2017b). Being in the clinical research industry, I have had everyday access to CT site listings at the hospital level. A query would have been run on my previous company's database listing of hospital CT sites which would have assisted me in determining which of the hospitals on the CMS website participated in CTs. This information was public as well and can be found on CTs.gov or found online via google search engine. For example, Children's oncology group online gives a national listing of CT hospitals working in pediatric oncology trials (Childrensoncologygroup.org. 2019). Internal Institutional Review Board permissions would not be obtained post proposal acceptance and would be included in Appendix A. I would not obtain or analyze data until the Walden IRB had approved my research proposal. After data analysis, I will keep all data in a secure location and store data on an external hard drive in a locked secure desk or box for five years.

Summary

This research design sought to analyze all linear mean scores for each given research question's survey variable per hospital, as well as the overall Medicare star rating per hospitals, both participating and non-participating in CTs and compare the mean scores to determine if a correlation existed between higher mean scores and

hospital participation in CTs based on the survey variables as defined in the research questions. The following section will describe the data collection methods, and statistical findings derived from the given hypotheses as well as an interpretation of the results.

Section 3: Presentation of the Results and Findings

Introduction

In this study, I aimed to examine the differences, if any, in the linear mean patient experience scores as determined by CMS. The purpose of this study was to examine the difference to determine if a correlation exists in linear mean HCAHPS scores in participating and nonparticipating CTs hospitals. Archival data were obtained for 153 hospitals (76 CT hospitals and 77 non-CT hospitals).

The research question and hypotheses to investigate if a correlation exists between the independent and dependent variables are as follows:

RQ1: To what extent, if any, are any of the 10 HCAHPS hospital quality indicators related to the type of hospital, CT participant versus non-CT participant?

H_0: No relationship exists between the HCAHPS indicators and the type of hospital, CT versus non-CT participant.

H_1: A relationship exists between the HCAHPS indicators and the type of hospital, CT versus non-CT participant.

Data Collection of Secondary Data Set

The 2019 HCAHPS survey linear mean scores and the ClinicalTrial.gov hospital data set for participating hospitals were used as the main data sets due to several factors. First, due to HIPAA compliance, actual patient survey scores could not be obtained. Second, finding hospitals that did participate in CTs was a challenge, a finding consistent with Johnson et al.'s (2018) assertions that CT recruitment at the hospital level was difficult. Thus, a lesson learned case study regarding difficulty in hospital collaboration

with clinical research was published (Johnson et al., 2018). Therefore, the sample size used (n = 153) was smaller than originally anticipated (n = 522) but still met the statistical significance criteria per GPower. The sample size used calculated the linear mean scores of the 10 HCAHPS survey variables from 76 hospitals participating in CTs and 77 nonparticipating hospitals. Last, the data set that was promised from OmniComm Systems was no longer viable due to a corporate buyout and power shifts that resulted in concerns regarding business and confidentiality clauses with clients.

Baseline Descriptive Statistics

The 153 hospitals were selected using two databases: ClinicalTrails.gov and CMS (2019). The 76 CT hospitals were identified using the CT database and were selected after finding that the hospitals were also included in the hospital database. The 77 non-CT hospitals were randomly selected from the remaining hospitals in the hospital database to be used as a comparison group.

Table 2 displays the descriptive statistics for the 10 patient experience variables sorted by highest mean. The highest mean scores were for doctor communication (M = 91.18) and nurse communication (M = 91.18). The lowest mean scores were for quietness (M = 81.01) and communication about medicines (M = 78.16). Table 3 displays the normality tests for the patient experience variables based on hospital group.

Table 2

Descriptive Statistics for the Patient Experience Variables Sorted by Highest Mean

Variable	*M*	*SD*
Doctor communication	91.18	1.98
Nurse communication	91.18	2.08
Recommend hospital	88.77	3.96
Overall hospital rating	88.63	3.12
Discharge information	86.62	3.12
Cleanliness	86.08	3.32
Staff responsiveness	84.10	3.37
Care transition	81.75	2.51
Quietness	81.01	4.96
Communication about medicines	78.16	3.47

Note. $N = 153$.

