

PUBLIC REPORTING OF HEALTHCARE-ASSOCIATED INFECTIONS:  
THE IMPACT OF PUBLIC POLICY ON HEALTHCARE ORGANIZATIONS AND  
PATIENT OUTCOMES

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## **DEDICATION**

This dissertation is dedicated to Nathan. You have followed me along this journey and this accomplishment is as much yours as it is mine. My sacrifices were only possible because of your sacrifices, and I appreciate all you have done to support me in accomplishing my professional and educational goals.

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## **ABSTRACT**

### **PUBLIC REPORTING OF HEALTHCARE-ASSOCIATED INFECTIONS: THE IMPACT OF PUBLIC POLICY ON HEALTHCARE ORGANIZATIONS AND PATIENT OUTCOMES**

Stephen Perez

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Healthcare-associated infections (HAIs) are a significant source of morbidity and mortality in U.S. hospitals. Policy makers have responded with a variety of state and federal policies to reduce infections by increasing the visibility and accountability of hospital performance. One policy initiative that has gained momentum is state-level legislative mandates requiring hospitals to report HAI-related performance data, which often includes public release of this data. These reporting mandates have produced mixed results, however, regarding their impact on healthcare organizational processes, patient outcomes or consumer decision-making.

This dissertation comprises three papers that explore the relationship between HAI public reporting, organizational climate and HAI infection rates. The first paper presents a conceptual framework derived from an integrative review of the HAI reporting literature that proposes new pathways for testing these relationships. The second paper uses data from the Prevention of Nosocomial Infections and Cost-Effectiveness Refined (P-NICER) survey, specifically the Leading a Culture of Quality for Infection Prevention (LCQ-IP) instrument, to examine differences in infection prevention organizational

climate between hospitals in states with and without HAI reporting mandates. Bivariate and multivariate analysis revealed no statistically significant associations between key climate domains supporting infection prevention and state reporting mandates, despite finding noted associations with other hospital characteristics. The final paper uses National Healthcare Safety Network (NHSN) surveillance data, from the P-NICER survey, to conduct a quasi-experimental longitudinal analysis examining the impacts of reporting mandates on *Clostridium difficile* (*C. difficile*) infections in U.S. hospitals. Poisson regression models yielded no statistically significant differences in incidence rate ratios for *C. difficile* at varying time intervals before and after implementation of reporting mandates. Sensitivity analysis showed similar findings, with no differences in rates of infections over time between hospitals in reporting and non-reporting states. This dissertation provides a well-circumscribed analysis of varying organizational factors and patient outcomes thought to be impacted by mandatory HAI reporting. Findings are used to propose new directions for nursing research and public policy.

# TABLE OF CONTENTS

<b>DEDICATION.....</b>	<b>II</b>
<b>ACKNOWLEDGMENTS .....</b>	<b>III</b>
<b>ABSTRACT.....</b>	<b>VI</b>
<b>TABLE OF CONTENTS.....</b>	<b>VIII</b>
<b>LIST OF ILLUSTRATIONS.....</b>	<b>XII</b>
<b>LIST OF TABLES.....</b>	<b>XIII</b>
<b>CHAPTER ONE: INTRODUCTION.....</b>	<b>1</b>
1.1 Introduction .....	2
1.2 HAIs as Policy Priorities in the United States .....	6
1.3 Public Reporting of Healthcare Performance Data .....	9
1.4 Public Reporting of HAI-related Performance Data .....	10
1.5 Conceptual Framework for the Public Reporting of Healthcare Outcomes .....	13
Figure 1.1 Conceptual Framework Linking Quality Measurement and Improvement .....	14
1.6 The Effectiveness of Public Reporting on Improving Performance and Patient Outcomes.....	16
1.7 Pathogenesis and Clinical Outcomes of MRSA Bloodstream and C.difficile Infections .....	20
1.8 The Epidemiology of MRSA and C. difficile within the Healthcare Setting .....	22
1.9 Public Reporting, Organizational Climate, and Outcomes.....	26
Figure 1.2 The Integrative Model of Organizational Climate .....	28
1.10 Significance of this Research.....	29
1.11 Specific Aims .....	31
References .....	33

<b>CHAPTER 2: THE PUBLIC REPORTING OF HEALTHCARE-ASSOCIATED INFECTIONS: A REVISED CONCEPTUAL FRAMEWORK FOR A DYNAMIC HEALTHCARE SYSTEM.....</b>	<b>44</b>
2.1 Abstract:.....	45
2.2 Introduction .....	47
2.3 Public Reporting of HAI-related Performance Data .....	48
2.4 Conceptual Framework for Quality Measurement and Improvement .....	51
Figure 2.1 Conceptual Framework Linking Quality Measurement and Improvement: Change and Selection .....	52
2.5 Methodology.....	55
Table 2.1 Inclusion and Exclusion Criteria for Integrative Review of the HAI and Public Reporting Literature .....	57
Table 2.2 Search terms and initial yield for Integrative Review of the HAI and Public Reporting Literature (2006-2016).....	59
2.6 Results.....	60
Figure 2.2 Literature Search Framework and Inclusion of Studies for Review.....	61
2.7 Discussion .....	73
Figure 2. 3 Revised Framework for Assessing the Impact of HAI Reporting Policy .....	74
2.8 Conclusion.....	81
References .....	83
<b>CHAPTER 3: THE IMPACT OF STATE-BASED MANDATORY REPORTING ON LABORATORY IDENTIFIED CLOSTRIDIUM DIFFICILE AND METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS IN ACUTE CARE HOSPITALS ACROSS THE U.S.....</b>	<b>92</b>
Abstract .....	93
3.1 Introduction .....	95
3.2 Healthcare-associated MRSA and C. difficile Infections .....	96
3.3 Public reporting of MRSA and C. difficile in Healthcare Settings .....	98
3.4 Methods.....	102

3.5 Results.....	110
Figure 3. 1 Frequency of MRSA HO-BSI LabIDs in the data set from 2008-2012. ....	111
Figure 3.2 State Public Reporting Mandates and Implementation Dates.....	112
Table 3.1 NHSN Survey Reported Facility Characteristics by C. difficile Reporting Status, 2008-2012 ...	113
Table 3.1 NHSN Survey Reported Facility Characteristics by C. difficile Reporting Status, 2008-2012 (continued) .....	114
Figure 3.3 Mean HO-C. difficile LabID rates by Month .....	115
Figure 3. 4 Mean Community-Onset Prevalence Rate for C. difficile Infection .....	116
Table 3.2 Results of Zero-Inflated Poisson Regression: Effects of HAI Mandates in Reporting States ...	118
Table 3.2 Results of Zero-Inflated Poisson Regression: Effects of HAI Mandates in Reporting States (Continued) .....	119
3.6 Discussion .....	119
3.7 Limitations .....	124
3.8 Conclusion.....	125
References .....	126

**CHAPTER 4: EXAMINING THE RELATIONSHIP BETWEEN THE MANDATORY REPORTING OF HEALTHCARE-ASSOCIATED INFECTIONS AND ORGANIZATIONAL CLIMATE IN U.S. HOSPITALS: IMPLICATIONS FOR POLICY AND ORGANIZATIONS..... 134**

Abstract .....	135
4.1 Introduction .....	137
4.2 Background .....	138
Figure 4.1 The Integrative Model of Organizational Climate .....	144
4.3 Methodology.....	146
4.4 Sample .....	146
4.5 Independent and Control Variables .....	147
4.6 Dependent Variables .....	148
4.7 Statistical Analysis .....	149

4.8 Results.....	150
Figure 4.2. List of LCQ-IP Organizational Climate Composite Scores and Individual Variables .....	151
4.8 Results.....	152
Table 4.1. States with Public Reporting Mandates Enacted before or in 2011 .....	152
4.9 Organizational Climate Findings .....	153
Table 4.2. Demographics and Characteristics of Respondent Hospitals .....	154
Table 4.3. Mean LCQ-IP Composite Scores .....	155
4.10 Discussion.....	156
Table 4.4. Multiple Regression Coefficients for LCQ-IP Composite Scores (Full Model) .....	157
Table 4.5. Stepwise Multiple Regression Coefficients for LCQ-IP Composite Scores (Final Model) .....	158
4.11 Study Limitations.....	162
4.12 Policy Considerations and Future Research .....	164
4.13 Conclusion.....	166
References .....	167
<b>CHAPTER 5: SUMMARY OF FINDINGS AND DISCUSSION.....</b>	<b>175</b>
5.1 Introduction .....	176
5.2 Key Findings .....	179
5.3 Discussion .....	186
5.4 New Directions for Nursing Research and Policy .....	190
5.5 Conclusion.....	194
References .....	195
<b>APPENDICES .....</b>	<b>202</b>
Appendix A. Integrative Review Matrix/Table of Evidence .....	203
Appendix B. List of State Abbreviations .....	221

## LIST OF ILLUSTRATIONS

Figure 1.1 Conceptual Framework Linking Quality Measurement and Improvement

Figure 1.2 The Integrative Model of Organizational Climate

Figure 2.1 Literature Search Framework and Inclusion of Studies for Review

Figure 2.3 Revised Framework for Assessing the Impact of HAI Reporting Policy

Figure 3.1 Frequency of MRSA HO-BSI LabIDs in the data set from 2008-2012

Figure 3. 2. State Public Reporting Mandates and Implementation Dates

Figure 3.3 Mean HO-*C. difficile* LabID rates by Month

Figure 3.4 Mean Community-Onset Prevalence Rate for *C. difficile* Infection

Figure 4.2. List of LCQ-IP Organizational Climate Composite Scores and Individual Variables

## **LIST OF TABLES**

Table 2.1 Inclusion and Exclusion Criteria for Integrative Review of the HAI and Public Reporting Literature

Table 2.2 Search terms and initial yield for Integrative Review of the HAI and Public Reporting Literature (2006-2016)

Table 3.2 Results of Zero-Inflated Poisson Regression: Effects of HAI Mandates in Reporting States

Table 4.1. States with Public Reporting Mandates Enacted before or in 2011

Table 4.2. Demographics and Characteristics of Respondent Hospitals

Table 4.3. Mean LCQ-IP Composite Scores

Table 4.4. Multiple Regression Coefficients for LCQ-IP Composite Scores (Full Model)

Table 4.5. Stepwise Multiple Regression Coefficients for LCQ-IP Composite Scores (Final Model)

# **CHAPTER ONE: INTRODUCTION**

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## ***1.1 Introduction***

Healthcare-associated infections (HAIs) are a significant source of morbidity and mortality within the United States (U.S.) healthcare system. The Centers for Disease Control and Prevention (CDC) defines HAIs as those infections which are acquired during the course of treatment and care at a healthcare facility, oftentimes causing some adverse reaction or outcome for the patient.<sup>1</sup> Although certain infections contracted or incubating outside of the healthcare setting can be transmitted through hospitals and other institutions, these are not considered HAIs and excluded from surveillance definitions.<sup>1</sup> HAIs can range in severity, from relatively mild cases of upper respiratory infections to life-threatening bloodstream infections, but all place a significant burden on patients, caregivers, and the larger health system. Data from 2011 suggest approximately 722,000 HAIs occurred in U.S. hospitals that year alone, resulting in 75,000 deaths<sup>2</sup>. Estimated direct costs to the health system range from \$28.4 to \$33 billion dollars.<sup>3</sup> Most recent surveillance data available from the CDC showed a national reduction in overall rates of HAIs since baseline data was collected in 2008, likely reflecting national efforts to implement evidence-based prevention efforts across healthcare settings.<sup>4</sup> While this trend is encouraging for all concerned with patient safety, closer examination of state-level HAI data yield a slower decline and less consistent trends within specific states.<sup>4</sup>

HAIs can have multiple microbial etiologies and range from localized to more systemic or disseminated infections. While all HAIs are of clinical importance to patients and caregivers within the health system, certain infections have long been targeted for reduction based both on their detrimental impact and their preventability when using

evidence-based interventions. Infections of particular interest encompass: those that are related to surgical or other medical/procedural interventions; those that are caused by multidrug-resistant organisms (MDROs); and, infections that, at their initial emergence, were epidemiologically linked to healthcare settings. Specifically, these infections include surgical site infections (SSIs), central line-associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), ventilator-associated pneumonias (VAPs), blood stream infections (BSIs) caused by Methicillin-resistant *Staphylococcus aureus* (MRSA), and gastrointestinal infections caused by *Clostridium difficile* (*C. difficile*).<sup>1,5</sup> In a 2014 point-prevalence study by Magill and colleagues<sup>5</sup>, these infections were noted as collectively responsible for over 50% of HAI infections in 2011, with the remaining half consisting of infections considered to be more varied in etiology, pathogenicity and cost.

The financial impact of HAIs on healthcare settings is significant. A recent study by Zimlichman et. al<sup>6</sup> found per-case costs for infections are highest in CLABSIs at approximately \$46,000 per patient; costs associated with CLABSIs in which MRSA was causative pathogen rose even higher. The same study found SSI costs contributing the most to overall HAI annual costs, responsible for nearly \$3.3 billion dollars annually.<sup>6</sup> Although other etiologies and types of HAIs permeate the healthcare environment, these infections have specific surveillance definitions, continue to be costly to patients and health systems and have been deemed preventable through evidence-based intervention.<sup>1,6</sup> A 2011 systematic review found nearly 65-70% of CLABSIs and CAUTIs were highly preventable within the healthcare setting.<sup>7</sup>

In addition to the costly outcomes from device-associated infections and surgical site infections, invasive MRSA and *C. difficile* HAIs have garnered increased attention and targeted prevention strategies over the past few years. These infections are prevalent in healthcare setting, can be difficult to treat, cause significant complications in compromised individuals, and can be transmitted back and forth between the community and healthcare environments. The burdens of these two infections in hospitalized patients can be immense with regard to complexity of treatment and prolonging the course of hospitalization, particularly in critically ill individuals and those with multiple co-morbid conditions. Despite the availability of evidence-based guidance for prevention of these infections, transmission and healthcare-associated cases continue to persist in healthcare settings.<sup>5,8-11</sup>

The past two decades have yielded growing concern over preventable HAIs among the public and policymakers. HAIs have played an increasing role in U.S. federal patient safety policy and have been a national target for improvement since 2013, with a goal of total elimination by 2020.<sup>12</sup> Federal and state-level lawmakers have used these infections as a means of monitoring performance and, in some cases, promoting improved performance among healthcare institutions.<sup>13</sup>

One policy intervention that has been widely used to promote improvements in the reduction of HAIs has been public reporting of hospital and statewide HAI-related data. Beginning in the mid-2000s, state-level policy began to mandate the public release of HAI data in a variety of formats and for varying infections. Originally CLABSIs were the most prominent infections to fall under reporting mandates, but data from additional

device-associated infections soon followed.<sup>14</sup> More recent mandates have expanded to include the public reporting of MRSA and *C. difficile* data in addition to device-associated HAIs. These data are also used for newer federal initiatives that promote improvements through incentives for healthcare systems if they are able to reduce their incident infections on an annual basis.<sup>12,13,15</sup> Healthcare-associated MRSA and *C. difficile* infections were recently added to these incentive programs as measures of patient safety and system improvement, reflecting state-level public reporting initiatives and the need to reduce morbidity and mortality resulting from these infections. However, little is known about the efficacy of these incentive programs and whether the public reporting of MRSA and *C-difficile* HAI data decreases infection rates and improves patient outcomes.

Studies evaluating the impact of publicly reporting HAI data have shown mostly mixed findings, consistent with broader research on the effects of releasing non-HAI healthcare data.<sup>16-21</sup> Both qualitative and quantitative methodologies have been used to analyze the effects of public reporting mandates and the mechanisms by which these laws may stimulate improvements. Yet while previous work has shown effects of the laws on healthcare organizations and infection rates, these effects have not been uniform across healthcare settings or outcomes. This suggests the need for further research on the impacts of these laws and the mechanisms by which these laws promote improvement or change in organizations.

The purpose of this dissertation is to explore the impact of HAI public reporting laws on patient outcomes and organizations. This work will examine these impacts from multiple perspectives. A revised conceptual framework detailing how the laws affect

patient outcomes, consumers and organizations will be presented using evidence from current HAI public reporting literature. This revision will build on previously proposed frameworks and examine their relevance to the current literature. This revised framework will provide new guidance for inquiry supported by what is currently known and where there is paucity in the available evidence. Public reporting mandates and their effects on patient outcomes, specifically MRSA blood stream infections (BSIs) and *C. difficile* infections, will be examined in the first of two studies. No previous U.S. studies have looked at these infections in relation to these laws, despite their prevalence in healthcare institutions and their prominence in public reporting mandates. While this study focuses on patient outcomes, the third study will center on the impact of these laws on organizations. The relationship of public reporting laws to infection prevention specific organizational climate measures will be examined by exploring responses to survey data designed to measure organizational climate specific to infection prevention. These responses will be examined in hospitals in states with and without public reporting to determine what, if any effects these laws may have on organizational climate. Findings from these inquiries will guide future research and provide new directions for policy evaluation and formative analysis.

## ***1.2 HAIs as Policy Priorities in the United States***

In 1999, the Institute of Medicine (IOM) released what would become a sentinel work examining the issue of patient safety and preventable errors in the modern healthcare system. *To Err is Human: Building a Safer Health System* quickly became a major impetus of advocacy and policy intervention to address the national growing

concern about patient safety issues within healthcare institutions. The report detailed the complex issues of errors committed within the healthcare system that often resulted in grave outcomes for patients, and avoidable financial burdens on systems<sup>22</sup>. Types of errors discussed in this report ranged from preventable medication errors to errors associated with the provision of medical care, including HAIs. While IOM didn't detail strategies for preventing HAIs specifically, they did propose several broader policy level recommendations to tackle the problem of HAIs and other preventable conditions within health systems. Part of those policy recommendations included a stronger research infrastructure to understand why these issues exist. Additionally a system of mandatory public reporting of these events inclusive of HAIs was proposed to foster accountability and provide incentives for strengthening quality of care.<sup>22</sup>

Shortly after the release of this report, issues of patient safety and HAIs gained more substantial standing in the policy priority environment. Data from the early 2000s suggested a trend toward rising HAIs and a need for improved accountability and transparency<sup>23</sup>. These needs were coupled with a new push for consumer empowerment and an ongoing national push toward improvement programs tied to financial incentives.<sup>24</sup> Public reporting of these infections began in some states as early as 2002 with a strong uptake among state legislative bodies and administrative agencies toward the end of the decade.<sup>14,25</sup> Yet this increase outpaced the available evidence that these mandates improved care; a fact that did not go unnoticed by industry and infectious disease experts.<sup>24</sup> Despite apprehensions from experts and health systems, the policies moved forward.

The U.S. Department of Health and Human Services (HHS) HAI Action Plan was launched in 2009 to highlight and combat the growing issue of HAIs across the country. This initiative originally focused on HAIs in the acute care setting but has since expanded to include community and outpatient settings and long-term care facilities. Components of this initiative span research, outreach, incentivizing health systems, and technology.<sup>12</sup> All aspects are focused on collaborative efforts between the federal government, payors, and health systems to reduce the incidence of HAIs in the U.S. while identifying best practices and evidence-based innovation. Federal involvement in HAI reduction and mandated reporting increased with the passage of the Patient Protection and Affordable Care Act (ACA).<sup>15</sup> This legislation centered on reporting hospital-acquired conditions (HACs) and mandating a subsequent reduction in payment to lower performing hospitals in hopes of motivating them to improve care by leveraging these financial penalties.<sup>15</sup> The total HAC score used to determine penalty payments involved several patient safety and quality measures; by fiscal year 2017 (FY17), five measures included incident HAIs.<sup>15</sup> Evidence from Lee et. al<sup>26</sup>, shows that HACs were ineffective in stimulating a reduction in HAIs. Utilizing a different approach, a policy intervention called Value Based Purchasing (VBP), also stipulated in the ACA, emphasized payment rather than non-payment for improved quality of care. VBP purchasing focuses on incentivizing hospitals by evaluating performance and providing additional payments based on baseline measures and ongoing improvements.<sup>13</sup> Early on in VBP implementation measures for incentive payments included some infection-related performance measures, but did not include *C. difficile* or MRSA. In FY17, incident hospital-onset *C. difficile* and MRSA infections were added to the list of critical performance measures central to the VBP

program. Even as other measures are slated for removal, all HAI-related measures appear to remain, signifying their importance as a policy priority.<sup>13</sup>

As public reporting and associated policies continue to expand and become ingrained in the larger healthcare system, HAIs remain a key component. However, as specific policies concerning public reporting of these infections continue to evolve, they remain diverse in their structure and implementation.

### ***1.3 Public Reporting of Healthcare Performance Data***

Public reporting of healthcare and health system performance measures has been a part of federal policy and guidelines since the mid-1980s.<sup>27</sup> While data collection and dissemination varies by disease process, outcome, and reporting body, certain tenets of public reporting policy remain constant. In a 2012 evidence report for the Agency for Healthcare Research and Quality (AHRQ), Totten and colleagues<sup>27</sup> describe public reporting as “data, publicly available or available to a broad audience free of charge or at a nominal cost, about a health care structure, process, or outcome at any provider level (individual clinician, group, or organizations [e.g., hospitals, nursing facilities]) or at the health plan level” (p.3). The same report speculates that the ability of public reporting to guide behavior lies in its capacity to influence the actions of both providers and consumers within the same healthcare system. At best, evidence that public reporting is effective in this capacity appears to be mixed in the current literature..<sup>20,27-29</sup> As Romano and colleagues<sup>30</sup> note, stimulating change from public reporting of quality measures is a complex endeavor that relies on the ability of an organization to assimilate and use data to improve their own processes and the ability of society and consumers to

use reported data for effective decision-making.<sup>30</sup> Yet, despite the rise in publicly reporting healthcare performance measures over the past three decades, empirical findings from examination of its impact on organizational processes, clinical outcomes and effectiveness in different types of health systems remains mixed. Public reporting of HAI data, newer still to the policy landscape, was largely crafted without this empirical evidence and has faced challenges in implementation.<sup>24</sup> Current research evaluating HAI reporting laws is subject to these same challenges since states may vary in their policy implementation and behaviors within health systems in ways that are not completely understood.

#### ***1.4 Public Reporting of HAI-related Performance Data***

Public reporting of HAIs, like those measures previously discussed, has gained momentum over the past decade. While hospitals have tracked HAI related data for many years, mandated reporting of data through state-level legislative initiatives has only recently gained policy traction.<sup>25</sup> This primarily involves requiring hospitals to report their data to state government bodies. While public reporting of HAI data can be mandated or voluntary, most states in the U.S. (37 states as of 2013) now have some type of HAI-related public reporting legislation, with a significant amount of that data now available at the federal level as well.<sup>14</sup>

HAI data collection in the U.S. is facilitated by the National Healthcare Safety Network (NHSN), a national HAI surveillance system managed by the CDC. NHSN receives reported HAIs from healthcare institutions around the country who follow specific surveillance criteria for the identification and reporting of certain HAIs.

Aggregate data from this system is available to the public through federal channels (i.e., Hospital Compare Website), and allows for uniform definitions for infection surveillance as well as some risk-adjusted comparison.<sup>1,31</sup> NHSN often uses the standardized infection ratio (SIR) as a measure of performance and progress around HAI prevention.<sup>4,32,33</sup> Centers for Medicare and Medicaid Services (CMS) uses the same HAI-related data published on their Hospital Compare Website in a variety of payment reduction plans including the HAC Reduction Program and incentive programs including VBP.<sup>13,15</sup>

Since its inception, the public reporting of HAI data has been met with controversy related to the perceived increased burden on healthcare systems, inconsistencies in data used for reporting, and the paucity of evidence concerning the effectiveness of publicly reporting data with regard to HAIs.<sup>24,34,35</sup> Since that time, some of these issues, primarily data inconsistencies, have been addressed with the use of the NHSN surveillance and reporting system. However, questions persist around the accuracy and validity of publicly reported HAI data.<sup>35,36</sup>

In preparation for compliance with state-mandated public reporting of HAI data, the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) published a systematic review of evidence evaluating public reporting in the literature in 2006.<sup>24</sup> The review included recommendations for evaluation of public reporting of HAIs, yet no studies to date had evaluated outcomes related to these mandates.<sup>24</sup> HICPAC recommended both process improvements and clinical outcomes be included as measures for evaluating the efficacy of publicly reporting HAI data.<sup>37</sup> Recommendations

for clinical outcome measures centered on infections that cause significant morbidity and mortality and are known to be preventable when employing evidence based prevention efforts. Specific considerations were given to the importance of selecting patient populations considered at-risk for these infections as well a means of validating reported data. These recommendations were emphasized and clarified in updated guidance from HICPAC in 2013.<sup>38</sup> Due to the increasing utility of publicly reported HAI surveillance data, HICPAC released new guidance to ensure that valid surveillance data is used properly. Along with HICPAC's praise for policymakers' shift toward using surveillance data for public reporting (vs. administrative data or some combination of both), the guidance recommended strict adherence to NHSN surveillance definition with supported documentation, methods for data validation, and support from hospital administration emphasizing the authority of the hospital epidemiology or infection prevention staff.<sup>38</sup>

A 2014 study by Reagan and colleagues<sup>14</sup>, showed that mandatory public reporting of *C. difficile* and MRSA varied across states. While one state, Missouri, began mandatory public reporting of MRSA infections in 2005, most states began reporting of *C. difficile* and MRSA after 2008. Many did not implement mandatory reporting of these infections until 2013.<sup>14</sup> By 2013, 20 states had passed laws mandating the reporting of MRSA HAI data, with nearly half of these states passing laws in 2012 or later. This paper also detailed 19 states that had mandatory reporting of *C. difficile* HAIs.<sup>14</sup> An additional study by Reagan and colleagues<sup>39</sup> in 2015 examined specific public reporting laws pertaining to *C. difficile*. While the study showed a gradual increase in mandated reporting of these infections since 2008, yet less than half of U.S. states were noted to

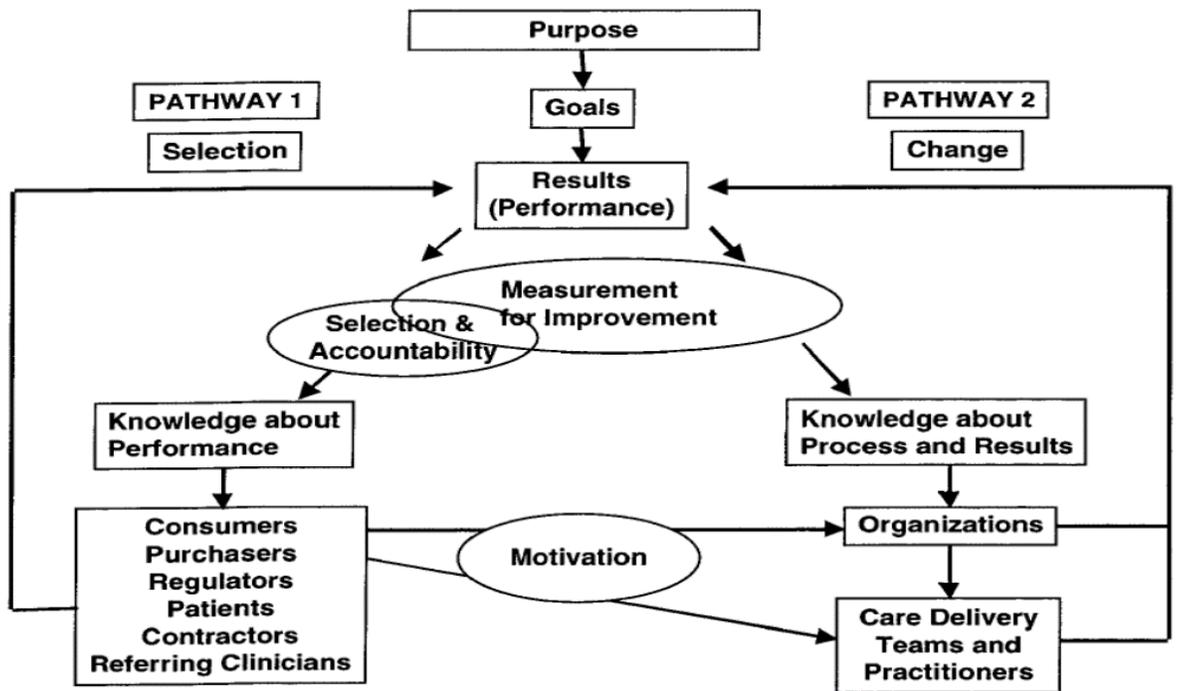
have *C. difficile* reporting laws. Reporting requirements were both by state statute and administrative ruling, such as the incorporation of healthcare quality reporting into state law.<sup>39</sup> Public reporting of these infections and others has gained momentum in states across the U.S. The value of these laws in their impact of health systems and patient outcomes continues to be studied in the literature. Yet, to the knowledge of this author, few studies have evaluated the effect of MRSA and *C. difficile* public reporting mandates on infection rates in acute care settings. Evaluation of these laws' effects on preventable infections such as *C. difficile* and MRSA are key to understanding the impact of these public policies on patient safety.

### ***1.5 Conceptual Framework for the Public Reporting of Healthcare Outcomes***

Evaluating the impact public reporting has on healthcare organizations and outcomes, relies first on understanding how these policies may impact these health systems and their consumers. In 2003, Berwick and colleagues<sup>40</sup> proposed the most widely used framework for understanding the effects of public reporting on the healthcare system. The authors illustrate two distinct pathways by which the measurement of quality in healthcare can stimulate improvement (Figure 1). Pathway One, the improvement through Selection pathway, describes the mechanism by which consumer choice drives the need for change and improvement. If publicly reported data alters the way consumers select their healthcare providers, this may stimulate improvement within that organization to prevent loss of market share.<sup>40</sup> Pathway Two, improvement through Change in care, describes systems' propensities toward internal drivers of change to improve outcomes, regardless of consumer choices and market.<sup>40</sup> Intrinsic motivations

stimulate change in health systems when performance data is reported internally or externally. However, Berwick et. al, contend that often these motivations are not enough to overcome the status quo performance-level in a health system.<sup>40</sup> In these instances, the Selection pathway may act on the Change pathway to drive the motivation of organizations and individuals through the change process. While this may contribute to changes in health systems, any measured improvements may be vulnerable to the variability in reporting policies and the ability of stakeholders to interpret data for decision-making .<sup>40</sup>

**Figure 1.1 Conceptual Framework Linking Quality Measurement and Improvement**



*Figure 1. Conceptual Framework Linking Quality Measurement and Improvement: Pathways proposed by Berwick and colleagues<sup>40</sup> linking performance measurement and improvement. These pathways have been used in subsequent literature to describe the pathways by which public reporting of healthcare performance data could stimulate improvement and promote better patient outcomes.*

Building off those pathways described by Berwick and colleagues<sup>40</sup>, Hibbard et al<sup>41</sup> discerns a third pathway which centralizes the role of a health system's reputation as pertinent to stimulating change from performance data. The authors gave health systems data regarding their own performance and assigned each health system to either public, private (in-house), or no reporting groups. Hibbard and colleagues<sup>41</sup> determined that low-scoring hospitals also had more negative associations with public reporting, and found that reported data would detract more from their reputation than their market share. Findings also showed more quality improvement processes in the hospitals that publicly report than in the other two groups.<sup>41</sup> The authors contented that since public reporting hospitals showed increases in quality improvement efforts in response to their performance data, intrinsic motivation and the previously described change pathway may be relatively weak.<sup>29</sup> Thus they proposed the Reputation pathway be added to the framework proposed by Berwick and colleagues<sup>29</sup> yielding to concerns about public reputation.

Although these frameworks hypothesize that publicly reporting hospital performance data stimulates improvements in care and better outcomes, findings in the scientific literature have left some of these pathways untested. Furthermore, these conceptual frameworks have not been examined considering more recent literature that explores the public reporting of performance data. Studies evaluating how HAI public reporting laws impact health system stakeholders and patient outcomes have been published since these conceptual frameworks have been proposed. Yet many of these studies do not specifically test these pathways. A revised conceptual framework, based

on a synthesis of the current HAI public reporting literature is needed to examine and update these complex pathways, and provide new directions for empirical testing. This is particularly true for HAIs, given their priority throughout state and federal policy initiatives. The first paper in this dissertation will propose this revised conceptual framework to describe the pathways by which publicly reporting HAI may impact consumers, health systems, and outcomes. This framework will draw on the current HAI public reporting literature to guide the development of revised pathways and delineate opportunities for empirical testing.

### ***1.6 The Effectiveness of Public Reporting on Improving Performance and Patient Outcomes***

Empirical findings on the effectiveness of public reporting to impact patient outcomes, health system improvement, or consumer decision-making, remain mixed. Two large reviews showed mixed results when evaluating impact of public reporting on healthcare outcomes. In 2000, Marshall and colleagues<sup>28</sup> reviewed 21 studies, three of which examined direct clinical outcomes, all cardiovascular mortality measures. Findings in each of the three reviewed studies confirmed reductions in mortality after public reporting. The authors believed that advocates for public reporting may see this as a small but valid justification in its use to drive improvements, despite possible alternative explanations that may have contributed to these findings.<sup>28</sup> Also, the authors note that little evidence supports consumer use of publicly reported data in decision-making, and the exact mechanism of system or organizational behavior change and improvement remains unknown. A systematic review published in 2008 found more

conflicting evidence around public reporting's effects on clinical outcomes than that which was presented in Marshall and colleagues' work.<sup>20,28</sup> Eleven studies examining hospital outcome data showed that while initial findings suggested improvements related to publicly reported data, additional studies showed similar declines in mortality data in states or systems without public reporting, particularly when mortality rates were adjusted for risk.<sup>20</sup> This review found some effect of public reporting on the stimulation of quality improvement in hospital settings with more inconsistent effects on the selection of hospitals or providers.<sup>20</sup> Both reviews show similar findings that suggest public reporting does stimulate process improvement yet may have a somewhat less appreciable effect on clinical outcomes.<sup>20,28</sup> While these reviews found some associations between the reporting of outcomes and effects on systems processes, mechanisms by which public reporting serves as a driver for change remains poorly understood.

