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Clostridium difficile Infection Occurrence in Academic Health Centers: Do
Organizational Factors Matter?

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor
of Philosophy at Virginia Commonwealth University

by

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Abstract

CLOSTRIDIUM DIFFICILE INFECTION OCCURRENCE IN ACADEMIC HEALTH CENTERS: DO ORGANIZATIONAL FACTORS MATTER?

By Amy Pakyz, PharmD, MS

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University

Virginia Commonwealth University, 2014

Director: Yasar A. Ozcan, Ph.D.

Healthcare-associated infections occur commonly in hospitals and have a major impact on patient well-being. The occurrence of the healthcare-associated infection, *Clostridium difficile*, has been occurring more frequently among hospitalized patients due to an epidemic strain, and is an important cause of antibiotic-associated diarrhea and colitis. This study examined the impact of several organizational factors on the occurrence of *C. difficile* infection (CDI) in hospitals using an institutional theory perspective.

Administrative claims were utilized from University HealthSystem Consortium hospitals to obtain hospital-level data for the calendar year 2011. Data were available for 89 hospitals. Hospital-level analyses, negative binomial regression models, were conducted to test eight developed hypotheses and the associations between organizational factors and the incidence of CDI in hospitals. Cases of CDI were risk-adjusted for known factors associated with CDI.

After controlling for factors known to be associated with CDI, the results of the analyses showed that one study hypothesis was supported. That is, hospitals with higher Leapfrog Group Safety Scores had CDI rates that were no different than hospitals with lower Safety Scores. Further, it was found that *U.S. News and World Report* Best Hospital Honor Roll member hospitals had significantly higher occurrence of CDI as compared to non-Honor Roll member hospitals, though it was predicted that there would be no difference in CDI rates. The organizational factors state-led CDI prevention collaboratives, state mandatory CDI reporting, Magnet status, the rate of central line-associated bloodstream infections and catheter-associated urinary tract infections, and CDI physician champions, were not significantly associated with CDI occurrence.

Chapter 1: Introduction

Healthcare-associated infections (HAIs) are an important concern for hospitalized patients. These types of infections occur in patients during their healthcare treatment for other conditions. In the past decade, infection prevention research and surveillance data have shown that HAIs take a major toll on hospitalized patients. In one clinical setting, up to 10% of patients experience an HAI (Smyth et al., 2008). An estimated 1.7 million infections and nearly 100,000 deaths occur per year in United States hospitals that are attributed to HAIs (Klevens et al., 2007). These statistics do not reflect the loss of productivity, or wages lost by patients stemming from patient illness and disability due to a HAI.

The Association for Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, the Infectious Diseases Society of America, the Association of State and Territorial Health Officials, the Council of State and Territorial Epidemiologists, the Pediatric Infectious Diseases Society and the Centers for Disease Control and Prevention (CDC) proposed together a call to action to move toward the elimination of HAIs. Many HAIs are preventable, which led the Centers for Medicare & Medicaid Services (CMS) to no longer reimburse hospitals for the extra costs associated with certain infections that develop during hospitalization, such as infections due to urinary or vascular catheter use after October 1, 2008 (Medicare Program., 2008). Further, HAIs are reported publicly and may have a deleterious effect

on an organization's credibility and accountability. As of February 2013, 31 states require public reporting of HAIs and the majority of the rest are proposing such legislation (The Association for Professionals in Infection Control and Epidemiology, 2013; Weinstein & Henderson, 2009). Mandatory public reporting is intended to allow key stakeholders, including the public, to make better healthcare choices. Consumer-oriented and professional websites are tracking state adoption of HAI reporting, including the type of infections reported, whether the data are publicly available, and whether hospital identifiers are released to the public (The Association for Professionals in Infection Control and Epidemiology, 2013).

Focus on *Clostridium difficile*

The purpose of this research is to focus on *Clostridium difficile* infection (CDI) for several reasons. First, *C. difficile* is an important cause of healthcare-associated antibiotic-associated diarrhea and colitis. Second, *C. difficile* is tied with methicillin-resistant *Staphylococcus aureus* (MRSA) as the most common organism to cause HAIs in the United States (McDonald, Owings, & Jernigan, 2006). Further, the incidence of CDI has been steadily increasing over the past decade, as reflected by the increase in the number of International Classification of Diseases, Ninth Revision, Clinical Modification codes for CDI. The ICD-9-CM is a classification system which assigns numeric codes to diagnoses for hospital stays. The number of CDI hospital stays increased four-fold over the time period from 1993 to 2009 (Lucado, J., Gould, C., Elixhauser, A., 2012). Patients with CDI have a 2.5-fold increase in 30-day mortality as compared to similar patients without CDI (Hensgens, Goorhuis, Dekkers, van Bentem, & Kuijper, 2013). Third, an emerging hypervirulent strain of *C. difficile* [currently referred

to as North American Pulsed Field type 1 (NAP1) and PCR ribotype 027 (NAP-1/027)](Kelly & LaMont, 2008) has been identified that is highly transmissible (Pakyz, MacDougall, Oinonen, & Polk, 2008) and virulent and has caused epidemics of CDI in a large number of institutions throughout North America (Loo et al., 2005; McDonald et al., 2005; Warny et al., 2005). Fourth, the CDC has established CDI as one of three types of infections that are at the urgent threat level (United States Department of Health and Human Services Centers for Disease Control and Prevention, 2013). Fifth, the management of CDI has been estimated to cost \$3.2 billion dollars per year in the United States (O'Brien, Lahue, Caro, & Davidson, 2007). Lastly, CDI may be modifiable by patient factors such as antibiotic use (Bignardi, 1998; Blossom & McDonald, 2007; Gaynes et al., 2004; Kazakova et al., 2006; Lai, Melvin, Menard, Kotilainen, & Baker, 1997; Loo et al., 2005; McCusker, Harris, Perencevich, & Roghmann, 2003; Modena, Bearely, Swartz, & Friedenber, 2005; Muto et al., 2005; Pepin, Saheb et al., 2005) and gastric acid suppressant (GAS) agent use (Akhtar & Shaheen, 2007; Al-Tureihi, Hassoun, Wolf-Klein, & Isenberg, 2005; Aseeri, Schroeder, Kramer, & Zackula, 2008; Dial, Alrasadi, Manoukian, Huang, & Menzies, 2004; Dubberke et al., 2007; Dubberke et al., 2008; Jayatilaka et al., 2007; Kazakova et al., 2006; Muto et al., 2005; Parente et al., 2003; Scagliarini et al., 2005; Yearsley et al., 2006). The role that appropriate antibiotic and GAS agent use serves in the prevention of CDI occurrence is described further below.

The monitoring of CDI has increased recently at the national level. Beginning in 2013, hospitals that participate in the CMS Inpatient Prospective Payment System Quality Reporting Program were required to report CDI cases using the CDC's National

Healthcare Surveillance Network (NHSN). Further, public reporting of hospital CDI cases will commence in 2014 on the Department of Health and Human Services Hospital Compare Website.

Prevention of *Clostridium difficile*: Patient-level Risks

Many patient-level risk factors for CDI have been delineated from case-control and cohort studies. Non-modifiable risk factors include advanced patient age and length of hospitalization, while modifiable risk factors include medication use, such as antibiotics and GAS agents (Howell et al., 2010; Loo et al., 2011; Stevens, Dumyati, Fine, Fisher, & van Wijngaarden, 2011). Receipt of antibiotics is regarded as the main modifiable risk factor for healthcare-associated CDI and serves as the primary target for antimicrobial stewardship efforts aimed at decreasing CDI occurrence (Valiquette, Cossette, Garant, Diab, & Pepin, 2007). Though most antibiotic classes have been associated with CDI, receipt of certain antibiotics, such as clindamycin and cephalosporins, may place hospitalized patients at the highest risk for acquiring CDI (Owens, Donskey, Gaynes, Loo, & Muto, 2008). The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) CDI Clinical Practice Guideline recommends that the restriction of these agents may be particularly helpful in reducing CDI development, though the decision to target certain antibacterials should be based on local epidemiology (Cohen et al., 2010). The receipt of fluoroquinolones, especially in settings where the CDI epidemic strain North American PFGE type 1 (NAP1) has been implicated, is also considered high-risk. Thus, fluoroquinolone use may also serve as a target to direct antimicrobial stewardship efforts (Cohen et al., 2010). Other agents that may be considered high-risk include the

broad-spectrum agents, the carbapenems, and β -lactamase inhibitor combinations. Though not as consistently as antibiotics, several studies have shown that the use of GAS agents, in particular, proton pump inhibitor agents (PPIs), is also a contributing factor to development of CDI (Cunningham, Dale, Undy, & Gaunt, 2003; Howell et al., 2010; Stevens, Dumyati, Brown, & Wijngaarden, 2011; Yearsley et al., 2006).

Prevention of *Clostridium difficile*: Organizational-level Risks

While many patient-level case-control studies to identify patient risk factors for CDI have been conducted, little is known about organizational-level risk factors. The Institute of Medicine (IOM) refers to the importance of the organizational-level in developing a patient safety culture in its *Crossing the Quality Chasm* report (Institute of Medicine, 2001). Through an organizational sociology theoretic perspective on healthcare organizational change, one can approach such questions as why and how healthcare organizations change, and what motivates them to change (Flood & Fennell, 1995). By taking an organizational view, this study seeks to address a gap in the literature by examining organizational factors that may impact an organization's response to HAIs. Though an organizational perspective has been increasingly applied to healthcare, there is a paucity of research regarding an understanding of organizational influencers that drive organization change in addressing HAIs from an organizational perspective. An organizational perspective can provide insights into the environment in which healthcare organizations function and the macro context that influences an organization's strategy (Murray & Holmes, 2012). Thus, an understanding of these factors may aid in understanding the internal and external factors that motivate change behavior among healthcare organizations. The ultimate goal is to identify rational

policies and interventions that could lead to a decrease in CDI independent of practices by individual clinicians. Other researchers have found correlations between organizational factors and patient infection outcomes, such as the influence of nurse staffing on the occurrence of MRSA infections (Haley et al., 1995; Vicca, 1999).

Conceptual Framework

The availability of a large data source of CDI cases among a consortium of academic health centers affords a framework in which to further understand organizational factors related to CDI. The line of inquiry is to identify organizational factors, after controlling for known CDI risk factors, that are associated with a reduced incidence of healthcare-associated (HA) CDI. Institutional theory, as a conceptual model, will be used to articulate hypotheses that will be used to analyze organizational factors that are associated with reduced HA-CDI. This is important because many of the interventions towards reducing HA-CDI occur at the organizational level, and because of the increasing regulatory actions associated with HA-CDI at the healthcare organization-level. This theory views organizational structure as an adaptive organism that is influenced by the characteristics of its participants and by its environment (Scott W, 2007). Further, as a response to environmental pressures, organizations will exercise strategic choice within the constraints posed by its capabilities and institutional environment.

According to institutional theory, organizations will adopt relevant institutional strategies to aid them in achieving legitimacy. Legitimacy is a resource that can assist organizations in acquiring other resources, such as knowledge, and financial and intellectual resources (Zimmerman & Zeitz, 2002). In order to maintain legitimacy in an

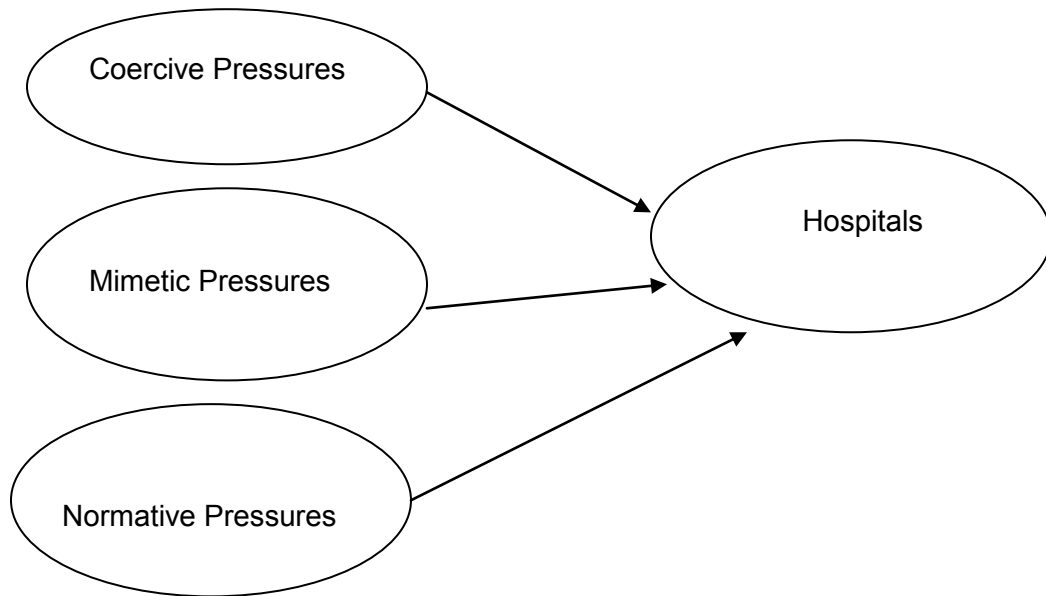
uncertain and demanding environment, organizations will tend to copy the practices of similar organizations (Yang, Fang, & Huang, 2007). The concept of 'institutional bandwagons' has been used to describe the forces of organizations to adopt an innovation, not due to an individual evaluation of the innovation, but because of the number of other organizations that have previously adopted the innovation (Abrahamson & Rosenkopf, 1993). DiMaggio and Powell have termed the process of organizations tending to become homogenous similar under the same environmental conditions as isomorphism (DiMaggio & Powell, 1983).

Healthcare organizations, such as hospitals, comprise a network of institutions that deliver acute care within the complex healthcare industry. Other entities that comprise the healthcare industry include other hospitals, long-term care facilities, insurers, policymakers, and regulators. Thus, there are many types of forces acting on hospitals stemming from the healthcare environment that impact their decisions in regards to adopting or not adopting certain preventative measures to prevent HAIs, such as CDI.

The main constructs from institutional theory that apply to hospital adoption of HAI prevention practices are the institutional pressures that play a role in adoption intent. DiMaggio and Powell have described three types of institutional isomorphism: coercive; normative; and mimetic (DiMaggio & Powell, 1983). Coercive isomorphic pressures represent authoritative forces, which would include those stemming from state government mandates in the form of mandatory regulations for HAI reporting. Mimetic isomorphism occurs when organizations copy other organization's practices in times of uncertainty. Normative pressures stem from those brought about by

professional norms; these could be licensure requirements, for example. Figure 1 displays how institutional forces will affect the adoption of CDI prevention practices by hospitals.

Figure 1. Theoretical Model of Isomorphic Pressures Acting on Hospitals



Research Question

Given the growing problem of HAI occurrence in hospitalized patients, it is important to gain a better understanding of the factors that motivate organizations, such as hospitals, to adopt effective prevention efforts to decrease the occurrence of HAIs.

Towards this goal, this study aims to apply an organization approach to infection prevention. Specifically, the research question (RQ) to be answered is the following:

RQ: *What are the organizational factors that are associated with HA-CDI in hospitalized patients?*

Scope and Approach

Administrative claims data were obtained from University HealthSystem Consortium (UHC) hospitals, an alliance of academic health centers, for the conduction of this study. A subset of UHC hospitals subscribe to the Clinical Resource Manager (CRM) program. The UHC CRM database is comprised of procedure- and diagnosis-specific data from discharge abstract summaries and inpatient drug use. Hospital-level data were obtained from aggregated patient-level data on adult patients (≥ 18 years of age) discharged from UHC CRM hospitals between January 1, 2011, and December 31, 2011. Complete data were available for 89 hospitals.

Hospital-level analyses will be conducted to ascertain whether there are associations between organizational factors that were derived from institutional theory and the incidence of HA-CDI in hospitals. Cases of HA-CDI in hospitals were risk-adjusted based on factors found to contribute to HA-CDI in hospitals. Then multivariable negative binomial regression models were conducted to test generated hypotheses.

Rationale and Significance

The occurrence of HAIs in hospitals poses a threat to patient safety. There are increasing pressures on healthcare organizations, such as hospitals, to report, in a public manner, information concerning their HAI rates. Further, there are increasingly more policies to forgo payment for complications that occur during the delivery of health care that are preventable. Given the importance for hospitals to decrease HAIs, such as CDI, this study potentially offers valuable information regarding the motivating forces on hospitals to take action to decrease HA-CDI using an institutional perspective. The

study findings can inform researchers and policymakers on potentially effective strategies for reducing HA-CDI among hospitalized patients.

Summary and Outline of Remaining Chapters

In summary, this chapter provided an introduction to the research described in the dissertation related to prevention of HAI occurrence, in particular HA-CDI. An introduction to the theoretical perspective used in the current research, institutional theory, was also provided. This perspective was used to address the research question of which organizational factors are related to HA-CDI in hospitals. Chapter two reviews the literature on HA-CDI epidemiology, pathogenesis, diagnosis, risk factors, and prevention. Chapter three presents the theoretical perspective, institutional theory, and conceptual model that were used to guide the development of study hypotheses in more detail. Chapter four provides the study methodology, while chapter five presents the study results. Finally, chapter six concludes with a discussion related to study findings.

Chapter 2: Literature Review

The occurrence of HAIs is an important safety problem in hospitals. Healthcare-associated infections contribute to unnecessary morbidity and mortality; the Centers for Disease Control and Prevention (CDC) estimates that 1 out of every 10-20 patients hospitalized in the U.S. develops a HAI, resulting in an estimated 100,000 deaths (Klevens et al., 2007). The estimated attributable costs of HAIs in hospitals are equal to \$28.4 to \$33.8 billion in excess medical costs (R. D. Scott, 2009). Many HAIs are seen as preventable adverse events caused by medical errors such as failure to adhere to evidence-based prevention strategies.

Some of the more common HAIs include ventilator-associate pneumonias (VAP), MRSA, central line-associated bloodstream infections (CLABSIs), surgical site infections, and *C. difficile* infection. Given the preventability of many HAIs, the growing public concern over HAIs, and the increased national attention on prevention of HAIs, more research is needed to discern what organizational factors influence hospitals in identifying the need to take specific steps to reduce HAI rates. Specifically, what kind of forces influence them, which ones influence them the most, and what causes them to take action towards reducing HAIs. Acquired knowledge in this field will be beneficial in planning future studies related to the development and adoption of strategies to decrease the occurrence of HAIs.

Focus on *C. difficile* Infection

Clostridium difficile infection is a potentially serious HAI; it is the most common cause of infectious diarrhea in hospitalized patients. Being diagnosed with CDI results in a threefold increase in the risk of death during hospitalization, with patients older than age 65 conferring the greatest risk (Oake et al., 2010). There has been a change in the epidemiology of CDI since 2000; reports suggest that there has been an increase in the number of CDI cases that are treatment failures to metronidazole, that relapse after treatment of CDI, and that cause severe disease/complications such as toxic megacolon, perforation, colectomy, shock and death (Blossom & McDonald, 2007; Kazakova et al., 2006; Musher et al., 2005; Pepin, Alary et al., 2005; Ricciardi, Rothenberger, Madoff, & Baxter, 2007). More worrisome is the recent identification of an emerging strain of *C. difficile* that hyperproduces toxins A and B, is highly transmissible and has caused epidemics of CDI in a large number of institutions throughout North America (Loo et al., 2005; McDonald et al., 2005; Warny et al., 2005). The change in CDI epidemiology is attributed to this epidemic strain of *C. difficile* as well as to changes in host immune systems, and in antibiotic prescription practices and other medications (McDonald et al., 2006).

