Impact of CMS designated Hospital Acquired Condition (HAC) regulations compared to a currently non-CMS regulated hospital acquired infection—*Clostridium difficile*

by

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ABSTRACT

Impact of CMS designated Hospital Acquired Condition (HAC) regulations compared to a currently non-CMS regulated hospital acquired infection—*Clostridium difficile*

INTRODUCTION: Healthcare-associated infections (HAIs) are among the leading causes of death in the United States. Many HAIs are preventable, considering the fact that effective strategies to reduce the incidence of HAIs are readily available. According to the U.S. Department of Health and Human Services (HHS), up to 70% of central line-associated bloodstream infections can be prevented. In 2008, the Centers for Medicare and Medicaid Services (CMS) implemented a policy intended to reduce the incidence of specific preventable conditions and to restrict reimbursement for services provided to treat such conditions. CMS has initially designated ten conditions as hospital-acquired conditions (HACs) or complications deemed preventable if not documented as present on admission (POA). Three of these conditions are HAIs—catheter-associated urinary tract infections, surgical site infections, and vascular catheter-associated infections.

METHODS: The purpose of this study is to assess the incidence of a designated HAC (central line-associated blood stream infection) compared to a non-HAC, hospital-acquired infection (*Clostridium difficile*). In order to do so, an interrupted time series design with a comparator group will be used to assess for any changes in *Clostridium difficile* infection (CDI) ICU rates compared to ICU rates of central line-associated blood stream infection (CLABSI) both before and after the implementation of reduced reimbursement for the treatment of HAIs designated as HACs by CMS. A case-series study design will also be performed to assess for potential opportunities for intervention

prior to discharge for patients readmitted within 30 days of a previous admission that have *C. difficile* enteritis documented as the principle diagnosis upon readmission.

RESULTS: ICU CLABSI rates did not statistically change over time during the study time period (Student's t test 1.04, p=0.3); meanwhile, ICU CDI rates trended in an upward direction during the study period (Student's test 2.68, p=0.01). For patient specific data analysis, 54 patients were readmitted for *C. difficile* enteritis coded as the principle diagnosis upon readmission. 33 of these 54 patients (61.1%) were discharged home prior to the readmission. Reasons for readmission varied but included new onset CDAD (10), potentially premature discharge (8), medication reconciliation discrepancies including patients being discharge on a gastric acid suppressant without a valid indication for therapy (5), poor adherence to medication therapy on an outpatient basis (4), duration of therapy less than recommended guidelines (3), and relapse or failed a previous therapy regimen (3).

CONCLUSIONS: While efforts have been made to reduce HAIs at the local, state, and national; the incidence of CDI in the ICU setting at an adult teaching hospital trended in an upward direction and the incidence of CLABSI in the same ICU setting did not significantly change over time during the study time period. Patient specific data revealed that potential interventions prior to discharge for patients readmitted with *C. difficile* enteritis documented as the primary diagnosis upon readmission include: utilization of a CDI severity assessment prior to discharge to minimize premature discharges, optimization of treatment strategies following IDSA guidelines, and completion of medication reconciliation prior to discharge.

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Acronyms Used

1. Affordable Care Act (ACA)
2. American Recovery and Reinvestment Act (ARRA)
3. Case mix index (CMI)
4. Centers for Disease Control and Prevention (CDC)
5. Centers for Medicare and Medicaid Services (CMS)
6. Central line-associated bloodstream infection (CLABSI)
7. *Clostridium difficile* (*C. difficile*)
8. *Clostridium difficile*-associated diarrhea (CDAD)
9. *Clostridium difficile infection* (CDI)
10. *Clostridium difficile* toxin B (CDTB)
11. Division of Healthcare Quality Promotion (DHQP)
12. Healthcare-associated infection (HAI)
13. Healthcare facility (HCF)
14. Hospital-acquired condition (HAC)
15. Intensive care unit (ICU)
16. Length of stay (LOS)
17. National Healthcare Safety Network (NHSN)
18. Patient days (PD)
19. Present on admission (POA)
20. Surgical site infection (SSI)
21. The Methodist Hospital (TMH)
22. United States Department of Health and Human Services (HHS)
23. University Health Consortium® (UHC)
24. Urinary tract infection (UTI)

Chapter One

Introduction

Healthcare-associated infections (HAIs), also known as hospital-acquired infections or nosocomial infections, are among the leading causes of death in the United States. Approximately two million patients per year in the U.S. are affected by HAIs, which amounts to approximately 5%-10% of all acute hospital admissions (Burke, 2003). The Centers for Disease Control and Prevention (CDC) estimates that 100,000 people die each year from complications of HAIs, making HAIs unofficially the sixth leading cause of death in the United States (Klevens et al., 2007; Kochanek KD, 2011). In a study attempting to capture the direct medical costs incurred when treating HAIs, hospital costs of treating HAIs across the nation were estimated to be between 28 and 45 billion dollars annually (Scott, 2009).

Many HAIs are preventable considering the fact that effective strategies to reduce the incidence of HAIs are readily available. For example according to the U.S. Department of Health and Human Services (HHS), up to 70% of central line-associated bloodstream infections can be prevented by implementing what we know works (Wright D, 2011). The authors of one study based on a coalition of 66 intensive care units (ICUs) in southwestern Pennsylvania reported a reduction in central line-associated bloodstream infection (CLABSIs) rates per 1,000 central line days by 68% from 4.31 to 1.36 over a 5-year period (CDC, 2005). One hundred three ICUs in Michigan achieved a similar reduction in CLABSIs after implementing a multistep checklist; this program is now utilized in forty-five states and has shown sustained results in reducing CLABSIs (Pronovost et al., 2006). Both of these efforts were based on collaboratives and utilized a

defined multifaceted approach to the prevention of HAIs which can include pre- and post-intervention measurements, standardized case findings, and interventions focused on an organizational culture committed to patient safety (Stone et al., 2010).

As part of the Deficit Reduction Act of 2005, Congress assigned the secretary of the Department of Health and Human Services to evaluate the incidence of high cost and high volume preventable conditions. In 2008, the Medicare division of the Centers for Medicare and Medicaid Services (CMS) implemented a policy intended to reduce the incidence of specific preventable conditions by no longer reimbursing hospitals for care related to several designated hospital-acquired conditions (HACs) or complications deemed preventable if not documented as present on admission (POA) (McNutt et al., 2010). In other words, such cases would be paid as though the secondary diagnosis was not present. The designated HACs targeted for payment reductions are as follows: foreign object retained after surgery, air embolism, blood incompatibility, Stages III and IV pressure ulcer, hospital-related falls and trauma, catheter-associated urinary tract infection (UTI), surgical site infection (SSI), and vascular catheter-associated infections (CMS, 2008). While it may be difficult to distinguish the onset of certain types of HACs, especially for patients who are transferred in and out of multiple facilities, certain conditions may be more readily distinguishable as HACs than others. For example, central venous catheters are one of seven known classic risk factors that place patients at higher risk for candidemia (Amrutkar et al., 2006). With these changes to CMS regulations, if a patient is diagnosed with candidemia after insertion of a central catheter, then the hospital providing care could potentially be reimbursed less for the treatment of candidemia if in fact it is not documented as POA.