A closer examination of public reporting literature regarding HAIs reveals similar mixed results. An initial systematic review published in 2006 found very little evidence supporting organizational or patient impact as a result of the public reporting of HAI performance data.<sup>24</sup> Since then, some studies have attempted to examine clinical outcomes and organizational change related to publicly reported HAI data. In 2014, Black and Kim<sup>42</sup> examined the changes in CLABSI rates in Pennsylvania before and after the implementation of public reporting laws. They found that rates of CLABSI fell in both administrative and reported data sets (19% and 40% respectively). Yet the authors noted there may have been evidence of gaming as a result of reporting that may have clouded the validity of the findings.<sup>42</sup> A retrospective cohort study evaluating public

reporting requirements and CLABSI SIRs showed no difference among facility level SIRs across states with varying strata and reporting requirements.<sup>16</sup> Like research from Black and Kim (2014), Marsteller and colleagues (2014) evaluated the effect of public reporting on CLABSI rates and participation in a performance improvement program. Results showed greater reduction in CLABSI rates after mandatory reporting within the first year of reporting and higher rates of participation in the CUSP: Stop BSI program, a national collaborative aimed at reducing CLABSIs among participating institutions.<sup>43</sup> CLABSI SIRs and prevention practices in neonatal intensive care units (NICUs) were evaluated in a 2014 study by Zachariah and colleagues. While this study showed greater than 95% compliance with prevention activities in mandatory reporting states compared to control states ( $p=.0002$ ), no statistically significant relationship was found in CLABSI SIRs between the two groups.<sup>17</sup> Rinke et. al (2015), evaluated effects of mandated reporting on CLABSI rates in critically ill pediatric patients using administrative data and found that regardless of reporting status all states experienced a decrease in CLABSI rates during the study period regardless of reporting mandates.<sup>44</sup> A recent study by Liu and colleagues (2016) used longitudinal data to evaluate the impact of HAI reporting laws on CLABSI rates and found ongoing reduction in CLABSI rates due to implementation of the laws after controlling for secular trends in infection data and facility characteristics. Additionally, the authors note decreasing trends in CLABSI rates, particularly in the 6 months leading up to the implementation of the laws when compared to the 25 months or more prior (incidence rate ratio [IRR] = 0.66 [ $p<.001$ ]).<sup>19</sup> The authors contend that this finding indicates that public reporting mandates stimulate changes in potential improvement processes even prior to their implementation<sup>19</sup>.

The only study to examine the relationship between public reporting of infection data and *C. difficile* infection was done in Canada by Daneman and colleagues and published in 2012. Their study compared observed rates to predicted rates used to simulate *C. difficile* rates in the absence of public reporting. Findings showed a rate of 8.92 cases per 10,000 patient days in Ontario in the calendar year after public reporting, which was lower than the predicted rate of 12.16 (p<.001, 95% CI 11.35 – 13.04) cases per 10,000 patient days<sup>45</sup>. Overall 26.7% (95% CI 21.4% - 31.6%) reduction in *C. difficile* cases was associated with public reporting<sup>45</sup>.

As of 2014, 23 states have implemented MRSA public reporting mandates, and 22 have implemented *C. difficile* mandates.<sup>4</sup> While findings from Canada support the positive impact public reporting may have on *C. difficile* infections, no studies evaluating reporting policy have been conducted to determine if similar effects are seen domestically regarding *C. difficile* rates. Additionally, MRSA-related outcomes remain unexamined in the context of state-level public reporting laws. As previously discussed these infections are increasingly important in federal HAI-related policy and hospital quality initiatives. Yet, no studies have evaluated these effects longitudinally on MRSA and *C. difficile* infections in U.S. hospitals. The second paper in this dissertation will use longitudinal data to evaluate the impact of state public reporting laws specifically on MRSA bloodstream infections (BSIs) and *C. difficile* infections. Given their associated morbidity and mortality, and financial impact, additional study is needed to evaluate the role of reporting mandates in improving patient outcomes related to these diseases.

## ***1.7 Pathogenesis and Clinical Outcomes of MRSA Bloodstream and C.difficile Infections***

*C. difficile* and MRSA BSIs are a preventable source of morbidity and mortality in hospitalized patients. This has led to ongoing concern among patients, policy-makers, clinicians and healthcare administrators. Policy mandates that require hospitals to report these infections aim at preventing their associated complications and improving outcomes.

MRSA is the most common cause of skin and soft tissue infections in the community setting and is well-documented as a cause of invasive infection in the hospitalized patient<sup>9,46-48</sup>. A Gram-positive, anaerobe, *Staphylococcus aureus* (*S. aureus*) is a frequent colonizer of the nares, pharynx, and skin of humans<sup>47,49</sup>. Individuals with known colonization who progress to infection with *S. aureus*, invasive or otherwise, often do so with their colonizing strain of the bacteria<sup>47</sup>. Persons with frequent exposure to the healthcare system, uncontrolled chronic disease, immune compromise, presence of invasive devices, and exposure to broad-spectrum antibiotics are most at risk for colonization and/or infection. Methicillin resistance was noted in *S. aureus* nearly immediately after the introduction of the antibiotic in the early 1960s<sup>49</sup>. *S. aureus* has multiple virulence factors which contribute to its pathogenesis and propensity for progression to invasive disease in compromised individuals<sup>11,47,50</sup>. Some virulence factors precipitate development of sepsis through toxin-mediated disease, while others assist with binding and evasion of host defenses<sup>47,49</sup>. Binding factors also contribute to the development of biofilms which can adhere to implanted devices in hospitalized patients

and may be significantly resistant to antibiotic treatments<sup>47</sup>. Studies of whether added virulence is propagated by methicillin resistance continue to yield mixed results<sup>11,47-49</sup>.

The increased prevalence of MRSA infections within the healthcare setting is mediated by inpatient use of antibiotics<sup>47</sup>. Methicillin resistance confers a decreased affinity to  $\beta$ -lactam antibiotics and broad spectrum antibiotic use can provide a selective advantage for MRSA in the hospital setting<sup>11</sup>. MRSA can be transmitted from healthcare provider to patient, or patient to patient, via normal contact associated with standard provision of care<sup>11</sup>. Infection within the healthcare setting can affect multiple systems, but invasive disease often occurs as a BSI, commonly referred to as MRSA bacteremia. The sequelae of MRSA bacteremia are significant. This manifestation of invasive disease is often associated with increased risk of death and prolonged hospitalization, particularly in older and critically ill adults<sup>50</sup>. Disseminated MRSA infection in the blood precipitates hematogenous spread of the bacteria to other organs, often resulting in organ dysfunction, sepsis and death<sup>50</sup>.

Like MRSA, *C. difficile* is an anaerobic, Gram-positive, bacteria. This spore-forming bacillus is transmissible in humans via the fecal-oral route. Spores are extremely resilient in the hospital environment and are not killed by conventional alcohol-based hand rubs; these are common products used for hand hygiene in healthcare settings<sup>51</sup>. Production of two exotoxins, toxin A (ToxA) and B (ToxB), is associated with its primary virulence factors and its resultant pathogenesis in the gastrointestinal system. These toxins' direct effects and their associated immunologic responses can cause diarrheal disease ranging from mild, self-limiting infection to severe colitis requiring

surgical intervention, systemic decompensation, and death<sup>52</sup>. Over the past decade a novel emergence of a more virulent strain of *C. difficile*, 027/BI/NAP1, has predominated in healthcare settings and been associated with more severe disease and worse clinical outcomes of *C. difficile infection* (CDI)<sup>52,53</sup>. Although some data suggests a decline in the 027 strain, additional lineages of *C. difficile* have arisen and are causing disease, including NAP07, PCR-Ribotype 078. This particular strain has been associated with the production of a binary toxin, which may amplify the effects of ToxA and ToxB and lead to enhanced pathogenicity<sup>8,51,53</sup>. The most significant risk factors for CDI are recent antibiotic exposure, older age (> 65 yrs) and contact with a healthcare setting<sup>52,54,55</sup>. While asymptomatic colonization of susceptible patients in the healthcare settings can occur, the majority of testing and eradication efforts are centered on confirming CDI in those with symptomatic disease as they are most likely to spread the infection to other patients and contaminate their surroundings. Both infections have experienced fluctuations in rates and prevalence both in the community and healthcare systems over the past two decades. Despite an encouraging trend downward in infections, their presence in healthcare settings continues to be of significant concern.

### ***1.8 The Epidemiology of MRSA and C. difficile within the Healthcare Setting***

MRSA and *C. difficile* infections in U.S. healthcare institutions continue to be of concern for both providers and policy makers, despite national decreases in their rates since 2008.<sup>4</sup> This is likely because these infections have been deemed preventable within healthcare systems and yet still cause significant morbidity and mortality in hospitalized patient.

Since its discovery in the early 1960s, rates of MRSA-associated disease rose within healthcare settings and the community through the mid-2000s.<sup>48,49</sup> As HAIs became a focal point of clinical and policy intervention, invasive healthcare-associated MRSA was targeted for enhanced prevention strategies. From 2005 to 2008 a decline in invasive healthcare associated MRSA has been noted.<sup>56,57</sup> A study from Kallen and colleagues in 2010 showed this decline was most prominent, -11.2% (95% CI -15.9 to -6.3%) in MRSA (BSIs).<sup>56</sup> An additional study using the same data set but examining rates through 2011 showed similar improvements, yielding an overall reduction in hospital onset invasive MRSA of approximately 54% during the study period.<sup>57</sup>

Similar findings are noted in a recently released HAI progress report from the CDC. This report analyzed data from 2014 and compared it to their national baseline data from 2008. SIRs are computed using risk adjusted models to compare both national and state-specific trends. In the most recent comparison data, SIRs for MRSA BSIs in reporting hospitals decreased by 13% nationally from 2011 to 2014.<sup>4</sup> Despite this national trend, state level SIRs have not uniformly seen a decrease. Closer examination of state level data yields an increase in some state-specific SIRs when comparing 2014 data to baseline SIRs calculated in 2011, suggesting that reductions are not ubiquitous across states and institutions<sup>4</sup> Additionally data from the CDC's Active Bacterial Core Surveillance program notes that the death rate from health-care associated MRSA infections remain nearly 5 times higher that of community acquired cases.<sup>58</sup> The same data show that MRSA BSIs continue to account for more than two-thirds of all invasive MRSA infections deemed healthcare-associated. These data show that despite overall

some overall reductions nationally MRSA BSIs continue to be a significant contributor to morbidity and mortality in the hospitalized patient.

Like MRSA, *C. difficile* infections are a significant concern in the hospital setting. *C. difficile* is the most common healthcare-associated gastrointestinal infection and the most common cause of antibiotic-associated diarrhea in the U.S.<sup>5,55</sup> Recent studies have indicated that *C. difficile* was responsible for more than 450,000 infections and 29,300 deaths in the U.S. in 2011, increasing excess healthcare expenditures by \$1.5 billion.<sup>6,8</sup> One modeling study by Desai and colleagues (2016) suggests that in 2014, an estimated 439,237 incident *C. difficile* infections occurred in the U.S with roughly two-thirds originating in hospital or long-term care settings. This same study yielded that roughly one-third of severe infections and deaths from *C. difficile* occurred in hospitalized patients.<sup>54</sup> Additional findings from this study confirmed that adults over 65 continue to suffer from the largest burden of *C. difficile* infections, and higher proportions on total deaths from *C. difficile* in hospitalized patients occurs in those with immune compromise and chronic kidney disease.<sup>54</sup>

Similar to data reported on incident MRSA infections, the CDC compiles reported data on hospital-onset *C. difficile*. SIRs are used to compare hospital performance to national and state baselines and year-to-year performance. As of 2014, *C. difficile* infections were down by 8% among reporting hospitals when compared to the 2011 baseline.<sup>4</sup> However, between 2013 and 2014, an increase in these infections were noted suggesting a recent upswing in infections. In fact, *C. difficile* infections were only one of two HAIs in this report to see an increase over the 2013 comparison; surgical site

infections related to colon surgeries were the other<sup>4</sup>. Some state-specific trends in SIRs also showed increases when compared to 2013 data, emphasizing that the issue of healthcare-associated *C. difficile* infection, is still a significant one.<sup>4</sup>

Decreasing rates of these infections and curbing their transmission within hospitals are a focal point of U.S. federal and state HAI-related policy. A wide range of evidence-based interventions are described in current guidelines that aim to achieve these outcomes. Yet while eliminating transmission of these infections within hospitals remains a prominent policy goal<sup>12</sup>, the implementation and response to these policies have led to inconsistencies in patient outcomes and infection rates. As previously discussed, a national decrease in MRSA and *C. difficile* infections has been observed, but within states and likely within hospitals, rates do not always echo the national trend.

One potential reason for these discrepancies is that healthcare organizations are unique entities and respond to policy initiatives in the context of their internal and external environments.<sup>40</sup> As policies become more widespread, organizations must adapt and implement these policies within their own unique environment. One framework for specific characteristics of healthcare organizations may contribute to patient outcomes is that of organizational climate. While organizational climate has been examined in healthcare literature, little is known about its relationship to public reporting policy and whether these policies act to strengthen infection prevention climate in health systems. The third paper in this dissertation will use survey data to explore how a climate infection prevention may be impacted by these policies. This pathway is important for understanding the true nature of how these public reporting laws impact organizations

and allows for new research on the relationship between policy, organizations and patient outcomes.

### ***1.9 Public Reporting, Organizational Climate, and Outcomes***

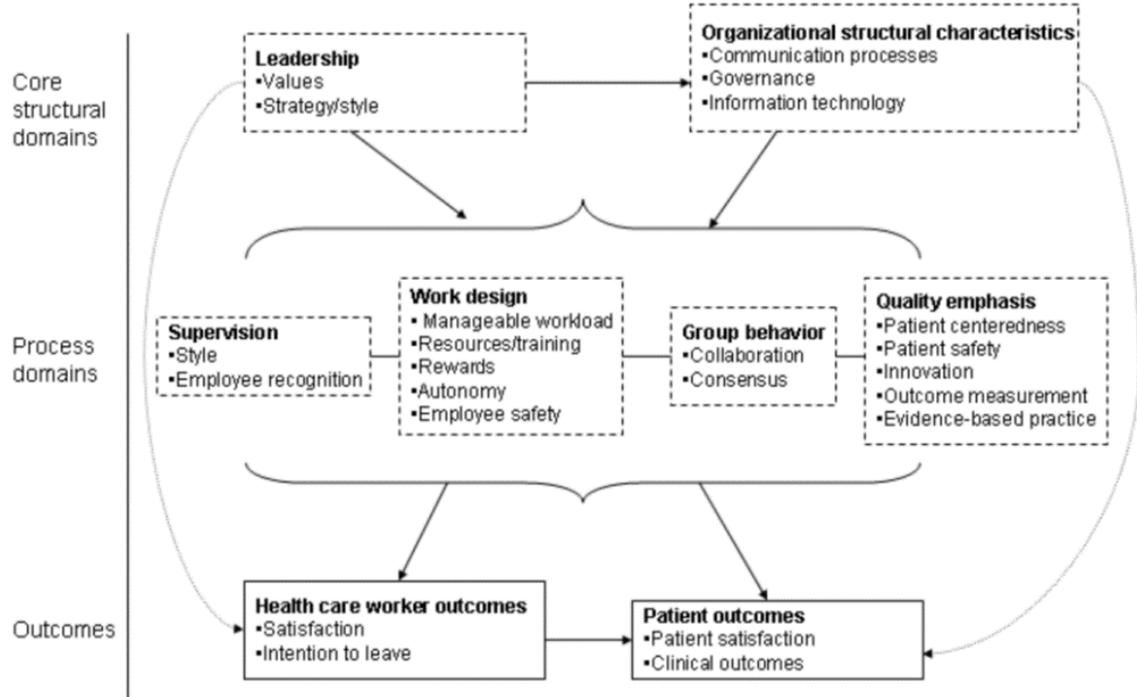
As some experts have noted, public reporting does not exist apart from larger structural components of organizations.<sup>30,40,59,60</sup> Organizations respond to publicly reported health outcomes, yet these outcomes are impacted by a considerable organizational characteristics, processes and structures. Thus, the effectiveness of public reporting to improve outcomes can potentially be mediated by these critical organizational factors. One concept related to organizational functioning which could be impacted by public reporting is the organizational climate.

Organizational climate is described in the literature as the perceptions regarding specific organizational attributes including leadership, accountability, communication and social norms, reported by persons within the organization.<sup>61,62</sup> Stone and colleagues<sup>61</sup> describe organizational climate as a set of core structural domains and process domains that impact outcomes and processes of care. They propose the Integrative Model of Organizational Climate as a means of describing the relationships between structural domains, processes and outcomes (Figure 2). In this model that is not specific to HAIs, structural domains, including leadership and organizational characteristics encompass inputs such as communication processes and values of the organization.<sup>61</sup> Process domains include quality emphasis, group dynamics, work design and supervision. These processes mediate the relationship between larger structural domains and healthcare worker-related outcomes (i.e., satisfaction) and patient outcomes

(i.e. clinical outcomes or patient satisfaction) .<sup>61</sup> The model was developed from surveys and data used in previous studies<sup>63</sup> to describe key structures and characteristics of organizations. Themes were analyzed and grouped into the domains and processes and the resultant model was tested with empirical evidence showing statistically significant associations between structural domains and healthcare worker outcomes, specifically intention to leave. While clinical outcomes were not evaluated in this study, the authors note the value of this model lies in its capacity to support further investigations concerning organizational climate in healthcare.<sup>61</sup> A later systematic review examined the relationship of organizational climate on both clinical outcomes and employee related outcomes using an adapted form of this model.<sup>62</sup> In this review, MacDavitt and colleagues<sup>62</sup> discuss conflicting findings regarding certain aspects of organizational climate and outcomes of care. The authors propose that this may be due to varying measures of climate and clinical outcomes.

Like the findings noted by MacDavitt et. al<sup>62</sup>, organizational climate literature related to HAIs has shown mixed findings. Stone et. al, (2007) studied the impact of nurse working conditions on various patient safety outcomes including CLABSI and CAUTI. Analyses showed slightly higher risk of CLABSI in units where nurses perceived a more positive organizational climate (adjusted OR 1.19; 95% CI, 1.05-1.36), but a lower risk of CAUTI (adjusted OR 0.61; 95% CI, 0.44-0.83) .<sup>64</sup> A 2013 study from Salge and colleagues examining organizational context and longitudinal MRSA rates, found climates that encouraged the reporting of errors were associated with reductions in MRSA blood stream infections over time.

**Figure 1.2 The Integrative Model of Organizational Climate**



*Published by Stone et. al in 2004, this model describes the relationship between core structural and process domains related to organizational climate. This model provides a framework for how organizational climate, can impact patient care related outcomes.*

Other factors from this study that were associated with decreased MRSA infections dealt more with infection control procedures and training than with organizational climate.<sup>65</sup> A more recent study from nurse researchers in Colorado examined organizational context and used secondary data from the Leading a Culture of Quality Instrument for Infection Prevention (LCQ-IP) from the Prevention of Nosocomial Infections and Cost-Effectiveness Refined Survey (P-NICER).<sup>66</sup> Using the Quality Health Outcomes Model, the authors conducted latent variable modeling within a structural equation modeling framework (SEM) to examine the relationships between constructs within the model, organizational climate variables, a CLABSI-related

intervention (Central Line Bundles), and outcome (CLABSI events). The final latent variable model suggested a relationship between high levels of adherence to the intervention and organizational context, but this did not extend to CLABSI outcomes.<sup>66</sup>

Broader climate-related conceptual relationships have been proposed to explain why organizations respond differently to policy initiatives and attain varying results in improving patient outcomes. Berwick et. al<sup>40</sup> contend that improving performance through the measurement and reporting of data relies heavily on an organization's ability to improve processes and promote an environment conducive to change. Core processes identified by Berwick include leadership, investment in time and change management, communication, and ongoing evaluation.<sup>40</sup> Marshall, Romano, and Davies<sup>30</sup> discuss the impact public reporting can have on organizational culture by empowering change-makers, strengthening the value of quality improvement, and improving accountability. They discuss how public reporting's impact on social norms within organizations can have long-lasting effects, but only with the understanding of the unique role internal structures and processes play in impacting behavior and outcomes.<sup>30</sup> Yet despite these proposals, few studies target the effect of public reporting on these organizational-level processes. These complexities require additional study to understand the relationship between public reporting, organizational climate and the impact on HAI-related patient outcomes.

### ***1.10 Significance of this Research***

The public reporting of HAI related data is now mandated in most states in the U.S. Yet despite widespread adoption and implementation, mixed empirical evidence

exists that supports its influence on HAI infection rates. Less still is known about which organizational characteristics may aid or hinder these laws in being effective. This research fills existing gaps by providing a comprehensive approach to examining these concepts in the context of HAI-related performance data. Paper one provides an updated framework for examining the pathways by which public reporting of HAI may impact organizations and, in turn, outcomes for patients and health systems. The associated literature review offers a thorough analysis about what is known regarding HAI public reporting using an existing public reporting framework to organize the findings.

The first study and second paper in this dissertation, examines the longitudinal relationship between public reporting and outcomes associated with *C. difficile* and MRSA blood stream infections. While similar methodologies to previous studies was used, this is the first study to use longitudinal surveillance data to evaluate the effect of these laws on a healthcare-associated MDRO and *C. difficile*, one of the most burdensome HAIs in the United States. Recent policy initiatives, including federal VBP, have included MRSA and *C. difficile* infections as prime measures for incentive programs during fiscal year 2017. Results of this retrospective study provides needed insight into the effects of these laws on infection rates within hospitals as well as lay the groundwork for policy evaluation and ongoing evaluation of these outcomes.

Organizational contexts and climate may potentially play a significant role in how HAI public reporting impacts outcomes. The second study and third paper in this dissertation examined variables related to organizational climate as reported by health systems and their relationship to public reporting. This exploratory study evaluated

associations between key domains of organizational climate and public reporting by examining comprehensive organizational climate data and specific climate-related factors associated with infection prevention and control within healthcare institutions. This study is the first to examine these relationships. The findings lay the foundation for understanding if and how these reporting mandates are associated with organizational climate and provide a baseline for additional studies including those examining outcomes.

These studies serve as an exploration into whether public reporting policies work to improve outcomes related to *C. difficile* and MRSA and begin to explore examine what factors contribute to these effects within the context of organizations. They shed light on an important policy initiative and guide new thinking about how to evaluate these laws given their continued evolution and growing complexity.

### ***1.11 Specific Aims***

This dissertation aims to illuminate the relationship between public reporting of HAI-related data and HAI outcomes, while exploring the relationship of specific organizational factors which may enhance or attenuate the impact of public reporting.

**Aim One:** To develop a revised conceptual framework that describes the relational pathways by which the public reporting of HAI data impacts health system organizational variables, subsequent impacts on HAI rates, and consumer decision-making. **Innovation:** In the existing literature, no conceptual frameworks for public reporting of HAI data have been developed for the purposes of guiding inquiry and policy evaluation. **Impact:** Development of a conceptual

framework specific to the public reporting of HAI data will help to guide evaluation of public reporting policy and new inquiry in public reporting and HAI research.

**Aim Two:** Using data from the National Healthcare Safety Network (NHSN), conduct a longitudinal secondary data analysis quasi-experimental study to determine the effect of mandatory HAI public reporting laws on Laboratory Identified MRSA blood stream infections and *C. difficile* infection (CDI) while controlling for other variables. **Hypothesis:** Implementing state-based mandatory public reporting of healthcare-associated CDI and MRSA is associated with a decrease in rates of these MDROs within hospitals from those states. **Innovation:** In the existing literature, no studies have evaluated the impact of state-mandated public reporting laws in Healthcare-associated CDI and MRSA rates in the United States using NHSN surveillance data. **Impact:** Understanding the impacts of state-based public reporting policy on healthcare-associated MDRO infection rates will help determine the efficacy of these broad policy-related interventions.

**Aim Three:** Using cross-sectional data from the P-NICER Survey, conduct an exploratory data analysis examining the relationship between the presence of HAI public reporting mandates and organizational climate in U.S. hospitals. **Innovation:** There is a gap in the present literature regarding the relationship between HAI public reporting mandates and concepts central to organizational climate. **Impact:** Examining this relationship will provide baseline data for future research to investigate the intricate relationship between reporting mandates, organizational climate and HAI related outcomes.

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**CHAPTER 2: THE PUBLIC REPORTING OF HEALTHCARE-  
ASSOCIATED INFECTIONS: A REVISED CONCEPTUAL FRAMEWORK  
FOR A DYNAMIC HEALTHCARE SYSTEM**

Dissertation

Paper One

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## **2.1 Abstract:**

**Background:** Healthcare-associated infections (HAIs) are a significant burden in the U.S. healthcare system. These infections are often considered preventable and multiple evidence-based guidelines that provide prevention strategies are widely available. However, despite the adoption and implementation of prevention practices, these infections continue to persist. Policy makers have responded to the problem with national and state-level mandatory reporting legislation or statutes that require hospitals to report their data to an oversight body, often times for public dissemination. Although there is some mixed evidence in the literature as to whether these mandates have any impact on hospitals and patient outcomes, less is known about the mechanisms by which these policies make their impact. Previous conceptual frameworks have attempted to broadly describe specific pathways (Change, Selection and Reputation) by which mandated reporting of healthcare performance data affects outcomes and organizations, but no framework exists specific to HAIs. **Purpose:** The aim of this paper is to propose a revised conceptual framework describing how mandated HAI reporting impacts outcomes and organizations, based on an integrative review of available literature that has specifically explored these relationships. **Research Design:** An integrative review was conducted to determine the existing evidence in the literature that supports or refutes previously described HAI reporting pathways from prior conceptual frameworks. **Methods:** Inclusion and exclusion criteria were developed and a search of SCOPUS, PubMed, and CINAHL data bases using targeted search terms was conducted. Abstracts were reviewed and final selections were made for inclusion in the review. Findings from qualitative, quantitative and mixed methodological studies were grouped by previously

proposed mandated reporting pathways and findings were integrated to support or challenge previously proposed pathways. New pathways were also proposed based on available evidence from the literature. **Results:** Nineteen publications were selected for inclusion in this review, spanning 18 empirical studies and 1 systematic review. Impacts of mandatory reporting largely support the Change and Selection Pathways but also suggest new relationships and variables which should be included in the revised framework. Additionally, the impact of the Reputation Pathway on consumer selection and organizations is significantly revised. **Conclusion:** This revised conceptual framework is the first to incorporate HAI-specific evidence regarding the impacts of public reporting on health systems, patient outcomes and consumers decision-making. The existing pathways supported or challenged by current evidence and the new pathways presented in this framework allow researchers to test the intricate effects public reporting policy may have on stakeholders and organizations within the healthcare system.

## **2.2 Introduction**

Healthcare-associated infections (HAIs) are a significant cause of morbidity and mortality in the United States (U.S.) healthcare system. The U.S. Centers for Disease Control and Prevention (CDC) estimates that on any given day, approximately 1 in 25 hospitalized patients in the U.S. experiences an HAI.<sup>1</sup> Each year, these infections result in roughly 75,000 deaths. Of the multitude of HAIs that can occur in a clinical setting, many of the costliest and most dangerous are those associated with medical devices, surgical procedures, multi-drug resistant organism (MDROs), and *Clostridium difficile* (*C. difficile*).<sup>1-3</sup> Central-line associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), surgical-site infections (SSIs), and ventilator-associated pneumonias (VAPs), are device and procedure associated infections that continue to be a preventable source of complications leading to higher healthcare costs, prolonged length of stay, increased complexity of care, and excess mortality in acute care settings.<sup>3,4</sup>

In response to the growing concern surrounding patient safety and preventable adverse patient outcomes including HAIs, policymakers have implemented multiple strategies to push healthcare institutions towards improving quality of care.<sup>5-7</sup> One of the most-widely propagated interventions is the mandated reporting of healthcare facility performance data.<sup>6,8-10</sup> These mandates typically have three components: the reporting of HAI-related performance data to an oversight body (often state health departments), the public release of that performance data, and the linkage of these performance data to facility identifiers, allowing the public to see which data belongs to which facilities.<sup>11</sup>

The linkage of facility identifier for release of information to the public is often a key component of these state mandates and driver of change in health systems.<sup>12,13</sup> Public reporting has gained ground in the past two decades as a potential means of holding health systems accountable for outcomes, improving quality of care, and empowering consumers and payors to make informed decisions about where to obtain services.<sup>6,8,10</sup> Most states as of 2013 do include a public reporting component to their HAI reporting mandates.<sup>14</sup> Evaluation of patient outcomes resulting from these policies has shown mixed results; nevertheless, they continue to be implemented throughout the U.S. and serve as a benchmark for federal incentive programs aimed at improving quality.<sup>5,7,8,15</sup>

The aim of this paper is to develop a revised conceptual framework that characterizes the impact of HAI public reporting on healthcare systems, patient outcomes, and consumers based on existing evidence in the available HAI public reporting literature. An integrative review of existing literature was used to examine these impacts and identify potential gaps in knowledge regarding specific pathways included in this revised framework. This framework will serve as a foundation for further inquiries regarding the public reporting of HAIs and identify new directions for HAI public reporting research

### ***2.3 Public Reporting of HAI-related Performance Data***

HAIs have been a focus of public reporting for over a decade.<sup>14</sup> McKibben and colleagues (2006) describe public reporting relevant to HAIs as “information provided to the public about the quality of health services” (p.143). Since 2003, policies to mandate the public reporting of HAIs have been implemented in a majority of states.<sup>14,15</sup> Over a

decade later, public reporting of HAI-related data continues to be a policy priority for legislators, federal administrators and patient advocates alike. However, effects on various stakeholders within healthcare systems, including consumers, infection prevention departments and personnel, and administrators is not fully understood. Additionally, impacts on organizational processes and improvements as well as specific HAI outcomes, particularly infection rates, has been explored in the literature but continues to remain somewhat ambiguous.

Public reporting of HAI data in the United States focuses primarily on infection-related data at the level of the healthcare system; these data are often used to make meaningful comparisons and observations regarding trends in patient outcomes or quality of care.<sup>1,14,16</sup> These policies can be legislatively enacted, implemented as part of an administrative statute, or mandated through participation in other public reporting programs.<sup>11,16</sup> A study from Herzig and colleagues in 2014 found that as of the prior year, 37 states had implemented mandatory HAI public reporting, with significant variability in types events reported.<sup>14</sup> Most state laws mandate that case-based surveillance data are reported by healthcare institutions to the National Healthcare Safety Network (NHSN), a national HAI surveillance system with oversight from the CDC. As of 2014 however, all states have hospitals that report HAI data to NHSN in some capacity whether in fulfillment of state mandates or federal requirements<sup>1,14</sup> These data are then made publicly available via federal channels, allowing for some risk-adjusted comparison of HAI-related outcomes.<sup>17</sup> These risk-adjustments allow for comparison among institutions with varying characteristics that may impact HAI outcomes such as size,

geography, or case-mix. The standardized infection ratio (SIR) is the main reported statistic used by the Centers for Medicare and Medicaid Services (CMS) and the CDC to publicly report HAIs.<sup>18</sup> This ratio examines the relationship between the number of observed infections to the number of expected infections based on a risk-adjusted model for device-associated HAIs, surgical site infections, MRSA bloodstream infections, and *C. difficile* gastrointestinal infections.<sup>1</sup> Specific criteria are used to meet surveillance definitions required for consistent case-reporting across states and facilities in an attempt to circumvent issues of variation in data reported and noted issues with validation of true HAI cases.<sup>16,19</sup> In addition to being publicly reported these data are also used for various incentive programs including the Hospital Value-Based Purchasing program (VBP).<sup>7</sup>

Although these laws have now been implemented in some states for over a decade, at the time of their original inception little evidence was available support their effect on reducing HAI events and improving patient care. In many cases policy mandates were outpacing evidence and HAI experts were left concerned that little empirical foundation existed with which the challenges of implementing these laws could be justified.<sup>15</sup> However the impacts of non-HAI public reporting mandates had been explored in the literature.<sup>9</sup> In addition, conceptual frameworks had been developed to hypothesizes the unique pathways and relationships by which reporting performance improvement data may impact outcomes and stimulate change hospitals. Berwick et.al<sup>20</sup> developed a conceptual framework describing the impact of performance measurement and data reporting on health system performance, consumer engagement, and quality of care.<sup>20-22</sup> While this framework does not specifically address the public reporting of

infection data, it identifies proposed pathways by which publicly reported performance data may stimulate change in healthcare systems.

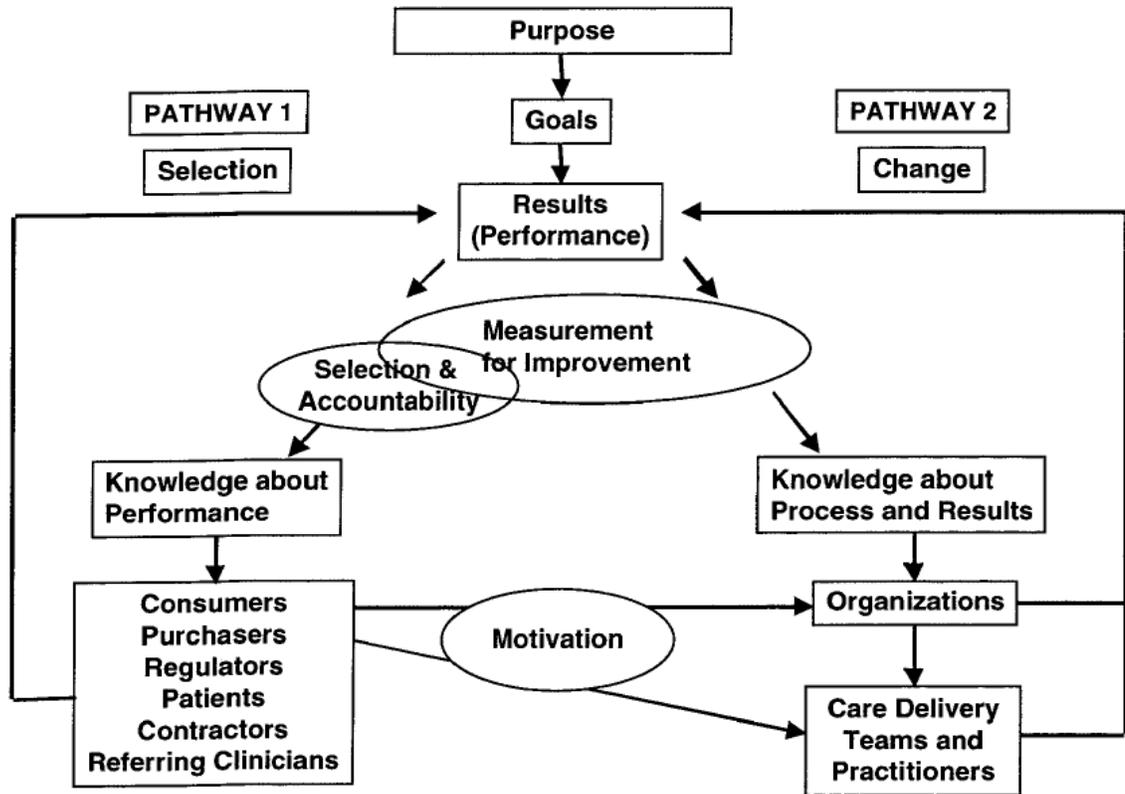
#### ***2.4 Conceptual Framework for Quality Measurement and Improvement***

In 2003, Berwick and colleagues<sup>20</sup> published one of the most highly referenced frameworks for how quality measurement might stimulate improvement in providers and organizations (Figure 1). The paper describes the varying pathways by which measuring performance might affect the actions and decisions of consumers, clinicians, payors and other various actors within the larger healthcare system.