The number of patients who have been discharged from short-stay, acute care healthcare facilities who received the International Classification of Diseases, Ninth Revision (ICD-9-CM) discharge diagnosis code for CDI increased from 5.6 hospitalizations per 1,000 adult discharges in 2001 to 11.5 in 2010, with a projected increase in the rate to 12.5 in 2011 and 12.8 in 2012 (Agency for Healthcare and Research and Quality, 2012). The CDC estimates that 250,000 cases of CDI occur per

year which require hospitalization, or affect already hospitalized patients. A total of 14,000 deaths per year are attributed to CDI (United States Department of Health and Human Services Centers for Disease Control and Prevention, 2013). *Clostridium difficile* infection is perceived to constitute a major economic impact and is a major financial drain (Dubberke & Wertheimer, 2009). Among patients hospitalized with CDI, their average age is 68, signifying that their inpatient stays are billed to Medicare the majority of the time, which contributes to the increase in Medicare costs nationally (J. Lucado, Gould, & Elixhauser, 2006) .

As of 2013, hospitals that participate in CMS's Hospital Inpatient Quality Reporting Program (QRP) are required to report CDI cases using the CDC's National Healthcare Surveillance Network. Public reporting of hospital CDI cases will commence in 2014 on the Department of Health and Human Service's Hospital Compare Website (The Centers for Medicare & Medicaid Services, 2013). The CMS will begin to collect data on hospitals' incidences of CDI for use in its fiscal year 2015 hospital inpatient QRP for inclusion in the agency's Value-based Purchasing (VBP) Program, which was mandated by The Patient Protection Affordable Care Act in October 2012. Under this program, baseline Diagnosis-related group (DRG) payments may be withheld (up to 1% in year one of program) depending upon hospital performance on a variety of quality indicators, including infections. In addition to CDI, hospitals must begin to report MRSA infections in January 2013. The reporting of these infections is in addition to the reporting of CLABSIs, catheter-associated urinary tract infections (CAUTIs), and infections from colon and abdominal hysterectomy, which convened prior to 2013.

Pathogenesis

Clostridium difficile infection is a common complication of hospitalization causing infectious diarrhea (Blossom & McDonald, 2007). Patients ingest either *C. difficile* spores or vegetative organisms obtained from the healthcare environment or from hands of healthcare workers who have touched contaminated items or surfaces; subsequently the spores germinate in the colon and change to the vegetative form. Toxin-producing strains secrete toxins A and B, which lead to production of tumor necrosis factor, pro-inflammatory interleukins, and increased vascular permeability (Blondeau, 2008). If infected, patients experience abdominal symptoms and diarrhea, and can also have dehydration. Potentially more serious complications include toxic megacolon and pseudomembranous colitis, a potentially lethal inflammatory condition that can lead to perforation of the colon. Symptoms of CDI can occur at any time during a course of antibiotic treatment--one of the main risk factors to developing CDI--for up to 8 weeks following antibiotic discontinuation (Hurley & Nguyen, 2002). The use of the two main treatment agents for CDI, metronidazole and oral vancomycin, facilitates recurrent infection, usually occurring within four weeks, by impairing resistance to colonization of *C. difficile*. Recurrence rates after treatment with metronidazole have been reported at 20%, and similarly with oral vancomycin treatment at 18.4% (Kelly & LaMont, 2008).

Diagnosis

Stool culture for and identification of a toxigenic *C. difficile* isolate in patients experiencing three or more unformed stools in 24 or fewer hours is considered the gold standard for CDI diagnosis; however, this testing strategy is not clinically practical due

to the time (up to 7 days) and microbiology expertise it takes to perform the test (Cohen et al., 2010). Another laboratory stool analysis test for CDI is the enzyme immunoassay (EIA) test for toxin A and B. This is a rapid test, but it is the least sensitive available test; EIA sensitivities may be as low as 60% and are rarely above 90% (Wilcox, Planche, Fang, & Gilligan, 2010). The cell culture cytotoxicity assay, which detects toxin B, is more sensitive than the EIA test, but this test is also less sensitive than the gold standard, and the assay is technically demanding with a turnaround time of up to two days (Bartlett & Gerding, 2008). The sensitivity of the toxin EIAs and the cell cytotoxicity assays can be improved by performing a two-step algorithm method that uses EIA detection of glutamate dehydrogenase (GDH) for an initial screen followed by a more specific test such as a cell cytotoxicity assay, a toxin A/B EIA, or a molecular assay. Molecular methods, such as polymerase chain reaction (PCR) testing are the most sensitive and specific tests available. Hospital laboratories that use molecular tests may have twice the detection rate of CDI than laboratories using other tests (Fong et al., 2011). From CDI rate data reported by the CDC's NHSN in 2010, 35% of reporting hospitals were using molecular tests (McDonald et al., 2012). The type of CDI testing methodology used can influence the speed as well as the amount of CDI cases detected, with a PCR method detecting more cases at a faster rate as compared to toxin EIA and two-step testing methods (Grein J, Ochner M, Jin A, Hoang H, Morgan M, Murthy R, 2011).

Risk Factors - Drugs

Clostridium difficile infection occurs almost entirely in patients who are receiving or have recently received antibiotic treatment. Administration of antibiotics alters the

indigenous microflora of the colon, allowing for the growth of *C. difficile* in high concentrations and proliferation of toxin-producing *C. difficile* (Owens et al., 2008). The cumulative dose, number, and duration of antibiotics have all been independently associated with the development of CDI, with higher exposure levels conferring the greatest risk (Stevens et al., 2011). Antibiotic use increases the risk for CDI development by seven- to ten-fold during the time the antibiotic is being taken and for one month after, and by nearly three-fold for two months after (Hensgens, Goorhuis, Dekkers, & Kuijper, 2012). While any antibiotic can promote CDI, broad-spectrum antibiotics such as cephalosporins, beta-lactamase inhibitor combinations, fluoroquinolones, and the agent clindamycin are associated with the greatest risk (Owens et al., 2008). The use of gastric acid suppressant agents (GAS), such as proton pump inhibitors (PPIs) and histamine-2 receptor antagonists may also augment the incidence of CDI (Akhtar & Shaheen, 2007; Al-Tureihi et al., 2005; Aseeri et al., 2008; Dial et al., 2004; Dubberke et al., 2007; Jayatilaka et al., 2007; Kazakova et al., 2006; Muto et al., 2005; Parente et al., 2003; Scagliarini et al., 2005; Yearsley et al., 2006). A meta-analysis of the studies that examined GAS use and the development of CDI obtained a pooled odds ratio of 1.94 (CI: 1.37-2.75) with GAS use (Leonard, Marshall, & Moayyedi, 2007). A possible mechanism is that while *C. difficile* spores are generally acid resistant, the vegetative form of *C. difficile* can survive on moist surfaces and in gastric contents at an elevated pH caused by excess use of agents such as PPIs, while normally vegetative *C. difficile* cells are rapidly killed at normal gastric pH (Jump, Pultz, & Donskey, 2007). A dose response effect has been documented for PPIs and the risk of CDI (Howell et al., 2010). Further, in 2011, the U.S. Food and Drug Administration

added a drug safety statement concerning PPI use and risk of CDI in package labeling (U.S. Food & Drug Administration, 2011). Besides antibiotic and GAS agents, chemotherapeutic drugs have been associated with CDI; this may be due to antibiotic properties of some chemotherapeutic agents and also due to their immunosuppressive side effects (Cohen et al., 2010; McFarland, Mulligan, Kwok, & Stamm, 1989).

Risk Factors - Direct Transmission

Clostridium difficile is shed in the feces; the main mode of CDI transmission is through the fecal-oral route (Cohen et al., 2010). Transmission between patients occurs when patients ingest *C. difficile* organisms obtained from contaminated surfaces or from hands of healthcare workers who have touched contaminated surfaces. The main reservoirs of *C. difficile* are contaminated surfaces and colonized or infected patients. Estimates of *C. difficile* colonization in stool among asymptomatic patients in hospitals range widely, from 7.0%-26% (Cohen et al., 2010). *Clostridium difficile* colonization pressure, or the risk of contracting CDI from surrounding colonized or infected patients, defined as the sum of a patient's daily exposure to patients with CDI who share the same unit or ward divided by patient's length of stay risk, has been found to be an independent risk factor for CDI (Dubberke et al., 2007). Further, patients with CDI that was acquired before a hospital admission, but who present to the hospital with CDI, community-onset (CO) CDI, can serve as a source of transmission. It has been shown that the prevalence of CO CDI, defined either as having a positive *C. difficile* specimen within 48 hours prior to or after inpatient admission, can increase the incidence of HA-CDI in a hospital by 3.0% (Zilberberg et al., 2011).

Risk Factors - Patient Demographics

Advanced patient age, in particular, ages 65 years or older,(McDonald et al., 2006; Pepin et al., 2004) having a history of hospitalization within the previous 60 days,(Dubberke et al., 2007) the duration of hospitalization, (McFarland et al., 1989) and having an intensive care unit (ICU) stay(Riddle & Dubberke, 2009) during hospitalization have all been associated with CDI occurrence. Having an immunosuppressing condition such as human immunodeficiency virus (HIV), having undergone a solid organ or stem cell or bone marrow transplant or a gastrointestinal surgery is also associated with increased CDI risk (Collini, Bauer, Kuijper, & Dockrell, 2012; Sanchez et al., 2005; Thibault, Miller, & Gaese, 1991). The hospital admission source of patients should also be considered when assessing patient risk factors for CDI; specifically, admittance from a long-term care facility or another hospital should be considered. A national point prevalence study found that among 1,143 patients hospitalized with CDI among 648 hospitals, 35% of them had been admitted to a long-term care facility within 30 days before hospitalization, while 47% of the patients had been previously hospitalized within 90 days (Jarvis, Schlosser, Jarvis, & Chinn, 2009).

Risk Factors - Hospital-level

There are a few published studies that have examined risk factors at the hospital-level. Chandler and colleagues (Chandler, Hedberg, & Cieslak, 2007) evaluated hospital-level characteristics (licensed bed capacity, number of intensive care units, number of operating rooms, and presence of hemodialysis units, hematology or oncology wards, and long-term care beds) associated with increases in CDI rates among 48 Oregon hospitals from 1995 to 2002. Policies for laboratory testing of C.

difficile, such as the testing method used (cytotoxin assay, bacterial culture or EIA) were evaluated. Infection control policies were also assessed, such as whether there were isolation precautions, a requirement of private rooms for patients with CDI, whether gloves and gowns were used by healthcare personnel, and what disinfectant agents were used for environmental cleaning. The results showed that hospitals with more than 250 beds and more than five ICU beds had higher rates of CDI. Hospitals that served more populated regions had the highest increase in CDI rates. None of the hospital infection control policies were associated with increases in CDI rates. The authors also evaluated antibiotic policies from 41 hospitals, including the formulary status for eight antibiotics; actual antibiotic use was not measured. No specific antibiotics with open formulary status were significantly associated with increasing rates of CDI.

Van der Kooi et al. (van der Kooi et al., 2008) examined the relationship between hospital aggregate antibiotic use and the incidence of CDI caused by the CDI epidemic strain, PCR ribotype 02, among 23 hospitals in the Netherlands. Antibiotics associated with CDI included second-generation cephalosporins and total antibiotic use. Among the five hospitals with occasional incidences of the epidemic strain, three of them were academic hospitals and these hospitals had significantly higher second-generation cephalosporin use as well as higher extended-spectrum penicillin use.

Gilca and colleagues (Gilca, Hubert, Fortin, Gaulin, & Dionne, 2010) examined hospital factors related to an increased incidence of CDI in epidemic and non-epidemic periods among 83 acute care hospitals that had at least 1,000 discharges per year in Quebec, Canada, from 1998 to 2006. Across both epidemic and non-epidemic periods,

the results were similar. A larger hospital bed size, a longer length of hospital stay, a greater proportion of elderly patients, a greater number of comorbidities among patients, and certain geographic regions (proximity to Montreal) were all associated with an increased incidence of CDI. A teaching profile was associated with a decreased incidence of CDI.

Prevention

The Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America (IDSA/SHEA) have published clinical practice guidelines for CDI (Cohen et al., 2010). One component of the guidelines is the infection control measures that should be implemented, especially in an outbreak situation, such as enhanced cleaning of patient care areas with 10% sodium hypochlorite, hand washing with chlorhexidine or soap and water, and use of both gowns and gloves when taking care of patients with CDI. Further, compliance to hand hygiene practices is encouraged. Other infection control measures such as prompt identification of patients with CDI through electronic alerts and single rooms or patient cohorting for CDI patients may also aid in containing CDI outbreaks (Gerding, Muto, & Owens, 2008). Another component of these guidelines is the recommendation to implement an antimicrobial stewardship program to lower the frequency and duration of antimicrobial therapy and the number of agents prescribed to lower the risk of CDI.

Implementation of interventions to reduce CDI in single-center studies have resulted in CDI rate reductions (Carling, Fung, Killion, Terrin, & Barza, 2003; Climo et al., 1998; Khan & Cheesbrough, 2003; McNulty, 1997; Muto, Blank, Marsh, Vergis, O Leary et al., 2007; Pear, Williamson, Bettin, Gerding, & Galgiani, 1994; Valiquette et al.,

2007). For example, after implementation of an antibiotic stewardship program in one institution designed to decrease the use of antibiotics associated with a CDI outbreak (third-generation cephalosporins, clindamycin, and fluoroquinolones) there was a significant reduction in the incidence in CDI (Valiquette et al., 2007). Muto and colleagues (Muto, Blank, Marsh, Vergis, O'Leary et al., 2007) were able to control a CDI outbreak due to the BI strain by institution of a comprehensive “bundle,” or multifaceted, approach towards controlling CDI whereby several measures were implemented targeted at CDI reduction, such as restriction of use of high-risk agents such as levofloxacin and ceftriaxone, development of a CDI management team, and expanded infection control measures. A collaborative CDI Intervention Program with a focus on the implementation of CDI standardized infection control measures among New York Metropolitan Regional hospitals has also been associated with a significant reduction in HA-CDI rates among participating institutions (Koll et al., 2013).

Though many institutions have increased their number of CDI prevention efforts, they are not always resulting in great improvements. According to the results from the Pace of Progress study conducted by the Association for Professionals in Infection Control and Epidemiology, among 14,000 members in January, 2013, a total of 70% of survey respondents reported that their hospital had adopted additional intervention towards CDI prevention since March 2010 (Association for Professionals in Infection Control and Epidemiology, 2013). However, only 42% of respondents reported a decrease in CDI during that time period.

This chapter provided a review on CDI epidemiology, diagnosis, treatment, prevention, and risk factors, both individual and organizational. Further, this review

provides the background in which to understand the factors that lead to HA-CDI development among patients and information concerning the types of strategies that hospitals can adopt in order to decrease HA-CDI. Chapter three will describe the use of institutional theory, the perspective used to generate hypotheses, to ascertain organizational factors that may influence whether hospitals take action to decrease HA-CDI. Further, chapter three presents the developed hypotheses and provides a conceptual framework for the research question. The hypotheses that were generated to be tested were designed to aid in the identification of the factors that contribute to the differing rates of HA-CDI among hospitals.

Chapter 3: Theoretical Framework and Conceptual Model

Despite the availability of evidence-based guidelines and examples of successful practices to decrease HA-CDI, this infection type remains an infection prevention target for hospitals. A better comprehension of contributing factors in hospitals is needed in order to identify why certain hospitals have lower rates compared to other hospitals. Further, in order to inform organizational-level policy, it is important to ascertain what factors have been specifically associated with reductions in HAIs. In studying organizational response to HAIs, it is useful to look at the ways hospitals, in general, respond to changes in their environment. Organizational theory can be used to predict or explain the strategic approach that may be taken by organizations when they are faced with threats to patient safety, as in the case of HA-CDI.

While there is a dearth of studies assessing the problem of HAIs using an organizational theory perspective, this view may offer insights to the motivating factors that drive behavior in healthcare organizations, such as hospitals. Specifically, the organizational theory perspective of institutional theory can serve as a useful framework in guiding the development of study hypotheses related to ascertaining the internal and external organizational factors that may impact on HA-CDI rates in hospitals. In the first part of this chapter, a review of the institutional perspective, institutional theory, is presented. Then a conceptual model of the research study is presented, followed by a

review of the organizational factors related to HA-CDI occurrence in hospitals and the proposed hypotheses.

Institutional Theory

Above all, institutional theory posits that an organization aims to ensure its survival. Achieving legitimacy and political power is important to its survival as a means to having access to resources (Scott, 2007). Though institutionalization has been defined in several ways by various theorists, a common theme is that institutionalization is a social process. Through this process, individuals begin to accept a shared definition of social reality that is independent of the individual's views, but is taken for granted as "the way things are to be done" (Scott, 1987). As per Meyer and Rowan, for example, the shared belief system, or rational myths, of an institution can aid in explaining the existence of organizational structure. The role of cultural elements, such as normative beliefs and symbols, is emphasized (Scott, 1987). By adopting a set of shared beliefs, organizations do so in order to increase their legitimacy and their survival capabilities (Meyer & Rowan, 1977).

One of the earliest versions of institutional theory was developed by a sociologist, Philip Selznick. According to Selznick, the institutional perspective examines the emergence of distinctive forms, processes, and strategies that evolve from patterns of organizational interaction and adaption in response to the internal and external environment (Selznick, 1948). From this perspective, "to institutionalize" means to "infuse with value beyond the technical requirements of the task at hand" (Scott, 1987). Further, through institutionalization and the instilling of value, this promotes persistence of the structure over time (Selznick, 1948).

A subsequent variant of institutional theory was developed by Meyer and Rowan (1977). According to these authors, the institutionalization of organizational techniques, services, policies, and programs or institutional rules, serve as powerful myths that organizations will adopt ceremonially, thereby establishing 'rationalized myths' (Meyer & Rowan, 1977). Rationalized myths become highly institutionalized and taken for granted as legitimate. By adopting rules, organizations seek to obtain legitimacy, resources, stability, and a greater chance of survival. Because organizational aspects that are adopted ceremonially are not necessarily in congruence with efficiency criteria (Meyer & Rowan, 1977), organizations that adopt institutional rules in order to maintain ceremonial conformity, and in order to achieve legitimacy, become loosely coupled. That is, organizations will decouple formal structures from the technical core to maintain legitimacy and organizational effectiveness (Meyer & Rowan, 1977).