Furthermore in 2009, the American Recovery and Reinvestment Act (ARRA) authorized $50 million in funding for states to engage in HAI planning and other activities, including public reporting. Patient safety advocates argue that public disclosure of preventable infections will encourage hospitals to take action to improve infection practices, reduce adverse events, and can also assist with reducing hospital length of stay and cut costs (Spencer A, 2010). A study that examined the impact of HAIs (sepsis, pneumonia, Staphylococcal infections, *and Clostridium difficile*–associated diarrhea) in trauma patients after controlling for patient demographics, mechanism of injury, injury type, injury severity, and co-morbidities; determined that mortality, cost, and length of stay were significantly higher in patients with HAIs compared with patients without HAIs. For example, patients with HAIs incurred medical costs on average that were approximately 2 to 2.5 fold higher compared to patients without HAIs (Glance, Stone, Mukamel, & Dick, 2011).

In June 2011, CMS extended Medicare's no-pay policy for preventable HACs not documented as POA to the nation's Medicaid program. In following with the Medicare model, the Medicaid policy only prevents hospitals from being paid at a higher rate for treating certain complications or injuries that occur during a hospitalized stay. CMS expects this new policy to produce only limited savings initially, with states spending $3 million less and the federal government $4 million less in the fiscal year 2012 (Trapp, 2011). Once fully implemented, this new policy is projected to reduce federal and state Medicaid spending by a combined $35 million by 2015 (Trapp, 2011).

CMS could potentially expand its list of designated HACs in the future. With regards to HAIs, there is some difficultly in classifying certain HAIs as POA. For example, patients admitted to healthcare facilities (HCF) with *Clostridium difficile*-associated diarrhea (CDAD) like symptoms whose stools test positive for *C. difficile* toxin B (CDTB) within 48 hours of admission have been previously defined as having CDAD on admission; meanwhile, patients who develop diarrheal stools and test positive for CDTB 48 hours or more after admission have previously been considered to have hospital-acquired CDAD (Price et al., 2007). Another factor for consideration is the potential gap in time between exposure to *Clostridium difficile* in a HCF and the development of CDAD. In one study, a working surveillance group, established surveillance and prevention guidelines for CDAD. The authors noted that when compared to outpatient control subjects who were also recently discharged, patients with CDAD onset after discharge on average had longer lengths of previous hospital inpatient stay, suggesting a longer period of exposure during which transmission could have occurred (McDonald et al., 2007). Going forward, could patients who appear to develop CDAD during a previous admission and are re-admitted to the same HCF with symptoms of CDAD be considered as having a HAI as POA or are HCFs at risk for reduced reimbursements if in fact the onset of CDAD is determined to have occurred during a previous in-patient visit?

Whether or not CMS attempts to designate CDAD subtypes as a HAC going forward, there have been efforts made both in the public and private sector aimed at reducing the prevalence and burden of CDAD. For example, the Partnerships for Patients is a public-private partnership focused on improving the quality, safety, and affordability

of healthcare for all Americans. One of the goals for this organization includes decreasing the incidence of preventable hospital-acquired conditions by forty percent by the year 2013 (Patients, accessed October 10, 2011). Not to mention, the National Healthcare Safety Network (NHSN) is a voluntary, secure, internet-based surveillance system that integrates and expands legacy patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at the CDC. NHSN was created by the Department of Health and Human Services as a way to establish national goals aimed at reducing, preventing, and ultimately eliminating HAIs (CDC, accessed November 1, 2011). In regards to both CDIs that occur during hospitalization and CDIs in general, the NHSN five-year prevention goal is to reduce CDIs by thirty percent (HHS, 2010).

While CMS appears to be as committed as any organization to reduce the burden of HAIs, CMS's decision to designate certain conditions as HACs is a form of pay-for-performance as part of a concerted effort by CMS to optimize value-based purchasing for health-care related services. There is currently limited data to validate whether or not this type of policy will improve quality in health care. The authors of one study, using Medicare data to compare patient outcomes, found no evidence that hospital-based pay-for-performance led to a decrease in 30-day mortality (Jha, Joynt, Orav, & Epstein, 2012).

To make matters even more complex, the Affordable Care Act (ACA), passed in 2010, further accelerates the need to address the incidence of HAIs. Under the ACA, CMS will calculate the average risk-adjusted 30-day hospital readmission rates for patients treated for myocardial infarction, pneumonia, or heart failure (Joynt & Jha,

2012). If a hospital's risk-adjusted readmission rate exceeds the national average, then CMS will penalize such hospitals in the following year. As with HACs, CMS could potentially expand this readmission pay-for-performance initiative to include other common diagnoses for which readmissions have been shown to be potentially preventable such as hospital-acquired infections and other complications, premature discharge, failure to coordinate and reconcile medications, and poor planning for transitions in care (Joynt & Jha, 2012).

Research hypothesis:

H1: The Methodist Hospital's initiatives to reduce CLABSIs, a type of hospital acquired infection (HAI) now designated as a hospital acquired condition (HAC), have also resulted in a reduction in the incidence of *Clostridium difficile* infection (CDI), a HAI which could potentially be regulated as a HAC by CMS going forward.

Primary objective:

To assess the incidence of a CMS designated hospital-acquired condition, central line-associated bloodstream infection (CLABSI), compared to a non-CMS designated hospital acquired condition, hospital acquired infection *Clostridium difficile* infection (CDI).

Specific aims for the primary objective:

1. Assess the incidence of ICU CLABSIs before and after CMS regulations on HACs compared to ICU *Clostridium difficile* rates during the same time period.
2. Assess ICU Echinocandin utilization patterns compared to oral Vancomycin utilization patterns before and after CMS regulations on HACs.
3. Assess ICU utilization patterns of medications, that have been shown to be either positively or negatively correlated with the onset of CDI, before and after CMS regulations on HACs.

Secondary objective:

To identify opportunities for intervention prior to discharge for patients with healthcare facility-onset, healthcare facility-associated CDI focused on reducing 30 day readmissions related to CDAD.

Specific aims for the secondary objective:

1. Analyze patient demographics for patients readmitted within 30 days with *Clostridium difficile* enteritis documented as the principle diagnosis upon readmission.
2. Evaluate antibiotic therapy regimens for patients treated for *Clostridium difficile* enteritis prior to the initial discharge compared to those who are treated initially upon readmission.
3. Assess for opportunities for intervention prior to the initial discharge that could potentially reduce the incidence of CDAD-related readmissions.

Chapter Two

Methods

Hospital setting:

This study was conducted at The Methodist Hospital (TMH), a member of The Texas Medical Center in Houston, TX. TMH is a licensed 900 bed adult, tertiary-care hospital with more than 100 ICU beds. Approval for this study was granted by the hospital's Institutional Review Board.

Study design:

A retrospective interrupted time series design with a comparator group was utilized to assess for any changes in ICU rates of *Clostridium difficile* per 1,000 patient days during hospitalization compared to ICU rates of central line-associated blood stream infections per 1,000 catheter days both two years before (October 1st, 2006 – September 30th, 2008) and two years after (October 1st, 2008 – September 30th, 2010) the implementation of policy changes by CMS regarding reimbursement for in-patient health care services provided for the treatment of HAIs now designated as HACs. The other independent variables analyzed were ICU case-mix index (CMI), ICU length of stay (LOS), and ICU patient days (PD). The dependent variables analyzed were ICU utilization patterns of specific antibiotics, antifungals, and other classes of medications (e.g., proton-pump inhibitors, statins). Both independent and dependent variables were analyzed utilizing two-tailed Student's t tests. A *P* value of less than 0.05 was considered to be significant.