The Selection Pathway described in this framework involves choice in the hands of consumers, payors and referring clinicians.<sup>20</sup> Decisions to select services are based on measurement of and access to performance data of the institution or provider in question. The threat of avoidance of lower performing institutions by informed payors and consumers motivates those organizations to improve practices. Not surprisingly, this pathway relies on the presentation of understandable, valid data as well as the ability of healthcare consumers to correctly interpret and use this data for decision-making.<sup>20</sup>

A second pathway identified by Berwick et. al<sup>20</sup>, the Change Pathway, describes a more intrinsically motivated health system. This pathway relies on the ability of health systems and providers to receive performance measurement feedback and implement change based on those data.

*Figure 2.1 Conceptual Framework Linking Quality Measurement and Improvement: Change and Selection*



*Pathways proposed by Berwick and colleagues<sup>20</sup> linking performance measurement and improvement. This pathway has been used in subsequent literature to describe the pathways by which public reporting of healthcare performance data could stimulate improvement and promote better patient outcomes.*

Significant investment on the part of these systems to collect and report data, promote the use of performance improvement techniques, and incentivize improvements in care is needed to ensure this pathway works optimally in the healthcare system environment. Berwick and colleagues<sup>20</sup> contend that individual intrinsic drivers such as pride, caring, and desire-to-achieve can help stimulate the change pathway. However, without an environment that supports and drives improvement initiatives, intrinsic drivers may fail to

move the dial on quality of care.<sup>20</sup> The Selection Pathway is also a recognized source of motivation for the Change Pathway, although in Berwick, et.al's work it remains an untested driver.<sup>20</sup> The authors hypothesize that provider and administrator aversion to loss of market share, community criticism, and other negative motivators can portend a shift toward improvement through the Change Pathway.<sup>20</sup>

The notion that selection could serve as a motivator for change was explored by Hibbard and colleagues which led to the proposal of a third pathway for public reporting to stimulate change within healthcare systems.<sup>21-23</sup> Their study contrasted the effect of issuing public versus private reports to health systems on performance improvement practices.<sup>22</sup> Findings from this work showed that those low-performing hospitals receiving publicized performance reports undertook more quality improvement activities than those hospitals receiving non-publicized reports.<sup>22</sup> Hibbard and colleagues argued that these findings indicated a concern for reputation served as a motivator for change. Findings from a subsequent paper indicated that this motivation is even greater than concern for loss of market share.<sup>23</sup> Hibbard contended that these findings support the relative weakness of the aforementioned Change Pathway to improve care through public reporting and that a Reputation Pathway may have a stronger propensity to stimulate improvement practices.<sup>21</sup>

In 2008, Fung and colleagues<sup>8</sup> published a systematic review of studies that examine how public reporting of performance data improves quality of care. They addressed the Berwick<sup>20</sup> framework in their review of the literature. Their findings showed that consumer selection of physicians and hospitals was affected by the

publishing of performance data, particularly in the specialty area of cardiac surgery. Health plan selection was also affected by reported performance, with several studies, both experimental and observational, showing a preference for selecting plans with higher performance ratings even though these plans may be higher cost and involve more restrictions.<sup>8</sup> The effects of public reporting on the consumer selection of hospitals and individual providers was more mixed. Fung et. al<sup>8</sup> reviewed 9 studies examining the effects of public reporting on hospitals and market share; overall studies showed that releasing hospital performance data had little or no effect on hospital utilization or market share. In studies examining provider selection after publicly reporting performance data, some effect was noted, particularly with regard to cardiac surgeons and the New York State Cardiac Surgery Reporting System.<sup>8</sup> Five studies examining this data found that physicians with better outcomes were more likely to see increases in growth for surgical charges, while those surgeons with higher mortality scores were less likely to be selected by Medicare enrollees.<sup>8</sup>

In addition to selection, Fung et. al<sup>8</sup> also examined the effects of reporting on clinical outcomes and process improvements. While a minority of studies in the review showed an improvement on mortality indicators after public reporting, most had inconclusive findings or could not account for secular trends in decreasing mortality in non-reporting environments.<sup>8</sup> Underlying trends in these outcomes, including regression to the mean, may be a key limitation in analyzing these data and isolating the effect of reporting mandates. This suggests the presence of additional complexity in the pathways between reporting and impact, highlighting the need for further review of the literature

and empirical investigation. Quality improvement activity was the outcome most widely affected by public reporting. Studies of hospital settings found that most healthcare systems responded to the publication of their performance data by initiating quality improvement efforts, including efforts in domains noted in the various reports.<sup>8</sup>

To date the most widely examined public reporting conceptual framework and its pathways have not been revised to account for the breadth of available evidence regarding the effect of public reporting and HAIs. The aim of this paper is to develop a revised public reporting framework that incorporates available literature concerning the effect of public reporting on HAI-related outcomes. This framework will allow researchers and policy-makers to target inquiries and develop relevant evaluation methods that address the impact of these public reporting laws on HAIs.

## ***2.5 Methodology***

An integrative review of the literature was conducted to examine the relationship between public reporting and HAIs.<sup>24</sup> The integrative review methodology is well-suited for the aim of this review.<sup>24,25</sup> Whittemore and Knafl (2005) discuss the integrative review as uniquely inclusive of diverse research methodologies and allowing for results aimed at a wide array of purposes, including the development of concepts and the review of evidence. Ganong<sup>25</sup> underscores the utility of the integrative review for examining theoretical issues and posing new directions for needed research. These reviews often are guided by the use of a previously determined conceptual framework related to the phenomenon of interest, guiding the sampling of publications and development of inclusion/exclusion criteria. The methodology put forward by

Whittemore and Knaf<sup>24</sup> was used to conduct all steps of this review.

Since the aim of this review is to develop a revised conceptual framework from current evidence, prior work from Berwick<sup>20</sup>, Hibbard<sup>21</sup>, and their colleagues was used to guide the development of inclusion and exclusion criteria for the final selected studies (Table 1). These previously discussed pathways and frameworks focus primarily on the impact of publicly reported performance data on various stakeholder groups within health systems. Thus, empirical studies and published work were reviewed with the intent of evaluating the impact of public reporting on stakeholder groups as a primary outcome. Similar to those outlined by previous frameworks, stakeholder groups are defined for this review as consumers or patients (inclusive of broad patient outcomes), health systems or organizations, payers and provider groups.<sup>20,21</sup> This strategy also reflects previous work published by the Agency for Health Research and Quality (AHRQ) in attempts to evaluate similar relationships.<sup>13</sup> A 2012 review was conducted by Totten et. al<sup>13</sup> for AHRQ, resulted in findings similar to those reported by Fung and colleagues<sup>8</sup>. However, Totten et. al<sup>13</sup> used a structured guide for reporting that specifies the Population (healthcare providers or consumers), Intervention (public reporting of data), Comparators (examining groups with different data reporting or no reporting), Outcomes (improvements in care or changes in processes), Timing (trajectory of reporting and outcome evaluation), and Setting (hospitals or other healthcare organizations). This guide is useful in identifying studies that are structured to evaluate the impact of public reporting on key stakeholders in the healthcare system.

***Table 2.1 Inclusion and Exclusion Criteria for Integrative Review of the HAI and Public Reporting Literature***

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>• <b>Published between 2006 and 2016</b></li> <li>• <b>Published in a peer-reviewed journal</b></li> <li>• <b>English language publication</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Studies with the following characteristics:</b> <ul style="list-style-type: none"> <li>○ Editorials, commentaries and papers describing the policy landscape</li> <li>○ Studies examining long-term care and outpatient setting</li> <li>○ Primary outcome is data validation</li> <li>○ Primary outcome is not evaluation of stakeholder impact</li> </ul> </li> </ul>

Searches were conducted in Scopus, PubMed and the Cumulative Index of Nursing and Allied Health Literature (CINAHL) querying for publications in peer-reviewed journals published between 2006 and 2016 and using specific search terminology (Table 2). This timeframe was selected since official guidance for the public reporting of HAIs was published in 2005<sup>26</sup>. Initial search was completed in Scopus and a subsequent review of titles and abstracts (where available) was conducted to exclude those studies or publications that met the exclusion criteria (figure 2). Relevance to exclusion criteria was ascertained by using abstracts to determine the purpose of the study, identify the outcome of interest, and identify the methodology used by the researchers. After this initial review, a full text review was done of the remaining publications to ensure relevance to the conceptual framework sampling and pathways previously described. This same process was completed with additional search terms

and strategies in Scopus, while also reviewing titles for duplicates from previous searches. The total publication yield from the full text review in Scopus indicated the potential need for expanded search terms to include “HAI”, “healthcare-acquired” and “mandated”. This was ascertained by a review of the references of selected papers from the Scopus review. These terms were subsequently applied to the additional searches.

Once results from the Scopus search were finalized, PubMed and CINHAL were queried using the same criteria and expanded search terms, with attention to duplicative results from the Scopus findings (figure 2). The final articles selected for inclusion were then reviewed, grouped and analyzed by where they fit within the various public reporting pathways. Again, references of the final selected studies were screened. Publications were analyzed for study design, relevance to previous frameworks, outcome of interest, strengths and limitations (appendix A).

Special attention and analysis was given to each study’s contribution to what is known about the impact of public reporting on specific stakeholder groups and cohesion with previously proposed pathways. Proposed pathways from prior conceptual frameworks were used to group the selected studies for analysis. Those studies which examined potential relationships or variables most fitting of the Change Pathway were analyzed to determine if findings supported, challenged or posed new relationships or variables along that pathway.<sup>20</sup> Similar methods were used for articles related to the Selection and Reputation Pathways.<sup>20,21</sup>

**Table 2.2 Search terms and initial yield for Integrative Review of the HAI and Public Reporting Literature (2006-2016)**

<b>Database/Search Engine</b>	<b>Boolean/Search Terms</b>	<b>Total Retrieved</b>
<b>Scopus</b>	<i>Public reporting (all text) *AND infections (all text)</i>	189
<b>Scopus</b>	<i>Public reporting (all text) *AND healthcare-associated (all text) *AND infections (all text)</i>	43
<b>Scopus</b>	<i>Mandatory reporting (all text) *AND healthcare-associated (all text) *AND infections (all text)</i>	42
<b>PubMed</b>	<i>Public (title/abstract) *OR Mandatory (title/abstract) *AND Reporting (title/abstract) *AND Infections (title/abstract)</i>	571
<b>PubMed</b>	<i>Public (title/abstract) *AND Reporting (title/abstract) *AND Healthcare-associated (title/abstract) *AND Infections (title/abstract)</i>	45
<b>PubMed</b>	<i>Mandatory (title/abstract) *AND Reporting (title/abstract) *AND Healthcare-associated (title/abstract) *AND Infections (title/abstract)</i>	24
<b>PubMed</b>	<i>Mandatory (title/abstract) *AND Reporting (title/abstract) *AND HAI (title/abstract)</i>	29
<b>PubMed</b>	<i>Mandatory (title/abstract) *AND Reporting (title/abstract) *AND Healthcare-acquired (title/abstract) *AND Infections (title/abstract)</i>	2
<b>CINAHL</b>	<i>Public (title/abstract) *AND Reporting (title/abstract) *AND Healthcare-associated (title/abstract) *AND Infections (title/abstract)</i>	72
<b>CINAHL</b>	<i>Mandatory (title/abstract) *AND Reporting (title/abstract) *AND Healthcare-associated (title/abstract) *AND Infections (title/abstract)</i>	46
<b>CINAHL</b>	<i>Mandatory (title/abstract) *AND Reporting (title/abstract) *AND HAI (title/abstract)</i>	53
<b>CINHAL</b>	<i>Public (title/abstract) *AND Reporting (title/abstract) *AND HAI (title/abstract)</i>	80

Results were organized and synthesized with regard to specific pathways examined by each article.<sup>20,21</sup> Evidence from the review was then used to update existing pathways and propose a revised conceptual framework specific to public reporting in the context of HAIs and its impact on specific stakeholder groups.

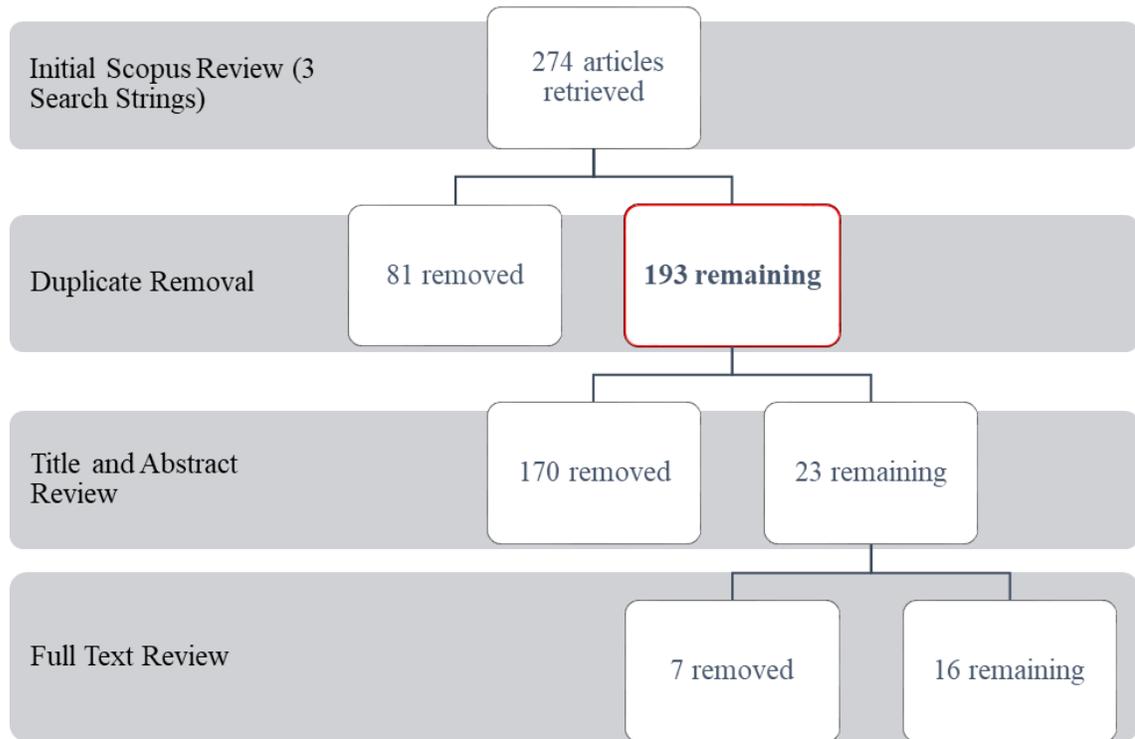
## ***2.6 Results***

Nineteen studies were identified for inclusion in this review.<sup>15,27-44</sup> Fifteen empirical publications and 1 systematic review of prior HAI public reporting literature were identified in the initial Scopus search. This review was deemed suitable for inclusion because its primary aim was to determine the impact of public reporting on HAI outcomes.<sup>15</sup> Subsequent PubMed searches identified 3 additional studies after removal of duplicates and reviews of abstracts and full text where applicable. Review of references of included publications was conducted, and one additional study was identified which was published as a research paper in the Northwestern University Pritzker School of Law, Law and Economics Research Paper Series.<sup>40</sup> It was noted that this paper served as the source of data for a narrative case-study paper identified in the Scopus search and already included in the review.

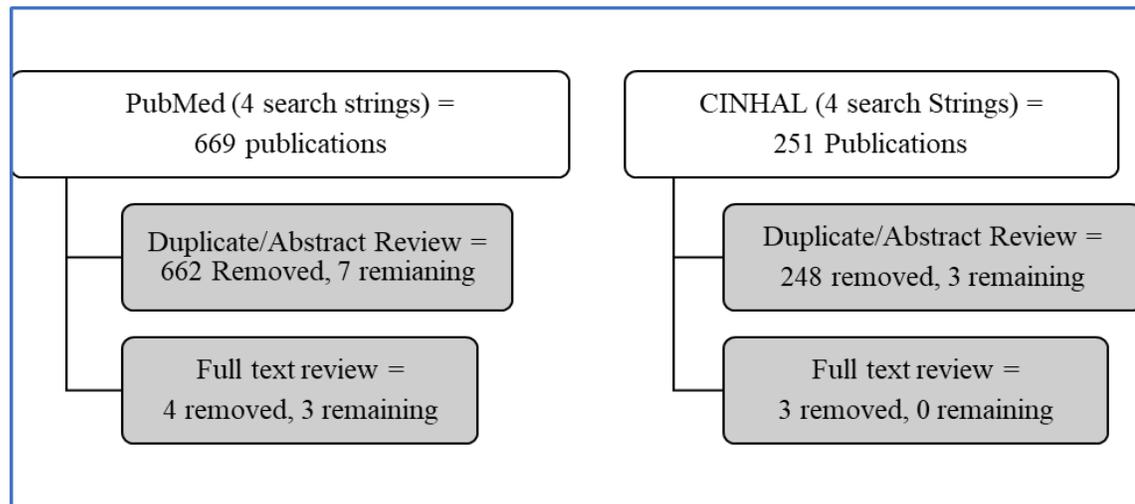
In consultation with the study team and after reviewing both texts, it was decided that the source paper from Black and Kim (2014) would be used as it contained data and results from the empirical study rather than a case description of challenges and findings. Studies were then grouped and analyzed in relevance to conceptual framework pathways and methodology.

**Figure 2.2 Literature Search Framework and Inclusion of Studies for Review**

Phase 1: Scopus



Phase 2. PubMed and CINHAL



In total 13 studies described their methodologies as quantitative, four as qualitative, one as mixed-methods, and one as a systematic review. Key characteristics of studies were collected and evaluated using a template described in the integrative review literature (Appendix A).<sup>45</sup> Five studies described a conceptual framework in their background or methods, including two that describe the specific pathways previously discussed. However, only one of these studies attempted to carry these pathways through to the analysis and discussion portion of the publication.<sup>29</sup>

*The Change Pathway: Patient Outcomes, Providers, and Organizations*

Berwick and colleagues describes the process of change within organizations and individuals as guided and stimulated by performance measurement, yet the specific sources of motivation for change remain highly variable.<sup>20</sup> In many of the studies that examine patient outcomes, the change pathway is invoked with some noted associations between public reporting mandates and patient outcomes.

Studies using quantitative methods to evaluate public reporting's impact on HAI outcomes showed conflicting results in that some showed decreases in HAI infection rates and others did not. These effects on *C. difficile* in Canada were noted when Daneman and colleagues conducted a longitudinal retrospective cohort study, comparing modeled rates of *C.difficile* without the presence of a mandate to observed rates of the infection after the implementation of a mandate.<sup>39</sup> Results showed a 26.7% reduction (p<0.001) from the expected outcome in *C.difficile* one year after implementation of

public reporting. This trend was seen across multiple institutions included in the study sample of administrative data.<sup>39</sup>

A study from Black and Kim (2014) described CLABSI rates before and after public reporting mandates in Pennsylvania.<sup>40</sup> Researchers used a difference-in-difference study design, to assess the change in CLABSI rates in Pennsylvania and control states, before and after public reporting implementation.<sup>40</sup> Comparing administrative inpatient CLABSI rates in Pennsylvania to that of control states, the authors noted that CLABSI rates fell by 24% in Pennsylvania during the reporting period compared to 3% drop in those states without reporting.<sup>40</sup> Hospitals with the highest rates in Pennsylvania had more significant decreases during the reporting period. Similar work from Pakyz and colleagues<sup>38</sup> evaluated the effect of public reporting on CLABSI SIRs through a cross-sectional retrospective cohort study. One-hundred and fifty hospitals were divided into three groups: those in states with public reporting meeting three legal requirements (data submission, reporting of data to the public and inclusion of facility identifiers), those in states with public reporting not meeting the three requirements, and those in states without public reporting.<sup>38</sup> Findings showed no differences in SIRs among all three groups.<sup>38</sup> Marsteller and colleagues<sup>36</sup> used a similar study design to Black and Kim<sup>40</sup> to examine the impact of public reporting on CLABSI rates with an additional outcome of participation in a national program aimed at reducing the rates of CLABSI in the inpatient setting (On the CUSP: Stop BSI program). Findings indicated that program participation was higher in states where reporting mandates were enacted at the time of On the CUSP: Stop BSI program implementation, potentially suggesting that pending or

new mandates may be associated with participation in process improvement initiatives.<sup>36</sup> Facilities in states with the voluntary or long-standing reporting requirements had higher rates at baseline and greater reduction in CLABSIs during the first 6 months of the program with incidence rate ratios (IRR) of 1.48 and 1.14 respectively ( $p=.002$ ,  $p=.033$ ).<sup>36</sup> All groups initiating the process improvement intervention saw decreases in CLABSI rates.<sup>36</sup> A more recent study by Liu and colleagues (2016) used a difference-in-difference design to examine CLABSI rates in ICUs and associations with mandatory reporting. With a longitudinal national sample of CLABSI data ( $n=244$  hospitals, with 1,902 ICU years) from NHSN, the study team concluded that when compared to 25 months or more prior to the law's implementation, notable decreases in CLABSIs were seen both in anticipation of the law (IRR = 0.66 ,  $p<.001$ ) and long after the laws went into effect (IRR=0.343,  $p=.009$ ) .<sup>41</sup>

Three studies involving data from the pediatric population contribute similar findings to previous literature.<sup>37,42</sup> In a study evaluating clinical outcomes from public reporting in critically ill pediatric patients, Rinke and colleagues (2015) used data from the Kid's Inpatient Database (KID) to determine the extent of public reporting's impact on CLABSI rates. Analysis yielded statistically significant reductions in CLABSIs in all 3 reporting groups regardless of when or if reporting was initiated (never reporting vs. reporting began in 2006 vs. reporting began in 2009) .<sup>37</sup> Differences in CLABSI reduction between groups were not statistically significant, except in the never reporting group which showed a greater reduction when compared to the group that began reporting in 2009 (OR=2.1,  $p<0.001$ ) .<sup>37</sup> Flett and colleagues (2015) examined CLABSI

public reporting and its impact on point-of-care indicators, specifically blood culture and antibiotic use in pediatric populations. Despite anticipating lower blood culture rates and antibiotic utilization multivariable linear regression showed no difference in adjusted rate ratios (ARRs) before and after public reporting implementation for either indicator.<sup>42</sup> A third study in the pediatric population by Zachariah and colleagues (2014) explored the relationship between mandated CLABSI reporting, process improvements and outcomes in the neonatal intensive care unit (NICU). The authors found that when compared to control states, NICUs in states with mandates more often reported greater than 95% compliance with all prevention practices ( $p=.002$ ).<sup>43</sup> However this did not translate into a difference in clinical outcomes as no statistical significance was found in CLABSI SIR differences between both groups (mandated reporting vs. no mandates).<sup>43</sup> These findings were also unable to significantly link NICUs that reported greater than 95% compliance with prevention activities and an SIR less than 1.<sup>43</sup> Finally, a 2006 systematic review by Mckibben and colleagues<sup>15</sup> was conducted to evaluate existing evidence for support newly enacted public reporting mandates. While the published report did include recommendations for implementing a public reporting program centered on HAI performance data, finding from the review showed little empirical evidence suggesting the effectiveness of public reporting to improve outcomes.<sup>15</sup>

Significant associations between public reporting and lower infection rates are noted in some studies, but in general remain inconsistent across the body of literature. Studies that showed statistically significant effects were those that used quasi-experimental methodologies for analysis.<sup>36,39-41</sup> . However, even studies that show a

decline in infection rates do not illuminate the pathways by which these laws impact these outcomes.

A diverse sampling of methodologies was used in studies that describe the organizational impact of public reporting. In the first study, Pegues<sup>34</sup> described the University of California, Los Angeles (UCLA) Health System's response to the 2009 Health and Human Services Federal and state HAI Action plan.<sup>34</sup> Pegues used the Context-Input-Process-Product model, to evaluate the state of HAI prevention prior, during, and after process improvements related to state and federal HAI policy, including public reporting. Specifically, he described the inputs of public reporting mandates for HAIs as main driver for a host of HAI prevention strategies and process improvements.<sup>34</sup> Specific needs around reporting prompted additional methods for data validation, unit and hospital-specific HAI data reporting strategies (dashboards), and stronger surveillance. These changes improved practice by highlighting trends in HAI rates in specific hospital units, allowing for improved infection prevention with targeted evidence-based interventions predetermined by the hospital.<sup>34</sup> A more expansive qualitative study by Uchida and colleagues<sup>33</sup> used semi-structured interviews of infection prevention personnel conducted in six hospitals throughout California. Thematic analysis of responses yielded both positive realizations and specific concerns generated by public reporting. Specifically, respondents believed that mandated reporting emphasizes the issue of HAIs in their respective health system and increases cognizance of HAI issues across the organization.<sup>33</sup> Frustration among respondents was due to a perceived disconnect between reporting data to external stakeholders and tangible

improvements in HAI-related outcomes. Specifically participants felt that public reporting could not be linked to specific outcomes in their patients, therefore the added burden of reporting was challenging to reconcile.<sup>33</sup> A larger study in California involving many of the same researchers from the previous paper used a mixed-methods longitudinal approach to evaluate the impact of new mandatory reporting law.<sup>31</sup> Pre- and post-public reporting surveys were conducted among hospital infection prevention leadership, examining a wide range of issues from work processes to outcome measures. These surveys were followed by in-depth interviews with six hospitals to gather further information. Statistically significant changes were noted between pre/post reporting mandates, specifically in reported adherence to evidence based protocols (use of barrier precautions [p<.01], and chlorhexidine usage [P=.02]), as well as a reported decrease in CLABSI rates (p<.01) and VAP rates (p=.02).<sup>31</sup> Themes of frustration with increased workload, data validation concerns, but also a heightened awareness and prioritization of infection prevention within organization were noted from qualitative interviews.<sup>31</sup> In a similar study with a larger multi-state scope, Stone and colleagues<sup>32</sup>interview key stakeholders, including hospital and state administrators from states with and without public reporting mandates. Results show that while public reporting is key to fostering collaboration and increasing organizational awareness, significant concerns still existed.<sup>32</sup> Yet interviewees noted that these public reporting laws are largely responsible for highlighting the importance of HAIs within hospital settings and garnering support for organizational initiatives to improve outcomes.<sup>32</sup> An additional national study from the University of Pennsylvania also queried infection control personnel in leadership roles, to determine the impact of state mandated reporting on infection prevention processes.<sup>35</sup>

Thirty-one states, 22 of which had mandated reporting requirements, were represented across 110 hospitals. Contrary to findings in other studies, respondents in states with mandatory reporting did not identify added process improvements or a perceived decrease in incidence of HAIs when compared to those in states with no reporting requirement<sup>31,35,43</sup>. Despite issues of small sample size, low external validity, and lack of infection-related data, these findings do provide perspective on how mandated reporting outcomes are perceived and reported by healthcare professionals.<sup>35</sup>

A final study by McGuckin et al. (2013) described the opinions of hospital epidemiologists with regards to mandatory reporting. Findings suggested that a majority of hospital epidemiologists found public reports generated at the state level to be useful (70%), and believed that they have a role in disseminating data (96%).<sup>30</sup> An additional finding from this study is that the majority of the epidemiologists surveyed believed that consumers would likely have difficulty understanding HAI data and interpreting it for the purposes of healthcare decision-making.<sup>30</sup> This finding highlights the proposed role of the consumer role in the HAI framework, particularly regarding the selection pathway, and yet suggests that consumers may not be well-suited to use these outcome data for decision-making. While clinical outcomes and organizational improvement data are key to understanding the effects of public reporting on HAIs, a full picture of the impact of public reporting HAI data must include a broader scope of how this available information is used by consumers. Consumer involvement in this decision-making is a central tenet to previously described frameworks<sup>20,21</sup>, however existing public reporting and HAI literature reveals a diminished comprehension of these data by consumers.

*The Selection and Reputation Pathways: Data-driven, Consumer Decision-making*

Understanding the utility of HAI data from the consumer perspective is essential to determine the best methods for dissemination and support informed decision-making if a goal of policy-makers is to empower consumers to use this data for healthcare decision-making.<sup>46</sup> Four articles discussing consumer knowledge of publicly reported HAI data and how those data affect healthcare choices were included in this review.

A study by McGuckin and colleagues described the results of a telephone survey across the U.S. examining public awareness of HAI reporting and its use in selecting a hospital for their care needs.<sup>44</sup> 28% of total respondents in states with HAI laws were aware of the reporting laws and the presence of publicly available data. Only 14% of respondents cited HAI data as a one of their top 2 considerations when choosing a hospital, with most listing provider recommendation as their main driver for hospital selection.<sup>44</sup> More education ( $p < .0001$ ), higher income levels ( $p = .0007$ ), and previous infection were noted in participants who appeared more engaged with and/or aware of the HAI data reported in their state ( $p < .0001$ ).<sup>44</sup>

Two additional studies from researchers at the University of Massachusetts examined the presentation and interpretation of HAI data and how these attributes might affect healthcare decision-making in a local population.<sup>28,29</sup> The first study was a cross-sectional survey of residents from Worcester, Massachusetts, evaluating formatting and structure of publicly available HAI data.<sup>29</sup> Eight versions of the reports, each differing in consistency of indicators, representation of the data, and the presence of confidence

intervals were mailed to participants, followed by the questionnaire.<sup>29</sup> From the 201 questionnaires returned and included in the study, researchers found that inconsistency in metrics (i.e. one hospital with highest overall safety score, yet not the lowest HAI or mortality rate) pushes consumers to select the aggregate score (safety score) as the predominant means of decision-making.<sup>29</sup> Similar to the findings from McGuckin et al<sup>44</sup> higher levels of education were associated with higher understandability ratings, suggestive of some influence of education on engagement and comprehension of publicly reported data.<sup>29</sup>

An additional study by Mazor and colleagues<sup>28</sup> used semi-structured, in-depth interviews, to describe the views about publicly reported HAI data as experienced by participants and generate new recommendations for publicly reporting HAI data. Data was shown to participants in three forms: a standard report from the State of Pennsylvania, a subsequent “improved” (p.414) report, using varying graphical representations and a composite score, and web-based reports<sup>28</sup>. Findings from 59 interviews suggested many participants were unfamiliar with HAI-related terminology but interested in the data and prevention strategies. However, confusion over interpretation of data and results continued even after general explanations of HAI concepts. Participants tended to prefer infection rates and mortality compared with other measures.<sup>28</sup> Similar to their previous study, Mazor and colleagues noted that while HAIs were a concern for patients with regard to decision-making and hospital selection, other factors predominated including: insurance status, family and friend recommendations,

and prior experiences.<sup>28,29</sup> Recommendations for improving data presentation included stipulations on content and formatting.

A more recent study from Mansick and colleagues (2015) assessed the interpretability of HAI data presented on the Hospital Compare website. Researchers conducted a survey with questions designed to evaluate various domains covered on the website including: written descriptions of the data with or without the SIR (Tasks 1 and 2), identical SIR descriptions with numerical SIRs (Task 3), and only numerical SIRs (Task 4).<sup>27</sup> Corresponding tasks were used to gauge how well participants interpreted these data in each domain. Overall, increased complexity of the data (written descriptions vs. only numerical SIR data) was associated with lower mean correct responses (Task 1: 72%, [95% CI, 66-79%] vs. Task 4: 38% [95% CI, 31%-45%]) meaning that as data becomes more complex, participants are less likely to interpret it correctly.<sup>27</sup> Similar to findings from Mazor<sup>28,29</sup> and McGuckin<sup>44</sup>, those with higher education levels had higher mean correct responses on more complex data interpretation<sup>27</sup>.

#### *A Revised Conceptual for HAIs and Public Reporting*

Considering these findings, a revised conceptual framework for assessing the impact of HAI public reporting policy is proposed (figure 3). This revised framework incorporates existing pathways previously described, but proposes new relationships, identifies the strength of existing evidence, and puts forward new frameworks for inquiry. With respect to the larger framework, new pathways are designated by solid or dotted

arrows indicating direct paths between variables of interested. Dotted arrows are consistent with pathways that may be hypothesized but lack evidence or support in the literature. Solid lines indicate conclusive or more mixed findings supporting that these pathways do exist, but the mechanism and mediating factors may not be well understood. Central to this new framework is the notion that patient outcomes are highlighted as a primary target for public reporting mandates and are effected, although inconsistently, by public reporting policy.<sup>35-38,40-43</sup> However, the pathways by which these outcomes are affected are not well described. The bi-directional nature of this reporting/outcomes relationship is important since outcomes are fed back to organizations and consumers, potentially stimulating the Change and Selection pathways. Yet the inconsistency in previous findings suggest additional mediating variables and pathways that likely play a role in impacting stakeholders.