Legitimacy

The main tenet of institutional theory is that organizations will adopt relevant institutional strategies to aid them in achieving legitimacy. Legitimacy is a resource that can assist organizations in acquiring other resources, such as knowledge, and financial and intellectual resources. Achieving legitimacy will guarantee having access to resources and support allowing survival due to the status granted by adopting institutional norms (Meyer & Rowan, 1977). The concept of 'institutional bandwagons' has been used to describe the forces of organizations to adopt an innovation, not due to an individual evaluation of the innovation, but because of the number of other organizations that have previously adopted the innovation (Abrahamson & Rosenkopf, 1993). Therefore, institutional theory differs from theories that focus on the place of

competition and resources, as it emphasizes factors in an institutional environment, such as professional groups and their influences in contributing to the legitimacy and performance of an organization (DiMaggio & Powell, 1983). Researchers (Meyer & Rowan, 1977; Zimmerman & Zeitz, 2002) have described a process whereby organizations adopt a set of shared normative beliefs in order to increase their legitimacy and their survival capabilities. Yielding to expectations and accepted norms from the institutional environment results in legitimacy and stability. In order to maintain legitimacy in an uncertain and demanding environment, organizations will tend to copy the practices of similar organizations (Yang et al., 2007). The pressures to conform to institutional forces can lead to the homogeneity of organizational form, or isomorphism (DiMaggio & Powell, 1983). Thus, organizations become isomorphic with their institutional environment to increase legitimacy, reduce uncertainty and increase standardization.

Isomorphism

The three general mechanisms of isomorphism are mimetic, normative and coercive isomorphism. Mimetic isomorphism occurs when organizations respond to practices or norms in the organization's institutional field and copy what appear to be successful organizations (Yang et al., 2007). Coercive isomorphic pressures represent authoritative forces, which would include those stemming from state and federal government mandates in the form of mandatory regulations. Normative isomorphic pressures represent forces deriving from professional and occupational groups. These include pressures to conform to values of powerful interest groups (Yang et al., 2007). These can also include values and expectations from society-at-large. These pressures

are often evident in times of uncertainty for an organization, thus organizations will copy what has been successfully accomplished among other organizations (Flood & Fennell, 1995).

The isomorphic forces represent the types of influencers that organizations must respond to and that impact organizational change. DiMaggio and Powell (1983) note that isomorphic processes occur even in the absence of evidence that they increase the efficiency of the organization, calling it the 'iron cage.' That is, the reasons for acting on the forces is unclear because the organization is an iron cage, imprisoned by isomorphic pressures, a state where there is decoupling of structure and efficiency. As Zucker (Zucker, 1987) points out, these forces influence the organization to be guided by 'legitimated elements' such as those influenced by professional certification or mandated by the state as opposed to task performance. Also adoption of the legitimated elements leads to isomorphism within the institutional field and increases survival probability. Adoption of processes and conformity influenced by mimetic, coercive, and normative forces increases the availability of resources. Through these processes, routines become embedded and hard to change and through institutionalization, stability is obtained. The reason for acting on the forces is unclear because the organization is in an iron cage, where there is decoupling of structure and efficiency (DiMaggio & Powell, 1983). Thus, institutional theory does not describe processes that make organizations more efficient, but only what forces make organizations more similar. That is, there is a focus on the institutional, as opposed to the technical environment, and less emphasis on competitive or organizational performance responses (DiMaggio & Powell, 1983).

To summarize, Institutional theory is a natural, ecological perspective that takes into account that organizations are not isolated from the environment, but are interdependent with the environment for staff, resources, and relevant information. From this perspective, organizations are subsets of a larger system of relations; organizations contain social systems that have differing interests (Scott, 2007). Through the process of isomorphism, organizations become more homogenous in structure over time (Scott, 2007). The three institutional forces that lead to homogeneity described by institutional theorists include coercive, mimetic, and normative forces. Responding to these forces can enhance an organization's legitimacy and increase their ability to obtain valuable resources. Further, by an institutional perspective, there exists a distinction between an institution's technical and institutional environment. Thus, organizational researchers can use the institutional perspective to study the processes by which an organization makes structural changes in order to conform to an institutional pattern (Scott, 1987).

Conceptual Model

Though there is a dearth of data regarding the organizational factors associated with HAIs using an institutional perspective, institutional theory has been applied by researchers previously to study why healthcare organizations have changed or innovated, or adopted innovations, due to motivating institutional forces. That is, there are examples that depict the types of isomorphic pressures or forces to which healthcare organizations respond to. For example, isomorphic forces have been used to describe the influencing factors leading to the adoption of Total Quality Management (TQM) by hospitals, in particular, the increase in conformity to normative TQM

processes over time (Westphal, Gulati, & Shortell, 1997). Other examples from the literature are provided below.

As discussed above, the three main types of coercive pressures are coercive, mimetic and normative. Coercive pressures represent those forces that are mandated by law, or encouraged by accrediting bodies. Major sources of coercive power acting on healthcare organizations are state and government agency policies. For example, changes in Medicaid reimbursement policies have been shown to impact the number of specialty care in nursing care facilities (Banaszak-Holl, Zinn, & Mor, 1996). A state Certificate of Need (CON) program was shown to impact the rate of hospital entry into management contract arrangements (Alexander & Morrissey, 1989). Changes in Medicare hospital reimbursement policies, such as the prospective payment system (PPS) have also been shown to impact hospital behavior. Implementation of Medicare PPS has resulted in hospital expansion of outpatient services such as in the form of an increase in ambulatory surgery centers and free-standing emergency centers (Updaw, 1987). After PPS was in effect, it has also been noted that the use of technology changed in hospitals; there was less ordering of routines tests and certain procedures such as the pyelogram, and a decline in non-surgical procedures was also seen (Sloan, Morrissey, & Valvona, 1988).

Organizations operate in a realm of bounded rationality and there exists pressures within the organization to respond to mimetic isomorphic pressures, especially in an uncertain situation, by copying other successful organizations (DiMaggio & Powell, 1983). Under institutional theory, groups of organizations that operate under the same regulatory scheme comprises an organizational field.

Organizations within a field will interact with each other more than organizations outside of the field (Noir & Walsham, 2007). It has been shown that the level of hospital community orientation within a geographic area increases a hospital's likeliness to also adopt a community orientation (Proenca, Rosko, & Zinn, 2000). The influence of the diffusion of hospitals adopting community orientation activities such as health promotion programs has also been shown to impact a hospital's likeliness to implement community oriented activities (Ginn, Shen, & Moseley, 2009). Another example of a mimetic force influencing adoption among healthcare organizations, includes the positive influencing factor of the number of hospitals having provider-based Rural Health Clinics in a state on a hospital's disposition to also adopt a provider-based Rural Health Clinic (Krein, 1999).

Other types of pressures facing healthcare organizations are normative forces. Normative pressures are present through forces originating from the professionalization of members who serve as powerful interest groups, or from specialization processes. Normative isomorphism implies that practicing certain professional standards is voluntary and depends on professional agents' knowledge (Yang et al., 2007). Professional agents have access to external knowledge in the relevant professional field (Tsai, 2001). DiMaggio and Powell (1983) refer to professionalization as the defining of the conditions and methods by professionals of their work in order to establish a cognitive base and to legitimize their autonomy. Thus, normative forces stem from the organization's professional groups to adopt forms or processes that are their profession's norms. Physicians have been the primary source of normative pressures in healthcare, but there has also been an increasing influence from other professional

groups, such as allied professionals and professional managers (Flood & Fennell, 1995). It has been shown that the greater the degree of support for human immunodeficiency virus (HIV) prevention practices by clinical supervisors among outpatient drug abuse treatment units, the greater the extent of the adoption of HIV prevention practices, such as condom distribution and HIV antibody testing (D'Aunno, Vaughn, & McElroy, 1999).

As organizational practices become institutionalized, they can become institutional 'rationalized myths' whereby a presumption is made that they are true because of widespread belief in them (Scott, 2007). The practices are adopted because of the perceived gains in legitimacy and survival benefits from conforming to widely held expectations rather than for an efficiency gain (DiMaggio & Powell, 1983). Per the institutional theory perspective, there exists a distinction between an organization's technical core and institutional demands. This decoupling process occurs so that organizations can maintain their external legitimacy and still be efficient; this process can affect the structure within an organization (Meyer & Rowan, 1977). That is, the adoption of certain practices can convey a legitimate external appearance; however, the full implementation of the practices may not be implemented within the organization. For example, it has been shown that while healthcare agencies had adopted case management in order to increase service coordination among centers providing HIV patient services – as it had become a normative institutional feature – there were actually very little operational connections between different agencies (Benson & Kenneth, 1981).

Hospitals are the unit of focus for this research study; hospitals are members of a network of institutions that deliver acute care within the complex healthcare industry. Hospitals interact with providers, other hospitals, professional organizations, nursing homes, patients, insurers, regulators, policymakers, politicians, and the community, among others, in delivering care to patients. By these interactions, there are forces and influences that can potentially influence hospitals' decisions to adopt certain measures to prevent HAIs, such as CDI.

One of these influencing isomorphic forces is coercive isomorphism. Coercive isomorphic pressures represent authoritative forces, which in the area of HA-CDI would include those arising from state government mandates in the form of mandatory regulations for HAI reporting, or from the governmental agency, CMS. For example, there are HAIs other than CDI, such as CLABSIs and CAUTIS, which are no longer reimbursed by CMS when they occur during a hospitalization. A no-payment CMS policy for some types of infections, but not others, may also impact on the occurrence of HA-CDI.

Another influencing isomorphic type in the areas of HAIs is mimetic isomorphism. This process occurs when organizations face environmental uncertainty or ambiguous goals and imitate the practices of other organizations that are viewed as more legitimate or successful. Through mimetic isomorphism, organizations within a field, and given similar environmental circumstances, will make themselves similar as they make changes. Thus, the organization will be deemed as legitimate as it appears similar to hospitals within the same field (DiMaggio & Powell, 1983). In the area of HAIs, there exists state-led multihospital CDI collaboratives. The goal of these collaboratives is to

share data and prevention practices concerning CDI and to institution prevention practices across hospitals, with the aim of reducing CDI.

Other types of pressures facing healthcare organizations are normative forces. Normative forces arise from professionalization. An organization's professional groups may influence the adoption of processes aimed to decrease HA-CDI. In the area of HA-CDI, professional groups such as nurses and CDI physician experts could potentially impact the quality of patient care, and serve as physician champions in the area of HA-CDI prevention, respectively.

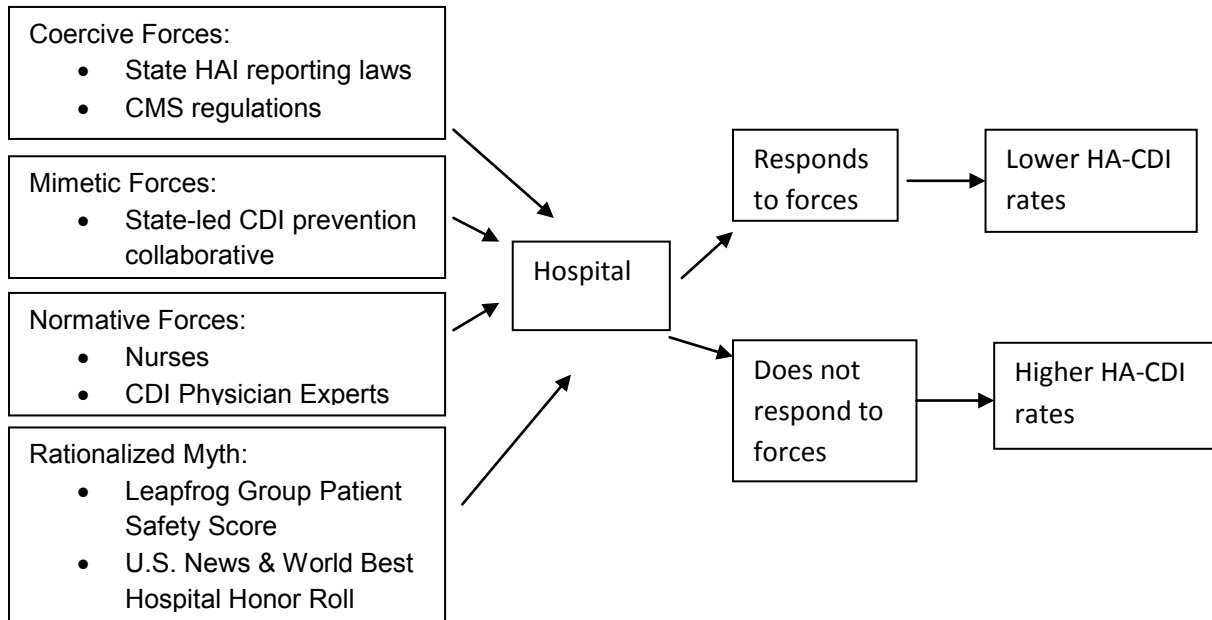
Finally, there potentially exists the presence of rationalized myths that may be associated with HA-CDI. For example, there are several hospital scoring systems in terms of quality and safety that are based in a large part on process measures and a hospital's reputation in certain areas. Though a high score on these scoring systems is meant to signify a safe hospital that delivers a high level of quality care, it is possible that the score does not fully represent aspects of the delivery of safe and quality care at the level of an institution's technical environment. Figure 2 below depicts the conceptual model of this research study, which uses an institutional theory perspective to guide the development of study hypotheses related to identifying associations between differing institutional forces and HA-CDI occurrence.

Development of Hypotheses

Coercive pressures.

One coercive pressure acting upon hospitals in the area of HA-CDI is the regulatory pressure in the form of required reporting, or state-mandated requirements for conformity. There are six states (CA, IL, NY, OR, TN, UT) that require public

Figure 2. Conceptual Model: Factors Influencing Decisions to Take Action to Decrease HA-CDI Using an Institutional Theory Perspective



reporting of facility-wide, laboratory-identified CDI (LabID), as of July 2012 (McDonald et al., 2012).

The purpose of HAI public reporting is to spur hospitals to take efforts to prevent the occurrence of infections by increasing accountability. A review published in 2005 conducted by the Healthcare Infection Control Practices Advisory Committee (HICPAC) found no published information regarding the effectiveness of public reporting in reducing HAIs. Thus, HICPAC concluded that there was insufficient evidence to recommend for or against HAI public reporting (McKibben, Fowler, Horan, & Brennan, 2006). Since publication of the HICPAC review, it has been shown that in Ontario, Canada, public reporting of hospital rates of CDI resulted in lower than predicted rates of infection (Daneman, Stukel, Ma, Vermeulen, & Guttman, 2012). Thus, it is

hypothesized that coercive forces in the form of mandatory state reporting of HA-CDI will result in decreased HA-CDI rates, leading to hypothesis one:

Hypothesis 1: Study hospitals that are located in states with mandatory CDI reporting will have lower rates of HA-CDI than study hospitals not located in states with mandatory CDI reporting.

A second source of coercive pressures is the looming regulatory pressure acting on hospitals in the form of inclusion of HA-CDI in CMS's 2015 hospital inpatient Quality Reporting program (QRP) for addition to the Value Based Purchasing (VBP) program. This would affect nearly all hospitals since most hospitals participate in CMS's QRP. Since October 2008, CMS has no longer reimbursed hospitals for extra costs associated with conditions that develop during hospitalization, including certain infections that develop during hospitalization, such as infections due to catheter-associated urinary tract infections (CAUTIs) or central line-associated bloodstream infections (CLABSIs). Further, the standardized infection ratios (SIRs) of both CAUTIs and CLABSIs are reported for individual hospitals on the U.S. Health and Human Services Hospital Compare Website (The Centers for Medicare & Medicaid Services, 2013). Thus, while potential payment penalties are looming in the case of CDI, other HAIs such as CLABSIs and CAUTIs, have been included on the non-payment list for several years. Lee and researchers (Lee et al., 2012) studied the impact of the CMS payment policy on infection prevention efforts and found that infection preventionists reported an increase in HAI prevention efforts at their hospitals, but found that resource shifting occurred (less time spent on non-targeted HAIs), especially in large hospitals. Lee and colleagues (Lee et al., 2012) demonstrated that the effect of non-payment for

certain conditions that develop during hospitalization by CMS had no effect on central line-associated bloodstream infections and catheter associated urinary tract infections , as compared to a third infection control group, ventilator-associated pneumonia. They attributed their findings to a downward trend for these infections that began years before implementation of the CMS policy and potentially a low incentive to decrease HAIs due to a small financial stake. Further, they also found that the policy had no effect in the subset of hospitals located within states with no mandatory reporting of HAIs, a group of hospitals that may be more motivated by the CMS policy (Krein, Kowalski, Hofer, & Saint, 2012). It appears that whether driven by CMS payment policies or other HAI prevention initiatives, hospitals have been focused on two specific HAIs: CLABSIs and CAUTIs. By focusing on CMS-monitored infections, hospitals can seek to gain legitimacy through a good performance in their HAI rates, which are reported on a public Website, though it may come at the expense of higher HA-CDI. In the study year of 2011, HA-CDI was a CMS non-monitored infection, while CLABSIs and CAUTIs were monitored. This leads to hypotheses 2 (a) & (b):

Hypothesis 2(a): Study hospitals that have lower rates of CLABSIs will have higher HA-CDI rates than study hospitals that have higher rates of CLABSIs.

Hypothesis 2(b): Study hospitals that have lower rates of CAUTIs will have higher HA-CDI rates than study hospitals that have higher rates of CAUTIs.

Mimetic pressures.

Mimetic pressures exist when an organization will imitate the actions of similar organizations because they are within the same organizational field. In the area of HAI prevention, it has been proposed that hospital participation in a surveillance system

which monitors and reports on HAIs in hospitals could result in reduced HAI rates (Gastmeier et al., 2006). Hospitals can use benchmark data to effect practice changes. Benchmarking allows hospitals with higher rates of infections to compare themselves with hospitals with lower rates and to set goals to copy the practices of the hospitals that are “best practice.” For example, a benchmarking study of the insertion and care of central venous catheters (CVCs) was conducted among academic medical center hospitals to compare hospitals’ adherence to recommended CVC insertion and maintenance practices as defined by a set of clinical and operational performance measures (Harting et al., 2008). An organization that perceives a great amount of mimetic isomorphic pressure within an organizational field is likely to imitate the practices of other organizations that have successfully implemented CDI practices. In 2011, there were 15 states that had implemented CDI Prevention Collaboratives. The goals for CDI collaboratives are usually related to sharing and identifying best practices in the prevention of CDI among collaborative members in order to reduce the occurrence of HA-CDI. There is some evidence that shows that hospitals that participated in CDI Prevention Collaboratives demonstrated reductions in their CDI rates (Koll et al., 2013). Thus, there is some data to suggest that hospitals located in states in which there is the presence of a multihospital collaborative will have lower rates of HA-CDI.

Hypothesis 3: Study hospitals that are located in states that have implemented CDI Prevention Collaboratives will have lower rates of HA-CDI than study hospitals located in states that did not implement CDI Prevention Collaboratives.

Normative pressures.

A source of normative forces within a hospital that may impact the occurrence of HA-CDI includes those stemming from the nursing profession. Nurses are an important factor in the delivery of high-quality care (Needleman & Hassmiller, 2009). A review of the nursing factors that have been shown to be important as they relate to HAIs include the nurse-to-patient ratio, the ratio of 'pool staff' to permanent staff, and the skill mix of total nursing personnel (Stone, Clarke, Cimiotti, & Correa-de-Araujo, 2004).

Associations have been found between patient-to-nurse ratios and urinary tract and surgical site infections, with higher rates of infections in hospitals in which nurses care for more patients. Further, nurse burnout as determined by the Maslach Burnout Inventory-Human Services Survey found that nurse burnout was also associated with higher rates of urinary tract and surgical site infections (Cimiotti, Aiken, Sloane, & Wu, 2012).

