Hospital Policies and Hospital-onset Methicillin-resistant *Staphylococcus aureus* Infections: A Mixed Method Evaluation

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Abstract

MRSA continues to spread in hospitals, despite modest recent success. Gaps exist regarding how hospital policies impact MRSA transmission in hospitals. Characterization of the policy environment has been useful in approaching other public health issues including alcohol control. Our goals were to develop a tool to identify measurable and modifiable hospital policy components designed to prevent MRSA, then utilize this tool to evaluate policies to examine the relationship between policies and MRSA incidence.

We developed a tool to systematically evaluate hospital policies that included instructional and implementation elements. Each policy element was evaluated for its presence and thoroughness. Four hospital policy types were evaluated from five hospitals in Minnesota: hand hygiene, multidrug-resistant organism (MDRO)/isolation, influenza vaccination, and whistleblower (corporate compliance).

Results demonstrated that the policies varied in comprehensiveness and thoroughness across hospitals and topics. Most policies included purpose and policy statements. Most policies lacked consequences for noncompliance, accountability, responsibility, monitoring and enforcement of policy expectations; when included, components scored low for thoroughness. Of the policies, influenza vaccination was the most complete while hand hygiene policies scored highest for thoroughness, followed by MDRO/Isolation.

Upon evaluation of policy scores and MRSA incidence rates, we found an indication of a negative correlation between the MDRO/Isolation policy score and MRSA incidence: the higher the mean score of the MDRO/Isolation policy, the lower the MRSA rate. We found a similar indication of a negative correlation between the mean hand hygiene policy score and MRSA incidence.

As we begin to characterize policy, endogenous in nature, as a potential exposure it is important that we develop rigorous measurement; we provided a first step in developing such an approach. The work of this dissertation will contribute to the field of epidemiology by gaining insight into organizational policy – including how we measure, analyze, and draw inferences with the results.

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1. Introduction

Healthcare-associated infections (HAI) are among the ten leading causes of death in the U.S. The Centers for Disease Control and Prevention (CDC) estimates that 1 in 20 hospitalized patients will acquire an infection during their hospitalization, which results in substantial preventable, excess healthcare expenditures ranging from $28 billion to $33 billion annually [Department of Health and Human Services 2013]. Methicillin-resistant *Staphylococcus aureus* (MRSA), a common HAI pathogen, continues to be problematic to prevent and control in hospitals. In 2013, CDC estimated the rate of hospital-onset invasive MRSA infection, among the most severe HAI, to be 3.6 per 100,000, with a mortality rate of 0.7 per 100,000 in the U.S. [CDC ABCs Report, 2013].

Previous research on the prevention and control of MRSA in hospitals has largely focused on proximal factors such as biological- and individual-level interventions [Gardam, Lemieux, Reason, et al, 2009; Gardam, Reason & Rykert, 2010; Pronovost, Rosenstein, Paine, et al, 2008; Sandora & Goldmann, 2012]. Evidence from previous research indicates that transmission of MRSA in hospitals is multifactorial involving human behavior factors, social norms, and organizational dynamics – factors that operate at the individual and organizational levels [Sandora & Goldmann, 2012; Grol, 1997; Saint, Howell & Krein, 2010; Pronovost, 2008]. MRSA bacteria certainly cause the infection but how are the bacteria distributed and what organizational arrangements cause the distribution of the bacteria?

Given that the distribution of MRSA in hospitals is not random and MRSA transmission in hospitals is preventable through proper adherence to infection prevention measures such adhering to central line insertion protocols and performing hand hygiene appropriately [Goldmann, Weinstein, Wenzel et al, 1996; Stone et al, 2010; Pittet, 2004], we are taking a much-needed step back. It is time to expand our approach to infection prevention and clinical epidemiology, and consider distal factors such as organizational policies, which codify the organizational direction and control with respect to MRSA prevention. At the end of the day, the organization is accountable for the care provided by their staff to their patients in their hospital.

This dissertation approaches MRSA prevention using a broader perspective that includes the importance of the organization as a social phenomenon to reveal a more complete story about the spread of MRSA in hospitals. The dissertation seeks to answer the question: do hospital policies impact hospital-onset MRSA bloodstream infection incidence rates? However, there are no data available to answer this question. There has been no work done in the hospital policy space that involves systematically evaluating policies. Despite numerous policies required by accrediting and regulatory bodies, there is a paucity of data demonstrating that hospital policy leads to positive patient outcomes. Specific to this dissertation, there have been no studies which have examined the relationship between hospital policy and MRSA prevention. Therefore, we employed a mixed-method approach to the question, using quantitative and qualitative methods, to study the practices associated with the policies. To restate, this dissertation seeks to answer the question: do hospital policies impact hospital-onset MRSA bloodstream infection incidence rates? To answer this question, this dissertation has four specific aims.

The objective of Aim 1 is to provide context to the primary research question by describing the epidemiologic trends and burden of disease of hospital-onset MRSA infection. Specifically, Aim 1a describes epidemiologic trends in invasive MRSA infection in the two most populous counties in Minnesota for years 2008-2013. The data source used is the invasive MRSA surveillance data collected by the Minnesota Department of Health as part of the CDC's Emerging Infections Program/Active Bacterial Core Surveillance program. Aim 1b describes the relationship between hospital-level characteristics and hospital-onset MRSA bloodstream infection rates in U.S. hospitals in 2013. The data source for the independent variables is the Centers for Medicare & Medicaid Services (CMS) "Provider of Services (POS) File" – hospital-level characteristics. The outcome is hospital-level MRSA bloodstream infection incidence rate derived from the CMS "Healthcare-Associated Infection (HAI) measures - provider data" (data reported via CDC's National Healthcare Safety Network).

The objective of Aim 2 is to develop a systematic method to evaluate organizational policies, identifying measurable and modifiable constructs, to advance measurement of hospital policies related to MRSA prevention.

The objective of Aim 3 is to apply the systematic method developed in Aim 2 to evaluate relevant policies in 5 Minnesota hospitals and then examine the relationship between hospital policies and hospital-onset MRSA bloodstream infection incidence. The outcome is hospital-level MRSA bloodstream infection incidence rate derived from the CMS "Healthcare-Associated Infection (HAI) measures - provider data" (data reported via CDC's National Healthcare Safety Network).

The objective of Aim 4 is to conduct qualitative interviews with healthcare personnel to describe practices related to the policies under study.

The research question of this dissertation is framed using the lens of social epidemiology and applying Coleman's theoretical framework [Coleman, 1990] which states that group-level change is grounded in the activity of individuals. Therefore, changes in infection rates in hospitals can only be explained by the actions of individual healthcare workers and patients within the context of organizational rules and social norms [Oakes, 2009]. Using policy as an organizational-level tool for organizational control, we seek to evaluate the social context to inform MRSA transmission within the hospital setting. The hypothesis is that effective organizational policies related to MRSA prevention and control impacts social norms for the organization which affect behavior of individuals and their interactions, producing an organization with low hospital-onset MRSA infection rates.

Through the integration of clinical and social epidemiologic methods, the proposed dissertation will produce several contributions. First, no study has systematically evaluated polices to identify measurable and modifiable constructs to utilize as an exposure measure in relation to a health outcome. Given that this research has not been conducted, there are no measures or tailored techniques for hospital policy evaluation and analysis. Therefore, with a strong methodological emphasis, the proposed research is important to open the door towards a

novel approach for hospital policy evaluation to identify what the important constructs are, whether they matter, and how much they matter with respect to the spread of MRSA infection. The dissertation will add to the healthcare epidemiology literature by identifying modifiable hospital-level factors that can prevent and control the spread of MRSA in hospitals. Additionally, this research will expand the body of literature regarding quantitative approaches for systematically evaluating organizational policies, providing insight into organizational policy in epidemiology – how we measure it as well as how we analyze and draw inferences with the results.

2. Background

2.1 Introduction to healthcare-associated infections (HAI)

HAI are defined as infections that result from healthcare provided while being treated for other conditions (CDC). HAI are among the ten leading causes of death in the U.S. [McKibben, Horan, Tokars, et al, 2005] and among the most common adverse events in healthcare [Leape, Brennan, Laird, et al, 1991]. CDC estimates that, at any point in time, 1 in 25 hospitalized patients are affected by HAIs [Magill, Edwards, Bamberg, et al, 2014]. HAI are associated with longer hospital stays, more intensive care, and higher healthcare costs. Infections acquired in hospitals were responsible for $28 billion to $33 billion in excess healthcare costs in 2002 – estimates that include direct costs only, indirect and less quantifiable measures such as productivity were not considered [Scott, 2009].

The slow progress to substantially reduce or eliminate HAI in hospitals has garnered federal attention and as part of national healthcare reform initiatives, the Centers for Medicare and Medicaid Services (CMS) included HAI as quality metrics to be included their Value-Based Purchasing program in accordance with the Patient Protection and Affordable Care Act. Effective in 2014, hospitals will not receive up to 2% of eligible reimbursement if HAI, including MRSA bloodstream infections acquired in the hospital, are above national benchmarks [CMS Federal Register].

2.2 Epidemiology of MRSA in hospitals

Staphylococcus aureus has long been recognized as an important human bacterial pathogen and is the leading cause of pus-forming infections in humans, including superficial skin infections such as boils as well as more serious infections such as bloodstream infections, pneumonia, and endocarditis. Humans are a natural reservoir for *S. aureus* and it is consistently estimated that 30% of humans are colonized with *S. aureus* at any given time [Kluytmans, van Belkum, Verbrugh, 1997; Chambers, 2001; Wertheim, Vos, Ott, et al, 2004; Wertheim, Melles, Vos, et al, 2005; Perl, Cullen, Wenzel, et al, 2002; Shopsin, Mathema, Martinez, et al, 2000; Cole, Tahk, Oren, et al, 2001; Kenner, O'Connor, Piantanida, et al, 2003].

MRSA, an antibiotic-resistant form of *S. aureus* bacteria, is a common HAI pathogen. Penicillin, the first antibiotic used on humans, was introduced in the U.S. in 1942 [Grossman, 2008]; by the mid-1940s, reports were published describing the isolation of penicillin-resistant *S. aureus* strains [Barber & Rozwadowska-Dowzenko, 1948; Kirby, 1944]. Following World War II, penicillin use became readily available resulting in widespread use and increased prevalence of penicillin-resistant strains [Chambers, 2001; Barber & Rozwadowska-Dowzenko, 1948]. In 1961 methicillin was introduced to combat penicillin resistance in *S. aureus*, and within less than a year methicillin-resistant strains were reported in the U.S. [Jevons, 1961]. The term MRSA is used to describe *S. aureus* bacteria with resistance to the beta-lactam class of antibiotics (penicillin-like antibiotics, including the penicillins [methicillin, dicloxacillin, nafcillin, oxacillin, etc]) and the cephalosporins.

Rarely reported from hospitals in the 1960s and 1970s, MRSA became endemic in U.S. hospitals by the early 1980s, with 18 hospitals from across the U.S. reporting MRSA outbreaks between 1976-1981 [Thompson, Cabezudo & Wenzel, 1982]. MRSA emerged to become an important cause of bloodstream infections, healthcare-associated pneumonia, and surgical site infections. It was estimated that 10% of all bloodstream infections in hospitals were caused by MRSA [Kuehnert, Hill, Kupronis et al, 2005].

Effective January 1, 2013, as part of the CMS Value-Based Purchasing program, medium- and large-sized hospitals (excludes military/Veterans Affairs-affiliated and rural hospitals with less than 25 beds) were required to report hospital-onset MRSA bloodstream infection using the CDC's National Healthcare Safety Network (formerly the National Nosocomial Infections Surveillance system), the gold standard for HAI surveillance in the U.S. Over time, as these data become available, a centralized tracking system will be utilized to estimate the burden of MRSA bloodstream infections acquired in hospitals, one of the most severe types of HAI.

Multiple methods using several different datasets have been utilized to estimate the burden of MRSA in U.S. hospitals. The CDC's National Nosocomial Infections Surveillance system began in 1970 as a voluntary method for use by hospitals to systematically track HAI

[Emori, Culver, Horan, et al, 1991]. Data reported to the National Nosocomial Infections Surveillance system were used by CDC to describe the burden and monitor trends of HAI in the U.S. [Emori et al, 1991]. From 1975 through 1991, the proportion of *S. aureus* resistant to methicillin increased from 2.4% to 29% [Panlilio, Culver, Gaynes, et al, 1992]. The proportion of *S. aureus* isolates resistant to methicillin among U.S. intensive care units increased 3.1% per year, from 35.9% in 1992 to 64.4% in 2003 [Klevens, Edwards, Tenover, et al, 2006].

Using National Hospital Discharge Survey data, CDC reported that an estimated 125,969 hospitalizations listed MRSA infection as a diagnosis annually from 1999-2000, accounting for 3.95 per 1,000 hospital discharges [Kuehnert et al, 2005]. Analyses using data from the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project from years 1993 to 2005 showed an increasing trend in hospital stays with MRSA infection (identified using the ICD-9 code for MRSA, available as a secondary diagnosis) which increased nearly 10-fold from 38,100 hospitalizations in 1995 to 368,600 in 2005 [Elixhauser & Steiner, 2007].

The CDC's Emerging Infections Program/Active Bacterial Core surveillance (ABCs) system, which includes 9 metropolitan regions across the U.S. (Hennepin and Ramsey counties in Minnesota), is currently the most comprehensive MRSA tracking system in the U.S. Initiated in 2005, this MRSA surveillance system employs a common protocol to consistently monitor invasive MRSA infections (e.g., sterile body sites such as blood, bones, joints) and uses clinical information to epidemiologically classify MRSA acquisition for each case (community-onset, healthcare-associated community onset, hospital-onset) [Klevens et al, 2007]. CDC estimated that 94,360 invasive MRSA infections occurred in 2005 in the U.S., of which 26.6% were acquired in the hospital and 20% resulted in death (approximately 18,900 hospital-onset MRSA bloodstream infections) [Klevens et al, 2007].

CDC reported that invasive MRSA infections acquired in the hospital decreased 9.4% per year for years 2005 to 2008, from an incidence of 1.02 (95% CI: 0.97-1.07) per 100,000 population in 2005 to 0.74 (95% CI: 0.70-0.78) per 100,000 in 2008 [Kallen, Mu, Bulens, et al, 2010]. In 2011, CDC reported a similar trend with the estimated number of invasive MRSA

infections in the U.S. at 80,461, representing a 31% decrease compared to the 2005 estimates [Dantes, Mu, Belflower, et al, 2013]. Of the total number of infections in 2011, 77% were classified as having onset in the community but with recent exposure to healthcare such as long-term care facility residents, dialysis patients, and patients recently discharged from the hospitals; among cases (excluding dialysis patients) with prior hospitalization, nearly two-thirds developed infection within 3 months of hospital discharge [Dantes et al, 2013]. Compared to adult cases, among pediatric cases, the incidence rate of invasive MRSA infection decreased 9.8% per year from 2005-2010, however the rate of hospital-onset MRSA infection in this patient population did not change over this same time period [Iwamoto, Mu, Lynfield, et al, 2013].

Recent reports from CDC suggested that the incidence of MRSA infection (particularly bloodstream infection) acquired in the hospital was decreasing [Burton, Edwards, Horan, et al, 2009; Kallen et al, 2010; Dantes et al, 2013]. While this trend is encouraging, administrative data, single-institution reports, and CDC surveillance systems indicate that MRSA remains a substantial burden in U.S. hospitals. MRSA prevention and control remains a challenge, and consequently, MRSA continues to be a major patient safety and public health threat.

2.3 MRSA Prevention and Control in Hospitals

MRSA is most frequently transmitted in hospitals through the failure of practicing basic infection prevention strategies such as hand hygiene, environmental cleaning/disinfection, and use of personal protective equipment [Goldmann et al, 1996; Sandora & Goldmann, 2012].

The CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), the federal advisory committee convened to provide guidance to CDC and HHS regarding infection control strategies in U.S. healthcare settings, recommends the use of single-patient rooms, as available, and Contact Precautions – an enhanced level of infection control precautions which includes the use of gowns and gloves – when caring for hospitalized patients with MRSA infection or colonization [Siegel et al, 2007a]. While there is no single approach or one-size-fits-all strategy that is recommended for MRSA prevention in hospitals, the generally accepted key components to a MRSA prevention and control program include compliance with hand hygiene,

cleaning/disinfection of the environment and equipment, Contact Precautions including gown and glove use when caring for patients infected or colonized with MRSA, isolating patients infected or colonized with MRSA in a private room or cohorting with other patients with the same organism or who are immunocompetent, device bundles (central line bundle and ventilator bundle), and active surveillance testing for MRSA to rapidly identify patients with MRSA colonization or infection [IHI 2006; Siegel et al, 2007a; APIC 2010]. The focus of these strategies is primarily on healthcare personnel preventing contamination of hands, patient care items, and surfaces encountered to thereby prevent spreading the bacteria to themselves, patients, and the hospital environment.

Several guidance documents are available for hospitals for MRSA prevention and control developed by HICPAC [Sehulster & Chinn, 2003; Siegel et al, 2007a, 2007b; Rutala & Weber, 2008], professional societies [Calfee, Salgado, Milstone, et al, 2014; Yokoe, Anderson, Berenholtz, et al, 2008; APIC 2010; IHI 2006; AORN 2007; Muto, Jernigan, Ostrowsky, et al, 2003; American Society of Anesthesiologists 1999; Engelman, Shahian, Shemin, et al, 2007; Chambers, Eisenhauer, McNicol, et al, 2006], as well as guidance for specify categories of infection in which MRSA is a frequent cause (surgical site infection, healthcare-associated pneumonia, catheter-associated urinary tract infection, and intravascular catheter-related infection) [O'Grady, Alexander, Burns, et al, 2011; Gould, Umscheid, Agarwal, et al, 2009; Tablan, Anderson, Besser, et al, 2004; Mangram, Horan, Pearson, et al, 1999]. The MRSA prevention and control strategies are consistent across guidance documents apart from the strategies about active surveillance for MRSA and the use of decolonization protocols, which some consider as strategies beyond the "core" MRSA prevention strategies.

The HICPAC MDRO Guideline includes recommendations for organizational level strategies such as "Make MDRO prevention and control an organizational patient safety priority"; "Provide administrative support, and both fiscal and human resources, to prevent and control MDRO transmission within the healthcare organization"; and "Provide education and training on risks and prevention of MDRO transmission during orientation and periodic educational updates for healthcare personnel; include information on organizational experience with MDROs and

prevention strategies." [Siegel et al, 2007a]. The Committee designated none of these strategies to be supported by the highest level of scientific rigor (e.g. "category 1A"), indicating that no "well-designed experimental, clinical, or epidemiologic studies" have been conducted in these areas [Siegel et al, 2007a].

The guidance documents that are available focus heavily on implementation of individual-level practices for MDRO/MRSA prevention without much attention to organizational strategies. Notably, the HICPAC MDRO Guideline only recommends evaluating healthcare system factors as an "intensified intervention", indicating that the practice is recommended only when the facility has failed to "decrease the prevalence or incidence of a specific MDRO…despite infection control efforts to stop its transmission" [Siegel et al, 2007a]. Well-designed studies are clearly needed to evaluate organizational-level and systems-level factors that impact infection transmission in hospitals.

Guidance for MRSA prevention and control in hospitals indicates that MRSA is preventable when appropriate infection prevention strategies are implemented appropriately. Yet despite the availability of guidance for hospitals, implementation remains a considerable challenge, and consequently MRSA transmission in hospital remains a challenge.

2.4 MRSA previous studies and gaps in the literature

A PubMed search for "MRSA prevention in hospitals" returned over 1,700 results in English, of which 685 were published in the last 5 years (searched April 6, 2014). Previous research on the prevention and control of MRSA in hospitals has largely focused on proximal factors such as biological- and individual-level interventions [Pronovost et al, 2008; Gardam et al, 2009; Gardam, Reason, Rykert, 2010; Sandora & Goldmann, 2012; Jain, Kralovic, Evans, et al, 2011].

From a clinical infectious disease epidemiologic perspective, the acquisition of pathogens in the hospital occurs through one of three routes: endogenous transmission – from the patient's own flora; exogenous transmission – bacteria are transmitted directly (e.g., from hands of healthcare personnel); and exogenous transmission via surfaces – bacteria are transmitted

indirectly through secondary transmission of bacteria from surfaces to patients. Research aims to interrupt transmission routes to prevention MRSA infection/colonization. Three current areas of interest in MRSA prevention in the hospital setting include the practice of actively screening patients for MRSA, the practice of universal decolonization for all patients to protect against all pathogens (not solely MRSA), and the practice of topical antibiotic prophylaxis among MRSA-colonized patients.

The practice of actively screening patients upon admission to the hospital (or unit/ward) to rapidly identify patients with MRSA colonization to thereby prevent infection has been debated for several years. Despite several studies of varying design and rigor [Ellingson, Muder, Jain, et al, 2011; Jain et al, 2011; Rodriguez-Bano, García, Ramírez et al, 2010; West, Guerry, Hiott, et al, 2006; Muder, Cunningham, McCray, et al, 2008; Singh, Squier, Wannstedt, et al, 2006; Papia, Louie, Tralla, et al, 1999; Huang, Yokoe, Hinrichsen, et al, 2006; Robicsek, Beaumont, Paule, et al, 2008; Clancy, Graepler, Wilson, et al, 2006; Jeyaratnam, Whitty, Phillips, et al, 2008; Nijssen, Bonten & Weinstein, 2005; Harbarth, Fankhauser, Schrenzel, et al, 2008; Huskins, Huckabee, O'Grady, et al, 2011; Fätkenheuer, Hirschel & Harbarth, 2014; McGinigle, Gourlay & Buchanan, 2008], the strategy has been met with mixed results with no consistent trend that the practice decreases MRSA acquisition in hospitalized patients.

There is growing interest in moving away from targeting specific pathogens like MRSA with special precautions – a so-called vertical approach to infection prevention. Instead, some favor the use of a horizontal approach whereby infection prevention strategies are applied universally to patients to prevent infection from any type of organism [Wenzel, Bearman & Edmond, 2008; Wenzel & Edmond, 2010; Edmond & Wenzel, 2013; Septimus, Weinstein, Perl, et al, 2014]. Horizontal transmission relies on consistent infection prevention strategies such as hand hygiene [Harris, Pineles, Belton, et al, 2013], care bundles [Ellingson et al, 2011; Jain et al, 2011; Perlin, Hickok, Septimus, et al, 2013], and chlorhexidine gluconate (CHG) bathing in place of usual soap and water baths [Bleasdale, Trick, Gonzalez, et al, 2007; Climo, Sepkowitz,

Zuccotti,et al, 2009; Popovich, Hota, Hayes, et al, 2009; Batra, Cooper, Whiteley, et al, 2010; Climo, Yokoe, Warren, et al, 2013; Derde, Cooper, Goossens, et al, 2014].

Another area of research regarding MRSA prevention in the hospital setting is use of topical antibiotic prophylaxis to decolonize MRSA-colonized patients in order to decrease the risk of infection and transmission. The antibiotic mupirocin, considered the most effective agent available for eliminating MRSA colonization, has been tested using over fifty different regimens [Boyce, 1996]. While mupirocin remains the antibiotic of choice for most MRSA decolonization regimens the efficacy remains unclear, there is a lack of established national guidance surrounding its use, and data are lacking to demonstrate its effectiveness as an infection prevention strategy [Robicsek, Beaumont, Thomson, et al, 2009; Simor, 2011].

Recent research indicates a growing interest in organizational-level and behavioral factors in relation to MRSA transmission in hospitals [Henderson et al, 2012; Jain et al, 2011] yet major gaps in the literature exist including:

- Rigorous evaluation of organizational-level factors as risk factors for MRSA transmission in hospitals
- Evaluation methods for hospital policies and other organizational control methods
- Well-designed studies on the effectiveness of hospital policies on patient outcomes
- Well-designed studies regarding the effect of hospital policies and compliance by healthcare personnel
- Studies often are atheoretical or not grounded in behavioral change theory

Considerable gains have been made through studying biological-level and individual-level factors in the transmission of MRSA in hospitals yet gaps are apparent regarding how organizational factors impact MRSA transmission in hospitals. The idea is not to deny those gains but add to them by approaching HAI prevention in hospitals through a broader perspective that includes the importance of the organization as a social phenomenon to reveal a more complete story about the relationship between hospital policies and the spread of MRSA. Here, the objective is to utilize the social to inform the distribution of the biological.

2.5 Organizational policy

Organizations are social phenomena. Charles Barnard, an expert on management and leadership, viewed the organization as a "complex social system," defining an organization as a "system of consciously coordinated activities or forces of two or more persons" [Barnard, 1938]. Arnold Tannenbaum, organizational psychologist and author of the text *Control in Organizations*, described organizations as "orderly arrangements of individual human interactions, in which control is an essential ingredient" [Tannenbaum, 1962]. He noted that the organization was of particular interest to the sociologist and the psychologist because one finds within them an "important juncture between the individual and the collectivity" [Tannenbaum, 1962].

In the early 20th Century, the formalization of organizational control methods substantially changed due to the growing scope, scale, and advancing technologies in business [Volti, 2012]. This growth created managerial challenges that resulted needs for transforming the organization of the work in an effort to create order [Volti, 2012]. Organizational control has been studied by organizational sociologists, administrative theorists, and organizational psychologists. With varying perspectives, the construct of organization control has a variety of definitions and often overlaps with leadership, power, influence, and control [Flamholtz, Das & Tsui, 1985; Ouchi, 1979]. Ouchi straightforwardly defined organizational control as mechanisms through which an organization can be managed to move it towards its objectives [Ouchi, 1979] while Flamholtz described organizational control as "attempts by the organization to increase the probability that individuals and groups will behave in ways that lead to the attainment of organizational goals" [Flamholtz et al, 1985].

Organizational control systems include formal, informal, output and behavior controls, administrative and social controls, and results, actions, and personnel controls [Langfield-Smith, 1997]. Organizational policy is a type of formal organizational control developed to "ensure that specific outcomes will be achieved and involve monitoring, measuring, and taking corrective actions" [Langfield-Smith, 1997]. Organizational policy is a control process that codifies the direction and control of the organization, whereby the leadership of the organization articulates

expectations for staff. Tannenbaum described the function of control processes as "…to invoke conformance to organizational requirements necessary for the accomplishment of organizational goals. Such processes are needed to establish a minimum order of order out of potential chaos of diverse and often conflicting interests. Hence, an effective control policy enables the pursuit of organizational goals by circumscribing idiosyncratic behaviors." [Tannenbaum, 1962].

> Characterizing an organization in terms of its patterns of control is to describe an essential and universal aspect of organization, an aspect of organizational environment which every member must face and to which he must adjust. Organization implies control. A social organization is an ordered arrangement of individual human interactions. Control processes help circumscribe idiosyncratic behaviors and keep them conformant with the rational plan of the organization. Organizations require a certain amount of conformity as well as the integration of diverse activities. It is the function of control to bring about conformance to organizational requirements and achievement of the ultimate goals of the organization. The co-ordination and order created out of the diverse interests and potentially diffuse behaviors of members is largely a function of control. It is at this point that many of the problems of organizational functioning and of individual adjustment arise. [Tannenbaum,1962].

Policy in an organization provides the rules to the game, so to speak. Policy impacts how humans interact, organize. It impacts social norms within the organizations – through implementation and adherence. Social norms are unwritten standards for a social group such as table manners. "Social norms are shared understandings about actions that are obligatory, permitted, or forbidden" [Crawford & Ostrom, 1995]. Independent of government, social norms are rules enforced through various types of sanctions, and importantly, once established, norms are very difficult to undue [Posner & Rasmusen, 1999]. It is not fully understood how norms become established and even less is known about how to change social norms [Posner & Rasmusen, 1999].

Organizational policy is a common control method used in hospitals. Informed by best practice documents and guidelines, the goal of an effective organizational policy is to create a standard for the staff within the organization through the development and implementation of protocols/procedures. Components of an effective policy may include the expectations and accountability for staff, the rationale for policy instruction/guidance, instruction on how to properly

carry out specified actions to meet facility expectations, and consequences of violation of the policy. Inclusion of protocols and/or procedures augments the effectiveness of organizational policies by providing detailed documentation for implementation and adherence. When changes occur – for any reason such as failure to comply, failed implementation, new/changed guidance or regulation – a change control process should be in place to modify the policy. Additionally, organizational policy is a useful method to incorporate prevention practices into daily/routine workflow, avoiding initiative fatigue [Gardam, Reason & Gitterman, 2012]. An effective policy indicates support from leadership in contrast to a focused educational or awareness campaign/initiative that may improve staff compliance in the short term but such improvements often are not maintained without fundamental changes in behavior and expectations [Gardam et al, 2012].

The characterization of the policy environment has been useful in approaching other public health issues such as alcohol control [Naimi, Blanchette, Nelson, et al, 2014; Nelson, Xuan, Babor, et al, 2013; Toomey, Nelson, Winters, et al, 2013; Toomey Kilian, Gehan, et al, 1998; Saltz, 1987], gun control [Fleegher, Lee, Monuteaux, et al, 2013], tobacco control [Gilpin, Stillman, Hartman, et al, 2000; Joossens & Raw, 2006; Schaap, Kunst, Leinsalu, et al, 2008], seatbelt use [Harper, Strumpf, Burris, et al, 2014], and obesity prevention [Nanney, Nelson, Wall, et al, 2010]. In the example of alcohol policy, great strides have been made with evaluating various levels of policy – from countries to states to the establishments that serve and sell alcohol. Following the development of a successful method to evaluate a variety of policies for establishments that serve and sell alcohol, training programs were developed and tested using a randomized controlled trial design to study the effect of the training policy on alcohol-related outcomes [Toomey, Erickson, Lenk, et al, 2008].

To qualify for CMS certification and reimbursement, providers and hospitals must comply with minimum health and safety standards of CMS termed Conditions of Participation. Hospitals that receive payment from by the CMS must be in compliance with the CMS Conditions of Participation. The CMS Conditions of Participation were developed to protect patient safety,

ensure quality of care, and reduce spending. In the CMS *State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals Table of Contents* (Rev. 122, 09-26-14), there are 23 Conditions of Participation, each with accompanying Standards. The Conditions of Participation include Patient's Rights, Medical Record Services, Governing Body, and Infection Control, among others.

The overarching guidance in the Infection Control Condition of Participation is that the hospital must provide a "sanitary environment" to avoid infection transmission through an infection control program developed, implemented, and coordinated by a trained infection control officer(s). The Condition has two Standards: "Organization and Policies" and "Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services." The nine activities outlined under the Organization and Policies Standard are as follows:

1. Maintenance of a sanitary hospital environment (includes ventilation, food sanitation, cleaning/disinfecting the environment and equipment, etc);
2. Development and interpretation of infection control measures related to hospital personnel (includes vaccinations, new employee training, etc);
3. Mitigation of risks associated with patient infections present on admission (includes early identification for patients requiring isolation, appropriate use of PPE, etc);
4. Mitigation of risks contributing to HAI (includes surgical site infection risk measures, aseptic technique practices, hand hygiene, prevention measures specific to antibiotic-resistant infections, device utilization, measures specific to device-related infections, isolation procedures, adherence to infection control precautions, infection education for staff, patients, and visitors, etc);
5. Active surveillance for infections (includes surveillance for patients and employees, infections that are reportable to local health authorities, infections resistant to multiple classes of antibiotics, etc);
6. Monitoring compliance with all policies, procedures, protocols, and other infection control program requirements (includes provisions to monitor compliance);

7. Program evaluation and revision of the program, when indicated (includes provision for evaluation);
8. Coordination with federal, state, and local authorities as required by law to address communicable disease threats, bioterrorism, and outbreaks (includes policies and procedures to address communicable disease threats, bioterrorism, and outbreaks);
9. Compliance with reportable disease requirements of the local health authority (includes procedures for meeting reportable disease requirements).

The two activities outlined under the Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services Standard are as follows:

1. Ensure that the hospital-wide quality assessment and performance improvement program and training programs address problems identified by the infection control officer or officers;
2. Be responsible for the implementation of successful corrective action plans in affected problem areas.

Policies and procedures are to be based on national guidelines to the degree possible for the nine elements of the infection control program. The Infection Control Condition of Participation is not highly prescriptive in that it provides broad guidance but details regarding the specifics needed to meet each policy, procedure, protocol required are not clearly stated.

The only additional guidance document related to MRSA prevention at the state level (relevant to this dissertation) is the *Recommendations for Prevention and Control of Methicillin-Resistant Staphylococcus aureus (MRSA) in Acute Care Settings*, developed by the Minnesota Department of Health (MDH) to comply with Minnesota Statutes, section 144.585, which passed in 2007. The legislation required that MDH establish guidance for acute care hospitals in Minnesota to develop and implement MRSA infection prevention and control programs, effective January 1, 2009. The guidance was intended to provide a variety of infection prevention strategies for MRSA that hospitals selected based on the MRSA prevalence and the patient population and services provided. The only “required” strategy for hospitals was to conduct an

annual risk assessment for MRSA in their hospital to determine the MRSA infection rate in order to identify prevention priority areas. While the legislation exists, there is no regulatory component and, therefore, the guidance is not enforceable by CMS surveyors. However, Minnesota hospitals actively participated in developing the MRSA guidance document and anecdotal information suggests that many hospitals complied with the legislation (MDH, personal communication).

In summary, organizations are social phenomena, and work is a highly social activity. The workplace is a "repository of values, attitudes, norms, accepted procedures" [Volti, 2012]. Effective organizations require effective control. Paveljit Bindra, chief medical and information office at Citrus Valley Health Partners stated, following an organizational restructure, "Working here is their choice, but how they work here is our choice" [Wartzman, 2012]. This perspective is easier said than done – particularly in a highly specialized and complex industry where factors such as hierarchy, autonomy, and lack of collaboration act as major barriers to effective organizational policy implementation. When considering control methods within the organization, the context of the organization is critical. The biological (bacteria, antimicrobials, disinfectants), the individual (behavior, culture), and the organization (norms, expectations) – factors that work to produce complex feedback loops and intersections – must be considered when trying to fully understand MRSA transmission in a hospital in order to effectively prevent it.

2.6 Medical errors

The practice of medicine in a hospital setting is highly complex. In an example described by Leape, the act of administering a single dose of a drug into a hospitalized patient involves 10-15 steps, with the potential for error occurring at each step [Leape, 1997].

The Institute of Medicine (IOM) defined medical error as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim," and includes adverse drug events, wrong-site surgeries, surgical injuries, falls, burns, mistaken patient identities, and HAI [IOM 1999]. A 1999 IOM report, *To Err is Human*, estimated that 44,000 - 98,000 deaths occur annually in the U.S. as a result of medical errors with a price tag of $17 – 29 billion [IOM 1999].

Published reports following the IOM report suggested that the number was substantially underestimated, given that HAIs have been estimated to cause 90,000 deaths annually in the U.S. and that hospital-acquired bloodstream infections, alone, are the 8th leading cause of death in the U.S. [Leape & Berwick 2005; Klevens et al 2006; Wenzel 2007]. An updated estimate of medical errors in U.S. hospitals reported that 210,000 – 400,000 deaths occur annually in the U.S. as a result of medical errors and "serious harm" events not resulting in death were estimated to be 10- to 20-fold higher than harm leading to death [James 2013]. Unstable estimates result from the lack of a standardized measurement system for medical errors in the U.S. While the estimates of morbidity and mortality due to medical errors vary, it is clear that medical errors, including HAI, are serious patient safety and public health issues.

Historically, research on human error focused on high-hazard industries such as transportation (air, sea, road) and nuclear energy plants where accidents had large-scale impact, often garnering public attention [Reason, 1995]. In comparison, a medical error generally impacts an individual patient and rarely causes public attention. Research into medical errors gained headway in the 1990s, but it was the 1999 IOM report that highlighted medical errors as a national priority.

Error management requires a two-fold approach: limiting the incidence of errors, and because that is not completely possible, development of systems that can tolerate errors and reduce their effects [Reason, 2000]. The term "high reliability organization" is used to describe industries comprised of complex systems that can withstand operational hazards and still effectively achieve its goals [Reason, 2000; Hofmann, Jacobs & Landy, 1995]. The focus of high reliability organization research, as compared to industrial accident research, for example, is the reliability of the organization in its entirety – "how the organizational structure promotes (or inhibits) the coordination and execution of these complex processes" [Hofmann et al, 1995].

Reason categorized error into two main types: slips (lapses) and mistakes [Reason, 1990]. Slips (e.g., slip of the tongue, slip of the pen) and lapses (e.g., memory failures) occur when "some failure in the execution and/or storage stage of an action sequence, regardless of

whether or not the plan which guided them was adequate to achieve its objective. Mistakes, which generally lead to greater danger and are more difficult to detect than slips/lapses, occur when “deficiencies or failures in the judgmental and/or inferential processes involved in the selection of an objective or in the specification of the means to achieve it, irrespective of whether or not the actions directed by this decision-scheme run according to plan” [Reason, 1990].

Error prevention researchers emphasize focusing on systems/organizational processes, a major shift from focusing on individual practice in healthcare [Leape, Berwick & Bates, 2002]. “…the clear message from the IOM report, *To Err is Human*, is that safety is primarily a systems problem” [Leape et al, 2002]. Research on accidents in complex systems, such as the airline and nuclear energy industries, has moved away from analyzing individuals and proximal causes of error, and instead moved toward analyzing the system that produced the error and how the organization “makes safety,” including the organizational factors that mold and influence behavior [Leape et al, 1998].

The healthcare field has been slow to embrace the progress made by cognitive psychologists and human factors scientists in human error prevention. Several factors specific to healthcare contribute to the industry’s challenges with human error: medical training that stresses error-free practice and a sense of responsibility for patients (and therefore personal responsibility for errors), and a system that expects perfection and then takes disciplinary action when that is not achieved [Leape, 1997]. A common perspective of the practice of medicine is that it is an individual endeavor involving the physician and his/her patient – reflected in most policy recommendations and prevention strategies – yet analysis of medical errors a different story, highlighting the “influence of the inter-relationship among health-care professionals and administrative actions on errors” [Andrews, Stocking, Krizek 1997; Leape et al, 1998; Leape et al, 2002].