Consumer choice operates within the more nebulous concept of the Selection Pathway. It has been established that consumer education level has a remote effect on their healthcare decision-making, but most have difficulty interpreting data specifically for that purpose.<sup>28,29,44</sup> However, one common theme present was reputation, specifically how a hospital's reputation was more likely to impact decision-making than HAI data alone. Because HAI data may contribute to more global reputation and prior evidence shows that hospitals are concerned with public reporting's effects on reputation, it is considered a potent mechanism by which data can affect consumer choice.<sup>21</sup> This is different from the prior stand-alone pathway, and couches the Reputation Pathway within the larger concept of selection. There is a paucity in evidence that selection by providers

(referrals) or payers (insurance companies) is affected by reported HAI data, however this may be seen in other public reporting literature.<sup>8</sup> Likewise, any change undertaken by an organization to address its reputation resulting from publicly reported HAI data may affect outcomes and, subsequently, consumer choice, but that relationship is not well-understood. Improved outcomes or perceived positive changes within the organization may stem from an organizational climate conducive to better HAI performance and garner a higher reputation in the community possibly enhancing selection. However, the circular relationship between the Selection Pathway and the more intrinsic Change Pathway is not well explored in this group of studies.

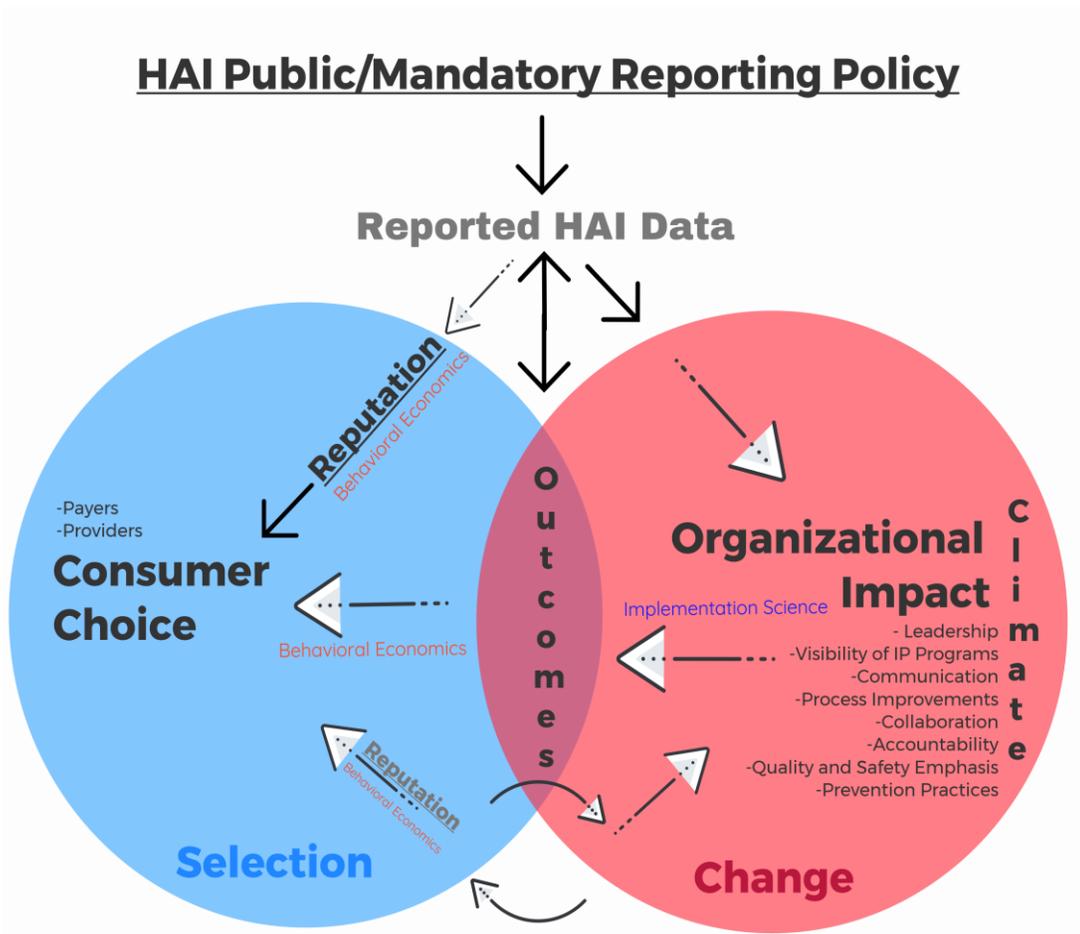
## ***2.7 Discussion***

This review examines a diverse, but inclusive body of literature specific to public reporting of HAI data and its impacts on specific stakeholder groups within the healthcare system. The review encompassed the current state of HAI literature evaluating the impact of public reporting mandates on various stakeholder groups, while allowing for a wide range of methodologies and inquiry. However, these methodologic variations, coupled with inconsistency in data sources, diversity of outcomes and stakeholder groups, produce an incomplete picture of the public reporting's effects on outcomes, organizations and consumer choice. Yet, the range of findings from these empirical investigations do help illuminate the public reporting pathways that drive change within health systems and affect consumers' healthcare decision-making.

This review shows similar findings to previous work regarding the conflicting evidence that the public reporting of healthcare performance data has a significant impact

on patient or clinical outcomes.<sup>8,15,47</sup> The Change Pathway described by Berwick and colleagues<sup>20</sup>, relies on this conceptualized relationship between performance monitoring,

**Figure 2. 3 Revised Framework for Assessing the Impact of HAI Reporting Policy**



**Framework for Assessing the Impact of HAI Public Reporting Policy**

*This framework, adapted from Berwick et. al,<sup>20</sup> and Hibbard, et. al,<sup>21</sup>, addresses the complexities in relationships between public reporting, outcomes, organizations and consumers. Dotted arrows represent limited or lacking evidence for proposed directional pathways by which the larger encircled concepts may be affected by public reporting. For example, public reporting has a notable impact on organizations, but the specific ways in which their impacted and how they affect outcomes is still not well documented. Solid lines are indicative of more established relationships in the literature (i.e. findings showed hospital reputation impacted consumer decision-making, but how HAI data affects reputation is not well understood). Dotted lines are used to describe the impact of HAI data on consumer choice, largely because consumers report an overall lack of awareness around publicly reported data.*

intrinsic change in organizations, and improving outcomes. However, while some studies in this review showed significant HAI reduction associated with these laws, few could delineate mediating pathways or processes that may explain these reductions.<sup>36,39-41</sup> Sensitivity analysis conducted by Liu and colleagues<sup>41</sup> showed a reduction in central line days and increasing work-time by infection preventionists in the months leading up to and well-after the laws were in place. Interestingly, anticipation of the law seemed to influence outcomes as well, suggesting organizational change and preparation in anticipation of these laws is a possible explanation for their impact.<sup>36,41</sup> Although any change in the organization would be pushed through to providers, when clinical decision-making was evaluated, no evidence of reporting policies' impact was seen on antibiotic use or blood culture rates suggesting the change pathway may be more complex than previously described when applied to HAIs.<sup>20,38</sup> Although some studies have found a reduction in HAIs associated with these laws, the presumed effects of organizational change that potentially mediates this pathway is not well understood. Essentially the “why’s and how’s” of the Change Pathway, remain elusive.

These gaps in the literature are partially illuminated by the qualitative and mixed-methods studies examined in this review. Both Pegues<sup>34</sup> and Stone et. al<sup>31</sup> directly describe the development and implementation of process improvements to improve HAIs in response to public reporting mandates. Perhaps even more importantly, four studies identify the improved awareness and heightened attention that public reporting brings to HAIs within an organization.<sup>31-34</sup> The study by Stone and colleagues<sup>31</sup> in 2011 also pointed to the importance of organizational climate-related concepts including teamwork,

accountability and communication. These organizational climate findings were echoed in work by Uchida et. al<sup>33</sup>, and described in detail by interview respondents. Findings pointed to the importance of effective communication and sustained collaboration.<sup>33</sup> While these studies may help to explain aspects of the Change Pathway, additional research is needed to describe fully the effects of these laws on both organizations and their outcomes. Mediating processes and organizational contexts may play an influential role, and research examining these factors is essential. Where these studies fall short however, is describing the proposed Selection Pathway with regard to provider and payor selection. No effects of public reporting on provider or payor selection were identified in the HAI literature included in this review. However, the Selection Pathway does appear to play a role in consumers' use of the data, albeit with the caveat that understanding and utility of the data among consumers remains challenging.

Results from this review contend that while consumers do acknowledge publicly reported data as a factor in hospital selection, interpretability of the data remains difficult and other factors predominate in healthcare decision-making.<sup>27-29,44</sup> HAI outcomes remain a lower priority for selecting a care provider or institution behind insurance status, prior experience, recommendations of family or a provider, and location.<sup>28,29,44</sup> While HAI data do not appear to directly affect the Selection Pathway for consumers, the Reputation Pathway may be an important mediator. Mazor, Dodd and Kunches<sup>29</sup> qualitative work from 2011 found that a hospital's reputation was second only to personal experience when influencing consumers' decision-making around hospital selection. The larger concept of healthcare facility reputation may in fact be affected by publicly

reported HAI data and could alter consumer choice when selecting a hospital. However given the difficulty consumers have shown in interpreting HAI data, the concept of reputation would likely be more global than nuanced, when using HAI data alone.<sup>27,29</sup> Three studies also pointed to the recommendations of healthcare providers as an important consideration for facility selection.<sup>28,29,44</sup> Hospital reputation perceived by healthcare providers may be more affected by publicly reported healthcare data and contribute recommendation for one institution over the other. This presumption has not been well-explored in the published HAI public reporting literature, and remains a hypothesized pathway by which reputation affects selection. The available data suggests varying ways that consumers may approach the HAI data and select the hospital where they receive their care.

A potential theoretical foundation for empirical investigation of the relationship between publicly reported HAI data and consumer choice is behavioral economics (BE) research. BE examines the impact of multiple emotional, psychological and social factors or constructs that can alter decision-making. With respect to healthcare, BE posits that people do not make decisions based only solely on available knowledge that would signal the highest quality hospital, but are greatly affected by a host of social contexts, and attentional and cognitive restraints that cloud rational choice.<sup>48,49</sup> Concepts of heuristics, framing, limited time and/or capacity to assess all available knowledge (bounded rationality) and loss aversion could provide testable pathways for exploring HAI data and consumer decision-making.

Work from Mazor and colleagues<sup>29</sup> discussed in this review, reports on the

potential importance of framing HAI data as a means of invoking consumers' desires to avoid losses and seek gains.<sup>29</sup> However, this concept remains largely unexplored in the HAI public reporting literature. BE and its associated theories fit well within the revised public reporting framework developed from this review. Decision-making can be guided by data if presented in an effective manner and behavior change can be perpetuated by thoughtful BE-focused initiatives.<sup>50</sup> In future research that tests components of these pathways, interventions supported by BE principles may prove useful and more sustainable. As described previously, the Change Pathway remains somewhat undefined in this body of HAI literature.

It is apparent that quantitative and qualitative methodologies are both needed to elucidate the specific mechanisms that affect hospitals as a result of public reporting. Organizational process improvements and climate characteristics are presented in this revised framework as potentially lying on the causal pathway between HAI data and outcomes. Organizational climate and its associated constructs (i.e. leadership strategy, communication, and collaboration) serve this framework well as a structures for defining relationship between data reporting and outcomes.<sup>51</sup> While the impact of these HAI-related changes is difficult to link to outcomes, a specific relationship between implementation of public reporting and an improvement in outcomes was evidenced in quantitative studies.<sup>36,39-41</sup> Outside literature has also had difficulty linking organizational climate components to outcomes, however some positive findings have been noted in previous investigations.<sup>51</sup> Presumably organizational climate, as impacted by the presence or implementation of public reporting may be perpetuating outcomes

oriented around HAI performance. More salient in this new framework is the knowledge that reported data may stimulate some change toward better outcomes, yet the exact mechanisms of how this happens and in what contexts these changes are implemented, remain largely unknown.

A potentially valuable strategy for exploring the relationships between publicly reported HAI data, organizations, and outcomes is the use of implementation science (IS) research. IS investigates how evidence-based practices are systematically implemented and sustained in practice and has been promoted as means of improving uptake of infection prevention practices.<sup>52</sup> While IS incorporates many concepts and constructs, the goal of this research is to understand the challenges and successes specific to implementation and sustainability. The discipline has embraced structured frameworks to guide these inquiries while incorporating larger contextual factors, such as broad policy mandates that contribute to organizational functioning. The Consolidated Framework for Implementation Research (CFIR) proposed by Damschroder and colleagues<sup>53</sup> could help to guide inquiry around the unique pathways by which publicly reported data stimulates and sustainable change within healthcare organizations. Two constructs within the framework lend themselves particularly well to examining the effect of public reporting. The Outer Setting is described as a set of factors that exert influence on the healthcare organization and affect its ability to implement and/or sustain evidence-based practices.<sup>53</sup> These factors may include relationships with the community or other healthcare facilities (i.e. reputation and perception), peer pressure, and external incentives or policies (i.e. public reporting mandates and benchmarking) .<sup>53</sup> The Inner Setting

construct involves the complex relationships and characteristics that enable or slow the implementation of process improvements and evidence-based practices. Some of these factors noted in the CFIR framework include communication structure and practices, leadership engagement and feedback mechanisms.<sup>53</sup> These factors are similar to those identified in this review as organizational factors that are often reported as being affected by public reporting mandates. Since IS research accounts for these constructs as facilitators or barriers to successful process improvements, the models and frameworks within this emerging field are well-suited to examine the organizational effects of policy mandates. However, public reporting remains distinct in that the mandate itself is not an evidence-based intervention, but more so meant to stimulate improvement-oriented changes within individual organizations. Still, IS may prove useful in unpacking the intricate relationships between these laws and implementing sustainable improvement processes in organizations.

This review is subject to limitations. First, the limited time-period for study inclusion potentially missed other articles that fit within the sampling framework and discussed HAI outcomes of public reporting. However, the bulk of HAI public reporting policies were implemented during this time, and previous reviews showed little evidence of HAI outcomes relative to public reporting laws in empirical research prior to 2006.<sup>8,9,15</sup> Second, commentaries, HAI data validation studies, and theoretical papers were excluded from this research, despite their contribution to the HAI public reporting body of literature. While these studies impact the larger picture of public reporting controversy, they do not target specific components of existing frameworks, nor do they empirically

evaluate the impact on stakeholder groups. Additionally, over the past 4-5, years data validity has improved across states and institutions with the use of NHSN for publicly reporting HAI data. The primary aim of this paper was to integrate findings from these studies to propose a revised conceptual framework that illuminates the pathways through which public reporting may influence HAI outcomes and processes. Yet the diverse methodologies, study designs, and outcomes made this body of literature less conducive to a systematic review methodology. An integrative review methodology was specifically chosen for the purposes of synthesizing diverse empirical sources and conceptualizing a revised framework for evaluating the relationships between HAI public reporting, outcomes and stakeholder groups. However, this review and the subsequent framework may have missed critical pathways because they have not yet been empirically explored or published. This remains a proposed framework and will need ongoing evaluation as new pathways emerge or existing pathways are tested.

## ***2.8 Conclusion***

The public reporting of HAI data impacts stakeholders through a multitude of potential pathways and mechanisms. Prior to this work, no reviews had sought to examine the Selection, Change and Reputation Pathways in the context of HAI data and their impact on various healthcare system stakeholders and outcomes.<sup>20,21</sup> This review contends that these pathways are important, but much more complex than previously assumed. A revised framework for understanding these complexities is presented; it illustrates the directional components and key concepts that drive improvements and determine choice using publicly reported HAI data. The framework also highlights BE

and IS as new foundations and directions for investigation by which researchers can examine causal pathways and conceptual relationships. Despite the expansiveness of these laws, much is still unknown their effects on consumers, organizations and the larger policy environment. More research is needed to determine how best to design, implement, and evaluate these policies to ensure they are meeting their intended goals, to improve patient outcomes and guide consumer choice.

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**CHAPTER 3: THE IMPACT OF STATE-BASED MANDATORY  
REPORTING ON LABORATORY IDENTIFIED *CLOSTRIDIUM DIFFICILE*  
AND METHICILLIN RESISTANT *STAPHYLOCOCCUS AUREUS* IN ACUTE  
CARE HOSPITALS ACROSS THE U.S.**

Dissertation

Paper Two

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## ***Abstract***

***Background:*** Healthcare-associated infections(HAIs) are a significant cause of morbidity and mortality in U.S. hospitals. Blood stream infections (BSIs) with *Methicillin-Resistant Staphylococcus aureus* (MRSA) and gastrointestinal infections caused by *Clostridium difficile* (*C. difficile*) are HAIs associated with increased risks for complication, prolonged-hospitalization and death in acutely ill populations. As a result, policy-makers have implemented state laws that mandate the reporting of these infections to state officials, often for the purposes of publicly disseminating this information.

***Purpose:*** The purpose of this study is to determine the impact of state HAI reporting mandates on laboratory identified *C. difficile* infections and MRSA BSIs in U.S.

hospitals. ***Research Design:*** This is a quasi-experimental longitudinal secondary data analysis was conducted using state public reporting law information and infection data from a national sample of U.S. hospitals. ***Methods:*** Bivariate analysis was completed to examine differences in characteristics of reporting hospitals and baseline infection data in hospitals in reporting and non-reporting states. Poisson regression was used to model temporal impacts of implementation of the law on hospital-wide, Hospital-onset *C. difficile* and MRSA BSI laboratory-identified event rates as compared to hospitals in the same month in non-reporting states. ***Results:*** Compared to pre-law implementation, no statistically significant difference was seen in *C. difficile* infection rates in the time after the law, when controlling for secular trends and hospital characteristics. Sensitivity analyses revealed similar findings. Outcomes related to MRSA BSIs were unable to be ascertained due to an inability of the model to converge. ***Conclusions:*** State mandates for HAI reporting are present in most US states. Our investigation did not show a change

in infection rates relative to implementation of these laws. More research is needed to determine the impacts of these laws over time.

### **3.1 Introduction**

Healthcare-associated infections (HAIs) continue to be a significant source of morbidity and mortality in the United States (U.S.). Device-associated infections including central line-associated blood stream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), and ventilator-associated pneumonia (VAP) continue to impose a significant burden to health systems and patients. Approximately 722, 000 HAIs occurred in 2011, resulting in some 75,000 deaths in the U.S.<sup>1</sup>, while healthcare costs attributable to these infections can be upwards of 33 billion dollars.<sup>2</sup> Device-associated infections, including those previously mentioned, are often targets for improvement within the healthcare system because they are often perceived as a preventable source of extraneous health system expenditures and poor patient outcomes.<sup>3</sup>

However non-device associated HAIs including those caused by *Clostridium difficile* (*C. difficile*) and *Methicillin Resistant Staphylococcus aureus* are also implicated in poor patient outcomes and excess financial burdens for payers and systems.<sup>2,4-6</sup> Recently the U.S. Department of Health and Human Services (HHS) has included MRSA and *C. difficile* measures as part of the Value Based Purchasing program (VBP) to provide incentive to hospitals that successfully decrease these infections.<sup>7</sup> This is in accordance with the HHS HAI Action Plan<sup>8</sup> and subsequent updated targets for MRSA and CLABSI reductions by 2020. While guidelines for the prevention of healthcare-associated MRSA<sup>9</sup> and *C. difficile* infection<sup>10</sup> are well established, policymakers have used mandated reporting of HAI-related performance measures as means of attempting to inform consumers and stimulate organizations to improve quality of care. As of 2013, 37

states had some mandate for public reporting of HAI data including 20 states requiring the reporting of MRSA bloodstream infections and 20 requiring *C. difficile* reporting.<sup>11,12</sup>

The aim of this study is to conduct a secondary longitudinal data analysis to determine the impact of public reporting mandates on MRSA and *C. difficile* rates in acute care hospitals across the U.S. No previous studies have examined the impact of these laws on rates of these infections; this study will evaluate these effects and inform the design of health policy interventions for the reduction of HAIs.

### ***3.2 Healthcare-associated MRSA and C. difficile Infections***

Both MRSA and *C. difficile* infections are prevalent HAIs within health systems across the U.S. While disease course and pathogenesis differ, both bacterial infections can lead to prolonged hospital stays and worsened clinical outcomes for patients.

MRSA BSIs are associated with an increased risk of death particularly in older and critically-ill adults.<sup>13</sup> Rates of MRSA-related disease rose in healthcare settings in the early 2000s; soon reducing its incidence became a priority for both policymakers and health systems.<sup>6,14</sup> Invasive MRSA, particularly BSIs, declined starting in 2005<sup>15</sup> but continued to be a prominent source of HAI-related morbidity and mortality. Kallen and colleagues<sup>15</sup> showed a total reduction in MRSA BSIs (-11.2% [95% CI, -15.9% to -6.3%]) from 2005 to 2008. A study examining rates from 2005-2011 showed a total reduction in invasive MRSA of 54% during the study period yet noted a continued presence of the HAI with 14,156 healthcare facility-onset MRSA infections occurring in 2011.<sup>16</sup> Data from the U.S. Centers for Disease Control (CDC) notes that Hospital Onset

(HO) MRSA BSIs, have decreased nationally by 13% from 2011 to 2014.<sup>1</sup> However, closer examination of the data yields some increases in certain states during the same period. These variations indicate that some states have not seen the same HO-MRSA BSI reductions as others.

Similar to MRSA BSI, *C. difficile* infections have also continued to pose a burden to healthcare systems across the country. Recently, a study by Desai et. al (2016), estimated 439,237 incident *C. difficile* infections occurred in 2014, with roughly two-thirds originating in healthcare settings. Data from the CDC's National Healthcare Safety Network (NHSN) showed an 8% reduction in infections in 2014 when compared to the 2011 baseline<sup>1</sup>. However, comparison of 2013 to 2014 data showed increases in these infections despite the overall decreasing trend; *C. difficile* being only one of two HAIs to see an increase during this time.

Despite some indication that these infections are decreasing within healthcare institutions, their financial impact on the system continues to be burdensome. *C. difficile* infection contributed an estimated an \$1.5 billion USD in expenditures in 2011<sup>17</sup>. A review of the literature conducted by Scott in 2009<sup>2</sup>, found attributable costs to healthcare-associated *C. difficile* was between \$5,042 and \$7,179 USD per infection. However, the author noted that the study reviewed did not include operative costs should the patient have surgical complications from infections, potentially understating the true costs of complex *C. difficile* cases<sup>2</sup>. A more recent modeling study from 2016 estimated the total cost of *C. difficile* infections within the healthcare system, including long term care facilities (LTCs) and long term acute care hospitals (LTACs), was \$4.7 billion

accounting for 87.6% of total *C. difficile* related healthcare expenditures in the U.S.<sup>18</sup> Zimlichman and colleagues (2013) published a paper detailing the total burden of HAIs on the U.S. health system and found that CLABSIs due to MRSA had some of the highest costs at \$58,614 USD ([95% CI, \$16 760-\$174 755]). A 2010 study comparing costs associated with MRSA and Methicillin-Susceptible *Staphylococcus aureus* (MSSA) infection showed unadjusted median costs to be more than twice as high in hospitalized patients with MRSA versus MSSA infection (P <.001)<sup>19</sup>. The authors found that MRSA infections were associated with higher costs across multiple strata including age, infection site, severity of comorbid conditions (Charlson indices); those with MRSA and a Charlson index of 4 or greater had mean adjusted costs roughly \$25,000 higher than those with MSSA<sup>19</sup>. Since these infections serve as a significant source of financial burden and patient morbidity within the health systems, over that past decade policymakers devised laws to mandate the reporting of these infections, often for public dissemination to promote health system accountability, aid in consumer decision-making and improve patient outcomes.

### ***3.3 Public reporting of MRSA and C. difficile in Healthcare Settings***

Laws mandating the public reporting of healthcare-associated MRSA and *C. difficile* have been in place since 2005 and 2008, respectively<sup>11</sup>. As of 2013, 20 U.S. states had laws mandating the reporting of these infections, although not all states report all HAIs uniformly. A study by Herzig and colleagues<sup>11</sup>, showed that after initial laws were passed for the public reporting of these infections, an accelerating trend in the passage of these laws was noted. Nearly half of the laws pertaining to MRSA were

passed during or after 2012, and those pertaining to *C. difficile* were passed in 2013. The authors noted that this trend coincided with the implementation of Centers for Medicare & Medicaid Services' (CMS') Hospital Inpatient Quality Reporting Program(IQR)<sup>11</sup>, a program designed to provide hospital-related data to consumers and financially reward hospitals for reporting their quality-related data. The Hospital IQR program began requiring data submission for HO-MRSA BSI and HO-*C. difficile* infections in January of 2013.<sup>20</sup> Similar to these national reporting policies, the majority of state mandates for HAI reporting include provisions for submission of data to an oversight entity (typically state health departments or NHSN), the dissemination of that data to the public, and the public reporting of facility identifiers that coincide with that data.<sup>21</sup>

While much has been written about *C. difficile* and MRSA BSIs in the healthcare setting, little is known about the effect of mandated reporting laws on these infections. A widely-referenced framework that describes the relationship between reporting healthcare performance related data, indicate that the potential of these reporting laws to stimulate change and improve care is related to various pathways by which these laws impact behavior<sup>22</sup>. Berwick and colleagues<sup>22</sup> relate the impetus of monitoring and reporting to change behavior via a Change Pathway and Selection Pathway. These pathways are reliant on intrinsic motivators within providers and organizations who want to improve care and outcomes and the stimulus of external stakeholders (consumers, payors, etc) to drive improvement by potentially effecting market-share and revenue.<sup>22</sup> An additional pathway proposed by Hibbard et al.,<sup>23</sup> posits that hospital's concern for market share and reputation are actually stronger drivers of change than those pathways suggested in

previous frameworks. This effect was most noted in hospitals which tended to perform more poorly on key quality measures when compared to their peers.<sup>23</sup>

The current body of literature exploring the impact of mandatory reporting on infection rates has yielded mixed findings. A recent systematic review and meta-analysis exploring clinical outcomes, primarily mortality, found that implementing public reporting was associated with a noted improvement in mortality across 10 studies (RR of 0.895 [95% CI 0.79-0.92]).<sup>24</sup> However this review only included one study with an HAI related outcome. More HAI-centric literature has attempted to evaluate the impact of these laws, focusing primarily on CLABSIs. A recent study by Liu and colleagues<sup>25</sup> used longitudinal data to examine the impact of reporting mandates over multiple states. The authors found a reduction in mean CLABSI rates both in anticipation of the laws and long after the laws' implementation. Similar findings were seen in a study by Black and Kim.<sup>26</sup> CLABSI data from Pennsylvania was examined longitudinally with data from 16 states with no reporting mandates used as a control. The researchers found a statistically significant reduction in CLABSI rates, particularly in hospitals with higher baseline rates.<sup>26</sup> A subsequent study by Marsteller et al.<sup>27</sup> found hospitals in states that had pending or recent implementation of mandates had increased participation in a performance improvement program designed to aid in CLABSI reduction. The authors did show a trend toward greater reductions in CLABSI rates in states with reporting mandates, but the differences were not statistically significant. Additional studies examining the impact of these laws to reduce CLABSI rates have not shown an effect, including in point-of-care practices such as antibiotic and blood culture utilization

rates.<sup>28,29</sup> To the authors' knowledge, only one study has been published examining the effects of public reporting on *C. difficile* rates.<sup>24</sup> Studies specifically evaluating the effects of mandatory reporting have shown some positive effects, but also more mixed findings. While a host of studies have examined CLABSI rates and mandated reporting, the only study to date has examined the relationship between public reporting and *C. difficile* rates.

A study from Daneman and colleagues<sup>30</sup> evaluated the impact of hospital public reporting laws on *C. difficile* infections using longitudinal data from 2002 through 2010. Public reporting in this cohort began in September 2008, and the authors used the previous data to model age-specific predicted monthly *C. difficile* rates as if had no public reporting occurred<sup>30</sup>. These 2008 modeled rates were then compared to 2008 observed rates to determine the impact of public reporting during the study period. The authors found a significant reduction in observed *C. difficile* rates in the post-intervention period compared to predicted rates (8.92 per 10,000 patient days compared to 12.16 per 10,000 patient days,  $P < 0.001$  [95% CI 11.35-13.04])<sup>30</sup>. The authors also noted a total reduction of *C. difficile* cases of 26.7% (95% CI 11.35-13.04) over the first year of post-public-reporting implementation.

While these findings show an effect of the Canadian public reporting laws, additional study is needed to determine the effect of reporting mandates in U.S. states has similar impacts on *C. difficile*. Additionally, no studies have evaluated the impact of these laws on MRSA rates in U.S. hospitals. Further investigation is warranted to understand if the impact of these laws seen in previous studies extends to MRSA BSIs,

and coincides with previous findings regarding *C. difficile*. To address this need, our study aims to investigate the impact of state reporting mandates on both *C. difficile* and MRSA in U.S. hospitals.

### **3.4 Methods**

This study used a quasi-experimental design to determine the effect of public reporting mandates on Hospital Onset *C. difficile* (HO-*C. difficile*) and Hospital Onset MRSA blood stream infections(HO-MRSA) in hospitals across the U.S. This design allows for the examination of longitudinal trends in the pre-and-post policy intervention period.<sup>31</sup> A difference-in-difference design is often used to compare changes in outcomes over a time period between two groups, one of which has experienced a particular treatment or intervention.<sup>31</sup> This study design involves a variant in the traditional difference-in-difference in that varying implementation times by state are considered in the analysis. Hospitals which submitted pre-and post-reporting mandate infection data were included to model the effect of the law on infection rates relative to pre-reporting infection rates in states with mandated reporting. This methodology allows for the assessment not only of the impact of the law, but of how these effects may change in the time prior to and after the laws implementation. This model was adapted from a study by Liu and colleagues<sup>25</sup> who examined the impact mandatory reporting on CLABSI rates in ICUs, the results of which were discussed previously.

The study compared the rates of HO-*C. difficile* and HO-MRSA laboratory-identified events (LabIDs) over time in hospitals in states without public reporting to those in states that implemented mandatory reporting during the study period. Hospitals

were selected as the unit of analysis rather than intensive care units (ICUs) because hospitals reported facility-wide *C. difficile* and MRSA data with equal or greater frequency than individual ICUs in this data set as is in keeping with NHSN reporting structure.<sup>32</sup> Additionally, this allowed the capture of infection data across the facility including infections reported outside of the ICU setting. State-level public reporting status was determined through a review of the published literature and legislative documents.<sup>11,12,33</sup> This was set as the date of implementation for this analysis.

### Sample

Infection and hospital level data used for this analysis comes from facilities participating the Prevention of Nosocomial Infections and Cost Effectiveness Refined (P-NICER) survey, completed in 2011 study (National Institutes of Health, RO1NR010107: Stone, P.). Sampling methods and specifics of survey development are described elsewhere.<sup>34</sup> Briefly the P-NICER survey was conducted among infection prevention and control leadership in hospitals that participated in the NHSN. Participation in NHSN at the time of the survey was voluntary if hospitals were not mandated to report infection data. All non-VA hospitals were eligible for inclusion. Researchers who developed and implemented the survey decided against recruitment outside of the NHSN reporting hospitals due to concerns around quality and validity of the data.<sup>34</sup> Participation in NHSN allows for infection event reporting based on specific surveillance criteria as well as pre-defined outcome measures including guidance on determining infection rates, prevalence and risk-adjusted standardized infection ratios (SIR).<sup>32,35</sup> The P-NICER survey captured data on a variety of infection prevention related resources and practices

as well as organizational climate, public reporting and process improvements.<sup>34</sup> A subset of participating hospitals joined the P-NICER NHSN research group and agreed to provide NHSN reported infection data from the *C. difficile*/MDRO reporting module, as well as data regarding CLABSIs.

A total of 975 hospitals were represented in the sample (29% response rate).<sup>34</sup> To determine the generalizability of survey results, the CDC compared characteristics between responders and non-responders and did find some differences in facility characteristics.<sup>34</sup> Non-responders tended to be smaller facilities with fewer admissions and patient days; additionally, differences were noted in geographical region. No significant differences were noted when comparing CLABI rates in respondents and non-respondents which supports generalizability of survey results despite a moderate response rate.<sup>34</sup>

At the time of the survey (2011) approximately 73% of facilities were located in states with mandated HAI public reporting.<sup>36</sup> As part of the NHSN reporting program, hospitals fill out a plan designating measures and frequency of data reporting. Hospitals that chose to participate in the various surveillance modules must use the pre-designated criterion for case definitions of HAIs and subsequent infection reporting.<sup>37</sup> Both active and passive surveillance techniques are encouraged for each appropriate reporting module. Hospitals are also required to complete an annual survey which collects information regarding certain facility characteristics, relevant annual denominator data, infection control practices, and microbiology laboratory practices<sup>38</sup>. Surveillance-defined

infection data are submitted regularly along with the appropriate denominator data according to pre-specified reporting frequencies.<sup>32</sup>

### Outcome Variable

The outcome variables of interest for this study were HO-*C. difficile* LabIDs and HO-MRSA blood stream infection (BSIs) LabID events weighted by patient days as defined in the MDRO and *C. difficile* reporting module in NHSN.<sup>32</sup> HO-*C. difficile* LabID rates were calculated as the number of HO-*C. difficile* LabID events per 10,000 patient days whereas the number of HO-MRSA blood LabID rates are defined as events per 1,000 patient days as defined in the most NHSN reporting module<sup>32</sup>. Rates per patient days for each hospital were evaluated at monthly intervals, the smallest unit of time at which data is aggregated and reported through the NHSN. Typically in federal and state-based reporting, HO-*C. difficile* and HO-MRSA BSIs are reported as LabIDs, but are also reported as surveillance-defined infections separate from the LabID event.<sup>32</sup> These infection definitions are slightly different than the LabID event definition, relying on additional patient level information, including symptomology to meet the infection criteria. Because LabIDs for both HO-MRSA and HO-*C. difficile* rely on the presence of positive diagnostics rather than symptoms or case definition, reporting these events was meant to be less burdensome on the healthcare institution while providing an appropriate proxy for the incidence of surveillance-defined infections.<sup>32</sup> HO-MRSA BSI LabIDs are reported for unique blood specimens that test positive for MRSA greater than 3 days after admission. Similarly HO-*C. difficile* LabIDs are those positive test results (the presence of *C. difficile* organism and or its associated toxin) in unformed stool specimens greater

than 3 days after admission.<sup>32</sup> The guidance from NSHN is clear that reporting for both these LabID results should be on specimens sent for the purposes of diagnostic testing only, to prevent inflated infection counts as a result of screening initiatives or other screening protocols. The use of LabIDs as a proxy for infection surveillance-defined cases of *C. difficile* and MRSA BSIs can lead to some discrepancy between metrics. An evaluation of data submitted to the New York State Health Department in 2009 showed the incident HO-LabID *C. difficile* rate to be 29% higher than that of surveillance-defined hospital onset infections, but overall case-status match for all *C. difficile* infection of 81.3%.<sup>39</sup> The authors also noted this effect was relatively consistent across hospitals included in the study (Pearson Correlation Coefficient = 0.84) and proposed the reporting of LabID events to be a sound and valid measure for the public reporting of *C. difficile* events.<sup>39</sup> A similar study examining MRSA blood LabID reporting to surveillance defined MRSA BSIs showed larger discrepancies than in *C. difficile*, with concordance ranging from 61%-76% in HO-MRSA BSIs.<sup>40</sup> The authors suggested that a majority of the discrepancy lies with the differences in onset definition; for surveillance defined HO-MRSA BSIs any cases on or after day 3 are reported, whereas for HO-MRSA blood LabIDs those specimens positive on or after day 4 are reported.<sup>40</sup> To date, however, this definition has not changed in NHSN reporting and remains a key component in state reporting mandates.<sup>32</sup> Additionally LabID events for both *C. difficile* and MRSA BSIs remain the metric mandated by other reporting initiatives including CMS' Hospital IQR program and Value-Based Purchasing.