The American Nurses Credentialing Center (ANCC) accredits organizations with a Magnet® status if they have a high level of quality nursing, including a high rate of nurse retention and a positive work environment that is supportive of high-quality nursing care (The American Nurses Credentialing Center (ANCC), 2013). Aiken and colleagues showed that Magnet hospitals had lower rates of inpatient mortality and failure-to-rescue among surgical patients compared to non-Magnet hospitals (McHugh et al., 2012). Better outcomes have also been displayed for very-low-birthweight babies hospitalized in Magnet hospitals compared to non-Magnet hospitals (Lake et al., 2012). It has also been shown that among Magnet hospitals, there is a higher rate of adoption of National Quality Forum (NQF) Safe Practices as compared to non-Magnet hospitals

(Jayawardhana, Welton, & Lindrooth, 2012). Thus, it appears that hospitals with Magnet status--with the implicit devotion to high-quality nursing care--should have lower rates of HA-CDI. Leading to the fourth hypothesis,

Hypothesis 4: Magnet-designated study hospitals will have lower rates of HA-CDI than non-Magnet-designated study hospitals.

In relation to CDI another source of normative pressures stem from professional groups, such as the infectious diseases practitioners and organizations such as SHEA and IDSA. The Infectious Diseases Society of America and SHEA have published a clinical CDI guideline regarding the diagnosis and treatment of CDI. Included in the guideline are recommendations for improving the diagnosis and management of CDI in adult patients. Also included in the guideline are recommended methods of infection control and environmental management of *C. difficile* (Cohen et al., 2010). Further, members of the organization SHEA have published a series of guidelines regarding strategies for the prevention of CDI as part of its compendium of 'best practices' for the prevention of HAIs in the acute care setting (Dubberke et al., 2008). The author composition of the two guidelines is comprised of a panel of experts in the epidemiology, diagnosis, prevention, and/or clinical management of CDI; the majority of these experts are on staff at academic health centers. A very active involvement of these professionals at the local level could impact organizational goals regarding CDI reduction. The role of an infection prevention 'Champion' has been shown to be a very important aspect of successful infection prevention efforts (Saint et al., 2010). Saint and colleagues found that the utilization of engaging, well-respected champions was a strategy to deal with 'active resistance' among clinicians who were impeding the use of

recommended practices to prevent HAIs (Saint et al., 2009). Further, Seto and colleagues showed that information that was transferred by opinion leaders was more effective in the implementation of a new guideline on urinary catheter care than other strategies (Seto, Ching, Chu, & Seto, 1991). This leads to the next hypothesis to be tested:

Hypothesis 5: Study hospitals that have CDI experts who participated in SHEA/IDSA guideline development on staff will have lower rates of HA-CDI than study hospitals that do not have CDI experts who participated in SHEA/IDSA guideline development on staff.

Rationalized myths.

Regarding the study question and the occurrence of HAIs, a preventable harm, there exist several hospital scoring, or ranking, systems that aim to provide patients information concerning a hospital's quality and safety profile. Scoring well on the ranking systems implies that a hospital has adopted processes attributed to better care and improved patient outcomes. The Leapfrog Group has developed a Hospital Safety Score that uses publicly available national performance measures from the Leapfrog Group Hospital Survey, the Agency for Healthcare Research and Quality (AHRQ), the CDC, and CMS to provide a single composite patient safety score from 28 measures (represented in a letter grade: A-F), representing a hospital's overall safety performance in terms of keeping patients safe from preventable harm and medical errors (Austin et al., 2013). A nine-member expert panel developed the composite scored from process/structural measures and outcome measures which are used by national measurement and reporting programs, which are weighted equally at 50%.

Similarly, the U.S. News & World Report provides an annual listing of the “Best Hospitals;” these rankings were developed to help patients ascertain which hospitals provide the best care for the most serious or complicated medical conditions. Hospital data are examined across a broad spectrum of patient care in terms of survival rates and patient safety across a broad range of sixteen adult medical specialties. For twelve of the specialties (Cancer; Cardiology & Heart Surgery; Diabetes & Endocrinology; Ear, Nose, & Throat; Gastroenterology; Geriatrics; Gynecology; Nephrology; Neurology & Neurosurgery; Orthopedics; Pulmonology; and Urology), the hospital ranking is based largely on data from organizations such as the American Hospital Association (AHA) and CMS. For four of the specialty areas (Psychiatry; Rehabilitation; Rheumatology; Ophthalmology), the ranking is based solely on a reputational survey that is completed by physicians. An index of hospital quality (IHQ) is generated that is based on three dimensions of healthcare, structure, process and outcomes. Further, the U.S. News & World Report tabulates what is known as the Best Hospitals Honor Roll. This is an additional classification that designates excellence across a range of specialties. To qualify for the Honor Roll, a hospital needs to be ranked at least three standard deviations above the mean IHQ in at least six out of sixteen specialties.

It could be theorized that hospitals that achieve Honor Roll status or that have a high Safety Score letter grade have adopted practices perceived to be institutional norms regarding patient safety and quality. However, the internal hospital operations of these hospitals may not reflect the ranking or score in terms of quality or safety. For both the Honor Roll and Safety Score designations, some components of the score are based on structural data obtained from survey data (e.g., Is the cancer center a National

Cancer Institute-designated center?; Is the epilepsy center a designated Level 4 Center by the National Association of Epilepsy Center?; Does the hospital have computerized Physician Order Entry). Also, a component of the score is based on CMS process measures (e.g., Are antibiotics given within one hour of surgical incision?). However, some structural or process indicators have not necessarily been associated with better patient outcomes. Regarding the process measures for community-acquired pneumonia, for example, there are limited randomized data to support many of the guideline recommendations regarding the timing and choice of antibiotic, and the performance of blood culture obtainment (Metersky, 2008). The measures are often derived from practice guidelines developed by professional organizations. Thus, these performance measures are not necessarily based on high-quality evidence.

Implementation of some process measures has caused unintended harmful consequences, including patient harm. Indeed, implementation of a process measure concerning administration of an antibiotic within four hours of a pneumonia diagnosis was possibly associated with an increase in severe CDI in one medical center (Polgreen et al., 2007). Further, a change in the CMS process measures to provide antibiotics within four hours instead of eight hours for a pneumonia diagnosis resulted in a decrease of 10% in the accuracy of the detection of pneumonia (Welker, Huston, & McCue, 2008). Also, an increase in the false-negative blood culture rate has been associated with an increased hospital length of stay in patients with a diagnosis of pneumonia (Metersky, Ma, Bratzler, & Houck, 2004).

Further, as described above, a component of the Honor Roll criteria is established by a reputational survey, which is conferred by an external group of

evaluators. As such, a designation such as an Honor Roll hospital may not necessarily reflect on the internal processes in a hospital related to patient quality and safety. For example, a high safety letter grade or Honor Roll designation would not necessarily reflect on the extent of implementation of a practice in a hospital (such as hand hygiene) and that patient outcomes, such as HA-CDI, would not necessarily be better in these hospitals. That is, adoption of structural and process measures recognized as legitimate performance measures by such groups as Leapfrog Group and CMS may serve as rationalized myths. The designation of an Honor Roll Hospital or a high safety grade confers legitimacy to the external environment, but may not necessarily reflect the quality and safety of the internal environment. This leads to the last set of hypotheses:

Hypothesis 6 (a): HA-CDI rates will not vary by the study hospitals' Leapfrog Group Hospital Safety Scores.™

Hypothesis 6 (b): Study hospitals that are ranked as a U.S. News & World Report Best Hospital Honor Roll member will not have HA-CDI rates that are different than non-Honor Roll member hospitals.

In summary, in response to institutional pressures, organizations need to conform to these forces in order to acquire legitimacy and necessary resources, as well as a competitive advantage. The more of these pressures present in the organization's external environment, the more of an impact these factors should have on an organization's decision to, for example, adopt or improve a necessary innovation, such as HA-CDI prevention practices. From an institutional theory perspective, there are isomorphic pressures that organizations face when developing strategies in response to forces external to an organization. Specifically, there are forces acting on hospitals that

may influence actions that hospitals take to decrease rates of HA-CDI. Table 1 outlines the organizational forces that may impact rates of HA-CDI represented in the developed hypotheses and their direction of their predicted relationship to HA-CDI rates.

An overview of the institutional theory perspective presented in this chapter provided a framework to generate study hypotheses related to the research question of which organizational factors impact on hospitals decisions to adopt measures to decrease HA-CDI. The next chapter, chapter four, describes the study design and the analyses that will be used.

Table 1
Summary of Hypotheses and Expected Results

Hypothesis	Organizational Factor	Expected Result
Coercive Forces		
1	State mandatory CDI reporting	(-) States with mandatory reporting will have lower HA-CDI
2 (a)	CLABSI rates	(-) Higher CLABSI SIR hospitals will have lower HA-CDI
2 (b)	CAUTI rates	(-) Higher CAUTI SIR hospitals will have lower HA-CDI
Mimetic Forces		
3	State-led CDI Prevention Collaborative	(-) States with prevention collaboratives will have lower HA-CDI
Normative Forces		
4	Magnet hospital designation	(-) Magnet-designated hospitals will have lower HA-CDI
5	CDI physician experts	(-) Hospitals with a CDI physician expert on staff will have lower HA-CDI
Rationalized Myths		
6 (a)	Leapfrog Group™ Safety Score	No association between Safety Score and HA-CDI
6 (b)	U.S. News & World Report Best Hospital Honor Roll	No association between being a Best Hospital Honor Roll member and HA-CDI

Chapter 4: Methodology

Overview

Using an institutional theory perspective and a hospital-level analysis, organizational factors will be tested with a multivariable negative binomial regression model to determine the relative contribution of each factor on rates of hospital HA-CDI. The HA-CDI rate will be risk-adjusted with hospital factors thought to be related to HA-CDI occurrence in hospitals in order to make rates comparable across hospitals.

Data Source

Administrative claims data, including procedure- and diagnosis-specific data from discharge abstract summaries, were available from UHC members, an alliance of non-profit academic health centers. A subset of UHC hospitals subscribe to the Clinical Resource Manager (CRM) program. The UHC CRM database is comprised of data regarding inpatient drug use. The subset of non-specialty UHC hospitals (cancer hospitals such as M.D. Anderson and City of Hope were excluded) that participate in the UHC administrative database, including the CRM database, during calendar year 2011 served as the data source. Only data from adult patients ages 18 years or older were used. Data from UHC have been used extensively in health services research investigations, including several that have been published in 2012 (Billeter et al., 2012; David, Medvedev, Hohmann, Ewigman, & Daum, 2012; Jalisi, Bearely, Abdillahi, & Truong, 2013; Keroack et al., 2007; Utter et al., 2012).

Along with administrative data, the UHC database includes detailed information regarding every medication administered in the hospital setting for which charges were generated. Patient-level use of antibiotics for systemic use are measured and aggregated to hospital-wide use. Antibiotic use is measured in days of therapy (DOTs). The methodology of measuring antibiotic use as DOTs is the standard for antibiotic drug measurement established by the CDC's NHSN (Centers for Disease Control and Prevention, 2012). For example, if a patient received a single dose of an antibiotic drug on a given day, whether or not multiple doses are administered, it is registered as '1 DOT.' If a patient received more than one antibiotic drug on the same day, each antibiotic is counted as 1 DOT. The UHC CRM drug database has been described in detail in previous investigations as well as its validation (Pakyz et al., 2008). Cases of HA-CDI will be defined as patients with any (primary or secondary) ICD-9 CM diagnosis code for CDI (008.45) and the Present on Admission (POA) indicator equal to 'No', meaning no, not present at the time of the inpatient admission.

Development of HA-CDI Risk-adjusted Dependent Variable

Risk adjustment methodologies are established for some cardiac outcomes, (Krumholz et al., 2006a; Krumholz et al., 2006b) but as yet there is not yet an identified gold standard methodology for risk-adjustment of infection rates among hospitals. As there is not a standard methodology, the risk-adjustment strategy employed is dependent on available data (Harris & McGregor, 2008). The NHSN has established a methodology for calculating CLABSI Standardized Infection Ratios (SIRs) (The National Healthcare Safety Network., 2010). An overall hospital CLABSI SIR compares the number of CLABSIs (or CAUTIs) in a hospital's ICUs to a national benchmark based on

data reported to the CDC's NHSN from 2006-2008, adjusted by type of ICU location. The hospital SIRs are compared to national sample of hospitals; the national baseline SIR is 1.0. A SIR value of less than 1.0 means that the hospital had fewer CLABSIs than were predicted, while a value of more than 1.0 indicates that the hospital had more CLABSIs than were predicted. Thus, the CLABSI SIR provides a single risk-adjusted summary statistic that reflects several different ICU locations. For the surgical site infection (SSI) SIR, the NHSN, for a given operative procedure, divides the number of observed infections by the number of expected infections (The National Healthcare Safety Network., 2010). The number of expected infections is derived from a logistic regression model. For example, for a particular NHSN operative procedure category, the factors that were included in the regression model were patient age, duration of procedure, and medical school affiliation status of the hospital. The California Department of Public Health Center for Health Care Quality HAI Program suggests that CDI rates should be adjusted for patients who are 65 years of age or older, the rate of CDI community-onset (CO) cases, with these infections serving as a potential source for intra-hospital transmission, and severity of illness in the hospital patient population (California Department of Public Health, January 6, 2012.). Members of the CDC's NHSN presented at a scientific meeting in 2012 that the following hospital characteristics will be considered to determine risk-adjusted rates for the NHSN CDI reporting module: hospital teaching type (major or other); bedsize; diagnostic test type (PCR, other); and CO CDI prevalence . As the current study sample is comprised of academic health centers, there is no need to adjust for the characteristic teaching type in the current study. The characteristic bedsize will be considered as a risk-adjustment

factor in the model, while the CO CDI prevalence will be incorporated into the final model as a control variable. In addition, there are other factors that will be considered for the risk-adjusted models in the current study that are not available to the NHSN, but are available in the UHC CRM, and are predicted to relate to the number of HA-CDI cases in hospitals. For risk-adjustment models, it is common to use stepwise procedures to build the models, meaning variables are either added or deleted to the model, a forward vs. a backward stepwise procedure, respectively, depending on the contribution of that variable on model fit (Lisa I. Iezzoni, 2012). Forward stepwise variable selection is the most commonly used method and will be used in the current study (Harrell, 2001). Specifically for the research study, a forward stepwise negative binomial regression technique will be used to select the most statistically important risk factors to predict HA-CDI occurrence. That is, one variable will be added at a time, for each stage of model building, which contributes most to the model fit until a stopping point. The stopping point will be based on the Akaike information criterion (AIC) value. Model building will begin with the two variables with the lowest p-values; the variables with the next lowest p-values will be added to the regression model one at a time; the model building process will stop once the AIC value increases. The variable total antibiotic use will be forced into the model due its importance as a risk factor for HA-CDI. The risk-adjusted number of HA-CDI cases per hospital ascertained by the procedure described above was used in all the negative binomial regression models conducted to test the study hypotheses.

There were a total of ten factors that were considered in the risk-adjustment negative binomial regression models. The total number of hospital beds was included

as this variable has previously been found to be positively associated with HA-CDI (Labbe et al., 2008). A geographic region variable was also added to the model, as the Northeast geographic region has been associated with higher rates of HA-CDI (Agency for Healthcare and Research and Quality, 2012). Hospitals with a patient population that is more severely ill would be expected to have higher occurrence of HA-CDI; the California Department of Public Health has recommended that hospital case-mix index be considered in the adjustment of HA-CDI rates in California hospitals (California Department of Public Health, January 6, 2012.). Thus, the hospital case-mix index (CMI) variable for discharges was included as a possible risk-adjustment factor. The CMI variable represents the average diagnosis-related group (DRG) relative weight for a given hospital. As longer lengths of hospital stay and older age is associated with the occurrence of HA-CDI (Bignardi, 1998; McDonald et al., 2006), the average hospital length of stay and the proportion of patients aged 65 years or older were also included as potential risk-adjustment factors. Individual medication patient risk factors for HA-CDI include medication use such as antibiotics, PPIs, and chemotherapeutic agents (Howell et al., 2010; McFarland et al., 1989; Owens et al., 2008; Stevens et al., 2011). Therefore the hospital-level use of these agents (expressed as days of therapy per 1,000 patient days) was also included as potential risk-adjustment factors. The CDI testing methodology type, either molecular testing (e.g. PCR) or non-molecular tests, was also included as a potential risk factor in the negative binomial risk-adjustment regression model, as the use of varying tests by laboratories to detect HA-CDI has resulted in differing HA-CDI rates among hospitals (Fong et al., 2011). Finally, a lag variable representing a study hospital's previous year (2010) rate of HA-CDI was

included in the HA-CDI risk-adjusted model. Table 2 displays the predictors that will be entered into a multivariable regression model in order to obtain risk-adjusted hospital HA-CDI rates for each hospital, along with the expected impact of the factor on HA-CDI, and how the factor will be specified in the current study.

Table 2

Hospital-level Risk Factors Considered in Multivariable Risk-adjustment Regression Model

Risk-adjustment Factor	Predicted Impact on HA-CDI Occurrence	Factors Considered for Dependent Variable Construction	Source
Number of beds	Larger bed sizes are associated with higher rates of HA-CDI (Dudeck M, Malpiedi P, Edwards J, MStat, Fridkin S, Mcdonald C, Sievert D. Centers for Disease Control and Prevention, (Labbe et al., 2008)	Continuous	UHC
Region	The Northeast is associated with higher rates of HA-CDI (Agency for Healthcare and Research and Quality, 2012)	Four dichotomous variables that are coded 1 to indicate the four main geographic regions of the census divisions <u>Northeast:</u> CT, NJ, MA, NY, MD, PA, NH, RI, VT <u>South:</u> AR, AL, DE, FL, MS, KS, LA, OK, GA, TN, TX, MO, NC, SC, VA, WV, Washington DC <u>Midwest:</u> IL, IO, IN, KS, MI, MN,OH, MO, WI, NE, ND, SD <u>West:</u> AZ, AL, AK, CO, A, ID, HI, OR, MT, NM, UT, WY, NV, WA Source: UHC	(Agency for Healthcare and Research and Quality, 2012)

Table 2 (continued)

Risk-adjustment Factor	Predicted Impact on HA-CDI Occurrence	Factors Considered for Dependent Variable Construction	Source
Case Mix Index (CMI)	Hospitals with a higher case mix index would be expected to have higher rates of HA-CDI indicating greater patient severity (California Department of Public Health, January 6, 2012.)	Continuous: average Medicare CMI, usually averages around 1.0	UHC
Total Antibiotic Days of Therapy	Antibiotics are associated with HA-CDI (Cohen et al., 2010; Owens et al., 2008; Stevens et al., 2011)	Continuous: DOTs/1000PDs in year 2011	UHC
Proton Pump Inhibitor Agents	Gastric acid suppressant use is associated with HA-CDI (Howell et al., 2010; Stevens et al., 2011; U.S. Food & Drug Administration, 2011)	Continuous: DOTs/1000PDs in year 2011	UHC
Chemotherapeutic agents	Chemotherapeutic agent use is associated with HA-CDI (McFarland et al., 1989)	Continuous: DOTs/1000PDs	UHC
Hospital Length of Stay (LOS)	Longer LOS is associated with HA-CDI (Cohen et al., 2010)	Continuous: average LOS in 2011	UHC
Percentage of all inpatients \geq 65 years	Older age is associated with HA-CDI (McDonald et al., 2006)	Percentage: number of admissions with patients ages 65 or greater divided by total admissions in 2011	UHC
CDI test methodology type	Molecular testing is associated with higher HA-CDI rates than two-step testing and toxin immunoassay (EIA) (Fong et al., 2011; Grein J, Ochner M, Jin A, Hoang H, Morgan M, Murthy R, 2011).	Categorical variable: testing methodology (1) molecular testing for whole year 2011 (2) molecular testing at least partial year or (3) other [two-step process (e.g. glutamate dehydrogenase (GDH) + cytotoxin or PCR) cytotoxin assay or EIA testing]	Hospital Websites/ laboratory personnel at hospitals

Table 2 (continued)

Risk-adjustment Factor	Predicted Impact on HA-CDI Occurrence	Factors Considered for Dependent Variable Construction	Source
2010 HA-CDI	Represents lag variable: the hospitals previous year's HA-CDI cases are likely to be related to the number the following year	Continuous: # of CDI ICD-9-CM codes in 2011 for which POA equals 'No', per 1,000 patient-days.	UHC

Note: The outcome variable will be the number of HA-CDI cases in 2011 (ICD-9 CM diagnosis code for CDI (008.45) and the Present on Admission (POA) indicator equal to 'No'); the model will include an exposure function for the number of total patient days for each hospital in order to account for different number of patient days at each hospital (exposure rate).