A case-series study design utilizing descriptive statistics was also conducted to assess patients readmitted to TMH within thirty days of a previous admission that had *Clostridium difficile* enteritis documented as the principle diagnosis upon readmission.

Study population:

The study population was compromised of two unique patient populations. Patients admitted to one of the five adult ICUs at TMH during the study time period (October 1st, 2006 to September 30th, 2010) that were documented as having acquired either a CLABSI or CDI in an ICU were included in the time series analysis. Patients readmitted to TMH, within thirty days of a previous admission that were coded in the University Health Consortium® (UHC) online database as having *Clostridium difficile* enteritis as the principle diagnosis for readmission at any time from October 1st, 2008 – September 30th, 2010, were also included in the study analysis.

Exclusion criteria:

1. Patients transferred to TMH from any outside facility with either a CLABSI or CDI documented prior to transfer.
2. Non-ICU line days and non-ICU patient days were excluded in the time series analysis.
3. Patients previously admitted more than thirty days prior to readmission to TMH for treatment of CDAD.
4. Patients discharged somewhere other than to home or self-care and readmitted to TMH within thirty days with CDI being documented as the principle diagnosis upon readmission.

Case definitions:

Laboratory-Confirmed Bloodstream Infection (LCBI): patients must meet one of the following criteria outlined by the CDC (CDC, accessed January 10, 2011):

Criteria 1: Patient has a recognized pathogen cultured from one or more blood cultures AND organism cultured from blood is not related to an infection in another site.

Criteria 2: Patient has at least one of the following signs or symptoms: fever (>38^{o}C), chills, or hypotension AND signs and symptoms and positive laboratory results are not related to an infection at another site AND common commensal is cultured from two or more blood cultures drawn on separate occasions.

Healthcare Facility-Onset, Healthcare Facility-Associated (HO-HCFA) acquired CDI was defined in conjunction with the CDC and DHQP definitions of healthcare facility-onset CDI: positive laboratory assay for a toxin-producing *Clostridium difficile* organism (e.g. toxin EIA, cytotoxin assay, toxigenic culture, PCR) from a stool specimen from a patient collected greater than forty eight hours after admission to a health care facility (McDonald et al., 2007).

Community-Onset, Healthcare Facility-Associated (CO-HCFA) CDAD: community-onset with a positive laboratory assay for a toxin-producing *Clostridium difficile* organism from a patient who was discharged from a healthcare facility less than or equal to four weeks prior to the date that the stool specimen was collected (McDonald et al., 2007).

Community-associated (CA) CDAD: CDI case patients with symptom onset in the community or 48 hours or less after admission to a HCF, provided that symptom onset was more than twelve weeks after the last discharge from a HCF (McDonald et al., 2007).

Indeterminate CDAD: CDI case patients who do not fit any of the above criteria for an exposure setting (e.g., a patient who has CDAD symptom onset in the community, but who was discharged from the same or another healthcare facility 4-12 weeks before symptom onset) (McDonald et al., 2007).

Unknown CDAD: CDI cases for which the exposure setting cannot be determined because of a lack of available data (McDonald et al., 2007).

Data collection:

De-identified patient data from the hospital's infection control department and data from the UHC® online database was utilized to identify patients who were admitted to TMH from October 1st, 2006 to September 30, 2010 and met the study inclusion criteria. The data was stored and maintained in a computerized database (Microsoft® Excel 2010). A unique study ID was given to each patient and no patient identifiers were transferred to the database.

Demographic variables:

The following variables were collected for each patient readmitted for treatment of CDI within 30 days of a previous admission: age, sex, serum creatinine, white blood cell count, body temperature, antibiotics administered, gastric acid suppressants administered, statins administered, average hospital length of stay, and patient charges incurred during readmission.

Chapter Three

Results

For the primary objective, ICU CLABSI rates did not statistically change over time during the study time period (Student's t test 1.04, p=0.3); meanwhile, ICU CDI rates trended in an upward direction during the study period (Student's t test 2.68, p=0.01), (See Figure 1 and Table 1).

Figure 1: ICU CDI rates and ICU CLABSI Rates

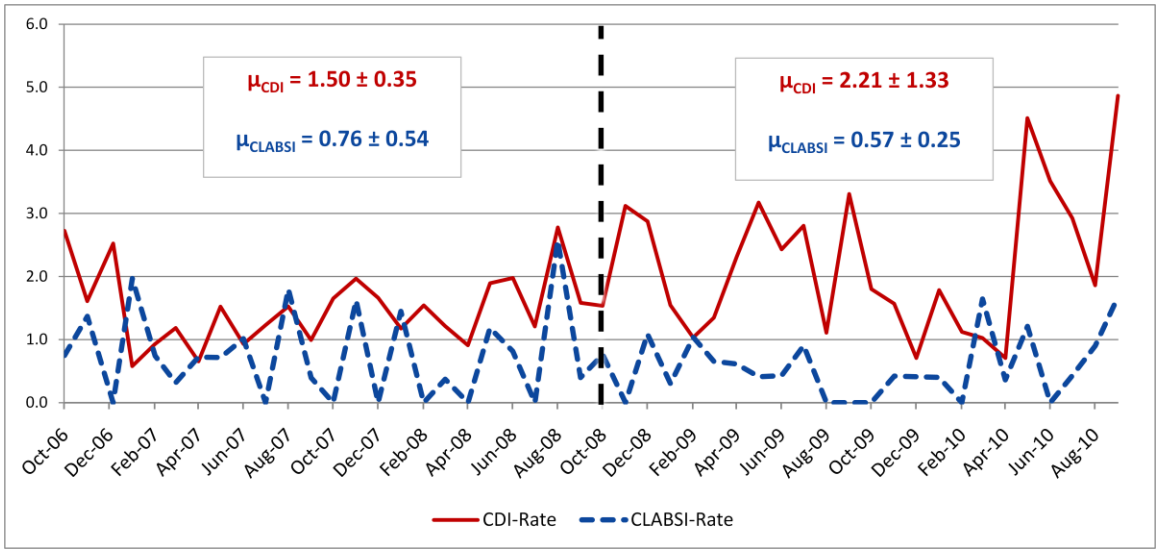
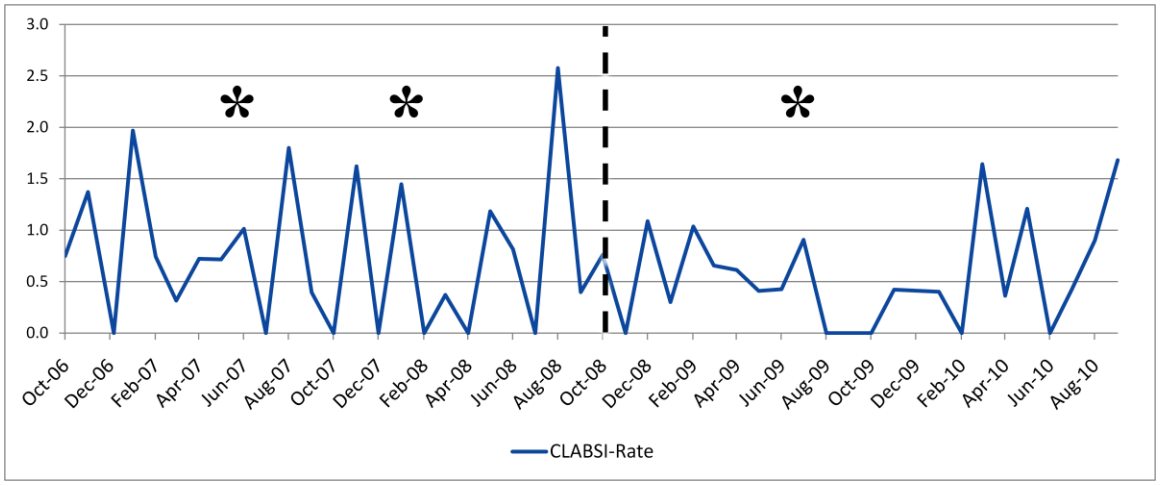