### Statistical analysis

Descriptive statistics of sample hospital characteristics were conducted. Testing for differences between groups was completed *t*-tests and  $\chi^2$  for hospitals in reporting states and non-reporting states from 2008 to 2012. Unadjusted trends in HO-*C. difficile* LabID rates and HO-MRSA blood LabID rates were calculated based on mean monthly rates for all hospitals and compared between reporting and non-reporting states.

To model the effects of public reporting mandates on HO-*C. difficile* and HO-MRSA BSI LabID rates a Poisson regression model was selected. This model is well suited for modeling count data and has been used previously to examine the effects of public reporting on incident HAIs<sup>25</sup>. The Poisson model assumes that the mean and variance of the distribution from which observations are counted are equal and that the count data has the possibility of zero counts.<sup>41</sup> Separate models were developed for both *C. difficile* and MRSA count outcomes. As hospital characteristics reported in the NHSN survey are largely independent of temporal trends (e.g. affiliation with an academic medical center and profit status), a hospital (unit-level) fixed effect was used to control for these potential covariates that might confound the relationship between reporting and infection rates. A fixed-effect model was selected because it is robust to unobserved variables, particularly those may differ across units, but are unchanging within units over time. Additionally, admission prevalence rates for these infections were assessed and noted to have an increasing trend over the study period and are likely not associated time-invariant characteristics of the hospitals (figure 3). Therefore, this prevalence rate was added as a covariate in the model. Consistent with NHSN rate calculations, monthly

patient days as defined specifically for *C. difficile* and MRSA (exclusive of units designated with a separate CMS designation as inpatient rehabilitation facilities or inpatient psychiatric facilities and, for *C. difficile* only, infant-designated locations) for a given hospital at a given month was included and will serve as the offset in the model. The use of an offset allows the count data to be modeled as a rate and serves as the main exposure for modeled events.

Indicators representative of the timing of implementation of the law in each hospital's state serves as an interaction term for the presence of the law and being in a reporting state. A series of binary 3-month indicators will be used to account for time differences relative to implementation of the laws during the study period and are represented in the model for each given hospital at a given month. This will allow for the determination of the policy effect with relevance to the timing of implementation of the public reporting law, which vary from state to state. Implementation time (time when data submission was first required) was determined by review of existing literature and review of state HAI websites and/or published legislation.<sup>11,12</sup> To account for trends in *C. difficile* and MRSA BSIs over the study period, monthly indicators were used as a fixed effect for calendar time. The independent variable of interest is  $L_{i,s(t)}$  in the model below where the term is defined as the time difference relative to the law in hospital  $i$ , in state  $s$ , during month  $t$ .  $D_{it}$  serves as the offset and represents the log of patient days respective to facility  $i$  in month  $t$ , while  $\beta_{admprevit}$  is the term representing admission prevalence rates. The coefficient  $\lambda$  is the estimated mean difference in incident rates for the infection of interest relative to non-reporting states in the same time-period. The proposed model is

as follows, where  $Y_{it}$  is the LabID counts for facility $_i$  at month $_t$ ) has a Poisson distribution with a mean  $\mu_{it}$  and  $\beta_i$  and  $\beta_{m(t)}$  are fixed effects for facilities and calendar time, respectively:

$$Y_{it} = \beta_i + \beta_{m(t)} + \beta_{admprevit} + \gamma \log(D_{it}) + \lambda L_{i,s(t)}$$

Appropriateness of the Poisson distribution was assessed using the Chi-square goodness of fit test. Robust standard errors were used to correct for overdispersion in the model, a common problem in Poisson regression often resulting from correlation between responses as is possible here between repeated hospital unit measures over the study period.<sup>41</sup>

The prevalence of zero values in the outcome data was assessed to determine the impact of excess zero counts on the need for further measures to address this. Zero-inflated Poisson regression was used with the same terms and covariates as the original model, but addressing the issue of excess zero counts, by assessing both the binary probability model of zero as the outcome and the Poisson probability delineating the outcome of infection (zero or a count) given an exposure (patient days). In our model, we hypothesize the binary probability to stem from outside factors which may influence hospitals ability to report on *C. difficile* infections during the study period. This may include lack of infrastructure or ability to conduct surveillance and report infections. This was assessed by examining data points to look for patterns which may indicate difficulty with reporting that would predispose the data to excess zeros outside of the risk for infection, particularly serial rates, infection counts, or exposures of zero in hospitals

throughout the study period. The Vuong test for the preference for the zero-inflated model was conducted.

A random effects model incorporating time as a continuous variable and including a hospital random effect was used as a sensitivity analysis. “Reporting” and “non-reporting” status was refined to include hospitals in states with reporting mandates now defined as “non-reporting” if they were in the pre-law period. This allowed us to evaluate baseline IRR between reporting and non-reporting groups as well as the differences in slope, indicating change in infection rates over time between the two “reporting status” groups. The random-effects estimator allows for modeling changes in rates in while accounting for correlation within states.<sup>42</sup>

Coefficients generated from the Poisson model are reported as incidence rate ratios (IRRs) for the relative time interval before or after implementation of the law and are interpreted as change in the mean rates of HO-*C. difficile* and HO-MRSA BSI LabIDs<sup>25,41</sup>. Statistically significant differences from the referent category will be reported for those IRRs with a pre-determined p-value < .05. All analyses were conducted using Stata statistical software version 14.2.<sup>43</sup>

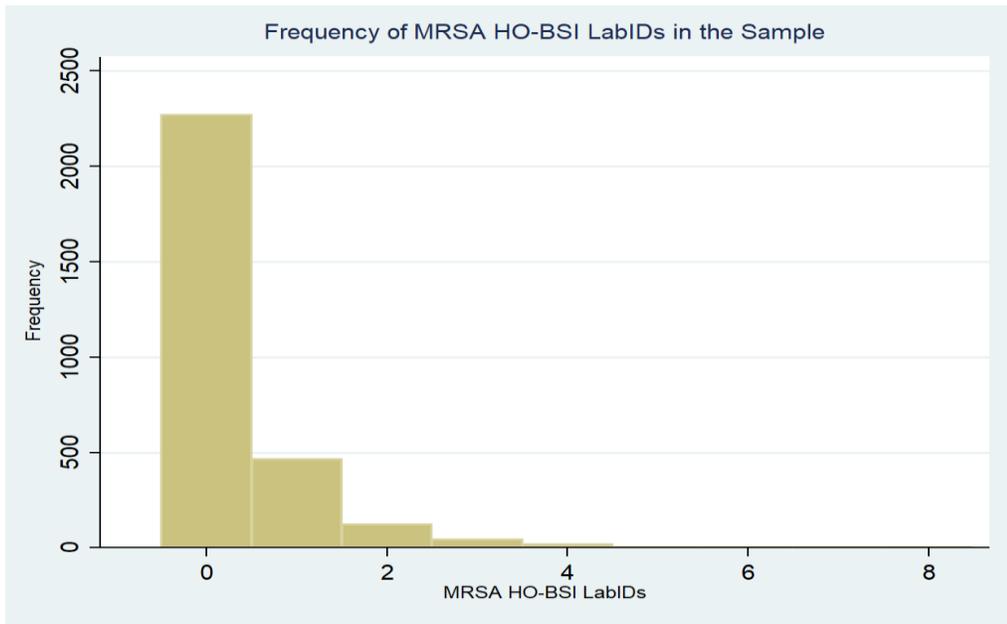
### **3.5 Results**

Early in model determination and testing, we discovered that the data for HO-MRSA BSI LabIDs would not converge in our analysis. Subsequent testing and evaluation hypothesized that the count data within the data set was unable to generate findings given our proposed model, due to an abundance of zero counts and counts of 1

(Figure 1). As a result it was decided that MRSA BSIs will be dropped from the analysis for this study and primary analyses and interpretation of results would center on HO-*C.difficile* events.

Over the study period, specifically from September 2008 to June 2012, 5,454 hospital-months of *C.difficile*-related data were provided by 242 hospitals across the U.S. Of these, 219 hospitals with 4,328 hospital-month observations included complete data relative to our proposed model. These complete cases were used as the final analytical sample. Also during the study period, ten states had *C.difficile* reporting mandates with eight states implementing data reporting during the study period (Figure 2).

**Figure 3. 1 Frequency of MRSA HO-BSI LabIDs in the data set from 2008-2012.**



MRSA, Methicillin-resistant *Staphylococcus aureus*; HO-BSI, hospital-onset blood stream infection; LabIDs, Laboratory-Identified events.

**Figure 3.2 State Public Reporting Mandates and Implementation Dates**

Year of Mandate	State*	Date Data Submission First Required
2008	OH	October 2009
2008	PA	January 2008
2009	CA	January 2009
2009	NY	July 2009
2010	TN	July 2010
2011	RI	January 2011
2012	IL	January 2012
2012	ME	January 2011
2012	NM	January 2012
2012	OR	January 2012

\*Guide to state abbreviations in Appendix B. Dates of mandates and implementation/data submission ascertained from existing literature and review of state legislation or HAI reports<sup>11,12</sup>

Distribution of facility characteristics of the overall sample were different between hospital-month observations in reporting and non-reporting states (Table 1). Proposed time-invariant characteristics including academic medical center affiliation, ownership status, and bed size all differed significantly between reporting and non-reporting states ( $p < .001$ ,  $p < .001$ , and  $p < .001$  respectively). Event level data also differed significantly between the two reporting groups with hospitals in states without mandates reporting fewer *C. difficile* patient days than hospitals in states with reporting mandates (3,840.57 vs. 5798.09, respectively [ $p < .001$ ]). Hospitals in non-reporting states also reported fewer counts of HO-*C. difficile* LabIDs than those in states with mandates (2.25 vs. 4.78 respectively, [ $p < .001$ ]). Both community-onset rates and HO rates were lower in hospitals with reporting mandates in this sample, with HO rates from hospitals under a reporting mandate at nearly half the rate of those without mandates (7.23 vs. 13.48 respectively, [ $p < .001$ ]).

Overall trends in HO-*C. difficile* LabID rates over the study period yielded decreasing rates of events in states with and without reporting mandates and in the total

sample (Figure 3). Analysis of rates was complicated by hospital-months with very few patient days reported, causing significantly elevated rates, in some instances >1000 events per 10,000 patient days. To account for this, the analysis of rate trends was conducted across all three groups (reporting, non-reporting, and total sample) after removing observation months with patient days less than or equal to 25. Removing these the observations diminished the rate extremes seen in the initial evaluations without eliminating smaller hospitals (bed size <100) in the sample. Removing extremely high rates made comparison in trends smoother, yet still allowed for a wide range of hospitals size representation while still discerning differences in

**Table 3.1 NHSN Survey Reported Facility Characteristics by *C. difficile* Reporting Status, 2008-2012**

<i>NHSN Survey Characteristics</i>	<i>Non-Reporting</i>	<i>Reporting</i>	<i>Totals</i>	<i>p-value<sup>†</sup></i>
<i>Number of Hospital Months of Data (mean, SD)<sup>§</sup></i>	616.02, ± 8.64	613.521, ± 9.31	614.068, ± 9.22	<b>p&lt;0.01</b>
<i>Affiliation with Academic Medical Center (hospital months, %)</i>				
<i>Yes</i>	439 (41.53)	1,732 (46.53)	2,171 (45.43)	<b>p&lt;0.01</b>
<i>No</i>	618 (58.47)	1,990 (53.47)	2,680 (54.57)	
	1,057	3,722	<b>Total = 4,779</b>	
<i>Ownership (hospital months, %)</i>				
<i>Non-profit</i>	672 (63.58)	2,391 (63.39)	3,063 (63.43)	<b>p&lt;.001</b>
<i>For profit</i>	113 (10.69)	474 (12.57)	587 (12.16)	
<i>Government</i>	23 (2.18)	167 (4.43)	190 (3.93)	
<i>Not-reported</i>	249 (23.56)	719 (19.06)	968 (20.05)	
<i>Physician Owned</i>	0 (0.0)	21 (0.56)	21(0.43)	
	1,057	3,772	<b>Total = 4,829</b>	

**Table 3.1 NHSN Survey Reported Facility Characteristics by *C. difficile* Reporting Status, 2008-2012 (continued)**

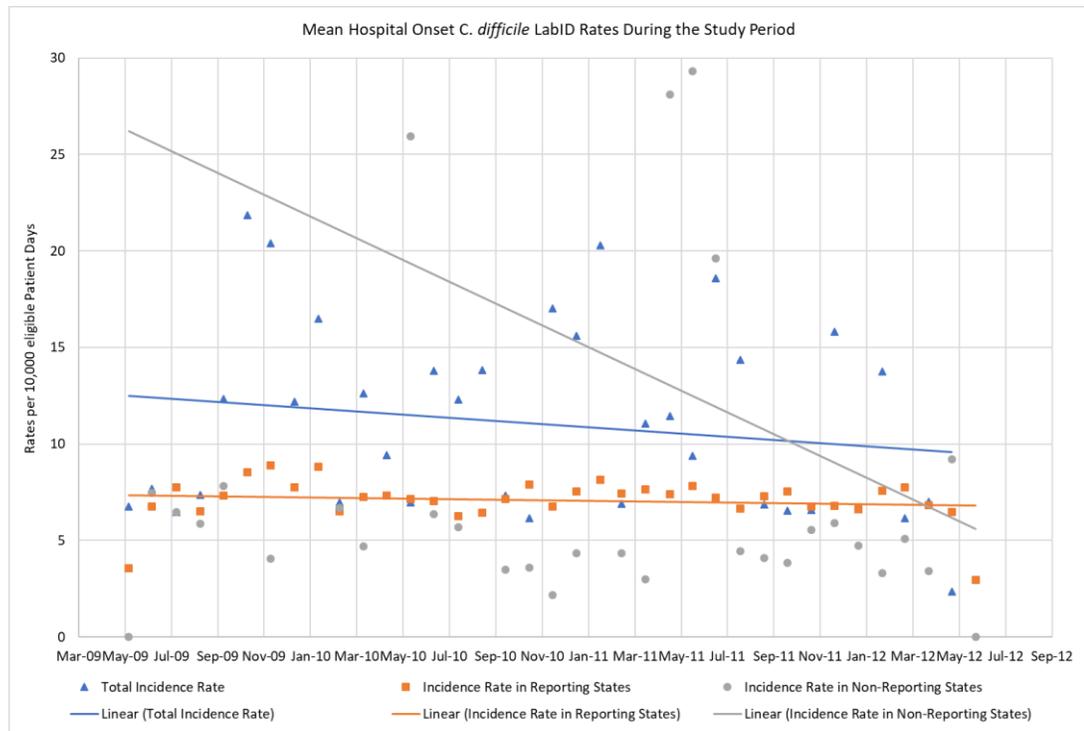
<i>NHSN Survey Characteristics</i>	<i>Non-Reporting</i>	<i>Reporting</i>	<i>Totals</i>	<i>p-value<sup>†</sup></i>
<i>Bed Size (hospital months, %)</i>				
<i>&lt;=25</i>	82 (7.76)	215 (5.70)	297 (6.15)	<b>p&lt;.001</b>
<i>26-100</i>	270 (25.54)	522 (13.84)	792 (16.40)	
<i>101-200</i>	280 (26.49)	1,003 (26.59)	1,283 (26.57)	
<i>201-500</i>	319 (30.18)	1,498 (39.71)	1,817 (37.63)	
<i>501-1000</i>	106 (10.03)	527 (13.97)	633 (13.11)	
<i>&gt; 1000</i>	0 (0.00)	34 (1.57)	34 (1.06)	
<i>Not reported</i>	0	7 (0.19)	7 (0.14)	
	1,057	3,806	<b>Total = 4,829</b>	
<i>Number of C. difficile Patient Days (mean, SD)</i>	3840.57, ± 4155.91	5798.90, ± 5067.12	5483.82, ± 4983.70	<b>p&lt;.001</b>
<i>Number of HO-C. difficile LabIDs (mean, SD)</i>	2.25, ± 3.74	4.78, ± 6.01	4.38, ± 5.78	<b>p&lt;.001</b>
<i>*Rates of HO-C. difficile LabIDs per 10,000 patient days (mean, SD)</i>	13.48, ± 80.46	7.23, ± 6.47	8.19, ± 32.21	<b>p&lt;.001</b>
<i>C. difficile Community Onset Prevalence Rate per 100 admissions (mean, SD)</i>	2.85, ± 14.29	0.50, ± 1.71	0.86, ± 5.88	<b>p&lt;.001</b>

<sup>†</sup>P-values in bold indicate statistical significant at  $\alpha < .05$ . All continuous variables tested for normality using Shapiro-Wilk W test for normality. All values  $p < .001$ . Differences in reporting/non-reporting continuous variables evaluating using Wilcoxon Rank Sum test. Differences in categorical variables testing using Chi-square test. HO-C.difficile LabID rate adjusted for patient days  $\geq 25$  days. NHSN, National Healthcare Safety Network; HAI, Healthcare-associated infection; *C. difficile*, *Clostridium difficile*; MRSA, *Methicillin-resistant Staphylococcus aureus*; SD, standard deviation, HO, Hospital Onset. \*Rates exclusive of facilities that reported less than 50 (73 observations) *C. difficile* patient days as defined by NHSN.

trends. Additionally, trends were evaluated beginning with data from July 2009, as observations prior to those were largely count values of zero and represented on 0.5% of the total hospital-month sample. Overall larger declines were seen in non-reporting states during the study period when compared to hospitals in reporting states and the overall sample. A much more minimal trend was noted in reporting states with mean rate for HO-C. *difficile* LabIDs lower in the third quarter of calendar year 2009 (6.70 events per

10,000 patient days) compared to the second quarter of calendar year 2012 (5.41 events per 10,000 patient days). Evaluation of community-onset prevalence rate yielded an increasing rate over the entire sample during the study period (Figure 4).

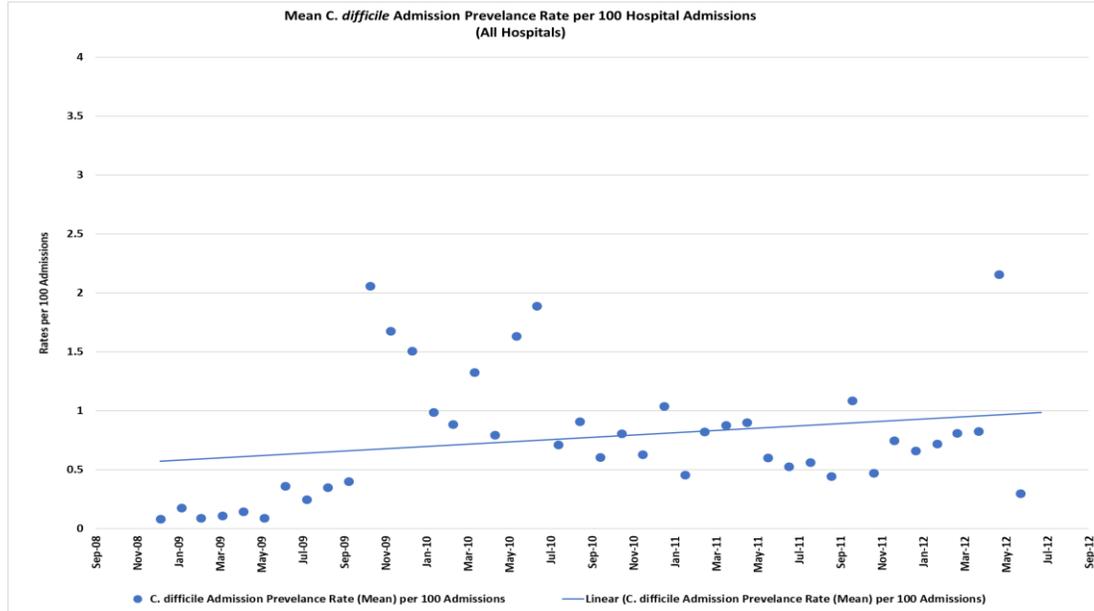
**Figure 3.3 Mean HO-C. difficile LabID rates by Month**



*Effects of State HAI Mandatory Reporting Laws*

Zero-inflated Poisson regression models with unit-level indicator variables for hospital fixed effects were used to determine the change in mean rates relative to the implementation of state reporting mandates.

**Figure 3. 4 Mean Community-Onset Prevalence Rate for *C. difficile* Infection**



Community-Onset Prevalence defined as *C. difficile* LabID identified on hospital day 3, or earlier.

The Vuong test yielded a p-value of <.002, indicating a preference for a zero-inflated model given this data set. IRRs were interpreted as change in mean rates in the modeled time interval as compared to the reference group, 30-to-28 months prior to the law’s implementation.

With the exception of 3-to-5 months after the law, all IRRs from post-implementation time-periods were less than 1.0, indicating a decreasing trend in HO-*C.difficile* LabID rates when controlling for secular time trends and hospital characteristics. However, in both the pre-and-post time periods, all but one of the rate ratios were not statistically significant (Table 2). Similar trends were noted prior to the law’s implementation, specifically at 18-to-16 months before the law (IRR 0.568, p = 0.034). This interval period is associated with a 43% lower mean rate in HO-*C. difficile*

LabIDs compared with 30 to 28 months prior to the law's implementation. An IRR of 0.452 was noted with in the farthest time distance interval from the law, 51-to-53 months post-implementation although this was not statistically significant. Hospitals in non-reporting states had an average mean rate 3.6 times higher than those in reporting states 30 to 28 months prior to the law (IRR 3.578,  $p < 0.001$ ). This difference is also reflective of the findings in the bivariate analysis presented in Figure 3.

### *Sensitivity Analysis*

In addition to the zero-inflated Poisson regression a standard Poisson regression with hospital and time fixed effects was modeled to ascertain the robustness of the zero-inflated Poisson model. Results of the panel data modeled with the standard Poisson yielded similar results with overall trends to decreasing IRRs after the implementation of the law, but none of them with statistically significant differences. The 18-to-16-month time interval prior to the law did remain statistically significant with an IRR of 0.616 indicating a 39% lower mean rate in this time-period compared to 30-to-28 months before the law.

An additional sensitivity analysis was conducted by fitting a random effects model interacting hospital month, as a continuous variable, with reporting status. Reporting status here was refined and modeled as all hospitals in non-reporting states and hospitals in the pre-reporting period as "non-reporting" status. The model was used to determine the difference between the rate of infection increase from month-to-month in reporting compared to non-reporting groups. Results from the model indicate that over

time the infection rate of the non-reporting status group changes at the same rate compared to the non-reporting group, although these results were not statistically significant (IRR 1.002,  $p = 0.304$ ).

**Table 3.2 Results of Zero-Inflated Poisson Regression: Effects of HAI Mandates in Reporting States**

<i>Month Time Interval</i>	<b>IRR</b>	<b>Robust Std. Err.</b>	<b>P-value*</b>	<b>95% Confidence Interval</b>
<i>Reference -30 to -28 Months Prior to Law Implementation</i>				
<i>27 to 25 months prior</i>	1.100	0.286	0.714	0.660, 1.832
<i>24 to 22 months prior</i>	0.885	0.233	0.642	0.529, 1.481
<i>21 to 19 months prior</i>	1.020	0.250	0.936	0.630, 1.650
<i>18 to 16 months prior</i>	0.568	0.152	<b>0.034</b>	0.337, 0.956
<i>15 to 13 months prior</i>	1.035	0.292	0.904	0.594, 1.799
<i>12 to 19 months prior</i>	0.993	0.263	0.978	0.590, 1.670
<i>9 to 7 months prior</i>	0.851	0.263	0.601	0.464, 1.560
<i>6 to 4 months prior</i>	0.942	0.267	0.834	0.541, 1.641
<i>3 to 1 months prior</i>	0.912	0.266	0.752	0.515, 1.614
<i>0 to 2 months after</i>	0.989	0.264	0.968	0.586, 1.670
<i>3 to 5 months after</i>	1.168	0.367	0.621	0.631, 2.164
<i>6 to 8 months after</i>	0.866	0.288	0.665	0.451, 1.661
<i>9 to 11 months after</i>	0.864	0.305	0.678	0.433, 1.724
<i>12 to 14 months after</i>	0.836	0.295	0.612	0.419, 1.668
<i>15 to 17 months after</i>	0.877	0.328	0.726	0.421, 1.827
<i>18 to 20 months after</i>	0.816	0.307	0.589	0.390, 1.706
<i>12 to 23 months after</i>	0.851	0.338	0.685	0.391, 1.854
<i>24 to 26 months after</i>	0.816	0.329	0.614	0.371, 1.798
<i>27 to 29 months after</i>	0.830	0.350	0.659	0.364, 1.896
<i>30 to 32 months after</i>	0.791	0.335	0.581	0.345, 1.816

**Table 3.2 Results of Zero-Inflated Poisson Regression: Effects of HAI Mandates in Reporting States (Continued)**

<i>Month Time Interval</i>	<b>IRR</b>	<b>Robust Std. Err.</b>	<b>P-value*</b>	<b>95% Confidence Interval</b>
<i>33 to 25 months after</i>	0.869	0.390	0.754	0.361, 2.093
<i>36 to 38 months after</i>	0.845	0.381	0.709	0.350, 2.044
<i>39 to 41 months after</i>	0.978	0.472	0.963	0.380, 2.517
<i>42 to 44 months after</i>	0.834	0.561	0.788	0.223, 3.119
<i>45 to 47 months after</i>	0.616	0.442	0.500	0.151, 2.517
<i>48 to 50 months after</i>	0.957	0.643	0.948	0.256, 3.573
<i>51 to 53 months after</i>	0.452	0.471	0.446	0.059, 3.487
<i>non-reporting</i>	3.578	0.768	<b>0.000</b>	2.350, 5.449

Zero-Inflated Poisson Regression was used. IRRs are exponentiated coefficients controlling for time and hospital fixed effects as well as community onset prevalence rates (IRR not shown). Dependent variable modeled above is the count of HO-*C. difficile* LabIDs per 10,000 patient days as the exposure (offset) variable in the model. IRRs, Incident Rate Ratios; HO-Hospital Onset; *C. difficile*, *Clostridium difficile*; Robust std. err, Robust Standard Errors. \*p-values in bold are statistically significant at the  $\alpha=.05$  level.

### **3.6 Discussion**

To our knowledge this is the first study that models the longitudinal effects of public reporting laws on *C. difficile* infection events in U.S. hospitals. While the effects of these laws on average rates, failed to reach statistical significance in the model, important trends were noted in the findings. Additional methodological implications for analyzing the impact of these laws were also apparent from study results.

Similar to previous work examining HAIs, lower average rates of HO-*C. difficile* LabIDs were noted in the months after the laws' implementation.<sup>25,26,30</sup> Declining rates of HO-*C. difficile* infection both during and after the study period have been observed in other literature, as are the noted increasing trend in community-onset *C. difficile*

infection, which in this sample, is noted on hospital admission or shortly after.<sup>1,44</sup>

Although not statistically significant, the general trends appreciated in the data may reflect the effect of these laws, particularly as this model controlled for the secular time trend in HO-*C. difficile* rates. The only lower rate that was statistically significant in reporting institutions was noted in the time frame of 16-to-18 months prior to the laws' implementation. Upon a more granular review of the data, it was noted that data which reached this far back in time was from the same reporting state and institution as that which populated the reference time interval (30-to-28) months prior to the law). This effect is likely an incidental finding of a single institution being compared to its own previously reported data, albeit possibly in anticipation of the law. While the model did control for correlation between repeated hospital observations, its possible that in addition to the impending law a time-variant extenuating factor or unobserved covariate affecting that institution was implemented. These may include additional *C. difficile* prevention programs including CDC supported state *C. difficile* collaborative groups or other more local initiatives taken irrespective of the presence of state mandate.<sup>12</sup>

Interestingly, the IRR for HO-*C. difficile* LabIDs 50-to-53 months after implementation of reporting mandates indicates a long-term reduction in these infections when compared to mean pre-law rates. This may be an indicator that the strength of these laws is more in their ability to impact hospitals over the long term, rather than stimulating immediate change. Similar findings were noted in previous studies<sup>25,27</sup> when examining CLABSI rates in relation to state reporting mandates. Although the *C. difficile* study by Daneman et. al, did not report findings beyond 20 months post-reporting, they too reported prolonged reductions in observed cases compared to predicted cases as result of reporting

mandates.<sup>30</sup> Although our finding was not statistically significant, it may suggest that these laws have long-standing impact which warrant further longitudinal investigation

Review of this data yielded many zeros counts, some across the same institution for the entirety of the longitudinal observations. These zero values included both patient days and outcomes, suggesting that hospitals may have had difficulty reporting infections or reporting the proper metrics associated with NHSN surveillance. While support for implementation of NHSN reporting exists, many hospitals may still have struggled with or questioned surveillance definitions, data validation and implementation of reporting infrastructure, causing incorrect reporting or missing. These struggles have been described in other literature<sup>45,46</sup> and may reflect a difficulty with implementation of public reporting. These effects may represent one possibility for the over representation of zeros in the data, justifying the need for the Zero-Inflated Poisson model.

There may be several reasons why little statistically significant effect was seen on HO-*C. difficile* LabIDs resulting from state HAI reporting mandates. First these affects may be attenuated by other additional policy interventions including federal policies. During the study period, the CMS Hospital IQR was in effect and reporting of *C. difficile* infections was slated to begin in January of 2013.<sup>12</sup> These larger federal policy initiatives may have stimulated additional process improvements during the study period that contributed to declining rates of *C. difficile* in hospitals and made the effect of state mandates difficult to isolate. Additionally, *C. difficile* infections may have been affected by prior state reporting mandates for other HAIs. Before the enactment of reporting laws specific to *C. difficile*, multiple states had mandatory reporting of CLABSIs which may

have stimulated additional efforts at curbing HAI infection rates. Any novel process improvements or programs that are put in place for the management of specific HAIs may stimulate additional improvement in other HAI rates. Prior studies<sup>45-47</sup> have shown that any public reporting mandates tend to affect hospitals as a whole, rather than just focusing on one particular outcome, and it may be that these effects are difficult to separate from specific effects of a singular HAI reporting mandate.

### *Implications for Policy and Future Research*

HAI reporting mandates have gained momentum over the past decade and have been evaluated in the literature regarding their impact on health systems, process improvements, and outcomes. However, many of the studies attempting to delineate an impact on specific infection rates have yielded mixed results. Ours is the first study to examine the effect of specific *C. difficile* reporting mandates in U.S hospitals, and does illuminate specific policy implications.

While the findings in this study didn't isolate a statistically significant effect on *C. difficile* outcomes, it does show a potential trend toward reductions in these infections. Yet, it may still be difficult to ascertain how and why these effects occur. Some studies have attempted to examine specific process improvements and organizational impacts resulting from these mandates in hopes of better understanding the relationships between reporting mandates and decreased infection rates. Many of these studies have also yielded mixed findings noting that process measures may or may not be affected by these policies.<sup>27,28</sup> However, these impacts may not readily translate to changes in infection

rates.<sup>48</sup> While mediating factors were not a focus of this study, understanding the role of process improvements and point-of-care changes may be an important component of how these laws affect hospitals, and ultimately outcomes, and should be examined in future research.

The methodological considerations of this study lend themselves well to future mandated reporting policy research. Adapted from a model put forward by Liu and colleagues<sup>48</sup>, our model aimed to isolate the effects of the law on *C. difficile* infections at varying time distances before and after its implementation. This approach is valuable in that it allows investigators to examine trends in the effects of the law, particularly if reductions in infection rates persist, plateau or diminish over time. The importance of these findings for policy makers lies in the understanding that broad policy initiatives, such as state reporting mandates, may have stronger impacts in time points leading up to or immediately after the law as has been seen in previous studies.<sup>25,27</sup> This analysis may also yield longer term policy impacts that may have sustained effects on outcomes over many years. These considerations are key to crafting and evaluating broad policy mandates. If its established that the effect of reporting mandates are likely to be strongest in the months surround their implementation, then focused research on how, specifically, health systems respond to those within that critical period is essential. If the converse is true, indicating more long-term impacts from these state mandates, understanding sustained patterns of change and how these laws have re-shaped hospitals would be essential as well. In either case, defining the outcomes associated with these laws is as

important as understanding what is likely a multifactorial response by hospitals to their implementation.