Development of HA-CDI Main Independent Variables

In order to test each of the individual main hypotheses, eight separate multivariable regression models will be constructed to test the main independent variables with the risk-adjusted HA-CDI rate as the dependent variable. These variables were previously described in both chapter 2 and 3, in the sections related to risk factors for HA-CDI and in the discussion of the proposed hypotheses. Table 3 displays a summary of the construct, the variable construction, and the data source for each main independent variable.

Table 3

Independent Variable Definitions, Construction, and Data Sources

Main Independent Variables	Construct	Construction	Source
H1 State-required CDI public reporting	State Regulatory Force	Dichotomous variable, = 1 if hospital in a state that requires CDI reporting, 0 otherwise	CDC Morbidity and Mortality Weekly Report (MMWR) Publication (McDonald et al., 2012)

Table 3 (continued)

Main Independent Variables	Construct	Construction	Source
H2 (a) CAUTIs	Federal (CMS) Regulatory Force	Hospital CAUTI Standardized Infection Ratio (SIR): Value ranges around 1.0. A SIR value of less than 1.0 means that the hospital had fewer CLABSIs than were predicted, while a value of more than 1.0 indicates that the hospital had more CLABSIs than were predicted	Hospital Compare Website (The Centers for Medicare & Medicaid Services, 2013) Data reporting period: 1/1/12-3/31/12
H2(b) CLABSIs	Federal (CMS) Regulatory Force	Hospital CLABSI Standardized Infection Ratio (SIR): Value ranges around 1.0. A SIR value of less than 1.0 means that the hospital had fewer CLABSIs than were predicted, while a value of more than 1.0 indicates that the hospital had more CLABSIs than were predicted	Hospital Compare Website (The Centers for Medicare & Medicaid Services, 2013) Data reporting period: 4/1/11-3/31/12
H3 State-led CDI collaborative	State Regulatory Force	Dichotomous variable, = 1 if hospital in a state that implemented a CDI collaborative, 0 otherwise	CDC Website (Centers for Disease Control and Prevention, 2013)

Table 3 (continued)

Main Independent Variables	Construct	Construction	Source
H4 Magnet designation	Normative Force: Nursing Care	Categorized as 0,1, 2; 0 = not a Magnet hospital; 1= a Magnet hospital in year 2003 or earlier; 2 = a Magnet hospital from year 2004-2011,in order to assess the impact of early vs. later adopter of Magnet designation vs. no adoption	American Nurses Credentialing Center (ANCC) Website (The American Nurses Credentialing Center (ANCC), 2013)
H5 CDI physician experts	Normative Force: CDI Medical Experts	Dichotomous variable, = to 1 if author of IDSA/SHEA or SHEA CDI guidelines, 0 otherwise	SHEA Guideline & SHEA/IDSA CDI Guidelines (Cohen et al., 2010; Dubberke et al., 2008)
H6 (a) Leapfrog Group Patient Safety Score	Normative Force: Patient Safety	Categorical variable: the Leapfrog Group's Hospital Safety Score™ ('A', 'B', 'C', 'D', 'F'). [Some categories may be combined due to low number of observations in a category, such as the Grades of 'D' and 'F'.]	The Leapfrog Group's Hospital Safety Score™ Website (grades for the 2 MD hospitals in the sample will be based on other best hospital scoring systems such as the U.S. News & World Report's ranking. If the hospital was a Best Hospital Honor Roll hospital, it will be given a grade of 'A', otherwise it will be given the average grade of all other hospitals).
H6 (b) U.S. News & World Report Best Hospital Honor Roll	Normative Force: Patient Safety	Categorical , = to 1 if ranked a Honor Roll member for 2011-2012, 0 otherwise	Website (U.S. News & World Report, 2012)

Development of HA-CDI Control Variables

Several structural, market, and environmental control factors were included in all of the regression models. Factors that were considered include the types of patients that a hospital serves (demographics, severity), or patient mix. To account for the patient mix of the hospital, several control variables were included. First, the proportion of patients in the hospital who had received care in an intensive care unit (ICU) was included in the regression models. Increased patient severity, such as ICU stay, has been associated as a risk factor for acquiring HA-CDI (Riddle & Dubberke, 2009). The number of patients with a diagnosis of HIV, or who had undergone a gastrointestinal procedure, or a solid organ or bone marrow transplant, was also included as a control variable. These patient comorbid conditions have also been associated with an increased risk of HA-CDI in hospitalized patients (Collini et al., 2012; Sanchez et al., 2005; Thibault et al., 1991). Further, the proportion of patients who had been admitted from either a long-term care facility or another hospital was also included as a control variable. Patient admission from these admission source types has also been associated with an increased risk for HA-CDI (Jarvis et al., 2009). Further, the number of patients with a diagnosis code for CDI with a POA indicator equal to 'Y' or 'W' or 'U', indicating that the patient was admitted with CDI, or, community-onset CDI (CO CDI) was also included as a control variable. An increased admission prevalence of CDI has also been associated with an increased risk of a patient developing HA-CDI when hospitalized (Zilberberg et al., 2011) .

Several variables were included in the model to account for hospital environmental factors that may impact on a hospital's quality performance, and

therefore impact HA-CDI occurrence. The hospital location, whether located in a metropolitan region or not, was considered as a control variable in the regression models for its potential impact on health outcomes. For example, smaller hospitals located in rural areas have been shown to have an increase in 30-day mortality rates for acute myocardial infarction, congestive heart failure, and pneumonia as opposed to hospitals located in urban regions which saw a decrease; mortality rates for the three conditions were found to be higher in hospitals located in rural areas (Joynt, Orav, & Jha, 2013). The Disproportionate Share Hospital (DSH) patient percentage, which represents the sum of the percentage of Medicare inpatient days that are attributed to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days that are attributed to patients eligible for Medicaid, but not Medicare Part A, was used as a measure of socioeconomic disadvantage (Centers for Medicare & Medicaid Services, 2013). That is, if a hospital was in the upper quartile of the study sample of DSH patient percentages, it was considered a safety-net hospital (Ryan, Blustein, Doran, Michelow, & Casalino, 2012). Hospitals that serve disadvantaged populations have been shown to perform less well on performance measures for acute myocardial infarction (Popescu, Werner, Vaughan-Sarrazin, & Cram, 2009). Race was also considered as a socioeconomic factor. Regarding quality outcomes, race has been found to be a determinant of LOS, mortality, and readmissions among patients admitted for congestive heart failure (Philbin & DiSalvo, 1998). Race has also been associated with a decrease in the use of invasive procedures after acute myocardial infarction (Philbin et al., 2000). There has also previously been shown an association between older black Medicare patients and

minority-serving hospitals and higher 30-day readmission rates for patients with congestive heart failure, pneumonia, and acute myocardial infarction (Joynt, Orav, & Jha, 2011).

Finally, the Herfindahl-Hirschman Index (HHI) was used to represent hospital competitive pressure. The HHI was based on bed capacity. Specifically, the squared sum of beds per metropolitan statistical area was calculated for each hospital, which ranged from 0-1, with numbers closer to 0 signifying a less concentrated market, and numbers close to 1 signifying a greater market concentration of hospitals. A value of 1.0 would indicate only one hospital in the specified market. Hospital competition may spur quality. Indeed, regarding quality outcomes, the HHI effect has been negatively associated with pneumonia mortality rates among hospitals in different system types (Chukmaitov et al., 2009), implying that hospitals with located in markets with increased competition had better outcomes. Increased competition has also been associated with a greater performance on quality indicators among nursing homes (Zinn, 1994). Table 4 displays a summary of the construct, the variable construction, and the data source for each control variable as described above.

Table 4

Control Variable Definitions, Construction, and Data Sources

Independent Control Variables	Construct	Construction	Source
CO CDI	CDI cases that are community-onset (not hospital-acquired)	# of CDI ICD-9-CM cases for which POA = 'Yes', 'U' or 'W' in 2011 by 1,000 patient days	UHC

Table 4 (continued)

Independent Control Variables	Construct	Construction	Source
Solid organ and bone marrow transplantation center, digestive system surgeries performed, and number of HIV-infected patients	Organizational structural feature: case mix (high risk medical complexity for CDI)	Total # of solid organ and bone marrow transplant procedures (MS-DRG codes: 1, 2, 5-9, 14-17) + total # of digestive system operations (MS-DRG codes: 326-358) + # of HIV cases (MS-DRG codes: 969-977) by 1,000 patient days	UHC ICD-9-CM Disease and Procedure Codes obtained from CDC Website (Centers for Disease Control and Prevention, 2011)
Intensive Care Unit Days	Organizational structural feature: case mix acuity	Percentage: # of ICU admissions in patients ages 65 or greater divided by total admissions for persons ages 18 or greater	UHC
Source of Admission: long-term care or hospital	Organizational structural feature: case mix	Percentage: # of admissions in patients ages 65 or greater with admission source of long-term care or hospital divided by total admissions for persons ages 18 or greater	UHC
Herfindahl-Hirschman index (HHI)	Environmental: competitive pressure	Calculated by squared sum of beds/ total beds per metropolitan statistical area; ranges between 0-1 (Phibbs & Robinson, 1993)	AHA
Race/ethnicity	Environmental: socioeconomic mix of patient population	Proportion of patients that are Black and Other (non-Caucasian and non-Black)	UHC

Table 4 (continued)

Independent Control Variables	Construct	Construction	Source
Hospital location	Environmental: patient mix of population	Dichotomous variable, = to 1 if hospital located in a metropolitan region, 0 otherwise	AHA
Safety-net Hospital	Environmental: socioeconomic patient mix of population	Dichotomous variable, = to 1 if hospital in top quarter of Medicare Disproportionate Share index [Medicare Supplemental Security (SSI) days ÷ total Medicare days] + Medicaid days among non-Medicare patients ÷ total patient days], 0 otherwise	Medicare Hospital Cost Report

Note: POA classifications:

Y = Yes, present at the time of inpatient admission

U = Unknown, documentation is insufficient to determine if the condition is present on admission

W = Clinically undetermined, provider is unable to clinically determine if the condition is present on admission or not.

Empirical Model

The following empirical model was tested (the model included patient days as an offset):

$$\text{Hospital Risk-Adjusted HA-CDI cases} = \exp (\text{Intercept} + B_1 \cdot \text{Hypothesis} + B_2 \cdot \text{CO} \\ \text{CDI} + B_3 \cdot \text{SOT/BMT/HIV/Surgery} + B_4 \cdot \text{ICU} + B_5 \cdot \text{Source} + B_6 \cdot \text{HHI} + B_7 \cdot \text{Race-} \\ \text{Black} + B_8 \cdot \text{Race-Other} + B_9 \cdot \text{Location} + B_{10} \cdot \text{Safety-Net})$$

Where hospital risk-adjusted HA-CDI rate is the dependent variable, the risk-adjusted number of hospital cases of HA-CDI; where hypothesis is one of eight independent variables, either whether the hospital is located in a state with mandatory CDI reporting (dummy variable 0/1), or whether the hospital is located in a state with a

state-led CDI prevention collaborative (dummy variable 0/1), or the CAUTI SIR (continuous variable), or the CLABSI SIR (continuous variable), or the Leapfrog Group Patient Safety Score (dummy variable 1/2/3), or whether the hospital is a U.S. News & World Report Best Hospital Honor Roll member (dummy variable 0/1), or whether the hospital is designated as a Magnet hospital (dummy variable 0/1), or whether there is a CDI physician expert on staff at the hospital (dummy variable 0/1); where CO CDI represents the CDI cases that are community-onset (continuous variable); where SOT/BMT/HIV/Surgery represents the number of patients with either a solid or bone marrow organ transplant, gastrointestinal surgery, or with an HIV diagnosis (continuous variable); where ICU represents the hospital percentage of patients with ICU admissions; where source represents the proportion of patient admissions with an admission source of either long-term care facility or hospital; where HHI represents the Herfindahl-Hirschman index (continuous variable); where Race-Black represents the proportion of patients that are Black; where Race-Other represents the proportion of patients that are a race other than black or Caucasian, non-Hispanic; where location represents whether the hospital is located in a metropolitan area (dummy variable 0/1); and where Safety-net represents whether a hospital is in the top quartile of the DSH patient percentage (dummy variable 0/1).

Analytic Approach

Descriptive analyses of all the main independent and control variables were conducted, including calculation of the mean, standard deviation, median, and range for continuous variables. Bivariate analyses were conducted to assess the relationship between the independent variables and the dependent variable.

Eight multivariable negative binomial regression models were conducted to test the individual hypotheses concerning organizational risk factors associated with higher HA-CDI rates. Negative binomial regression binomial models were chosen as they are used when the dependent variable is a count of events (Woolridge, 2009). Poisson regression techniques are also appropriate for count data when the variance of the dependent variable equals its mean. A dispersion test will be conducted, if the results are not significant, meaning that the variance does not exceed the mean, then Poisson regression techniques will be used. For all regression models, robust standard errors were applied as defined by the statistical software package (such as the Huber/White heteroscedastic consistent estimator of the variance/covariance matrix in Stata) to produce valid standard error estimates and t-statistic values in the presence of heteroscedasticity and correlation. Variance Inflation Factors (VIF) were generated by running least squares regression models with all the variables to assess for collinearity. Model diagnostics were not conducted to assess residual normality or variable linearity since a negative binomial regression model was utilized; independent variables are not expected to be linearly related to the dependent variable. Since negative binomial regression models were used to conduct the analyses, in order to assess goodness of fit of the models, Information Criteria statistics were used, such as the Akaike's Information Criteria (AIC). The AIC of the empty model containing the intercept was compared to the explanatory models. Stata version 12 (StataCorp LP) was used for all analyses; a two-sided significance value of < 0.05 was considered significant.

Sensitivity Analyses

Additional analyses were conducted in order to evaluate the robustness of the results. The regression models were re-run using a different definition for HA-CDI. The new definition included not only the CDI ICD-9-CM code with POA = 'No' to define HA-CDI, but also including POA = 'U', unknown, and POA = 'W', clinically undetermined, to assess the impact of potentially differing coding practices across hospitals on study results. Further, additional analyses were conducted to assess the robustness of the laboratory testing methodology classification; the variable was re-classified per the following: (1) molecular (e.g. PCR) for whole year 2011; (2) molecular at least partial year or two-step process (e.g. glutamate dehydrogenase (GDH) + cytotoxin or PCR) or cytotoxin assay; (3) EIA testing.

In summary, this chapter reviewed the methodology of the current research including the data source, the study sample, study design, construction of main independent variables of interest and control variables, and the analytic approach. In short, eight separate multivariable negative binomial regression models will be conducted in order to test the generated hypotheses concerning whether institutional pressures are associated with the occurrence of CDI in hospitals. Chapter five provides the results of these analyses.

Chapter 5: Results

The results of the analyses are presented in this chapter. Descriptive statistics are provided for the model variables, as well as the results of the bivariate and final negative binomial regression model analyses that assess the forces that influence risk-adjusted HA-CDI. Further, the results of the sensitivity analyses are presented in this chapter.

Sample

Of the 98 UHC CRM members, a total of 89 (91%) were represented in the study sample. Three hospitals were eliminated from the study sample as they were cancer specialty hospitals (2) or a correctional facility hospital (1). The remainder six hospitals were removed from the sample because of incomplete or unreliable drug data for year 2011. Specifically, either drug data were not reported for all four quarters for a hospital in year 2011(4), or the data were not accurate due to implementation of a new electronic medical record system in the hospital (2).

Descriptive Statistics

Table 5 displays the descriptive statistics for the potential risk-adjustment variables. The average hospital bedsize was 623, and the median was 553, indicating that the study sample was comprised of mainly larger sized hospitals; the average CMI among hospitals was 1.92, well over 1.0, indicating the severity and complexity of patients hospitalized in academic health centers. Antibiotics were used more commonly

Table 5

Characteristics of Potential Risk-adjustment Factors

Risk-adjustment Factor	Mean (standard deviation); Range
Number of beds	623 (255); 204 - 1,280 (median = 553)
Region, No (%)	
Northeast	25 (28%)
South	27 (30%)
Midwest	20 (23%)
West	17 (19%)
Case Mix Index (CMI)	1.92 (0.228); 1.35-2.54
Total Antibacterial Days of Therapy / 1000 patient- days	518 (77); 236-686
Total Proton Pump Inhibitor (PPI) Days of Therapy / 1000 patient- days	440 (121); 92-745
Total chemotherapeutic agents Days of Therapy / 1000 patient- days	14 (9.5); 1.43-56
Average hospital Length of Stay (LOS)	6.03 (0.765); 4.57-8.0
Percentage of all inpatients ≥ 65 years	34 (10); 11-57
CDI test methodology type No. (%)	
Molecular (e.g. PCR) testing for whole 2011	32 (36%)
Molecular testing at least partial year	20 (22%)
Other: two-step process (e.g. glutamate dehydrogenase (GDH) + cytotoxin assay or PCR) or cytotoxin assay test or EIA testing	37 (42%)
2010 HA-CDI (# of 2010 POA = 'N' cases/1,000 patient days)	0.724 (0.295); 0.121-1.39

than PPIs; chemotherapeutic agents were used less frequently, with the average hospital total DOTs/1,000PDs equal to 518, 440, and 14, respectively. On average, among hospitals, 34% of all inpatients were aged 65 or greater. The majority of hospitals, 58%, used PCR the whole year in 2011, or at least partial year for the CDI testing methodology. Before risk-adjustment of HA-CDI cases, the average number of HA-CDI cases highly varied; the average number of cases was 57.1 (standard deviation = 45.0), range 3-239.