Table 1: Summary of ICU CLABSI and ICU CDI Rates

Variable	μ ± SD (Years 1-2)	μ ± SD (Years 3-4)	t test	p value (p<0.05)
ICU CLABSI	0.76 ± 0.73	0.57 ± 0.50	1.04	0.30
ICU CDI	1.50 ± 0.59	2.21 ± 1.15	2.68	0.01

Point interventions made at the study site during the study time period intended to reduce the incidence of CLABSIs included: standardizing an insertion line checklist (July 2009*), switching to chlorhexidine gluconate as the antiseptic agent of choice for prepping the skin prior to catheter insertion (May 2007*), updating the sterile line insertion policy to include wording regarding the requirement to use full barrier precautions when inserting a central venous catheter (March 2006), and a hospital-wide campaign to improve compliance rates with hand washing by providing employees with a quarterly bonus if compliance rates are maintained above 95% (January 2008*), (See Figure 2).

Figure 2: Summary of Point Interventions Made to Reduce CLABSIs



*Note: the timing of point interventions implemented to reduce the incidence of CLABSIs were assess based on meeting minutes of the study center's Infection Prevention and Control Committee.

ICU considerations analyzed that may have affected ICU CLABSI and ICU CDI rates included: patient days (PD), length of stay (LOS), and case mix index (CMI), (See Figures 3 – 4, Table 2).

Table 2: Summary of ICU Considerations

Variable	μ ± SD (Years 1-2)	μ ± SD (Years 3-4)	t test	p value (<0.05)
ICU PD	3208 ± 128	2849 ± 177	8.04	<0.001
ICU LOS	4.09 ± 0.24	3.42 ± 0.24	9.69	<0.001
ICU CMI	1.76 ± 0.04	1.88 ± 0.05	8.97	<0.001

Figure 3: ICU Patient Days

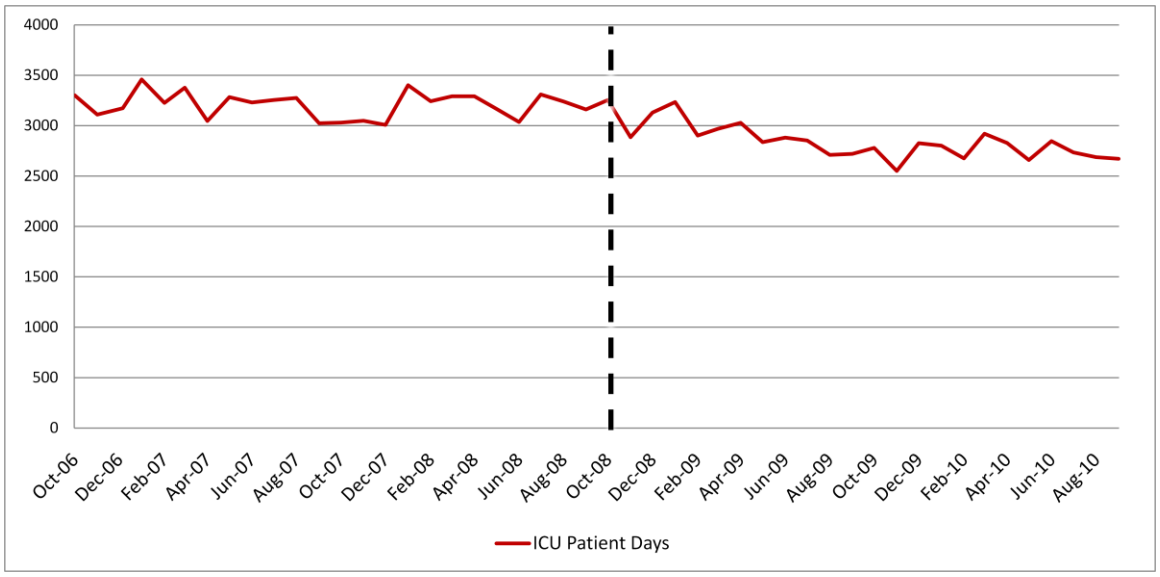
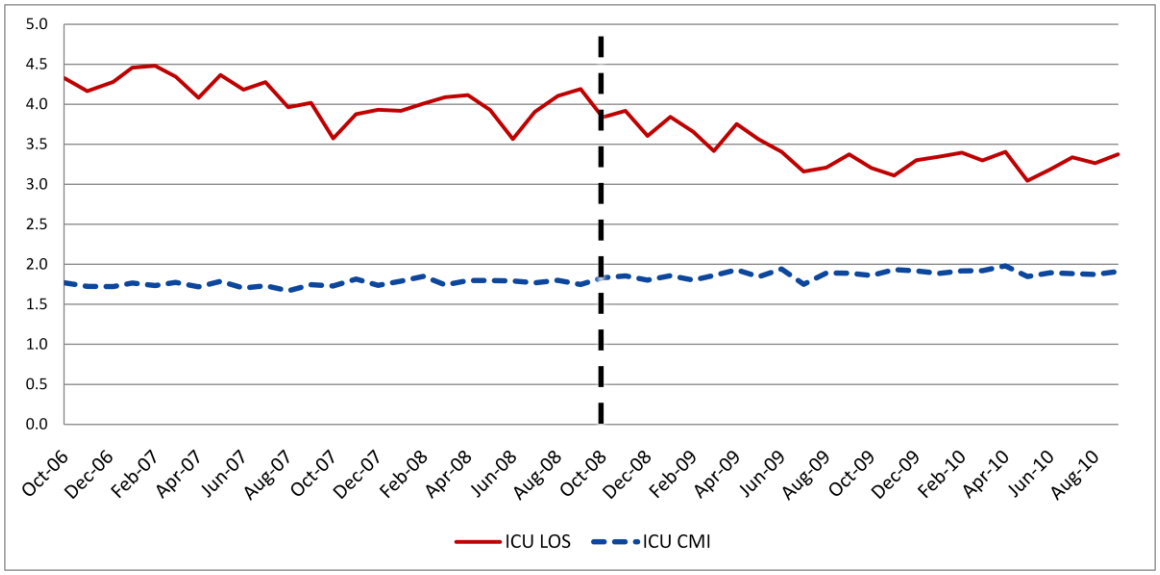


Figure 4: ICU Length of Stay vs. ICU Case Mix Index



ICU mean rates of both oral vancomycin (Student's t test=4.60, $p<0.001$) and Echinocandin utilization (Student's t test 2.57, $p<0.01$) trended upward over time during the study time period (See Figure 5, Table 3).