Two important lessons have been learned from research on human errors – human error is common and human errors occur because of defects in the way that systems are designed [Leape, 1997; Reason, 1990; Perrow, 1984]. Reason [1990] and Perrow [1984] both posit that the

root causes of errors are systems failures. “These are failures in the design of processes, the management of the conditions of work, and in the training of individuals for their jobs” [Leape, 1997]. Most errors result from environments that increase the risk of mistakes such as “excessive reliance on memory, lack of standardization, inadequate information availability and poor work schedules” [Leape, 1997]. Inferred from this theory is that in order to prevent human error in hospitals is to design systems that prevent human error.

We can use what has been learned with error prevention in high reliability organizations to conceptualize how medical errors, including HAI, are allowed to happen in a hospital. What systems are in place in hospitals to prevent errors that may lead to MRSA transmission, and are these reflected in hospital policies?

2.7 Summary

Patients are living longer and with complex medical conditions due to the development of new medical devices and treatments. Susceptible patients with medical devices that can easily become contaminated and quickly enter the patient’s body (e.g., central lines, ventilators) present new challenges in the prevention of HAI. However, the length of stay in recent years has not changed substantially [Bernstein, Hing, Moss, et al, 2003; MDH Health Economics Program], MRSA prevention and control guidelines are available, effective disinfectants are available for the hospital environment, effective products/methods for cleaning/disinfecting healthcare personnel hands are available, and there have been no substantial changes in MRSA strains causing hospital-onset infections in Minnesota [MDH, personal communication]. Generally, MRSA strains found in the hospital are clonal, suggesting that there are a few dominant strains that persist [Chambers, 2001; Enright, Robinson, Randle, et al, 2002; Holden, Hsu, Kurt, et al, 2013]. To echo the healthcare quality researchers that authored the IOM report, “what’s taking so long?” [IOM 1999].

Despite recent successes, MRSA continues to spread in hospitals. The spread is not random, indicating that human behavior plays a role in altering the distribution of MRSA in the hospital setting. Given the state of the science, it is essential to understand what can be gained

through studying the context in which the individual- and biological-level interventions are intended to be applied in order to wholly understand MRSA transmission in hospitals. Clearly, further work in this area is needed and the focus of study must be broadened to evaluate upstream factors that can impact MRSA transmission in hospitals, enhancing what we know about biological- and individual-level factors.

3. Theoretical Framework

3.1 Overview

The fundamental question of this dissertation addresses whether MRSA acquired in the hospital is impacted by organizational policy. Ideally, one would conduct a randomized controlled trial, the gold standard in epidemiologic studies, whereby hospitals would be randomized to Policy A (treatment group) or randomized to implement Policy B (control group), and subsequently the hospital-acquired MRSA rates would be measured in all hospitals. Such a design would allow one to test whether the MRSA rates between treatment and control hospitals were the same, but for the policy, assuming the randomization was successful. Due to the scientific gaps in organizational policy evaluation in relation to MRSA control in hospitals, the state of the science is not at a place where the ideal experiment can be conducted to adequately answer the research question. This dissertation aims to begin to fill the gaps needed to eventually conduct such an experiment through systematically evaluating key policies in hospitals in an attempt to measure the social context of the organization.

3.2 Intersection of social epidemiology and infectious disease epidemiology

The subfield of infectious disease and the subfield of social epidemiology naturally intersect due to the interdependencies of the individual and environment to explain disease patterns and causality. Infectious disease epidemiology is characterized by the focus on the ways in which host, agent and environmental interactions influence the transmission of infectious agents. The study of transmission and prevention considers connectedness and social arrangements between individuals, and the aggregate goes beyond the summation of the individual. For infectious disease epidemiology, the individual's risk of infectious disease necessarily considers the risk for the group. Two examples include the fact that incidence depends on the prevalence of disease [Halloran & Struchiner, 1995; McMichael, 1999]. The second is the concept of herd immunity which cannot simply be explained by aggregating individual-level risk because the risk of disease relies on the interdependencies of the group and its members [McMichael, 1999].

Social epidemiology is the branch of epidemiology that considers how “social interactions and collective human activities affect health” [Oakes & Kaufman 2006]. Social epidemiology aims to include the social interactions, institutions, and other social arrangements when examining exposures/interventions on health-related outcomes [Oakes 2013]. Notably, the field of social epidemiology appreciates that macro-level forces are a function of micro-level forces; forces at the macro level affect the individual just as forces at the micro level forces affect the group [Oakes 2013]. “Relevant constructs are always between persons and are often group-level phenomena…such measures reflect complex functions of individual action, interactions, and largely unknown feedback systems [Oakes & Kaufman 2006]. Noted by Susser in 1985, “Epidemiologic research takes place within the larger society. Its guiding concepts cannot be disconnected from that context, although they may transcend it” [Susser 1985].

The perspective of the infectious disease epidemiologist is on the microbiological agent; essentially, find the bug and eliminate it. The relevance of social epidemiology is complementary in the theoretical framework as its perspective is to explain the distribution of the bacteria. For example, the MRSA bacteria most certainly cause infection but how are the bacteria distributed and what organizational arrangements cause the distribution of the bacteria? There is no doubt that MRSA causes disease, but with the social epidemiology perspective, the causal mechanisms are more distal, providing a more complete story of disease transmission. The causal mechanism for infectious disease outcomes includes the social structure.

Given that the distribution of MRSA in hospitals is not random and MRSA transmission in hospitals is preventable through proper adherence to infection prevention measures such as washing hands after patient care [Goldmann et al, 1996; Stone, Glied, McNair, et al, 2010; Pittet, 2004] it is prudent to consider distal factors such as organizational policies, which codify the organizational direction and control with respect to MRSA prevention. McMichael wrote, “The preoccupation with seeking specific proximate risk factors has been disdainfully referred to as ‘risk factorology.’ The criticism is misleading; the fault is not in doing such studies, but in only doing such studies. We should also be looking upstream for a fuller account of disease causation

within a population context; we must extend our focal length" [McMichael, 1999].

There is an increasing discourse regarding the importance of considering structural factors in studying HAI in hospitals [Gardam et al, 2009; Gardam, Reason, Rykert, 2010; Saint et al, 2010]; however, studies that evaluate the relationship between structural factors and MRSA are rare. One remark from a recent commentary was: "HAIs have more in common with social problems such as littering than with our traditional perception of an adverse event, which tends to have a more linear association between cause and effect" [Gardam M, Reason P & Gitterman, 2012]. Traditional epidemiologic approaches to MRSA prevention in hospitals aim to find the bug and eradicate it. However, infection transmission in the hospital setting is a systems and human behavior problem. As such, a conceptual framework that includes the social system of the individual must be applied to approach the research question of this dissertation. While the epidemiologist interested in biological interventions asks the question "what's the probability of getting MRSA in the hospital?" the social epidemiologist asks "what's the probability of getting MRSA in the hospital with that policy? The social epidemiologist in interested in the "cause of causes" [Oakes, personal communication].

3.3 Previous theoretical models

Commonly, intervention studies in infection prevention research are carried out without incorporating behavioral theory. Behavioral theory frameworks that have been applied in the infection prevention research have been primarily to examine individual-level healthcare worker behavior related to influenza vaccination, compliance with precautions, and motivation for and compliance with hand hygiene.

Behavioral theories that are often used to explore the relationship of behavior on health outcomes include the Social Cognitive Theory and the Theory of Planned Behavior/Reasoned Action. These behavior theories emphasize individual knowledge, attitudes, beliefs, and skills related to health [Glanz, Rimer, Viswanath, 2008]. The Theory of Planned Behavior/Reasoned Action [Ajzen, 1985, 1987] considers individual motivations such as attitudes, norms, and perceived control when an individual carries out a behavior [Glanz et al, 2008]. The Social

Cognitive Theory [Bandura, 1986] considers the interplay of behavior, personal factors, and environmental factors that produce a particular behavior [Glanz et al, 2008].

While useful for some studies, to approach the research question of this dissertation, these theories fall short in that they fail to demonstrate how the individual's behavior affects the sum of the individuals in the group which then results in group-level change, producing the social context of the group. Social change occurs only when individuals and their interactions change [Coleman, 1990]. To summarize, for the purposes of this dissertation, we are only interested in the individual in as much as his/her behavior impacts the outcome of the group. As such, the Social Cognitive Theory framework, which incorporates the influence of the environment on individual actions, is not sufficient because the resulting health outcome measure is the aggregated changes in individuals. The framework is too simplistic in that the individuals' interactions and social relationships that impact the social context of the group are excluded [Oakes & Kaufman, 2006]. The misstep is to assume that "all macro-level forces are exogenous to individual actors and circumstances" [Oakes, 2013].

3.4 Conceptual model: Coleman's theoretical framework

The research question of this dissertation is most usefully framed using the lens of social epidemiology and applying Coleman's theoretical framework [Coleman, 1990]. Rooted in sociology, in 1990 Coleman proposed a multilevel approach to study the mechanisms of social change. Coleman was interested in how a social organization, such as a society, changes from one time point to another. Coleman posited that because social phenomena does not originate through simply summing behavior of individuals – "the focus must be on the social system whose behavior is to be explained…the essential requirement is that the explanatory focus be on the system as a unit, not the individuals or other components which make it up." [Coleman, 1990].

Coleman depicted his multilevel approach using a trapezoidal figure (the "bathtub") (Figure 1) [Oakes & Kaufman, 2006]. The bathtub is useful as it illustrates that social change at the macro level comes about through the group changing the individual (macro-micro level; Figure 1, arrow "a"), and changed individuals and their interactions (micro level; Figure 1, arrow

"b") then affect change at the group level (micro-macro level; Figure 1, arrow "c"). It is the macro-micro and micro-micro transitions that are of interest to the social epidemiologist since the individuals are of interest only as much as they affect the group level [Oakes & Kaufman, 2006].

Coleman's framework is most appropriate for this dissertation research question because the focus is multi-level, connecting the group level to the individual level. Of course, for social epidemiology, the outcome of interest is health related – hospital-onset MRSA in this dissertation. The macro level allows the social context and environment to be considered. The micro level allows the membership of the group – the individuals and their interactions – to be considered. The diagonal lines that connect the macro and micro levels are of most interest to the social epidemiologist. For this dissertation, the leftmost larger circle represents the hospital at time point one. The leftmost smaller circle represents a healthcare worker in that hospital. The rightmost smaller circle represents the healthcare worker following implementation of an organizational policy and the rightmost larger circle represents the hospital following the implementation of the organizational policy. The outcome of interest is the HO-MRSA at the hospital level following policy implementation. Policy is a tool that can be used to impose or change social norms for the organization – impacting the macro to micro transitions, as conceptualized with Coleman bathtub.

Group-level change is grounded in the activity of individuals [Oakes, 2009]. Therefore, changes in infection rates in hospitals can only be explained by the actions of individual healthcare workers and patients within the context of organizational rules and social norms [Oakes, 2009]. The group necessarily changes through its individuals but how does society "get into" [Oakes & Kaufman, 2006] the individual whereby the behavior of individuals and interactions between individuals changes leading to society at time point two [Coleman, 1990]. Related to this dissertation, the question can be asked: does a hospital's organizational policy "get into" a healthcare worker, changing behavior to comply with the policy, subsequently producing compliant individual behavior that ultimately leads to a hospital with reduced HO-MRSA rates?

Using policy as an organizational-level tool for organizational control, we seek to evaluate the social circumstances or social context in an effort to inform infection prevention and control of

MRSA. How can we effectively leverage forces working at the group level to impact change at the micro level which consequently produces effective change for the macro level? The hypothesis is that effective organizational policies related to MRSA prevention and control impacts social norms for the organization which affect behavior of individuals and their interactions, producing an organization with low hospital-onset MRSA infection rates.

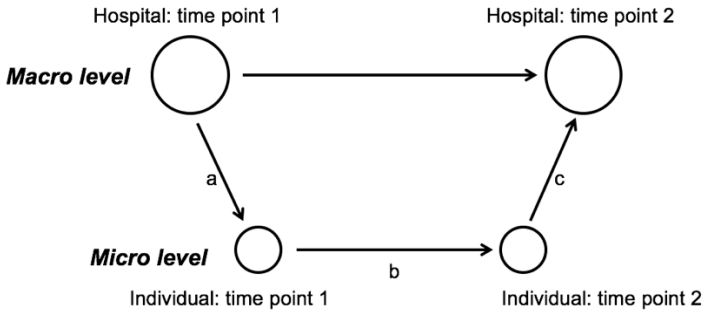

Figure 1. Coleman [1990] "bathtub" – diagram representing multilevel theory of social change

3.5 Summary

MRSA transmission is challenging to prevent and control in hospitals despite published guidelines and policy requirements by CMS. Thus far, the epidemiologic approaches utilized have been limited to “Robinson Crusoe” perspectives. The Robinson Crusoe analogy suggests that often in epidemiologic practice, individuals are studied without consideration given to social interactions, “Without any attention to social arrangements and institutions, epidemiologic research on humans is almost indistinguishable from an application to, say, livestock.” [Oakes & Kaufman, 2006]. Transmission of MRSA in hospitals is multifactorial involving human behavior factors, social norms, and organizational dynamics – factors that impact adherence to infection control strategies and that operate at the individual and organizational levels [Sandora & Goldmann, 2012; Grol, 1997; Saint et al, 2010; Pronovost, 2008.]. Applying a social epidemiologic framework to study the relationship between hospital policies and MRSA infection rates is necessary to understand hospital-level factors that impact MRSA transmission. Such a

framework will provide a comprehensive assessment of MRSA transmission in hospitals by considering distal and proximal factors.

4. Methods

4.1 Overview

The research question this dissertation asks is: do hospital policies impact hospital-onset MRSA bloodstream infection (HO-MRSA BSI) rates? This dissertation aims to begin to answer that question using a mixed-method ecological cross-sectional design. Data from several sources were used to address the specific aims of this research, which are as follows:

The objective of **Aim 1** was to provide context to the primary research question by describing describe the epidemiologic trends and burden of disease of MRSA infection. Specifically, **Aim 1a** described epidemiologic trends in invasive MRSA infection in the two most populous counties in Minnesota for years 2008-2013. **Aim 1b** explored the relationship between hospital-level characteristics and HO-MRSA BSI rates in U.S. hospitals in 2013 using two hospital-level CMS data sources. The objective of **Aim 2** was to develop a systematic method to evaluate organizational policies, identifying measurable and modifiable constructs, to advance measurement of hospital policies related to MRSA prevention.

The objective of **Aim 3** was to apply the systematic method developed in Aim 2 to evaluate relevant policies in 5 Minnesota hospitals and then examine the relationship between hospital policies and hospital-onset MRSA bloodstream infection incidence. The objective of **Aim 4** is to conduct qualitative interviews with healthcare personnel to describe practices related to the policies under study.

4.2 Aim 1a: Data source

The data source used for Aim 1a was invasive MRSA surveillance data maintained at the Minnesota Department of Health (MDH). The surveillance system was a program coordinated through CDC's Emerging Infections Program/Active Bacterial Core surveillance (ABCs) that included nine geographically diverse metropolitan areas in the U.S., covering approximately 15 million persons in 2008 [Kallen, Mu, Bulens, et al, 2010]. The sites included the state of Connecticut; the Atlanta, Georgia metropolitan area (Clayton, Cobb, DeKalb, Douglas, Fulton, Gwinnett, Newton, Rockdale counties); the San Francisco Bay area, California (Alameda, Contra

Costa, San Francisco counties); the Denver, Colorado metropolitan area (Arapahoe county); the Portland, Oregon metropolitan area (Clackamas, Multnomah, Washington counties); Monroe County, New York; Baltimore City, Maryland; Davidson County, Tennessee; and the Twin Cities metropolitan area, Minnesota (Ramsey and Hennepin counties).

Initiated in 2005, the MDH invasive MRSA surveillance was an active, population-based surveillance system with two inclusion criteria: a positive MRSA culture from a sterile body site (such as the blood, bone, joint, etc) and patient residence in Hennepin or Ramsey county in Minnesota. For each patient that met the surveillance inclusion criteria, the hospital submitted a standardized data collection form to MDH along with the MRSA isolate. MDH coordinated with microbiology laboratories and infection control departments at hospitals in the surveillance catchment area of Hennepin and Ramsey counties to identify cases. Standardized case report forms that included information on demographic characteristics, clinical syndrome, and outcome of illness were completed for each case. The surveillance program initially included Ramsey county; Hennepin county was added in 2008. The dataset used for this dissertation included surveillance years 2008-2013.

The strengths of the data source were that all sterile body sites were included (versus blood only), the surveillance was coordinated by CDC and standardized across sites with data collection and data entry protocols, and MDH staff conducted laboratory audits to ensure accurate and complete case ascertainment. The primary limitation of using the data for this dissertation was that a hospital-based measure (e.g., hospital-onset MRSA incidence rate) could not be calculated due to the population-based methodology used for the surveillance since case finding was based on the patient's home address (to generate population-based estimates).

Data analyses using aggregated data from all sites included in the surveillance system have been conducted by CDC [Klevens et al, 2006; Lucero, Hageman, Zell et al, 2009; Limbago, Fosheim, Schoonover et al, 2009; Kallen, Mu, Bulens, et al, 2010; Nguyen, Lessa, Belflower, et al, 2013; Iwamoto et al, 2013; Dantes et al, 2013]. MDH published annual, brief invasive MRSA data summaries that were available to the public (MDH Disease Control Newsletter; MDH

Invasive Bacterial Disease Surveillance Report), yet no comprehensive analysis had been completed for years 2008-2013 for the Minnesota site. The objective of summarizing these data was to provide context to the outcome of interest for Aims 1-4. Specifically, what were the HO-MRSA BSI trends in Minnesota in the years leading up to the dissertation project?

4.3 Aim 1a: Outcome

The outcome for this aim was the invasive MRSA incidence rate calculated as such:

$$Invasive\ MRSA\ incidence\ rate = \frac{invasive\ MRSA\ infections}{yearly\ population\ (Hennenpin + Ramsey\ counties)} * 10{,}000$$

The numerator, invasive MRSA infections, was defined as MRSA isolated from a normally sterile body site such as the blood, bone, joint, etc. The denominator was calculated using U.S. Census estimates for the population of Hennepin and Ramsey counties for each year. Incidence rates were stratified by epidemiological category (hospital-onset, healthcare-associated community-onset, or community-associated).

4.4 Aim 1a: Independent variables

Data collection followed detailed guidance included in the CDC's ABCs Invasive MRSA Surveillance protocol for documentation of variables (Table 1).

Table 1. Variable descriptions for invasive MRSA infection

Variable	Description / Definition
Epidemiologic class	Each case of invasive MRSA infection was classified into mutually exclusive categories based on epidemiologic criteria: • Hospital-onset (HO): MRSA culture obtained on or after hospital day 4 (day of admission counted as day 1) • Healthcare-associated community-onset (HACO): MRSA cultured from an outpatient or an inpatient ≤ 3 days after a hospital admission and recent healthcare exposure was documented • Community-associated (CA): MRSA cultured from an outpatient or an inpatient ≤ 3 days after a hospital admission and no recent health care exposure was documented The 4-day time period for categorization aligned with the CDC's National Healthcare Safety Network's (NHSN) "Multidrug-Resistant Organism & Clostridium difficile Infection (MDRO/CDI) Module" definition for classifying MRSA bloodstream infections as hospital-onset [CDC NHSN MDRO Module]. Healthcare exposure data was collected per the CDC's ABCs Invasive MRSA Surveillance protocol and included presence of a central venous catheter at hospital admission or documentation of at least 1 of the following in the one year prior to MRSA culture: acute care or long-term care facility admission, receipt of dialysis, or surgery.
Clinical syndrome	Infection syndromes were classified as bloodstream infection, skin and soft tissue infection (cellulitis, abscess, ulceration), pneumonia, osteomyelitis, arthritis/joint infection/bursitis, abscess (not skin), endocarditis, urinary tract infection, surgical site infection, or other. A case was categorized as a bloodstream infection if there was a positive blood culture for MRSA Each case could have more than one type of clinical syndrome.
Underlying medical conditions	Underlying medical conditions were classified as skin conditions (abscess/boil, decubitus/ pressure ulcer, chronic skin condition), chronic liver disease, chronic pulmonary disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]), chronic renal insufficiency, heart disease (congestive heart failure, myocardial infarction, atherosclerotic cardiovascular disease), connective tissue disease, current smoker, cerebrovascular accident (CVA)/stroke, cystic fibrosis, dementia, diabetes, cancer/immunosuppressive conditions (metastatic solid tumor, immunosuppressive therapy, hematologic malignancy), hemiplegia/paraplegia, HIV/AIDS, influenza (within 10 days of culture), drug use (intravenous [IV] drug use, other illicit drug use), obesity, peptic ulcer disease, peripheral vascular disease, premature birth, unknown, or other.
Dialysis in year prior to infection	Receipt of dialysis within year before initial MRSA culture date
Type of dialysis	Hemodialysis or peritoneal dialysis
Type of vascular access for hemodialysis	Arteriovenous fistula/graft, hemodialysis central venous catheter, or unknown
Age	Age at time of MRSA culture collection. Categories included CDC-developed age groups: <1, 1, 2-4, 5-17, 18-34, 35-49, 50-64, and ≥ 65 years [https://www.cdc.gov/abcs/reports-findings/survreports/mrsa13.html]

Race	Race categories: White, Black/African American, Asian, American Indian/Alaska Native, Native Hawaiian or Other Pacific Islander [https://www.census.gov/topics/population/race/about.html]. Due to small numbers, an "other" category was created that combined the following: Asian, American Indian/Alaska Native, Native Hawaiian or Other Pacific Islander.
Patient outcome	Patient outcomes were evaluated using the following methods: • Death (all causes), • Death within 7 days of culture (all causes), • Death occurred within hospital admission (among hospitalized patients).
Patient location at the time when MRSA culture was collected	Locations included: emergency department, inpatient unit/nonintensive care unit, intensive care unit, long-term acute care hospital, long-term care facility, outpatient, surgery/operating room, unknown, and other.

4.5 Aim 1a: Analytic approach

Descriptive analyses were conducted to assess differences in characteristics among patients with invasive MRSA overall and by epidemiologic category (hospital-onset, healthcare-associated community-onset, and community-associated). The Pearson $\chi 2$ test was used to determine whether there was a statistically significant difference between the expected frequencies and the observed frequencies in one or more categories of a characteristics in the cross tabulations. As a non-parametric test, it does not require assumptions about the distribution from which the data drawn but it does require sufficient sample size [Dawson & Trapp, 2001]. Where cell frequencies were low (less than 5 observations), the Fisher exact test was used for categorical variables [Dawson & Trapp, 2001]. Stata/SE 13.1 was used for all analyses.

4.6 Aim 1b: Overview

The objective of Aim 1b was to describe the relationship between hospital-level characteristics and hospital-onset MRSA bloodstream infection rates in U.S. hospitals in 2013.

4.7 Aim 1b: Data Sources

Two main data sources were used to examine the relationship between hospital characteristics and HO-MRSA bloodstream infections. The two data sources used for this analysis were the Centers for Medicare & Medicaid Services (CMS) "Provider of Services (POS) File" and the CMS "Healthcare-Associated Infection (HAI) measures - provider data." Datasets included data for calendar year 2013.

We hypothesized that hospitals with higher MRSA bloodstream infection rates could be characterized by structural characteristics, staffing levels, and types of services provided.

4.7.1 CMS Provider of Services Dataset

The CMS Provider of Services (POS) file was a comprehensive source for information on Medicare-enrolled healthcare facilities. The POS dataset was created by extracting data from the Quality Improvement Evaluation System database, which stored the data related to the CMS certification. The data were collected through CMS Regional Offices, updated quarterly, and contained an individual record for each Medicare-approved provider. The dataset was publicly available for download via the CMS website (https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/POS2013.html).

The POS dataset contained characteristics of hospitals, including demographics (name, address, bed count, academic affiliation, urban/rural, etc), staffing (registered nurse count, certified registered nurse anesthetists count, licensed practical nurse count, physician count, physician resident count, physician's assistant count), and services provided – whether by staff and/or under arrangement – such as gerontological, pediatrics, pediatric ICU, physical therapy, occupational therapy, burn unit, ICU (coronary care/cardiac, medical/surgical, surgical, neonatal, pediatric), surgical (cardiothoracic, orthopedic, ophthalmic, etc), transplant, dedicated emergency department, and trauma center.

Using the CMS POS file data offered several strengths. These data were hospital level (versus patient level) and were required to be reported by all participating facilities, updated on a quarterly basis. The data provided a comprehensive overview of the services and staffing. Additionally, the dataset was publicly available. Similar datasets that offered hospital-level characteristics were proprietary and costly (e.g., American Hospital Association, Healthcare Cost and Utilization Project).

While there are many strengths of this dataset, there are limitations, as well. From the available documentation, it was unclear as to whether these data are validated. For the benefit of

this dissertation, additional characteristics would have been useful to gain insight into the relationship between hospital characteristics and infection rates, including:

- Average length of stay for the hospital (average length of stay or number of admissions to construct a calculated measure (total number of annual patient days divided by total number of annual admissions): given the time required to develop an infection in the hospital, inherent in the outcome definition, an indicator such as the average length of stay for each hospital would have provided insightful information. Length of stay in the hospital, due to intrinsic patient characteristics, has been related to increased risk of developing hospital-onset infections [Stewart, Robertson, Kennedy, et al, 2020]. Yet, healthcare-associated infections may result in longer hospital stays [Stewart, Robertson, Pan, et al, 2021]. Therefore, measurement and interpretation of this relationship can be challenging as this is a "chicken and the egg" situation – did the infection cause the increase the length of stay or did the length of stay cause the infection?
- Infection control practitioner ("infection preventionists") staffing or staffing ratio, and infection control practitioner training/certification: recommendations have been put forth by infection control and healthcare epidemiology professional associations [Scheckler, Brimhall, Buck, et al, 1998] and previous literature demonstrated that infection prevention certification was related to lower rates of MRSA BSI [Pogorzelska, Stone, Larson, 2012]
- Infectious diseases physicians count: the relationship between infectious diseases physicians and improved clinical outcomes has been described due to specific training and familiarity with hospital procedures [McQuillen & McIntyre, 2017; Lahey, Shah, Gittzus, et al, 2009; Stone, Pogorzelska, Kunches, et al, 2008]. Bai, et al reported ID consultation was associated with better adherence to quality measures, reduced in-hospital mortality, and earlier discharge in patients

with *S. aureus* bloodstream infections [Bai, Showler, Burry, et al, 2015]. Infectious diseases training informs policy/protocol development such as early identification (ordering lab tests), appropriate antibiotics, and prompt device removal. Infectious diseases physicians' value extends beyond clinical, such as leading or participating in antimicrobial stewardship and infection prevention teams/initiatives to implement infection prevention policies and protocols.

- Health system affiliation: indicator of whether a hospital was included as part of a broader network of hospitals would provide insight into support available to the hospital, such as shared resources and technologies, which theoretically could support processes to improve patient care and outcomes [Johnston, Wiemken, Hockenberry, et al, 2020; Dafny and Lee, 2015]. While it remains an unanswered question in existing literature as to whether large hospital merger and acquisitions result in improved patient care and thus improved outcomes [Beaulieu, Leemore, Landon, et al, 2020], health system affiliation has been associated with improved quality reporting – likely due to technological and dedicated staffing resources [Johnston et al, 2020].
- Number of ICU beds: overall beds, rehab beds, and psych beds, along with specific ICU services (medical/surgical, cardiac, etc), were provided in the POS dataset. Inclusion of ICU beds would offer additional information into to the size (proportion of beds) and therefore patients needing higher acuity care. Higher acuity patients require more complex cares and have higher device utilization, which results in hospital staff to employ more infection prevention practices with increased risk of infection prevention breaches, which puts the patient at an increased risk of infection.
- Use of nonpermanent staff: use of temporary staff has been negatively related to patient outcomes, due to reduced familiarity with hospitals policies/protocols and

lack of relationships needed for clear communication [Stone, Pogorzelska, Kunches, et al, 2008; Gawande 2007].

- Case mix index (CMI): Developed by CMS, CMI was a facility-level measure of patient acuity, derived from administrative data. CMI was associated with hospital-level hospital-onset *Clostridium difficile* infection rates after adjusting for other hospital-level covariates [Thompson, Edwards, Dudeck, et al, 2016]. CMI was designed for hospital payment purposes and while there may be value in evaluating this type of measure, this dissertation aimed to push beyond patient-level factors and focus on the organization.

4.7.2 CMS Healthcare-Associated Infection (HAI) Measures Dataset

As part of the CMS Value-based Purchasing program, hospitals reported specific quality metrics, of which HO-MRSA bloodstream infection was included. The CMS Value-based Purchasing program included nearly all non-rural medium- and large-sized hospitals in the U.S. Excluded hospitals from the Value-based Purchasing program were as follows: Maryland hospitals, non-U.S. hospitals (e.g., Puerto Rico), critical access/rural hospitals, Department of Defense and Veterans Administration Hospitals, inpatient rehabilitation facilities, long-term acute care hospitals (termed “long-term care hospitals” by CMS), selected oncology hospitals, and some pediatric hospitals. The program was a long-standing effort to link Medicare’s payment system to a value-based system to improve the quality of care provided in the inpatient hospital setting. In 2014, according to the American Hospital Association, there were 5,723 registered hospitals; approximately 3,500 (61%) hospitals participated in the Value-based Purchasing program [www.stratishealth.org/providers/vbp.html].

Infection indicators were added to the Value-based Purchasing program as part of the 2010 Affordable Care Act, with reporting of the MRSA bloodstream infections beginning January 1, 2013. Hospitals were at risk of losing financial incentives paid by the inpatient Prospective Payment System if their hospital-onset MRSA rates were above the national average. Quarterly, hospitals submitted deidentified patient data to the Centers for Disease Control and Prevention’s

(CDC) web-based National Healthcare Safety Network (NHSN) surveillance system. Data were sent quarterly from CDC/NHSN to CMS and compiled as the CMS "Healthcare-Associated Infection (HAI) measures - provider data" file. The data were publicly available for download via the CMS Hospital Compare website (https://data.medicare.gov/data/hospital-compare).

To measure hospital-level performance of MRSA infection, CMS used the standardized infection ratio (SIR), standardized to U.S. hospitals using a 2010-2011 baseline. The dataset included the SIR (observed infections divided by the expected number of infections) and confidence intervals, along with the data used to derive the measure: observed number of infections, expected number of infections, patient days, and a text field that provided interpretation of how the hospital's SIR compares to the national benchmark ("Better than the U.S. National Benchmark" [<1.0], "Worse than the U.S. National Benchmark" [>1.0], or "No Different than the U.S. National Benchmark" [=1.0]).

The SIR numerator considered infection, exposure time in the hospital, the specimen, and duplicate specimens. The SIR denominator, the expected number of infections, was estimated using a negative binomial regression model which was developed to "allow CDC and external partners to calculate risk adjusted measurements of these data that are appropriate for public reporting purposes" [Dudeck, Weiner, Malpiedi, et al, 2013]. The model included medical school affiliation, facility bed count, and community-onset MRSA bacteremia prevalence rate to estimate the expected number of infections for a given hospital. The SIR was selected as the metric for interhospital comparison in its *HHS Action Plan to Prevent Healthcare-Associated Infections*, in which hospitals were compared simultaneously against the NHSN reference population. For the 2013 dataset, the infection rates were risk adjusted and compared to a 2010-2011 baseline, which only included hospitals that voluntarily reported data (reporting for CMS was not yet required) [Dudeck et al, 2013].

One major strength of this dataset was that outcome of interest was identified via lab testing as evidence of infection, which provided an objective determination, compared to claims or administrative data. Infection was used purposefully to distinguish from tests for colonization in

patients. Rather, when microbiological testing was conducted on blood specimens, it was nearly universally associated with clinical infection [Trick, Zagorski, Tokars, et al, 2004]. Additionally, the MRSA identification method reduced measurement error of the outcome. From the infection identification methodology, we were confident that this method was valid, measuring what was intended to be measured, as designed. By including only bloodstream infections only ensured that the specimen was sterile and by omitting other body sites, the probability was lowered that the MRSA was colonization or contamination. Additionally, infections of the bloodstream have been reported as the most common type of invasive infection. Among invasive MRSA infections reported to MDH, nearly 70% were isolated from the bloodstream [MDH Annual Summary of Communicable Diseases, 2013].

The “hospital-onset” portion of the measure was defined using information about the timing of specimen collection in relation to hospital admission. CDC defined hospital-onset as identification of the infection on or after day 4 of the hospital admission (the admission date is day 1); this was a generally accepted definition for classifying infections for HAI surveillance [Cohen, Calfee, Fridkin, et al, 2008]. This time period incorporated exposure time spent in the hospital and considered the incubation period of microorganisms; however, the incubation period could be impacted substantially if the organism was acquired in a manner that allowed direct entry into the body, such as the bloodstream, resulting from poor sterile technique when handling lines that enter the body to provide medication. The hospital-onset portion of the measure was calculable using the patient admission date and blood culture collection date, eliminating human error in calculating this portion of the measure and ensuring complete data.

The NHSN data was the most comprehensive MRSA data collection system in the U.S. Other options for datasets were National Hospital Discharge Survey data (nonpublic) and AHRQ/HCUP (nonpublic) – both derived from billing data in which ICD-9/10 codes were used to identify infection, which has been shown to be an inaccurate method for infection surveillance [McKibben et al, 2005]. The Emerging Infections Program/Active Bacterial Core surveillance (ABCs) system data for all nine catchment areas within the U.S. (further described and used for

Aim 1a) would not have been appropriate since the surveillance was population based and not intended for hospital-level evaluation. An additional strength of these data was that they were collected via NHSN, which used a standardized data collection protocol for surveillance, and was the gold standard for HAI surveillance in the U.S. and endorsed by the National Quality Forum, an independent quality body that advises federal agencies.

While there are many strengths of this dataset, there are limitations, as well. The NHSN surveillance system lacked an independent and systematic validation method, and therefore we had no data to support that the surveillance was conducted reliably or accurately. Additionally, no military, Veterans Administrations, or Indian Health Services hospitals were included since they did not participate in the programs which required reporting by CMS. The HO-MRSA BSI measure prevented small, rural hospitals from participating in this surveillance since patients would not meet the hospital-onset timing definition (annual average length of stay must be 96 hours or less).

For the benefit of this dissertation, additional characteristics would have been useful to gain insight into the relationship between hospital characteristics and infection rates, including:

- Low-volume indicator: this variable existed; however, CDC/NHSN did not include it in the publicly available dataset and was not willing to provide it upon request.
- Adherence to evidence-based process measures to prevent infection: the inclusion of such data would provide an objective measure for staff compliance with infection prevention protocols. This information would be applicable to all hospital settings. Furthermore, process measures do not require consideration of the patient's underlying conditions or risk of infection [McKibben et al, 2005]. An example relevant to MRSA prevention would be adherence to central line insertion practices.

It was possible that infection data were manipulated to avoid financial penalties, or "gaming." Gaming may occur when hospitals make efforts to screen patients without symptoms to assert a preexisting condition to avoid getting "dinged" for the infection in the hospital-onset

definition timeframe [HHS OIG 2017]. An additional limitation of the data source was that since it only included MRSA infections in the blood, this measure underestimated the burden of MRSA in hospitals. MRSA is a common cause of skin and soft tissue infections; however, if the infection did not reach the blood, it would not be reported. Finally, MRSA bloodstream infection data were available for less than 2,000 (40%) of approximately 5,000 acute care facilities in the U.S. (critical access, pediatric, military and Veterans Administration hospitals were not included) [Kavanaugh, Abusalem, Calderon, 2017]. In summary, the use of NHSN MRSA data was an objective effort to capture severe MRSA infections in the adult non-rural, acute care population.

The two datasets were linked using the CMS provider number, a unique 6-digit identifier assigned to each hospital and available in both datasets. Using this identifier, the datasets were linked to construct the analytic dataset that included structural factors and hospital-onset MRSA bloodstream infections for hospitals included in the CMS Value-based Purchasing program in year 2013 (Figure 2).

4.7.3 Inclusion and exclusion criteria

The types of "hospitals" included in the CMS inpatient prospective payment system datasets contained a substantial number of limited-service or specialty hospitals. Most of the patients in these facility types would not have had the opportunity to develop hospital-onset MRSA infections, based on the hospital-onset definition. Yet in order to meet the broader CMS VBP program requirements, it was required of them to report zero infections in NSHN. These facilities were small in size and operated differently than general acute care inpatient hospitals, such as same day surgery centers, eye institutes, cancer hospitals, orthopedic surgery hospitals, etc. These facilities were not comparable to general acute care inpatient hospitals, and therefore were omitted from the sample. With no clear way to identify such facilities in the publicly-available datasets, it was assumed that the limited-service or specialty hospitals would have low patient volume compared to acute care hospitals. We evaluated several variables to use to indicate low patient volume to identify limited-service or specialty hospitals to apply as exclusion criteria (length of stay was not available in the datasets).

After evaluating bed count, patient days, average daily census, average number of claims, and emergency services as indicators, average daily census (patient-days/365) were used to measure low-volume and specialty hospitals. Ultimately, we included only hospitals with a calculable SIR. This decision focused on the outcome of interest and aligned with other published literature and CDC and CSTE guidance which recommended against calculating the SIR for any facility that did not have a large enough exposure volume to have at least one predicted infection [Kavanaugh et al, 2017; CSTE 2015; CDC 2013]. Figure 2 depicts the construction of the analytic dataset.