Table 6 displays the descriptive statistics for the main independent variables. Regarding the main independent variables of interest, nearly one-half of hospitals were located in a state where there was a state-led CDI collaborative. Approximately one-quarter of hospitals (26%) were located in a state with mandatory CDI reporting. The average SIR for CAUTIs was higher than for CLABSIs, 1.28 vs. 0.059, respectively. The most common Leapfrog Group Patient Safety Grade was C (44%), followed by an A (35%), and then B (17%). Three hospitals had a grade of D, while one hospital had a grade of F. Sixteen percent of the hospitals were a U.S. News & World Report Best Hospital Honor Roll member and sixteen percent of hospitals had a CDI guideline member on staff. Forty-five percent of hospitals did not have a Magnet designation, while 25% received a Magnet designation in year 2003 or prior, and 30% received a Magnet designation in year 2003-2011.

Regarding the control variable characteristics, the average percent of admissions in patients aged 65 or greater to ICUs was 19%, while the average percent of admissions among patients aged 65 or greater with an admission source of long-term care or another hospital was 14%. The average Herfindahl index was 0.143, reflecting

Table 6

Characteristics of Main Independent Variables

Main Independent Variables	Mean (standard deviation); Range
Hospitals located in states with mandatory CDI reporting in year 2011 or before, No. (%)	23 (26%)
Hospitals located in state that implemented a CDI collaborative, No. (%)	43 (48%)
Hospital CAUTI Standardized Infection Ratio (SIR)	1.28 (1.03); 0-7.32
Hospital CLABSI Standardized Infection Ratio (SIR)	0.059 (0.32); 0.023-1.89
Leapfrog Group Patient Safety Score, No. (%)	
'A'; 'B'; 'C'; 'D'; 'F'	31 (35%); 15 (17%); 39 (44%); 3 (3%); 1 (1%)
U.S. News & World Report Best Hospital Honor Roll, No. (%)	14 (16%)
Magnet designation None; year 2003 or earlier; year 2004-2011, No. (%)	40 (45%); 22 (25%); 27 (30%)
Number of hospitals with CDI guideline member on staff, No. (%)	14 (16%)

Note: Based on variable distribution, variable categorized into 'A' = referent, 'B' = 1, 'C', 'D' & 'F' = 2. One of the two Maryland hospitals was classified as an 'A' as it was a U.S. News & World Report Best Hospital Honor Roll member, the other was classified as a 'C', which was the most common grade among the study sample.

that hospitals were generally located in competitive markets, while the average DSH patient percentage was 40%, but ranged from 6.0%-95%. This indicated a wide range by individual hospital in the proportion of patients whose payer was either Medicare or Medicaid, representing differences among hospitals in the amount of care provided for poorer patients. The average percent of admissions was 20% and 17% among Black patients and Other race patients, respectively. The average rate of CO-CDI among hospitals was 1.67, while the average rate of solid organ and bone marrow transplant/HIV/gastrointestinal surgery cases was 5.95. All but one hospital was located in a metropolitan region; this variable was not included in the final analyses due to lack of variability in its distribution among hospitals. These results are displayed in Table 7.

Table 7

Characteristics of Control Variables

Independent Control Variables	Mean (standard deviation); Range
CO CDI: # of CDI ICD-9-CM cases for which POA = 'Yes, U and W'* in 2011 per 1,000 patient days	1.67 (0.729); 0.390-4.24
Total # of solid organ and bone marrow transplant procedures (MS-DRG codes: 1, 2, 5-9, 14-17) + total # of digestive system operations (MS-DRG codes: 326-358) + # of HIV cases (MS-DRG codes: 969-977) per 1,000 patient days	5.95 (1.60); 3.22-10.5
Percentage: # of ICU admissions in patients ages 65 or greater divided by total admissions for persons ages 18 or greater	19 (7.6); 4.6-55

Table 7 (continued)

Independent Control Variables	Mean (standard deviation); Range
Percentage: # of admissions in patients ages 65 or greater with admission source of long-term care or hospital divided by total admissions for persons ages 18 or greater	14 (7.0); 0.038-33
Herfindahl index: Calculated by squared sum of beds/ total beds per metropolitan statistical area; ranges between 0-1	0.143 (0.190); 0.01-1.0
Race/ethnicity: percentage	
Other	17 (15); 1.0-84
Black	20 (16); 0.068-86
DSH patient percentage	40 (18); 6.0-95
Hospital Location. No. (%)*	
Metropolitan Region	88 (99%)
Other	1 (1.0%)

*Note: The variable hospital location was not used in negative binomial models due to lack of variability

Results of Risk-adjustment Analyses

The variables specified for risk-adjustment analyses were entered in a multivariable negative binomial regression model to ascertain associations with the number of HA-CDI cases. The variables with the smallest p-values in ascending order were: HA-CDI rate 2010 (P = 0.000); proportion of patients > 65 years of age (P = 0.000); testing methodology (P = 0.012); total antibiotics (P = 0.099); average LOS (P = 0.137); chemotherapy agents (P = 0.166); region (P = 0.332); GAS agents (P = 0.432); bedsize (P = 0.657); and CMI (P = 0.670). In order to ascertain the number of risk-adjusted HA-CDI cases for hospitals, the two variables with the smallest p-values were first entered into a negative regression binomial model to obtain the AIC value; subsequently the next variable entered into the model was the variable with the next

smallest p-value until the AIC value started to increase. The variable total antibiotic was forced in the model due to its importance as a risk factor for HA-CDI. The final risk-adjustment model included the following five variables: HA-CDI rate 2010; proportion of patients > 65 years of age; total antibiotics [AIC = 713.6] ; testing methodology [AIC = 712.4] ; and average length of stay [AIC = 712.0]. The risk adjusted HA-CDI number of cases ranged from 6.8 to 238 (mean = 57; median = 43) across hospitals.

The following represents the final risk-adjustment model:

$$HA-CDI \text{ cases} = \text{Exp} (\text{Intercept} + B_1 * HA-CDI \text{ rate } 2010 + B_2 * Prop-65 + B_3 * LOS + B_4 * \text{Testing methodology} + B_5 * \text{Antibiotics})$$

Where HA-CDI rate 2011 is the dependent variable, the number of hospital cases of HA-CDI; where HA-CDI rate 2010 is the lag variable, representing the number of hospital cases of HA-CDI in 2010 (continuous variable; the number of cases with a diagnosis code for CDI equal to 'Y' or 'W' or 'U' per 1,000 patient days); where Prop-65 is the proportion of hospital patients aged 65 or greater; where LOS is the average hospital LOS; where testing methodology was whether molecular tests were used whole, or partial year, or not used (dummy variable 1/2/3); and where antibiotics is the total antibiotic drug use per hospital in year 2011 (continuous variable; DOTs/1,000 patient days).

Table 8 displays the results of the bivariate analyses of the main independent variables of interest and risk-adjusted HA-CDI. The bivariate analyses showed that three of the main independent variables of interest were significantly associated with HA-CDI: CLABSIs; U.S. News & World Report Honor Roll hospital; and Magnet designation in year 2006 or before (as compared to non-Magnet hospital). The direction of association was negative as predicted for CLABSIs, while the direction of association

was positive for U.S. News & World Report Honor Roll hospitals, which was predicted to be non-significant. Also, the direction of association was the opposite as predicted for a Magnet designated hospital in year 2006 or before (as compared to non-Magnet hospitals), which was positive, but predicted to be negative.

Table 8

Results of Bivariate Associations Between Main Independent Variables and Dependent Variable

Main Independent Variables	Estimate (β) (standard error)	Z	P-value	95% CI	
State CDI reporting	0.1670921 (0.1010)	1.65	0.098	-0.0309287	0.3651128
CDI collaborative	0.0647483 (0.0989)	0.65	0.513	-0.1292745	0.2587711
CAUTI Standardized Infection Ratio (SIR)	-0.019877 (0.0465)	-0.43	0.669	-0.1110797	0.0713257
CLABSI Standardized Infection Ratio (SIR)	-0.303368 (0.1493)	-2.03	0.042*	-0.5959332	-0.0108027
Leapfrog Group Patient Safety Score ('A' = referent)					
'B'	-0.1876632 (0.1487)	-1.26	0.207	-0.4791674	0.103841
'C', 'D', or 'F'	-0.080461 (0.1047)	-0.77	0.442	-0.2857347	0.1248127
U.S. News & World Report Best Hospital Honor Roll	0.1820901 (0.0886)	2.06	0.040*	0.0084907	0.3556894

Table 8 (continued)

Main Independent Variables	Estimate (β) (standard error)	Z	P-value	95% CI	
Magnet designation (not a Magnet hospital = referent)					
Magnet designation in year 2003 or prior	0.3278988 (0.11638)	2.82	0.005*	0.0997824	0.5560151
Magnet designation years 2004-2011	0.1388881 (0.1150)	1.21	0.227	-0.0864899	0.3642661
CDI guideline member	-0.0114591 (0.1293)	-0.09	0.929	-0.2650657	0.2421475

*significant at $P < 0.05$

Testing the Hypotheses: Negative Binomial Regression Results

Results of the dispersion test ($P < 0.01$) indicated that binomial regression techniques were more appropriate for the count data than Poisson regression, an indication that the variance exceeded the mean for the outcome variable distribution. The VIFs revealed that there were no issues with collinearity among the variables in the negative binomial regression models. The average VIFs for the eight models were 1.36, 1.38, 1.40, 1.40, 1.40, 1.41, 1.41, and 1.48. No individual variable VIF value exceeded 1.74 in any of the models. All of the explanatory models had lower AIC values than the empty model containing only the intercept, indicating that the models

with explanatory variables had predictive ability greater than the model with no explanatory variables. The AIC for the empty model was 807.1; the AIC values for the eight negative binomial regression models were 734.9, 745.5, 745.6, 745.7, 745.9, 744.2, 746.8, and 745.6 for U.S. News Best Hospital Honor Roll member, CDI physician expert, CAUTIs, CLABSIs, Magnet designation, state CDI public reporting, Leapfrog Group Patient Safety Grade, and state-led CDI Prevention Collaborative models, respectively.

H1: State-required CDI public reporting.

The results of the model testing whether hospitals located in states where there was mandatory HA-CDI reporting showed that the mandatory CDI reporting variable was not significant ($P = 0.169$), and that that direction of the coefficient was opposite as predicted. That is, the coefficient was positive, while it was predicted that hospitals in states with mandatory HA-CDI reporting would have lower rates of HA-CDI. There were three control variables that were significant including: CO CDI ($P = 0.000$); HHI ($P = 0.021$); and Safety-net ($P = 0.000$). For CO CDI, the coefficient was positive and for HHI and Safety-net, it was negative.

H2 (a): Central line-associated bloodstream infections (CLABSIs).

For the model with CLABSIs as the main independent variable, the CLABSI variable was not significant ($P = 0.737$); the coefficient was negative as predicted. Control variables that were significant include HHI ($P = 0.012$), CO CDI ($P = 0.000$), and Safety-net ($P = 0.000$); the HHI coefficient and Safety-net coefficients were negative, while the CO CDI coefficient was positive.

H2 (b): Catheter-associated urinary tract infections (CAUTIs).

The results of the model with CAUTIs as the main independent variable showed that this variable was not significant ($P = 0.685$) and the coefficient was positive vs. negative as predicted. The control variable CO CDI was significant and positive ($P = 0.000$). The control variable coefficients HHI and Safety-net were significant and negative, ($P = 0.009$) and ($P = 0.000$), respectively.

H3: State-led collaborative.

For the model testing whether hospitals located in states where there was a state-led HA-CDI prevention collaborative had lower occurrence of HA-CDI, the results indicated that this variable was not significantly associated with HA-CDI ($P = 0.663$); the direction of the coefficient was negative, as predicted. The control variable CO CDI was significant and positive ($P = 0.000$). The control variables HHI and Safety-net were significant and negative, ($P = 0.011$) and ($P = 0.000$), respectively.

H4: Magnet-designated hospital.

The results of the model with Magnet-designated hospital as the main independent variable showed that this variable was not significant ($P = 0.208$) for Magnet designation, prior to year 2004, or for Magnet designation from 2004-2011 ($P = 0.942$), as compared to no Magnet designation. The coefficients were positive vs. negative as predicted. There were three control variables that were significant including: CO CDI ($P = 0.000$); HHI ($P = 0.015$); and Safety-net ($P = 0.001$). For CO CDI, the coefficient was positive, while for HHI and Safety-net, the coefficients were negative.

H5: *Clostridium difficile* physician expert.

For the model testing whether hospitals that had a CDI expert on staff had lower HA-CDI, the results indicated that having an expert on staff was not significantly associated with HA-CDI ($P = 0.562$); the coefficient was negative as predicted. The control variable CO CDI was significant and positive ($P = 0.000$). The control variables HHI and Safety-net were significant and negative, ($P = 0.008$) and ($P = 0.000$), respectively.

H6 (a): Leapfrog group hospital safety score.

The results of the model with the Leapfrog Group Safety Score as the main independent variable showed that this variable was not significant for a safety score equal to “B” ($P = 0.314$), or for a safety score equal to “C, D, or F” ($P = 0.586$), as compared to a safety score of “A.” It was predicted that there would be no association between a hospital’s safety score and HA-CDI. There were three control variables that were significant including: CO CDI ($P = 0.0008$); HHI ($P = 0.011$); and Safety-net ($P = 0.001$). For CO CDI, the coefficient was positive, while for HHI and Safety-net, the coefficients were negative.

H6 (b): *U.S. News & World Report* best hospital honor roll.

The results of the model testing whether Best Hospital Honor Roll designation was associated with HA-CDI showed that being an Honor Roll hospital was significant and positively associated with HA-CDI ($P = 0.000$). It was predicted that there would be no association between Honor Roll designation and HA-CDI. There were five control variables that were significant including: CO CDI ($P = 0.000$); HHI ($P = 0.016$); Safety-net ($P = 0.001$); the number of solid and bone marrow organ transplants,

gastrointestinal surgeries and HIV diagnoses (P = 0.042); and other race (P = 0.041).

For CO CDI, the coefficient was positively significant, while for the other four variables it was negative.

Tables 9-16 show the coefficient, standard errors, the z-value and p-values, as well as the 95% Confidence Intervals (CI) for the independent and control variables for the eight negative binomial regressions conducted to test the study hypotheses.

Table 9

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: State Mandatory CDI Reporting

Variable	Coefficient (β) (Standard error)	z	p-value	95% CI	
<i>Mandatory CDI reporting</i>	0.1024047 (0.0745273)	1.37	0.169	-0.043666	0.2484755
CO CDI	0.3663505 (0.0548395)	6.68	0.000*	0.258867	0.473834
Solid organ and bone marrow transplants/HIV/ GI surgery	-0.0201965 (0.0215682)	-0.94	0.349	-0.0624694	0.0220765
ICU admissions	0.0005042 (0.0053795)	0.09	0.925	-0.0100395	0.0110479
Admissions with source of long-term care or hospital	0.8163196 (0.5170657)	1.58	0.114	-0.1971105	1.82975
Herfindahl index	-0.3840308 (0.166279)	-2.31	0.021*	-0.07099328	-0.0581287
Race: other	-0.0037164 (0.0026358)	-1.41	0.159	-0.0088825	0.0014497
Race: black	-0.0028602 (0.0021504)	-1.33	0.183	-0.0070748	0.0013544
Safety-net	-0.3056553 (0.0798875)	-3.83	0.000*	-0.4622318	-0.1490788

*significant at P < 0.05

Table 10

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: CLABSIs

Variable	Coefficient (β) (Standard error)	z	p-value	95% CI	
<i>CLABSI</i>	-0.0422447 (0.1258)	-0.34	0.737	-0.2887624	0.2042729
CO CDI	0.3687994 (0.05630)	6.55	0.000*	0.2583777	0.4792211
Solid organ and bone marrow transplants/HIV/ GI surgery	-0.0183833 (0.02148)	-0.96	0.392	-0.060494	0.0237273
ICU admissions	-0.0000319 (0.0054)	-0.01	0.995	-0.0106774	0.0106137
Admissions with source of long-term care or hospital	0.8476775 (0.5266)	1.61	0.107	-0.1844991	1.879854
Herfindahl index	-0.4224874 (0.1677)	-2.52	0.012*	-0.7512152	-0.0937595
Race: other	-0.0027429 (0.0026)	-1.04	0.297	-0.0079004	0.0024145
Race: black	-0.0030784 (0.0021)	-1.46	0.144	-0.0072116	0.0010548
Safety-net	-0.3049218 (0.0834)	-3.65	0.000*	-0.4684556	-0.1413879

*significant at $P < 0.05$

Table 11

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: CAUTIs

Variable	Coefficient (β) (Standard error)	z	p-value	95% CI	
CAUTI	0.0171014 (0.0422)	0.40	0.685	-0.0656613	0.0998641
CO CDI	0.3698435 (0.0568)	6.51	0.000*	0.258484	0.481203
Solid organ and bone marrow transplants/HIV/ GI surgery	-0.017613 (0.0209)	-0.84	0.401	-0.0587379	0.023512
ICU admissions	-0.0004652 (0.0053)	-0.09	0.931	-0.0109339	0.0100034
Admissions with source of long-term care or hospital	0.8136177 (0.5323)	1.53	0.126	-0.2297651	1.857
Herfindahl index	-0.4242856 (0.1634)	-2.60	0.009*	-0.7446171	-0.1039541
Race: other	-0.0028563 (0.0025)	-1.10	0.270	-0.0079276	0.0022151
Race: black	-0.0031424 (0.0021)	-1.46	0.144	-0.0073541	0.0010694
Safety-net	-0.3143923 (0.0823)	-3.82	0.000*	-0.4758547	-0.15293

*significant at $P < 0.05$

Table 12

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: State-led CDI Prevention Collaborative

Variable	Coefficient (β) (Standard error)	Z	p-value	95% CI
<i>CDI collaborative</i>	-0.029163 (0.0668327)	0.44	0.663	-0.1018261 0.1601532
CO CDI	0.3709888 (0.0568732)	6.52	0.000*	0.2595194 0.4824583
Solid organ and bone marrow transplants/HIV/ GI surgery	-0.0192562 (0.0215411)	-0.89	0.371	-0.061476 0.0229637
ICU admissions	.0001847 (0.0053627)	0.03	0.973	-0.010326 0.0106953
Admissions with source of long-term care or hospital	0.8354038 (0.526968)	1.59	0.113	-0.1974356 1.868243
Herfindahl index	-0.4139172 (0.1625813)	-2.55	0.011*	-0.7325708 - 0.0952637
Race: other	-0.0029468 (0.0026159)	-1.13	0.260	-0.0080738 0.0021803
Race: black	-0.0028878 (0.0021761)	-1.33	0.184	-0.0071529 0.0013773
Safety-net	-0.310611 (0.833008)	-3.73	0.000*	-0.4738775 - 0.1473445