Figure 5: ICU PO Vancomycin Utilization vs. ICU Echinocandin Utilization

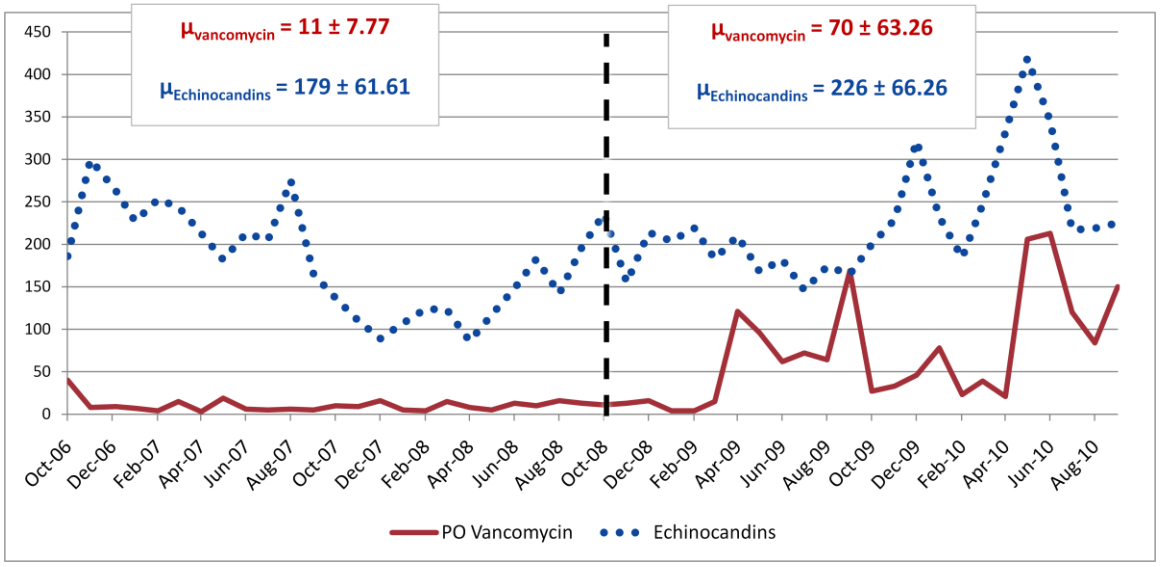


Table 3: Summary of ICU PO Vancomycin Utilization vs. ICU Echinocandin Utilization

Variable	μ ± SD (Years 1-2)	μ ± SD (Years 3-4)	t test	P value (<0.05)
PO Vancomycin	11 ± 7.77	70 ± 63.26	4.60	<0.001
Echinocandins	179 ± 61.61	226 ± 66.26	2.57	0.01

To account for potential variations in prescribing practices for the treatment of CDIs and candidemia related CLABSIs, ICU utilization patterns of oral metronidazole, IV fluconazole, IV voriconazole, and amphotericin formulations were analyzed (See Figures 6 – 7, Table 4).

Figure 6: Summary of ICU Antibiotic and Antifungal Utilization

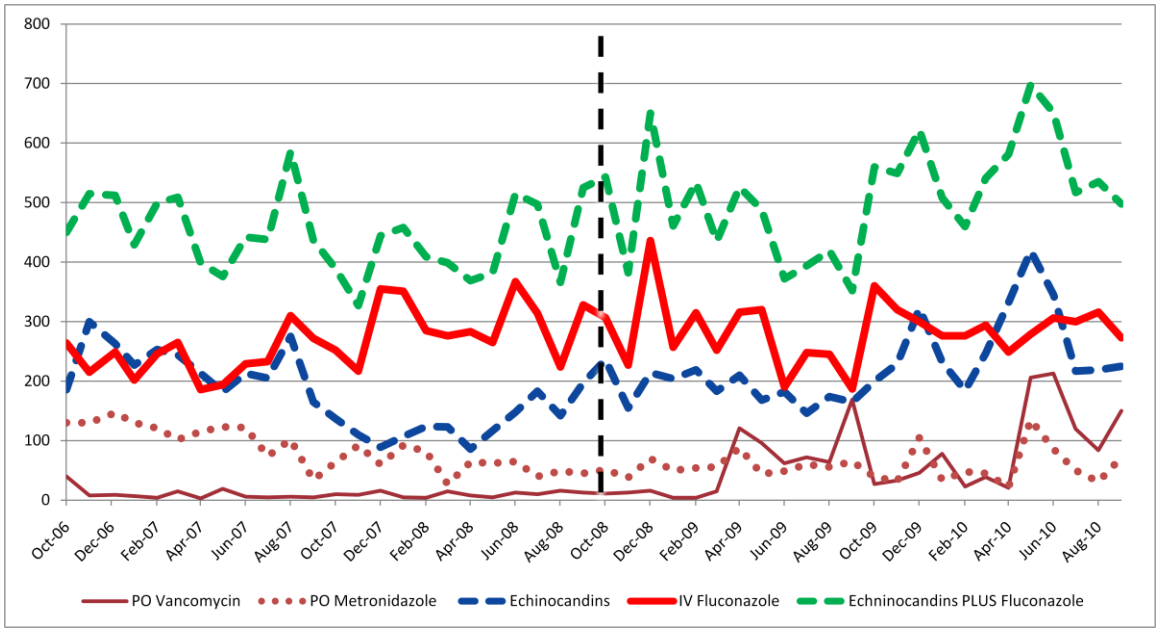


Figure 7: Summary of ICU Antifungal Utilization

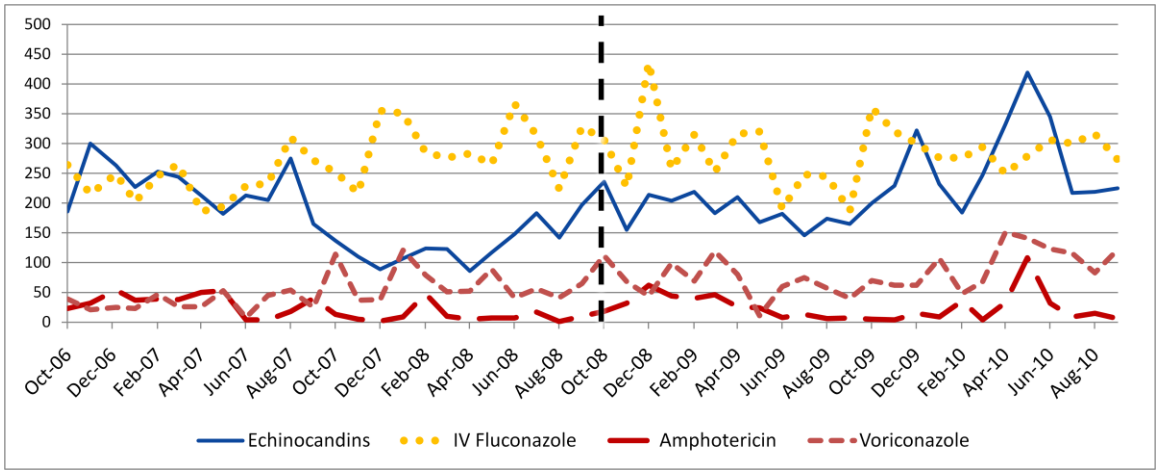


Table 4: Summary of ICU Antibiotic and Antifungal Utilization

Variable	μ ± SD (Years 1-2)	μ ± SD (Years 3-4)	t test	P value (<0.05)
PO Vancomycin	11 ± 7.77	70 ± 63.26	4.60	<0.001
PO Metronidazole	86 ± 35.52	58 ± 25.53	3.23	<0.001
Echinocandins	179 ± 61.61	226 ± 66.26	2.57	0.01
IV Fluconazole	266 ± 51.08	285 ± 52.60	1.30	0.20
IV Voriconazole	49 ± 28.08	83 ± 34.84	3.70	<0.001
Amphotericin	22 ± 18.34	25 ± 23.86	0.52	0.61

ICU utilization patterns of certain medications that have been shown to either increase the risk of CDI (e.g., clindamycin, fluoroquinolones, aminoglycosides, and gastric acid suppressants) and medications that are hypothesized to reduce the risk of CDI (e.g., statins) were also analyzed (See Figures 8 – 9, Table 5).