### ***3.7 Limitations***

There are several limitations to this study. As previously discussed, the data set likely did not have sufficient diversity in counts for its HO-MRSA BSI LabID for the proposed model to converge, leading to the inability of the authors to model the laws' effects on this outcome. While MRSA findings would have been complementary to the findings related to *C. difficile* ultimately the difference in these two infections did not represent a new or different process under investigation that was specific to MRSA. Our sensitivity analyses confirmed the *C. difficile* results noted in the final model. However, it is likely that data limitations were also applicable to the *C. difficile* analysis, primarily in the lack of available pre-reporting data. Reporting of *C. difficile* to NHSN began in March of 2009. This may have contributed to a lack of pre-data and inaccuracies in reported data as hospitals scaled up reporting programs. While some pre-reporting data was present, a larger panel of observations may have allowed us to detect a stronger effect of these reporting mandates relative to their implementation time. Although this was self-reported data and based on surveillance criteria it is possible that count and denominator data was not accurate for every observation in this data set. This could contribute to the underestimations in assessing the differences between pre-and-post-implementation rates. Some states do have data validation structures in place, but this likely would have limited our analysis and, thus, we did not focus only on observations from those states. Also, the data used in this analysis is from 2008 to 2012, representing

a span of five years between data collection and this study. Ongoing changes in the epidemiology *C. difficile* coupled with additional state reporting mandates and new federal policy initiatives may diminish relevance to the current HAI policy environment. However, the majority of *C. difficile* reporting mandates were implemented during the study time-period or within one year of the final observation months.<sup>12</sup> This allowed for modeling of the effects of those laws during the critical time before, during and after implementation. The number of hospitals included in this study is a subset of participants in the P-NICER survey.<sup>34</sup> While external validity is a potential limitation, the original authors of the survey noted that comparison between respondents and non-respondents yielded similar CLABSI rates between the two groups, despite difference in other hospital characteristics.<sup>34</sup> Finally, while our model controlled for secular trends in infection rates and time-invariant hospital characteristics, additional process improvements and programs implemented during the study period across differing hospitals may have confounded effects of the state mandates on our outcome measure.

### ***3.8 Conclusion***

Most US states now have HAI reporting mandates in place. This study is the first to examine the impact of these laws on *C. difficile* infections in US hospitals. Findings may suggest a trend toward a reduction in rates, particularly after the law's implementation, although these changes were not statistically significant. Additional research is needed to examine trends in infections associated with these laws and by what mechanisms are these laws impacting hospitals to improve HAI related patient outcomes.

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**CHAPTER 4: EXAMINING THE RELATIONSHIP BETWEEN THE  
MANDATORY REPORTING OF HEALTHCARE-ASSOCIATED  
INFECTIONS AND ORGANIZATIONAL CLIMATE IN U.S. HOSPITALS:  
IMPLICATIONS FOR POLICY AND ORGANIZATIONS**

Dissertation

Paper Three

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## ***Abstract***

***Background:*** Over the past decade, various policy initiatives have been implemented to reduce the burden of healthcare-associated infections (HAIs). Mandating hospitals to publicly report HAI performance data is a key legislative policy aimed at stimulating improvement and reducing HAIs. Yet, little is known about how these state level reporting mandates galvanize the organizational changes in hospitals needed to reduce HAIs. The organizational climate of hospitals is the perception culture and specific domains such as leadership, communication, and social norms. ***Purpose:*** The purpose of this study is to examine the relationship between state HAI public reporting mandates and specific domains of organizational climate, as they relate to infection prevention.

***Research Design:*** This cross-sectional study uses organizational climate variables from the Prevention of Nosocomial Infections and Cost-Effectiveness-Refined (P-NICER) Survey. Infection Prevention organizational climate composite scores are developed from the previously validated Leading a Culture of Quality for Infection Prevention (LCQ-IP) instrument nested within the P-NICER survey. ***Methods:*** Bivariate analysis was used to compare hospital characteristics in both reporting and non-reporting states. Multiple linear regression is used to determine the effect of public reporting mandates on organizational climate scores for the following climate-related concepts: Psychological Safety, Prioritization of Quality, Supportive Work Environment, and Improvement Orientation. These effects are examined while controlling for hospital level characteristics. ***Results:*** There was no statistically significant difference in mean

organizational climate composite scores between hospitals in states with and without public reporting mandates. However, facility bed size and the presence of an infection control director did have statistically significant associations with composite scores. Additionally, hospitals in public reporting states reported a slightly higher sense of urgency related to HAIs compared to those not in public reporting. **Conclusion:** Although no statistically significant effect of public reporting was seen on organizational climate composite scores, other key hospital and infection prevention program characteristics did show an effect. Policy makers and researchers would benefit from understanding more about how organizational climate domains are impacted by these factors. New directions for empirical investigation are needed to better understand their significance in improving HAI-related outcomes.

#### **4.1 Introduction**

Healthcare-associated infections (HAIs) are a significant source of morbidity and mortality in hospitalized patients in the United States. The U.S. Centers for Disease Control and Prevention (CDC) estimates that approximately 722,000 HAIs occur annually and contribute 75,000 deaths.<sup>1</sup> Device-associated infections including central line-associated blood stream infections (CLABSIs) and others often cause severe complications in patient. Similarly, infections caused by *Clostridium difficile* (*C. difficile*) and multidrug resistant organisms (MDROs) such as Methicillin-Resistant *Staphylococcus Aureus* (MRSA) contribute to poor patient outcomes and prolonged hospitalizations.<sup>2,3</sup>

Mandated public reporting of HAI-related outcomes has gained momentum as a policy initiative over the past decade.<sup>4</sup> These policies are directed at improving hospital performance and empowering consumers to make informed choices about their care by mandating hospitals to report HAI performance data to various state and federal stakeholders. The evidence of their effectiveness in stimulating a reduction in HAIs remains mixed. Policy makers and healthcare facilities understand that, along with public reporting, additional factors intrinsic to an organization , such as organizational climate, can play a role in changing behavior and improving performance around patient safety and HAIs.<sup>5-7</sup>

Organizational climate, or shared perceptions of various features and attributes of an organization and its functioning, has at times been associated with improved outcomes

and processes for staff and patients.<sup>8</sup> Yet, little is known about the relationship between mandated public reporting of HAI performance data and specific domains of organizational climate as they related to infection prevention (IP) within the hospital setting. The aim of this study is to explore the relationship between state-mandated public reporting of HAI-related data and IP organizational climate. Understanding these relationships will guide future research to examine the pathways by which organizational climate domains impact the outcomes of HAIs within the structure of public reporting policy.

#### ***4.2 Background***

HAIs in U.S. hospitals continue to be a significant source of morbidity and mortality, as well as a prominent policy issue for various stakeholders concerned with patient safety and quality of care.<sup>1,9</sup> These infections are estimated to contribute to 75,000 deaths per year in this country and cost health systems in excess of \$28.4 to \$33 billion dollars annually.<sup>1,10</sup> Over the past decade, growing patient safety and quality of care concerns have led to HAI performance data being used in payment incentive programs and reimbursement.<sup>9,11</sup> These efforts center on infections associated with medical devices including central venous catheters, indwelling urinary catheters and ventilators, as well as surgical site infections and those caused by *C. difficile* and MRSA. Evidence has shown that more than half of device-associated infections could be prevented with the use of current evidence based guidelines, yet some organizations continue to struggle with reducing infection rates despite efforts to implement prevention initiatives.<sup>1,12</sup> Infections such as those attributable to *C. difficile* and MRSA are not

readily attributable to devices but are known to be transmitted within the healthcare environment. Both infections can cause serious complications in the hospitalized patient and contribute to excess financial burdens on institutions.

The past two decades have yielded growing concern over preventable HAIs. These infections garner attention in the mainstream media and serve as drivers for policymakers and administrators to address key issues around patient safety and quality of care. HAIs play a central role in U.S. federal patient safety policy and have been a national target for improvement since 2013, with a goal of total elimination by 2020.<sup>9</sup> Federal and state-level lawmakers have used these infections as a means of monitoring performance and driving improved performance among healthcare institutions.<sup>11</sup>

One policy intervention that has been widely used to promote the reduction of HAIs has been public reporting of hospital and statewide HAI-related data. Beginning in the mid-2000s, state-level policy began to mandate the public release of HAI data in a variety of formats and for varying infections. Public reporting of healthcare and health system performance measures has been a part of federal policy and guidelines since the 1980s.<sup>13</sup> In a 2012 evidence report for the Agency for Healthcare Research and Quality (AHRQ), Totten and colleagues<sup>13</sup> describe public reporting as “data, publicly available or available to a broad audience free of charge or at a nominal cost, about a health care structure, process, or outcome at any provider level (individual clinician, group, or organizations [e.g., hospitals, nursing facilities]) or at the health plan level” (p.3).

Public reporting of HAIs has gained momentum over the past decade. While hospitals have tracked HAI-related data for many years, mandated reporting of data

through state-level legislative initiatives has only gained traction over the past decade.<sup>14</sup> This primarily involves requiring hospitals to report their HAI data to state government bodies. Public reporting of HAI data can be mandatory or voluntary; most states in the U.S. (37 states as of 2013) now have some type of state-level HAI-related public reporting legislation, with a significant amount of that data reported at the federal level as well.<sup>4</sup> HAI data collection in the U.S. is facilitated by the National Healthcare Safety Network (NHSN), a national HAI surveillance system managed by the CDC. NHSN receives reported HAIs from healthcare institutions around the country who follow specific surveillance criteria for the identification and reporting of certain these infections. Aggregate data from this system is available to the public through federal channels (i.e., Hospital Compare Website), and allows for uniform definitions for infection surveillance as well as some risk-adjusted comparison.<sup>15,16</sup> Centers for Medicare and Medicaid Services (CMS) uses the same HAI-related data published on their Hospital Compare Website in a variety of payment reduction plans, including the HAC Reduction Program, the Hospital Inpatient Quality Reporting Program and incentive programs such as Value Based Purchasing.<sup>11,17</sup>

These policies are directed at improving hospital performance and empowering consumers to make informed choices about their care by mandating hospitals to report performance data to various state and federal stakeholders. The evidence on their effectiveness in stimulating a reduction in HAIs remains mixed. Studies evaluating the impact of public reporting of HAI data have shown mostly mixed findings<sup>18-20</sup>, and most of these studies focus only on a singular infection: CLABSIs. Some studies have shown

a longitudinal reduction in CLABSI rates across various populations related to the implementation of these laws.<sup>20-23</sup> However other studies employing other methodologies have shown no effect of these laws, particularly with regard to CLABSI as well as point-of-care practices.<sup>18,19,24,25</sup> This mix of findings is consistent with the larger body of research examining the relationship between public reporting and patient outcomes.<sup>26-28</sup> The inconsistency in these findings suggest that larger systemic and organizational factors impact their implementation and efficacy in promoting patient safety and improvement.

Berwick et. al,<sup>7</sup> contend that in order for the reporting of performance data to improve organizational processes and quality of care, the environment within organizations must be conducive to change. Some key characteristics of these organizational environments include leadership, investment in time and change management, communication, and ongoing evaluation.<sup>7</sup> Similarly, Marshall, Romano, and Davies<sup>29</sup> describe the impact that public reporting can have on organizational culture by empowering change-makers. The authors argue that strengthening the value of quality improvement and improving accountability are key factors impacted by publicly reporting data. Additionally, they discuss the impact of public reporting on guiding quality of care social norms within healthcare organizations.<sup>29</sup> They describe these effects as potentially long-lasting, but only in the context of organizational factors that promote behaviors that emphasize patient safety and improving patient.<sup>29</sup> Few studies have examined the effect of public reporting on these organizational-level processes and characteristics. Thus policy makers and healthcare entities may fail to appreciate that

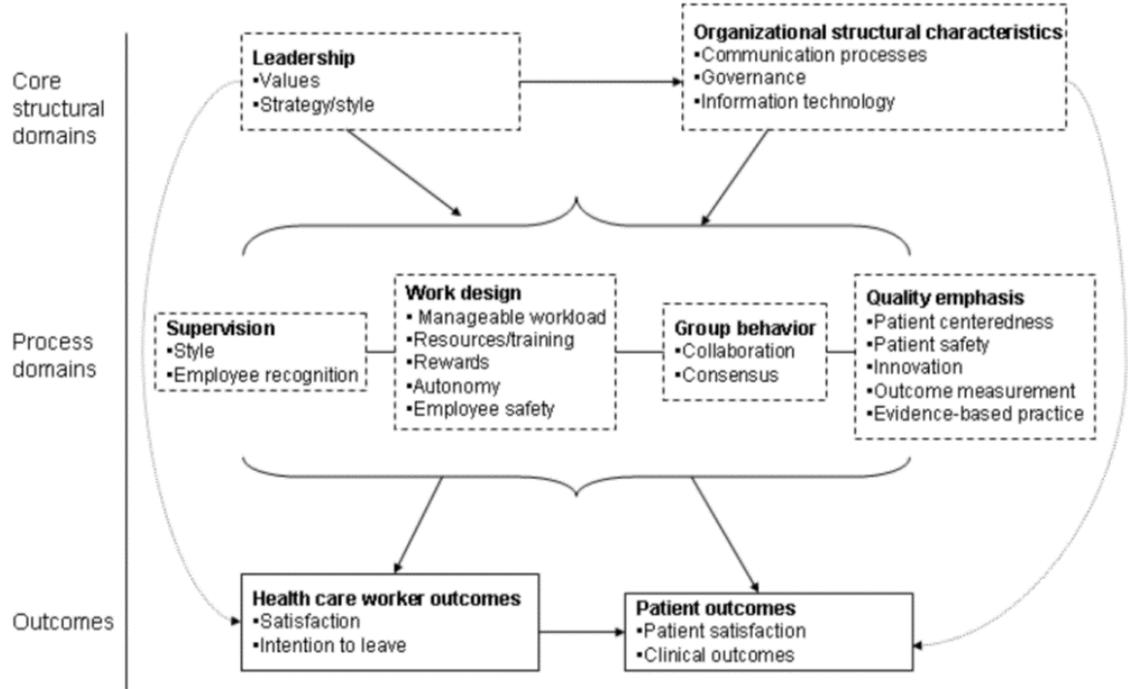
both public reporting and key organizational factors can play a role in changing behavior and improving patient safety and HAI performance.<sup>5-7</sup> These key organizational factors have been captured in measures of organizational climate. Organizational climate, or shared perceptions of various features and attributes of an organization and its functioning, has been found to be associated with improved outcomes and processes for staff and patients.<sup>8</sup> Yet, little is known about the relationship between mandated public reporting of HAIs and organizational climate in hospitals.

In the Institute of Medicine's 2000 report *To Err is Human*,<sup>30</sup> the report's authors determined that organizations must understand why and how preventable errors or adverse events happen within healthcare systems. Causes of adverse events were multifactorial and were not solely attributable to individual healthcare providers.<sup>30</sup> The authors contend that specific conditions including the working environment, guidance around acceptable performance, and proper communication all contribute to improvements in quality of care and reduction of errors.<sup>30</sup> In subsequent literature the notion of organizational climate has been discussed as the perception of the culture within an organization including characteristics such as leadership, communication, and norms.<sup>8</sup> It has been argued that since climate is a representation of perceptions of an organization, it can be more easily measured and evaluated than that broader notion of culture.<sup>8</sup> Climate may be an effective way to capture various leadership and process domains within an organization and assess their impact on the overall functioning or outcomes within that organization. Stone and colleagues<sup>31</sup> put forward an Integrative Model of Organizational Climate (Figure 1) which incorporates structural and process

domains and their relationship to outcomes in both healthcare workers and patients. These domains comprise a host of interrelated concepts including leadership, communication processes, work environment, innovation and collaboration.<sup>31</sup> The effect of these structural domains on outcomes is mediated by process domains that directly impact worker related outcomes and patient outcomes. In 2007, MacDavitt<sup>8</sup> and colleagues published a systematic review evaluating the domains described in this model and their impact on patient outcomes. Findings from the review suggested that some organizational climate domains including work environment, collaboration, and the availability of technology were associated with lower mortality, but these results were not consistent across studies.<sup>8</sup>

Although the Integrative Model of Organizational Climate was not specifically developed for infection prevention (IP), many of its domains are components of comprehensive IP programs. The impact of public reporting mandates on organizational climate domains related to IP programs has been explored, primarily in qualitative studies. Stone and colleagues<sup>32</sup> conducted interviews as part of a mixed-methods study to evaluate these impacts on hospitals in California. They found an overall increase in infection prevention awareness and priority within hospitals as a result of these mandates.<sup>32</sup>

**Figure 4.1 The Integrative Model of Organizational Climate**



*This model provides a framework for how organizational climate, can impact patient care related outcomes by associating core structural domains with potential mediating processes that affect measurable outcomes. Developed by Stone et. al<sup>31</sup>*

A study from Uchida and colleagues<sup>33</sup> using the same data, but centering on quality improvement factors, broadly describes the state of IP in California hospitals using qualitative interviews of nurse leaders, hospital epidemiologists, infection prevention directors, and other administrators across six hospitals. Results of the analysis specifically identified the emergence of mandatory public reporting as a primary theme among respondents, with a subtheme that indicated that public reporting had led to a heightened awareness of infection prevention within the hospital. A separate, theme of organizational climate emerged related to IP and highlighted the importance of increased collaboration and teamwork for HAI prevention.<sup>33</sup> Participants also reported additional

IP climate components such as improved communication within the hospital and renewed emphasis on quality of care.<sup>33</sup> In a later qualitative study by Stone et. al,<sup>34</sup> interviews with multiple stakeholders across the country to examined the impact of federal and state policy on health departments and hospitals specifically with regard to infection prevention efforts. Participants included infection preventionists, state health department officials, hospital administrators and epidemiologist. Findings were similar to previous work regarding the impact of reporting mandates, but less so in differentiating between state and broader federal mandates.<sup>34</sup> Participants noted that these laws increased collaboration between hospitals and health departments, and intensified the focus on HAI reduction in hospitals.<sup>34</sup>

It's clear from this prior work that these policy mandates strengthen the importance of HAI prevention in healthcare organizations, but less is known about their association with key organizational climate domains that relate to IP programs. It remains unclear whether these laws impact patient outcomes by impacting key organizational climate domains which then contribute to improved enhanced infection prevention. While previous studies are valuable in their contribution to the public reporting and HAI literature, they do not explore the specific relationship between public reporting mandates and IP organizational climate domains. Given the number of states that have implemented reporting mandates, understanding the association between public reporting and the climate of organizations is crucial to exploring potential pathways by which these laws improve outcomes. This study used survey data assessing IP organizational climate domains to examine this issue. We proposed that higher

organizational climate scores will be associated with the presence of public reporting mandates. This study serves as a foundation for understanding the impact of public reporting mandates on specific IP organizational climate concepts and build on previous work that has explored this relationship in a more qualitative fashion.

### ***4.3 Methodology***

The data for this study came from the Prevention of Nosocomial Infections and Cost-Effectiveness-Refined (P-NICER) survey (National Institutes of Health, RO1NR010107: Stone, P.), a component of a mixed-methods study capturing the complexities and structure of infection prevention programs in the U.S. and subsequently informing the development of the survey tool.<sup>32,35,36</sup> A subset of the P-NICER survey, the Leading a Culture of Quality for Infection Prevention (LCQ-IP), was developed and validated for the purposes of measuring organizational climate variables related to HAIs and IP.<sup>37</sup> The primary analysis in this study will examine the association of the validated IP organizational climate domain composite scores and the presence of state public reporting mandates.

### ***4.4 Sample***

All non-Veteran's Administration hospitals who reported to NHSN during the study period were eligible for participation in the P-NICER study. One infection prevention director or leader from each participating institution was invited to participate in the web-based survey in 2011. A modified Dillman technique was used for recruitment as well as lottery-based incentives to promote participation.<sup>36</sup> A total of 1064

hospitals were represented in the survey (29% response rate) with 975 of hospitals providing complete data on the organizational climate measures.<sup>37</sup> Hospitals completing the survey were invited to participate in the P-NICER NHSN research group.<sup>36</sup> This group agreed to provide researchers with access to device-associated infection data as well as *C. difficile* and MRSA data reported to NHSN for the previous 6 years (2006-2011).<sup>36</sup> Additionally, data from the NHSN survey detailing hospital demographic characteristics was also made available through NHSN and hospital size, location, and ownership status.

#### ***4.5 Independent and Control Variables***

The primary independent variable was the presence of a state public reporting mandate. The presence of a state reporting mandate at the time of survey participation and data collection was ascertained by using published literature detailing the presence of public reporting mandate by time of passage for any type of HAI.<sup>4</sup> Any hospitals located in a state with an HAI-related reporting mandate in effect in 2011 was counted as having a mandate.

Control variables included hospital demographics and characteristics previously known to impact HAI related outcomes<sup>19,36,38</sup> and may be related to organizational climate. These include location (Northeast, Midwest, South, West, other), ownership status (for profit, not for profit/other), medical school affiliation (major, graduate, limited, non-teaching), size (bed size  $\leq 200$ , 201-500, 501-1000, >1000) and specific IP program characteristics including the presence of an infection prevention director (yes/no), presence of a hospital epidemiologist (yes/no) and number of infection preventionists on

staff (continuous). Facility affiliation and facility ownership status were pulled from additional NHSN survey data submitted by a subset of respondents.

#### ***4.6 Dependent Variables***

The P-NICER survey captured a breadth of organizational level data including information regarding processes and climate as it relates to the prevention of HAIs. Imbedded within the P-NICER survey was the LCQ-IP survey. This was adapted from the Leading a Culture of Quality (LCQ) instrument which was designed to assess quality oriented climates by evaluating 9 quality related components.<sup>37</sup> The subsequent LCQ-IP was validated in a separate analysis that identified specific to organizational climate domains as they relate to infection prevention. The organizational climate factors related to infection prevention included 19 questions, grouped into 4 domains: Improvement Orientation, Psychological Safety, Prioritization of Quality, and a Supportive Work Environment (Figure 2). Psychometric analysis determined the LCQ-IP instrument to be psychometrically sound and a reliable measure of infection prevention organizational climate among respondents (Chronbach  $\alpha$  for 19-item instrument = .926).<sup>37</sup>

Infection prevention organizational climate composite scores from the LCQ-IP are the dependent variables in this analysis. These composite scores are reflective of the IP organizational climate domains and are summed from a groups of variables found to be related and representative of the larger IP climate domains from the previous psychometric validation study(Figure 2).<sup>37</sup> Responses to the individual organizational climate components within each domain were measured on a Likert scale (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree) and are coded so a higher

score indicates a more positive organizational climate (Figure 2). Composite scores for each domain are the sum of the individual components related to the climate domain (Figure 2). Values for composite scores for larger climate-related domains are treated as continuous variables for this analysis.

#### ***4.7 Statistical Analysis***

Descriptive statistics were used to describe facility level demographics and characteristics including geographic distribution, bed size, ownership status and medical school affiliation. Differences in mean organizational climate composite scores for the sample were analyzed between hospitals in public reporting and non-public reporting state using the Wilcoxon rank-sum test to account for non-parametric data

Bivariate analysis was used to assess differences in demographics and characteristics of hospitals with and without public reporting mandates. Additionally, key structural components of IP programs including personnel and leadership, as well as participation in HAI quality improvement initiatives were examined. Evaluation of categorical variables (coded as either present or absent) was conducted using a Fisher's exact test, while Wilcoxon Rank-sum tests were used to evaluate the differences in the means of continuous variables and mean composite scores. The null hypothesis of  $H_0=0$ , indicating no difference in these characteristics between institutions in reporting and non-reporting states, was rejected at a pre-determined alpha level  $\leq 0.05$ .

A subset of the 975 hospitals with complete organizational climate data was used to examine the relationship between public reporting laws and organizational composite

scores. This subset (n = 662) is inclusive of all respondents who provided full data on all organizational climate variables and covariates. Stepwise linear regression was used to assess the association between public reporting mandates and IP organizational climate composite scores while controlling for covariates. The association between public reporting and composite score variables was modeled inclusive of control variables in a stepwise fashion using backward elimination with covariates inclusion set at  $\alpha < .05$ . Coefficients for those states with reporting laws were evaluated as the change in organizational climate score when reporting mandates are present. While these models are inclusive of hospital characteristics selected a priori, they do not account for state variation in HAI reporting law or timing of implementation, both of which may impact organizational. Since the association between the presence of the law and the hospital organizational was the primary outcome of interest, hospital characteristics were the covariates of focus in the model. All statistical analyses were conducted using Stata statistical software version 14.2.<sup>39</sup>

#### ***4.8 Results***

In all, 1064 hospitals across 50 states and Puerto Rico participated in the survey. Hospitals in the District of Columbia were not represented in the sample. At the time of the survey, 34 states had HAI public reporting mandates while 17 did not (Table 1). The majority of respondent hospitals in this sample (76%, n=811) were located in states that had public reporting mandates in place in 2011 (Table 2). Respondents' hospitals were geographically distributed around the country, but were primarily in the South (36%) and

Midwest (28%), and rather than the West (16%) and Northeast (19%). Most hospitals identified as suburban or rural (74%) and smaller to mid-range in bed size (85%).

**Figure 4.2. List of LCQ-IP Organizational Climate Composite Scores and Individual Variables**

Concept	Variable
<b>Prioritization of Quality</b>	<b>Prioritization of Quality Composite Score</b>
	The health care-associated infection prevention goals and strategic and strategic plan of our organization are clear and well-communicated
	Results of our infection prevention efforts are measured and communicated regularly to staff
	There is good information flow among departments to provide high-quality patient safety and care
	People here feel a sense of urgency about preventing health care-associated infections
	Employees are encouraged to become involved in infection prevention
	Members of this organization are able to bring up problems and tough issues
<b>Psychological Safety</b>	<b>Psychological Safety Composite Score</b>
	The climate in the organization promotes the free exchange of ideas.
	Staff will freely speak up of they see something that may improve patient care or affect patient safety.
	I feel free to express my opinion without worrying about the outcome.
	In general, people in our organization treat each other with respect.
	If you make a mistake in this organization, it tends to be held against you.
	People in this organization are comfortable checking with each other if they have questions about the right way to do something.
	The people in this organization value others' unique skills and talents.
	Members of this organization are able to bring up problems and tough issues.
<b>Supportive Work Environment</b>	<b>Supportive Work Environment Composite Score</b>
	Senior leadership here has created an environment that enables changes to be made
	Where I work, people are held accountable for the results of their work
	The quality of work suffers because of the amount of work staff are expected to do
	Most people in this organization are so busy that they have very little time to devote to infection prevention efforts (reverse coded)
	Employees are encouraged to become involved in infection prevention.
<b>Improvement Orientation</b>	<b>Improvement Orientation Composite Score</b>
	I can think of examples when problems with patient infections have led to changes in our procedures or equipment
	I know of one or more health care-associated infection prevention initiatives going on within our organization this year
	I have a clear understanding of the organization's mission, vision and values.

Responses to the individual organizational climate variables were measured on a Likert scale (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, 5=strongly agree) and are coded to indicate a higher score consistent with a more positive organizational climate.

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**Table 4.1. States with Public Reporting Mandates Enacted before or in 2011**

<b>Public Reporting Mandate (2011, n=34)</b>	<b>AL, AR, CA, CO, CT, DE, FL, HI, IL, IN, MA, MD, ME, MN, MO, NC, NH, NJ, NV, NY, OH, OK, OR, PA, PR, RI, SC, TN, TX, UT, VA, VT, WA, WV</b>
<b>No Public Reporting Mandate (2011, n=17)</b>	<b>AK, AZ, GA, IA, ID, KS, KY, LA, MI, MS, MT, ND, NE, NM, SD, WI, WY</b>

*Data in the above table gathered from empirical evidence presented in Herzig, et. al in 2014.<sup>4</sup> See Appendix B for guidance on state abbreviations.*

Bivariate analysis of respondent hospitals in reporting states versus non-reporting states yielded significant findings regarding the hospitals' participation in national IP improvement initiatives and characteristics of individual hospital infection IP (Table 2). Participation in an infection prevention improvement campaign outside of those stipulated in the survey (On the CUSP Stop BSI Initiative and IHI 5 million Lives Campaign) was noted to be different between hospitals in public reporting and non-public reporting states ( $p = .05$ ). Additionally, statistically significant differences were seen in specific components of facility IP programs. The mean number of full-time hospital

epidemiologists (physicians) was 0.41 in hospitals in reporting states compared to 0.31 in non-reporting states ( $p = 0.04$ ). While the mean number of infection preventionists (IPs) in these hospitals did not differ between the two groups, IPs with specialty certification appeared to be more prominent in hospitals with public reporting laws, however this difference failed to reach statistical significance with mean in reporting hospitals vs non-reporting 1.01 and 0.83 respectively, ( $p = .06$ ).

#### ***4.9 Organizational Climate Findings***

Four composite scores were created from 19 variables previously psychometrically validated to measure organizational climate specifically related to IP.<sup>37</sup> When compared between hospitals in reporting and non-reporting states, mean composite scores for all four organizational climate domains did not differ significantly between the two groups (Table 3). Mean scores for both reporting and non-reporting hospitals were well above the mid-range, indicating more positive IP organizational climates across the all respondent hospitals. Analysis of individual components within each composite score yielded similar findings except for the question asking respondents if people in their hospital system feel a sense of urgency about HAIs. Overall hospitals in public reporting states reported a slightly higher mean score than those without mandates, (3.7 vs. 3.5 out of 5,  $p = 0.03$ ).

**Table 4.2. Demographics and Characteristics of Respondent Hospitals**

Demographic/Characteristic	Public Reporting (% or SD)	Non-public Reporting (% or SD)	Total (%) [p-value]
<b>Total Hospitals</b>	811 (76)	253 (24)	<b>1,064</b>
<b>Location</b>			
<b>Northeast</b>	197 (24)	0 (0)	197 (19)
<b>South</b>	288 (35)	99 (39)	387 (36)
<b>Midwest</b>	189 (28)	106 (42)	295 (28)
<b>West</b>	129 (16)	44 (17)	173 (16)
<b>Other (AK, PR, HI)</b>	8 (1)	4 (2)	12 (1)
<b>Total</b>	<b>811</b>	<b>253</b>	<b>1,064 [p &lt; .0001]</b>
<b>Setting</b>			
<b>Urban setting</b>	224 (28)	52 (21)	276 (26)
<b>Suburban</b>	278 (34)	63 (25)	341 (32)
<b>Rural</b>	304 (38)	136 (54)	440 (42)
<b>Total</b>	<b>806</b>	<b>251</b>	<b>1057 [p &lt; .0001]</b>
<b>Bed Size</b>			
<b>≤200 beds</b>	413 (53)	151 (61)	564 (55)
<b>201-500</b>	285 (36)	73 (29)	358 (35)
<b>501-1000</b>	76 (8)	24 (10)	100 (9)
<b>&gt;1000 beds</b>	8 (1)	0 (0)	8 (1)
<b>Total</b>	<b>782</b>	<b>248</b>	<b>1030 [p = .06]</b>
<b>Participation in IP Improvement Projects</b>			
<b>Participation in the CUSP Initiative<sup>1</sup></b>			
<b>Yes</b>	267 (33)	96 (38)	363 (34)
<b>No</b>	544 (67)	157 (62)	701 (66)
<b>Total</b>	<b>811</b>	<b>253</b>	<b>1064 [p = 0.08]</b>
<b>Participation in IHI Five Million Lives Campaign<sup>2</sup></b>			
<b>Yes</b>	272 (34)	81 (32)	353 (34)
<b>No</b>	539 (66)	172 (68)	711 (66)
<b>Total</b>	<b>811</b>	<b>253</b>	<b>1,064 [p = .356]</b>
<b>Participation in any other similar program</b>			
<b>Yes</b>	199 (25)	78 (31)	277 (26)
<b>No</b>	612 (75)	175 (69)	787 (74)
<b>Total</b>	<b>811</b>	<b>253</b>	<b>1,064 [p = .03]</b>
<b>Infection Prevention Program Structure</b>			
<b>Mean number of Full-time Hospital Epidemiologists -MD Only (SD)</b>	0.41 (±0.734)	0.31 (±0.693)	<b>0.38 (±0.729)</b> [p = 0.04]
<b>Mean number of Infection Preventionists (SD)</b>	1.94 (±1.56)	1.79 (±1.23)	<b>1.91 (±1.48)</b> [P = 0.36]
<b>Mean number of Infection Preventionists Certified in Infection Control (SD)</b>	1.01 (±1.22)	0.83(±0.99)	<b>0.974 (±1.71)</b> [P = 0.06]
<b>Hospital has an Infection Control Director</b>			
<b>Yes</b>	560 (69)	188 (74)	748 (70)
<b>No</b>	249 (31)	65 (26)	314 (30)
<b>Total</b>	<b>809</b>	<b>253</b>	<b>1,062 (p = .07)</b>

<sup>1</sup>Denotes participation in On the CUSP: Stop BSI Project, CUSP = Comprehensive Unit-based Safety Program. <sup>2</sup>Denotes participation IHI Five Million Lives Campaign, IHI = Institute for Healthcare Improvement. IP = Infection Prevention. All means compared using Wilcoxon Rank-sum test. Normality assessed for continuous variables using Shapiro-Wilks test, all p<0.001. All other comparisons made using Fisher's exact test.

**Table 4.3. Mean LCQ-IP Composite Scores**

LCQ-IP Composite Scores: Mean (N=975)			
	Public Reporting Hospitals	Non-Public Reporting Hospitals	Total Composite Mean
Mean Prioritization of Quality Composite Score (range 7 – 30)	23.92 (±3.66)	23.66 (±3.50)	<b>23.86</b> (±3.62) [ <i>p</i> = 0.26]
Mean Psychological Safety Composite Score (range 8 – 40)	31.47 (±4.50)	31.11 (±4.86)	<b>31.38</b> (±4.59) [ <i>p</i> = 0.60]
Mean Supportive Work Environment Composite Score (range 5 – 25)	17.88 (±3.23)	17.86 (±3.29)	<b>17.87</b> (±3.28) [ <i>p</i> = 0.97]
Mean Quality Improvement Orientation Composite Score (range 3 – 15)	13.29 (±1.56)	13.23 (±1.52)	<b>13.28</b> (±1.56) [ <i>p</i> = 0.62]

*All scores tested for difference using Wilcoxon Rank-sum test. Normality assessed for continuous variables using Shapiro-Wilks test, all  $p < 0.001$ . LCQ-IP = Leading a Culture of Quality – Infection Prevention.*

Four separate multiple linear regressions were conducted to determine the relationship between HAI public reporting mandates and each IP organizational climate composite score. Analyses of fully-specified models showed no statistically significant impact of public reporting mandates on organizational composite scores, however other hospital characteristics emerged as associated with organizational climate (Table 4). In the Improvement Orientation composite score, an average decrease of more than 0.5 points in the mean score was noted in hospitals who reported being located in a rural setting and those within the 500 - 1,000 bed range ( $p < 0.001$  and  $p = 0.04$ , respectively). Larger facility size was also associated with a decrease in mean Supportive Work Environment composite scores, by an average of 1.20 ( $p = .001$ ) and 4.38 ( $p = 0.01$ ) points in hospitals with 500 – 1,000 beds, and more than 1,000 beds, respectively. A similar association was seen in Prioritization of Quality composite scores in hospitals of the same size. Conversely no association with size was seen on mean Psychological Safety composite scores.