*significant at $P < 0.05$

Table 13

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: Magnet status

Variable	Coefficient (β) (Standard error)	z	p-value	95% CI	
<i>Magnet status</i> (Referent = no Magnet status)					
1: Magnet status, 2003 or prior	0.1098461 (0.0872)	1.26	0.208	-0.0611117	0.2808039
2: Magnet status, 2004-2011	0.0063016 (0.0868)	0.07	0.942	-0.1639555	0.1765588
CO CDI	0.3622099 (0.0576)	6.28	0.000*	0.2491964	0.4752234
Solid organ and bone marrow transplants/HIV/GI surgery	-0.0194318 (0.0203)	-0.96	0.388	-0.0592157	0.0203522
ICU admissions	0.0001597 (0.0055)	0.03	0.977	-0.0106142	0.0109336
Admissions with source of long-term care or hospital	0.8443038 (0.5032)	1.68	0.093	-0.1419358	1.830543
Herfindahl index	-0.4041426 (0.1667)	-2.42	0.015*	-0.730922	-0.0773632
Race: other	-0.0023227 (0.0027)	-0.84	0.403	-0.0077701	0.0031247
Race: black	-0.0025981 (0.0021)	-1.23	0.220	-0.0067515	0.0015554
Safety-net	-0.2999 (0.0899)	-3.33	0.001*	-0.4762468	-0.1236483

*significant at $P < 0.05$

Table 14

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: CDI Physician Expert

Variable	Coefficient (β) (Standard error)	Z	p-value	95% CI	
<i>CDI physician expert</i>	-0.0570609 (0.0983)	-0.58	0.562	-0.2498156	0.1356939
CO CDI	0.3671686 (0.0560)	6.55	0.000*	0.2572378	0.4770994
Solid organ and bone marrow transplants/HIV/ GI surgery	-0.0159 (0.0217)	-0.73	0.463	-0.0585156	0.0266447
ICU admissions	-0.0003 (0.0054)	-0.06	0.955	-0.0110169	0.0103957
Admissions with source of long-term care or hospital	0.8014497 (0.5258)	1.52	0.128	-0.2292789	1.832178
Herfindahl index	-0.426737 (0.1601)	-2.66	0.008*	-0.7406126	-0.1128613
Race: other	-0.002733 (0.0025)	-1.06	0.290	-0.0077991	0.0023331
Race: black	-0.0027828 (0.0021)	-1.28	0.202	-0.0070604	0.0014947
Safety-net	-0.3274162 (0.0864)	-3.79	0.000*	-0.4967106	-0.1581218

*significant at $P < 0.05$

Table 15

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: Leapfrog Group Hospital Safety Grade

Variable	Coefficient (β) (Standard error)	z	p-value	95% CI	
<i>Leapfrog Group</i> (referent = A)					
2: B	-0.0964683 (0.0958)	-1.01	0.314	-0.2842419	0.0913052
3: C, D, or F	-0.0410463 (0.07543)	-0.54	0.586	-0.1888955	0.106803
CO CDI	0.367344 (0.0553)	6.65	0.0008*	0.2590177	0.4756703
Solid organ and bone marrow transplants/HIV/GI surgery	-0.0185125 (0.0210)	-0.88	0.379	-0.0597862	0.0227612
ICU admissions	-0.0000693 (0.00550)	-0.01	0.990	-.0107833	.0106447
Admissions with source of long-term care or hospital	0.8139796 (0.5094)	1.60	0.110	-0.1844484	1.812408
Herfindahl index	-0.418355 (0.1654)	-2.53	0.011*	-0.7426025	-0.0941074
Race: other	-0.0029594 (0.0026)	-1.14	0.255	-0.0080565	0.0021378
Race: black	-0.003056 (0.0021)	-1.44	0.151	-0.0072225	0.0011105
Safety-net	-0.3013834 (0.0886)	-3.40	0.001*	-0.4750306	-0.1277361

*significant at $P < 0.05$

Table 16

Results of Multivariable Regression Associations Between Main Independent Variables and Dependent Variable: U.S. News Best Hospital Honor Roll

Variable	Coefficient (β) (Standard error)	z	p-value	95% CI	
<i>U.S. News Best Hospital Honor Roll</i>	0.2965953 (0.0755)	3.92	0.000*	0.1484623	0.4447284
CO CDI	0.3969 (0.0566)	7.00	0.000*	0.2858746	0.5080881
Solid organ and bone marrow transplants/HIV/ GI surgery	-0.0389145 (0.0191)	-2.03	0.042*	-0.0764023	-0.0014266
ICU admissions	0.0018839 (0.0052)	0.36	0.717	-0.008315	0.0120828
Admissions with source of long-term care or hospital	0.7347096 (0.4343)	1.69	0.091	-0.1164802	1.585899
Herfindahl index	-0.3759739 (0.1562)	-2.41	0.016*	-0.6822263	-0.0697215
Race: other	-0.0050439 (0.0024)	-2.04	0.041*	-0.0098845	-0.0002033
Race: black	-0.0032509 (0.0022)	-1.46	0.145	-0.007622	0.0011203
Safety-net	-0.2580862 (0.0786)	-3.28	0.001*	-0.4121763	-0.1039961

*significant at $P < 0.05$

Results of Sensitivity Analyses

For the results of the sensitivity analyses whereby the testing methodology was categorized per the following: (1) molecular (e.g. PCR) for whole year 2011; (2) molecular at least partial year or two-step process (e.g. glutamate dehydrogenase (GDH) + cytotoxin or PCR) or cytotoxin assay; and (3) EIA testing, the results were similar for all the negative binomial regression models as to the primary set of analyses. The variable U.S. News & World Report Honor Roll member remained significant and positively associated with risk-adjusted HA-CDI [coefficient = 0.2811417, standard error = 0.080427, $z = 3.50$, $p\text{-value} = 0.000$, and 95% CI = 0.1235076 -0.4387757].

For the results of the sensitivity analyses whereby the definition of HA-CDI cases included not only the CDI ICD-9-CM code with POA = 'No' to define HA-CDI, but also including POA = 'U', unknown, POA = 'W', clinically undetermined, to assess the impact of potentially differing coding practices across hospitals on study results, the results were also similar to the primary analyses. The variable U.S. News & World Report Honor Roll member remained significant and positively associated with risk-adjusted HA-CDI. [coefficient = 0.1143165, standard error = 0.048409, $z = 2.36$, $p\text{-value} = 0.018$, and 95% CI = 0.0194348 -0.2091983]. For both of the sensitivity analyses, there were no other significant findings among the main variables of interest, similar to the primary set of analyses.

This chapter presented descriptive statistics for all study variables, and the results of the bivariate and negative binomial regression model analyses. Further, the results of the sensitivity analyses were also presented. The next chapter will interpret

and discuss the results. The future research direction stemming from these analyses will also be discussed.

Chapter 6: Discussion and Conclusions

Clostridium difficile infection is an HAI that is associated with great morbidity among hospitalized patients; since the early 2000s, CDI has been increasing in severity and incidence due to an epidemic strain. The purpose of this research was to ascertain the types of organizational factors that are associated with HA-CDI occurrence using an institutional theory perspective to derive hypotheses. This chapter summarizes and interprets the study results, and also discusses the study implications.

Summary and Interpretation of Analysis Results

The descriptive analyses revealed that the study sample was comprised of large academic health centers, with the median number of beds being 553. Hospitals were located relatively evenly throughout the four geographic census regions of the United States. These analyses also revealed that the study sample of hospitals provided complex medical care with the average CMI being 1.92 among hospitals, and the average LOS equal to 6.03 days. Over one-half of the hospitals were using state-of-the-art technology for CDI detection, such as the molecular-based tests, for the entire study year, or at least for the partial study year, an indication of a trend towards a switch to the molecular-based tests from less sensitive CDI testing methods, such as the EIA methodology.

Regarding HA-CDI, there was a wide range of HA-CDI occurrence among hospitals, with the average number of HA-CDI risk-adjusted cases being 57, with a range from 7-238 cases. Among the factors that were considered in the risk-adjustment

analyses, the number of 2010 HA-CDI cases, the proportion of patients greater than 65 years of age, the testing methodology utilized, the hospital average length of stay, and total antibiotics were included in the final risk-adjustment models. The hospital geographic region, the hospital number of beds, the CMI, and the total hospital days of therapy of chemotherapeutic and gastric acid suppressant agents were not included in the risk-adjusted HA-CDI model.

The bivariate analyses showed that three of the eight main independent variables of interest were significantly associated with HA-CDI: CLABSIs; *U.S. News & World Report* Best Hospital Honor Roll hospital; and Magnet designation in year 2006 or before (as compared to non-Magnet hospital). The CLABSI variable was negative as predicted, meaning that hospitals that had a higher CLABSI SIR (meaning higher rates of CLABSIs), had lower HA-CDI. It was theorized that if hospitals had higher rates of CLABSIs, that this would be associated with lower rates of HA-CDI, since hospitals with higher CLABSI rates may not have been focusing only on CMS-monitored infections. It was also theorized that hospitals that were designated as a U.S. News & World Report Best Hospital Honor Roll hospital would have rates of HA-CDI that were no different than hospitals that were not an Honor Roll member. Instead, on bivariate analysis, it was found that being an Honor Roll hospital was associated with more HA-CDI occurrence, as opposed to a non-Honor Roll hospital. It was also theorized that hospitals with Magnet status would have lower occurrence of HA-CDI; however, it was found that hospitals that had received Magnet status in year 2003, or prior, had higher rates of HA-CDI. The Leapfrog Group Patient Safety Score was not found to be significantly associated with HA-CDI, as predicted. It was theorized in this case that

hospitals that had a higher safety score, such as a letter grade of 'A', would have HA-CDI occurrence among hospitalized patients no different than hospitals that had a lower safety letter grade, such as a 'B', or lower.

These analyses imply that at least two of the hypotheses would potentially be supported by the multivariable models (CLABSIs and Leapfrog Group Safety Score). However, the only hypothesis supported by the current research upon conduction of the multivariable negative binomial regression models was the hypothesis stating that there would be no significant association between the Leapfrog Group Safety Score and HA-CDI. Indeed, hospitals with a safety score of either 'B' or 'C', 'D', or 'F', had rates of HA-CDI that were no different than hospitals with a safety score of 'A.' There was one significant finding among the eight models for the main independent variables, which was for the model testing *U.S. News & World Report* Honor Roll Hospitals and HA-CDI. The relationship predicted here was that there would be no difference in HA-CDI occurrence between Honor Roll hospitals and non-Honor Roll hospitals, but the relationship was found to be significant and positive, similar to the bivariate analyses. This indicated that being an Honor Roll member hospital was associated with higher rates of HA-CDI, as compared to non-Honor Roll hospitals.

Other independent control variables that were found to be significantly associated with the outcome variable were the rate of CDI cases that were community-onset (CO CDI), the HHI, and the hospital Safety-net variable. The CO CDI rate was positively associated with risk-adjusted HA-CDI, while the HHI and Safety-net variables were negatively associated with HA-CDI. While the direction of the coefficient for CO CDI was as predicted, meaning that a higher prevalence of CO CDI in the hospital was

associated with higher HA-CDI occurrence, the directions of the other coefficients were unexpected findings. That is, it was predicted based on previous literature, that decreased hospital competition would be associated with increased rates of HA-CDI. What the regression analyses revealed, however, was that with an increase in hospital competition, there was decreased HA-CDI occurrence. Further, it was predicted that Safety-net hospitals, as defined by the top quartile of the DSH patient percentage, would have a positive relationship to HA-CDI. That is, hospitals caring for a greater proportion of poorer patients would have higher rates of HA-CDI. Instead, a negative relationship was found in all of the regression analyses, indicating that being a Safety-net hospital, as defined in the current proposal, was associated with less HA-CDI occurrence. The control variable 'other' race was significant and negatively associated with risk-adjusted HA-CDI in the *U.S. News & World Report* Best Hospital Honor Roll member model, also indicating that patient socioeconomic status may be associated with HA-CDI. The rate of patients with diagnoses codes for HIV and bone marrow and solid organ transplants, as well as gastrointestinal surgeries was also significant in the *U.S. News & World Report* model; the relationship was negative (opposite of predicted). The remaining control variables were not significant in any of the models: the proportion of patients that were black; the proportion of patients with an ICU stay; and the proportion of patients admitted from another hospital or long-term care facility.

In summary, the multivariable analyses showed that one study hypothesis was supported (Leapfrog Group Patient Safety Score), and that another hypothesis had a positive significant finding by multivariable regression analyses results (*U.S. News & Report* Best Hospital Honor Roll); however the association was predicted to be non-

significant. Table 17 displays a summary of the negative binomial regression model expected and final results, followed by a section describing study findings in more detail regarding each study hypothesis.

Table 17

Summary Table of Final Hypotheses Testing Results

Hypothesis	Organizational Factor	Expected Result	Final Result
Coercive Forces			
1	State mandatory CDI reporting	(-) States with mandatory reporting will have lower HA-CDI	(+)
2 (a)	CLABSI rates	(-) Higher CLABSI SIR hospitals will have lower HA-CDI	(-)
2 (b)	CAUTI rates	(-) Higher CAUTI SIR hospitals will have lower HA-CDI	(+)
Mimetic Forces			
3	State-led CDI Prevention Collaborative	(-) States with prevention collaboratives will have lower HA-CDI	(-)
Normative Forces			
4	Magnet hospital designation	(-) Magnet-designated hospitals will have lower HA-CDI	(+)
5	CDI physician experts	(-) Hospitals with a CDI physician expert on staff will have lower HA-CDI	(-)
Rationalized Myths			
6 (a)	Leapfrog Group™ Safety Score	No association between Safety Score and HA-CDI	No association
6 (b)	U.S. News & World Report Best Hospital Honor Roll	No association between being a Best Hospital Honor Roll member and HA-CDI	(+)*

*significant at $P < 0.05$

H1: State-required CDI public reporting.

It was hypothesized that hospitals located in states with mandatory CDI reporting would have lower rates of HA-CDI. While the coefficient for this variable was not significant, it was positive. Indeed, the average number of CDI cases was higher in hospitals located in states with CDI mandatory reporting as opposed to hospitals located in states that did not have mandatory CDI reporting, 64.9 (standard deviation = 9.3) vs. 54.5 (standard deviation = 5.2), respectively.

An increased rate of HA-CDI in those hospitals located in states with mandatory CDI reporting may be due to increased detection of HA-CDI in those hospitals, or due to the increased surveillance taking place in these hospitals. Another investigation has shown that the number of adverse drug events reported after implementation of a system to track errors resulted in a forty-fold increase in event reporting (Classen, Pestotnik, Evans, & Burke, 1992). Alternatively, it is a possibility that mandatory reporting of HAIs does not result in decreased HAI rates. An investigation that examined the effect of mandatory CLABSI reporting in states found that the reporting laws had no impact on CLABSI occurrence (Pakyz & Edmond, 2013). However, in Ontario, Canada, it was found that after mandatory monthly public reporting of CDI was implemented, that the occurrence of CDI decreased by 26% across Ontario hospitals (Daneman et al., 2012). The authors of the Canadian study attributed the decreased rate in CDI to a possible increased attention by hospitals to adhere to best practices for CDI prevention. More research is needed regarding the impact of mandatory public reporting of HAIs. Further, the impact of CMS's reporting of CDI on the Hospital Compare Website, commencing in 2014, and of the future addition of CDI as one of the

performance measures considered in Value Based Purchasing, will need to be assessed.

H2 (a & b): Central line-associated bloodstream infections (CLABSIs) & catheter-associated urinary tract infections (CAUTIs).

It was hypothesized that due to CMS' policy of no-payment for the extra costs associated with CLABSI or CAUTI development in hospitals that hospitals would be focused on the prevention of these two types of HAIs vs. CDI, which is not on the no-payment list. It was found that neither of these variable coefficients was significant, though the coefficient for CLABSIs was negative as predicted. That is, increased CLABSI occurrence, as reflected by the CLABSI SIR, was associated with less HA-CDIs.

It is possible that a lack of significance for this variable indicates that hospitals, while they may target certain HAIs that are monitored by CMS, that this may not come at the expense of infection prevention efforts for other infection types. However, it has been demonstrated that the CMS no-payment policy for CLABSIs had no impact on CLABSI rates in hospitals (Lee et al., 2012). Further, an alternate explanation for the study finding is that hospitals are anticipating the upcoming CDI focus by CMS and the VBP program and have started to target CDI specifically, in addition to other CMS-monitored infections.

H3: State-led CDI prevention collaborative.

It was hypothesized that hospitals located in states with a state-led CDI Prevention Collaborative would have less HA-CDI occurrence. Despite the success of a CDI prevention collaborative being documented (Koll et al., 2013), this variable

coefficient was not significant, though was negative as predicted. As there was another state variable considered in the study analyses, state mandatory reporting of HA-CDI, an additional negative binomial regression model was conducted to account for both state variables in the model. The results were the same as the individual regression models with the two state variables, that is state-led CDI Prevention Collaborative and CDI mandatory reporting coefficients were not significant, ($P = 0.513$ and 0.098 , respectively) in the combined model. These results indicate that there may be competing CDI infection prevention efforts ongoing at the local or regional level that were not captured in the current study.

H4: Magnet-designated hospital.

It was theorized that hospitals that had a Magnet designation would have lower occurrence of HA-CDI. A Magnet designation would confer that the hospital provides a gold standard of nursing care quality. However, in the current study, hospitals that had Magnet Status did not have HA-CDI rates any different as compared to non-Magnet hospitals ($P = 0.208$ for Magnet status in year 2003 or prior and ($P = 0.942$) for Magnet designation in years 2004-2011); the direction of the coefficients was positive, the opposite as predicted.

There are three goals and guiding principles of the Magnet recognition program: to promote quality in a setting that supports professional practice; identify excellence in the delivery of nursing services to patients; and to disseminate best practices in nursing services. The current Magnet recognition process focuses on structure and processes as opposed to outcomes. An assumption of the recognition process is that good outcomes will follow appropriate structures and processes (The American Nurses

Credentialing Center (ANCC), 2013). Though previous studies have shown better outcomes in Magnet hospitals as compared to non-Magnet hospitals (Lake et al., 2012) and higher adoption of National Quality Forum safe practices (Jayawardhana et al., 2012; McHugh et al., 2012) , the current study showed that there was no association between Magnet status and HA-CDI. It is possible that while Magnet designation may correlate with some aspects of hospital quality, that Magnet status may not necessarily confer better outcomes in the area of HAIs. It is possible, too, that Magnet designation may serve in some regards as a 'rationalized myth.' That is, it is perceived that with Magnet status, a hospital provides better quality care, but in actuality, the care among Magnet hospitals is no different than non-Magnet hospitals. More research is needed in this area to gain a better understanding of the impact of a Magnet status designation on various aspects of hospital quality measures, including HAIs.

H5: *Clostridium difficile* physician expert.

It was hypothesized that hospitals that had a CDI physician expert on staff, as defined by a member of the SHEA/IDSA CDI guideline, would have lower rates of HA-CDI, with the assumption that they would serve in the role of a Physician Champion who would lead efforts in CDI prevention. Previously, it has been demonstrated that Physician Champions were instrumental in improving the quality of antibiotic prescribing for acute respiratory tract infections (Aagaard et al., 2010) However, in the current study, this hypothesis was not supported; this variable coefficient was in the direction as predicted, negative, but was not significant (P =0.562).