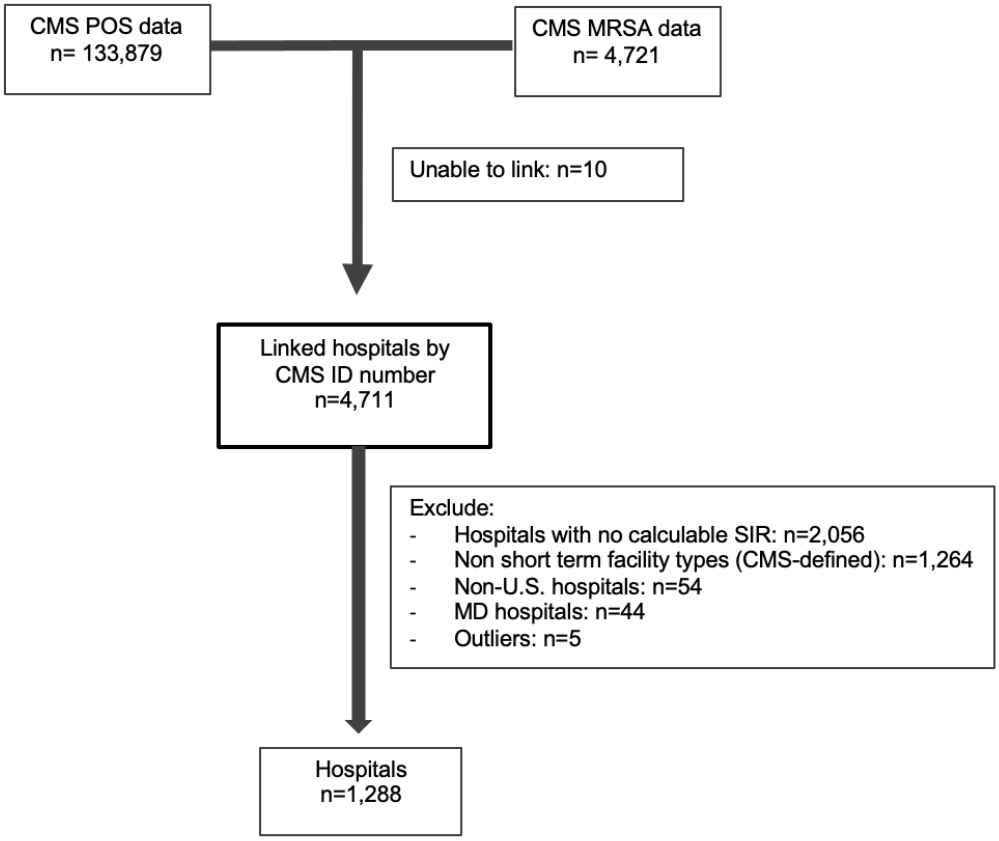

Figure 2. Flowchart illustrating construction of the analytic dataset for Aim 1b.

4.8 Aim 1b: Variables

4.8.1 Outcome: hospital-onset MRSA bloodstream infection incidence rate

CDC National Healthcare Safety Network (NHSN) defined MRSA bloodstream infection as MRSA isolated from the blood in a patient with no prior positive blood culture for MRSA in the 2 weeks prior in the same patient care area (i.e., there should be 14 days with no positive MRSA blood culture result from the laboratory for the same patient and hospital location); infections that occurred greater than three calendar days after admission were defined as hospital-onset [CDC NHSN MDRO Module].

$$HO - MRSA\ BSI\ incidence = \frac{\#\ of\ MRSA\ BSI\ identified\ > 3\ days\ after\ hospital\ admit}{\#\ of\ patient - days\ for\ the\ hospital\ x\ 10{,}000}$$

4.8.2 Independent variables

Appendix A provides a table of independent variables included in the analytic dataset. The exposure variables of interest were primarily the structural characteristics from the CMS POS dataset. Structural characteristics were evaluated in terms of bed count, ownership type, rural or urban location, and medical school affiliation. Staffing was evaluated in terms of counts or the number of full time equivalent medical doctors, registered nurses, nurse practitioners, pharmacists, and medical residents, among other roles. Services provided were evaluated such as acute renal dialysis, gerontological, pediatrics, pediatric ICU, pharmacy, occupational therapy, ICU (burn unit, coronary care/cardiac, medical/surgical, surgical, neonatal, pediatric), surgical (cardiothoracic, orthopedic, ophthalmic, etc), presence of an emergency department and/or transplant center, among others.

In addition to the structural characteristics from the CMS POS dataset, we included region of the country and disproportionate share hospital (DSH) classification.

Published data described MRSA rates varying by region of the country [Kallen, Mu, Bulens, et al, 2010; Kuehnert, Hill, Kupronis, et al, 2005; Elixhauser & Steiner, 2007; CDC National and State Healthcare-Associated Infections Progress Report, 2016]. Therefore, region of the country was evaluated, as defined by the US Census.

We evaluated whether hospitals qualified for the disproportionate share hospital (DSH) reimbursement from Medicare. Previous literature reported that low-income populations have greater unmet healthcare needs [Ayanian, Weissman, Schneider, et al, 2000], which could lead to increased susceptibility to MRSA infection. Initially, the rationale for the DSH adjustment was that "poor patients are more costly to treat, so that hospitals with substantial low-income patient loads would likely experience higher costs for their Medicare patients than otherwise similar institutions. Over the last decade, many observers shifted to arguing that the adjustment subsidizes uncompensated care provided to the uninsured and underinsured." [MedPAC 2007]. However, in 2007, the Medicare Payment Advisory Commission reported "no positive cost relationship with the low-income patient care percentage for other hospitals" [MedPAC 2007]. The DSH variable was evaluated to assess a common hospital reaction: "It's not us; it's our patients." The DSH data were obtained from the CMS "FY 14 Impact File" that contained data elements by provider used to calculate final FY 2014 rates and impacts; the data were publicly available at no cost [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html]. Three variables were evaluated for analyses using the DSH patient percent as determined from cost report data and social security administration data: DSH percentage as a continuous variable, DSH percentage using quartiles [Chatterjee, Joynt, Orav, et al, 2012; Jha, DesRoches, Shields, et al, 2009], and DSH percentage categorized as high versus low, cut at 15% ("current minimum DPP necessary for qualification as a DSH hospital is 15%") [Marier, 2014].

4.9 Aim 1b: Analytic approach

The analytic approach was exploratory and therefore several independent variables were assessed from the dataset. Based on conceptual knowledge and previously published literature, we assumed that hospital size would be the most important predictor of the outcome. The relationship between the variables available to evaluate hospital size (bed count, average daily census, patient-days) were assessed by plotting the data and utilizing univariate linear regression to assess the relationships.

Building on the relationship between the hospital size and MRSA rate, a multivariable linear regression model was constructed to evaluate the relationship between hospital-level characteristics and MRSA rates to understand whether other hospital-level characteristics, including demographics, staffing, and services, mattered when describing the broad relationship of hospital size and MRSA rate. The independent variables included in the model were selected based on conceptual and biological plausibility, in addition to identified risk factors from previously published studies and univariate regression methods. We drew from the epidemiology and infection prevention literature to select the most appropriate variables to estimate hospital-level infection rates, given the data.

Multivariate linear regression was selected as the model because the outcome of the dependent variable was continuous, and it was determined to be an adequate representation of the relationship between the outcome and the hospital variables related to size (bed count, average daily census, patient-days). For this aim, the model assumed that as the size of the hospital increased, the average value of the HO-MRSA incidence rate increased linearly. The simple linear regression equation can be described as follows [Vittinghoff, Glidden, Shiboski, et al, 2012]:

$$E[y|x] = \beta_0 + \beta_{1x} + \varepsilon$$

where *E[y|x]* is the expected or average value of the outcome y at a given value of the predictor x. B_0 is the intercept, the average value of the outcome when x is zero. B_1 gives the slope of the regression line.

Ordinary least squares (OLS) estimation was used in estimating the linear regression model. This estimation method can be sensitive to outliers, due to the squaring the differences [Vittinghoff et al, 2012]. Outliers were evaluated to ensure the linear relationship was appropriate and to detect unusual values in the data to avoid distorting results or impacting model assumptions. Outliers were examined as follows:

- Extreme values were assessed in the data (Stata command “extremes”) using the 1.5*IQR rule of thumb [Tukey, 1977] to identify potential data entry errors or

nonsensical values. One hospital-reported bed count value was identified as an outlier and corrected, verified using the bed count value available in the CMS "FY 14 Impact File", the American Hospital Association website, and the hospital website.

- Scatter plots were used to visually inspect values that appeared to be outside of the predicted linear relationship between MRSA rate and bed count (or average daily census). The scatter plot of MRSA rate and bed count indicated that there were a few values that likely did not follow the trend of the relationship and possibly would impact the regression model – these values warranted further investigation to determine whether they had the potential to be high leverage values (Similar results were found for the MRSA rate and average daily census scatterplot.).
- Scatter plots of the residuals were created following regressing bed count on MRSA rate; no obvious discernible pattern was apparent in the plot, and the spread of the residuals was similar across the range of fitted values, above and below the line. Similar results were found when average daily census was regressed on MRSA rate.
- Cook's distance (d), a regression diagnostics tool, was calculated in Stata ("predict *varname*, cooksd") and used to measure the influence of the observation, using the rule of thumb d > 4/N where N was the sample size. Stata defined Cook's distance as the "aggregate change in the estimated coefficients when each observation is left out of the estimation" [Hamilton, 2004].
    - Values of Cook's distance (d) that were greater than 4/N (in this case, 4/1293 = 0.0031) were possibly problematic. These values were investigated.
- Leverage, a regression diagnostics tool, was calculated using Stata ("predict *varname*, leverage") to identify observations that were likely to influence the data,

and consequently, the regression estimates. Leverage (h) was calculated as: h > 2*k/N where k is the number of parameters (including the intercept) and N is the sample size. With a range of 0 to 1, a leverage value that was closer to 1 or greater than 0.5 was investigated as a potential high leverage value.

- Additionally, a leverage versus residual-squared (L-R) plot (Stata "lvr2plot" command), a graph of leverage against the (normalized) residuals squared, was used to identify to identify observations that have an abnormally high leverage or large residuals. High leverage values have the potential to "exert undue influence on regression coefficient estimates" [Vittinghoff et al, 2012]. This regression diagnostics tool was employed following the regressing bed count on MRSA rate and identified a few potential high leverage observations and one large residual. An L-R plot was created following regressing average daily census on MRSA rate, with similar results.

The goal of the identification and evaluation of outliers was to better understand the distributions of the outcome and hospital size variables, and to ensure that the data were sensical and supported the analytic approach. Various methods were used to identify data entry/coding/reporting errors and values that could potentially minimize impact to regression estimates. As there were a handful of observations identified as high leverage and high influence, and appeared problematic in the data, we used a CDC outlier definition, which was defined as an incidence rate that was five times the IQR above the 75th percentile [Thompson et al, 2016; Dudeck et al, 2013]. This outlier definition has been used previously with NHSN data. Using this outlier definition, five hospitals' data were excluded, for a total of 1,288 hospitals included in the study sample.

With any model, the linear regression model came with a set of assumptions. The assumptions of the linear regression model concerned the distribution of the errors (ε) – it was assumed that the error term (ε) was independently and identically distributed and met the following assumptions [Vittinghoff et al, 2012]:

- Normal distribution
- Mean zero at every value of x
- Constant variance ($\sigma^2\varepsilon$) at every value of the independent variable
- Independent

When the model assumptions hold, this would provide confidence that B_0 and B_1 are unbiased estimates. To test the linear regression assumptions, the two separate variables used to measure hospital size were evaluated: average daily census regressed on MRSA rate, and separately, bed count (continuous) regressed on MRSA rate. The residuals, the difference between the predicted response value as calculated by the estimated regression equation and the actual response value, were used to check the assumptions of linear regression.

To test the linear regression assumptions with the data, the two separate variables used to measure hospital size were evaluated: average daily census regressed on MRSA rate, and separately, bed count (continuous) regressed on MRSA rate. (The relationship between the outcome and average daily census, and the relationship between the outcome and patient-days was identical. Therefore, average daily census was used in further analyses.) The assumptions of linear regression were assessed as follows:

Linearity assumption – linear relationship between the dependent and independent variable. The outcome of interest was continuous. Using scatterplots and univariate linear regression, there was a positive linear relationship between the outcome and bed count, and separately, the outcome and average daily census.

Normality assumption – the residuals (errors) of the regression line are independent and approximately normally distributed.

- Scatter plots of the residuals (residual versus predictor (RVP) plots) were created following regressing bed count on MRSA rate; no obvious discernible pattern was apparent in the plot, and the spread of the residuals was similar across the range of fitted values, above and below the line.

- Q-Q (quantile-quantile) plots of the residuals were created, which offered a method to visually inspect whether the regression residuals were normally distributed. The Q-Q plots for the residuals of average daily census and bed count (separately assessed), demonstrated that the residuals tended to deviate slightly from the 45-degree line at the tail ends, which could be diagnostic of skewness or other indication that they were not normally distributed. However, since this sample was not small and "regression coefficients are approximately normal in larger samples even if ε does not have a normal distribution," we were confident that relaxing this assumption would not be problematic for the model [Vittinghoff et al, 2012].

Constant variance (homoskedasticity) assumption – assumes the variance of the error term is constant and unrelated to the independent variable. If variations in the errors are detected in the data, this would result in a violation of the assumption that information contained for each observation should be assumed the same. Additionally, the standard errors are biased when heteroskedasticity is present, which leads to biased test statistics and confidence intervals [Vittinghoff et al, 2012].

- Scatter plots of the residuals (residual versus predictor (RVP) plots) were created following regressing bed count on MRSA rate; no obvious discernible pattern was apparent in the plot, and the spread of the residuals was similar across the range of fitted values, above and below the line.
- The Breusch-Pagan/Cook-Weisberg test for heteroskedasticity in a linear regression model was performed using Stata ("estat hettest" command). The null hypothesis for this test was that the variance was homoscedastic, meaning the variance for each observation was around the same finite value (i.e., uniform variance). The null hypothesis of homoscedasticity was not rejected and therefore heteroscedasticity was not detected. Recognizing that statistical tests

for homoscedasticity can be sensitive to sample size, we employed this method with caution and curiosity, primarily focusing on the residual plots.

- Based on the visual inspection of the residuals plots and the Breusch-Pagan/Cook-Weisberg test, we did not detect heteroscedasticity in the residuals of the regression model (average daily census regressed on MRSA rate or bed count regressed on MRSA rate, separately).

Based on the findings from the methods described above that tested the assumptions of linear regression, we were confident that the linear model was appropriate for the analytic approach for Aim 1b. Stata/SE 13.1 was used for all analyses.

4.10 Aim 2: Overview

The objective of Aim 2 was to develop a systematic method to evaluate organizational policies, identifying measurable and modifiable constructs, to advance measurement of hospital policies related to MRSA prevention. The goal of the policy evaluation was to identify constructs that had the potential to be measurable and modifiable.

Recall, the primary research question of this dissertation addresses whether MRSA acquired in the hospital is impacted by organizational policy. Ideally, one would conduct a randomized controlled trial, the gold standard in epidemiologic studies, whereby hospitals would be randomized to Policy A (treatment group) or randomized to implement Policy B (control group), and subsequently the hospital-acquired MRSA rates would be measured in all hospitals. Such a design would allow one to test whether the MRSA rates between treatment and control hospitals were the same, but for the policy, assuming the randomization was successful.

The exposure of interest included the evaluation of five key hospital policies that potentially affected MRSA transmission in hospitals. The selected policies included hand hygiene, environmental cleaning and disinfection, healthcare personnel influenza vaccination, multidrug-resistant organism (e.g., MRSA) infection prevention and/or isolation and transmission-based precautions (may be separate or combined policies), and corporate compliance or "whistleblower." The exposure of interest had not been studied in relation to MRSA transmission, and, consequently, the measurement of the exposure had to be honed before it could be studied

properly. To conduct the ideal experiment, one would need to have modifiable, measurable constructs from hospital policies that were able to be tested.

4.10 Aim 2: Support for selected hospital policies

Of the policies selected, three of the five policies were directly related to the prevention and control of MRSA in hospitals – MDRO/isolation, hand hygiene, and environmental cleaning/disinfection policies. The additional two policies – influenza vaccination and corporate compliance – were selected to get a sense of the organizational climate surrounding infection prevention and control, and transparency, respectively. By looking at all the policies together, we aimed to gain a comprehensive sense of the organizational climate for HAI prevention. A summary of support for each policy selected is provided below.

4.10.1 Environmental cleaning/disinfection policy

The hospital policy on environmental cleaning and disinfection policy was selected for several reasons. There was mounting evidence supporting pathogen survival on surfaces and objects in the hospital environment such as furniture, bed rails, and medical equipment [Sehulster & Chin, 2003]. Pathogens such as MRSA are not confined to the bodies of patients and healthcare personnel. The hands of healthcare personnel are reservoirs for transmission whether pathogens are acquired from patients or the environment. Reports suggest that MRSA can survive in hospital dust for as long as one year; however, survival of the organism depends on several factors such as humidity, surface material, and temperature [Wagenvoort, Sluijsmans & Penders, 2000].

Thus, the importance of the role of surface contamination in transmission of HAI pathogens is critical given that transmission can be interrupted by appropriate hand hygiene and cleaning/disinfection of environmental surfaces. The process of cleaning is essential to remove organic material such as dirt, food, and bodily fluids. The disinfectant product is rendered ineffective by organic material which is why the cleaning step is critical. Additionally, the disinfectant product must be appropriate for the pathogen and the surface and requires a

minimum amount of contact time for the chemicals to disinfect. The cleaning and disinfection process is complex and as such requires effective training and education.

It was hypothesized that an important piece of training and education within hospital policies would be culturally appropriate training/education materials. The environmental services personnel in Minnesota hospitals often include persons from diverse backgrounds and being an English speaker is often not a condition of employment. Therefore, it was important to evaluate whether training/education materials procedures/protocols were offered in languages that were culturally appropriate and included visual aids. We hypothesized that another important component of training/education would be the inclusion of competency testing and return demonstration to determine whether training and education was effective. Following a published environmental cleaning/disinfection evaluation, the authors concluded: “Persistent environmental contamination reflects personnel, rather than procedure or product, failures” [Hota, Blom, Lyle, et al 2009].

An emerging practice in hospitals is to contract with companies with cleaning/disinfection expertise. Two contractual models commonly used were 1) the environmental services workers were contractors and the environmental services management was employed as hospital staff, or 2) the environmental services workers were employed as hospital staff and the environmental services management was contracted. The staffing model was documented since it was hypothesized that staffing model may impact policy implementation.

The key documents utilized to guide the policy evaluation for cleaning/disinfection included:

- HICPAC Guideline for disinfection and sterilization in healthcare facilities [Rutala WA & Weber DJ; HICPAC, 2008]
- CDC/HICPAC Guidelines for environmental infection control in health-care facilities [Sehulster & Chin, 2003].

4.10.2 Hand hygiene policy

Hand hygiene is the act of cleaning and disinfecting the hands with the goal of reducing or eliminating pathogenic microorganisms in effort to prevent transmission to others. In hospitals, it is the single most important measure in preventing and controlling the spread of infectious organisms [WHO 2009]. MRSA is primarily spread through the hands of healthcare personnel. Substantial evidence exists to support the importance of hand hygiene to infection prevention in healthcare settings [WHO 2009; Boyce & Pittet, 2002].

The importance of hand hygiene for the prevention of spreading disease was recognized over 150 years ago by Ignaz Semmelweiss [Rotter, 1998] yet compliance with hand hygiene is low (range, 5%–81%; overall average 40%) [Boyce & Pittet, 2002]. The practice of hand hygiene is straightforward, and it is established that the practice is not difficult to learn and personnel know why they should wash hands (to protect patients and themselves) [O'Boyle, Henly & Duckett, 2001]. Common reasons cited for poor compliance include skin irritation, lack of availability of hand hygiene supplies, gloves as a substitute for hand hygiene, time constraints, or forgetting to think about doing it, to name a few [Pittet et al, 2000].

In a study regarding nurses' motivation to perform hand hygiene, "concern about the impact of receiving a poor job evaluation as an outcome of failing to wash hands as recommended" received the second lowest of 14 possible outcomes indicates that organizational accountability and expectations for implementation of HAI prevention measures is lacking and is a factor in behavioral motivation [O'Boyle et al, 2001].

Sandora stated, "MDROs are transmitted mainly on the hands of caregivers who do not practice effective hand hygiene after every contact with patients and their environment. Once hospitals have trained clinical personnel, verified that they know how to use alcohol-based hand rubs and soap and water, and placed full, operating dispensers and sinks where personnel can use them during routine care, anything less than complete adherence to hand-hygiene guidelines constitutes a violation of sound practice and requires accountability" [Sandora & Goldmann, 2012].

While seemingly straightforward, hand hygiene proves to be a complicated behavior with the greatest struggle being healthcare worker compliance with recommended hand hygiene practices. Cleaning one's hands is a behavior learned at a young age and carries through into adulthood. In an effort to understand the human behavior aspects of hand hygiene, one study found that healthcare workers ritualize the behavior and that one simple behavior was not apparently obvious [Whitby, McLaws & Ross, 2006]. Two general categories were described – the first focused on perceived risk to the individual, termed 'inherent handwashing' where one cleans hands when visibly dirty and, for nurses, added emotionally dirty places such as the groin or axillae, or after touching someone who appears unhygienic [Whitby et al, 2006]. The second category focused on contact or situations when there was no or little perceived risk to the individual, termed 'elective handwashing' such as cleaning hands prior to eating a meal or, for nurses, noninvasive, impersonal patient contact (e.g., taking a pulse or contact with fomites) [Whitby et al, 2006]. Cleaning hands is a deep-seated behavior and more complex than one may predict. Thus, we hypothesized that monitoring and enforcement by the hospital would be critical policy elements for hand hygiene compliance.

The key documents utilized to guide the policy evaluation for hand hygiene included:

- WHO Hand Hygiene Self-Assessment Framework 2010 [www.who.int/gpsc/country_work/hhsa_framework.pdf]
- WHO guidelines for hand hygiene in health care [WHO 2009]
- Guideline for hand hygiene in health-care settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force [Boyce & Pittet, 2002].

4.10.3 Multidrug-resistant organism policy

Multidrug-resistant organisms (MDRO), such as MRSA, are defined as microorganisms that are resistant to one or more classes of antimicrobial agents [Siegel et al, 2007a]. The limited treatment options and potential for transmission of antimicrobial-resistant mechanisms among bacteria provide the rationale for requiring special attention for MDRO [Siegel et al, 2007a]. In

2006, the Healthcare Infection Control Practices Advisory Committee, a federal advisory committee to CDC and the Department of Health and Human Services for HAI and infection prevention in healthcare facilities, published the *Management of Multidrug-Resistant Organisms In Healthcare Settings* [hereafter referred to as the MDRO Guideline] [Siegel et al, 2007a]. This guideline provides a tiered approach to MDRO prevention and control – strategies include the use of Contact Precautions in addition to Standard Precautions, isolation/cohorting of patients, flagging patient medical records, screening for high-risk patients/patient populations, and annual risk assessments [Siegel et al, 2007a].

In 2007, the Minnesota legislature passed legislation that required every acute care hospital in the state to have a MRSA prevention and control policy, following recommendations published by the Minnesota Department of Health, effective January 1, 2009 (Minnesota Statutes, section 144.585). Additional detail regarding MRSA-specific recommendations is found in section "MRSA Prevention and Control in Hospitals" in Chapter 2 of this document.

The key documents that were used to guide the MDRO/MRSA policy evaluation included:

- HICPAC Management of Multi-drug Resistant Organisms in Healthcare Settings, 2006.
- HICPAC 2007 Guidelines for isolation precautions: Preventing transmission of infectious agents in healthcare settings
- IDSA/SHEA Strategies to Prevent Transmission of Methicillin-Resistant *Staphylococcus aureus* in Acute Care Hospitals (2014).

4.10.4 Healthcare personnel influenza vaccination policy

The influenza vaccination policy was included for evaluation because influenza vaccination is an important tool to prevent transmission of influenza by healthcare workers in the hospital setting. Healthcare worker influenza vaccination is strongly recommended by CDC [Grohskopf et al, 2017; Pearson et al, 2006] and the Advisory Committee on Immunization Practices [ACIP 2011; Fiore et al, 2010] as well as professional associations including American Academy of Pediatrics [AAP Committee on Infectious Diseases 2017], American Hospital

Association [AHA 2011], Association for Professionals in Infection Control and Epidemiology [APIC 2008], Association of Occupational Health Professionals in Healthcare [AOHP 2011]. Infectious Diseases Society of America [Harper et al, 2010], National Patient Safety Foundation [NPSF 2015], Society for Healthcare Epidemiology of America [Talbot et al, 2010], and The Joint Commission [TJC 2009]. The Society for Healthcare Epidemiology of America stated, “SHEA views influenza vaccination of HCP as a core patient and HCP safety practice with which noncompliance should not be tolerated” [Talbot et al, 2010]. The US Health and Human Services Healthy People 2020 initiative included a national objective to increase healthcare worker influenza vaccination rate to 90% (compared to an estimated 55.8% based on data from years 2010-11) [Healthy People 2020].

The rationale for healthcare personnel to be vaccinated against influenza includes the following: influenza is a communicable disease that can result is severe illness associated with considerable morbidity and mortality, especially among high-risk patients; influenza vaccination can prevent influenza infection and complications; influenza vaccination has minimal adverse effects; healthcare personnel are at risk for occupationally-acquired influenza; healthcare personnel can act as a reservoir for influenza virus; healthcare personnel have contact with high-risk, vulnerable patients; promotion of patient safety and quality [ACIP 2011; Fiore et al, 2010] and reduced absenteeism which can stress the healthcare system [TJC 2009].

While influenza vaccination for healthcare personnel is strongly recommended, the rate of healthcare personnel vaccination is estimated to be 55.8% [Healthy People 2020]. To obtain higher healthcare personnel vaccination rates, some hospitals have implemented mandatory vaccination policies. While some hospitals may not go so far as to make the vaccination mandatory, hospitals implement other actions to encourage vaccination such as requiring those that decline to wear masks while providing patient care or displaying visual indicators on employee identification badges. Fear of litigation, being perceived as coercive by personnel, and union backlash all contribute to challenges with vaccination policy implementation for hospitals. Mandatory vaccination policies may not be warranted, depending on staff compliance with

vaccination. CMS includes influenza vaccination to be addressed in policies, however their guidance is limited and vague.

The key documents that were used to guide the influenza vaccination policy evaluation included:

- The Joint Commission Providing a safer environment for health care personnel and patients through influenza vaccination [TJC 2009]
- Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010 [Fiore et al, 2010]
- Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP) [ACIP 2011]
- CDC Prevention Strategies for Seasonal Influenza in Healthcare Settings [https://www.cdc.gov/flu/healthcareworkers.htm]
- Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel [Talbot et al, 2010].

4.10.4 Whistleblower / corporate compliance

The corporate compliance/whistleblower policy was included to gain insight into the hospital climate towards transparency. It was hypothesized that whistleblower and corporate compliance elements could be included in a single policy under the umbrella of a corporate compliance program. To cast a wide net, so to speak, the terms “corporate compliance” and “whistleblower” were used when collecting hospital policies. While limited research exists about the relationship between organizational transparency and patient outcomes, the hypothesis was that transparency leads to improvements in care outcomes through the use of clinical performance data and a sense of professionalism or the reputation of the hospital [IOM Report 2010].

The term “whistleblower” has been defined as “organization members who disclose employers' illegal, immoral, or illegitimate practices that are under the control of their employers to persons or organizations who may be able to affect act.” [Miceli & Near, 1984]. A process to

address complaints that includes whistleblower protections must be in place in Minnesota hospitals per state [Minn. Stat. § 181.932] and federal laws [Whistleblower Protection Act, 1989; Whistleblower Protection Enhancement Act of 2012], and as recommended by the U.S. Internal Revenue Service [IRS 2007].

Specific to healthcare, corporate compliance has been defined as efforts "designed to establish a culture within a hospital that promotes prevention, detection and resolution of instances of conduct that do not conform to Federal and State law, and Federal, State and private payor health care program requirements, as well as the hospital's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to the compliance process." [HHS 1998]. "A successful compliance program addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care providers' operations; improving the quality of health care services; and reducing the overall cost of health care services." [HHS 2005]. The corporate compliance program should provide information on what compliance means to the organization and promote methods for reporting violations.

In 1991, the U.S. Sentencing Commission published the "Federal Sentencing Guidelines for Organizations" which "impose severe economic sanctions on corporations convicted of criminal wrongdoing and eliminate most judicial discretion in corporate sentencing. Further, the Guidelines pro- vide that corporations can significantly reduce sanctions by adopting 'an effective program to prevent and detect violations of law.'" [U.S. Sentencing Commission 1991]. The U.S. Sentencing Guidelines Manual, Chapter 8, states that organizations with effective corporate compliance programs in place may receive reduced penalties [U.S. Sentencing Commission 1991].

Compared to other industries, health care has been slower to adopt corporate compliance programs. In reaction to increasing health care fraud and abuse in the U.S., the Health Insurance Portability and Accountability Act (HIPAA) of 1996 was established, along with a funding program, for investigative and enforcement efforts by the Federal Bureau of Investigation,

Health and Human Services, and Department of Justice [Health Insurance Portability and Accountability Act of 1996]. The Department of Justice subsequently developed the “Evaluation of Corporate Compliance Programs” document to provide “some important topics and sample questions” to “assess the effectiveness of corporate compliance programs” in the context of a health care fraud investigation (https://www.justice.gov/criminal-fraud/strategy-policy-and-training-unit/compliance-initiative).

Voluntary for hospitals until 2010, the establishment of compliance programs became a requirement for hospitals as a condition of enrollment in Medicare, Medicaid, or the Children’s Health Insurance Program, per the Patient Protection and Affordable Care Act of 2010 [Patient Protection and Affordable Care Act of 2010]. The Office of Inspector General of the U.S. Department of Health and Human Services published “Compliance Program Guidance for Hospitals,” which promoted the seven elements of an effective compliance program as described in Chapter 8 of the Federal Sentencing Guidelines [United States Sentencing Commission 2015]

The purpose of the CMS Conditions of Participation, under which the infection control guidance included is to provide guidance for “health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries.” [https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/CFCsAndCoPs/]. CMS provides separate guidance for the implementation of the hospital’s Corporate Compliance program published by the Office of Inspector General of the U.S. Department of Health and Human Services [HHS 1998; HHS 2005]. The Office of Inspector General recommends that each hospital “adapt the objectives and principles underlying this guidance to its own particular circumstances” [HHS 1998].

The intention of the corporate compliance/whistleblower policy ought to be to articulate facility expectations and protocols/procedures for incidents in which healthcare personnel become aware of an actual or suspected violation of the hospital policy or law. Overall, policies were evaluated to determine whether compliance program elements were included, which

primarily focus on issues related to accounting, as well as mention of patient safety issues such as provisions about reporting drug diversion, infection control and patient safety breaches, and ethics questioned in the practice of patient care.

The key guidance documents that were used to evaluate the corporate compliance/whistleblower policy included:

- U.S. Health and Human Services Compliance Program Guidance for Hospitals (HHS 1998)
- U.S. Health and Human Services Supplemental Compliance Program Guidance for Hospitals (HHS 2005)
- IRS Instructions for Form 990 Return of Organization Exempt From Income Tax [https://www.irs.gov/forms-pubs/about-form-990]
- Department of Justice (DOJ) Evaluation of Corporate Compliance Programs

4.10.5 Clinical practice guidelines relevant to policy evaluation

Practice guidelines that would likely affect the policies under study did not change in the years corresponding to the timeframe of the outcome data (2009-2013) so there was no strong rationale to expect that policy content would change substantially. The CDC Hand Hygiene guideline was published in 2002, the CDC/HICPAC MDRO guideline was published in 2006, the CDC/HICPAC Isolation guideline was published in 2007, and the WHO Hand Hygiene guideline was published in 2009. While practice guidelines have not changed substantially since 2009, CMS requirements for HAI public reporting changed substantially. As part of the Value-based Purchasing program, CMS required medium and large hospitals to report a variety of HAIs starting in January 2011. In 2011, CMS required reporting of central-line associated bloodstream infection from ICUs. In 2012, CMS required reporting of surgical site infection following abdominal hysterectomies and colon procedures, catheter-associated urinary tract infection in ICUs. In 2013, CMS required reporting of healthcare personnel influenza vaccination, *Clostridium difficile* infection, and MRSA. The revision date, details of the revisions, and the original policy date were documented, and policies were assessed for exogenous and endogenous forces that could have

impacted the policy content. Additionally, the infection preventionist interview included a question about policy changes in the years prior to the outcome data.

4.11 Aim 2: Exposure measurement: hospital policy evaluation

The goal of the policy evaluation was to identify constructs that have the potential to be measurable and modifiable in the prevention of MRSA in hospitals. We aimed to turn the policy language into quantifiable constructs. Using this approach, we hypothesized that we would be able to identify what the important constructs are, whether they matter, and how much they matter with respect to the spread of MRSA infection.

Ideally, a comprehensive policy evaluation study would consider all policies of the hospital to characterize the policy environment and would include a breath of historical versions of policies to assess trends over time. Yet it was not possible to eat the whole elephant, so to speak, and therefore policies that appeared obviously related to MRSA prevention along with the hospital policy on corporate compliance/whistleblower were evaluated.

Due to the cross-sectional nature of the dissertation, what was available to analyze was just that – it was what existed at that point in time. It is a common standard of practice for hospital policies to include the date of the last revision, the original policy date, and major revisions to the policy and the date they occurred. To the degree possible, details of the revisions were collected and reviewed to identify motivations and indications for policy change.

There were assumptions that came with the evaluation of policies, such as:

1. Multiple policies were likely to be better than one single policy for a hospital
2. Some policies were more effective than other policies
3. Some policies would carry more weight compared to other policies
4. The natural experiment cannot be denied; we were only able to evaluate what existed.

Each selected policy was a topic required as part of the CMS Conditions of Participation. As such, it was anticipated that the topic existed as a stand-alone policy or was included in a broader policy or program.

4.11.1 Policy evaluation tool development

To systematically evaluate the policies, a tool was developed for each policy topic. The development of the policy evaluation tools was guided using the Alcohol Epidemiology Program Implementation Model [Jones-Webb, Nelson, McKee, et al, 2014] (Figure 3). This model was developed to guide alcohol control policy implementation, focusing on implementation components, "activities required to put an adopted policy into practice and sustain its effectiveness [Jones-Webb et al, 2014]. The authors of this model hypothesized that, "By more explicitly attending to implementation activities,…policies can be made stronger and more likely to achieve their intended purpose over time" [Jones-Webb et al, 2014].

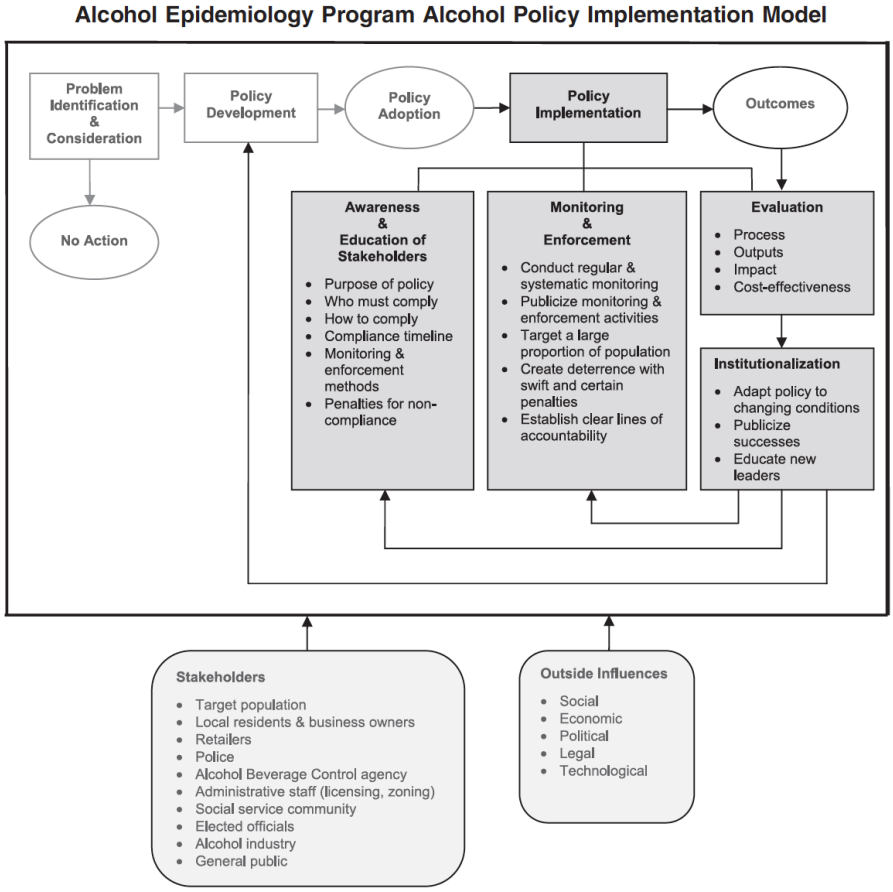

Figure 3. Alcohol Epidemiology Program Implementation Model [Jones-Webb et al, 2014].

The four key elements of the policy implementation included: awareness and education of stakeholders, monitoring and enforcement, evaluation, and institutionalization [Jones-Webb et al, 2014].