Table 3

Normality Tests for Patient Experience Variables Based on Hospital Group

		K-S		S-W	
Variable	CT Group	Statistic	*p*	Statistic	*p*
Care transition					
	No	0.15	.001	0.96	.03
	Yes	0.12	.009	0.96	.009
Cleanliness					
	No	0.11	.02	0.97	.12
	Yes	0.11	.02	0.98	.14
Communication about medicines					
	No	0.13	.004	0.96	.02
	Yes	0.12	.007	0.96	.03
Discharge information					
	No	0.15	.001	0.94	.002
	Yes	0.16	.001	0.91	.001
Doctor communication					
	No	0.19	.001	0.95	.007
	Yes	0.22	.001	0.92	.001
Nurse communication					
	No	0.12	.005	0.96	.01

	Yes	0.19	.001	0.89	.001
Overall hospital rating					
	No	0.10	.04	0.98	.27
	Yes	0.14	.001	0.95	.007
Quietness					
	No	0.13	.003	0.96	.03
	Yes	0.11	.02	0.97	.10
Recommend hospital					
	No	0.10	.08	0.98	.39
	Yes	0.14	.001	0.95	.003
Staff responsiveness					
	No	0.11	.03	0.97	.05
	Yes	0.11	.02	0.96	.02

Note. K-S = Kolmogorov-Smirnov; S-W = Shapiro-Wilk.

Results

Initially, the two hospital groups were planned to be compared using *t* tests for independent means. After performing normality assumption testing for *t* tests, 19 of 20 Kolmogorov-Smirnov tests (10 patient experience variables times two hospital groups) were discovered to be significant (see Table 3). This meant that most of the variables were not normally distributed; thus, Mann-Whitney tests were used instead to address this issue.

According to the Laerd (2021) statistics website, Mann-Whitney tests have four statistical assumptions that need to be met: (a) continuous or ordinal dependent variables; (b) categorical independent variable with two groups; (c) independence of observations; and (d) data distributions for both groups were similar. The first three assumptions (continuous dependent variable, two groups, and independent observations) were met based on the design of the study. The fourth assumption (similar distributions) was met

based on inspection of the frequency histograms for both groups for all 10 dependent variables. With that, the data set adequately met the assumptions for the Mann-Whitney tests.

The primary research question for this study was, to what extent, if at all, are any of the 10 HCAHPS hospital quality indicators related to the type of hospital (CT versus non-CT)? The related null hypothesis was none of HCAHPS indicators are related to type of hospital.

The alternative hypothesis was that at least one of the 10 HCAHPS indicators is related to type of hospital. Table 4 displays the Mann-Whitney tests comparing the two types of hospitals based on the 10 patient experience scores. This analysis revealed that seven of 10 patient experience scores were significantly higher for the CT hospitals. Specifically, CT hospitals had significantly more favorable scores for care transition (p = .001), communication about medicines (p = .03), discharge information (p = .01), doctor communication (p = .001), nurse communication (p = .001), overall hospital rating (p = .001), and hospital recommendation (p = .001) (see Table 3). This combination of findings provided support to reject the null hypothesis and accept the alternative hypothesis.

The Spearman correlations (r_s) shown in Table 4 between each of the 10 patient experience variables and their hospital group. Cohen (1988) suggested some guidelines for interpreting the strength of linear correlations. He suggested that a weak correlation typically had an absolute value of r = .10 (r^2 = one percent of the variance explained), a moderate correlation typically had an absolute value of r = .30 (r^2 = nine percent of the

variance explained) and a strong correlation typically had an absolute value of $r = .50$ (r^2 = 25 percent of the variance explained). Inspection of Table 4 found five of the 10 correlations to be of moderate strength using the Cohen (1988) criteria.