Refined models determined by stepwise regression with backward elimination showed that the structure and characteristics of the hospital's IP program had statistically significant associations with specific organizational climate composite scores (Table 5). Many of the statistically significant covariates were held in the refined models. The presence of an infection control director had a consistent finding across three composite scores: Prioritization of Quality, Psychological Safety, and Supportive Work Environment. Number of infection preventionist staff was also associated with an average increase in the Supportive Work Environment composite score, suggesting a 0.37 average increase in the mean score for every one infection preventionist on staff. In addition to the size of the facility, higher mean Improvement Orientation and Prioritization of Quality composite scores were modestly associated with the number of infection preventionists certified in their specialty.

#### ***4.10 Discussion***

This study estimates the association between HAI public reporting mandates and perceptions of infection prevention organizational climate in hospital settings. Overall no statistically significant differences in organizational climate composite scores were noted in the association between states with and without public reporting mandates. While no effect of state-level mandates were seen, it is possible that some of the effects of these specific laws were masked by federal reporting mandates and incentive programs specifically targeting HAIs. Inpatient Hospital Quality Reporting, Value Based Purchasing and the HACS Reduction Program are federal initiatives aimed at reducing HAIs.

**Table 4.4. Multiple Regression Coefficients for LCQ-IP Composite Scores (Full Model)**

	Prioritization of Quality (p-value, 95% CI)	Psychological Safety (p-value, 95% CI)	Supportive Work Env (p-value, 95% CI)	Improvement Orientation (p-value, 95% CI)
Composite Range (SD)	7-30 ( $\pm$ 3.62)	8-40 ( $\pm$ 4.59)	5-25 ( $\pm$ 3.28)	3-15 ( $\pm$ 1.56)
Public Reporting Mandate (Yes)	0.051 (0.883; [-.63, .73])	0.420 (0.35; [-0.45, 1.29])	-0.023 (0.942; [-0.64, 0.59])	-0.172 (0.246; [-0.46, 0.11])
Setting				
Urban (Ref)	-	-	-	-
Suburban	-0.595 (0.145; [-1.40, 0.21])	-0.194 (0.709; [-1.21, 0.83])	0.050 (0.891; [-0.67, 0.77])	-0.249 (0.151; [-0.59, 0.09])
Rural	-0.842 (0.071; [-1.76, 0.07])	-0.945 (0.112; [-2.11, 0.22])	-0.068 (0.871; [-0.89, 0.75])	-0.770* ( $<$ 0.001; [-1.16, -0.38])
Bed Size <sup>§</sup>				
$\leq$ 200 beds (Ref)	-	-	-	-
201-500	-0.095 (0.801; [-0.84, 0.65])	-0.165 (0.732; [-1.11, 0.78])	-0.419 (0.216; [-1.08, 0.25])	-0.001 (0.993; [-0.32, 0.31])
501-1000	-1.379* (0.048; [-2.74, -0.01])	-0.427 (0.630; [-2.17, 1.31])	-1.994* (0.001; [-3.22, -0.77])	-0.609* (0.040; [-1.19, -0.027])
$>$ 1000 beds	-3.761* (0.049; [-7.51, -0.01])	-2.934 (0.229; [-7.72, 1.85])	-4.377* (0.011; [-7.74, -1.01])	-0.583 (0.473; [-2.18, 1.01])
IP Program Characteristics				
Infection Control Director (Yes)	0.883* (0.005; [0.27, 1.49])	1.188* (0.003; [0.41, 1.97])	1.058* ( $<$ 0.001; [0.05, 1.61])	0.176 (0.182; [-0.08, 0.43])
Number of Full-time HE	0.225 (0.228; [-0.14, 0.59])	0.003 (0.991; [-0.46, 0.47])	-0.029 (0.863; [-0.36, 0.30])	0.078 (0.326; [-0.08, 0.23])
Number of IPs	0.326 (0.159; [-0.09; 0.57])	0.150 (0.482; [-0.27, 0.57])	0.463* (0.002; [0.168, 0.76])	-0.021 (0.771; [-0.16, 0.12])
Number of IPs with CIC?	0.236 (0.080; [-0.04, 0.69])	0.113 (0.634; [-0.35, 0.58])	-0.027 (0.870; [-0.35, 0.30])	0.236* (0.003; [0.08, 0.39])
IP Improvement Initiatives				
IHI Campaign (Yes)	0.541 (0.08; [-0.06, 1.14])	0.294 (0.45; [-0.47, 1.06])	0.104 (0.70; [-0.43, 0.64])	0.209 (0.114; [-0.05, 0.47])
On the CUSP Program (Yes)	0.428 (0.16; [-0.175, 1.03])	-0.251 (0.53; [-1.03, 0.52])	0.225 (0.47; [0.32, 0.76])	0.207 (0.115; [-0.05, 0.47])
Other Similar Program (Yes)	-0.138 (0.66; [-0.75, 0.48])	-0.002 (0.99; [-0.79, 0.78])	-0.097 (0.73; [-0.65, 0.45])	0.286* (0.034; [0.02, 0.55])

**\*Regression coefficients significant at the  $p \leq .05$  level.** Categorical variables not shown did not reach statistical significance in the model. IP = infection prevention, CIC = Certification in Infection Control, HE = hospital epidemiologist, CUSP = Comprehensive Unit-based Safety Program, IHI = Institute for Healthcare Improvement. Not shown are coefficients for geographic location, medical school affiliation/type, facility ownership, all of which had no statistically significant coefficients. <sup>§</sup>Wald Test conducted to determine significance of bed size as a group (Prioritization of Quality Composite,  $F = 2.66$ ,  $p = .047$ ; Supportive Work Environment Composite,  $F=4.43$ ,  $p = .0043$ )

**Table 4.5. Stepwise Multiple Regression Coefficients for LCQ-IP Composite Scores (Final Model)**

	Prioritization of Quality (p-value, 95% CI)	Psychological Safety (p-value, 95% CI)	Supportive Work Env (p-value, 95% CI)	Improvement Orientation (p-value, 95% CI)
Composite Range (SD)	7-30 ( $\pm 3.62$ )	8-40 ( $\pm 4.59$ )	5-25 ( $\pm 3.28$ )	3-15 ( $\pm 1.56$ )
Public Reporting Mandate (Yes)	0.051 (0.883; [-.63, .73])	0.233 (0.574; [-0.57, 1.04])	-0.027 (0.942; [-0.60, 0.54])	-0.125 (0.370; [-0.39, 0.15])
Setting	-0.379* (0.046; [-0.75, -0.01])	-0.521* (0.012; [-0.96, -0.09])	-	-0.34* ( $p < 0.001$ ; [-0.50, -0.18])
Bed Size <sup>§</sup>	-	-	-0.637* (0.008; [-1.11, -0.17])	-
IP Program Characteristics				
Infection Control Director (Yes)	0.940* (0.002; [0.35, 1.53])	1.023* (0.007; [0.27, 1.77])	0.981* ( $< 0.001$ ; [-0.45, 1.51])	-
Number of Full-time HE	-	-	-	-
Number of IPs	-	-	0.379* (0.001; [0.17, 0.59])	-
Number of IPs with CIC?	0.314* (0.015; [0.06, 0.57])	-	-	0.183* (0.001; [0.08, 0.29])
IP Improvement Initiatives				
IHI Campaign (Yes)	-	-	-	-
On the CUSP Program (Yes)	-	-	-	-
Other Similar Program (Yes)	-	-	-	0.301* (0.024; [0.04, 0.56])

*\*Regression coefficients significant at the  $p \leq .05$  level. Model was refined using stepwise regression technique with backward elimination and model re-fitting for variables meeting the predetermined  $\alpha \leq .05$ . Categorical variables not shown did not reach statistical significance in the model. IP = infection prevention, CIC = Certification in Infection Control, HE = hospital epidemiologist, CUSP = Comprehensive Unit-based Safety Program, IHI = Institute for Healthcare Improvement.*

This finding may also be explained in part by the sample of survey respondents.

This was primarily a survey of IP departments and leadership, who responded to

organizational climate items from their unique perspective. Since organizational climate is a perception of specific organizational features and domains, these IP professionals may have more positive perceptions of measures specific to IP organizational climate. This effect has been seen in other literature, specifically regarding infection prevention staff's increased favorable perception of senior management's engagement in patient safety compared to non-infection prevention quality improvement staff; an effect that was higher in infection prevention directors versus non-directors.<sup>40</sup> Overall, organizational climate composite scores were noted to be high with no difference between reporting groups. This could be reflective of respondents enhanced perception of their own organizations' IP infrastructure. Moreover, while the findings of regression analyses presented here indicate no statistically significant association between overall composite scores and reporting mandates, other hospital characteristics were noted to be associated with organizational climate.

Size of the facilities was significantly associated with lower IP organizational climate scores in three domains: Prioritization of Quality, Supportive Work Environment and Improvement Orientation. The greatest effect sizes of coefficients were seen in the Prioritization of Quality and Supportive Work Environment scores. These scores include measures designed to assess the communication within organizations regarding quality and strategic plan, as well as open dialogue concerning problems or concerns. The Supportive Work Environment composite score is comprised specifically of measures that address issues of accountability, amount of work tasked to staff and the ability of leadership to promote an environment conducive to change. While it's possible that

larger hospitals may face more challenges surrounding the concepts addressed by these measures (i.e. issues of distant leadership, stifled communication, obstructed chain of command), more research is needed to determine reasons for these associations.

Leadership and communication have been noted as integral climate domains that promote a high quality of care, particularly with regard to IP.<sup>41-43</sup> The association of hospital size with these IP organizational climate composite scores may indicate an important consideration for leadership of larger institutions. Administrators in these hospitals may benefit from taking additional steps to ensure that their organizational climate promotes change, strong communication structures and accountability for infection prevention efforts.

Infection prevention program characteristics, particularly the presence of an infection control director, also impacted three composite scores in the final model. The Psychological Safety score was associated with the largest statistically significant increase ( $\beta=1.023$ ,  $(p=0.007$ ;  $[95\%CI, 0.27, 1.77]$ ) in institutions with a director present. This composite score addresses personnel feeling safe to express concerns over patient care, a climate that promotes open communication and a respect for persons within the institution. It's possible that the presence of an infection control director promotes more open communication and facilitates the discussion of problems or issues related to IP within the organization. While current literature contends that leadership plays an important role in building an organization where infection prevention is supported and promoted<sup>41</sup>; the specific role the infection control director plays in promoting a more positive IP organizational climate has not been well-established in the IP literature. It is

likely this role is critical to a well-functioning IP program and safe work environment, yet more research is needed to determine the mechanisms behind how this role contributes to these to an improvement IP organizational climate.

While all individual measures within each composite score were tested for differences between hospitals in public reporting and non-public reporting states, only the measure discussing a sense of urgency around HAIs was noted to be significantly different between the two groups (3.7 vs. 3.5 respectively,  $p = 0.03$ ). While this indicates a somewhat higher agreement with a sense of urgency around HAIs in hospitals in public reporting states, whether this difference is meaningful remains difficult to interpret. However this finding is consistent with previous qualitative work examining the impact of HAI public reporting mandates on organizations.<sup>32-34,44</sup> These findings suggest that perhaps a primary role of public reporting mandates is to highlight the importance of HAIs and motivate organizations to begin examining methods to improve HAI-related outcomes.

The IP organizational climate composite scores were inclusive of key domains discussed in the Integrative Model of Organizational Climate including leadership, communication processes, employee recognition and workload.<sup>31</sup> Although the LCQ-IP tool wasn't built to test this model, it did explore specific domains that the Integrative Model posits may contribute to clinical outcomes. Those scores that were most impacted by hospital characteristics concerned measures related to leadership, communication and accountability. These domains from the LCQ-IP are similar to those from the Integrative Model suggesting that the impact of IP organizational climate may be tested using this

framework. The Integrative Model of Organizational Climate does not account for factors such as public reporting that are external to the health system, thus it may not be useful in testing the role these policies play in impacting organizational climate. Despite being helpful in delineating the pathways between larger climate domains and clinical outcomes, an additional or separate framework may be needed to account for what, if any, role public reporting may play in shaping IP organizational climate. While public reporting was not associated with IP organizational climate in this study, it has been shown to be associated with climate domains in previous work.<sup>32-34,44</sup> Additionally it has been noted that the impact of public reporting of healthcare performance data may play stronger role in institutions where these domains have a stronger presence and can potentiate a more constructive and collaborative environment.<sup>7,29,44</sup> How these pathways contribute to HAI outcomes in the setting of IP organizational climate domains warrants further study.

#### ***4.11 Study Limitations***

This study did have some limitations. The cross-sectional data does not allow for causal inference; thus, it is not well suited to determine a causal effect of public reporting on organizational climate. Also, this data is from 2011 and public reporting mandates have changed considerably since that time, including the addition of more comprehensive reporting policy, standardized reporting mechanisms, newer federal policy aimed at improving HAI performance. Additional examination could be conducted to determine if timing of the laws (recent implementation vs. less recent) has an impact on organizational climate. While the sample size was considerable for the purposes of this study, the

original P-NICER survey had a response rate of 29%. The addition of NHSN related covariates further limited the sample to only those respondents who provided NHSN survey data in addition to the P-NICER survey data. As a result, a smaller subset of respondents was used to for regression analysis, potentially impacting ability to see statistically significant effect sizes. Also, it is likely that additional covariates exist that were not included in the model potentially contributing to confounding. A sensitivity analysis would be helpful in determining the impact of missing covariates particularly with regard to the full sample and the analytical sample. Finally sampling bias and self-report may be an issue with the P-NICER survey, given that IP professionals may be more willing to respond if they are affiliated with specific types of institutions. The authors who first reported on results of the P-NICER survey discussed a CDC comparison of respondents to non-respondents.<sup>45</sup> While no differences were noted in intensive care unit (ICU) CLABSI rates there were significant differences noted in hospital characteristics. Specifically, non-respondent hospitals tended to be smaller with fewer patient days, fewer beds and admissions.<sup>45</sup> While size of the facility was noted to be associated with organizational climate in this study, smaller hospitals appeared to be well-represented in our sample. Furthermore, organizational climate responses appeared consistent across comparisons and participants appeared to be well distributed across different geographic regions and facility characteristics so external validity appears sound.

#### ***4.12 Policy Considerations and Future Research***

Although public reporting was not shown to be associated with IP organizational climate in this study, findings did confirm that these policies stimulate a sense of urgency around HAIs in hospital settings. While the intent of these policies is to improve care and aid in consumer decision-making, they do not provide guidance as to how healthcare systems should make the changes necessary to facilitate these outcomes. This allows for flexibility within institutions to determine the best methods for improving care and decreasing HAIs. It reasons then, that hospitals and other healthcare institutions may be affected by these mandates in different ways. The results of this study are not meant to suggest that public reporting laws are ineffectual in impacting hospitals' organizational climate; only that additional investigation is needed to address the complexity of their impacts on health systems. Empirical study should continue to investigate how these public policies drive change in organizational climate. If certain organizational climate domains are identified as being related to public reporting policies, the relationship between those domains and outcomes may be investigated.

Qualitative methodologies have been successful in illuminating these concepts in previous literature<sup>32-34</sup>, and may be a beneficial strategy to investigate the large scope of these laws and the intricate ways health systems respond to their implementation. Organizational climate and its impact on patient outcomes has been studied in the literature with mixed findings using quantitative methodologies, however few have focused specifically in IP organizational climate.<sup>8</sup> An innovative study from Gilmartin and Sousa<sup>46</sup> used structural equation modeling to determine the association between

organizational climate, process improvements for CLABSI prevention and CLABSI outcomes. Their findings indicated that organizational climate was associated with CLABSI prevention activities, but not CLABSI outcomes, however the authors stress that more research is needed.<sup>46</sup> While quantitative methods may be helpful in illuminating the relationship between climate and outcomes, mixed methodological studies may be helpful in both understanding the effect of policy on climate and the subsequent effects of climate on outcomes. Studies that examine how organizations change in response to these laws as well as how these changes impact outcomes would help to paint a fuller picture of the wide-ranging effects of these laws on health systems.

Additionally, understanding how different hospital personnel perceive IP climate and their perceptions of publicly reported HAI data would shed important light on how these laws are assimilated not only by IP staff, but by other stakeholders within hospitals. Additional study of how physicians, nurses, and others view IP organizational climate and HAI data may help policy makers understand the how these mandates peruse through healthcare systems and gauge their effect on key stakeholders. This knowledge would highlight where these policies have their strongest effect in affecting decision-making and improving quality of care.

U.S. state and federal policy continues to promote public reporting of HAIs and other healthcare quality measures; law makers must understand the full scope of how these laws impact health systems. This knowledge may help drive new policy that promotes or incentivizes hospitals to build programs that strengthen their IP organizational climate in the hopes of achieving gains in patient outcomes related to

HAI. If the public reporting alone is not enough of a stimulus to propagate change and improvement, policy-makers should consider other potential drivers that strengthen to organizational climate domains. Policies that incentivize building a climate conducive to HAI improvements may prove to be a powerful adjunct to public reporting policy, or may prove more valuable to patients and organizations over the long term.

#### ***4.13 Conclusion***

In this study, organizational climate as measured here, did not differ between hospitals in states with and without mandatory HAI reporting. However important findings were seen concerning the effects of specific hospital characteristics including bed size and structure of IP programs that do have an impact on IP organizational climate. Hospital size and IP program characteristics did show some association with IP Organizational climate composite scores in the survey. However, more research is needed to determine the exact mechanisms behind these relationships. Policy-makers should consider the structure of IP programs and hospitals in addition to organizational climate when formulating or implementing policy around HAIs and public reporting.

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## **CHAPTER 5: SUMMARY OF FINDINGS AND DISCUSSION**

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## ***5.1 Introduction***

Healthcare-associated infections (HAIs) continue to be a significant source of morbidity and mortality in the U.S. healthcare system. Infections contracted during interactions with healthcare facilities or as a result of specific treatment interventions are considered to be healthcare-associated and may arise from multiple etiologies.<sup>1</sup> These infections can cause serious complications and prolonged length-of-stay in inpatient settings and can complicate treatments and cause additional morbidity in both inpatient and outpatient settings. Recent estimates from the CDC suggested that as recently as 2011, 722,000 HAIs occurred annually and were responsible for approximately 75,000 deaths in the United States.<sup>2</sup> Financial estimates place the monetary burden of HAI events as costing health systems anywhere from \$24.8 to \$33 billion dollars.<sup>2,3</sup> Over the past decade, attempts to curb rates of HAIs has centered on both the implementation of evidence-based process improvements and promotion of broad policy initiatives and patient safety programs. In many respects, these efforts may be considered successful, in that recent data from the U.S. Centers for Disease Control (CDC) show a general decreasing trend in HAIs in HAI incidence since 2008.<sup>4</sup> However, a more granular view of the data suggests these trends are not consistent across all states and all healthcare systems.<sup>4</sup> These fluctuations in trends indicate that there is still significant room for progress and additional policies or interventions that may be aimed at improving HAI outcomes. While it may be difficult to attribute specific gains to any particular policy or evidence-based intervention, understanding the mechanisms behind larger HAI policy

initiatives is the first step to evaluating how policy may impact organizations and, ultimately outcomes.

One policy-level approach to addressing the issue of HAIs over the past decade has been the wide-spread passage of legislation mandating healthcare facilities report HAI-related data to specific state-level overseers, typically health departments.<sup>5</sup> Although commonalities exist across most state-level reporting mandates, these laws do vary from state-to-state particularly in terms of which specific HAIs must be reported, whether the data is reported to the public, and whether the data is required to be submitted with facility identifiers indicating which facilities are associated with specific outcomes.<sup>6</sup> Each of these provisions carries the propensity to affect how hospitals and other healthcare entities respond to HAIs, particularly if they change their practices in response the external pressure of reporting these metrics. Yet it is often contended that the mandate to report HAI data for release to the general-public is what may play the largest role in generating specific responses from hospitals aimed at improving HAI outcomes.<sup>7-10</sup>

State HAI reporting mandates and their public reporting components have often been met with controversy and skepticism. As of 2013, 37 states had legislative mandates for reporting HAI-related performance data.<sup>5</sup> Many of these laws, particularly those mandating the report of device-associated infection data (central-line associated blood stream infections [CLABSI] and catheter-associated urinary tract infections [CAUTI]), were enacted in the mid or late 2000s<sup>5</sup>, even in the face of little evidence supporting their ability to reduce infection rates or empower consumers to use to the data for decision-making.<sup>11</sup> Since that time additional studies have attempted to evaluate the

impact of these laws on patient HAI-related outcomes, organizational process improvements, and consumer decision-making. The empirical evidence from these studies has yielded mixed results concerning the potential impacts of these mandates and HAIs continue to negatively impact patient outcomes, despite the persistence of these laws.

The aim of this dissertation is to illuminate the impacts of state HAI reporting mandates by examining their relationships to organizations and infection rates. Specifically, this dissertation was written as three papers, each contributing a new understanding and evaluating hypothesized relationships between these mandates and hospitals or infection-related outcomes. The first paper proposes a revised conceptual framework that builds on findings from existing literature to discern the various pathways by which reporting mandates may stimulate change in provider or system behavior, process improvements, outcomes and consumer decision-making. The second paper is a quasi-experimental longitudinal data analysis that examines the impacts of state public reporting mandates on *Clostridium difficile* (*C. difficile*) infections over time. The third paper is an exploratory data analysis that examines organizational climate and its relationship to state reporting mandates using cross-sectional survey data from the Prevention of Nosocomial Infections and Cost-Effectiveness-Refined (P-NICER) survey<sup>12</sup>. Each of these papers approaches the phenomenon of mandated reporting from a varying perspective: the impact on outcomes, the impact on organizations and the conceptual pathways which may guide those impacts.

## ***5.2 Key Findings***

Findings from each component of this dissertation contribute to the larger body of knowledge surround HAI public and mandatory reporting. These papers represent a different aspect of reporting that has larger implications for healthcare systems, patients and policy.

The first paper in this dissertation proposed a revised conceptual framework to describe the relational pathways by which the reporting of HAI data impacts health systems, consumers and infection-related outcomes. Prior pathways describing the impacts monitoring performance data<sup>7</sup> and public reporting<sup>8</sup> were used to guide the analysis and served as a foundation on which to build the revised framework. The intricate relationships between these laws, key stakeholders and outcomes is illuminated by current evidence in the literature and analyzed using an integrative review methodology to develop and propose a revised conceptual framework. The 19 studies reviewed, spanned a breadth of HAI reporting mandates and their associated impacts on healthcare organizations, consumers, and infection related outcomes. Studies with diverse methodologies including qualitative, quantitative, mixed-methods and one systematic review were included in the analysis. Key components of existing conceptual frameworks were used to organize the analysis and present findings. Building from existing frameworks 3 key stakeholder groups were the focus of the literature review. Studies centering on HAI reporting impacts on consumers, healthcare organizations and providers were analyzed. Findings were synthesized and compared to existing conceptual frameworks. The author then determined whether empirical evidence exists

to support these existing relationships and if needed proposed new directional pathways that describe the hypothesized impacts of reporting based on the findings of the review.

The Change pathway, first described by Berwick and colleagues<sup>7</sup>, centers on the intrinsic ability of organizations to respond to their own performance data and implement change to improve outcomes. In this pathway, motivational drivers of change include desire-to-achieve and caring, yet are still subject to the environments in which these changes are slated to occur. Studies examining the change pathway delineated mixed findings regarding patient outcomes and process improvements as a result of public reporting.<sup>13-22</sup> With regard to infection related outcomes, multiple studies do show an effect of public reporting in reducing infection rates<sup>14,16,17,23</sup>, particularly related to CLABSIs. Yet while these studies showed reductions in infection rates or events, the mechanism by which these laws generate these changes remained unclear. A study by Marsteller and colleagues<sup>14</sup> was able to link participation in process improvements to pending or recent reporting mandates, which in turn, was associated with decreased CLABSI rates. A paper from Liu et. al<sup>23</sup>, also hypothesized on the potential impacts of public reporting on healthcare systems, finding that reducing central line days and strengthening surveillance programs may be an effect of these laws that contribute diminished CLABSI rates. However additional studies were unable to find similar results with regards to both point-of-care processes, including antibiotic utilization, or infection rates.<sup>18,24</sup> Qualitative studies showed more specific impacts of HAI reporting mandates, particularly their effects on organizational climate, infection prevention infrastructure and process improvements. Studies examining California hospitals showed that after the

implementation of reporting laws, increased adherence to various infection prevention measures were noted as well as a general sense of increased infection prevention visibility and importance within the system.<sup>21,25</sup> However, study participants also noted frustration with HAI laws due to variability in reporting requirements between state and federal agencies and increased workload. Improved processes were described as a direct response to both federal and state reporting requirements in two other California hospitals, noting specifically that while challenges remain, reporting mandates had stimulated improvements in infection prevention infrastructure and implementation of evidence-based prevention practices.<sup>19</sup> In addition to process improvements, organizational climate factors such as leadership, accountability, communication, and support also emerged.<sup>20</sup> These factors were noted by respondents as being key components of broader responses to mandatory reporting within healthcare organizations.

Two additional pathways, the Selection Pathway and the Reputation Pathway, have also been proposed as drivers of change as a result of public reporting.<sup>7,8</sup> These pathways acknowledge the potential impact of reporting mandates and publicly reported data on consumers. However studies examining these potential pathways largely showed that publicly reported HAI data is not a prominent factor when consumers make decisions about their healthcare often outweighed by provider recommendations, geographic location or insurance status.<sup>22,26-28</sup> Additionally most consumer respondents across all studies had difficulty interpreting HAI data, particularly in the face of numerical or statistical complexity and variable outcome metrics. These findings suggest that while consumer selection may be a proposed pathway for public reporting mandates, additional

evidence is needed to examine the mechanism by which it affects consumer decision-making. Interestingly consumers often ranked provider and family recommendation as a contributing factor to their healthcare decision-making.

Findings from this review showed largely mixed support for the current pathways proposed by Berwick et. al<sup>7</sup>, and Hibbard<sup>8</sup>. A revised conceptual framework was proposed that used evidence from the literature to support existing pathways and propose new pathways and relationships between public reporting and various stakeholders within the healthcare system. In the revised framework, publicly reported data does have a direct impact on patient outcomes related to HAIs. Studies presented in this review have shown this relationship both for clinical outcomes and process improvements.<sup>14-17,23</sup> Yet the exact nature of the relationship between reporting and outcomes remains somewhat undefined. Improvement processes and organizational climate were noted in these studies to be key factors related to HAI reporting laws, yet evidence for how these components impact outcomes is not readily appreciable across findings. Thus, the framework describes a direct association of reporting mandates on HAI outcomes, but also a potential mediating impact through organizational processes and climate.

While consumer choice had less supportive data describing potential relationships within the Selection Pathway, evidence from this review suggests that the Reputation Pathway may play a greater role in selection than previously discussed. Findings from consumer-focused studies showed that consumers more often rely on recommendations from family and care providers for healthcare decision-making than publicly reported HAI performance data.<sup>22,26-28</sup> In this regard the Reputation Pathway may mediate the

Selection Pathway, if reported HAI data does in fact affect the reputations of healthcare organizations.

Despite these new hypothesized relationships further study is needed to determine how and to what magnitude these pathways impact outcomes, organizations and consumer decision-making. Understanding these relationships is crucial not only in the broader context of discerning public policy impacts on patient outcomes, but to ensure these policies are being implemented effectively and rationally to improve patient care.

To contribute to the body of literature and further discern the impacts of HAI reporting mandates on clinical outcomes and organizations, two additional studies were undertaken in this dissertation. Both studies explored the impacts of HAI reporting mandates at the state level, the first reporting on *C. difficile* events in hospitals and the second addressing impacts on organizational climate indicators.

The second paper in this dissertation examined the association between state HAI reporting laws and *C. difficile* and Methicillin-resistant *Staphylococcus aureus* blood stream (MRSA-BSI) events across a longitudinal sample of hospitals from varying states. Building from an analysis previously conducted by Liu and colleagues<sup>23</sup>, this paper used a quasi-experimental design to determine the effects of reporting mandates on hospital-onset (HO) *C. difficile* and MRSA-BSI Laboratory-Identified (LabID) events as defined by the CDC's National Healthcare Safety Network(NHSN).<sup>29</sup> These LabID events are the common metric used in both state and federal reporting mandates.<sup>4,5,30,31</sup> Data from the P-NICER survey was used for the primary analysis and included a final sample of

219 hospitals was included in the analysis, yielding 4,328 hospital-months of complete data. Outcome events were modeled with respect to effects of mandatory reporting laws at varying time distances before and after the laws' implementation. This design allows for the identification of time trends in infection rates as they related to implementation of the law.<sup>23</sup>

Early in the analysis phase of this study it was determined that the proposed model for MRSA-BSI LabID events would not converge, likely due to a high frequency of zero or one event counts in the panel data. MRSA outcomes were thus not included in the final analysis. Zero-inflated Poisson regression models for *C. difficile* showed no statistically significant effect of public reporting mandates either before or after implementation of these laws. One statistically significant incident rate ratio (IRR) at 18 to 16 months before the law was significant ( $p = 0.034$ ) but likely represented a decline in a single hospital during that period. Overall trends in IRRs indicated decreased rates in *C.-difficile* LabID events after implementation of the laws, when compared to 28-to-30 months prior. Although these IRRs did not reach statistical significance, findings may suggest some impact of mandatory reporting laws. Sensitivity analyses confirmed that the rate of change over time in both reporting and non-reporting groups was statistically not different, however, and further study is needed to determine the significance of these findings.

To approach the concept of mandated HAI public reporting from a different perspective, the third paper in this dissertation aimed to conduct an exploratory data analysis and examine the relationship between organizational climate variables and

public reporting. Organizational climate refers to the perception of culture within an organization inclusive of specific factors such as leadership, communication and social norms. Data on organizational climate was collected as part of the P-NICER survey and reported in a specific subsection of the Leading a Culture of Quality for Infection Prevention (LCQ-IP) survey.<sup>32</sup> Organizational climate factors included in this survey spanned multiple domains and assessed concepts specific to infection prevention.<sup>32</sup> Four domains emerged from grouping of individual factors related to infection prevention organizational climate. These domains included Improvement Orientation, Psychological Safety, Prioritization of Quality and Supportive Work Environment. Survey questions measured factors associated with each domain on a Likert Scale and were coded so higher scores indicated more positive organizational climates. These individual factor scores were then summed to generate composite scores for each domain. These scores were then compared across reporting and non-reporting states and linear regression was used to determine the impact of reporting laws and various facility-level characteristics on organizational climate domains.

Across all four climate domains, no statistically significant differences were noted in composite scores between hospitals in states with HAI public reporting and those without. Additionally, results of multiple linear regression found that the presence of public reporting laws had no statistically significant association with organizational climate composite scores. However, in the final models, some key hospital characteristics remained significant indicating associations with individual composite scores. The presence of an infection control director was shown to be associated with

higher mean composite scores in the Supportive Work Environment, Psychological Safety, and Prioritization of Quality composite scores ( $p < 0.01$ ). Similarly, the number of infection preventionists certified in infection control was also associated with a higher Improvement Orientation score and Prioritization of Quality score ( $p < 0.01$ ,  $p = 0.02$ , respectively). While not directly related to public reporting in this study, these findings do contribute to the larger body of knowledge regarding organizational climate and infection prevention. Future research will be needed to assess additional relationships and potential impacts among public reporting hospitals.

Together these three papers contribute a well-rounded perspective on HAI public reporting and its impacts on organizations and outcomes. They provide findings from empirical investigations and a revised framework gleaned from a substantive review of existing literature. The integration of these findings yields new knowledge regarding HAI public reporting mandates and proposes new directions for policy research.

### ***5.3 Discussion***

The mandated reporting of HAI performance data is a widely used policy intervention that attempts to promote consumer decision-making and healthcare system accountability.<sup>10,33</sup> Current reporting mandates in the United States span a breadth of states, include a variety of HAI reporting requirements, and promote a diverse methodology for data dissemination.<sup>5</sup> Most reporting mandates include three key legislative or administrative components: the mandate to report HAI data, the mandate to report that data to the public, and the inclusion of facility identifiers that link performance data to specific healthcare facilities. In much of the previously discussed literature the

publicizing of facility-linked performance data is often thought of the primary motivator behind consumer decision-making and changing practices to improve patient care.<sup>7,8,10</sup> Subsequently the primary body of knowledge surrounding HAI public reporting has attempted to describe or quantify the effect of these reporting mandates, often with diverse and innovative methodologies. The findings from each of the papers in this dissertation contribute significant findings to this body of knowledge. Yet, as a whole, they provide a new direction for future research and innovation needed to understand how and why these laws impact healthcare consumers and organizations.