Figure 8: Summary of ICU Antibiotic Utilization

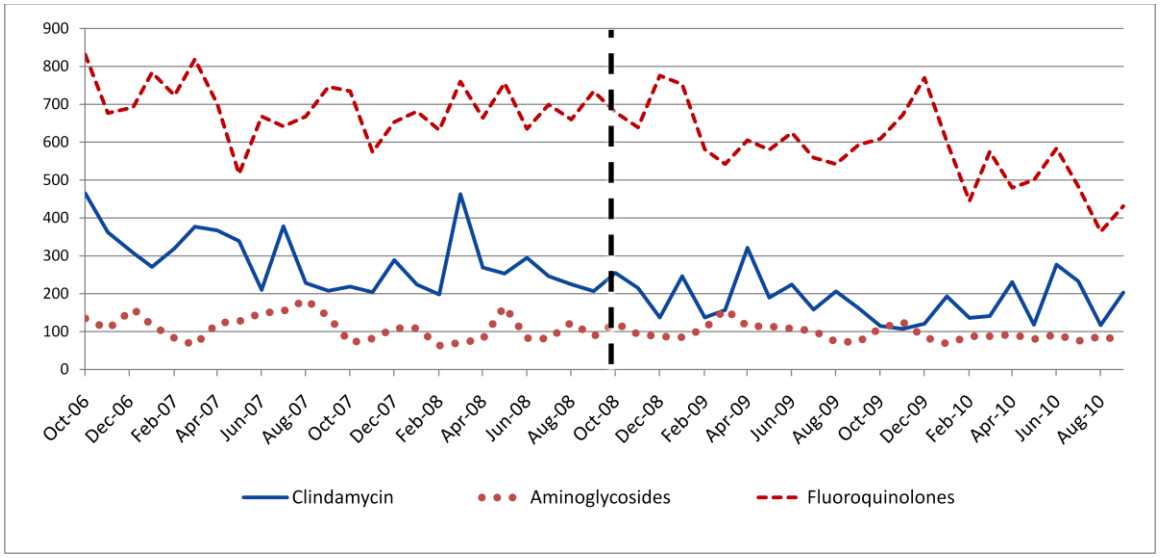


Figure 9: Summary of ICU Gastric Acid Suppressant and Statin Utilization

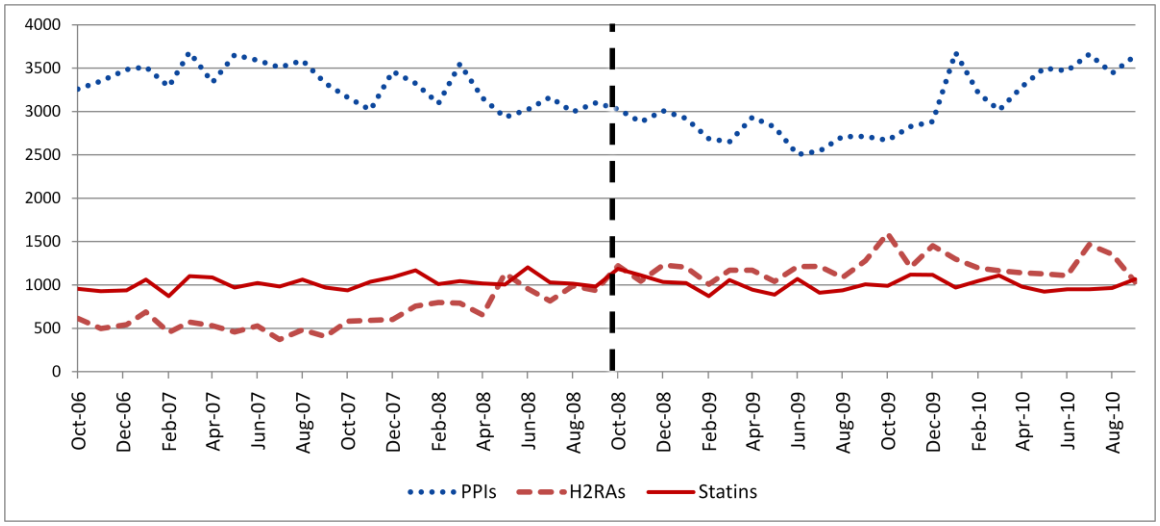


Table 5: Summary of Medication Related CDI Risk Factors

Variable	μ ± SD (Years 1-2)	μ ± SD (Years 3-4)	t test	p value (<0.05)
Clindamycin utilization	289 ± 80.22	183 ± 58.38	5.19	<0.001
Aminoglycoside utilization	111 ± 35.27	96 ± 21.00	1.83	0.07
Fluoroquinolone utilization	694 ± 72.01	583 ± 103.50	4.31	<0.001
PPI utilization	3315 ± 226.21	3028 ± 369.50	3.24	0.002
H_2RA utilization	656 ± 200.73	1209 ± 143.86	10.97	<0.001
Statin utilization	1021 ± 75.95	1010 ± 83.09	0.48	0.63

For the secondary objective of this study: there were 250 documented cases of CDI from October 1st, 2008 through September 30th, 2010. 54 unique patients were readmitted to TMH within 30 days of a previous admission with *C. difficile* enteritis documented as the principle diagnosis upon readmission. 33 of these 54 patients (61.1%) were discharged home or to self-care after the initial admission and the readmission. Baseline characteristics prior to the initial discharge for these 33 patients were assessed to identify potential opportunities for intervention to reduce readmissions (See Tables 6 – 8).

Table 6: Baseline Characteristics of Patients at Discharge Prior to Readmission

Baseline Characteristic	Readmitted Patients (N = 33)
Age (years) ± SD	61.0 ± 16.0
Female sex – no. (%)	24 (72.7%)
WBC (range)	8.13 (1.54 – 15.9)
Scr (range)	1.67 (0.5 – 10.4)
Temp ^{o}F (range)	97.8^{o}F (94.6^{o}F – 100.1^{o}F)

Table 7: Summary of Admissions and CDAD-related Readmissions

Variable	Initial Admission (N = 33)	Readmitted Patients (N = 33)
Average number of days to readmission (range)	N/A	12.8 days (1 – 26 days)
Average treatment duration for *C. difficile* (range)	13.8 days (6 – 19 days)	16.8 days (10 – 35 days)
Average hospital length of stay (range)	7.2 days (1 – 23 days)	7.0 days (2 – 19 days)
Average charges incurred during readmission	N/A	$49,938
Readmitted again within 30 days	N/A	12 (36.4%)

Table 8: Underlying Reasons for CDAD-related Readmissions

Reason for Readmission	Readmitted Patients (N = 33)
New onset CDAD	10 (30.3%)
Premature discharge	8 (24.2%)
Medication reconciliation discrepancies at discharge regarding high risk CDI medications	5 (15.2%)
Poor adherence to medication therapy	4 (12.1%)
Relapse/failed previous therapy regimen	3 (9.1%)
Therapy discontinued prematurely	3 (9.1%)

*Patients were classified as having new onset CDAD upon readmission if there was no documentation of any previous treatment of CDI prior to the readmission.