Table 4

Mann-Whitney Tests for Patient Experience Variables Based on Hospital Group-

Variable	CT Group	*n*	*M*	*SD*	r_s	*z*	*p*
Care transition					.33	4.01	.001
	No	77	81.04	2.19			
	Yes	76	82.47	2.62			
Cleanliness					.07	0.82	.41
	No	77	85.91	3.21			
	Yes	76	86.25	3.45			
Communication about medicines					.18	2.19	.03
	No	77	77.71	3.21			
	Yes	76	78.61	3.69			
Discharge information					.21	2.58	.01
	No	77	86.18	2.78			
	Yes	76	87.07	3.39			
Doctor communication					.31	3.87	.001
	No	77	90.56	2.16			
	Yes	76	91.82	1.56			
Nurse communication					.33	4.00	.001
	No	77	90.69	1.87			
	Yes	76	91.68	2.17			
Overall hospital rating					.39	4.74	.001
	No	77	87.56	2.49			
	Yes	76	89.71	3.32			
Quietness					.11	1.34	.18
	No	77	81.65	4.29			
	Yes	76	80.36	5.51			
Recommend hospital					.42	5.13	.001
	No	77	87.26	3.29			
	Yes	76	90.30	4.01			
Staff responsiveness					.04	0.47	.64

No	77	84.32	3.14
Yes	76	83.88	3.60

Note. $N = 53$.

Summary

In summary, this study used archival data for 153 hospitals to examine the differences, if any, in the linear mean patient experience scores as determined by CMS HCAHPS survey data. The primary research question for this study was, to what extent, if at all, are any of the ten HCAHPS hospital quality indicators related to the type of hospital (CT versus non-CT)? Seven of ten patient experience scores were significantly higher in the CT hospitals (see Table 4) which supported the alternative hypothesis. In the final section, these findings will be compared to the literature, conclusions and implications will be drawn, and a series of recommendations will be suggested.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

As healthcare reimbursement models move away from fee for service and toward shared responsibility and value-based reimbursement, it is imperative for healthcare administrators to understand patient perceptions that may drive clinical outcomes and, therefore, compensation. The purpose of this quantitative secondary data research study was to examine the difference, if any, in the mean of overall hospital star ratings as determined by CMS to determine if a correlation existed in linear mean HCAHPS scores in participating and nonparticipating CTs hospitals. The analysis sought a correlation, if any, between the dependent variable of linear mean patient experience scores and overall Medicare star ratings with the independent variable of hospital participation in CTs. This exploration may inform healthcare administrators that CT participation may inherently improve CP patterns and patient experience (Denburg et al., 2016).

Interpretation of the Findings

Key findings from this study relating to the alternative hypothesis suggest more favorable scores, to a statistically significant degree, for hospitals that participate in CTs, such as care transition ($p = .001$), communication about medicines ($p = .03$), discharge information ($p = .01$), doctor communication ($p = .001$), nurse communication ($p = .001$), overall hospital rating ($p = .001$), and will recommend hospital ($p = .001$) (see Table 4). Further, Spearman's tests moderately correlate CT participation for the variables of care transition, doctor communication, nurse communication, overall hospital ratings, and hospital recommendations.

These findings suggest that CT participation in hospitals may in fact have an impact or some type of infrastructure effect on organizations as a whole as surmised in Denburg et al.'s (2016) theory that clinical research initiatives improve institutional quality through the integration of CTs and CP. This finding supports cited literature that sought to empirically show that hospitals that participate in CTs have better patient mortality rates (Denburg et al., 2016; Karjalainen & Palva, 1989). The findings pointing to improved ratings in CT hospitals regarding the study variables of care transition and doctor and nurse communication not only show statistical significance, but also moderate correlations to CT participation. These findings may bolster or explain previous literature denoting a 10% increase in life span for patients admitted to participating hospitals (Karjalainen & Palva, 1989, as cited in Denburg et al., 2016), higher mortality rates in nonparticipating hospitals at 17.4%, with 95% confidence, and that survival for patients in hospitals participating in clinical research was in fact improved (Jha et al., 1996, as cited in Clarke & Louden, 2011).

Previous findings have indicated that in participating hospitals, adherence to CP guidelines was improved, mean length of stay was significantly decreased, and in one case testing for incidence of death, treatment in hospitals that did not participate in CTs was associated with significant risk of death (Jha et al., 1996, as cited in Clarke & Louden, 2011). The findings that correlate improved patient satisfaction scores with CT participation may support the literature surrounding the hypothesis that CT hospitals have improved patient satisfaction. Further, it is reasonable to state that patients who give better overall hospital ratings and are more likely to recommend CT hospitals to friends

and family may have come to this conclusion based on their experiences while admitted and also may be derived from lower readmission rates or lack of fatality.