- Awareness and education of stakeholders: increase compliance, facilitate enforcement, and generate support
    - Purpose of policy
    - Who must comply (and what actions constitute compliance)
    - Compliance timeline
    - Monitoring and enforcement methods
    - Penalties for non-compliance
- Monitoring and enforcement
    - Conduct regular and systematic monitoring
    - Publicize monitoring and enforcement activities
    - Target a large proportion of the population
    - Create a deterrence with swift and certain penalties
    - Establish clear lines of accountability
- Evaluation: how policy effectiveness is measured, what data are collected to track policy implementation and effectiveness, how findings are used to improve the policy
    - Process (implementation)
    - Outputs (policy outcomes)
    - Impact (is policy effective in reducing the unwanted behaviors it was developed to address; assess unintended consequences)
    - Cost-effectiveness (cost/benefit)
- Institutionalization: sustaining the policy over time
    - Adapt policy to changing conditions
    - Publicize successes

    - Educate new leaders

The policy evaluation tool was organized to align with the common structure of the policies (e.g., purpose, policy statement, scope, definitions, references, procedures/protocols, accountability, and enforcement) to facilitate data collection. The technical information included in the evaluation tools was guided by clinical practice guidelines and policies available from recognized hospitals through internet searches. The following outline describes the policy sections and elements included in the policy evaluation tool (See Appendix B for policy evaluation tools.):

- The first policy elements were informational and intended to put forth the what the policy was about, why it was important, desired effects of the policy (such as what the organization aimed to accomplish with this policy), to whom it applied, and supporting documentation:
    - Purpose – specified rationale describing why the subject matter merited formal rules
    - Policy statement – provided staff with a clear understanding of requirements, regulations (if applicable), what constituted appropriate behavior, including expectations and performance objectives
    - Scope/audience – intended audience for this policy (who was included and not included)
    - Definitions – key concepts and terms were defined
    - References – scientific rationale/evidence was provided
- The next section of policy elements included structural expectations intended to be developed at the hospital level to maintain and carry out the policy:
    - Expectations were specified for educating healthcare personnel about the policy topic
    - Expectations were specified for hospital-level strategies within the facility

    - Expectations for behaviors/actions/ practices that that are required to comply with the policy were specified
- The next policy elements were instructional regarding the appropriate methods to use to comply with the skills/techniques outlined by the policy (such as when to do what method)
    - Appropriate methods to use to comply with the skills/techniques outlined by the policy (excluded influenza, whistleblower) (e.g., hand hygiene: when to use soap and water vs alcohol-based hand rubs; MDRO: type of transmission-based precautions to be used in a given situation)
    - Expectations for monitoring and enforcing practices/skills/techniques required by the policy
- The next policy elements were about outlining responsibilities for carrying out components of the policy to ensure staff were provided the opportunity to be compliant, parties responsible for carrying out the policy elements, and how adherence was determined:
    - Responsibilities for selection, placement/management, availability of products/supplies [excluded whistleblower]
    - Responsibilities for staff training and education
    - Responsibilities for monitoring compliance with skills/techniques included in policy
    - Responsibilities for additional policy elements (excluded whistleblower) (e.g., hand hygiene: reporting and managing skin health concerns; MDRO: managing patients in isolation; influenza: maintaining records of vaccination obtained on- and off-site).
- The next policy elements were about governance:
    - Governance structure is in place to enforce the policy, which may be a component of a broader organization program (e.g., committees/workgroups

developed, organizational goals setting, performance indicators specified, administrative support for resourced, dedicated time, etc)

    - Governance structure/administration along with the respective workgroup/committee/task force evaluates data to identify strengths, weaknesses, and develop plans for improvement

- The next policy elements were about accountability and enforcement:
    - Policy compliance was considered/incorporated into the measure of an employee's overall performance
    - Corrective actions/consequences were specified for policy non-compliance
    - Expectations for managers to enforce compliance with the policy were specified
    - Expectations for staff to enforce compliance with the policy were specified (excluded influenza)
- Finally, the remaining policy elements were instructional, specific to step-by-step protocols and procedures in place to appropriately carry out practices/skills/techniques required by the policy:
    - Protocol/procedure developed with instructions for how to comply with skills/techniques specified in policy (excluded influenza, whistleblower)
    - Protocol/procedure developed with instructions for how to measure compliance with skills/techniques specified in policy
    - Protocol/procedure developed with instructions for how to comply with other policy components, as necessary

4.12 Aim 3: Relationship between hospital policy and HO-MRSA BSI incidence

The objective of **Aim 3** is to apply the systematic method developed in Aim 2 to evaluate relevant policies in 5 Minnesota hospitals and then examine the relationship between hospital policies and hospital-onset MRSA bloodstream infection incidence. The outcome is hospital-level MRSA bloodstream infection incidence rate derived from the CMS “Healthcare-Associated

Infection (HAI) measures - provider data" (data reported via CDC's National Healthcare Safety Network).

The primary research question for this dissertation was whether hospital policies impact MRSA rates in hospitals. To address the question, a mixed-method ecological cross-sectional study was carried out in a sample of Minnesota hospitals. This objective of this Aim was to assess components of hospital policies that potentially impact MRSA rates.

Purposive sampling was used to recruit hospitals to participate in this pilot study. Useful for pilot projects, purposive sampling is a non-random method whereby the study investigators deliberately choose participants based on knowledge and expertise [Bernard, 2002].

4.12.1 Inclusion criteria

Inclusion criteria for hospitals included the following: 1) location in Minnesota; 2) participation in the CMS Prospective Payment System to ensure the outcome of interest could be collected (MRSA reported to CDC/NHSN); and 3) one hospital per healthcare system, if applicable. Affiliation with a healthcare system was considered for recruitment to ensure variation across hospitals, and to avoid duplication of policies if healthcare systems developed system-wide policies. In Minnesota in the year 2015, there were 135 hospitals, of which 55% (74/135) were affiliated with a healthcare system (e.g., Allina Health, Mayo Clinic, etc) and 41% (55/135) and participated in the CMS Prospective Payment System.

Hospitals were recruited through direct contact with the hospital's infection prevention and control manager by study staff. A recruitment letter was sent via email that included a summary of the study outlining the aims and data collection required for participation. Hospitals were encouraged to respond within 30 days. Two weeks following the dissemination of the recruitment letter, the hospital was contacted via telephone to ensure that recruitment letters were received and to discuss participation in the project.

4.12.2 Data sources

Hospital policies, as evaluate using the tool developed in Aim 2, were used as the exposure variables. Hospital policies were submitted to study staff via email. Policies were

stripped of hospital names and assigned a study identification number. Original policies were stored on a secured computer.

The outcome of interest was HO-MRSA bloodstream infections per 10,000 patient-days for the hospital, as reported to CMS via CDC/NHSN. This was the same outcome used for Aim 1b. See Section 4.8.1 for details. Using the dataset constructed for Aim 1b, a dataset was created that included the MRSA infection data for the five participating hospitals. To construct the analytic dataset, the policy evaluation data and the MRSA data were linked by the CMS provider ID number.

4.12.3 Analytic approach

The study design was necessary because the exposure of interest was truly a group-level exposure, and a randomized controlled trial was not appropriate given that the exposure of interest was novel and no established measurement methods existed. Data collected for this dissertation were cross-sectional ecologic so there was no formal procedure for exposure assignment and the unit of observation was the organization. The cross-sectional nature of the data represented a snapshot or a cross-section of the hospital at one point in time. The strength of the study design was that we were able to generate hypotheses and gain insight into a novel question relatively quickly and inexpensively. With cross-sectional data, a bias was temporality – we were only able to study what was existing yet the exposure was likely to change over time. A limitation of this approach was that we were not able to formally test a hypothesis using statistical methods.

Since this dissertation question introduced a new perspective to MRSA prevention and control in hospitals, and there was no dataset to examine the relationship between exposure and outcome, and no existing method/technique to measure hospital policies – this required a mixed methods approach that relied on fundamental epidemiological methods. Descriptive epidemiologic methods were employed to organize, summarize, and analyze these to gain insight into the exposure measurement and the variations in the exposure in relation to the outcome to identify trends. This approach was used to describe whether a public health problem was

identified and to understand the distribution of the novel exposure, as well as the relationship between the novel exposure and the outcome. This exploratory approach was important for hypothesis formulation and as a stepping stone to more formal epidemiologic studies. To gain insight into the relationship between the outcome, HO-MRSA incidence, and the policy evaluation scoring, correlation was used. The outcome and policy measures were continuous so Pearson's product correlation coefficient (r) was used to measure linearity, the degree to which the paired observations fell on a straight line [Szklo & Nieto, 2007]. The correlation coefficient values range from −1 (perfect negative correlation) through 0 (no correlation) to 1 (perfect positive correlation) [Szklo & Nieto, 2007].

4.13 Aim 4: Overview

The objective of Aim 4 was to conduct qualitative interviews with healthcare personnel to describe practices related to the policies under study. This intention of the Aim was to collect qualitative data to better understand the policy implementation and to provide context in terms of the hospital as an organization in which the policies were implemented. The qualitative data were used to supplement the quantitative data collected for Aims 2 and 3. We hypothesized that the relationship between hospital policy and the MRSA infection rate was mediated by healthcare personnel practice. Therefore, through qualitative interviews, we sought to begin to describe the mechanism or process by which practice mediates the policy and MRSA relationship. "Qualitative findings in evaluation illuminate the people behind the numbers and put faces on the statistics, not to make hearts bleed, though that may occur, but to deepen understanding. [Patton, 2001].

4.13.1 Recruitment of healthcare personnel

Healthcare workers at participating facilities were recruited by the hospital staff via email communication and staff meetings. A template letter/email prepared by study staff was provided to hospitals as a recruitment tool. Interested participants were asked to directly contact the study staff.

Healthcare personnel in three roles were recruited: direct care provider (nurse, physician/physician's assistant), environmental services staff, and administration/leadership.

4.13.2 Inclusion criteria

The inclusion criteria for healthcare personnel to participate in the qualitative interviews were as follows: 1) direct care giver (e.g., nurse, physician, physician's assistant), environmental services staff, or administrative/leadership role (e.g., chief executive officer, chief medical officer, chief nursing officer, etc); 2) worked at least 20 hours/week at the participating hospital, 3) worked at the participating hospital for a minimum of 3 months; 4) at least 18 years of age; and 5) spoke English. Adults lacking capacity to consent themselves were excluded from the healthcare worker interview portion of the study.

4.13.3 Human subjects and IRB approval

The University of Minnesota Institutional Review Board (IRB) determined that this study was exempt from full IRB review given that secondary data analyses would be conducted on existing data hospital-level data (no patient identifiers), and that interviews would be conducted with hospital staff with the intention of collecting data on work practices related to hospital policies, and therefore would not evoke or introduce emotional harm to participants; no identifying information was be collected from human participants (IRB study number: 1510E79803). For exempt category 2 research, it was not necessary to obtain signed documentation of consent.

Subjects were informed that they would be asked a set of questions about policies used to control infections in their hospital; interviews were expected to take approximately 30 to 45 minutes. Subjects were informed that there were no benefits or compensation for participation, that they could refuse to answer any question and end the interview at any time. Also, subjects were informed that participation was voluntary, that their names would not be documented by study staff, that the data collected would be kept confidential, that they would be provided the names and contact information for the study investigators, and that their participation would not affect current or future relations with the University of Minnesota or their supervisor or their hospital. Subjects were informed that, following completion of the study, aggregated interview responses would be provided to the infection prevention staff at the respective hospitals, and that their responses could not be linked to identifying information.

Participating healthcare personnel were asked to sign a consent form to indicate that their agreement and understanding of the purpose, procedures, and risks/benefits of the study. Two copies of the consent form were used for each participant. The first consent form included the participant's name for the participant to keep; the second form included the participant's unique identification number for study records, which was unable to be linked to identifying participant information. The interview form also included the participant's unique identification number. Completed interview and consent forms were stored in a secured file cabinet in a secured building at the University of Minnesota. Interview forms were entered into a database maintained on a secured computer.

4.13.4 Interview questionnaire

Interviews were semi-structured – there was a set of interview questions asked systematically in order to compare responses across hospitals and participant job roles. Interview questions aligned with the relevant hospital policy evaluation tool (instruction, responsibility, accountability) and were primarily open-ended to explore the attitudes, knowledge, and beliefs of the participants. Questionnaires were tailored towards the role of the participant (e.g., direct care provider (nurse, physician), environmental services staff, and administration/leadership). The interviews were designed to be highly exploratory so as to provide an opportunity for broad information gathering given that research in this area is lacking.

Interviews included the following themes: 1) were healthcare personnel aware of the policy; 2) were healthcare personnel aware of instructional components of the policy including accompanying protocols/procedures that pertain to their practice (e.g., hand hygiene instructions); 3) open-ended questions to allow opportunities for staff to provide knowledge, attitudes, and beliefs regarding policy implementation and adherence. The questionnaire items were as outlined below – the questions were similar for each of the policies covered: hand hygiene, multidrug-resistant organisms (MDRO)/isolation, environmental cleaning/disinfection, influenza vaccination, and whistleblower/corporate compliance.

- Inclusion criteria: English speaking, age, position, hours per week worked at the hospital, length of time worked at the hospital
- Do you believe that the leadership thinks that hand hygiene is important for nurses? (Indicate ways in which leadership demonstrates that hand hygiene is/is not important.)
- When you first started at this hospital in a patient care role, was the importance of hand hygiene discussed?
- Were you trained on how to perform hand hygiene?
- Were you trained on when to perform hand hygiene? Put another way, was it made clear to you which patient care circumstances warrant hand hygiene protocols?
- Since you started your job, have you been asked to indicate your knowledge of hand hygiene requirements and the leadership's commitment through your signature (such as a behavioral contract or commitment board)?
- Did you know that your hospital has a policy about hand hygiene?
- Do you think that the hand hygiene policy makes a difference in how and when you clean your hands when you're at work?
- Do you think that the hand hygiene policy makes a difference in how others at this hospital clean their hands when they're at work?
- Do you know the rate of hand hygiene compliance in your hospital or hospital unit?
- What happens if you or someone else is caught violating the policy? For example, what would happen if someone provided care to a patient and then forgot to clean their hands before moving on to the next patient?
- Questions about the leadership's response to violations of the hand hygiene policy:
    - Does the unit or departmental leadership talk to the employee about the violation?
    - Do they find factors or things that contribute to noncompliance?
    - Do they implement corrective actions for workflow, equipment, or other common factors that impact compliance?

    - Do they take action on individuals that keep violating the policy?
- About how frequently do you think employees violate the hand hygiene policy without other employees or the leadership noticing?
- If you violated the policy, would you be concerned or afraid of getting caught?

4.13.5 Analytic approach

Following the in-person interviews, the responses were entered into a Microsoft Excel database. Discrete questions were summarized for all participants and by the role of the participant (i.e., nurse, physician, environmental cleaning, and administration/leadership). The responses were reviewed to identify key concepts, which were developed into common themes. Additionally, we assessed whether the interview data aligned with the policy evaluation data or would it include important information gaps detected by the policy evaluation. For example, where a hospital policy ranked low, did the interviews reflect the ranking? The information captured using qualitative methods was important to evaluate to inform the exposure measurement process, given that the exposure was novel.

5. Results

5.1 Aim 1a: Results

5.1.1 Overall

For years 2008-2013 in Hennepin and Ramsey Counties, 1,594 cases of invasive MRSA infection were reported. 59.2% were male; the median age was 61 years (range: 0-103); and 65.6% were of white race, 14.6% were of black race, 5.8% were of other race (Asian, American Indian, Pacific Islander), and 14.1% were reported with unknown race (Table 2). The most frequently reported underlying health conditions were diabetes (37.8%), chronic renal insufficiency (25.5%), chronic pulmonary disease (asthma and chronic obstructive pulmonary disease) (19.0%), and obesity (11.8%) (Table 2). Of the total cases reported, 1,589 (99.7%) were able to be categorized into epidemiologic classes: 219 (13.7%) were hospital-onset (HO), 1161 (72.8%) were healthcare-associated community-onset (HACO), and 209 (13.1%) were community-associated (CA). There were 184 (11.5%) deaths, of which 92 (50%) occurred within 7 days of the MRSA culture collection (Table 3). Among all cases, the most common culture site was the blood.

The incidence of invasive MRSA decreased among all epidemiologic categories over the surveillance period, from 2008 to 2013 (Table 4; Figures 4 and 5). Incidence rates were calculated using US census estimates for the annual population for the surveillance area of Hennepin and Ramsey counties as the denominator. Invasive MRSA decreased 39% from years 2008 to 2013, from 2.0 to 1.2 infections per 10,000 persons. The HO-MRSA bloodstream infection category experienced the largest decrease of 71% over the surveillance period. The smallest decrease of 15% occurred among CA-MRSA infections.

5.1.2 Healthcare-associated community-onset (HACO)-MRSA infections

Of the 1,380 healthcare-associated cases, 1,161 (84.1%) had onset in the community and therefore categorized as HACO. The median age was 65 years (range, 0-103), 688 (59.3%) were male, 790 (68.0%) were of white race. Risk factors for invasive HACO-MRSA infection included hospitalization (74.3%), surgery (38.7%), and residence in a long-term care facility

(39.9%) in the one year prior to infection, and 17.9% had a central venous catheter in the two days prior to infection. At the time of MRSA culture collection, most (88%) were at the hospital – in the emergency department, surgery/operating room or inpatient unit; 3% were in the ICU. Most (93%) cases reported underlying health conditions, most frequently diabetes (41.2%), heart disease (27.1%), chronic renal insufficiency (31.1%), and 21.0% reported hemodialysis in the year prior to infection (Table 2). Prior to culture collection, 46% were in a private residence and 26% were in a long-term care facility.

The most common type of infection among HACO-MRSA cases was bloodstream infection (74.8%), with 40% reporting additional diagnoses. 22.6% had bone or joint infection, 9.6% had skin infections (cellulitis, abscess, ulceration), 10.4% had pneumonia, and 5.6% had surgical site infections. Among the 1,380 HACO-MRSA cases, 135 (11.6%) died with 54.1% occurring within 7 days of MRSA culture collection.

5.1.3 Hospital-onset (HO) MRSA infections

Of the 219 HO-MRSA infections, the median age was 60 years (range, 0-94), 125 (57.1%) were male, 139 (63.5%) were of white race. Frequently reported underlying health conditions included diabetes (32.4%), chronic pulmonary disease (21.0%), heart disease (20.6%), cancer/immunosuppressive conditions (18.7%). More than 10% of HO-MRSA infections were cultured in the ICU, which occurred more frequently compared to HACO- and CA-MRSA cases (p=0.000). Prior to HO-MRSA infection, 45% were in a private residence, 36% were transferred from a different hospital, and 11% were in a long-term care facility. At the time of MRSA culture collection, 10.5% were in the ICU, 10.1% were in surgery/operating room, and 75.8% were in another inpatient care unit.

Risk factors for invasive HO-MRSA infection included hospitalization (60.3%), surgery (44.3%), and residence in a long-term care facility (21.0%) in the one year prior to infection, and 23.3% had a central venous catheter in the two days prior to infection. Bloodstream infection was the most common type of infection (67.4%) followed by bone or joint infection (16.3%), pneumonia (14.6%), and 9.6% had other types of infections (e.g., pleural effusion, infected

device, etc) (Table 3). Among the 219 HO-MRSA cases, 41 (18.7%) died with 36.6% occurring within 7 days of MRSA culture collection.

5.1.4 Community-associated (CA) MRSA infections

There were 209 (13.1%) CA-MRSA cases reported with the median age of 47 years (range: 0-92), 127 were male (60.8%), 113 (54.1%) were of white race. Compared to HACO- and HO-MRSA cases, CA-MRSA cases more commonly reported no underlying health conditions (p=0.000). Among those CA-MRSA cases with underlying conditions, 23.9% had diabetes, 22.0% were current smokers, 16.3% had chronic pulmonary disease (e.g., asthma, COPD), 13.4% had skin conditions (abscess/boil, decubitus/ pressure ulcer, chronic skin condition), and 13.4% reported drug use (intravenous drug use, other illicit drug use).

Prior to CA-MRSA infection, most cases (93%) were in a private residence; 3.5% reported being homeless. At the time of MRSA culture collection, 89.5% were at the hospital – in the emergency department, surgery/operating room or inpatient unit; 2.9% were in the ICU; 4.35 were cultured in the community, prior to arriving to the hospital.

Bloodstream infection was the most common type of infection (58.4%) followed by bone or joint infection (42.3%), skin infection (cellulitis, abscess, ulceration) (20.2%), and pneumonia (12.0%). Compared to HACO- and HO-MRSA cases, death in CA-MRSA cases occurred less frequently (p=0.000); 7 (3.4%) died with 42.9% occurring within 7 days of MRSA culture collection.

5.2 Aim 1a: Conclusion

We found that invasive MRSA infections in this catchment area decreased in Hennepin and Ramsey counties over years 2008 to 2013, HO-MRSA BSI was most pronounced compared to cases with HACO- and CA-MRSA infection. This reduction aligns with other reductions reported in similar timeframes following the publication of a successful infection prevention initiative and guideline publications, which included infections such as MRSA.

Table 2. Demographics of invasive MRSA infection cases reported by epidemiologic class, Hennepin and Ramsey Counties, MN, 2008-2013

	Hospital onset		Healthcare-associated community-onset		Community-associated		Total*		p
	n	%	n	%	n	%	n	%	
Total	**219**	**13.7**	**1161**	**72.8**	**209**	**13.1**	**1594**	**100**	
Sex									0.68
Male	125	57.1	688	59.3	127	60.8	944	59.2	
Female	94	42.9	473	40.7	82	39.2	650	40.8	
Age (years)									< 0.001
<1	7	3.2	6	0.5	5	2.4	18	1.3	
1	4	1.8	3	0.3	4	1.9	11	0.7	
2-4	4	1.8	4	0.3	5	2.4	14	0.9	
5 - 17	4	1.8	9	0.8	11	5.3	24	1.5	
18 - 34	11	5.0	69	5.9	33	15.0	113	7.1	
35 - 49	34	15.5	165	14.2	53	25.4	253	15.9	
50 - 64	72	32.9	326	28.1	51	24.4	449	28.2	
≥ 65	83	37.9	579	49.9	47	22.5	712	44.7	
Median (range)	60	(0-94)	65	(0-103)	47	(0-92)	62	(0-103)	
Race									< 0.001
White	139	63.5	790	68.0	113	54.1	1,045	65.6	
Black	33	15.1	167	14.4	31	14.8	232	14.6	
Other	7	3.2	74	6.4	11	5.3	92	5.8	
Unknown	40	18.3	130	11.2	54	25.8	225	14.1	
Dialysis within 1 year									n/a
Yes	20	9.1	243	20.9	0	0	263	16.5	
No	199	90.9	918	79.1	209	100	1331	83.5	
Healthcare risk factors									n/a
Hospitalization in 1 year prior to culture	132	60.3	863	74.3	0	0	995	62.4	
Surgery in 1 year prior to culture	97	44.3	449	38.7	0	0	546	34.3	
LTCF in 1 year prior to culture	46	21.0	463	39.9	0	0	509	31.9	
Central venous catheter within 2 days	51	23.3	208	17.9	0	0	259	16.3	
Underlying conditions									
None	17	7.8	85	7.3	50	23.9	153	9.6	< 0.001
Skin conditions	24	11.0	190	16.4	28	13.4	242	15.2	0.091
Chronic liver disease	25	11.4	72	6.2	5	2.4	102	6.4	0.001
Chronic pulmonary disease	46	21.0	222	19.1	34	16.3	302	19.0	0.450
Chronic renal insufficiency	35	16.0	361	31.1	10	4.8	406	25.5	< 0.001
Heart disease	45	20.6	314	27.1	22	10.5	383	24.0	< 0.001
Current smoker	27	12.3	149	12.8	46	22.0	222	13.9	0.002
CVA/stroke	16	7.3	95	8.2	8	3.8	119	7.5	0.088
Dementia	3	1.8	61	6.6	4	2.3	68	5.4	0.006
Diabetes	71	32.4	482	41.5	50	23.9	603	37.8	< 0.001
Immunosuppressive conditions	41	18.7	158	13.6	14	6.7	213	13.4	0.001
Hemiplegia/paraplegia	10	5.9	63	6.7	5	2.9	80	6.2	0.160
HIV/AIDS	3	1.4	20	1.7	2	1.0	25	1.6	0.850
Drug use (IV, other illicit drug use)	10	4.6	57	4.9	28	13.4	95	6.0	< 0.001
Obesity	37	16.9	128	11.0	23	11.0	188	11.8	0.044
Peripheral vascular disease	5	2.3	100	8.6	5	2.4	110	6.9	< 0.001
Premature birth	6	2.7	2	0.2	3	1.4	11	0.7	< 0.001

* Five cases with unknown epidemiologic category
CA: Community-associated
COPD: chronic obstructive pulmonary disease
CVA: cardiovascular accident
HACO: Healthcare-associated community-onset (HACO)
HO: Hospital-onset
IV: intravenous
LTCF: long-term care facility

Table 3. Characteristics of Invasive MRSA Infections Reported, By Epidemiologic Class, Hennepin and Ramsey Counties, MN, 2008-2013

	Hospital-onset		Healthcare associated community onset		Community associated		Total		p
	n	%	n	%	n	%	n	%	
Total cases	**219**	**13.7**	**1,161**	**72.8**	**209**	**13.1**	**1594**	**100**	
Hospitalized	219	100	1,081	93.1	191	91.4	120	6.5	
Location prior to date of initial culture (2009-2013)**									
Incarcerated	3	1.9	4	0.3	0	0	7	0.6	
Homeless	0	0	7	0.6	6	3.5	13	1.0	
Long-term acute care hospital	2	1.2	25	2.2	0	0	27	2.1	
Long-term care facility	17	10.5	303	26.1	0	0	320	25.4	
Private residence	73	45.1	538	46.3	160	93.0	772	61.2	
Transferred from hospital/acute care facility	59	36.4	15	1.3	0	0	74	5.9	
Unknown	3	1.9	24	2.1	5	2.9	34	2.7	
Other	5	3.1	10	0.9	1	0.6	16	1.3	
Location of culture collection**									
Emergency department	2	0.9	236	20.3	41	19.6	281	17.6	
Inpatient unit, nonintensive care unit	166	75.8	688	59.3	117	56.0	973	61.0	
Intensive care unit	23	10.5	38	3.3	6	2.9	67	4.2	
Long-term acute care hospital	6	2.7	22	1.9	0	0	28	1.8	
Long-term care facility	0	0.0	30	2.6	0	0	30	1.9	
Outpatient	0	0.0	27	2.3	7	3.4	34	2.1	
Surgery/operating room	22	10.1	101	8.7	29	13.9	153	9.6	
Unknown community location (nonhospital)	0	0.0	19.0	1.6	9	4.3	28	1.8	
MRSA infections diagnosis type (multiselect; >1 allowed)									
Any BSI	161	67.4	1,003	74.8	156	58.4	1,326	71.5	< 0.001
With CVC exit site or AV fistula infection	6	2.5	92	6.9	0	0	99	5.3	
Presence of CVC in prior 2 days	43	18.0	206	15.4	0	0	249	13.4	
No CVC documented	112	46.9	764	57.0	131	49.1	1,011	54.5	
BSI with other infection	70	29.3	546	40.7	108	40.5	725	39.1	
Skin infection (cellulitis, abscess, ulceration)	11	4.6	129	9.6	54	20.2	195	10.5	< 0.001
Pneumonia	35	14.6	140	10.4	32	12.0	207	11.2	0.259
Osteomyelitis	26	10.9	185	13.8	40	15.0	251	13.5	0.227
Arthritis, joint infection, or bursitis	13	5.4	118	8.8	73	27.3	204	11.0	< 0.001
Abscess (not skin)	15	6.3	72	5.4	24	9.0	111	6.0	0.12
Endocarditis	7	2.9	36	2.7	11	4.1	54	2.9	0.089
Urinary tract infection	7	2.9	76	5.7	11	4.1	94	5.1	0.091
Surgical site infection	7	2.9	75	5.6	2	0.8	84	4.5	< 0.001
Other	23	9.6	43	3.2	4	1.5	71.0	3.8	< 0.001
Patient outcome									
Death (all causes)***	41	18.7	135	11.6	7	3.4	184	11.5	< 0.001
Death within 7 days of culture (all causes)	15	36.6	73	54.1	3	42.9	92	50.0	0.14

** Primarily collected for years 2011-2013
*** One death did not have epidemiologic classification
AV: arteriovenous
BSI: bloodstream infection
CVC: central venous catheter
LTCF: long-term care facility

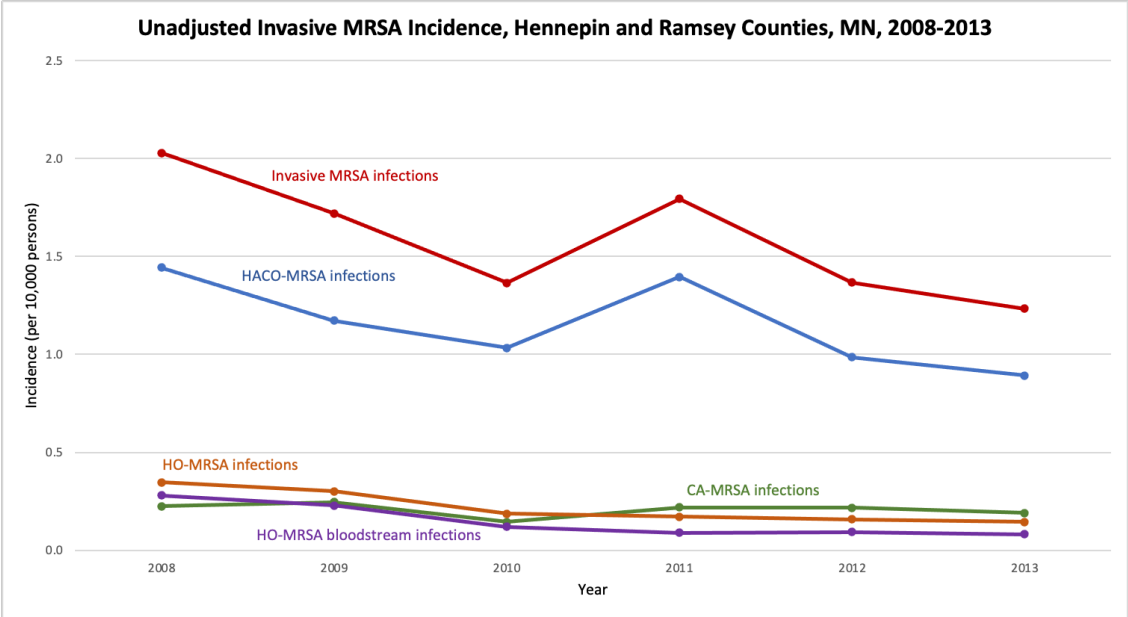

Figure 4. Invasive MRSA trends among epidemiologic categories, 2008-2013, Hennepin and Ramsey counties, MN.

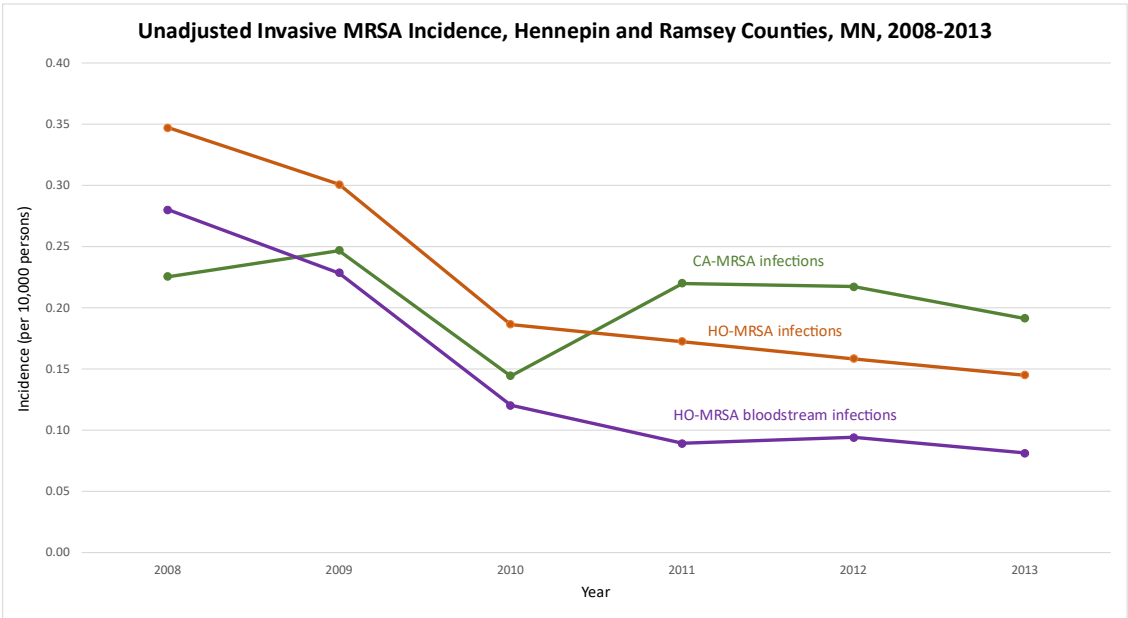

Figure 5. Invasive MRSA trends among CA-MRSA, HO-MRSA, and HO-MRSA bloodstream infections, 2008-2013, in Hennepin and Ramsey counties, MN.

Table 4. Percent Change among Epidemiologic Category of Invasive MRSA Infection, 2008-2013, Hennepin and Ramsey counties, MN.

Epidemiologic category	% Change, surveillance years 2008-2013
MRSA Incidence	-39.1
HACO-MRSA Incidence	-38.1
HO-MRSA	-58.3
CA-MRSA Incidence	-15.1
HOMRSA BSI Incidence	-71.0

5.3 Aim 1b: Results

5.3.1 Summary of hospital characteristics

Among the 1,288 hospitals included in the sample for calendar year 2013, 8,113 HO-MRSA BSI infections were reported over 122,029,081 patient-days. The mean number was 0.66 HO-MRSA BSI infections per hospital per 10,000 patient-days; the median was 0.53 with a minimum of 0 and a maximum of 2.78 infections per hospital per 10,000 patient-days (Table 5; Figure 6).

Bed count, average daily census (patient-days/365 days), and patient days were considered as hospital size indicators. Since average daily census (derived from patient days) and patient days were perfectly correlated (R^2=1.0), average daily census was selected for further analyses. Average daily census was informative since this metric estimated the number of patients in beds versus simply considering beds in the hospital, and it was interpretable. Among the sample of hospitals, the mean hospital bed count was 429.1 (SD: 254.8). The mean average daily census was 259.5 (SD: 172.1). Average daily census and bed count were strongly correlated (r=0.84) (Table 6; Figure 7). As expected, larger hospitals, on average, reported higher MRSA infection rates (average daily census: t=6.13, p<0.001; bed count: t=6.35, p<0.001).

The percentage of hospitals included by region was the same for the west, midwest, and the south, while the northeast included a higher percentage (37% vs 21%). The northeast region also had the highest mean HO-MRSA BSI rate per hospital (mean: 0.7 per hospital per 10,000 patient-days) which was followed by the south (mean: 0.6 per hospital per 10,000 patient-days) and then the midwest and west regions (for both, mean: 0.5 per hospital per 10,000 patient-days) (Table 7). Six percent of hospitals were located in rural areas of the U.S., which was sensical given that small, rural (critical access) hospitals were not included in reporting HO-MRSA BSI to NHSN by CMS.

Disproportionate share hospitals (DSH) received adjustment payments to provide additional help to those hospitals that served a disproportionate number of low-income patients since low-income patients would be more likely to be uninsured or Medicaid enrollees [CMS

DSH]. A larger DSH percentage indicated a larger number of low-income patient admissions. DSH percentage was grouped into quartiles and cut at the 15% threshold at which hospitals could qualify for the adjustment. Among this sample, 85.8% of the hospitals qualified for the DSH adjustment at the 15% cut-off, with a mean DSH percentage of 0.3 (SD: 0.2). The mean MRSA rate per hospital increased over the quartiles (Table 7).

When medical school affiliation was evaluated, 33% were graduate or major teaching hospitals, which had a higher mean MRSA rate compared to hospitals with limited or no medical school affiliation (0.70 vs 0.57 per hospital per 10,000 patient-days, $t=4.93$, $p < 0.001$). Most (98.4%) hospitals in the sample were accredited by an accrediting body; 91.7% were accredited by The Joint Commission.

Hospital ownership categories included church, private (not for profit), other, private (for profit), federal, state, local, hospital district or authority, physician ownership, or tribal. The "other" category was not defined, and when investigated, these were a variety of hospitals that included academic medical centers and community hospitals. Hospitals such as Cedars-Sinai Medical Center in Los Angeles, California, University of California campus-specific medical centers (Davis, San Francisco, San Diego), Kaiser Foundation Hospitals in California (n=10), and in Minnesota included Fairview Southdale and Allina Health Unity hospitals. Hospital ownership type was categorized by for profit and not for profit, given that organizational goals and/or leadership styles could impact infection prevention approaches for the hospital. Table 7 provides a summary of the hospital demographic characteristics.

The CMS POS dataset contained nearly 60 characteristics related to staffing and services provided. Staffing and services with low potential to be related to MRSA transmission in hospitals, based on conceptual and biological plausibility, were excluded such as such as dietary, dentistry, audiology, chiropractic, number of psychologists, number of social workers, among others. Tables 8-12 provide a summary of the staffing characteristics and services provided that were identified a priori as potentially related to MRSA transmission in hospitals.

The most common (>90%) services provided by the sample of hospitals were emergency, nuclear medicine, pharmacy, pediatrics, acute renal dialysis. Of the six types of surgical services included in the dataset, 40% of hospitals provided all six services. The mean number of surgical services for each hospital was 4.2 (SD: 2.0). Most (>98%) provided basic inpatient surgical services including inpatient surgery, operating room, anesthesia, and post-operative recovery care. The less common surgery types were neurosurgery (59.8%) and reconstructive (54%).

Of the six types of intensive care units (ICU) services provided, the mean number of ICU services for each hospital was 3.2 (SD: 1.4). Less than half of the hospitals provided four or more types of ICU services. Most (98.2%) hospitals had a medical/surgical ICU and 86% had a cardiac ICU or cardiac care unit. While nearly half of the hospitals had neonatal ICUs, less than a quarter had pediatric ICUs. The least common ICU type was the burn unit – provided at 11.8% of hospitals, which was expected given the highly specialized care required to treat burn-injured patients.

Thirty percent of hospitals in the sample provided some type of transplant service. A Medicare-certified transplant program indicated that it was certified by CMS and the hospital would receive additional Medicare funding to provide the service, which could indicate a high-quality program, potentially higher quality compared to one not certified by CMS. However, these categories were not mutually exclusive. The mean MRSA rate for hospitals with Medicare-certified transplant program (mean: 0.76, SD: 0.42) was slightly higher compared to those without a Medicare-certified transplant program (mean: 0.69, SD: 0.44).

5.3.2 Multivariate regression model

Multivariate linear regression was used to assess the relationship between hospital characteristics and HO-MRSA BSI incidence rate. The approach to the model was to start with the relationship between the size of the hospital and the HO-MRSA BSI incidence rate (model 1). Size was explored using bed count and average daily census per hospital for year 2013.

Building on the relationship between the hospital size and MRSA rate, a multivariate linear regression model was constructed to evaluate the relationship between hospital-level characteristics and MRSA rates to understand whether other hospital-level characteristics, including demographics, staffing, and services, helped to explain the relationship between hospital size and MRSA rate (model 2). The covariates included in the model were selected based on conceptual and biological plausibility, in addition to identified risk factors from previously published studies and univariate regression methods. We drew from the epidemiology and infection prevention literature to select the most appropriate variables to estimate hospital-level infection rates, given the data. A description of the variables included in the multivariate linear regression model is provided in Table 13.

Many of the selected variables were similar in nature. Therefore, a hospital with a burn unit, which required certification and highly specialized staff would be more likely to also have a trauma center, which also required certification. A hospital with a neonatal ICU, which required certification, would be likely to also have a pediatric ICU. Given the similarities in the variables, collinearity was measured in the models using the variance inflation factor (VIF). Goodness of fit was evaluated using R^2.