The fact that the coefficient was not significant in this case does not necessarily mean that Physician Champions are not important in the area of HA-CDI prevention. It

could be that the guideline members did not serve in the role of a Physician Champion, or that there were physicians serving in this role in study hospitals who were not members of the SHEA/IDSA guideline committee. Further, it is possible that other professional groups serve as Champions in this area, such as nurses. Nurses have served as clinical champions in the area of influenza immunization (Mouzoon et al., 2010) and in the implementation of central venous catheter infection prevention bundles (Lemaster, Hoffart, Chafe, Benzer, & Schuur, 2013).

H6 (a): Leapfrog group hospital safety score.

It was hypothesized that hospitals with a higher Leapfrog Group Hospital Safety Score would have HA-CDI rates that were no different than hospitals with a lower Safety Score. Indeed, it was found that there were no significant differences among hospitals with a grade equal to 'B' or 'C', 'D', or 'F' as compared to hospitals with a letter grade equal to 'A.' The Leapfrog Group Hospital Safety Score is based on 26 measures established by a panel of nine national expert members. A total of fifteen of these measures are either process or structural measures which are weighted at 50% of the composite score, while a total of eleven are outcomes measures, which are also weighted at 50%. The single composite score is meant to represent a single score to enable an overall view of a hospital's performance in the area of safety (Austin et al., 2013).

As this study hypothesis was supported by the results, it suggests that when hospitals adopt certain structural elements or comply with certain process measures, that this does not necessarily translate into all areas of hospital safety. Though one of the process measures was specifically related to the prevention of HAIs, hand hygiene,

many of the measures were not necessarily related to infection prevention. One of eleven outcome measures was related to another HAI, CLABSI occurrence; however, the vast majority of the outcome parameters used in the composite score were unrelated to HAI occurrence.

H6 (b): *U.S. News & World Report* best hospital honor roll.

Using an institutional theory perspective, it was predicted that the *U.S. News & World Report* Best Hospital Honor Roll members would have rates of HA-CDI that were no different than non-Honor Roll hospitals. The results were not as predicted. That is, the Best Hospital Honor Roll members had significantly higher rates of risk-adjusted HA-CDI as compared to non-Honor Roll hospitals.

In examining the criteria for an Honor Roll hospital designation, it is not immediately apparent as to why Honor Roll hospital membership would be associated with higher rates of HA-CDI. For twelve of sixteen specialty rankings, the generated index of hospital quality (IHQ) ranking is based on hard data (various secondary data sources), while for four of the sixteen specialties, the rankings are based on reputational surveys that are completed by physicians for the Best Hospital scoring system. The IHQ score is based on structure, process, and outcome criteria.

The scoring system uses data from the AHA Annual Survey Database, and CMS and other professional groups, such as the National Association of Epilepsy Centers, to acquire data concerning structural measures related to quality of care across 1,879 hospitals. The structural measures included certain key technologies and types of advanced care that would be provided from a “Best hospital.” For example, information concerning diagnostic radioisotope services, procedures that lead to ablation of

Barrett's esophagus, and endoscopic ultrasound procedures, among many other technology types, were considered. There were a total of fifteen technologies that were considered important in one or more specialty areas. There is also a volume index as part of the structural score, which takes into consideration the number of certain medical and surgical discharge types within specialty-specific MS-DRG groupings that were submitted to CMS for reimbursement. Other components of the structure process care include information regarding nursing staffing, trauma center designation, patient services such as language translation, and intensivist staffing.

Regarding the outcomes portion of the score, 30-day risk-adjusted mortality rates based on certain moderate intensity, or greater Medicare Severity Diagnosis Related Groups (MS-DRG) were used. The mortality rate was adjusted according to observed and expected mortality rates using the 3M Health Information System's MS grouper software, which uses the All Patient Refined DRG patient severity measures. Hospitals that had a higher than expected mortality rate were considered to have lower-than-average quality, and vice versa.

Regarding the process portion of the IHQ score, a proxy measure was used due to the difficulty in obtaining national data on process measures. This was based on the reputational scores from the past three Best Hospital rankings in 2009, 2010, and 2011. Specifically, a total of 200 physicians were asked to list up to five hospitals that were the "Best hospitals" in their specialty area for serious or difficult conditions, regardless of location or expense. It was thought that physician endorsement of a designated "Best hospital" served as a proxy to represent the healthcare processes, such as physicians' decision-making, choices about admission, treatment and medications, and length of

stay. For four of the specialty ranking areas (Ophthalmology, Psychiatry, Rehabilitation, Rheumatology), only the reputation score as described above is used to establish the Best Hospital ranking score, as structural and outcomes measures were not considered pertinent to these specialties.

Finally, a patient safety index component was also included as part of the IHQ. For this, information concerning the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs) was considered. A total of six of the fifteen PSIs were chosen for inclusion in calculation of the patient safety index. These included: death among surgical patients with serious treatable complications; iatrogenic pneumothorax; postoperative hemorrhage or hematoma; postoperative respiratory failure; postoperative wound dehiscence; and accidental puncture or laceration. The PSI component comprised 5.0% of the total specialty IHQ score, while outcome and process components comprised 32.5% each, and structure comprised a total of 30%.

The Honor Roll designation is meant to represent overall excellence, and is a method to establish relative distances between the 140 different hospitals that were ranked in at least one specialty. To be an Honor Roll hospital, a hospital had to have been ranked at least three standard deviations above the mean in at least six out of the sixteen specialty areas.

Similar to the Leapfrog Group Patient Safety Score, the Best Hospital Ranking Methodology does not incorporate many specific measures related to infection prevention. Though Honor Roll hospitals are thought to offer excellent care for complex and severely ill patients, this designation may not necessarily translate into safer care in the form of HAI occurrence. Despite the risk-adjustment techniques used in the Best

Hospital Methodology and the current study, it is possible that the study finding that Honor Roll hospitals had more HA-CDI may indicate that this group of hospitals provided the most complex care for the sickest of patients. Thus, their higher rates of HA-CDI may be reflective of patient mix that was not completely accounted for by risk-adjustment techniques.

Study Robustness

The results of the two sensitivity analyses suggest that the results of the primary study analyses were robust. The sensitivity analyses examined the robustness of the study results in regards to the methodology used to define HA-CDI cases and also the categorization of diagnostic testing for CDI. Specifically, there were no differences found among the study results when CDI ICD-9-CM code information was used that include POA = 'No' as well as POA= 'No' plus POA = 'U', unknown, plus POA = 'W', clinically undetermined vs. POA = 'No' alone to define HA-CDI cases. The study results were also not different upon categorizing the CDI testing methodology as (1) molecular (e.g. PCR) for whole year 2011; (2) molecular at least partial year or a two-step process (e.g. glutamate dehydrogenase (GDH) + cytotoxin or PCR) or cytotoxin assay; (3) or EIA testing, vs. categorized as either (1) molecular testing for whole year 2011, (2) molecular testing at least partial year or (3), or other [two-step process (e.g. glutamate dehydrogenase (GDH) + cytotoxin or PCR) cytotoxin assay or EIA testing].

Study Implications

Of the eight hypotheses proposed, a total of one was supported by the study results. That is, there was no difference in HA-CDI occurrence among hospitals with a Leapfrog Group Safety Score of 'A' vs. 'B', or 'A' vs. a grade of 'C', 'D', or 'F.' Further,

while it was predicted that Honor Roll hospitals would have no difference in HA-CDI occurrence, it was found that Honor Roll hospitals had higher-CDI occurrence. While these analyses are exploratory in nature, and the findings could be spurious, or even that study power was low, there are several implications to the study findings.

First, though the Leapfrog Group composite safety score is meant to provide patients and providers with a single score for hospital comparison in regards to safety performance, it does have some limitations. For one, as demonstrated in the current study, the score does not necessarily represent all areas of patient safety, such as HAIs. Second the structural, process, and outcome measures utilized in the score methodology may not be serving as appropriate indicators of patient safety. Further studies are needed to determine the utility of various hospital scoring systems in terms of safety outcomes and to ascertain whether the goal in providing these types of data to providers and patients serves the purpose in the identification of safer hospitals and in spurring quality improvement.

There may be other implications to the current study findings despite the fact that the majority of the hypotheses were not supported. For example, there were a few interesting trends that were noted. The rate of HA-CDI occurrence was higher in hospitals that were located in states with mandatory HA-CDI reporting, while accounting for several control variables and conducting risk-adjustment methodologies for HA-CDI rates. This finding, in particular, has potential implications related to policy-making. Though it is not clear whether state policies related to HAI reporting result in less infections, it may be that initially after policy introduction, that the rate of infection reporting may increase, resulting in an increased number of infections. This may be

especially true if there are infection validation procedures in place in hospitals (Oh et al., 2012). Regarding other state-led initiatives, in those states that had implemented a CDI Prevention Collaborative, it was found that there was no difference in HA-CDI occurrence as compared to hospitals located in states without a state-led collaborative. While state-led Prevention Collaboratives have been shown to be successful in reducing CDI, the voluntary nature of these programs may impact on their effectiveness. More research is needed to discern the impact in CDI rate reduction among different state policies directed towards reducing CDI.

Regarding the finding concerning no differences in HAI occurrence among hospitals with a Magnet designation and those without, the coefficients were positive. As the number of hospitals that seek Magnet adoption increases (Abraham, Jerome-D'Emilia, & Begun, 2013), the current study suggests that it is important that evaluations continue to study whether Magnet status implicates better patient outcomes and indeed serves as a gold standard in nursing quality. For pursuit of a Magnet designation, hospital resources are needed to accommodate the required structures and processes that need to be in place. If a Magnet designation does not necessarily warrant superior nursing care and result in better patient outcomes, these resources could be used to implement other quality program types that have been demonstrated to improve patient outcomes.

There is a study finding directly related to clinical practice. For one, the prevalence of CO CDI is important to consider when assessing risk for HA-CDI in hospitalized patients. A higher prevalence of CO CDI was consistently associated with higher HA-CDI occurrence. Further, there are study implications related to research

methodology. For example, there were several factors related to HA-CDI hospitals upon performance of the risk-adjustment models. These included the number of 2010 HA-CDI cases, the proportion of patients greater than 65 years of age, the testing methodology utilized, and the hospital average length of stay. Thus, it is important to calculate risk-adjusted cases of HA-CDI when comparing infection rates across hospitals.

The organizational theory, institutional theory, provided a perspective to guide the development of study hypotheses. That is, a framework was provided which allowed consideration of the isomorphic forces that shape an organization's response to environmental pressures, such as the need to adopt infection prevention measures targeted at HA-CDI, and to better explain variations in HA-CDI rates across hospitals. Of the eight hypotheses, however, only one was supported. There are several study limitations that may have contributed to this, such as variable measurement (see Limitations section below), but this may also be due to limitations of using an institutional theory perspective to evaluate factors associated with HA-CDI occurrence among hospitals. For one, additional organizational theories, such as organizational behavior theories, may offer further explanatory power in regards to assessing hospital response to HA-CDI. For example, what, if any, aspects of infection prevention teamwork contribute to HA-CDI occurrence. Further, a macro-level theory does not inform on the unit-level of an individual organization, or even an individual patient-level. A more appropriate perspective may be one that accounts for different levels of an organization (Diez Roux & Aiello, 2005).

Limitations

A limitation to this research stems from the inherent problems of conducting research using administrative data (Schneeweiss & Avorn, 2005). The ICD-9-CM codes, for example, are assigned by medical coders, who may not be able to correctly identify CDI as well as a physician or other medical professionals. Further, depending upon POA coder accuracy, the type of case of CDI, whether HA-CDI or CO CDI, may have been misclassified. The validation of antibiotic use and duration data acquired from the UHC CRM has been conducted, however (Schmiedeskamp, Harpe, Polk, Oinonen, & Pakyz, 2009). It was found that all drugs identified by the database were actually administered to patients, except for non-formulary antibiotics that were administered, but not captured by the database. Antibiotic use data were validated in only one UHC hospital, it is possible that this does not reflect all hospitals; however, it is not expected that the validation results would differ greatly across academic health centers. Another limitation is that there are no data available regarding infection prevention efforts being conducted at hospitals, such as environmental cleaning and CDI patient isolation policies. However, even if data were available on these policies, it would not be possible to ascertain the extent of adoption or effectiveness of the policies. Further, the UHC data does not provide information concerning antimicrobial stewardship program policies directed towards prevention of HA-CDI. However, the main goal of antibiotic stewardship programs is to reduce inappropriate antibiotic use (Dellit et al., 2007); the incorporation of the amount of antibiotics used in hospitals is incorporated in the risk-adjustment model and should account for any antibiotic stewardship program initiatives. One of the strengths of the UHC CRM data is the

availability of drug usage data; lack of these data was commonly a major weakness to other investigations concerning HA-CDI.

Another limitation is that results of the current research are subject to the ecological fallacy, that is, the results may not necessarily reflect risk factors for HA-CDI at the unit-level; each hospital unit can have its own subculture (Lee et al., 2012). Further, the results of the study do not establish causal relationships between the factors studied and their impact on HA-CDI occurrence. Not all academic health centers are UHC members, however nearly 90% are members, so while it is possible that a selection bias exists, it would not be expected to have a large impact on the results. Another limitation is the inability to test for interactions among the variables given the relatively small sample size of hospitals. Further, there exists potential endogenous variables in the models. For example, when assessing the impact of mandatory public reporting of HA-CDIs, it is possible that states that implemented these policies had higher rates of HA-CDI than states that did not implement mandatory HA-CDI reporting. Finally, the results of the study are only applicable to academic health centers, the results will not necessarily reflect on other types of hospitals.

A final area of limitation is that the variables constructed to test the generated hypotheses are proxies for the intended measures. For example, for the hypothesis testing the influence of mandatory reporting of CDI, the current study assessed CDI rates based on physician diagnoses for coding and reporting. However, for state mandatory reporting, laboratory-identified CDI rates (LabID) are reported; these rates are based on positive laboratory tests and do not incorporate clinical evaluation. A comparison between LabID events and CDI cases obtained from surveillance by

hospital infection preventionists among six hospitals in Rhode Island demonstrated that the LabID CDI events exceeded the surveillance rates (Baier, Morphis, Marsella, & Mermel, 2013). Another study that compared LabID event reporting to clinical infection surveillance reporting among 30 hospitals in New York found that there was 81.3% agreement between the two methods, with the LabID CDI rates being higher across hospitals than the rates acquired by clinical infection surveillance reporting (Gase, Haley, Xiong, Van Antwerpen, & Stricof, 2013).

Further, the Leapfrog Group composite safety score for hospitals reflects only a portion of measures that capture patient safety in hospitals. Further, few outcome variables are represented in the composite score, and a number of measures are derived from administrative as opposed to clinical data (Austin et al., 2013). The U.S. *News & World Report* Best Hospital Honor Roll ranking is also based on administrative and reputational data to a large degree.

Regarding the variables measuring the rates of CLABSIs and CAUTIs in hospitals, the CLABSI and CAUTI SIR, reported on the Hospital Compare website, is dependent upon accurate data recording by hospitals. Some hospitals may have under-reported these infections. One report found that in Oregon, an external validation review of hospital-reported CLABSIs resulted in an increase in the statewide ICU CLABSI rate (Oh et al., 2012). Another study conducted in Connecticut found that CLABSI surveillance performed by hospitals was only 48% sensitive (Backman, Melchreit, & Rodriguez, 2010). Another limitation with the CLABSI SIR measure in particular, is that there may be hospital-acquired bloodstream infections that are misclassified as CLABSI, since the infection may be due to a secondary source, such

as translocation, rather than a catheter, resulting in the over-calling of CLABSIs (Digiorgio et al., 2012). Thus, it is possible that the study results for this variable may be influenced by case misclassification, especially if there were varying degrees of sensitivity or specificity concerning HA-CDI case ascertainment among hospitals.

Finally, the measure of Magnet status hospital, which was included as a metric for nursing quality, also has potential limitations as a proxy measure. For example, one study that compared perceptions of hostility and job satisfaction among newly registered nurses from Magnet and non-Magnet hospitals found that nurses at both Magnet and non-Magnet-hospitals experienced nursing hostility and had similar job satisfaction scores (Hickson, 2013). Thus, the Magnet-status designation of a hospital may not fully reflect aspects of an individual nurse's workplace environment. Further evaluations of nursing satisfaction in Magnet hospitals vs. non-magnet hospitals are needed to delineate the usefulness of the Magnet designation as a marker for nursing quality. Finally, for the measure of CDI physician experts, it is possible that there are healthcare professionals other than physicians serving as Physician Champions and that there are likely healthcare Professional Champions that did not serve as CDI guideline committee members.

Suggestions for Future Study

In addition to the additional research needed in areas regarding Magnet designation, safety performance measures, and state policies on CDI as described above, there are several other research inquiry lines for future evaluation. First, future studies should examine the factors related to decreased HA-CDI in Safety-net provider hospitals. Though Safety-net hospitals are thought to be at a potential disadvantage in

having patient populations comprised of lower-income persons, the quality of care at Safety-net and non-Safety-net hospitals has been demonstrated to be nearly equal (Ross et al., 2012). In the current study, the rate of HA-CDI was significantly lower in Safety-net hospitals as compared to non-Safety-net hospitals. One factor that may be related to this is the amount of outpatient antibiotic use that is utilized by the surrounding hospital population. It has been reported that higher population-level antibiotic prescription rates were associated with higher hospital CDI rates (Daneman et al., 2012). It is possible that population antibiotic use may be lower in communities surrounding safety-net provider hospitals than in non-safety-net hospital communities. A follow-up evaluation into antibiotic prescribing patterns in the communities surrounding the study hospitals and the relationship to HA-CDI occurrence is warranted.

A second area of future study is the evaluation of the relationship between decreased market competition and lower HA-CDI found in the current study. Though increased competition has been shown to be related to better outcomes in some quality areas, the opposite finding was found in the current study. Similar to the discussion in the previous section regarding Safety-net provider hospitals, it is possible that patients hospitalized in hospitals located in markets with decreased competition have less exposure to healthcare facilities, and are hospitalized in hospitals with a lower CO CDI prevalence. In addition, it is possible that there is less outpatient antibiotic in communities that are in lower hospital-concentrated markets.

A third area of future study is the examination of the Best Hospital Honor Roll designation and the Leapfrog Group Patient Safety Score on other types of HAIs in addition to HA-CDI, such as CLABSIs, CAUTIs, and post-surgical infections. Further,

more research is needed regarding the correlation of hospital performance ranking systems among hospitals. That is, if a hospital ranks well in the *U.S. News & World Report Best* hospitals ranking, does it also perform well in other scoring systems related to hospital quality.

Conclusions

Using an institutional perspective, this study evaluated organizational factors related to HA-CDI, including the impact of state-led CDI Prevention Collaboratives, state mandatory HA-CDI reporting, Magnet status, the rate of CLABSIs and CAUTIs, CDI Physician Champions, and the performance ranking systems of the U.S. News & World Report and the Leapfrog Group. Of the eight study hypotheses proposed, one was supported. That is, hospitals with a higher Leapfrog Group Safety Score had HA-CDI rates that were no different than hospitals with lower Safety Scores. Further, it was found that Best Hospital Honor Roll member hospitals had significantly higher rates of HA-CDI, though it was proposed that their rates would be no different than non-Honor Roll member hospitals. The study results have potential implications concerning the role of regulatory policies aimed to decrease HA-CDI and the validity of quality performance ranking systems.

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