Limitations of the Study

While the original intent of the study's methodology was to obtain 522 hospitals for analysis, the researchers simply could not obtain enough data on hospitals participating in CTs, which may be indicative of the need for further insights into Johnson et al.'s (2016) theory that hospital recruitment was extremely difficult (Johnson et al, 2016). Further limitations include the subjective nature of the HCAHPS survey, as well as the ever-changing instrumentation itself (CMS, 2017b). The 2019 HCAHPS data set was used due to the researchers concern that the Coronavirus COVID-19 pandemic may have skewed the data set as more hospitals may now be participating in CTs due to the need for intensive research into the pandemic. Skewed data sets were found with many outliers at both CT and non-CT hospitals, making sample size recalculations necessary.

Recommendations

Key findings indicate that our nation's hospitals perform rather well overall regarding patient satisfaction with doctor and nurse communication, likelihood to recommend hospitals, overall ratings, discharge information and cleanliness. However, staff responsiveness, communication about medicines, quietness, and care transition are all rated least favorably by patients, with care transition, while showing a statistically significant improvement with a moderate correlation in CT hospitals, are still rated with lower scores than more favorable HCAHPS variables. These findings suggest that as a

nation, healthcare administrators must seek to find ways to improve these lower ratings not only for the betterment of patient health, safety and satisfaction, but also to ensure continued fiscal sustainability as the ACA (2010) expands and shared responsibility remains intact (see table 2.)

Spearman's correlation on the variable, will recommend hospitals to friends and family specifically indicates that 17.3% of the reason that patients were more likely to recommend a CT hospital can be derived from the actual participation in the CT at the hospital level. This finding begs for further understanding of the impact of clinical research participation in hospital settings, but also highlights the need for further study into what additional reasons motivated patients to recommend the hospital for the other 82% of respondents.

It is important to mention that Clarke & Louden's (2011) systematic review of the Cochrane Methodology Register searching for evidence of a "trial effect," that patients in CTs demonstrated better health outcomes than non-participating patients receiving the same or similar treatments, had inconclusive results (Clarke & Louden, 2011 as cited in Denburg, et al.,). Additionally, both Clarke and Louden (2011) and Denburg et al (2016) specifically indicate that a more rigorous examination of a CT or infrastructure effect is warranted. Given the findings of this study, those assertions can be mirrored.

Implications for Professional Practice and Social Change

There can be no doubt that as a human population, we are facing unprecedented times due to the Covid-19 pandemic. If ever there were a time to focus on becoming a LHS and increasing knowledge sharing and true unification via data driven analytics,

information sharing and scientific discovery, it is now. The future demand for CT participation may have lasting implications on society as a whole and the evidence linking CT participation with improved patient experience scores may provide some light at the end of this dark tunnel that we, as a global community have experienced. Those most adversely affected by COVID-19, our burgeoning aged patient population, coupled with our latest adversary highlights the need to truly understand patient perceptions of care in non-participating and participating CT hospitals. The expansion of the ACA due to COVID-19 and the latest administration changes in the oval office will demand that we, as a society, remain focused on not only saving lives, but maintaining our fiscal sustainability in times of crisis.

Conclusion

The question of whether CTs have a positive or negative effect on the patient population have been posited for decades; however, no research within the United States has quantitatively assessed the impact of CTs on our patient population or analyzed patient experience scores in relation to hospital participation versus non-participation in previous literature. The key findings of this study suggest that participation in CTs show statistically significant improved HCAHPS scores in seven out of ten domains, with five out of ten domains also showing a moderate correlation between hospital participation in CTs with higher HCAHPS scores. These findings are timely in a nation heading toward the expansion of the ACA (2010) while the COVID-19 pandemic may require previously nonparticipating hospitals to become participating hospitals out of obligation. The necessity and importance for further research into CT participation and the continuing

effect on HCAHPS scores in a time of unprecedented demand for clinical research in hospitals undergoing fiscal constraints with shared responsibility reimbursement models and a burgeoning aged population cannot be overstated.

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