The revised conceptual framework this dissertation presents is the first updated framework to specifically propose pathways between publicly reported HAI data, patient outcomes, organizations and consumers. While it does build from previously proposed frameworks<sup>7,8</sup>, these frameworks were not specific to HAI data. The importance of an HAI-specific framework lies in the need to address the pathways for the process improvements, epidemiologic considerations, evidence-based interventions and patient-related considerations that are unique to HAIs. Unlike other publicly reported healthcare performance data, HAIs are somewhat set apart both because of their implications for transmission to other patients within a health system and the medical and environmental conditions that put patients at risk for infection.<sup>1</sup> Additionally these infections can pose a threat to the larger community including patient families, healthcare workers and others.<sup>34</sup> These distinctive characteristics of HAIs pose a unique challenge to health systems attempting to curb their transmission, and often sets them apart from other metrics and prevention programs within healthcare settings. As federal and state policy makers have moved public reporting mandates forward, research into how these laws

impact these infections and the organizations trying to prevent them, is integral. The revised framework in this dissertation allows investigators to test direct pathways between laws and outcomes, or examine specific mediating variables that are evidenced in the literature as potentially being impacted by these laws and related to decreased HAI rates. Additionally, the idea that HAI performance data is driving consumer decision-making is perhaps an intuitive one, but the current available literature suggests that consumers are either not aware of the existence of this data<sup>22</sup> or have difficulty interpreting this data, particularly when metrics are varied or highly statistical and when consumers have less education.<sup>26-28</sup> The framework presented in this dissertation provides researchers and policy makers with new pathways for empirical testing and investigation of relationships between HAI reporting mandates, outcomes and organizational processes. In addition, it integrates the iterative role consumers play in influencing healthcare organizations, while keeping the unique pathways that may prove specific to consumers.

The two empirical studies in this dissertation tested specific components of this revised framework. The quasi-experimental longitudinal *C. difficile* and MRSA study evaluated the direct association between state reporting mandates and outcomes. The organizational climate study centered on examining the association between these laws and specific domains of organizational climate as they relate to infection prevention. Although different in aim, methods, and outcomes, these two studies contribute equally valuable findings, regarding the broader effects of reporting mandates.

Understanding the direct impacts of HAI reporting mandates and potential mediating factors of these effects is an important component in understanding how these

laws impact outcomes. The revised framework presented in the first paper proposes that a directed pathway exists between reporting of HAI data and an improvement in outcomes, which is often a reduction in infections. The evidence from previous studies has been mixed regarding this pathway and this dissertation was unable to find a statistically significant association. Although one other study had noted a decrease in *C. difficile* in Canada after implementation of reporting laws<sup>16</sup>, this paper was the first to examine these associations in the United States. While this does not confirm or strengthen the evidence underlying this pathway, further research will be needed to determine how this pathway differs with other types of HAIs, in other policy settings, and potentially in other types of care settings.

This direct pathway, likely has significant mediating organizational influences that may contribute to infection outcomes. These relationships have been explored in previous literature, again with mixed findings.<sup>14,15,23</sup> However qualitative exploration of organizational responses to HAI reporting mandates have shown significant impacts of these laws on infection prevention personnel and organizational climate factors.<sup>20,21,25</sup>

The exploratory analysis presented in this dissertation is the first to examine organizational climate variables specific to infection prevention and attempt to quantify a relationship between these variables and public reporting. While not specifically testing for mediation, this paper explores the first pathway from mandated reporting to potential impacts on organizations. Knowledge of this relationship can guide additional inquiry to understand how organizations may be impacted by these reporting laws. If these relationships are established, further analyses may show they are a mediating factor for decreasing HAIs in response to public reporting. Organizational climate is an integral

component to this pathway as it may not only contribute to better patient outcomes<sup>35</sup>, but it may help policy makers and healthcare administrators understand in what type of facilities, these laws may have the biggest impact.

The findings from this dissertation yield that much remains unknown regarding how these reporting mandates impact outcomes and organizations. Additional study is needed to explore these complex relationships presented in these studies and previous work. Examination of these interrelationships open the door for a significant amount of new research and innovative policy directions.

#### ***5.4 New Directions for Nursing Research and Policy***

This dissertation provides a comprehensive groundwork for additional nursing research and new considerations for policy-makers. In a dynamic policy environment both researchers and policy-makers will need to respond to the demand for new inquiry and thoughtful policy recommendation and implementation.

Nursing researchers have been at the forefront of investigating the effects of HAI reporting mandates. The larger implications for healthcare organizations and personnel cannot be understated. Nurse are often directly involved in the care for those at risk for, or affected by HAIs and some HAIs may be nursing sensitive to nursing processes and behaviors.<sup>36</sup> Although much has been examined regarding HAIs and reporting mandates, large gaps in knowledge persist. One significant paucity in the research is how healthcare workers and administrators outside infection control interpret and use publicly reported HAI data. Administrators and front-line staff play significant roles within healthcare systems and are often responsible for key decision making, implementing

process improvements and conducting patient education. HAI data is an important tool and consideration for many of these staff, yet little is known about if or how publicly reported HAI data impacts their roles or their decision-making. None of the studies reviewed investigate the knowledge base or attitudes of nursing or physician personnel, outside of infection control departments, regarding publicly reported HAI data and whether they can interpret or use the data to effectively. Additional study is needed concerning the impact public reporting continues to have on infection prevention personnel and as well as those healthcare workers not directly responsible for data submission or surveillance.

Nursing research can also play a key role in revealing what specific factors contribute to patients understanding of publicly reported HAI data. Some evidence has shown a relationship between educational level, prior healthcare experience and higher income levels.<sup>22,27,28</sup> Yet many of these studies were conducted on small populations and are difficult to extrapolate outside of the study setting. These findings should be further examined in other geographic regions with differing populations to establish and test hypotheses about how social determinants of health impact a consumer's ability to interpret data that may guide their decision-making.

Finally, there is ample opportunity for nursing researchers to develop novel interventions that aim to guide patients through the interpretation of HAI data and empower them to use that data to promote safer care environments. While not every consumer has the ability to choose from multiple healthcare institutions, they may still benefit from understanding their own hospital's HAI performance and become advocated

for their own high-quality care or that of their family members. Nurses are uniquely qualified to not only educate consumers about this data, but also to advise policy-makers and administrators about the best way to organize and disseminate this data to make it relevant and applicable across varying sociodemographic and socioeconomic groups.

In addition to nursing research, the implications of these findings on health policy is significant. Many of current federal policy initiatives centered on improving care include a component of mandated and/or public reporting. The Hospital Inpatient Quality Reporting Program (IQR), Healthcare-acquired Conditions Reduction Program (HACRP) and Value-Based Purchasing (VBP) are legislative mandates implemented by the Centers for Medicare and Medicaid Services (CMS), and require the submission of HAI data for various payment incentives and penalties at the healthcare facility level.<sup>30,31,37</sup> This data is then reported publicly on the Hospital Compare website. These data are received through the NHSN, a primary component of most state-based reporting mandates. Many state mandates require the public dissemination of reported data, sometimes in varying formats. A key consideration for policy-makers is the understanding of whether or not the impetus behind these laws' ability to instigate change in healthcare settings is the public reporting component of these mandates. This is likely a consideration for both policy-makers and researchers. While some studies attempt to evaluate the impacts of these public reporting mandate, few delve into what, if any, motivators are specific to public reporting. If the public dissemination of HAI facility-specific is a stronger motivator than internal reporting, examining the specific

mechanisms (i.e. social norms or intrinsic drivers) may be beneficial when applying similar policy interventions to other areas of society.

An additional policy consideration is the propensity to report outcomes rather than process indicators or process measures for HAI improvements. While some hospitals do report certain process measures, including Central Line Insertion Practices (CLIPs), most of the metrics required by public reporting mandates are outcome measures. The decision to mandate the implementation of process measures rather than outcomes reporting may be based on the feasibility of wide-spread process measure implementation. With the varying sizes, geographical regions, and financial resources across hospital settings, broad implementation of targeted process improvements may be challenging. However, the recent passage of mandated antimicrobial stewardship programs in California hospitals may serve as a model for future policy initiatives that target implementation of interventions rather than simply reporting outcomes.<sup>38</sup> Although some evidence exists that these public reporting mandates have a direct impact on infection-related outcomes, the association between process improvements and evidence-based prevention programs is more readily understood. It may prove worthwhile for policy makers to develop or promote structured interventions or provide funding for participation in broad process improvement initiatives as a means of improving HAI-related outcomes.

Finally, policy makers should would do well consider both the ethical components of these mandates and how to best use data to empower consumers across all measures of diversity and social determinants of health. Transparency in both the implementation and

evaluation of these laws' utility among consumers is essential to understanding and improving methods for effective and fair dissemination. Understanding the goals of these mandates and their effectiveness may guide needed changes in how data is reported and shared among multiple stakeholders. If a critical goal of reporting these data is to help consumers make decisions about their care, policy-makers should consider strengthening dissemination efforts to make reported data more meaningful. Data should be publicized in a way that acknowledges and is sensitive to the social determinants of health, differences in health literacy levels, and health disparities.

### ***5.5 Conclusion***

Mandated reporting of HAIs has been a prominent policy initiative in the United States for over a decade. This dissertation aimed to examine associations between these policy mandates, HAI outcomes and impacts on organizational climate in acute care hospitals. These studies provide critical foundations for ongoing inquiry regarding the effects of these mandates on patient outcomes, organizational characteristics and processes and consumer decision-making. More research is needed to examine the important implications of these HAI reporting mandates and determine the mechanisms by which they motivate change and improvement in healthcare systems.

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## APPENDICES

**Appendix A. Integrative Review Matrix/Table of Evidence**

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
Mansick et.al, 2015	To assess the interpretability of HAI data as presented on the hospital compare website.	Consumers/ Selection	None Specified	110 hospitalized patients at the University of Maryland Medical Center selected from a list of admissions in prior 24 hours.	Cross-sectional survey design. The mean correct score for each task is reported as percentage. Response to 4 domains was evaluated: Written description of data, written description plus SIR, IDENTICAL SIR descriptions with numbers, and only numbers.	Performance of hospitals with regards to HAIs was correctly assessed 72% of the time when plain language description of HAI rates/SIRs was used. Mean percent correct decreased as complexity increased. Similar decreasing trend seen among college graduates, those who were more likely to get question 1 correct, and healthcare workers/caregivers of frequently hospitalized persons	First quantitative study evaluating data interpretation specific to HAI data. Outside of the experimental environment real data is likely more difficult to interpret.	No critically ill patients, or members of the non-hospitalized population were used which excludes those who had the ability to use the data for decision making purposes.
McGuckin, et. al 2014	To assess consumer awareness, engagement, and intention to seek information on HAI rates.	Consumers/ Selection	None Specified	Random telephone sample of 3000 consumers from the U.S. All 18 y.o. and older.	Descriptive statistics and Pearson Chi-sq tests for differences in participants from public reporting vs. non-public reporting states.	3031 respondents took the survey, 1895 lived in states with an HAI reporting law and at least 1 HAI PR. In states with PR 28% knew this. Only 14% of respondents stated HAI data as one of the top 2 factors in decision	While some respondents were aware of HAI reporting, few listed it as a top motivator for healthcare decision-making.	Researchers don't analyze correlation with demographic variables (race/ethnicity) as predictors or correlates of responses.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						making regarding hospital choice with recommendation from HCW and reputation being the 2 most common criteria.		
Mazor & Dodd, 2009	To evaluate different approaches for reporting hospital-level comparative data on HAIs and the extent to which such data might influence hospital choice.	Consumers/ Selection/ Reputation	Berwick and Hibbard	Random sample of residents from Worcester MA selected from city clerk's office for mailing. 201 respondents included in the final sample.	Descriptive statistics for respondent characteristics, t-tests and Chi-2 to compare respondents to non-respondents. IV's impact on understandability were tested with t-tests and multivariate linear regression.	Reponses rate of 34% (201 total respondents of those able to respond), 25% of total solicited. Education was associated with correctly choosing the best and worst hospitals (65% of those with HS or less selecting the best hospital compared with 83% at least some college or higher p=.003). Understandability ratings were also associated with correct selection. Prior experience, hospital reputation, MD recommendation, insurance all ranked above infection data, practice score in terms of factors affecting hospital choice	Data on HAIs and safety ranked lower in hierarchy of factors affecting hospital choice, however reputation was the second most important factor. Overall understandability of these reports was high however there was sufficient evidence to suggest that education plays a role in understanding these reports. Numerical data were noted to be the least comprehensible. Aggregate scores were most impactful.	Low response rate. The respondents were more educated than the general community, so generalizability may be difficult, particularly if the goal is to evaluate or recommend how state reporting should be rolled out.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
Mazor et. al, 2009	To explore consumers' responses to a variety of HAI public reporting formats and content and to use the data to develop reporting and formatting recommendations.	Consumers/S election	None Specified	Random sample of residents from Worcester MA selected from city clerk's office for mailing. 59 consumers included in the final sample	Describe a range of opinions using qualitative descriptive techniques from data collected through interviews. Two themes were developed as well as subthemes.	59 interviews were completed and 2 major themes were identified: (1) responses and reactions to reporting with 4 subthemes: responses to HAIs in general, responses to specific indicators, reactions to different modes of reporting, and anticipated impact of reporting on hospital choice. (2) recommendations with 3 subthemes: recommendations related to report content, recs related to report format, and recs related to dissemination.	Significant recommendations were generated including recommendations on format and content. Most indicated other factors as paramount for selection of hospitals including insurance, past experience sand recommendations. Discrepant scores from the same institution posed a challenge for participants	Little diversity in race/ethnicity.
McGuckin et. al, 2013	To explore the hospital epidemiologist opinions regarding HAI public reports and their use of reports in their work with consumers and HCWs.	Providers/Change and Consumers/S election	None Specified	59 healthcare epidemiologists frim SHEA Research Network across 40 states and 30 of the 32 with public reporting.	Descriptive statistics of responses to survey items and open ended questions (categorized by theme)	36% response rate (N=59), 90% were from states with mandatory reporting. 93% reported seeing the state report, and 70% used reports with administrators and HCWs. Respondents marked consumer awareness , understanding, and use of data as low and 21% suggested	Supports the notion that this public ally reported data is used by hospital epidemiologists for work with administrators and other HCWs. However suggests they do not find it useful for general consumer purposes.	Small sample size of epidemiologists.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						that more explanation of data for consumers is needed.		
Larkin et. al, 2013	To evaluate the association between state-mandated public reporting of HAIs and perceptions of infection control process and outcome measures at their hospitals.	Outcomes/ Change	None Specified	137 infection professionals, representing hospitals in 35 states from SHEA Research Network.	Descriptive statistics of sample. Chi-sq and t-tests for differences in reporting groups.	110 respondents, 91 hospitals in reporting states. No outcomes were found to be associated with public reporting. Most respondents stated no increase in infection control resources and perceived risk of HAI was slightly decreased in the past 3 years. No perceived improved process measures or lower infection rates between two groups of hospitals.	No difference in 2 groups of hospitals were noted in any outcome variable. No demographic differences noted.	Cross-sectional design with a small and homogenous sample although representative of the academic medical center population.
Uchida et. al, 2011	To conduct in-depth semi structured interviews to gain insights about the experience of the infection prevention practice in California	Outcomes/ Change	Donabedian Framework of Healthcare Quality	25 participants from California hospitals participating in CHAIPI, representing a range of personnel.	Open coding and content analysis. Initial set of codes developed by two coders. Secondary coding completed to contextualize the phenomena and suggest meanings/themes	23 interviews (22 1:1, 1 with multiple personnel) 4 themes found (1) mandatory reporting/ (2) impact of technology for surveillance (3) IP role expansion (4) organizational climate. Mandatory reporting yielding an	Rich qualitative data that discusses the impact of public reporting and regulation on IP practices and organizations. These laws, while frustrating can also help to improve the profile and importance of IP within an organization. They	One state only included in the sample, this state had early adoption of mandatory reporting which limits external validity.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						increased awareness in infection control, however fair comparison is lacking, laws do not always address HAI of concern, significant increased workload. With regard to organizational climate subthemes of communication, organizational values and environment emerged.	can stimulate a more positive organizational climate for IP	
Pegues, 2014	To describe the impact of HAI Action Plans on an academic health system in California, in planning and implementing HAI prevention activities and reduce HAI rates	Outcomes/ Change	Context-input-Process-Product Model (CIPP)	Two acute care teaching hospitals within the UCLA Health System, both with dedicated infection control programs	Description of the implementation of the HAI action within the CIPP model.	Context- at the time of HAI action plan multiple processes already in place for HAI reduction, yet substantial organizational barriers as well. Inputs - Voluntary reporting in place to NHSN, yet the impact of state public reporting drove process implementation to improve HAI rates across the system (implementation of CVC bundle, policy development, data collection and	Implementation of evidence-based practices for HAI prevention can be stimulated by increased awareness from public policy initiatives. However, each setting must tailor practices to their own systems and allocate needed resources and organizational support.	Small sample size for description of implementation, and not generalizable in experiences. However, lessons learned may be generalizable to wider audiences.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						reporting structure. Difficulty with implementation, given time frame. External data validation proved to be a challenge, but spurred collaboration internally. Reporting lead to increases in awareness and focus in HAI reduction. Implementation practices for evidence-based interventions need to be tailored to practice settings and embedded into existing processes of care		
Stone et. al, 2015	To explore the impact of federal and state HAI policy on state health departments, hospital stakeholders in the USA and to explore perceptions across varying states.	Organizations/Change	Donabedian Framework of Healthcare Quality	Purposive sample to ensure equal number of states with and without HAI laws. 5-10 participants were recruited after snowball sampling. 12 states were selected 6 with laws, and 6 without.	Open coding and content analysis. Initial set of codes developed by two coders. Coded data were reviewed to develop necessary themes and evaluate differences based on the presence of public reporting	90 interviews conducted with state officials, regulatory officials, legal counsel, clinicians and IP professionals, and community partners. Four themes were identified: 1) Increased collaboration, 2) using public reported data for benchmarking and prioritization, 3)	Findings suggest that laws aimed at mandating public reporting of HAIs fosters and heightens collaboration and awareness within the acute care setting to improve HAI prevention efforts. The collaboratives include surveillance, implementation of prevention measures and data feedback. There was surprisingly little	Qualitative interviews yielded self-reported narrative data. The researchers report there is a potential for bias due to social desirability. Despite efforts for a representative sample, only 12 states were

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						<p>concerns related to public reported data and 4) resource needs. Public reporting was key in focusing importance on HAIs within hospital settings and garnering support for initiatives (reported by hospital staff). This was due to reputation and accountability of the institution. Data validation continued to be a concern. Resource needs are significant particularly at the hospital level for IP staff, but also at the state level for providing guidance. Data validation remains a concern.</p>	<p>variation between groups of states. This may be due to larger federal mandates where data is reported.</p>	<p>included, thus generalizability may be hampered.</p>

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
Stone et. al, 2011	To examine the impact of federal and state HAI policy on California hospital	Organization / Outcomes/ Change	None Specified	331 hospitals in CA with adult ICUs were eligible to participate. One staff member from each hospital's infection prevention and control department was asked to complete the web-based survey.	Descriptive statistics were presented. Survey results pre/post were computed using t-tests and chi-squares. Linear and logistic multivariate regression were used to examine changes over time while controlling for hospital characteristics. Qualitative data was coded and content analysis preformed.	207 Hospitals completed pre-surveys and 203 completed post. At time 2, IPs reported more time spent on surveillance, in offices rather than other locations, and increased data mining. Increase in CLABSI and CAUTI policies increased at time 2 as well as SSI and VAP-related policies. Increased adherence noted at time 2 to CHG use for CVC insertion and barrier precautions. Decreased ICU-specific rates of CLABSI and CAUTI were also noted. Subthemes gathered from mandatory reporting included increased workload and associated frustration, variation in reporting requirements between state and federal policy, increased awakened and priority of IP and	This finding confirms previous qualitative studies that show similar themes with regards to mandatory reporting. Sample size was large to evaluate the state hospitals with good response rates (>50%). Quantitative data capture was expansive and collected a wide-range of data on structure, processes and outcomes from policy implementation.	Pre-and post-measures are useful, but ultimately self-reported by survey respondents. Regression methods may show association with public reporting and outcomes, but not clear from the models how the trends were isolated from pre-to post implementation. This data was collected from a sample of hospitals from one state and may not be generalizable to experiences of other states in the U.S.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						increase use of technology and associated efficiency.		
Zacharia et. al, 2014	To determine the association between state legal mandates for data submission of central line-associated blood stream infections	Organization / Outcomes/ Change	None Specified	190 NICUs included in the study (107 located in states with mandates) from a national sample of NHSN participating hospitals and associated NICU (level II/III and level III).	Bivariate analysis were used to compare characteristics of NICUs, ANOV and Chi-sq were used to compare process measures and outcome measures. Multivariable logistic regression were used to test the association between mandates and process/outcome measures.	190 NICUs were included in this study (21.8%) of total NHSN NICUs. Over half were in states with reporting mandates. More NICUs in mandatory reporting states reported >95% compliance with all prevention practices compared to those in states with no requirement (36.4% vs. 16.8%, p=.002). No difference in NICU CLABSI rates overall. No statistically significant difference in SIR between the	Compliance with HAI prevention practices in NICUs appears to be associated with reporting mandates, yet the impact of this on outcomes remains unclear. An associated increase in compliance was seen with increased urgency of the mandates.	Cross-sectional design does not allow for causal inference and it may be hard to isolate the effect of the public reporting mandate. Small sample size may hamper generalizability.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						two reporting groups. (Mean SIR 1.6 vs. 2.7, $p = .02$ ). Greater than 95% compliance with prevention practices was associated with more recent mandates which compared to states with more than 3 years of mandates. CLABSI rates in low BW <750g infants were significantly lower in in states with reporting mandates.		
Flett et. al, 2015	To determine whether blood culture and antibiotic utilization changed after mandatory public reporting of CLABSIs	Clinical Processes and Outcomes/Change	None Specified	Children's hospitals that report to the Pediatric Health Information System database including 17 hospitals in 9 states with implemented mandated reporting and 4 hospitals in 4 states without.	Interrupted time series using generalized linear mixed-effects models were used to look at outcomes as adjusted rate ratios. Covariates were selected for inclusion in the model after pre/post 2-sided t-tests revealed significant differences ( $p < .2$ ) between before and after reporting implementation.	Blood culture utilization: No significant changes in rates. PICU Adjusted Annual rate ratio 1.01 [95% CI, 0.90-1.13], NICU 0.98 [95% CI, 0.88-1.09]. No difference found in Antibiotic days aARR 1.03 [95% CI, 0.94-1.13] for PICU and aARR 0.98 [95% CI, 0.88-1.10] for NICU. In hospitals without mandatory public reporting rates of monthly blood culture dropped in	Longitudinal analysis of outcomes measures overtime. These outcomes were focused more on point of care decision-making rather than broader process improvements. This could potentially illuminate a new pathway for examining how these laws work or don't work within organizations.	Administrative data can be subject to reporting and validity weaknesses. There may have been institutional differences among facilities that contributed to stable prescribing and culturing practices.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
						both PICU (p<.0001) and NICU (p<.0001). Antibiotic utilization dropped in the PICU but the change was not statistically significant. Yet was significant in the NICU, aARR 0.95, [95% CI, 0.93-1.01].		
Pakyz & Edmond, 2013	To evaluate the impact of state laws on reporting of HAIs on CLABSI rates	Outcomes/ Change	None Specified	Administrative data from the University Health System Consortium hospitals from calendar year 2011. 159 hospitals were included in the study. 34 in states with no mandate, 92 in states with all 3 legal requirements, 33 in states that did not meet the 3 legal requirements.	Ordered probit regression model used to test associations between legislation and CLABSI rates. Secondary analysis of state-level SIRs and their association with CLABSI reporting legislation using the Tukey Kramer HSD test.	Results of regression models showed no effect of the presence of legislation category on hospital SIRs. No difference in State-level SIRs was noted between the three legal mandate statutes.	This was a national sample covering 34 states and examining the impact in the differences in mandates as well as the presence of those mandates . Well controlled for case mix, academic setting and acuity of patients	Cross sectional design makes causal relationships difficult to analyze. The sample only included academic medical centers and may not have been powered enough to detect an association. The cross sectional nature of the data and analysis did not allow for temporal trends, thus it is unknown if rates

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
								are similar due to a natural trend in declining CLABSIs.
Daneman et. al, 2012	To determine whether mandatory reporting is associated with a reduction in hospital rates of C. difficile infection	Outcomes/ Change	None Specified	All admitted patients in the study period were identified with broad inclusion criteria. Excluded patients were those admitted to psych, rehab/complex continuing care and non-acute areas. Administrative data from the registered persons database, the Ontario Health	Primary analysis consisted of modeling temporal patterns of C. diff infection using generalized estimating equations, with the unit of analysis as the hospital, month, and age-group. Exponentiated post-month coefficient was the relative difference between the observed post-month and the predicted post-month.	Results from the primary analysis indicated a 26.7 % reduction in c. diff cases comparing the predicted to the observed outcomes. This translates to 5,417 cases observed compared to 7, 327 predicted, or 8.9/10,00 patient days vs. 12.16/10,000 patient days. (p<.001). This trend was seen across multiple hospital settings.	This is a well-designed longitudinal cohort study with significant power and high-fidelity models to detect the effect of mandatory reporting on C. diff. To date this is the only study to look at C. diff rates as an outcome of mandatory reporting. Sensitivity analyses were used to confirm robustness of primary findings.	All C.difficile cases were used in this study without attention to those that may have been transmitted outside of the acute care setting. Coding data can sometimes pose challenges although the authors did validate their data with public reporting statistics. Temporal confounders remain a challenge in this

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
				Insurance Plan database, the Canadian Institute for Health Information Discharge Abstract Database and the Ontario Drug Benefit database.				study design, and it is difficult to isolate the primary effect of reporting mandates.
Marsteller et. al, 2014	To examine the mandatory reporting impact on participation and performance in reducing CLABSIs in a national patient safety collaborative.	Organizations and Outcomes/Change	None Specified	Sample from the On the CUSP: Stop BSI program, organized in cohorts of state-level ICUs. 6 cohorts from 5/2009 to 3/2011.	Hospital participation for each group tested whether unit participation rates were different among each group using chi-square. Covariates were tested using Fisher's exact tests. Difference-in-difference design was used to evaluate the effect of each reporting group on CLABSI	56% of hospitals joined the national program in those states where mandatory reporting started within the program period. For those where mandate was in effect for <1 year, participation was 50%. For those hospitals with no reporting mandate or a mandate that was >1 year after the project, participation was low (22% and	Longitudinal design showed some potential effect of reporting mandates, when mandates are newer or on the horizon as signified by increased participation in On the CUSP in these states. These mandates may influence participating and improvement initiatives within hospitals. Hospitals may already see lower CLABSI rates states with long term reporting.	No non-participating ICUs were used to compare impacts of public reporting, which may be different than the sample provided. Also CMS reimbursement policy in 2008 may have been a factor in changes, yet this would have

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
					rates.	23%). Results of the regression showed voluntary reporting (G3) or longer duration of mandatory reporting (G2) had higher baseline CLABSI rates (G3 IRR = 1.48, 95% CI, 1.16-1.89; G2 IRR = 1.14, 95% CI, 1.01-1.29), but greater reductions in CLABSI rates during the first 6 months of the On the CUSP program. Toward the end of the program period, hospitals in states with mandatory reporting showed a trend toward a larger reduction in CLABSI than those hospitals in states without reporting (not statistically significant).	The presence of a mandate is not predicative of how well these initiatives may be implemented however.	impacted all ICUs.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
Rinke, M et. al, 2015	To test the impact of pediatric-specific public CLABSI reporting on rates of CLABSI as defined by the AHRQ PQI 12.	Organization / Outcomes/ Change	None Specified	Discharges identified in the Kids' Inpatient Database (KID). States were identified as public reporters if states had facility identification as part of its mandate.	Patient and hospital characteristics where compared using chi-squared statistics and F-test for means of continuous variables. Multivariable logistic regression was used to estimate the odds of PDI12 during each three-year period for EACH reporting group. Random intercept was included to account for correlation within hospitals over time. Covariates included patient age, sex, payer, number of diagnosis, hospital bed size, location (urban/rural), and teaching status. Odds ratios estimated change in the PDI12 rates over time by comparing rates in time groups 2006 and 2009 to the 2003 baseline. Relative OR were	There 7 states and 1006 hospitals in the 2009 reporting group, 2 states in 135 hospitals in the 2006 reporting group and 18 states and 2066 hospitals in the never reporting group totaling 4,705, 857 observations. States that began reporting in 2006 outcome rates dropped by 46% [95% CI, 31%-68%] (2006) and by 90% [ 95% CI, 83%-94%], (2009) compared to baseline. Those who began reporting in 2009, PDI12 rates began decreased by 35% [95% CI, 30%-39%] in 2006, 74% [95% CI, 72%-76%] in 2009. The never reporting group had similar decreases including a greater decrease in PDI12 in later reporting periods when compared to reporting begun in 2009 group (OR .12 for never reporters,	This is the first study to evaluate pediatric CLABSI outcome in the advent of public reporting. The results indicate that CLABSI rates as defined by the study decreased across all 3 groups, mirroring a national trend in CLABSI prevention/patient safety and improvement in quality.	There is some potential for bias by the data indicated in the PDI12 database, from the way that data is coded. Potential for misclassification exists. The public reporting in 2006 group only had 2 states and a subsequent low number of hospitals.

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
					used to compare these to the never reporting group.	and OR 0.26 for 2009 reporters, relative OR:2.1 p<0.001).		

Author(s), Year	Purpose of the study	Stakeholder Group/ Pathway	Conceptual Framework	Sample	Data Analysis Methods	Attrition and Results	Significance of Findings	Limitations
Black and Kim, 2014	To provide a narrative and case study description of the challenges of studying the effect of public reporting and HAIs.	Outcomes/ Change	None Specified	Data is sampled from the PA Health Care Cost Containment Council and PA Inpatient Discharge dataset, and National Inpatient Sample. 16 additional states no reporting laws.	A difference-in-difference design was used to determine the impact of state mandated public reporting policy on CLABSI rates, for reported rates and inpatient rates.	High rate hospitals find that reporting decreases inpatient data, yet gaming (time-inconsistent reporting) exists. Facilities with higher rates experience more significant drops.	These findings use a quasi-experimental design to show a strong association between public reporting implementation and decreases in CLABSI rates. Differences in reported findings also include changes in reported data vs. discharge data, suggestive of gaming.	While a strong study design is used, only one experimental group is evaluated against the control.
Liu et. al, 2016	To determine the impact of mandatory reporting laws on CLABSI rates in a national sample of intensive care units.	Outcomes/ Change	Berwick and Hibbard	A total of 244 hospitals, with 1,902 ICU years. Hospitals reporting to NHSN between 2006 and 2012. All non-VA acute care hospitals enrolled in NHSN were eligible to participate.	Variant of a difference-in-difference design, using a fixed effects Poisson regression model of CLABSI counts for each ICU month at a given time interval. Sensitivity analysis with CLABSIs by central line days and time spent by infection preventionists (#hours per 100 hospitals beds per week) on surveillance.	When compared to 25 months or more prior to the law's implementation, notable decreases in CLABSIs are seen both in anticipation of the law (IRR = 0.66, p<.001) and long after the laws went into effect (IRR=0.343, p=.009)	These findings use a quasi-experimental and multi-state longitudinal analysis to show an impact of public reporting on CLABSI outcomes. This is the first study to use surveillance data from NSHN to examine CLABSI in adult ICU across the country. Findings also show longitudinal and sustained impacts of these laws on CLABSI rates.	There is a potential for selection bias as well as changes in the CLABSI definition, however this would have affected all hospitals within the sample. Process improvements and point of care decision-making were not evaluated.

<b>Author(s), Year</b>	<b>Purpose of the study</b>	<b>Stakeholder Group/ Pathway</b>	<b>Conceptual Framework</b>	<b>Sample</b>	<b>Data Analysis Methods</b>	<b>Attrition and Results</b>	<b>Significance of Findings</b>	<b>Limitations</b>
McKibben et. al, 2006	To conduct a systematic review of the available literature to determine the ability of public reporting laws to improve care.	Outcomes/ Change	None Specified	Of the 450 papers selected for review with inclusion/exclusion criteria. 10 papers in the final analysis.	Systematic review of empirical evidence presented in the papers.	No significant empirical evidence was found supporting the recommendation that public reporting may improve HAI outcomes or improve care.	First systematic review to focus on HAI related empirical evidence for the purposes of policy recommendations.	Potential for publication bias as with any systematic review.

***Appendix B. List of State Abbreviations***

<b>Appendix B. U.S. State Abbreviations</b>					
<b>AL</b>	Alabama	<b>MI</b>	Michigan	<b>UT</b>	Utah
<b>AK</b>	Alaska	<b>MN</b>	Minnesota	<b>VA</b>	Virginia
<b>AR</b>	Arkansas	<b>MO</b>	Missouri	<b>VT</b>	Vermont
<b>AZ</b>	Arizona	<b>MS</b>	Mississippi	<b>WA</b>	Washington
<b>CA</b>	California	<b>MT</b>	Montana	<b>WI</b>	Wisconsin
<b>CO</b>	Colorado	<b>NC</b>	North Carolina	<b>WV</b>	West Virginia
<b>CT</b>	Connecticut	<b>ND</b>	North Dakota	<b>WY</b>	Wyoming
<b>DC</b>	District of Columbia	<b>NE</b>	Nebraska	<b>UT</b>	Utah
<b>DE</b>	Delaware	<b>NH</b>	New Hampshire	<b>VA</b>	Virginia
<b>FL</b>	Florida	<b>NJ</b>	New Jersey		
<b>GA</b>	Georgia	<b>NM</b>	New Mexico		
<b>HA</b>	Hawaii	<b>NV</b>	Nevada		
<b>IA</b>	Iowa	<b>NY</b>	New York		
<b>ID</b>	Idaho	<b>OH</b>	Ohio		
<b>IL</b>	Illinois	<b>OK</b>	Oklahoma		
<b>IN</b>	Indiana	<b>OR</b>	Oregon		
<b>KS</b>	Kansas	<b>PA</b>	Pennsylvania		
<b>KY</b>	Kentucky	<b>PR</b>	Puerto Rico		
<b>LA</b>	Louisiana	<b>RI</b>	Rhode Island		
<b>MA</b>	Massachusetts	<b>SC</b>	South Carolina		
<b>MD</b>	Maryland	<b>SD</b>	South Dakota		
<b>ME</b>	Maine	<b>TN</b>	Tennessee		
<b>MI</b>	Michigan	<b>TX</b>	Texas		