To attempt to simplify the model but maintain or improve model fit, we ran model 2 using stepwise regression (model 3). Stepwise regression was selected to aid with constructing a more parsimonious model. With this method, the full model was fit with all of the variables and then at each step, variables were removed using a significance level of $p \geq 0.2$ and added back to the model based on significance level of $p < 0.1$. The multivariate regression model and model fit results are provided in Tables 16 and 17, respectively.

When MRSA rate was regressed on average daily census and bed count (model 1), the results showed that with increasing number of beds and census, the rate of MRSA increased. While the positive relationship was statistically significant for bed count ($t=2.17$, $p=0.030$), it was not statistically significant for average daily census ($t=1.46$, $p=0.144$). For model 1, the R^2 was

0.03, indicating that average daily census and bed count explained only 3% of the variability of MRSA rate (Table 14).

When the mean values for this sample were plugged into the estimated regression equation, the estimated value for the hospital-level MRSA rate was as follows:

HO-MRSA BSI incidence rate per 10,000 patient-days

= 0.48 + 0.0001903(average daily census) + 0.0001917 (bed count) + E

= 0.48 + 0.0001903(259.6) + 0.0001917 (429.5)

= 0.61

When all 30 of the variables of interest were included in the model (model 2), the R^2 increased to 0.14, indicating that the size, demographic, staffing, and services variables explained 14% of the variability of MRSA rate (Table 14). Of the 30 variables included in model 2, only a third were statistically significant at the $p < 0.1$ level (Table 15). The characteristics that were statistically significant were as follows:

- Hospital size variables (n=2): none
- Hospital demographics (n=5): 80% (4/5) of the demographic variables were statistically significant – geographic region, DSH quartile, compliance status, medical school affiliation
- Staffing variables (n=7): 29% (2/7) of the staffing variables were statistically significant – number of FTE other salaried personnel employed, number of FTE resident physicians employed.
- Services variables (n=16): 25% (4/16) of the services variables were statistically significant – acute renal dialysis, CARF inpatient rehab, ICU - burn unit, ICU - neonatal

Model 2 estimated that geographic region, DSH quartile, compliance status, medical school affiliation, number of FTE resident physicians employed, acute renal dialysis, rehab, ICU - burn unit increased the average HO-MRSA BSI incidence rate – while number of FTE other salaried personnel employed, CARF inpatient and ICU – neonatal decreased the average rate.

When model 2 was run using stepwise linear regression (model 3), the R^2 decreased slightly to 0.13 (Table 14), indicating that the size, demographic, staffing, and services variables explained 13% of the variability of MRSA rate (Table 16). Of the 30 variables included in the model, half were statistically significant using the stepwise thresholds (removing terms with $p \geq 0.2$ and adding those with $p < 0.1$). With the inclusion of two factor categorical variables (region and DSH quartile), this method selected specific categories based on the thresholds (e.g., DSH quartiles vs including all categories of the variable). The characteristics that selected in this model based on the thresholds were as follows:

- Hospital size variables (n=2): bed count
- Hospital demographics (n=5): 80% (4/5) of the demographic variables were statistically significant – geographic regions south and northeast, DSH quartiles 3 and 4, compliance status, medical school affiliation
- Staffing variables (n=7): 29% (2/7) of the staffing variables were statistically significant – number of FTE other salaried personnel employed, number of FTE resident physicians employed
- Services variables (n=16): 31% (5/16) of the services variables were statistically significant – acute renal dialysis, inpatient rehab, ICU - burn unit, ICU - neonatal, gerontological service

Model 3 estimated that bed count, geographic regions south and northeast (compared to the west), higher DSH percentage (quartiles 3 and 4 compared to quartile 1), compliance status, medical school affiliation, number of FTE resident physicians employed, acute renal dialysis, rehab, ICU - burn unit increased the average HO-MRSA BSI incidence rate – while number of FTE other salaried personnel employed, CARF inpatient and ICU – neonatal decreased the average rate.

We ran the model to specify inclusion all levels of DSH and geographic region, which resulted in the same selected characteristics and similar model fit (R^2=0.13, F=12.28, df=16)

(data not shown). A comparison of regression coefficients for model 1, model 2, and model 3 is shown in Table 17.

5.3.3 Summary

Among this sample of U.S. hospitals, using the CMS POS file and CDC/NHSN data, we evaluated the relationship between the hospital-level characteristics and HO-MRSA BSI incidence for hospitals. Using a multivariate model that employed stepwise linear regression for final variable selection, we found that bed count, residing in the southern or northeastern regions of the U.S. (compared to the west), higher DSH percentage (quartiles 3 and 4 compared to quartile 1), not being in compliance with CMS, medical school affiliation (teaching or graduate level), number of physician residents employed, providing acute renal dialysis, having a burn unit, and providing gerontological specialty service increased the hospitals' HO-MRSA BSI incidence rate, while the number of other salaried employees, having a neonatal ICU, and having a CARF inpatient rehab decreased the hospitals' HO-MRSA BSI incidence rate ($df=16$, $R^2=0.13$, $F=12.28$, $p<0.001$).

First, we evaluated whether there was a relationship between hospital size and MRSA rates. We found that when we assessed average daily census and bed count as measures of hospital size, only bed count was statistically significant. We found a positive relationship between the estimated average MRSA rate and bed count, though this model only explained 3% of the variability. When thoughtfully selected hospital-level demographics, staffing, and services were added to bed size measures, 13% of the variability was explained, and the effect of bed count was diminished. Many of these variables aligned with our hypotheses since, for example, burn unit and renal dialysis services required meticulous attention to infection prevention and control practices. Additionally, it would be critical for gerontological providers to adhere to infection prevention practices given a more susceptible patient population, in addition to increased exposure to settings (i.e., long-term care facilities) in which MRSA may be prevalent given frequent healthcare encounters and cares/devices required. The regions of the country with previously reported higher rates of HO-MRSA rates, the South and northeast, aligned with

geographic differences reported in the literature [Kallen, Mu, Bulens, et al, 2010; Kuehnert, Hill, Kupronis, et al, 2005; Elixhauser & Steiner, 2007; CDC 2014 National and State Healthcare-Associated Infections Progress Report, 2016].

The model estimated that as other salaried staff increased, the rate of MRSA decreased. While no clear definition was provided by CMS, we would expect that other salaried staff comprised those outside of direct patient care that provided structure to the services provided, and could have included infection preventionists, quality and patient safety personnel, managers, and administration. It was plausible that hospitals with resources to employ more supporting staff would contribute to an organization's efforts to reduce infections. There was a positive relationship between the number of physician residents employed and the estimated MRSA rate. This relationship reenforced the relationship between medical school affiliation and MRSA rates, with the mean HO-MRSA BSI rate among hospitals with medical school affiliation was higher compared to hospitals with limited/none affiliation ($t=15.47$, $p<0.001$).

The model estimated lower relative MRSA rates among hospitals with CARF inpatient rehab services provided compared to those without that service, despite CARF inpatient rehab hospitals having higher mean bed counts ($t=6.63$, $p< 0.001$). CARF inpatient rehab was not related to medical school affiliation (Pearson $X^2=1.4921$, $p=0.222$) indicating that hospitals with these rehab units provided less complex medical services to less medically complex patients.

We demonstrated there was a positive relationship between certain hospital characteristics and HO-MRSA BSI incidence rates among medium- to large-sized U.S. hospitals. Despite the range of variables used to explore this relationship, our model only explained 13% of the variability. Clearly, additional study is be warranted, especially considering the severity of MRSA bloodstream infections which manifest as a result of the bacteria gaining entrance to the main circulatory system of the body. It is of particular importance to advance the study of this relationship through studying hospital-level factors that could directly measure the constructs in place that impact the staff behaviors which, in turn, lead to increased adherence to the policies and protocols in place to prevent these infections.

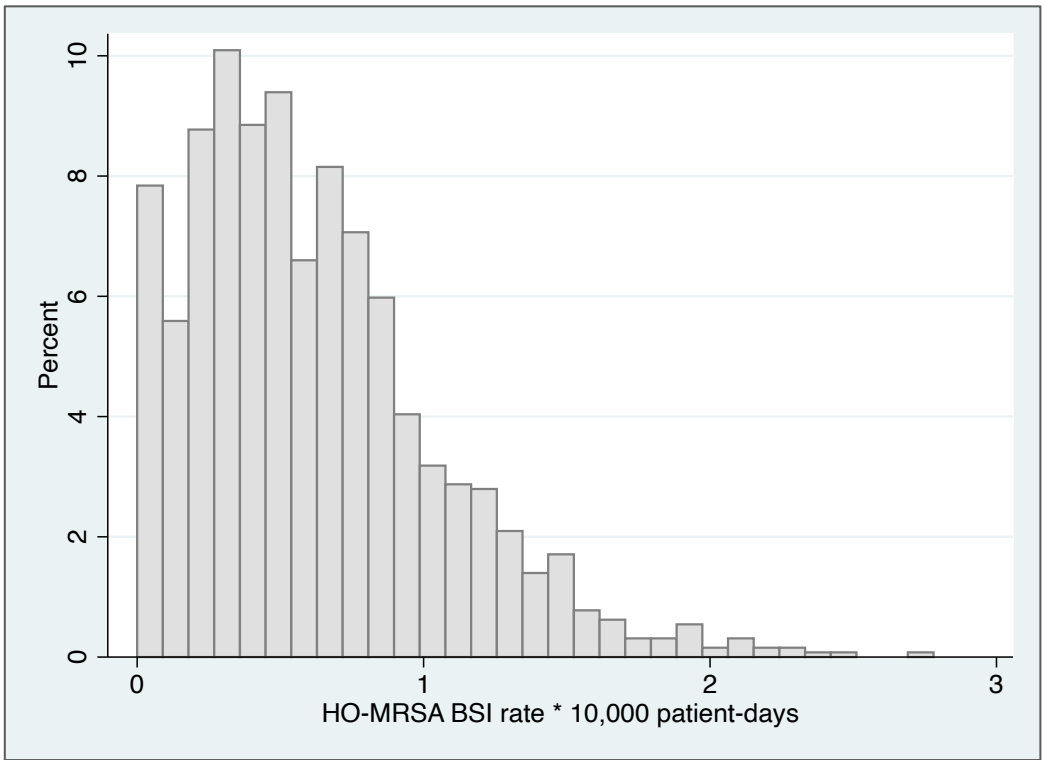

Figure 6. Histogram of HO-MRSA BSI rate per 10,000 patient-days per hospital among hospitals in the sample (n=1,288).

Table 5. Summary of the outcome, HO-MRSA BSI incidence rate per 10,000 patient-days

	HO-MRSA BSI incidence (n=1,288)
Mean (SD)	0.62 (0.44)
Median (IQR)	0.53 (0.55)
Range	0 - 2.78

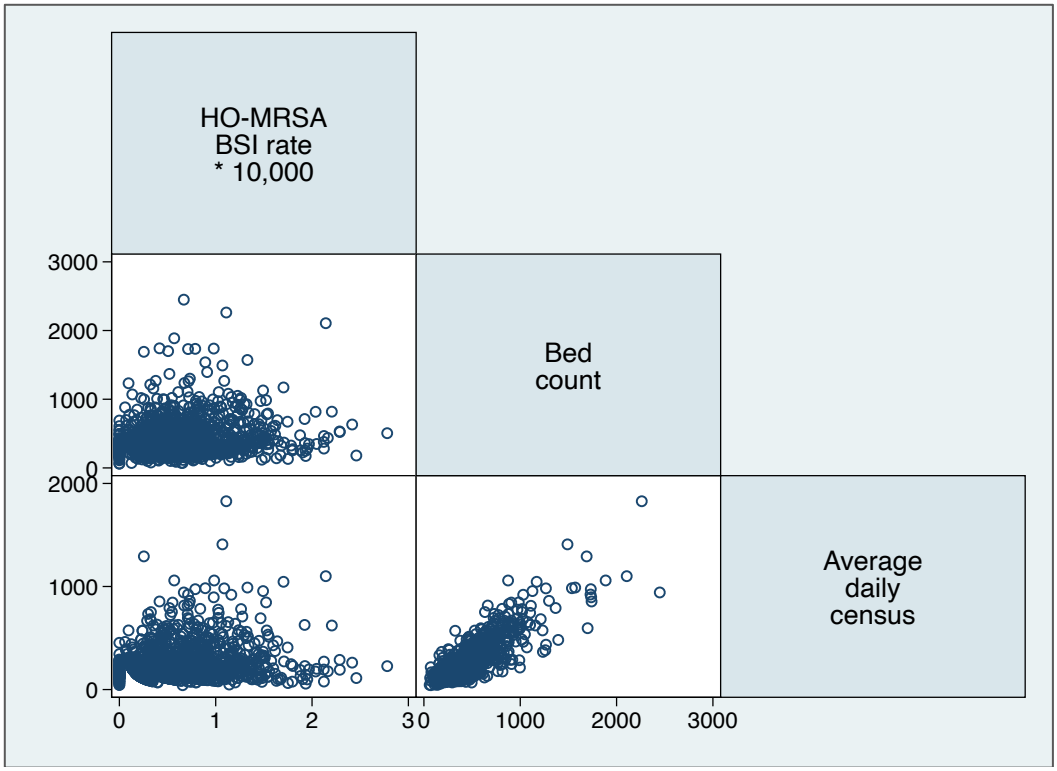

Figure 7. Scatter plots of hospital size variables and HO-MRSA BSI incidence rate per 10,000 patient-days per hospital.

Table 6. Correlation (Pearson product correlation coefficient) between hospital size variables and HO-MRSA BSI incidence rate per 10,000 patient-days per hospital

	HO-MRSA BSI incidence rate	**Average daily census**	**Bed count**
HO-MRSA BSI incidence rate	1.0	--	--
Average daily census	0.169	1.0	--
Bed count	0.174	0.844	1.0

Table 7. Hospital characteristics and mean HO-MRSA BSI incidence rate per 10,000 patient-days per hospital (n=1,288)

			HO-MRSA BSI incidence rate	
Hospital characteristic	**n**	**%**	**Mean**	**SD**
Geographic region*				
West	264	20.5	0.50	0.38
Midwest	278	21.6	0.54	0.41
South	268	20.8	0.64	0.46
Northeast	478	37.1	0.71	0.45
Location				
Rural	76	5.9	0.56	0.42
Urban	1,212	94.1	0.62	0.44
Bed count category				
1-199	120	9.3	0.55	0.44
200-299	307	23.8	0.54	0.42
300-399	313	24.3	0.58	0.43
400-499	190	14.8	0.63	0.43
>=500	358	27.8	0.72	0.44
DSH percentage* quartiles				
Quartile 1: 0 - 0.198	322	25.0	0.54	0.43
Quartile 2: 0.199 - 0.2746	322	25.0	0.55	0.40
Quartile 3: 0.2747 - 0.3837	322	25.0	0.63	0.40
Quartile 4: 0.3838 - 1.124	322	25.0	0.74	0.48
DSH percentage* threshold				
Low (<0.15)	186	14.4	0.54	0.45
High (>= 0.15)	1,102	85.6	0.62	0.44
Compliance status: compliance status at the time of certification survey				
In compliance	944	73.3	0.59	0.41
Not in compliance	344	26.7	0.68	0.51
Hospital ownership type (1)				
For profit	199	15.5	0.64	0.48
Nonprofit	731	56.8	0.60	0.43
Government	188	14.6	0.69	0.44
Other	170	13.2	0.55	0.42
Hospital ownership type (2)				
Nonprofit/government	1089	84.6	0.61	0.43
For profit	199	15.5	0.64	0.48
Medicare / Medicaid participation				
Medicare only	41	4.0	0.70	0.46
Medicare & Medicaid	1247	96.8	0.61	0.44
Accreditation^				
No	21	1.6	0.55	0.37
Yes	1267	98.4	0.62	0.44
Medical school affiliation				
None or limited	859	66.7	0.57	0.42
Major or graduate	429	33.3	0.70	0.46

*Denotes a characteristic not from the CMS Provider of Services variable
^Accreditation: The Joint Commission, American Osteopathic Association, Healthcare Facilities Accreditation Program, or Det Norske Veritas
DSH: disproportionate share hospital

Table 8. Summary CMS POS services offered by hospitals and mean HO-MRSA BSI incidence rate per 10,000 patient-days per hospital

			HO-MRSA BSI incidence rate	
Hospital service provided (yes or no)	**n** (n=1,288)	**%**	Mean	SD
Acute renal dialysis	1,206	93.6	0.63	0.44
Anesthesia	1,264	98.1	0.62	0.44
ICU - burn unit	152	11.8	0.81	0.49
ICU - surgical	676	52.5	0.65	0.46
ICU - pediatric	308	23.9	0.68	0.46
ICU - neonatal	589	45.7	0.63	0.44
ICU - cardiac (non-surgical)/CCU	1,117	86.7	0.62	0.43
ICU - medical/surgical	1,265	98.2	0.62	0.44
CARF inpatient rehab	519	40.3	0.62	0.44
Cardiac catheterization lab	836	64.9	0.62	0.44
Emergency dept (dedicated)	1271	98.7	0.62	0.44
Gerontological specialty	1,271	22.0	0.70	0.45
Obstetrics	1,147	89.1	0.61	0.44
Pediatrics	1,064	82.6	0.61	0.44
Operating room	1,274	98.9	0.62	0.44
Postoperative recovery room	1,266	98.3	0.62	0.44
Surgery - inpatient	1,266	98.3	0.62	0.44
Surgery - cardiothoracic	954	74.1	0.63	0.44
Surgery - orthopedic surgery	877	68.1	0.63	0.45
Surgery - ophthalmic	1,147	60.7	0.62	0.45
Surgery - neurosurgical services	770	59.8	0.63	0.45
Surgery - reconstructive	695	54.0	0.63	0.44
Transplant services - any	392	30.4	0.69	0.43
Transplant center (Medicare certified)	175	13.6	0.76	0.42
Organ transplant (not Medicare certified)	301	23.4	0.69	0.44
Trauma Center (designated)	531	41.2	0.65	0.44
Urgent care center	285	22.1	0.62	0.44

CARF: Commission on Accreditation of Rehabilitation Facilities
CCU: cardiac care unit
ICU: intensive care unit

Table 9. Summary of continuous CMS Provider of Services variables for hospitals in the sample, overall (n=1,288)

	Mean	SD	Minimum	Median	Maximum
Hospital size/demographic					
Average daily census*	259.6	172.4	41.7	206.6	1826.9
Patient-days*	94743.1	62927.7	15226.0	75401.5	666825
Bed count	429.5	254.9	60.0	366	2449
Rehab unit bed count	15.5	19.6	0	12	220
Swing bed count (n=11)	1.6	0.5	1	2	2
DSH percentage	0.31	0.18	0	0.27	1.12
Staffing					
Number of times provider changed ownership	1.4	1.4	0	1	8.0
Number of FTE other salaried personnel employed	1158.5	1132.7	0	867	15953.3
Number of FTE certified registered nurse anesthetists employed	8.5	32.7	0	0	772
Number of FTE LPN employed	63.1	677.4	0	25	23700.2
Nurse practitioner count	10.2	40.6	0	1	1075
Physicians count	40.7	127.2	0	4.5	2130.3
Physician assistants count	7.0	35.7	0	0	1117.0
Number of FTE resident physicians employed	55.5	157.6	0	0	1689.4
Registered pharmacists count	22.9	24.19	0	16	247.3
Registered nurses count	679.3	2959.7	0	415	68094.4
Ratio of LPN to RN (n=1,272)	0.3	2.5	0	0.06	61
Percentage of LPN of nurses (LPN/(LPN + RN) (n=1,279)	0.09	0.1	0	0.06	1
Ratio of physicians to bed count	0.08	0.2	0	0.01	2.4
Services provided					
Total ICU services	3.2	1.4	0	3	6
Total surgical services	4.2	2.0	0	5	6

*Indicates variable was not included or derived from the CMS POS file
**Certified bed count: number of beds in Medicare and/or Medicaid certified areas within a facility
***Bed count: total number of beds in a facility, including those in non-participating or non-licensed areas
DSH: disproportionate share hospital
FTE: full-time equivalent
ICU: intensive care unit
LPN: licensed practical nurse or licensed practical vocational nurse
RN: registered nurse

Table 10. Summary of univariate regression results for hospital demographic variables: HO-MRSA BSI incidence rate per 10,000 patient-days regressed on hospital characteristic (n=1,288)

Hospital characteristic	n	Mean MRSA incidence rate	Coef.	95% CI Lower	95% CI Upper	p
Geographic region (US Census)						
West (reference)	264	0.50				< 0.001
Midwest	278	0.54	0.04	-0.03	0.12	0.246
South	268	0.64	0.14	0.07	0.22	< 0.001
Northeast	478	0.71	0.21	0.15	0.28	< 0.001
Location						
Rural (reference)	76	0.56				
Urban	1,212	0.62	0.06	-0.04	0.16	0.258
Bed size category						
1-199 (refence)	120	0.55				< 0.001
200-299	307	0.54	-0.005	-0.10	0.09	0.917
300-399	313	0.58	0.034	-0.06	0.13	0.459
400-499	190	0.63	0.082	-0.02	0.18	0.106
>=500	358	0.72	0.178	0.09	0.27	< 0.001
DSH percentage quartiles						
Quartile 1: 0-0.19845 (reference)	322	0.54				< 0.001
Quartile 2: 0.19881999-0.2746	322	0.55	0.010	-0.057	0.077	0.775
Quartile 3: 0.27472001-0.3837	322	0.63	0.085	0.019	0.15	0.012
Quartile 4: 0.3839-1.12379	322	0.74	0.20	0.14	0.27	< 0.001
DSH percentage cut-off						
Low (<0.15) (reference)	186	0.54				
High (>= 0.15)	1,102	0.63	0.09	0.024	0.16	0.008
Compliance status						
In compliance (reference)	944	0.59				
Not in compliance	344	0.68	0.09	0.03	0.14	0.001
Hospital ownership type						
Nonprofit/government (reference)	1089	0.61				
For profit	199	0.64	0.02	-0.04	0.09	0.480
Medicare / Medicaid Participation						
Medicare only (reference)	41	0.70				
Medicare & Medicaid	1247	0.61	-0.07	-0.22	0.05	0.210
Accreditation^						
No (reference)	21	0.55				
Yes	1267	0.62	0.07	-0.12	0.26	0.495
Medical school affiliation						
None or limited (reference)	859	0.57				
Major or graduate	429	0.70	0.13	0.08	0.18	< 0.001

*Denotes a characteristic not from the CMS Provider of Services variable
^Accreditation: The Joint Commission, American Osteopathic Association, Healthcare Facilities Accreditation Program, or Det Norske Veritas
DSH: disproportionate share hospital

Table 11. Summary of univariate regression results for hospital services and staffing variables: HO-MRSA BSI incidence rate per 10,000 patient-days regressed on hospital characteristic (n=1,288)

Hospital service	%	Mean MRSA incidence rate	Coef.	95% CI Lower	95% CI Upper	p
Acute renal dialysis						
No (reference)	6.4	0.46				
Yes	93.6	0.63	0.168	0.07	0.27	0.001
Anesthesia						
No (reference)	1.9	0.49				
Yes	98.1	0.62	0.126	-0.05	0.30	0.162
Cardiac catheterization lab						
No (reference)	35.1	0.60				
Yes	64.9	0.62	0.025	-0.03	0.08	0.327
CARF inpatient rehab						
No (reference)	59.7	0.61				
Yes	40.3	0.62	0.002	-0.05	0.05	0.923
Emergency department (dedicated)						
No (reference)	1.3	0.49				
Yes	98.7	0.62	0.130	-0.08	0.34	0.226
Gerontological specialty						
No (reference)	78.0	0.59				
Yes	22.0	0.70	0.106	0.05	0.16	< 0.001
ICU - burn						
No (reference)	88.2	0.59				
Yes	11.8	0.81	0.215	0.14	0.29	< 0.001
ICU - cardiac (nonsurgical)/CCU						
No (reference)	13.3	0.57				
Yes	86.7	0.62	0.051	-0.02	0.12	0.160
ICU - medical/surgical						
No (reference)	1.8	0.57				
Yes	98.2	0.62	0.048	-0.13	0.23	0.601
ICU - neonatal						
No (reference)	54.3	0.60				
Yes	45.7	0.63	0.024	-0.02	0.07	0.335
ICU - pediatric						
No (reference)	76.1	0.60				
Yes	23.9	0.68	0.081	0.02	0.14	0.005
ICU - surgical						
No (reference)	47.5	0.58				
Yes	52.5	0.65	0.071	0.02	0.12	0.004
Nuclear medicine						
No (reference)	0.9	0.59				
Yes	99.2	0.62	0.026	-0.24	0.29	0.846

Obstetrics						
No (reference)	11.0	0.67				
Yes	89.1	0.61	-0.064	-0.14	0.01	0.102
Operating room						
No (reference)	1.1	0.29				
Yes	98.9	0.62	0.327	0.10	0.56	0.006
Pediatrics						
No (reference)	17.4	0.65				
Yes	82.6	0.61	-0.047	-0.11	0.02	0.147
Pediatrics - any service						
No (reference)	7.1	0.65				
Yes	92.9	0.61	-0.042	-0.14	0.05	0.383
Pharmacy						
No (reference)	0.5	0.33				
Yes	99.5	0.62	0.292	-0.03	0.62	0.080
Postoperative recovery room						
No (reference)	1.7	0.41				
Yes	98.3	0.62	0.206	0.02	0.39	0.029
Surgery - cardiothoracic						
No (reference)	25.9	0.57				
Yes	74.1	0.63	0.067	0.01	0.12	0.016
Surgery - inpatient						
No (reference)	1.7	0.45				
Yes	98.3	0.62	0.174	-0.01	0.36	0.066
Surgery - neurosurgical						
No (reference)	40.2	0.59				
Yes	59.8	0.63	0.046	0.00	0.10	0.063
Surgery - ophthalmic						
No (reference)	39.3	0.60				
Yes	60.7	0.62	0.021	-0.03	0.07	0.405
Surgery - orthopedic						
No (reference)	31.9	0.59				
Yes	68.1	0.63	0.038	-0.01	0.09	0.146
Surgery - reconstructive						
No (reference)	46.0	0.60				
Yes	54.0	0.63	0.025	-0.02	0.07	0.309
Organ transplant (not Medicare certified)						
No (reference)	76.6	0.59				
Yes	23.4	0.69	0.091	0.03	0.15	0.002
Transplant center (Medicare certified)						
No (reference)	86.4	0.59				
Yes	13.6	0.76	0.162	0.09	0.23	< 0.001

Transplant services - any type						
No (reference)	69.6	0.58				
Yes	30.4	0.69	0.112	0.06	0.16	< 0.001
Trauma center (designated)						
No (reference)	58.8	0.59				
Yes	41.2	0.65	0.054	0.006	0.10	0.029
Urgent care center						
No (reference)	77.9	0.61				
Yes	22.1	0.62	0.008	-0.05	0.07	0.794

^ Accreditation organizations: Joint Commission, American Osteopathic Association, Det Norske Veritas
CARF: Commission on Accreditation of Rehabilitation Facilities
CCU: cardiac care unit
ICU: intensive care unit

Table 12. Summary of univariate regression results for continuous hospital services and staffing variables: HO-MRSA BSI incidence rate per 10,000 patient-days regressed on hospital characteristic (n=1,288)

Hospital characteristic	Mean	Coef.	95% CI Lower	95% CI Upper	p
Average daily census	259.6	0.00043	0.00029	0.00057	< 0.001
Patient-days	94743.1	1.2E-06	8.0E-07	1.6E-06	< 0.001
Bed count	429.5	0.00030	0.0002	0.0004	< 0.001
Rehab unit bed count	15.5	0.0010	-0.0002	0.0022	0.108
DSH percentage	0.31	0.38	0.24	0.51	< 0.001
Number of times provider changed ownership	1.4	0.013	-0.004	0.031	0.139
Number of FTE other salaried personnel employed	8.5	0.00004	0.00002	0.00007	< 0.001
Number of FTE certified registered nurse anesthetists employed	8.5	0.0011	0.0003	0.002	0.004
Number of FTE LPN employed	63.1	0.00001	-0.00002	0.00005	0.519
Nurse practitioners	10.2	0.00044	-0.0002	0.0010	0.144
Physicians	40.7	0.00036	0.0002	0.0005	< 0.001
Physician assistants	7.0	0.00020	-0.0005	0.0009	0.559
Number of FTE resident physicians employed	55.5	0.00050	0.0003	0.0006	< 0.001
Registered pharmacists	22.9	0.0022	0.0013	0.0032	< 0.001
Registered nurses	679.3	6.2E-06	-1.9E-06	0.00001	0.140
Ratio of LPN to RN (n=1,272)	0.3	0.0081	-0.001	0.018	0.097
Percentage of LPN of total nurses (LPN/(LPN + RN) (n=1,279)	0.09	0.094	-0.09	0.28	0.310
Ratio of physicians to bed count	0.08	0.14	0.02	0.27	0.028
Total ICU services	3.2	0.035	0.018	0.052	< 0.001
Total surgical services	4.1	0.012	-8.6E-05	0.024	0.052

DSH: disproportionate share hospital
FTE: full-time equivalent
ICU: intensive care unit
LPN: includes licensed practical nurses and licensed practical vocational nurses

Table 13. Variables included in the multivariate linear regression model, including the description, rationale, and data source

Variable	Description	Rationale	Data source
Hospital size variables			
Average daily census	• Average daily census for each hospital, calculated: patient-days/365 • Type: Continuous	Conceptually, larger hospitals provide more complex care to more patients; NHSN data based on voluntary reporting demonstrated higher HO-MRSA BSI incidence in larger hospitals	Derived using patient-days from CMS HAI data, 2013
Bed count	• Total number of beds in a facility, including those in non-participating or non-licensed areas • Type: Continuous		CMS POS file, 2013
Demographic variables			
Geographic region	• Region defined by the US Census • Type categorical (west, midwest, south, northeast)	Published data described MRSA rates varying by region of the country [Kallen et al, 2010; Kuehnert et al, 2005; Elixhauser & Steiner, 2007; CDC 2014 National and State Healthcare-Associated Infections Progress Report, 2016].	U.S. Census
Medical school affiliation	• Defined by CMS: none, limited, teaching, graduate • Type: categorical – none/limited or teaching/graduate	Included given that hospitals with medical school affiliation were staffed with specialized training and resources to provide care to more medically complex patients and offer specialized services.	CMS POS file, 2013
Compliance status	• Compliance status at the time of certification survey • Type: categorical – in compliance or not in compliance	Hypothesized to be an important indicator of recent hospital situation.	CMS POS file, 2013
Hospital ownership	• CMS-defined ownership categories: church, private (not for profit), other, private (not for profit), federal, state, local, hospital district/authority, physician ownership, tribal • Type: categorical – for profit or not for profit	Hospital ownership type was categorized by for profit and not for profit, given that organizational goals and/or leadership styles could impact infection prevention approaches for the hospital.	CMS POS file, 2013
Disproportionate share hospital (DSH) percentage	• DSH percentage: equal to the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income, and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A • Type: quartiles	Previous literature reported that low-income populations have greater unmet healthcare needs [Ayanian, Weissman, Schneider, et al, 2000], which could lead to increased susceptibility to MRSA infection.	CMS Inpatient File, 2013

Hospital staffing variables			
Physicians	• Number of physicians • Type: continuous	Healthcare personnel play key roles in applying infection prevention and control practices. While physician staffing has not been associated with healthcare-associated infection levels, physician staffing has been related to related to decreased length of stay, and complications, particularly in the ICU. [Stone et al, 2008; Dimick, Pronovost, et al, 2001].	CMS Inpatient File, 2013
Physician residents	• Number of FTE resident physicians employed by the hospital • Type: continuous	Healthcare personnel play key roles in applying infection prevention and control practices. Physician residents would be more likely than physicians to perform bedside tasks and procedures, and therefore their role would necessitate adhering to infection prevention and control practices.	CMS Inpatient File, 2013
Certified nurse practitioners	• Number of certified nurse practitioners (CNPs) • Type: continuous	Healthcare personnel play key roles in applying infection prevention and control practices. CNPs may be utilized for management or critical care units.	CMS Inpatient File, 2013
Registered nurses	• Number of registered nurses • Type: continuous	Healthcare personnel play key roles in applying infection prevention and control practices. Nurses comprise the largest workforce in hospitals and provide the most direct and continuous role in performing the cares and procedures/interventions which impact the risk of infection [Stone et al, 2008].	CMS Inpatient File, 2013
Licensed practical nurses	• Number of FTE LPN and LPVN employed by the hospital • Type: continuous	Healthcare personnel play key roles in applying infection prevention and control practices. The amount and role of LPNs may be increased during nursing shortages. It is unclear how patient outcomes may be impacted with less skilled, relatively, workforce.	CMS Inpatient File, 2013
Other personnel	• Number of FTE other salaried personnel employed by the hospital • Type: continuous	Other salaried personnel would include infection preventionists, administrators, managers, and others that work to support the hospital functions.	CMS Inpatient File, 2013
Ratio of physicians to bed count	• Calculated ratio of physicians to beds for the hospitals • Type: continuous	Included as an additional measure to explore staffing in relation to the hospital size.	Derived from CMS Inpatient File, 2013
Hospital services variables			
Acute renal dialysis	• Acute renal dialysis service • Type: categorical – yes or no	Infection prevention and control measures were critical to prevent infection when providing acute renal dialysis which included manipulation of invasive devices.	CMS POS file, 2013

Surgical services	• Surgical services: cardiothoracic, neurosurgical, ophthalmic, orthopedic, reconstructive • Inpatient surgical service was not included since most hospitals provided • Type: categorical – yes or no	Infection prevention and control measures were critical to prevent infection at every stage of the surgical process (pre-, peri-, and post-operative) and therefore considered related to MRSA infection prevention in hospitals.	CMS POS file, 2013
ICU services	• CMS-defined ICU services: burn unit, surgical, pediatric, neonatal, coronary care • Type: categorical – yes or no	Infection prevention and control measures were critical to prevent infection given the level of care required for ICU patients – for example, device insertion and manipulation.	CMS POS file, 2013
Transplant services	• Combined CMS variables for transplant to indicate any transplant service provided by the hospital • Type: categorical – yes or no	Infection prevention and control measures were critical to prevent infection given the level of care required for transplant patients, which have suppressed immune systems and prolonged healthcare exposure.	CMS POS file, 2013
Commission on Accreditation of Rehabilitation Facilities (CARF) inpatient rehab	• Inpatient rehab accreditation • Type: categorical – yes or no	Hypothesized that this service could indicate a hospital with medically complex patients with prolonged hospitals stays.	CMS POS file, 2013
Gerontological specialty	• CMS-defined service • Type: categorical – yes or no	Hypothesized that this service could indicate a hospital with patients more advanced age and potentially those in congregate living situations, which could indicate increased medical complexity, and/or increased exposure to infectious organisms, including MRSA.	CMS POS file, 2013
Trauma center	• CMS-defined • Type: categorical – yes or no	Infection prevention and control measures were critical to prevent infection given the level of care required for trauma patients	CMS POS file, 2013
Urgent care centers	• CMS-defined – similar level of care as clinics • Type: categorical (yes or no)	Hypothesized that care for patients with nonlife-threatening emergencies would be lower compared to inpatient cares but still required infection prevention precautions, and potentially a high volume of patients (increased opportunities for transmission).	CMS POS file, 2013

Table 14. Model fit results from multivariate linear regression with outcome HO-MRSA BSI per 10,000 patient-days per hospital.

Model	Variables	n	Model df	R^2	F	p	Mean VIF
1	Size variables	1288	2	0.032	21.23	<0.001	3.47
2	Size variables + demographic variables + staffing variables + services variables	1288	34	0.14	6.06	<0.001	2.24
3	Size variables + demographic variables + staffing variables + services variables • Stepwise regression	1288	14	0.13	14.01	<0.001	1.43

df: degrees of freedom
VIF: variance inflation factor

Table 15. Multivariate linear regression model (model 2) with outcome of HO-MRSA BSI incidence rate per 10,000 patient-days per hospital.