**Patients were classified as being discharge prematurely based on the severity of CDI symptoms documented in the electronic medical record prior to the initial discharge.

***Patients were classified as having a medication reconciliation discrepancy contributing to readmission if there was no indication for gastric acid suppression at the time of the initial discharge or if patients were initially discharged home on antibiotics and more than one type of gastric acid suppressant.

Chapter Four

Discussion

Primary objective: To assess the incidence of a CMS designated hospital-acquired condition, central line-associated bloodstream infection (CLABSI), compared to a non-CMS designated hospital acquired condition, hospital acquired infection *Clostridium difficile* infection (CDI).

In this study, ICU CLABSI rates did not statistically change over time during the study time period (Student's t test 1.04, p=0.3); meanwhile, ICU CDI rates trended in an upward direction during the study time period (Student's test 2.68, p=0.01). These findings are consistent with previously published studies. While interventions to decrease catheter-related bloodstream infections in ICU settings have resulted in large and sustained reductions in rates of catheter-related bloodstream infections (Pronovost et al., 2006), a 2011 AHRQ progress report on a national effort to eliminate bloodstream infections determined that the national average CLABSI rate per 1,000 line days remains above 1.0 (Clancy, 2012). One of the plausible explanations for rates remaining above 1.0 is due to the fact that a relatively small percentage of units have CLABSI rates over 5 per 1,000 central line days. Several studies have also noted the importance of sustaining reduced rates and driving them down even lower over time will require a sustainable intervention at both the hospital and the State levels (Clancy, 2012; P. J. Pronovost, Marsteller, & Goeschel, 2011).

While efforts to reduce rates of hospital acquired infections have been made on local, state, and national levels; the clinical profile of *C. difficile* infection has worsened, with an increase in the number of cases and an increase in morbidity during the past

decade (Louie et al., 2011). In some hospitals, hospital-acquired CDI has surpassed Methicillin-resistant *Staphylococcus aureus* infections as the leading cause of health-care associated infection (Miller, Chen, Sexton, & Anderson, 2011). This can be even more problematic in an ICU setting because infectious causes of diarrhea in such settings increases the likelihood of patients developing complications and that the causative agent can be transmitted between patients and health-care workers (Bobo, Dubberke, & Kollef, 2011). Unfortunately, ICU CDI rates in this study (Student's t test 2.68, p=0.010) reaffirm previously published data that the incidence of CDI is still on the rise.

The rationale for comparing ICU CLABSIs rates versus ICU CDI rates was that both types of hospital acquired infections have been under surveillance and interventions were implemented at TMH prior to CMS policy changes outlining certain HAIs as HACs going forward starting October, 1st, 2008. For central line insertions, the hospital's Infection Control Department has established policies and procedures for the insertion and maintenance of central venous catheters based on CDC guidelines (CDC, accessed January 10, 2011). Implemented in 1998 and last revised in 2011, central line insertion requirements at TMH include:

1. Use a standard insertion kit or cart for catheter insertion. The standardization includes using a checklist to ensure compliance with aseptic practice.
2. Healthcare personnel should be empowered to stop the procedure if breaches in aseptic technique are observed.
3. Proper hand hygiene must be performed by washing hands with conventional antiseptic-containing soap and water or with waterless alcohol-based gels or

foams. Sanitize hands before and after palpating, inserting, replacing, or dressing any intravascular device.

4. Use sterile technique, including a sterile gown and gloves, a mask, and a large sterile drape, i.e., maximal barrier precautions, for the insertion of central venous, arterial catheters or exchanges over a guide-wire. Sites include subclavian, jugular, femoral, brachial, and radial.
5. The assistant to the inserter must wear a sterile gown, sterile gloves, mask and head cover if over the sterile field.
6. Chlorhexidine gluconate (CHG) is the antiseptic agent of choice for prepping the skin prior to catheter insertion and at the time of dressing changes. Allow the CHG to dry completely before insertion or dressing change.

For CDI present at any time during admission, the hospital's Infection Control Department has established contact precautions, which were implemented in 1999 and last revised in 2011 and include:

1. Wash hands with soap and water before entering and exiting patient rooms.
2. Wear gloves and personal protective equipment (PPE) upon entering patient rooms.
3. Remove gloves and PPE prior to exiting patient rooms.
4. Equipment and supplies for use in the care of patients requiring Contact Precautions are provided via a cart located outside a patient's room. The cart, Contact Isolation Sign, and supplies are obtained from Central Services. The isolation sign must be placed outside the patient's room at all times.

While policies alone may not always reflect practices in care provided for patients at the bedside, it is important to note that there were few changes in practice focused on reducing ICU rates of CLABIs or CDIs as outlined above during the study time period (See Figure 2). Furthermore, it is difficult to assess whether or not such point interventions impacted the rates of CLABSIs or CDIs during the study time period.

To further support the study hypothesis, that CMS policy changes impacted both CLABSI and CDI rates at TMH, ICU utilization patterns of antimicrobials to treat both CLABSIs and CDIs were also analyzed. Based on IDSA guidelines, ICU oral vancomycin utilization rates were compared to ICU Echinocandin utilization rates. The rationale for assessing oral vancomycin rates is due to the fact that ICU patients are more likely to present with a higher severity of CDI than non-ICU patients; and therefore, would more than likely be candidates for oral vancomycin therapy as opposed to oral metronidazole therapy (Zar, Bakkanagari, Moorthi, & Davis, 2007). The rationale for assessing ICU Echinocandin utilization rates is due to the fact that Echinocandins are now considered to be a first line treatment option for systemic candidemia (Sobel & Revankar, 2007), which is highly correlated with central venous catheters and ICU stay at the time of culture (Amrutkar et al., 2006). The mean rates of both oral vancomycin (Student's t test=4.60, $p<0.001$) and Echinocandin utilization (Student's t test 2.57, $p<0.01$) in the ICU setting trended upward over time during the study time period. To account for any potential variations in prescribing practices, utilization patterns of oral metronidazole, IV fluconazole, and IV voriconazole, and amphotericin formulations were also analyzed. Of these antimicrobial agents, only utilization patterns of IV voriconazole

statistically changed over time during the study time period (Student's t test 3.70, $p<0.001$).

The prescribing patterns in this study suggest that the incidence and severity of CDI in the ICU setting trended in an upward direction over time during the study time period. Strategies focused on decreasing a patient's risk of exposure to CDAD are multifactorial but should include utilizing antimicrobial stewardship because the first line of defense against CDI is healthy intestinal flora (Bobo et al., 2011). Bobo and colleagues further clarified this statement by stating, "By decreasing the number of patients taking antimicrobials and decreasing high-risk antimicrobial exposures, the number of patients at risk for CDIs is decreased if *C. difficile* exposure occurs". Furthermore, one study noted that up to 25% of antibiotic usage in a hospital setting is not necessary (Lawrence & Kollef, 2009). Prescribing patterns of antibiotics previously shown to increase the risk of CDI were analyzed in this study to assess for any changes in utilization patterns compared to changes in ICU CDI rates over time. ICU utilization patterns of clindamycin (Student's t test 5.19; $p<0.001$) and fluoroquinolones (Student's t test 4.31; $p<0.001$) trended downward during the study time period; however, ICU CDI rates trended in an upward direction (Student's t test 2.68, $p=0.01$).