	Coef.	95% CI lower	95% CI upper	p
Intercept	0.25	0.12	0.37	<0.001
Average daily census	0.000018	-0.00027	0.00031	0.902
Bed count	0.00011	-0.000066	0.00029	0.220
Geographic region West (reference)				
Midwest	0.028	-0.046	0.10	0.462
South	0.15	0.071	0.22	<0.001
Northeast	0.23	0.17	0.30	<0.001
DSH percentage Quartile 1 (reference)				
Quartile 2	-0.0011	-0.066	0.064	0.973
Quartile 3	0.057	-0.010	0.12	0.095
Quartile 4	0.14	0.073	0.21	<0.001
Compliance status: not in compliance	0.12	0.059	0.17	<0.001
Medical school affiliation: major/graduate	0.054	-0.0026	0.11	0.061
Ownership: for profit	0.0067	-0.060	0.073	0.844
Number FTE other salaried personnel employed	-3.2E-05	-0.000067	3.7E-06	0.079
Number FTE LPN employed	7.2E-07	-0.000033	0.000034	0.966
Nurse practitioner count	-0.00040	-0.0010	0.00021	0.202
Physician count	0.00021	-0.00021	0.00063	0.334
Number FTE resident physicians employed	0.00025	0.000040	0.00046	0.020
Registered nurses count	3.3E-06	-0.000004	0.000011	0.404
Ratio of physicians to bed count	-0.062	-0.32	0.19	0.633
Acute renal dialysis	0.13	0.028	0.22	0.012
CARF inpatient rehab	-0.052	-0.11	0.0039	0.068
Gerontological specialty	0.045	-0.020	0.11	0.172
ICU - burn unit	0.14	0.061	0.22	<0.001
ICU - surgical	0.034	-0.039	0.11	0.357
ICU - pediatric	-0.016	-0.085	0.054	0.655
ICU - neonatal	-0.057	-0.12	0.0084	0.087
ICU - cardiac	-0.016	-0.091	0.059	0.677
Surgery - cardiothoracic	0.036	-0.025	0.098	0.249
Surgery - orthopedic	0.024	-0.095	0.14	0.695
Surgery - ophthalmic	-0.034	-0.12	0.050	0.427
Surgery - neurosurgical	0.028	-0.058	0.11	0.521
Surgery - reconstructive	-0.021	-0.093	0.052	0.580
Transplant - any	0.021	-0.034	0.076	0.453
Trauma center	-0.023	-0.076	0.031	0.412
Urgent care center	-0.026	-0.087	0.036	0.412

CARF: Commission on Accreditation of Rehabilitation Facilities
DSH: disproportionate share hospital
FTE: full-time equivalent
ICU: intensive care unit

Table 16. Multivariate model (model 3) using stepwise linear regression with outcome of HO-MRSA BSI incidence rate per 10,000 patient-days per hospital

	Coef.	95% CI lower	95% CI upper	p
Intercept	0.26	0.16	0.36	<0.001
Bed count	0.00014	0.000012	0.00027	0.033
Geographic region West (reference)				
Midwest				0.973
South	0.13	0.063	0.19	<0.001
Northeast	0.22	0.17	0.28	<0.001
DSH percentage Quartile 1 (reference)				
Quartile 2				0.465
Quartile 3	0.052	-0.0046	0.11	0.072
Quartile 4	0.13	0.075	0.19	<0.001
Compliance status: not in compliance	0.12	0.068	0.18	<0.001
Medical school affiliation: major/graduate	0.054	-0.00022	0.11	0.051
Number FTE other salaried personnel employed	-0.000029	-0.000060	2.6E-06	0.072
Number FTE resident physicians employed	0.00027	0.000078	0.00047	0.006
Acute renal dialysis	0.13	0.038	0.23	0.006
ICU - burn unit	0.13	0.057	0.21	0.001
ICU - neonatal	-0.055	-0.11	-0.0023	0.041
CARF inpatient rehab	-0.047	-0.099	0.0047	0.075
Gerontological specialty	0.044	-0.017	0.10	0.161

CARF: Commission on Accreditation of Rehabilitation Facilities
DSH: disproportionate share hospital
FTE: full-time equivalent
ICU: intensive care unit

Table 17. Comparison of regression results from model 1, model 2, and model 3

	Model 1		Model 2		Model 3	
	Coef	**p**	**Coef**	**p**	**Coef**	**p**
Intercept	0.48	<0.001	0.25	< 0.001	0.26	< 0.001
Hospital size						
Average daily census	0.00019	0.144	0.000018	0.902	dropped	0.900
Bed count	0.00019	0.030	0.00011	0.220	0.00014	0.033
Demographic						
Geographic region						
West (reference)						
Midwest			0.028	0.462	dropped	0.973
South			0.15	< 0.001	0.13	< 0.001
Northeast			0.23	< 0.001	0.22	< 0.001
DSH percentage						
Quartile 1 (reference)						
Quartile 2			-0.0011	0.973	dropped	0.465
Quartile 3			0.057	0.095	0.052	0.072
Quartile 4			0.14	< 0.001	0.13	< 0.001
Compliance status: not in compliance			0.12	< 0.001	0.12	< 0.001
Medical school affiliation: major/graduate			0.054	0.061	0.054	0.051
Ownership: for profit			0.0067	0.844	dropped	0.842
Staffing						
Number other salaried personnel			-3.2E-05	0.079	-0.000029	0.072
Number LPN employed			7.2E-07	0.966	dropped	0.966
Nurse practitioner count			-0.0004	0.202	dropped	0.203
Physician count			0.00021	0.334	dropped	0.257
Number resident physicians			0.00025	0.020	0.00027	0.006
Registered nurses count			3.3E-06	0.404	dropped	0.384
Ratio of physicians to bed count			-0.062	0.633	dropped	0.611
Services Provided						
Acute renal dialysis	--		0.13	0.012	0.13	0.006
ICU - burn unit	--		0.14	< 0.001	0.13	0.001
ICU - surgical	--		0.034	0.357	dropped	0.328
ICU - pediatric	--		-0.016	0.655	dropped	0.639
ICU - neonatal	--		-0.057	0.087	-0.055	0.041
ICU - cardiac	--		-0.016	0.677	dropped	0.589
CARF inpatient rehab	--		-0.052	0.068	-0.047	0.075
Gerontological specialty	--		0.045	0.172	0.044	0.161
Surgery - cardiothoracic	--		0.036	0.249	dropped	0.218
Surgery - orthopedic	--		0.024	0.695	dropped	0.696
Surgery - ophthalmic	--		-0.034	0.427	dropped	0.557

Surgery - neurosurgical	--		0.028	0.521	dropped	0.440
Surgery - reconstructive	--		-0.021	0.580	dropped	0.596
Transplant - any	--		0.021	0.453	dropped	0.473
Trauma center	--		-0.023	0.412	dropped	0.391
Urgent care center	--		-0.026	0.412	dropped	0.299

CARF: Commission on Accreditation of Rehabilitation Facilities
DSH: disproportionate share hospital
FTE: full-time equivalent
LPN: includes licensed practical nurses and licensed practical vocational nurses
ICU: intensive care unit

5.4 Aim 2 - Aim 4. Results

5.4.1 Sample of participating hospitals

Five metropolitan hospitals in Minnesota participated in the study, all located in the seven-county metropolitan area that comprises the Minneapolis-St. Paul area. Three hospitals were located in urban areas and two were located in suburban areas. The hospitals were of medium and large sized, with a mean average daily census of 288 (range, 126-444) for calendar year 2013 (Table 18).

Four types of hospital policies were evaluated from five metropolitan hospitals in Minnesota: hand hygiene, multidrug-resistant organism (MDRO)/isolation, healthcare personnel influenza vaccination, and whistleblower (corporate compliance). Policies were collected for years 2013-2014.

To systematically evaluate the policies, a tool was developed for each topic that included 23 elements (purpose, expectations, education/training, monitoring, enforcement, responsibilities, corrective actions) guided by regulatory and clinical practice guidelines (Appendix B). Each policy element was evaluated for its presence (yes/no) and thoroughness (nonexistent=0, cursory=1, thorough=2). The scoring for thoroughness of the policy element was based on frequencies of the component items. When components included guiding or example content, or if the available content was minimal, the element was scored as “cursory” (thoroughness=1). When all or most of the components included guiding or example content, or if the available content was comprehensive, the policy element was scored as “thorough” (thoroughness=2). For example, the

purpose element of the policy included a definition for “purpose” along with 3 components: purpose was specified, rationale was specified, and desired effects of the policy were specified.

The environmental cleaning/disinfection policies were not evaluated because the participation and suite of policies from the hospitals varied substantially. One hospital was unable to provide the policy because it was owned by the company that was contracted for the EVS management (the EVS workers were hospital employees). One hospital provided the infection control-owned environmental cleaning/disinfection policy, which read as a directive for the EVS department to be in compliance with infection control policies. One hospital provided the infection control-owned terminal cleaning/disinfection (cleaning/disinfection process following patient discharge) policy. One hospital provided two infection control-owned policies: cleaning/disinfection processes for patient care equipment (e.g., endoscopes, blood glucose monitors, etc), and cleaning/disinfection processes for patient rooms (daily and at discharge). Finally, one hospital provided the infection control-owned general (non-isolation) infection control policy. A take-away regarding this policy topic was that a variety of environmental cleaning/disinfection policies exist within a hospital with different owners and purposes. Ultimately, it was decided that the environmental cleaning/disinfection policies were too variable to systematically evaluate.

5.4.2 Summary of aggregated policies

Of the hospitals in the study, 100% of hospitals had hand hygiene and MDRO/isolation policies; 60% (3/5) had influenza vaccination policies (2/5 had seasonal initiatives), and 60% (3/5) had whistleblower policies. Policies varied in comprehensiveness and thoroughness across hospitals and topics (Table 19).

The policy with the highest mean number of policy elements was hand hygiene (mean: 12.60, range: 11-17) followed by the whistleblower (mean: 9.20, range: 0-18), then MDRO (mean: 8.60, range: 7-10) and influenza (mean: 8.60, range: 0-18) (Table 20). The policy with the highest mean score of policy elements was MDRO/isolation (mean: 1.35, range: 1.11-1.63), followed by

hand hygiene (mean: 1.31, range: 1.08-1.50), then influenza (mean: 0.61, range: 0-1.47), and whistleblower (mean: 0.50, range: 0-0.93) (Table 21).

Most policies included purpose and policy statements with a statement of organizational rules (87.5% [14/16] and 100% [16/16], respectively) with cursory mean scores (1.04 and 1.20, respectively). Most policies lacked consequences for noncompliance (37.5%), accountability (37.5%), monitoring and enforcement of policy expectations (31.3%); when stated, the policy components scored as cursory. Fifty percent (8/16; range: 20% for hand hygiene, 100% for influenza vaccination) of policies specified expectations for educating staff about the policy topic with a mean score of 0.75. Responsibilities for policy expectations were lacking (23.1% for product needs/availability; 6.3% for training/education, 25.0% monitoring compliance with skills/techniques). Of the four policy types, influenza vaccination was the most complete (all policies with >= 50% of categories completed vs hand hygiene: 26%, MDRO: 17.4%, whistleblower: 26.3%). The hand hygiene policies scored highest with 47.8% of policy elements scored >1.0 (vs MDRO: 21.7%, influenza: 25%, whistleblower: 10.5%)

Table 18. Summary of characteristics of participating hospitals (n=5)

Characteristic	
Hospital size	**Mean (range) per hospital**
Bed count*	417 (range, 178-604)
Average daily census*	288 (range, 126-444)
Metropolitan status	**n (%)**
Urban	3 (60%)
Suburban	2 (40%)
Medical school affiliation	**n (%)**
Limited or none	2 (40%)
Teaching or graduate	3 (60%)
Hospital-onset (HO) MRSA BSI^	**Mean per hospital**
Number of HO-MRSA BSI	4.8 (range, 0-11)
HO-MRSA BSI incidence rate^	3.8/100,000 patient-days

* Data source: 2013 CMS POS file
^Data source: Derived from CMS HAI 2013 data

Table 19. Summary of policy elements: presence and completeness

Policy element	Element present n (n=16)	Element present %	Element mean score
Informational			
Purpose – provided rationale describing why the subject matter merited formal rules	14	87.5%	1.04
Policy statement – provided staff with a clear understanding of requirements, regulations (if applicable), and what constituted appropriate behavior, including expectations and performance objectives	16	100.0%	1.20
Scope/audience – policy outlined the intended audience for this policy	11	68.8%	1.45
Definitions – key concepts and terms were defined	9	56.3%	1.56
References – scientific rationale/evidence were provided to support policy	15	93.8%	1.50
Structural expectations			
Expectations were specified for educating healthcare personnel about the policy topic	8	50.0%	0.75
Expectations for hospital-level strategies within the facility	15	93.8%	1.67
Expectations for behaviors/actions/ practices that that were required to comply with the policy are specified	12	75.0%	1.21
Instructional – intended for compliance with skills/techniques included in policy			
The appropriate methods to comply with skills/techniques included in the policy were outlined	11	68.8%	1.27
The policy outlines expectations for monitoring and enforcing practices/skills/techniques required by the policy (Influenza, Whistleblower policies excluded) (n=10)	2	20.0%	0.75
Responsibilities for carrying out policy elements			
Responsibilities for product types, locations, availability (Whistleblower policy excluded) (n=13)	3	23.1%	1.17
Responsibilities for training and education	1	6.3%	0.50
Responsibilities for additional policy elements (Whistleblower policy excluded) (n=13)	10	76.9%	0.90
Responsibilities for monitoring compliance with skills/techniques included in policy	4	25.0%	0.88
Governance			
A governance structure was in place to enforce the policy, which may be a component of a broader organization program	6	37.5%	0.67
The governance structure/administration along with the respective workgroup/committee/task force evaluated data to identify strengths, weaknesses, and develop plans for improvement.	5	31.3%	0.70
Accountability and enforcement			
Performance considered compliance with the policy	1	6.3%	0.50
Corrective actions/consequences were specified for non-compliance with the policy	6	37.5%	0.75
Expectations for managers to enforce compliance with the policy were specified	7	43.8%	0.79
Expectations for staff to enforce compliance with the policy were specified (Influenza policy excluded) (n=13)	6	46.2%	0.80

Instructional protocols and procedures			
Protocol/procedure developed with instructions for how to comply with skills/techniques specified in policy	11	68.8%	1.23
Protocol/procedure developed with instructions for how to measure compliance with skills/techniques specified in policy	5	31.3%	0.90
Protocol/procedure developed with instructions for how to comply with specific requirements of the policy (Influenza, Whistleblower policies excluded) (n=10)	6	60.0%	1.83

Scoring: Non-existent=0; Cursory=1; Thorough=2

The policies were reviewed to identify commonalities and variations in themes within each policy.

Informational policy elements – intended to inform the what the policy was about, why it was important, to whom it applied, and supporting documentation:

- Purpose and policy statements: while most policies included purpose and policy statements with a statement of organizational rules (87.5% [14/16] and 100% [16/16], respectively), they scored as cursory (1.04 and 1.20, respectively)
- Scope: 68.8% (11/16) of policies included the scope/intended audience for the policy with a mean score of 1.45
- Definitions: 56.3% (9/16) of policies included key concepts and terms with definitions with a mean score of 1.56
- References: 93.8% (15/16) of policies included scientific rationale/evidence were provided to support policy with a mean score of 1.50

Structural expectations policy elements – intended to be developed at the hospital level to maintain and carry out the policy:

- Educating healthcare personnel: 50.0% (8/16) specified expectations for educating healthcare personnel about the policy topic with a mean score of 0.75 (range: 20% for hand hygiene, 100% for influenza vaccination)
- Hospital-level strategies within the facility: 93.8% (15/16) of policies specified expectations for hospital-level strategies with a mean score of 1.67.

- Behaviors/actions/practices: 75.0% (12/16) of policies specified expectations for behaviors/actions/practices that were required to comply with a mean score of 1.21

Instructional policy elements pertaining to the appropriate methods – intended for compliance with the skills/techniques outlined by the policy (such as when to use what method)

- Appropriate methods to use to comply with the skills/techniques outlined by the policy (excluded Influenza, Whistleblower) (e.g., hand hygiene: when to use soap and water vs alcohol-based hand rubs; MDRO: type of transmission-based precautions to be used in a given situation): 68.8% (11/16) of policies outlined appropriate methods to comply with skills/techniques included in the policy with a mean score of 1.27
- Expectations for monitoring and enforcing practices/skills/techniques required by the policy: 20.0% (2/10) of polices outlined expectations for monitoring and enforcing practices/skills/techniques required by the policy. [excludes Influenza, Whistleblower policy] with a mean score of 0.75

Policy elements about outlining **responsibilities** for carrying out components of the policy:

- Responsibilities for selection, placement/management, availability of products/supplies [excluded Whistleblower]: 23.1% (3/13) of policies included responsibilities for product types, locations, availability with a mean score of 1.17
- Responsibilities for staff training and education: only one policy included language and it scored as 0.5, nearly non-existent
- Responsibilities for monitoring compliance with skills/techniques included in policy: 25.0% (4/16) included responsibilities for monitoring compliance with skills/techniques included in policy with a mean score of 0.88
- Responsibilities for additional policy elements (excluded Whistleblower) (e.g., hand hygiene: reporting and managing skin health concerns; MDRO: managing patients in isolation; influenza: maintaining records of vaccination obtained on- and off-site): 76.9% (10/16) of policies included responsibilities for additional policy elements with a mean score of 0.90

Governance policy elements – a governance structure in place to enforce and evaluate the policy:

- Policy elements related to governance were only identified in the influenza and whistleblower policies
- Governance structure to enforce the policy: 37.5% (6/16: whistleblower 3/3; influenza 2/3; hand hygiene 1/5) of policies included specification of a governance structure in place to enforce the policy (which may have been a component of a broader organization program) with a mean score of 0.67
- Governance structure to evaluate the policy: 31.3% (5/16; whistleblower 2/3; influenza 3/3) of policies included specification of a governance structure/administration along with the respective workgroup/committee/task force evaluates data to identify strengths, weaknesses, and develop plans for improvement – with a mean score of 0.70

Accountability and enforcement policy elements

- Staff performance considered compliance with the policy: 6.3% (1/16) of policies included a specification that staff performance considers compliance with the policy – with a mean score of 0.50
- Corrective actions/consequences were specified for policy non-compliance: 37.5% (6/16; hand hygiene 1/5, MDRO 1/5, influenza 2/3, whistleblower 2/3) of policies included corrective actions/consequences were specified for non-compliance with the policy with a mean score of 0.75
- Expectations for managers to enforce compliance with the policy: 43.8% (7/16: hand hygiene 4/5, MDRO 0, influenza 1/3, whistleblower 2/3) of policies included expectations for managers to enforce compliance with the policy with a mean score of 0.79
- Staff enforcement of expectations (excluded influenza): 46.2% (6/13: hand hygiene 3/5, MDRO 1/5, influenza vaccination: n/a, whistleblower 2/3] of policies included expectations for staff to enforce compliance with the policy with a mean score of 0.80

Policy elements for **instructional protocols and procedures** – instructional, specific to step-by-step protocols and procedures in place to appropriately carry out practices/skills/techniques required by the policy:

- Protocol/procedure developed with instructions for how to comply with skills/techniques specified in policy (excluded influenza, whistleblower): 68.8% (11/16) of policies included a protocol/procedure developed with instructions for how to comply with skills/techniques specified in policy with a mean score of 1.23
- Protocol/procedure developed with instructions for how to measure compliance with skills/techniques specified in policy: 31.3% (5/16) of policies included a protocol/procedure developed with instructions for how to measure compliance with skills/techniques (e.g., audits) specified in policy with a mean score of 0.90 (hand hygiene 2/5, MDRO 0/5, influenza 3/3, whistleblower 0/3)
- Protocol/procedure – other (excluded influenza, whistleblower policies): 60.0% (6/10) policies included a protocol/procedure develop developed with instructions for how to comply with specific requirements of the policy with a mean score of 1.83

Technical policies (hand hygiene, MDRO), which included specific skills to carry out policy expectations, provided clear guidance on how to carry out policy expectations; the elements scored as thorough in stating what was needed to be done and how. The MDRO/isolation policies were thorough with respect to how MDRO patients were handled (screening, isolation, etc) – beyond that, minimal information was provided or expected the reader to refer to a different policy (broader infection control policy).

Generally, the MDRO/isolation policy read as though it was put forth as “this is the rule from Infection Prevention and Control, as determined by infection prevention and control, for the use of infection prevention and control.” Given the lack of implementational elements, the utility beyond documenting the rule for infection prevention and control was unclear. The MDRO policies were similarly written; the exception was hospital H04, which was especially

comprehensive (30 versus mean of 5.8 pages) and included thorough protocols/procedures with language that was interpretable beyond the infection prevention and control department.

Compared to the hand hygiene and MDRO policies, the influenza policies read more similar to a plan with implementational elements to carry it out. Additionally, the influenza policies included many stakeholders such as infection prevention and control, employee/occupational health, medical executive committee/medical leadership, education, communications and marketing, pharmacy, and committee to oversee the program. The influenza policies more commonly included responsibilities and accountabilities and enforcement elements. Responsibilities were assigned and included a variety of departments/committees (vs. hand hygiene and MDRO, which mainly assigned roles to infection prevention and control department).

The most complete policy that was reviewed was the influenza vaccination policy. These policies included most of the policy element categories – compliance, education, governance structure, monitoring and measuring compliance, enforcement. The policy/program evaluation included a protocol (a requirement for The Joint Commission). An important consideration was that reporting compliance with healthcare worker influenza vaccination was included in the hospital CMS reimbursement structure.

Overall, the evaluation revealed that many elements were addressed in the policies; however, the information included often lacked details and specifics. For example, the goals and targets for compliance were general; corrective actions were addressed generally but lacked detail; a governance structure was referenced but lacked detail (no purpose, roles, responsibilities, or accountabilities included).

These policies lacked cohesion and connection to the broader infection prevention goals of these hospitals. When the policies were reviewed for each hospital, the narrow focus of the polices was apparent – they read as siloed as opposed to woven into or synergistic with supporting and related policies. Putting forth the rules about PPE usage without hand hygiene or without cleaning/disinfection suggested the staff were operating in a vacuum. These processes must be implemented effectively and cohesively to set up staff for success to execute infection

prevention expectations. The hospitals often had broader "programs" (hand hygiene and whistleblower) – yet there were no references to these broader initiatives in the polices. In fact, through internet searches, the participating hospitals' whistleblower/corporate compliance programs included more robust information on the hospitals' websites than any of the policies submitted for this project.

When the policies were evaluated by hospital, while the whistleblower policy had the highest total number of policy elements for all hospitals, the mean scores for these policies were the lowest among all hospitals (Tables 22-23; Figures 8-9).

Table 20. Number of policy elements by hospital policy

Policy	n	Mean	SD	Min	Max
Hand Hygiene	5	12.60	2.51	11	17
MDRO/Isolation	5	8.60	1.14	7	10
Influenza	5	8.60	8.17	0	18
Whistleblower	5	9.20	8.56	0	18

Table 21. Policy elements scores by hospital policy

Policy	n	Mean	SD	Min	Max
Hand Hygiene	5	1.31	0.21	1.08	1.50
MDRO/Isolation	5	1.35	0.23	1.11	1.63
Influenza	5	0.61	0.63	0	1.47
Whistleblower	5	0.50	0.47	0	0.93

Table 22. Number of policy elements by policy and hospital

Hospital ID	Hand Hygiene Policy (n=23)		MDRO/Isolation Policy (n=23)		Influenza Policy (n=23)		Whistleblower Policy (n=23)	
	n	%	n	%	n	%	n	%
H01	11	48%	8	35%	0	0	14	61%
H02	11	48%	10	43%	13	57%	0	0
H03	12	52%	9	39%	12	52%	14	61%
H04	17	74%	9	39%	0	0	18	78%
H05	12	52%	7	30%	18	78%	0	0
Mean of Total	12.6	--	8.6	--	8.6	--	9.2	--

Table 23. Policy elements mean scores by policy and hospital

Hospital ID	Hand Hygiene Policy (n=23)	MDRO/Isolation Policy (n=23)	Influenza Policy (n=23)	Whistleblower Policy (n=23)
	Mean score	Mean score	Mean score	Mean score
H01	1.44	1.62	0	0.9
H02	1.08	1.11	0.65	0
H03	1.08	1.17	0.92	0.93
H04	1.47	1.56	0	0.65
H05	1.50	1.29	1.47	0
Total	1.31	1.35	0.61	0.50

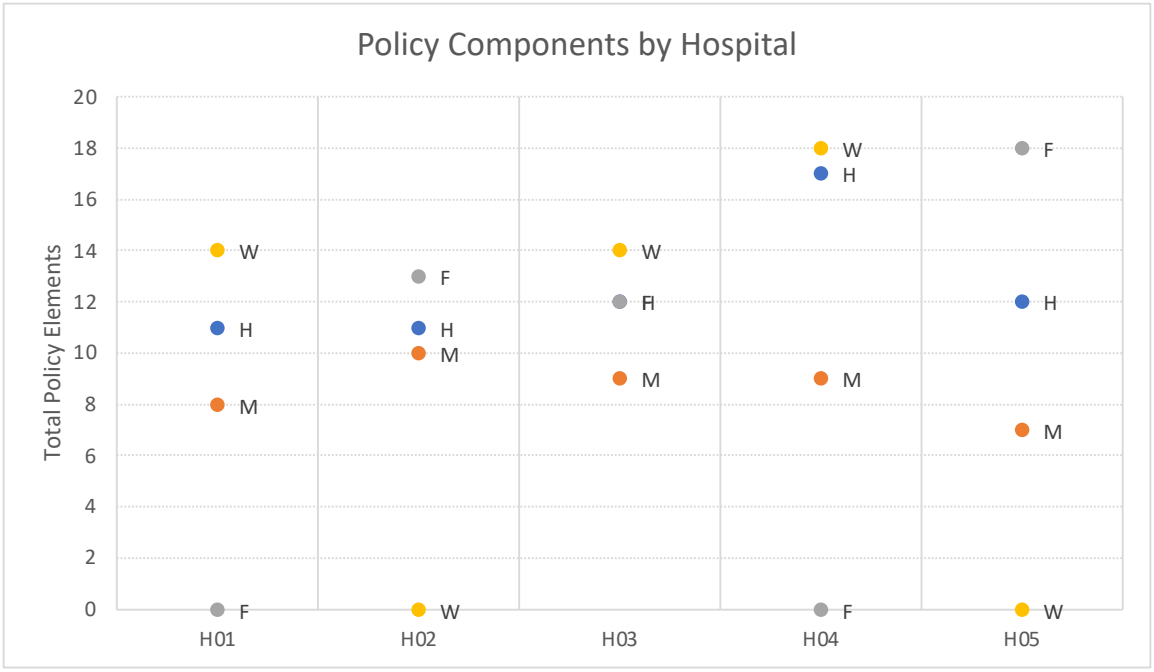

Figure 8. Number of policy elements by policy and hospital. H= hand hygiene policy; M= MDRO/Isolation policy; F= Influenza policy; W= Whistleblower policy

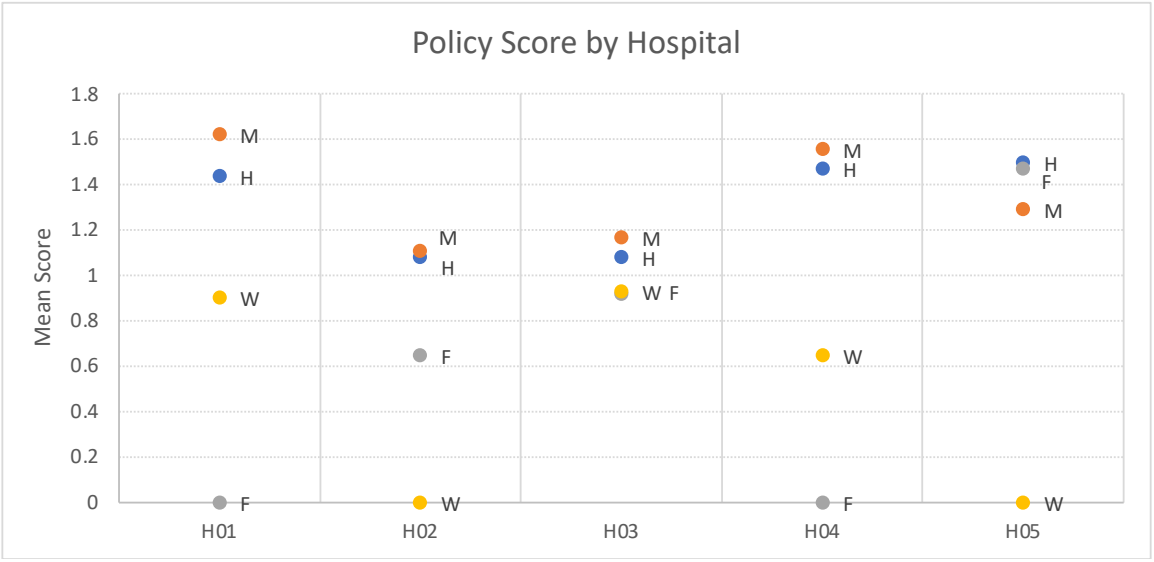

Figure 9. Policy score by policy and hospital. H= hand hygiene policy; M= MDRO/Isolation policy; F= Influenza policy; W= Whistleblower policy

5.4.3 Evaluating hospital policies with qualitative interview data

While some elements were not specifically called out in the policies, through qualitative interviews with staff (Aim 4), it was apparent that some of these elements were in place at the hospitals.

For example, with the hand hygiene policy, only one of the five hospital hand hygiene policies included specifics on “Expectations were specified for educating healthcare personnel about the policy topic” and a “Protocol/procedure developed with instructions on how to comply with specific requirements of the policy”. When staff were asked about the hand hygiene policy, it was clear that staff were provided education using a variety of methods including signage, email/newsletter communication, videos, staff meetings/huddles. The following comments reinforced this across hospitals:

- “Hand hygiene initiatives have been in place since I started here six years ago. Dr. X's face [hospital leader] is on every floor (signage). They also send staff messages in email and newsletters.”
- “At daily huddle meetings, they tell us over and over about hand hygiene.”
- “A video was created with EVS staff and doctors about hand hygiene. There is a global challenge to speak up to a superior. There is a problem with communicating due to title and status - so we had to break that. "Nobody has a title when it comes to hand hygiene."
- “Foam in, foam out.”

With the MDRO/Isolation policy, only one in five hospitals specified expectations for education, and none of the policies included the element: “Protocol/procedure developed with instructions for how to measure compliance with skills/techniques specified in policy.” When staff were asked about the MDRO/isolation policy, it was clear they were provided education (more commonly written versus interactive with return demonstration) and that signage/visual cues were used to outline PPE usage for certain MDRO/isolation protocols/procedures. The following comments reinforced this across hospitals:

- “You are expected to know how to do that [how to don PPE] since you're a nurse. Instructions are given in annual education.”
- “Annual fit testing” [training frequently called out with respect to respirator use and fit since this is an OSHA regulation]
- “We had training with the Ebola outbreak, specialty training, mostly written. Before that, there wasn't anything special. They did annual fit testing - there they showed demonstrations for PAPRs [respirators].”
- “You’re encouraged to remind peers. Signage and isolation carts are important. They have worked hard to make usable signs.”
- “People see the sign on the patient room and do more, or maybe they're more aware or more cautious…Maybe it's because it's [the infection] known - so you follow the procedures a little more closely.”
- “There are signs and carts at the door of the patient room – without them, PPE would not happen.

In contrast to the hand hygiene and MDRO/isolation policies, expectations for influenza vaccination education were specified for all hospitals. Qualitative interviews with staff reflected this theme, as well:

- “They let us know when it’s flu season. They provide us with free shots around the clock. It’s all over the internet at work. Mail. They broadcast it all over.”
- “An email is sent hospital wide from the CEO. Make it really easy to get it. It's publicized in emails.”
- “Visual indicator if you get the flu shot.”
- “More attention to this. We get blast emails for months - flu clinics, percent complete, must decline using the online consent form.”

For the influenza vaccination policy, only one hospital included expectations for managers to enforce compliance and none of the hospitals included staff performance

expectations; yet enforcement and compliance were themes that clearly emerged through staff interviews:

- “It's [influenza vaccination] mandatory for all hospital employees.”
- “Staff vaccination compliance data shared with supervisors/managerial staff.”
- “It's almost punitive - yellow mask is required for patient care if you don't get it.”
- “You get chased down. It’s tied to Healthy Rewards, an incentive program. It requires a declination form to get out of it. They offer clinics in the hospital and off site and on the unit. A list is sent to supervisors.”
- “Every year - required to get it or declination form. Strong admonishment if you don't get it. An email is sent hospital wide from the CEO. They make it really easy to get it. It's publicized in emails.”
- “CEO involved in this topic - every employee (in an office or at the bedside). CEO efforts motivated by regulatory requirements. As more regulated, this is more of a priority. From the patient safety perspective, this is a priority. When staff are sick, this costs the hospital money.”
- “They want 100% [vaccination compliance]. If you get a shot, you get a visual indicator for your badge. You shouldn't have to get it. There’s pressure now that money with the government is involved.”

For the whistleblower policy, only one of the three hospitals specified expectations for behaviors/actions/practices that that were required to comply with the policy. Additionally, only one of the three hospitals outlined the appropriate methods to comply with skills/techniques included in the policy. These elements for expectations and compliance methods were clearly provided to staff via training and other means, as was identified through qualitative interviews:

- “It’s included in mandatory education…they have a reporting system. If you’re uncomfortable reporting it, you can report online.”
- “Education at orientation; narc counts at every shift; there is a system set up to report.”

- “There is a chain of command; everyone is approachable. Feedback is provided to staff at a town hall event.”
- “It's part of mandatory education. There's a number listed to report with the option to do it anonymously.”
- “The mandatory education, records that you read and passed the test at the end.”
- “Attestation in annual compliance training modules.”
- “It’s part of mandatory online education (annual) – that’s primarily where it’s talked about. It’s not intended to be punitive but more of if something is broken, then we need to fix it, more about safety.”
- “They heavily invested in a compliance system for reporting”
- “There's a big push for event reporting. It's evident on the front page of the intranet.”
- “Annual compliance training module – there’s an integrity line.”
- “They track patient/visitor safety reports, track near misses. It's encouraged all the time. They give feedback on events that occurred – anonymous education pieces.”
- “You have people watching all the time – as cameras and people. People are obligated to say something. You can lose your license.”
- “Because of the heavier consequences with this one. For example, if you look at a patient's chart or charge for something that you're not supposed to, you're going to lose your job.”

5.4.4 Evaluating hospital policies and HO-MRSA BSI incidence rates

We explored the relationship between HO-MRSA incidence and the policy score for each policy (Table 24; Figures 10-11). The hospitals in this sample with the lowest MRSA incidence rates did not have influenza policies yet did have whistleblower policies; these hospitals were scored as zero. These analyses were exploratory given the limited number of participating hospitals.

When evaluating HO-MRSA BSI incidence and the total number of hand hygiene policy elements by hospital, there a weak, negative correlation identified (r=-0.19; Figure 10). The more

policy elements included in the policy, the lower the HO-MRSA BSI incidence rate for the hospital. Most (4/5) hospitals were within one point of one another when regarding hand hygiene policy elements (range of total: 11-12, nearly 50% of policy elements) and the remaining hospital (third lowest MRSA incidence) had a substantially higher number (policy elements=17, 74% of policy elements).

When evaluating HO-MRSA BSI incidence and the number of MDRO/isolation policy elements by hospital, there was a weak, positive correlation (r=0.23; Figure 10), indicating that the more policy elements, the higher the HO-MRSA BSI incidence for the hospital. This policy had the lowest number of total policy elements of all of the policies.

When evaluating HO-MRSA BSI incidence and the number of influenza policy elements by hospital, there was a relatively strong, positive correlation (r = 0.83; Figure 10), indicating the more policy elements, the higher the HO-MRSA BSI incidence for the hospital. Three of the five hospitals had policies while two had programs/initiatives were scored as zero for their totals. The hospital with the highest MRSA incidence rate had the lowest number of influenza policy elements, which was more than half of the policy elements (n=12, 52%). Of the other two hospitals with similar MRSA incidence rates, one had 52% and the other had 74% of the total policy elements included for evaluation.

When evaluating HO-MRSA BSI incidence and the number of whistleblower policy elements by hospital, there was a moderate, negative correlation (r = 0.45; Figure 10). The hospitals with whistleblower policies included the hospital with the highest and the hospitals with the two lowest MRSA incidence rates. The hospital with the highest MRSA incidence rate had the same number of policy elements as the hospital with the lowest MRSA incidence rate. Three of the five hospitals had policies while two did not submit policies which were scored as zero for their totals.

When evaluating HO-MRSA BSI incidence and the mean hand hygiene policy score by hospital, there was a moderate, negative correlation (r = -0.65; Figure 11), indicating that as the mean score increased, the HO-MRSA BSI incidence decreased.

When evaluating HO-MRSA BSI incidence and the mean MDRO/isolation policy score by hospital, there was strong, negative correlation (r = -0.93; Figure 11), indicating that as the mean score increased, the HO-MRSA BSI incidence decreased substantially.

When evaluating HO-MRSA BSI incidence and the mean influenza policy score by hospital, there was a relatively strong, positive correlation (r = 0.78; Figure 11), indicating that as the mean score increased, the HO-MRSA BSI incidence increased substantially.

When evaluating HO-MRSA BSI incidence and the mean whistleblower policy score by hospital, there was a moderate, negative correlation (r = -0.35; Figure 11), indicating that as the mean score increased, the HO-MRSA BSI incidence increased substantially.

With the small number of participating hospitals in this study, the correlations should be interpreted with caution. However, they provide a glimpse into potential relationships between the outcome and the policy elements as scored by counts and by comprehensiveness. The MDRO/Isolation policy was an interesting example since it demonstrated a positive correlation between the number of policy elements and the MRSA rate; yet there was a strong negative correlation between the score and the MRSA rate. This was a key learning that as the policy may be comprehensive based on total elements, the information included in the elements was not necessarily thorough, when our measurement tool was used for evaluation.

Table 24. Correlation between HO-MRSA BSI incidence and policy evaluation scores among hospitals (n=5)

	Total Policy Elements	**Mean Policy Score**
Policy	**r**	**r**
Hand hygiene	-0.19	-0.65
MDRO/Isolation	0.23	-0.93
Influenza	0.83	0.78
Whistleblower	-0.45	-0.35

MDRO: multidrug-resistant organism
r: Pearson's product correlation coefficient

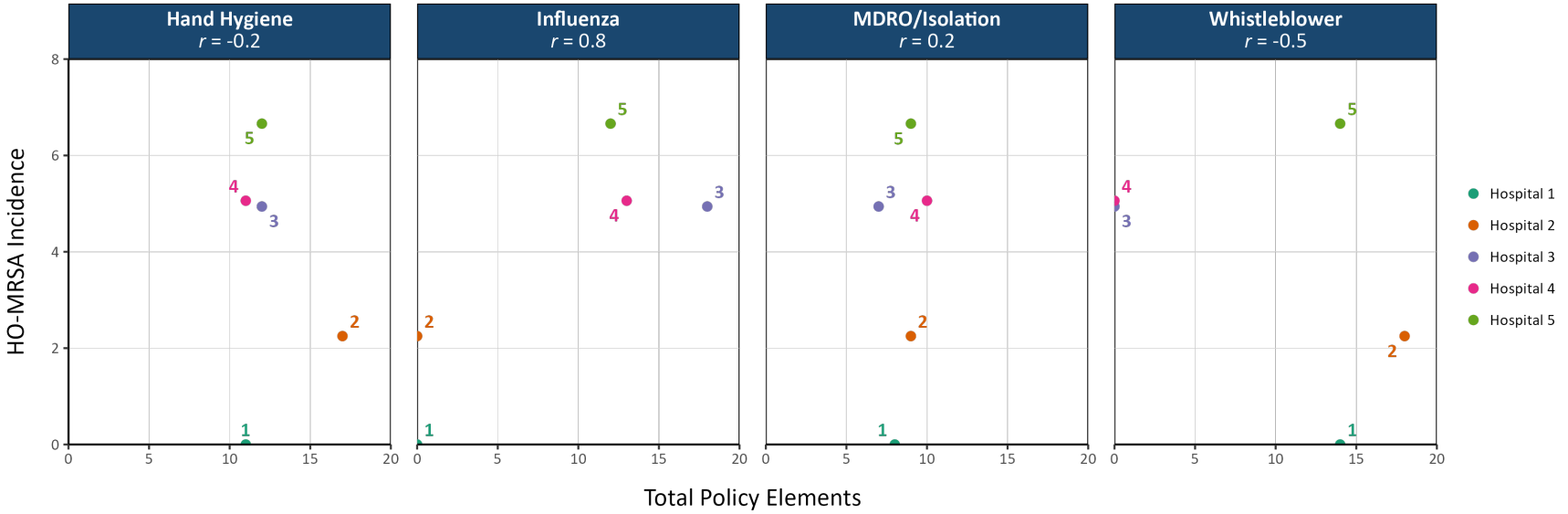

Figure 10. Relationship between Hospital-onset (HO)-MRSA and Total Policy Elements by Hospital

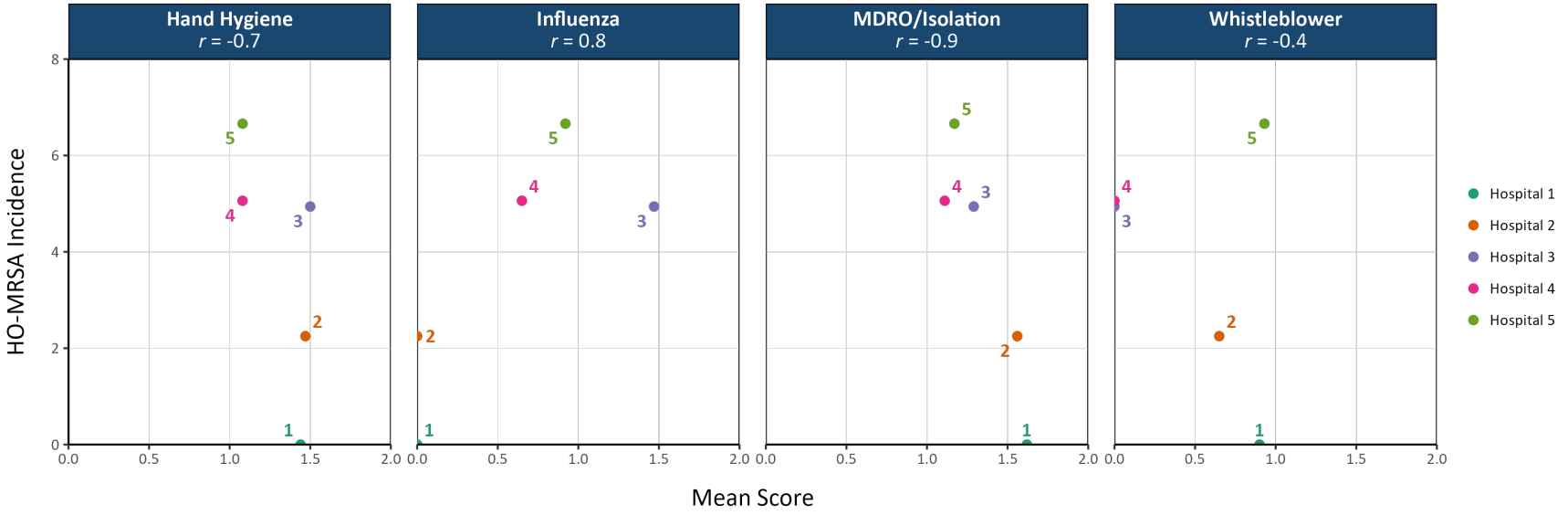

Figure 11. Relationship between Hospital-onset (HO)-MRSA and Mean Policy Score by Hospital

5.4.5 Conclusion

We developed a systematic method to quantitatively evaluate hospital policies. Our review of hospital policies found that the policies frequently contained thorough instructional elements such as organizational requirements and protocols/procedures. Policies often lacked implementation elements such as expectations for monitoring, enforcement, responsibilities, accountabilities, and staff training/education. We found it valuable to use two metrics to demonstrate the thoroughness and comprehensiveness of each policy. We found that more policy elements do not necessarily equal a more comprehensive or better policy. This finding was clear with the influenza policy where there was the most variability across hospital scores despite the hospitals having most or all of the policy elements.

When we evaluated hospital-level MRSA incidence and the hospital policy scores, we found of a negative relationship between MDRO/Isolation policy score and MRSA incidence: the lower the score of the hospital's MDRO/Isolation policy, the higher the hospital's MRSA rate. We found the indication of a negative relationship between hand hygiene policy score and MRSA incidence, as well. For the influenza policy and whistleblower policies, with only three hospitals, trends were challenging to detect. Of all of the policies evaluated, the influenza policy scores were the most variable across hospitals, and the whistleblower policies scored the lowest.

Influenza and whistleblower policies were included in the evaluation to provide context of the infection control and reporting culture of the hospital. The hospitals with the two lowest MRSA incidence rates did not have influenza policies but did have whistleblower policies.

Upon review of four hospital policies, we found that the policies most commonly contained instructional elements such as organizational specifications and protocols/procedures. Policies often lacked implementation elements such as expectations for monitoring, enforcement, responsibilities, accountabilities, and staff training/education. These results align with previous research on policy implementation.

6. Discussion

6.1 Overview

This chapter summarizes the findings of this dissertation and contextualizes them within this work, as well as the published literature. Strengths and weaknesses are examined, and finally, future research opportunities and contributions are presented.

The research question of this dissertation addressed whether MRSA acquired in the hospital was impacted by organizational policy. Ideally, one would conduct a randomized controlled trial, the gold standard in epidemiologic studies, whereby hospitals would be randomized to Policy A (treatment group) or randomized to implement Policy B (control group), and subsequently the hospital-acquired MRSA rates would be measured in all hospitals. Such a design would allow one to employ the counterfactual framework to test whether the MRSA rates between treatment and control hospitals were the same, but for the policy, assuming the randomization was successful.

We were not at the stage of the science which would have been appropriate to conduct such a trial. Without existing data or methods of measurement, we could not determine whether hospital policy was a public health problem or whether it was measurable. This dissertation sought to identify whether a novel exposure existed and how to begin to measure it.

6.2 Aim 1a: conclusion

We found that invasive MRSA infections decreased in Hennepin and Ramsey counties over years 2008 to 2013; HO-MRSA BSI was most pronounced compared to HACO- and CA-MRSA infection cases. This reduction aligned with other reductions reported in similar timeframes following the publication of a successful infection prevention initiative and guideline publications, which included infections such as MRSA. Starting in 2003, the Michigan Keystone intensive care unit project to reduce central line associated BSI (CLABSI) was being implemented across U.S. hospitals with remarkable success, which contributed to substantial hospital-onset MRSA CLABSI reductions [Burton et al, 2009; Pronovost et al, 2006; CDC MMWR, 2005]. Further, the advisory committee for infection prevention (Healthcare Infection Control Practices Advisory Committee)

published cornerstone prevention guidelines in 2006 and 2007 (Management of Multidrug-Resistant Organisms In Healthcare Settings, 2006; 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings), which included comprehensive evidence-based prevention measures preventing the transmission of infections in hospitals, including MRSA [Siegel et al, 2007a; 2007b].

From 2005 to 2011, Dantes, et al reported results from the EIP surveillance system (eight U.S. catchment areas, in addition to Hennepin and Ramsey counties in MN) that demonstrated a 54% decrease in hospital-onset invasive MRSA infections [Dantes et al, 2013]. Between 2005 and 2010, Landrum, et al reported a 28.6% decrease in MRSA BSI among U.S. military medical treatment facilities, which included Department of Defense health care population varied sizes in urban, semiurban, and rural settings (i.e., hospitals not included in CDC's surveillance systems). [Landrum et al, 2012]. Between 2007 and 2012, the VA reported a 45% decrease in healthcare-associated MRSA infections among VA hospitals in the U.S. following an MRSA intervention directive (universal nasal screening and use of contact precautions) [Jain, et al]. Continued declines were reported in VA hospitals, resulting in healthcare-associated MRSA infections dropping 87% in ICUs and 80% in non-ICU patient care areas [Evans et al, 2017]. CDC reported that between years 2005 and 2016, the incidence of HO-MRSA BSI decreased 74%, with an annual decrease of 17% until 2012 when that progress stalled and no significant change occurred between 2013 to 2016 ($p = 0.25$) [Kourtis, Hatfield, Baggs, et al, 2019].

The timeframe of this work was important as it provided context for the timeframe leading up to the 2013, the first year of the CMS requirement to publicly reporting HO-MRSA via CDC's NHSN system.

6.3 Aim 1b: conclusion

To study the relationship between hospital-level characteristics and HO-MRSA BSI rates in U.S. hospitals, we used existing data from CMS to construct and analyze a dataset with hospital characteristics including hospital size, demographics, staffing, services, and the outcome of interest, HO-MRSA BSI incidence rate per hospital per 10,000-patient days. Our approach

sought to understand whether hospital characteristics beyond hospital size were associated with HO-MRSA BSI incidence. We first explored the relationship between HO-MRSA BSI incidence and hospital size, which found that bed count (and not average daily census) was associated with HO-MRSA BSI incidence. To further examine the relationship, we included additional independent variables including hospital demographics, staffing, and services.

Despite the range of variables used to explore the relationship between hospital-level characteristics and HO-MRSA BSI incidence, the multivariate linear regression model only explained 13% of the variability for this relationship. This model estimated that bed count, residing in the southern or northeastern regions of the U.S., higher DSH percentage, not being in compliance with CMS, medical school affiliation (teaching or graduate level), number of physician residents employed, providing acute renal dialysis, having a burn unit, and providing gerontological specialty service increased the average hospital HO-MRSA BSI incidence rate, while the number of other salaried employees, having a neonatal ICU, and having a CARF inpatient rehab decreased the average hospital HO-MRSA BSI incidence rate.

This was the first study to examine the relationship between hospital-level characteristics and HO-MRSA rates. A limited number of studies have evaluated the role of hospital-level characteristics and rates of infections acquired while hospitalized. Ricciardi, et al evaluated the relationship between structural characteristics of hospitals in California, Arizona, and Minnesota (American Hospital Association data) and high *C. difficile* infection (CDI) rates as measured using ICD-9 codes [Ricciardi, Harriman, Baxter, et al, 2008]. Their findings showed an increased risk of CDI in hospitals with transplant services but decreased risk of *C. difficile* in hospitals with emergency department services, trauma services, and faster bed turnover as well as an additional increased risk in hospitals providing hemodialysis services (OR 1.87, 95% CI 1.09-3.21). Gibbons, et al studied the relationship between hospital-level factors (n=39) and MRSA BSI in Scottish hospitals. Their findings demonstrated that, after adjusting for bed count, high MRSA BSI hospitals were “well-connected,” those that received high volumes of transfer patients from several other facilities [Gibbons, van Bunnik, Blatchford, et al, 2016]. Thompson, et al

evaluated the relationship between hospital-level CDI incidence rate and CMS's case mix index (CMI), a hospital-level measure of patient acuity, derived from administrative data. After controlling for community CDI prevalence, medical school affiliation, hospital size, and type of CDI test used, they found that CMI was associated with hospital-level CDI incidence ($p < .0001$) [Thompson, Edwards, Dudeck, et al, 2016].

There were limitations of this aim including the lack of a systematic validation process for the outcome of interest. Blood culture collection techniques could have contaminated the blood sample, thereby producing false positive blood tests, which could have resulted in measurement error of the outcome variable. Reported blood culture contamination rates in hospitals vary widely (0.6% to 12.5%), with the highest rates in the in the emergency department [Snyder, Favoretto, & Baetz, 2012]. If blood culture collection technique differed systematically by service/unit or role, this could result in measurement error of the outcome. As a result, there was the potential for false positives of the outcome variable. While there was no evidence to suggest that hospitals would differ or differ in a systematic way to bias the results, contamination or poor lab technique could produce false positive blood cultures, which could lead to misclassification of the outcome since the outcome measure relied solely on a positive lab result. If blood culture collection technique differed systematically by service/unit or role, for example, resulting in differential misclassification, the model could estimate biased estimates of the measure of association toward or away from the null. If the misclassification was nondifferential, it would tend to bias the measure of association towards the null [Szklo & Nieto, 2007]. Since we analyzed the first year of the required NHSN MRSA data, the outcome measurement may have been impacted by reporting experience by the hospital staff. Lack of experience with NHSN reporting or differential resources available to meet the reporting requirements could have impacted the outcome data.

Additionally, there were likely other unmeasured variables that could have further explained the relationship yet were unavailable in this dataset or unknown. Of the variables available, they were assessed differently (continuous, categorical, quartiles, transformation) to best describe the relationship and maximize model fit.

While there could have been measurement issues with the outcome of interest, we believe the strength of using a lab-based measure outweighed the potential risks. Since the outcome of interest was identified via lab testing, this method provided an objective determination, compared to claims or administrative data. A major strength of this study was that it was the first to describe the relationship between hospital characteristics and HO-MRSA BSI incidence in medium- and large-sized hospitals in the U.S. These findings demonstrated that the spread of HO-MRSA in hospitals was not at random. These findings could be used to characterize where and how to prioritize infection prevention resources from an organizational perspective. However, the findings did not reveal a comprehensive story and the characteristics determined to be important, as estimated with our model, and did not point to actionable factors which would be modifiable with respect to MRSA transmission in the hospital. We would not expect that hospitals would be able to leverage this work to then employ more salaried staff to perform other, nonclinical roles, for example, and expect to lower HO-MRSA BSI rates. More staff would not likely be the solution prevent HO-MRSA infections. Rather, it is the behaviors of the staff within the organization that matter. The findings from this aim reinforced the importance of employing a social epidemiologic framework when approaching this public health problem. Additionally, this context demonstrates the importance of characterizing measurable, modifiable factors, extrinsic to the patient, that operate at the hospital level through the staff, and which can be tested.

6.4 Aim 2 – Aim 4: conclusions

We developed a tool to systematically evaluate organizational policies and demonstrated that this tool can identify measurable and modifiable constructs in hospital policies (Aim 2). Provided that there was no gold standard or any existing tool, the tool was developed using the Alcohol Epidemiology Program Alcohol Policy Implementation Model [Jones-Webb et al, 2014], together with relevant guideline and evidence-based practices.

Our review of hospital policies found that the policies frequently contained thorough instructional elements such as organizational requirements and protocols/procedures. Policies

often lacked implementation elements such as expectations for monitoring, enforcement, responsibilities, accountabilities, and staff training/education. We found it valuable to use two methods to score the elements included in the policies. Had we limited the evaluation to the presence or absence of the policy element, we would have constrained the amount of meaningful information collected. By scoring the policy element, we were able to measure substance or lack thereof. We found that more policy elements did not necessarily equal a more comprehensive or better policy. This finding was clear with the influenza policy where we identified substantial variability across hospital scores despite the hospitals having most or all of the policy elements.

When we evaluated HO-MRSA BSI incidence and the hospital policy scores (Aim 3), we found an indication of a negative correlation between the MDRO/Isolation policy score and HO-MRSA BSI incidence: the higher the mean score of the hospital's MDRO/Isolation policy, the lower the hospital's MRSA rate. We found a similar yet slightly weaker indication of a negative correlation between the mean score of the hospital's hand hygiene policy score and hospital's HO-MRSA BSI incidence. For the influenza policy and whistleblower policies, with only three hospitals that submitted complete policies, correlations were challenging to interpret. The influenza policy scores were the most variable across hospitals, and the whistleblower policies scored the lowest. While not directly related to MRSA prevention, we included influenza and whistleblower policies in the evaluation to provide context of the infection control and reporting culture of the hospital. The hospitals with the two lowest MRSA incidence rates did not have influenza "policies" – instead they had annual flu vaccination campaigns or initiatives – but these hospitals did have whistleblower policies.

As research in this area advances, it will be important to consider other policies to assess the policy climate of the hospital. This concept of describing policy climate has been effective in alcohol control policy research since it considers other factors that contribute to the effectiveness of policies [Naimi, Blanchette, Nelson, et al, 2014].

These results of our hospital policy evaluation, align with previous research on policy implementation. In the public policy space, the lack of implementation following policy adoption

has been described [Jones-Webb et al, 2014; Jacobson & Wasserman, 1997; Elmore 1979; Sabatier 1986]. In the organizational policy space, policy implementation research is lacking. Internet searches revealed an abundance of organizational policy implementation guidance that lacked an evidence base, relying mostly on anecdotes and experience. Yano of the U.S. Department of Veterans Affairs' Quality Enhancement Research Initiative (QUERI) commented, “Many guidelines do not contain recommendations that consider organizational factors. It is thus essential to begin to consider the implications of the differences between the characteristics of the health care organizations in which efficacy and effectiveness have been established vs. those in which the evidence-based practices will subsequently be applied in order to improve their reach and adoption” [Yano, 2008].

Qualitative interviews with staff at the participating hospitals (Aim 4), revealed that policy implementation elements identified as gaps were often apparent for all of the policies at all hospitals. Through interviews with infection preventionists at the hospitals, it was uncovered that documentation of policy implementation elements has been discouraged by leadership due to implications of accrediting/regulating agencies. Additionally, one administrator remarked that if staff-level policy compliance data were collected, then they “would have to do something with it.” Given the nascent stage of organizational policy evaluation, including qualitative data collection was meaningful to gain insight into the policy implementation as to whether the policy was doing was it was intended to do. The staff interviews offered supplemental information that was not captured through the policy evaluation tool, including behaviors and practices that were particular to certain units (references to dogged unit leadership with strong policy enforcement) or to certain job roles and existing hierarchies (environmental services staff that knew the inner workings of the facility yet the perceived hierarchies prevented them from speaking up when noncompliance was observed). We also learned that since training and education was mostly absent from the policies yet was occurring as identified through staff interviews, that specifically including that program information would benefit future evaluation efforts. Additionally, it was reported that corrective actions or actions related to noncompliance would be stored in human resources

policies, not the infection prevention policy – yet there was no evidence of that in the policy itself. This point speaks to the importance of considering a range of policies to better characterize the patterns of the policies and their implementation. The qualitative interviews were necessary to inform this novel measurement process – these interviews provided valuable information that will produce a more robust evaluation process in future iterations.

There were limitations of this study including the small number of hospitals that participated in this study. Further, we only had one rater who evaluated the policies. Additional raters would allow measurement of the agreement of the rating, such as the kappa statistic that considers whether the agreement occurred not just by chance alone [Szklo & Nieto, 2007]. As discussed in the limitations for Aim 1b, the data collection processes for the outcome of interest lacked a systematic validation process, which could have resulted in measurement error. Additionally, since we conducted a cross-sectional study, there was no ability to account for temporality. Potential temporality bias or reverse causality issues could be limited by collecting additional data to assess recent outbreaks or infection control breaches, compliance issues, change in leadership or other situations that may have impacted the policy development and implementation strategies. For example, from our findings we identified that the hospital with the second lowest MRSA rate had an incredibly comprehensive MDRO/isolation policy – substantially more pages and substance than the other hospitals. We cannot determine whether this comprehensive policy caused the lower MRSA rates or if the strong policy was the result of an infection prevention situation.

The organizational policies were endogenous in nature – they were created by those at the organization, which presents challenges with disentangling the exposure of interest from the organization when attempting to measure an organizational-level construct. As discussed in the introduction to this chapter, ideally, we would conduct the group randomized trial where the study team would develop the policy and introduce it to the organization to be tested. Since we were not at that stage of the science to conduct such a trial, we used an existing policy implementation

model and evidence-based guidelines to develop the measurement tool to be systematic, to the degree possible.

The strengths of the study were that we developed a novel tool to systematically evaluate organizational policies and demonstrated that this tool can identify measurable and modifiable constructs in hospital policies. We relied on a rigorous model developed by those in the alcohol control space that was particularly applicable since the model focused on the aspects of policy implementation. This model translated effectively to the organizational policy space, which, to our knowledge, has not begun to measure or evaluate policies and their relationship to patient safety in hospitals.

As a federal healthcare quality metric and a Healthy People 2030 goal, this is a public health issue that is important and preventable, and continued examination of hospital-level factors, including policy, is needed. Future studies should continue evaluating hospital policies related to MRSA prevention, in addition to other policies in the hospital. More work is needed to understand the contributions of certain policies in relationship to the broader hospital policy environment including use of weighting schemes. Through Aim 1a, HO-MRSA patient risk factors included presence of a central line in the two days prior to detection of the MRSA and recent surgery (Table 2). The primary prevention measures for HO-MRSAS BSI should be specified in the relevant infection prevention policies such as hand hygiene, MDRO/isolation, and central line associated BSI (CLABSI). Therefore, as this work continues, the broader policy environment should be considered giving more weight to the infection control policies directly related to MRSA prevention in comparison to supporting policies. As the work policy progresses and more rigorous studies are planned, the findings from Aim 1b would be important to consider. As we demonstrated, MRSA transmission in hospitals is not random, and therefore the extrinsic risk to the patient is not homogenous, based on staffing, services, areas within the hospital, and types of hospitals. As such, when comparing policies across hospitals, these hospital-level characteristics should be included to ensure appropriate selection and/or comparisons through matching, adjustment, or other methods. Additionally, through qualitative interviews with staff, the policy

implementation varied within hospitals. To effectively measure policy implementation, the units and job roles must be considered and studied, given social norms and accepted procedures which develop through the course of the work.

6.5 Contribution

This exploratory evaluation included only five hospitals in the metropolitan area of Minneapolis-St. Paul, MN. With a small sample size, the intention of the work was hypothesis generating and a step forward in advancing this body of literature. Based on the Alcohol Epidemiology Program Alcohol Policy Implementation model, we developed a tool to quantitatively evaluate hospital policies. With this tool, we were able to gain traction in the measurement of hospital policies as an exposure for hospital-associated infections. Through this dissertation, we began the work to identify important hospital policy constructs, whether they matter, and how much they matter with respect to MRSA transmission.

Hospital-onset MRSA bloodstream infections are the result of the interactions between people and the system in which they work. In order to better understand the system, we must consider the organization control methods in place which affect human performance in the context of the system. Yet in order to assess impact of any approach, we must use rigorous methods to test these approaches. Chief concerns of observational epidemiologic studies are confounding and bias, which can result from the process through which the data are collected. Key to data collection processes is measurement – before we can even begin to study the causes and effects of policy, we needed to begin to understand how to measure it. With this policy evaluation, we rapidly learned that the evaluation process was complicated. There was a web of tangential policies and protocols, including the environmental cleaning policies and protocols which were numerous and disparate with varying ownership, and in some circumstances not owned by the hospital. What was the role of the policy, why was it developed, who developed it? These were important considerations knowing that this information would impact measurement, and thus the interpretation of results.

Since the exposure measurement was novel, we utilized a mixed method approach to supplement the quantitative data with qualitative data collection. Given that the policy evaluation was novel, to thoroughly study it, we needed to understand the policy in practice at the hospital. Through staff interviews, we were able to assess whether staff were aware of the policy, whether the policy was trained, and how it was perceived. (We received mixed responses upon directly asking about the policy. Commonly, staff were more familiar with the output of the policy implementation such as an educational flyer, etc.) Measurement of the policy with the practice provided a more comprehensive understanding of the qualitative evaluation of the policies under study.

This work of this dissertation clearly demonstrated that despite modest recent successes in HO-MRSA BSI incidence, there remains substantial work to be done to reduce these infections. HO-MRSA BSI are among the most severe infections and despite the abundance of guidelines and research at the patient and biological levels, they continue to occur in hospitals. The current approaches for infection prevention and control of MRSA are not enough – or perhaps they are not enough for all areas of the hospital or all types of hospitals. As demonstrated in the work of Aim 1b, the hospitals that provide complex care report higher rates of HO-MRSA BSI. With the recent HO-MRSA BSI declines having plateaued, we need to continue to push using a concerted effort to address these severe infections. How do we address this public health problem using tools the operate at the organizational level? New approaches, new frameworks, and ways of thinking are needed to gain progress. What is the role of the hospital? When a patient enters the hospital for care and then experiences an infection throughout that care – who is accountable? We know humans error, we know organizations set the rules for their workers, so what can be done at the organizational level?

At the end of the day, the hospital is accountable for the care provided by their staff to their patients. How do we design prevention efforts at the organizational level to set up staff for success in these highly complex organizations, recognizing that human error is a considerable factor where a plethora of processes that require consistent adherence are expected to be

performed in order to deliver safe care? This dissertation aims to begin this complicated effort, which involves taking an organization control tool, the hospital policy, evaluating it, and then determining whether it can impact patient outcomes.

We applied a social epidemiologic framework ("cause of causes") to assess organizational factors related to MRSA transmission in hospitals by considering distal and proximal factors which will expand approaches and insight into various fields. This work will expand quantitative approaches for systematically evaluating organizational policies and providing insight into organizational policy in epidemiology. In the healthcare and clinical epidemiology realm, this work will broaden approaches by identifying modifiable hospital-level factors that can prevent and control the spread of MRSA in hospitals. This work would serve policy makers who utilize organization policy and who have recognized that hospital-acquired infections are a major public health issue. Further, the work from this dissertation would be important to hospital administrators to inform control strategies as leaders of hospitals. Finally, the work of this dissertation will contribute to the fields of social epidemiology, infectious diseases epidemiology, clinical epidemiology, and healthcare epidemiology by gaining insight into organizational policy – including how we measure, how we analyze, and how we draw inferences with the results.

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Appendix A. Complete List of Aim 1b Variables

Variable description	Variable type	Variable values	Dataset
Provider Category Subtype Code Description: Identifies the subtype of the provider, within the primary category. Used in reporting to show the breakdown of provider categories, mainly for hospitals	categorical	01=Short Term 02=Long Term 03=Religious Non-Medical Health Care Institutions 04=Psychiatric 05=Rehabilitation 06=Children's Hospitals 07=Distinct Part Psychiatric Hospital 11=Critical Access Hospitals 20=Transplant Hospitals 22=Medicaid Only Short-Term Hospitals 23=Medicaid Only Children's Hospitals 24=Medicaid Only Children's Psychiatric 25=Medicaid Only Psychiatric Hospitals 26=Medicaid Only Rehabilitation Hospitals 27=Medicaid Only Long-Term Hospitals	CMS POS dataset, 2013
Compliance status: Compliance status of a provider at the time of certification survey	categorical	0 = Not in compliance 1 = In compliance	CMS POS dataset, 2013
Reason for certification - Identifies the reason for the certification	categorical	1=initial 2=recertification 3=termination 4=change of ownership 5=validation 8=full survey after complaint	CMS POS dataset, 2013
Hospital ownership type: nature of the organization that operates a provider of services	categorical	01=Church 02=Private (not for profit) 03=Other (specify) 04=Private (for profit) 05=Federal 06=State 07=Local 08=Hospital district or authority 09=Physician ownership 10=Tribal	CMS POS dataset, 2013
Location (urban / rural) [CMS POS: "CBSA (Core Based Statistical Area) indicates whether the county is defined as Urban or Rural"]	categorical	0 = Rural 1 = Urban	CMS POS dataset, 2013

Indicates the organization that is responsible for the accreditation of the provider [Indicates an accrediting organization deeming the provider. If a provider is deemed by multiple accrediting organizations, then the accrediting organization with the earliest active deeming effective date is displayed in this field.]		0 = Not accredited 1 = Accredited (The Joint Commission [TJC], American Osteopathic Association [AOA]/ Healthcare Facilities Accreditation Program [HFAP], or Det Norske Veritas [DNV])	CMS POS dataset, 2013
Medical school affiliation; Description: Type of affiliation that a hospital has with a medical school.	categorical	0 = No affiliation 1 = Medical school affiliation (major, limited, graduate)	CMS POS dataset, 2013
Medical school affiliation; Description: Type of affiliation that a hospital has with a medical school.	categorical	0 = No or limited affiliation 1 = Major or graduate affiliation (major or graduate)	CMS POS dataset, 2013
Program participation: Medicare / Medicaid Participating Provider - indicates if the provider participates in Medicare, Medicaid, or both programs	categorical	1 = Medicare only 2 = Medicaid only 3 = Medicare & Medicaid	CMS POS dataset, 2013
Number of times a change of ownership has taken place for a particular provider	continuous		CMS POS dataset, 2013
Certified bed count: Number of beds in Medicare and/or Medicaid certified areas within a facility	continuous		CMS POS dataset, 2013
Bed count: Total number of beds in a facility, including those in non-participating or non-licensed areas	continuous		CMS POS dataset, 2013
Psych unit bed count	continuous		CMS POS dataset, 2013
Rehab unit bed count	continuous		CMS POS dataset, 2013
Number of FTE other salaried personnel employed by facility	continuous		CMS POS dataset, 2013
Number of FTE Certified Registered Nurse Anesthetists (CRNA) employed by hospital	continuous		CMS POS dataset, 2013
Number of full-time equivalent licensed practical or vocational nurses employed by a facility	continuous		CMS POS dataset, 2013
Number of full-time equivalent medical social workers employed by a hospital or hospice	continuous		CMS POS dataset, 2013
Nurse Practitioner Count	continuous		CMS POS dataset, 2013

Occupational Therapist Count	continuous		CMS POS dataset, 2013
Physicians Count	continuous		CMS POS dataset, 2013
Physician Assistants (PA) Count	continuous		CMS POS dataset, 2013
Number of full-time equivalent residents (physicians) employed by a hospital	continuous		CMS POS dataset, 2013
Registered Pharmacists Count	continuous		CMS POS dataset, 2013
Number of FTE respiratory therapists employed by a hospital	continuous		CMS POS dataset, 2013
Registered Nurses Count	continuous		CMS POS dataset, 2013
Swing Bed Count (beds can be used for either hospital or long term care services)	continuous		CMS POS dataset, 2013
Pharmacy	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Acute renal dialysis	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Anesthesia	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Burn unit	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Cardiac Catheterization Lab	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Cardiac - Thoracic Surgery	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
CARF Inpatient Rehab	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Chemotherapy	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Coronary Care Unit /ICU Cardiac (non-surgical)	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Trauma Center (Designated)	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Emergency Department (Dedicated)	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Gerontological Specialty	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013

Inpatient Surgical	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
ICU Medical/Surgical	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Transplant Center (Medicare Certified)	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
ICU Neonatal	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Neonatal Nursery	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Neurosurgical Services	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Organ Transplant (Not Medicare Certified)	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Nuclear Medicine	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Obstetrics	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Ophthalmic Surgery	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Operating room	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Orthopedic Surgery	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Pediatrics	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Pediatric ICU	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Postoperative Recovery Room	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Reconstructive Surgery	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Surgical ICU	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Urgent Care Center	categorical	0 = Not provided 1 = Provided (by staff and/or under arrangement	CMS POS dataset, 2013
Pediatrics - any service type	categorical	0 = No 1 = Yes	derived from CMS POS, 2013

Surgery - any (inpatient surgical, cardiothoracic, neurosurgical, ophthalmic, reconstructive, orthopedic, operating room; does not include outpatient surgical services)	categorical	0 = No 1 = Yes	derived from CMS POS, 2013
ICU - any (pediatric, burn, medical/surgical, neonatal, surgical)	categorical	0 = No 1 = Yes	derived from CMS POS, 2013
Transplant services – any (Organ Transplant (Not Medicare Certified) or Transplant Center (Medicare Certified))	categorical	0 = No 1 = Yes	derived from CMS POS, 2013
US Census Region	categorical	"West" = ID, MT, WY, UT, CO, NV, AZ, NM, WA, OR, CA, HI, AK "Midwest" = ND, SD, NE, KS, MN, IA, MO, WI, IL, MI, IN, OH "South" = WV, VA, DC, MD, DE, NC, SC, GA, FL, KY, TN, MS, AL, OK, TX, AR, LA "Northeast" = NY, PA, NJ, ME, NH, VT, MA, RI, CT	derived from CMS POS, 2013
Quarter 1 number of observed MRSA infections	continuous		CMS HAI/MRSA, 2013
Quarter 1 number of predicted MRSA infections	continuous		CMS HAI/MRSA, 2013
Quarter 1 SIR	continuous		CMS HAI/MRSA, 2013
Quarter 1 SIR upper confidence interval	continuous		CMS HAI/MRSA, 2013
Quarter 1 SIR lower confidence interval	continuous		CMS HAI/MRSA, 2013
Quarter 1 patient-days	continuous		CMS HAI/MRSA, 2013
Quarter 1 CMS rank	text	“Better than the U.S. National Benchmark” [<1.0] “Worse than the U.S. National Benchmark” [>1.0] “No Different than the U.S. National Benchmark” [=1.0]	CMS HAI/MRSA, 2013
Quarter 2 number of observed MRSA infections	continuous		CMS HAI/MRSA, 2013
Quarter 2 number of predicted MRSA infections	continuous		CMS HAI/MRSA, 2013

Quarter 2 SIR	continuous		CMS HAI/MRSA, 2013
Quarter 2 SIR upper confidence interval	continuous		CMS HAI/MRSA, 2013
Quarter 2 SIR lower confidence interval	continuous		CMS HAI/MRSA, 2013
Quarter 2 patient-days	continuous		CMS HAI/MRSA, 2013
Quarter 2 CMS rank	text	"Better than the U.S. National Benchmark" [<1.0] "Worse than the U.S. National Benchmark" [>1.0] "No Different than the U.S. National Benchmark" [=1.0]	CMS HAI/MRSA, 2013
Quarter 3 number of observed MRSA infections	continuous		CMS HAI/MRSA, 2013
Quarter 3 number of predicted MRSA infections	continuous		CMS HAI/MRSA, 2013
Quarter 3 SIR	continuous		CMS HAI/MRSA, 2013
Quarter 3 SIR upper confidence interval	continuous		CMS HAI/MRSA, 2013
Quarter 3 SIR lower confidence interval	continuous		CMS HAI/MRSA, 2013
Quarter 3 patient-days	continuous		CMS HAI/MRSA, 2013
Quarter 3 CMS rank	text	"Better than the U.S. National Benchmark" [<1.0] "Worse than the U.S. National Benchmark" [>1.0] "No Different than the U.S. National Benchmark" [=1.0]	CMS HAI/MRSA, 2013
Quarter 4 number of observed MRSA infections	continuous		CMS HAI/MRSA, 2013
Quarter 4 number of predicted MRSA infections	continuous		CMS HAI/MRSA, 2013
Quarter 4 SIR	continuous		CMS HAI/MRSA, 2013
Quarter 4 SIR upper confidence interval	continuous		CMS HAI/MRSA, 2013

Quarter 4 SIR lower confidence interval	continuous		CMS HAI/MRSA, 2013
Quarter 4 patient-days	continuous		CMS HAI/MRSA, 2013
Quarter 4 CMS rank	text	"Better than the U.S. National Benchmark" [<1.0] "Worse than the U.S. National Benchmark" [>1.0] "No Different than the U.S. National Benchmark" [=1.0]	CMS HAI/MRSA, 2013
MRSA rate (MRSA BSI incidence rate = (observed infections/patient-days)*100,000)	continuous	[most recent data available for each hospital – through quarter 3 or quarter 4]	derived from CMS HAI/MRSA, 2013
DSH percentage DSH Patient Percent = (Medicare SSI Days / Total Medicare Days) + (Medicaid, Non-Medicare Days / Total Patient Days) (CMS)	continuous		derived from CMS Impact File, 2013
DSH percentage: quartiles	categorical		derived from CMS Impact File, 2013
DSH categorical: High vs Low	categorical	High (>= 0.15) Low (<0.15)	derived from CMS Impact File, 2013
LPN to RN nurse ratio	continuous	LPN/RN	derived from CMS POS, 2013
Percentage of LPN nurses (LPN/(LPN + RN))	continuous	(LPN/(LPN + RN))	derived from CMS POS, 2013
Bed count category (2)		1 = 1-199 2 = 200-299 3 = 300-399 4 = 400-499 5 = >=500	derived from "bed count" CMS POS, 2013
Bed count category (3) CDC/NHSN-defined: used as a predictor for expected number of infections (SIR model 2013)		0 = 1-400 1 = >400	derived from "bed count" CMS POS, 2013