In addition to antibiotics; gastric acid suppressants, such as proton pump inhibitors (PPIs) and H_2-receptor antagonists, have been associated with an increased risk of CDI. However, the degree of association can be difficult to assess considering that "studies have yielded conflicting results, including no increased risk of CDI with gastric acid suppressants, increased risk with PPIs alone associated with a dose response, or increased risk with both PPIs and H_2-receptor antagonists" (Bobo et al., 2011).

Regardless of the extent of association between administering gastric acid suppression medication and the onset of CDI, there are opportunities for interventions considering that as many as 50% of patients on gastric acid suppression therapy do not have an indication for it (Bobo et al., 2011). In this study, ICU utilization patterns of PPIs trended in a downward direction (Student's t test 3.24, p=0.002). Not to mention, few published studies to date have shown prophylactic medication therapy to be beneficial in reducing CDI; however, statins have been hypothesized to reduce the risk of *C. difficile* infection.(McGuire, Dobesh, Klepser, Rupp, & Olsen, 2009) For this study, ICU utilization patterns of statin medications did not statistically change over time (Student's t test 0.48, p=0.63).

Secondary objective: To identify opportunities for intervention prior to discharge for patients with HCF-onset, HCF-associated CDI focused on reducing 30 day readmissions.

In this study time period, 54 patients were readmitted for *C. difficile* enteritis coded as the principle diagnosis upon readmission during the study time period. Thirty-three of these 54 patients (61.1%) were discharged home or to self-care prior to the readmission. These 33 patients' electronic medical records were reviewed for potential opportunities for intervention prior to discharge as part of a case-series analysis. Baseline characteristics of patients at the time of the initial discharge included: an average age 63 years old, 24 of the patients were female (72.7%), average white blood cell count upon discharge was 8.13 (range: 1.54 – 15.9), average serum creatinine upon discharge was 1.67 (range: 0.5 – 10.4), and average body temperature upon discharge was 97.8^{o}F (range: 94.6^{o}F – 100.1^{o}F). Once baseline characteristics were determined, electronic

medical records were analyzed to assess for underlying reasons for readmission. Reasons for readmission varied but included new onset CDAD (10), potentially premature discharge (8), medication reconciliation discrepancies including patients being discharge on a gastric acid suppressant without a valid indication for therapy (5), poor adherence to medication therapy on an outpatient basis (4), duration of therapy less than recommended guidelines (3), and relapse or failed a previous therapy regimen (3). Potential interventions that could be implemented to assist patients being treated for CDI prior to discharge include:

1. Utilization of a CDI severity assessment prior to discharge to minimize premature discharges. For example, the severity assessment score algorithm established by Zar and colleagues clearly defines which patients are considered to have severe CDI (Zar et al., 2007).
2. Optimizing treatment strategies following IDSA guidelines. For example, IDSA guidelines now recommend oral vancomycin 125mg QID for 10-14 days for the treatment of an initial episode of severe CDI (Cohen et al., 2010).
3. Optimize medication reconciliation prior to discharge. Interventions could potentially include having patients refrain from taking gastric acid suppression medication if possible until after antibiotic regimens are completed and to inquire about a patient's ability to afford and/or obtain outpatient prescription(s) for the treatment of CDAD prior to discharge.
4. Better planning for transitions in care. For example, ensure that all family and potential care providers are aware of how *C. difficile* can be transmitted from one person to another.

Interventions to create and sustain reductions in readmissions typically range from $100 to $200 per discharge (Berenson, Paulus, & Kalman, 2012). Berenson and colleagues also noted that "hospitals face economic disincentives to fully implement programs focused on reducing readmissions for a specified diagnosis considering that the direct costs of such programs and decreased revenues resulting from successful interventions that reduce readmissions negatively affect hospitals' finances". At this time, it is difficult to assess whether or not the costs of interventions made prior to discharge for patients with CDAD described above would offset the costs of any potential reimbursement penalties to TMH for patients readmitted within 30 days of a previous admission considering that CMS is initially assessing readmission rates based on only three conditions (myocardial infarction, pneumonia, and heart failure). Going forward, CMS plans to expand this program to include other common diagnoses for which readmissions are theoretically preventable, which could potentially include hospital-acquired infections such as *Clostridium difficile* infection.

Implications:

The findings of this study can be used to acknowledge the fact that TMH still has some work to do to minimize CLABSI and CDI rates in the ICU setting. CMS policy changes on hospital acquired infections did not appear to have a direct impact on ICU rates of CLABSIs or CDIs during the study time period. While prescribing patterns may contribute to the incidence of CDI; ICU utilization patterns of fluoroquinolones, clindamycin, and proton-pump inhibitors trended downward over time during the study time period; however, ICU rates of CDI trended upward.

Patients readmitted to TMH within 30 days of previously admission with *C. difficile* enteritis coded as the principle diagnosis upon readmission were assessed for opportunities for intervention prior to the initial discharge. Utilizing a CDI severity assessment to assist in reducing the incidence of patients discharged prematurely and following IDSA treatment guidelines for *C. difficile* may assist in reducing readmissions more so than other types of interventions.

Limitations:

As with any study there were limitations. A single site center may not be representative of practices at other institutions. For example, certain institutions may be utilizing different strategies to prevent CLABSIs and CDIs than what is currently in practice today at TMH. Thus, it is difficult to quantify the impact (if any) that CMS policy changes have had at the bedside of all adult tertiary care hospitals. Also, it is difficult to assess whether or not potential interventions could have prevented CDAD-related readmissions considering that the study design was a case-series analysis.

Potential Future Studies:

Some of the studies that could potentially be conducted as an extension of this project may include an assessment of whether or not financial incentives for quality in healthcare (i.e. "pay-for-performance") result in improvements in quality of care (e.g., reductions in overall adverse events including adverse drug events, reductions in length of stay, and reductions in the incidence of hospital-acquired conditions). A study could also be carried out to assess if the costs of interventions made prior to discharge (e.g., medication reconciliation and patient discharge counseling) can offset prospective financial penalties imposed by CMS associated with excessive readmissions. Another study could also be done to analyze causes of "near-term" readmissions (e.g., within 3 days up to 7 days from a previous admission) versus later readmissions (e.g., up to 30 days from a previous admission).

Chapter Five

Conclusions

This study was conducted to assess whether or not CMS policy changes, designating certain hospital acquired infections as Hospital Acquired Conditions, have impacted ICU rates of CLABSIs and CDIs at a private, adult teaching hospital located within The Texas Medical Center. While ICU CLABSI rates did not significantly change over time during the study time period, ICU CDI rates did trend in an upward direction. Prescribing patterns in the ICU setting were also analyzed to assess whether or not the prescribing culture of the hospital may have contributed to the incidence of CDI. ICU utilization rates of fluoroquinolones and clindamycin, antibiotics previously implicated in precipitating CDAD, trended downward over time during the time study period. While efforts have been made to reduce the incidence of HAIs at the local, state, and national; the incidence of CDI at a single study center trended in an upward direction during the study time period.

Patient specific data was analyzed to assess for opportunities for intervention prior to discharge for patients determined to have healthcare facility-associated CDAD. For patients readmitted within 30 days of a previous admission and readmitted with a principle diagnosis upon readmission documented as *C. difficile* enteritis, potential opportunities for intervention include: utilization of a CDI severity assessment prior to discharge to minimize premature discharges, optimizing treatment strategies following IDSA guidelines, and completing medication reconciliation prior to discharge. At this time, it is difficult to assess whether or not the costs of such interventions can reduce readmissions and ultimately improve the quality of care provided.

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