Appendix B. Hospital Policy Evaluation Tools

Policy Evaluation Tool: Hand Hygiene

Score: 0=nonexistent, 1=cursory, 2=thorough

Section / Policy Element	Score
1. Purpose section	
The purpose provides rationale describing why the subject matter merits formal rules ☐ Purpose of the policy is specified ☐ Rationale is specified (e.g., hand hygiene has been shown to prevent the spread of infectious diseases) ☐ Desired effects of the policy are specified, such as what the organization hopes to accomplish with this policy; benefits that this policy will deliver to the organization, staff, patients/visitors ☐	____ Yes ___ No Score: _____
2. Policy section	
a. Specific requirements, behavior, regulations (if applicable)	
The policy provides staff with a clear understanding of requirements, regulations (if applicable), and what constitutes appropriate behavior, including expectations and performance objectives ☐ Organizational rules are clearly communicated (e.g., when and how to perform hand hygiene) ☐ A timeline for compliance is specified ☐ Expectation is specified that staff are familiar with and adhere to the policy elements ☐ Contact information is specified to inform staff of who to contact with policy-related questions	____ Yes _____ Score: _____
b. Scope/audience	
The policy outlines the intended audience for this policy ☐ Policy outlines who is expected to comply with policy ○ Staff, sites, facilities, business units ☐ Policy outlines staff, and under what circumstances (as appropriate), that are not included (e.g., surgical team for surgical prep or surgical scrub – may reference a different policy/procedure) ☐	____ Yes ___ No Score: _____
c. Definitions	
Key concepts and terms are defined. For hand hygiene, this may include: ☐ Staff/healthcare workers ☐ Hand hygiene ☐ Alcohol-based hand rub ☐ Antimicrobial soap ☐ Plain soap ☐ Visibly soiled/contaminated hands ☐ Healthcare-associated/acquired infection	____ Yes ___ No Score: _____
d. References: scientific rationale / evidence	
References are provided to support policy development, such as: ☐ Regulations ☐ Specific federal or state statute(s) ☐ Standards ☐ Guidelines/recommendations from relevant governmental agencies, professional associations/groups ☐ Published literature ☐ Total:_____	____ Yes ___ No Score: _____

e. Appropriate methods to comply with skills/techniques	
The appropriate methods to comply with skills/techniques included in the policy are outlined. For hand hygiene, this may include: ☐ Specifications for hand hygiene indications (when to perform hand hygiene) ☐ Specifications for the appropriate methods – when to use alcohol-based hand rub vs soap and water ☐ Specifications for appropriate glove use / glove use not a substitute for hand hygiene ☐ Specifications for avoiding the use of bar soap ☐ Specifications for use of hand lotion/efforts to maintain skin health	____ Yes ___ No Score: _____
f. Expectations for behaviors/actions/practices that compromise effective hand hygiene	
Expectations for behaviors/actions/practices that compromise complying with the policy are specified. For hand hygiene, this may include: ☐ Expectations are specified to use only facility-approved/appropriate hand hygiene products ☐ Jewelry use (acceptable jewelry is specified, if any) ☐ Nail length (appropriate length is specified) ☐ Use of artificial nails/nail enhancements ☐ Use of nail polish ☐ Any circumstance in which compliance with proper hand hygiene practices cannot be performed – such as use of braces/casts/bandages/assistive devices ☐ Compromised skin/skin health • Description • How to minimize occurrence • Instructions for who to contact (e.g., Occupational/Employee Health) • Availability of alternative products ☐	____ Yes ___ No Score: _____
g. Expectations for compliance with hand hygiene practices	
The policy outlines expectations for monitoring and enforcing practices/skills/techniques required by the policy. For hand hygiene, this may include: ☐ Expectations are specified regarding monitoring of compliance with hand hygiene practices ○ How ○ By whom ☐ Expectations are specified regarding enforcement of compliance with hand hygiene practices ○ How ○ By whom ☐	____ Yes ___ No Score: _____
3. Responsibilities section (indicates which parties are responsible for carrying out policy elements and how policy adherence will be ensured) To ensure staff have the opportunity to be compliant, structural policy elements include parties responsible for carrying out the policy elements and how adherence will be ensured are specified	

a. **Responsibilities for equipment/product types, locations, availability**

□ **Responsibilities are specified for hand hygiene product types, locations, availability**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
□ Determine appropriate indications, technique	___Yes ___ No	___Yes ___ No
□ Determine appropriate products	___Yes ___ No	___Yes ___ No
□ Maintenance of hand hygiene product inventory (units/areas; shared spaces)	___Yes ___ No	___Yes ___ No
□ Maintenance of product dispensers	___Yes ___ No	___Yes ___ No
□ Ordering of hand hygiene products	___Yes ___ No	___Yes ___ No
□ Storage of hand hygiene products	___Yes ___ No	___Yes ___ No
□ Determination of appropriate hand hygiene product dispenser locations	___Yes ___ No	___Yes ___ No
□ Installation of hand hygiene product dispensers	___Yes ___ No	___Yes ___ No
□ Ensure compliance with fire safety and other requirements related to dispenser locations	___Yes ___ No	___Yes ___ No
□ Cleaning of hand hygiene product dispensers	___Yes ___ No	___Yes ___ No
□ Evaluation of products (manufacturer information such as cost; product information; interactions with products, skin care, etc)	___Yes ___ No	___Yes ___ No
□ Routinely monitoring hand hygiene product dispensers and facilities to check availability and condition	___Yes ___ No	___Yes ___ No

b. **Responsibilities for training and education**

□ **Responsibilities are specified for hand hygiene training and education**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
□ Development of content for hand hygiene indications, techniques	___Yes ___ No	___Yes ___ No
□ Development of training and educational materials such as posters, flyers, other visual aids (to ensure/cue/promote use of appropriate procedure/protocol)	___Yes ___ No	___Yes ___ No
□ Delivery of hand hygiene training and education at orientation	___Yes ___ No	___Yes ___ No
□ Delivery of hand hygiene training and education at ongoing intervals (e.g., annually, staff meetings, regular communications such as newsletters)	___Yes ___ No	___Yes ___ No
□ Development of content for observational hand hygiene compliance training/education (e.g., how to conduct direct/observational audits)	___Yes ___ No	___Yes ___ No
□ Delivery of observational hand hygiene compliance training/education	___Yes ___ No	___Yes ___ No

c. **Responsibilities for additional policy elements**

☐ **Responsibilities are specified for skin health issues**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability defined
☐ Taking action/seeking advice for skin health issues	___Yes ___ No	___Yes ___ No
☐ Reporting hand hygiene product concerns	___Yes ___ No	___Yes ___ No
☐ Responding to and evaluating skin health issues	___Yes ___ No	___Yes ___ No

d. **Responsibilities for monitoring compliance with skills/techniques included in policy**

□ **Responsibilities are specified for monitoring compliance with hand hygiene practices**

Policy element	Responsibility specified	Accountability defined
□ Coordination of hand hygiene compliance monitoring – how and when hand hygiene monitoring will be carried out (e.g., methods [observation, product use evaluation], frequency, data collection/compilation, data summaries)	___Yes ___ No	___Yes ___ No
□ Monitor compliance with hand hygiene practices (e.g., observational and product use methods)	___Yes ___ No	___Yes ___ No
□ Development of hand hygiene compliance goals (e.g., observational and product use methods)	___Yes ___ No	___Yes ___ No
□ Development of methods to measure compliance with hand hygiene (e.g., observational audits, product use audits)	___Yes ___ No	___Yes ___ No
□ Development of recognition process for units/areas/departments that meet/surpass hand hygiene compliance goals	___Yes ___ No	___Yes ___ No
□ Development of process for units/areas/ departments that fail to meet hand hygiene compliance goals	___Yes ___ No	___Yes ___ No
□ Development of corrective action process for individuals that fail to meet hand hygiene compliance goals	___Yes ___ No	___Yes ___ No
□ Development of recognition process for individuals that meet/surpass hand hygiene compliance goals	___Yes ___ No	___Yes ___ No
□ Monitor compliance with hand hygiene training/education as required	___Yes ___ No	___Yes ___ No
□ Development of process for individuals that fail to meet training/education compliance goals	___Yes ___ No	___Yes ___ No
□ Development of a process to monitor hand hygiene product dispensers and facilities to check availability and condition	___Yes ___ No	___Yes ___ No
□ Routine monitoring of hand hygiene product dispensers and facilities to check availability and condition (e.g., conduct environmental audits)	___Yes ___ No	___Yes ___ No
□ Results from hand hygiene monitoring are communicated to facility leadership at regular intervals	___Yes ___ No	___Yes ___ No
□ Results from observational hand hygiene monitoring are communicated to staff at the individual level (e.g., individual non-compliance communicated to staff)	___Yes ___ No	___Yes ___ No
□ Results from observational hand hygiene monitoring are communicated to staff at the unit/area/ department level (e.g., unit/area/ department non-compliance communicated to staff)	___Yes ___ No	___Yes ___ No

____ Yes ___ No

Score: _____

□	Results (aggregated) from observational hand hygiene monitoring are publicized (e.g., posted on a dashboard, scorecard, staff information board, etc)	___Yes ___ No	___Yes ___ No

4. Enforcement section	
Administration / Governing body	
a. A governance structure is in place to enforce the policy, which may be a component of a broader organization program. For hand hygiene, this may include: ☐ Committee/task force/working group – to devise and oversee policy, program ☐ Organization goal for hand hygiene compliance is established ☐ Hand hygiene performance indicators are specified ☐ Administrative support is specified for staff compliance with hand hygiene ☐ Administrative support is specified for the resources needed to carry out effective hand hygiene ☐ Administrative support is specified for dedicated staff time for hand hygiene-related activities such as participation on committees, training/education, monitoring, and/or enforcement activities, etc ☐	____ Yes ___ No Score: _____
b. The governance structure/administration along with the respective workgroup/committee/task force evaluates data to identify strengths, weaknesses, and develop plans for improvement. For hand hygiene, this may include: ☐ Evaluation of hand hygiene practice monitoring (e.g., observational audits; product audits) ☐ Evaluation of hand hygiene program and policy (e.g., policy elements and responsible parties; resource review; education gaps) ☐ Evaluation of hand hygiene environmental audits ☐ Evaluation of skin health issues/complaints ☐ Conduct root cause analyses / systematic evaluation of audit data to identify 1) incidents/systems that result in failures/barriers to comply and 2) areas that are meeting/surpassing goals; to identify strengths and weaknesses; to develop action plans where gaps are identified ☐	____ Yes ___ No Score: _____
c. Performance considers compliance with the policy. For hand hygiene, this may include: ☐ Expectations are specified that hand hygiene compliance is considered/incorporated into the measure of an employee's overall performance	____ Yes ___ No Score: _____
d. Corrective actions/consequences are specified for non-compliance with the policy. For hand hygiene, this may include: ☐ Corrective actions/consequences are specified for units/areas/departments that fail to meet adherence goals (e.g., corrective action plan if below specified goal) ☐ Corrective actions/consequences are specified for individuals that fail to adhere to the hand hygiene policy/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) ☐ Corrective actions/consequences are specified for managers that fail to enforce the hand hygiene policy/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) ☐	____ Yes ___ No Score: _____
e. Expectations for managers to enforce compliance with the policy are specified. For hand hygiene, this may include: ☐ Expectations for managers to enforce compliance with all elements of the policy (e.g., appropriate methods, techniques; skin health; jewelry; nails; etc.) ☐ Expectations for managers or designees to conduct observational practice audits to monitor adherence to hand hygiene ☐ Expectations for managers to provide feedback to staff from observational hand hygiene practice audits ☐ Expectations for managers to enforce requirements for training and education ☐ Expectations for managers to enforce the process for failing to meet with hand hygiene compliance goals	____ Yes ___ No Score: _____

☐ Expectations for managers to enforce the process for meeting/surpassing hand hygiene compliance goals	
f. Expectations for staff to enforce compliance with the policy are specified. For hand hygiene, this may include: ☐ Expectations that all staff are responsible for their own practice compliance ☐ Expectations that all staff are responsible for adhering to the policy ☐ Expectations for all staff members to role model expected practices ☐ Expectations for all staff are specified for situations in which he/she observes non-compliance (e.g., verbal reminder/coaching/speaking up, report incident to appropriate person) ☐ Expectations for staff to educate patients/visitors to practice hand hygiene while in the facility ☐	____ Yes ___ No Score: _____
5. Procedures/protocols	
Protocol/procedure for skills/technique	
a. Protocol/procedure developed with step-by-step instructions for how to comply with skills/techniques specified in policy. For hand hygiene, this may include: ☐ Step-by-step technique is specified for use of alcohol-based hand rub • Indications | Amount | Procedure | Length of time ☐ Step-by-step technique is specified for use of soap and water • Indications | Amount | Procedure | Length of time ☐ Step-by-step technique is specified for use of automated hand hygiene stations • Indications | Amount | Procedure | Length of time ☐ Step-by-step technique is specified for use of surgical prep/scrub • Indications | Amount | Procedure | Length of time ☐ Special circumstances, such as: ○ After caring for patients with *Clostridium difficile* infection/gastrointestinal illness/diarrhea ▪ Indications | How ○ Food preparation ▪ Indications | How ○ Food delivery ▪ Indications | How ○ Medication preparation ▪ Indications | How ○ Handling of trash, linens ▪ Indications | How ○ Cleaning/disinfection ▪ Indications | How ○ Patient transport ▪ Indications | How ☐ Special settings, such as: ○ NICU ▪ Indications | How ○ Nursery ▪ Indications | How ○ Surgery ▪ Indications | How ○ Interventional radiology ▪ Indications | How ○ Catheter lab ▪ Indications | How	____ Yes ___ No Score: _____

Protocol/procedure to measure compliance with policy standards	
b. Protocol/procedure developed with step-by-step instructions for how to measure compliance with skills/techniques specified in policy. For hand hygiene, this may include: □ Protocol developed for observational hand hygiene monitoring	____ Yes ___ No Score: _____
Protocol/procedure to comply with policy expectations, requirements	
c. Protocol/procedure developed with step-by-step instructions for how to comply with specific requirements of the policy. For hand hygiene, this may include: □ Skin health issues procedure/protocol	____ Yes ___ No Score: _____

Descriptive information

Total pages:	
Language used is plain/simple, easy to read	____ Yes _____ No
Audience for the policy is clear	____ Yes _____ No
Related policies referenced	____ Yes _____ No
Specify policies referenced	*Specify*:
Attachments/appendices/supporting or related documents referenced: (e.g., dress code [nails, jewelry], exposure control plan)	____ Yes _____ No
Specify attachments/appendices/supporting or related documents referenced	*Specify*:
Number of pages of attachments/appendices:	
Policy owner/sponsor listed	____ Yes _____ No
Specify policy owner/sponsor	*Specify*:
Language used to describe "responsibility" of policy	Open-ended
Approving body/committee listed	____ Yes _____ No
Specify approving body/committee	*Specify*:
Policy includes the date when policy issued (origin date)	____ Yes _____ No
Date of origin	
Policy includes the date when policy last reviewed/approved	____ Yes _____ No
Date of last review/approval	
Key changes to document are specified following each review	____ Yes _____ No
Policy includes all dates policy was revised	____ Yes _____ No
Policy includes the date of next review	____ Yes _____ No
Next review date	
General notes:	

Policy Evaluation Tool: Multidrug-resistant Organisms/Isolation

Score: 0=nonexistent, 1=cursory, 2=thorough

Section / Policy Element	Score
6. Purpose section	
The purpose provides rationale describing why the subject matter merits formal rules ☐ Purpose of the policy is specified ☐ Rationale is specified (e.g., prevent the spread of infectious diseases) ☐ Desired effects of the policy are specified, such as what the organization hopes to accomplish with this policy; benefits that this policy will deliver to the organization, staff, patients/visitors ☐	____ Yes ___ No Score: _____
7. Policy section	
h. Specific requirements, behavior, regulations (if applicable)	
The policy provides staff with a clear understanding of requirements, regulations (if applicable), and what constitutes appropriate behavior, including expectations and performance objectives ☐ Organizational rules are clearly communicated (e.g., when and how to perform hand hygiene) ☐ A timeline for compliance is specified ☐ Expectation is specified that staff are familiar with and adhere to the policy elements ☐ Contact information is specified to inform staff of who to contact with policy-related questions ☐	____ Yes ___ No Score: _____
i. Scope/audience	
The policy outlines the intended audience for this policy ☐ Policy outlines who is expected to comply with policy ○ Staff, sites, facilities, business units ☐ Policy outlines staff, and under what circumstances (as appropriate), that are not included ☐	____ Yes ___ No Score: _____
j. Definitions	
Key concepts and terms are defined. For the MDRO policy, this may include: ☐ Staff/healthcare workers ☐ MDRO ☐ Infection ☐ Colonization ☐ Decolonization ☐ Personal protective equipment ☐ Active surveillance/screening ☐ Hand hygiene ☐ Contact precautions ☐ Enteric precautions ☐	____ Yes ___ No Score: _____
k. References: scientific rationale / evidence	
References are provided to support policy development, such as: ☐ Regulations ☐ Specific federal or state statute(s) ☐ Standards ☐ Guidelines/recommendations from relevant governmental agencies, professional associations/groups ☐ Published literature ☐ Total:___ ___	____ Yes ___ No Score: _____

l. Expectations for behaviors/actions/practices required comply with the policy	
Expectations for behaviors/actions/practices that are required to comply with the policy are specified. For the MDRO policy, this may include: □ Criteria are outlined to define MDROs □ Expectations are specified that the use of transmission-based precautions will not compromise the quality of patient care □ Expectations are specified for communicable disease exposures □ Expectations are specified for monitoring/tracking and performing risk assessments (i.e., surveillance) for MDRO in the hospital □ Indications are specified for actively identifying/screening patients for MDRO upon admission (e.g., active surveillance testing) □ Expectations are specified for work restrictions/staffing □ Indications are specified for the use of special approaches to prevent transmission in the event of an outbreak or for target patient populations identified by risk assessment or other methods □	____ Yes ___ No Score: _____
m. Expectations for early identification of patients with MDROs	
The policy specifies strategies for early identification of patients with MDROs, such as: □ Active surveillance/screening testing to identify the presence/carriage of MDROs for the purpose of instituting isolation precautions (e.g., nasal swab for MRSA) □	____ Yes ___ No Score: _____
n. Expectations to reduce transmission via barrier precautions	
The policy specifies efforts to reduce transmission via barrier precautions, such as: □ Expectations for indications for transmission-based precautions for MDRO (e.g., indications for the use of contact precautions for patients with MRSA) □ Expectations for the appropriate PPE usage (e.g., gloves, gown, facial protection) □ Expectations are specified that the implementation of transmission-based precautions will be instituted in consultation with the appropriate personnel/department (e.g., infection prevention and control) □ Expectations are specified that the discontinuation of transmission-based precautions will be in consultation with the appropriate personnel/department (e.g., infection prevention and control) □ Specifications for a competency-based training/education program for use of personal protective equipment (PPE) (orientation and annual competencies) □ Expectations are specified for the availability of PPE supplies to ensure compliance with appropriate use □ Expectations are specified for MDRO patient placement – single room or cohort (i.e., isolate the MDRO patient) □ Specifications for restrictions on patient movements while within the facility – personal □ Specifications for restrictions on patient movements while within the facility – surgery / out of room services □	____ Yes ___ No Score: _____
o. Expectations for clear communication regarding MDRO status	
The policy outlines expectations for clear communication regarding MDRO status, such as: □ Expectations for prompt notification of MDRO test results from lab to patient care staff □ Communication of patient status in the medical record – implementation of alerts/flags in the medical record □ Communication of patient status upon entry to patient room – implementation of visual aids (e.g., signage) □ Communication of patient status upon transport internally or to another facility	____ Yes ___ No Score: _____

p. Expectations for patient and visitor education about MDROs	
The policy specifies instructions/education for patients and visitors, such as: □ Education on isolation precautions for patients with MDROs □ Expectations for performing hand hygiene □ Expectations for the use of PPE	____ Yes ___ No Score: _____
q. Expectations for efforts to reduce transmission via patient equipment/supplies	
Efforts to reduce transmission via patient equipment, supplies, medications, etc, such as: □ Specifications for dedicating equipment/supplies where possible □ Specifications for the management of medication for patients with MDROs (i.e., the physical placement, including the handling of medications upon patient discharge – to avoid contamination)	____ Yes ___ No Score: _____
r. Expectations for environmental cleaning/disinfection practices	
Expectations are specified for reliable environmental cleaning/disinfection practices, such as: □ Cleaning/disinfection – patient room □ Cleaning/disinfection – shared patient equipment/supplies □ Specifications for a competency-based training/education program for use of cleaning/disinfection products and protocols □	____ Yes ___ No Score: _____
s. Expectations for the use of decolonization strategies	
Expectations are specified for the use of decolonization strategies, such as: □ Use of daily chlorhexidine bathing □ Use of intranasal decolonization for patients with MRSA □ Not using decolonization strategies (or only in particular situations)	____ Yes ___ No Score: _____
t. Expectations for screening healthcare workers for MDROs	
The policy specifies expectations for screening healthcare workers for MDROs, such as: □ Expectations for routine decolonization of healthcare workers with MDROs □ Expectations for management of healthcare workers with MDROs □ Expectations for testing/screening healthcare workers during a MDRO outbreak/cluster situation □ Expectations for managing healthcare workers, if associated with a MDRO outbreak/cluster situation □ Expectations for decolonization of healthcare workers in MDRO outbreak/cluster situations	____ Yes ___ No Score: _____
u. Expectations to ensure adherence with appropriate precautions	
The policy specifies expectations for monitoring and enforcing practices/skills/techniques required by the policy. For the MDRO policy, this may include: □ Expectations are specified regarding monitoring of compliance with PPE practices o How o By whom □ Expectations are specified regarding enforcement of compliance with PPE practices o How o By whom □ Expectations are specified regarding monitoring of compliance with cleaning/disinfection practices o How o By whom □ Expectations are specified regarding enforcement of compliance with cleaning/disinfection practices o How o By whom	____ Yes ___ No Score: _____

8. Responsibilities section (indicates which parties are responsible for carrying out policy elements and how policy adherence will be ensured)

To ensure staff have the opportunity to be compliant, structural policy elements include parties responsible for carrying out the policy elements and how adherence will be ensured are specified

e. **Responsibilities for equipment/product types, locations, availability**

☐ **Responsibilities are specified for product types, locations, availability**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
☐ Determine appropriate indications, technique for isolation precautions	___Yes ___ No	___Yes ___ No
☐ Determine appropriate products for PPE	___Yes ___ No	___Yes ___ No
☐ Maintenance of PPE product inventory (units/areas; shared spaces)	___Yes ___ No	___Yes ___ No
☐ Ordering of PPE products	___Yes ___ No	___Yes ___ No
☐ Storage of PPE products	___Yes ___ No	___Yes ___ No
☐ Determination of appropriate PPE locations	___Yes ___ No	___Yes ___ No
☐ Evaluation of PPE products (manufacturer information such as cost; product information; etc)	___Yes ___ No	___Yes ___ No
☐ Routinely monitoring PPE availability	___Yes ___ No	___Yes ___ No

f. **Responsibilities for training and education**

☐ **Responsibilities are specified for PPE training and education**

____ Yes ___ No

Score: _____

* Staff who are involved in direct patient care may need a different type of training than EVS, dietary staff, etc

Policy element	Responsibility specified	Accountability specified
☐ Development of content for isolation indications, techniques	___Yes ___ No	___Yes ___ No
☐ Development of training and educational materials such as posters, flyers, other visual aids (to ensure/cue/promote use of appropriate procedure/protocol)	___Yes ___ No	___Yes ___ No
☐ Delivery of PPE education at orientation	___Yes ___ No	___Yes ___ No
☐ Delivery of PPE training and education at ongoing intervals (e.g., annually, staff meetings, regular communications such as newsletters, etc)	___Yes ___ No	___Yes ___ No
☐ Development of content for observational PPE compliance training/education (e.g., how to conduct direct/observational PPE audits)	___Yes ___ No	___Yes ___ No
☐ Delivery of observational PPE compliance training/education	___Yes ___ No	___Yes ___ No

g. **Responsibilities for additional policy elements**

☐ **Responsibilities are specified for managing healthcare workers with MDROs or involved in MDRO outbreak/cluster situations**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability defined
☐ Assessment of healthcare workers with MDROs	___Yes ___ No	___Yes ___ No

h. **Responsibilities for monitoring compliance with skills/techniques included in policy**

□ **Responsibilities are specified for monitoring compliance with PPE practices**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability defined
□ Initiating MDRO isolation precautions	___Yes ___ No	___Yes ___ No
□ Discontinuing MDRO isolation precautions	___Yes ___ No	___Yes ___ No
□ Coordination of hand hygiene compliance monitoring – how and when hand hygiene monitoring will be carried out (e.g., methods, frequency, data collection/compilation, data summaries)	___Yes ___ No	___Yes ___ No
□ Monitor compliance with PPE practices (e.g., observational and product use methods)	___Yes ___ No	___Yes ___ No
□ Development of PPE compliance goals (e.g., observational and product use methods)	___Yes ___ No	___Yes ___ No
□ Development of methods to measure compliance with PPE use (e.g., direct observational audits)	___Yes ___ No	___Yes ___ No
□ Development of recognition process for units/areas/departments that meet/surpass PPE compliance goals	___Yes ___ No	___Yes ___ No
□ Development of process for units/areas/ departments that fail to meet PPE compliance goals	___Yes ___ No	___Yes ___ No
□ Development of corrective action process for individuals that fail to meet PPE compliance goals	___Yes ___ No	___Yes ___ No
□ Development of recognition process for individuals that meet/surpass PPE compliance goals	___Yes ___ No	___Yes ___ No
□ Monitor compliance with PPE training/education as required	___Yes ___ No	___Yes ___ No
□ Development of process for individuals that fail to meet training/education compliance goals	___Yes ___ No	___Yes ___ No
□ Development of a process to monitor PPE supplies to check availability and condition	___Yes ___ No	___Yes ___ No
□ Routine monitoring of PPE supplies product to check availability and condition (e.g., conduct environmental audits)	___Yes ___ No	___Yes ___ No
□ Results from PPE use monitoring are communicated to facility leadership at regular intervals	___Yes ___ No	___Yes ___ No
□ Results from observational PPE monitoring are communicated to staff at the individual level (e.g., individual non-compliance communicated to staff)	___Yes ___ No	___Yes ___ No
□ Results from observational PPE monitoring are communicated to staff at the unit/area/ department level (e.g.,	___Yes ___ No	___Yes ___ No

	unit/area/ department non-compliance communicated to staff)		
□	Results (aggregated) from observational PPE monitoring are publicized (e.g., posted on a dashboard, scorecard, staff information board, etc)	___Yes ___ No	___Yes ___ No

9. Enforcement section	
Administration / Governing body	
a. A governance structure is in place to enforce the policy, which may be a component of a broader organization program. For MDROs, this may include: ☐ Committee/task force/working group – to devise and oversee policy, program ☐ Organization goal for PPE compliance is established ☐ Performance indicators are specified for appropriate PPE use ☐ Administrative support is specified for staff compliance with appropriate PPE use ☐ Administrative support is specified for the resources needed to carry out effective PPE usage ☐ Administrative support is specified for dedicated staff time for MDRO/isolation/PPE use-related activities such as participation on committees, training/education, monitoring, and/or enforcement activities, etc ☐	____ Yes ___ No Score: _____
b. The governance structure/administration along with the respective workgroup/committee/task force evaluates data to identify strengths, weaknesses, and develop plans for improvement. For hand hygiene, this may include: ☐ Evaluation of monitoring (e.g., observational audits) for appropriate PPE use ☐ Evaluation of MDRO program and policy (e.g., policy elements and responsible parties; resource review; education gaps) ☐ Evaluation of PPE environmental audits ☐ Evaluation of PPE issues/complaints ☐ Conduct root cause analyses / systematic evaluation of audit data to identify 1) incidents/systems that result in failures/barriers to comply and 2) areas that are meeting/surpassing goals; to identify strengths and weaknesses; to develop action plans where gaps are identified ☐	____ Yes ___ No Score: _____
c. Performance considers compliance with the policy. For MDROs, this may include: ☐ Expectations are specified that PPE compliance is considered/incorporated into the measure of an employee's overall performance	____ Yes ___ No Score: _____
d. Corrective actions/consequences are specified for non-compliance with the policy. For MDROs, this may include: ☐ Corrective actions/consequences are specified for units/areas/departments that fail to meet adherence goals (e.g., corrective action plan if below specified goal) ☐ Corrective actions/consequences are specified for individuals that fail to adhere to the policy/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) ☐ Corrective actions/consequences are specified for managers that fail to enforce the policy/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) ☐	____ Yes ___ No Score: _____
e. Expectations for managers to enforce compliance with the policy are specified. For MDROs, this may include: ☐ Expectations for managers to enforce compliance with all elements of the policy (e.g., appropriate methods, techniques) ☐ Expectations for managers or designees to conduct observational practice audits to monitor adherence with appropriate PPE use ☐ Expectations for managers to provide feedback to staff from observational PPE practice audits ☐ Expectations for managers to enforce requirements for training and education ☐ Expectations for managers to enforce the process for failing to meet with PPE compliance goals ☐ Expectations for managers to enforce the process for meeting/surpassing PPE compliance goals	____ Yes ___ No Score: _____

f. Expectations for staff to enforce compliance with the policy are specified. For MDROs, this may include: ☐ Expectations that all staff are responsible for their own practice compliance ☐ Expectations that all staff are responsible for adhering to the policy ☐ Expectations for all staff members to role model expected practices ☐ Expectations for all staff are specified for situations in which he/she observes non-compliance (e.g., verbal reminder/coaching/speaking up, report incident to appropriate person) ☐ Expectations for staff to educate patients/visitors to perform hand hygiene and comply with PPE requirements (if applicable) while in the facility ☐	____ Yes ___ No Score: _____
10. Procedures/protocols	
Protocol/procedure for skills/technique	
a. Protocol/procedure developed with step-by-step instructions for how to comply with skills/techniques specified in policy. For MDROs, this may include: ☐ Step-by-step technique is specified for use of PPE • Indications | Procedure ☐ Step-by-step technique is specified for collection of screening/surveillance tests • Indications | Procedure ☐ Step-by-step technique is specified for room assignment (isolating/cohorting) • Indications | Procedure ☐ Step-by-step technique is specified for patient activity outside of room • Indications | Procedure ☐ Step-by-step technique is specified for discontinuing Contact Precautions • Indications | Procedure ☐ Special circumstances, such as: ○ Food delivery ▪ Indications | How ○ Cleaning/disinfection ▪ Indications | How ○ Patient transport ▪ Indications | How ☐ Special settings, such as: ○ Surgery ▪ Indications | How ○ Dialysis ▪ Indications | How ○ Physical therapy/occupational therapy ▪ Indications | How ○ Behavioral health ▪ Indications | How ☐	____ Yes ___ No Score: _____
Protocol/procedure to measure compliance with policy standards	
b. Protocol/procedure developed with step-by-step instructions for how to measure compliance with skills/techniques specified in policy. For hand hygiene, this may include: ☐ Protocol developed for observational hand hygiene monitoring ☐	____ Yes ___ No Score: _____
Protocol/procedure to comply with policy expectations, requirements	
c. Protocol/procedure developed with step-by-step instructions for how to comply with specific requirements of the policy. For hand hygiene, this may include: ☐ Instructions for implementing transmission-based precautions for MDRO (e.g., contact, enteric) – (private room/cohorting, signage, use of PPE, hand hygiene) ☐ Instructions for specific MDRO	____ Yes ___ No Score: _____

○ MRSA ○ VRE ○ CDI ○ Multidrug-Resistant Gram-Negative Rods (e.g., extended spectrum beta-lactamase (ESBL), carbapenamase-producing *Enterobacteriaceae* (CRE)) ○ *Staphylococcus aureus* with reduced susceptibility to vancomycin (VISA and VRSA) ○ Outbreak situations ☐ Instructions for transporting patients with MDRO ☐ Isolation signage in the management of patients with MDRO ☐ Instructions for monitoring/tracking/surveillance for MDRO in the hospital ☐	

Descriptive information

Total pages:	
Language used is plain/simple, easy to read	____ Yes _____ No
Audience for the policy is clear	____ Yes _____ No
Related policies referenced	____ Yes _____ No
Specify policies referenced	*Specify*:
Attachments/appendices/supporting or related documents referenced: (e.g., dress code [nails, jewelry], exposure control plan)	____ Yes _____ No
Specify attachments/appendices/supporting or related documents referenced	*Specify*:
Number of pages of attachments/appendices:	
Policy owner/sponsor listed	____ Yes _____ No
Specify policy owner/sponsor	*Specify*:
Language used to describe "responsibility" of policy	Open-ended
Approving body/committee listed	____ Yes _____ No
Specify approving body/committee	*Specify*:
Policy includes the date when policy issued (origin date)	____ Yes _____ No
Date of origin	
Policy includes the date when policy last reviewed/approved	____ Yes _____ No
Date of last review/approval	
Key changes to document are specified following each review	____ Yes _____ No
Policy includes all dates policy was revised	____ Yes _____ No
Policy includes the date of next review	____ Yes _____ No
Next review date	
General notes:	

Policy Evaluation Tool: Healthcare Personnel Influenza Vaccination

Score: 0=nonexistent, 1=cursory, 2=thorough

A. Healthcare Personnel Influenza Vaccination Policy description
Stand alone policy or included in another policy? _____ [2= stand alone; 1= included in another policy; 0= not a policy (e.g., incorporated into an infection control program]

Describe:
_____

Section / Policy Element	Score
1. Purpose section	
The purpose provides rationale describing why the subject matter merits formal rules ☐ Purpose of the policy is specified ☐ Rationale is specified (e.g., prevent the spread of infectious diseases, maintain a critical workforce during outbreaks) ☐ Desired effects of the policy are specified, such as what the organization hopes to accomplish with this policy; benefits that this policy will deliver to the organization, staff, patients/visitors ☐	____ Yes ___ No Score: _____
2. Policy section	
a. Specific requirements, behavior, regulations (if applicable)	
The policy provides staff with a clear understanding of requirements, regulations (if applicable), and what constitutes appropriate behavior, including expectations and performance objectives ☐ Organizational rules are clearly communicated ☐ A timeline for compliance is specified ☐ Expectation is specified that staff are familiar with and adhere to the policy elements ☐ Contact information is specified to inform staff of who to contact with policy-related questions ☐	____ Yes ___ No Score: _____
b. Scope/audience	
The policy outlines the intended audience for this policy ☐ Policy outlines who is expected to comply with policy o Staff, sites, facilities, business units o Non-staff such as volunteers, vendors, contract workers, independent practitioners, students, etc ☐ Policy outlines staff/healthcare personnel, and under what circumstances (as appropriate), that are not included ☐ Policy outlines expectations for non-staff healthcare personnel (e.g., contracted personnel and vendors) (e.g., required to show proof of immunization as described in their contracts and in the vendor management system) ☐	____ Yes ___ No Score: _____
c. Definitions	
Key concepts and terms are defined. For the Healthcare Personnel Influenza Vaccination policy, this may include: ☐ Staff/healthcare personnel ☐ Infection ☐ Colonization ☐ Influenza ☐ Influenza season	____ Yes ___ No Score: _____

d. References: scientific rationale / evidence	
References are provided to support policy development, such as: □ Regulations □ Specific federal or state statute(s) □ Standards □ Guidelines/recommendations from relevant governmental agencies, professional associations/groups □ Published literature □ Total:_____	____ Yes ___ No Score: _____
e. Expectations for educating healthcare personnel about policy topic	
Expectations are specified for educating healthcare personnel about the policy topic. For the Healthcare Personnel Influenza Vaccination policy, this may include**:** □ General influenza education addresses topics, such as: o Influenza virus (e.g., epidemiology, signs/symptoms of illness, diagnosis, transmission) o Potential impact/severity of influenza for healthcare personnel and their patients o Influenza vaccine o Nonvaccine control and prevention measures for influenza (e.g., antiviral medications, isolation precautions, hand hygiene, etc) o Staying home from work when experiencing influenza-like illness □ Influenza education is integrated into multiple educational opportunities, such as: o New Employee Orientation o Annual Infection Control Training module o Unit and department-level education and skills review o Other staff meetings and presentations by request o Periodic communications regarding influenza prevention □	____ Yes ___ No Score: _____
f. Expectations for hospital-level strategies for the prevention of influenza within the facility	
The policy specifies strategies for prevention of influenza within the facility [*hospital level*], such as: For the Healthcare Personnel Influenza Vaccination policy, this may include: □ Expectation that the hospital sets an expectation for influenza vaccination (e.g., receive an annual influenza vaccination or provide an approved exception) o Expectation for the hospital to inform healthcare personnel about vaccination expectations/requirements, procedures, policies, and timeline for compliance o Expectation that hospital defines vaccination exceptions/exemptions deemed acceptable to be compliant by the policy/program (e.g., religious, medical) □ Specifications for strategies to make vaccine accessible to healthcare personnel in order to be compliant with the policy, such as: o Annual influenza vaccination is offered to healthcare personnel by the hospital o Organized campaigns are used to promote influenza vaccination o Efforts are made to reach personnel about program, such as email, articles, posters, announcements [*single vs multiple attempts*] ▪ Email ▪ Articles (newsletters, intranet, etc) ▪ Posters (public spaces, staff-only spaces, etc) ▪ Announcements (staff meetings, organization-wide meetings, etc) o Influenza vaccine is made easily accessible using multiple modes to reach personnel with vaccination opportunities, such as: [*single vs multiple modes*] ▪ Mobile/rolling carts	____ Yes ___ No Score: _____

▪ Vaccination clinics ▪ Off-hours vaccination clinics ▪ Vaccination offered in department/unit meetings ▪ Staff that act as a resource for staff, educating and providing vaccinations in their practice areas [flu "deputies," "captains," etc] ○ Role models are used to promote vaccine through visible vaccination of leaders, senior medical staff, opinion leaders, etc ○ Incentives offered for receiving influenza vaccination ○ Vaccine provided at no cost to healthcare personnel ○	
g. Expectations for behaviors/actions/practices required to comply with the policy	
Expectations for behaviors/actions/practices that are required to comply with the policy are specified. For the Healthcare Personnel Influenza Vaccination policy, this may include: ☐ Expectations are specified for healthcare personnel that receive vaccination ○ Specifications are provided about the time frame for compliance to receive an annual influenza vaccination ○ Expectations are specified for healthcare personnel that receive vaccination off-site (private clinic, etc) (e.g., provide receipt/proof of vaccination to the hospital) ☐ Expectations for healthcare personnel that refuse vaccine ○ Expectations are specified for healthcare personnel that decline influenza vaccination, if applicable (e.g., process/procedure for vaccination declinations, facemask required when providing patient care, restricted access, lose privileges, not permitted to provide patient care during influenza season, etc) ☐ Expectations for healthcare personnel that decline vaccine for allowable reasons ○ Expectations for staff with approved exceptions, if applicable (e.g., facemask required when providing patient care, etc)	____ Yes ___ No Score: _____ ____ Yes ___ No Score: _____ ____ Yes ___ No Score: _____
h. Expectations for monitoring and enforcing practices/skills/techniques required by the policy	
The policy specifies expectations for monitoring and enforcing practices/skills/techniques required by the policy. For the Healthcare Personnel Influenza Vaccination policy, this may include: ☐ Expectations are specified regarding monitoring of compliance with influenza vaccination expectations ○ How ○ By whom ☐ Expectations are specified regarding enforcement of compliance with influenza vaccination expectations ○ How ○ By whom	____ Yes ___ No Score: _____
3. Responsibilities section (indicates which parties are responsible for carrying out policy elements and how policy adherence will be ensured) To ensure staff have the opportunity to be compliant, structural policy elements include parties responsible for carrying out the policy elements and how adherence will be ensured are specified	

a. **Responsibilities for equipment/product types, locations, availability**

□ Responsibilities are specified for product types, locations, availability

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
□ Determine appropriate influenza vaccination products	___Yes ___ No	___Yes ___ No
□ Determine appropriate influenza vaccination products to supply vaccine clinics/stations/carts, if applicable	___Yes ___ No ___ N/A	___Yes ___ No
□ Order influenza vaccination products/supplies	___Yes ___ No	___Yes ___ No

b. **Responsibilities for training and education**

□ Responsibilities are specified for influenza training and education

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
□ Development of educational content	___Yes ___ No	___Yes ___ No
□ Development of educational/promotional materials such as posters, flyers, other visual aids	___Yes ___ No	___Yes ___ No
□ Delivery of influenza education at orientation	___Yes ___ No	___Yes ___ No
□ Delivery of influenza training and education at ongoing intervals (e.g., annually, staff meetings, regular communications such as newsletters, etc)	___Yes ___ No	___Yes ___ No
□ Dissemination of educational/promotional materials such as posters, flyers, other visual aids (to ensure/cue/promote use of appropriate procedure/protocol)	___Yes ___ No	___Yes ___ No

c. **Responsibilities for additional elements included in the policy**

☐ Responsibilities are specified for coordination of the implementation of the policy

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
☐ Determine policy requirements and timelines (e.g., whether vaccine will be mandated/voluntary, etc)	___Yes ___ No	___Yes ___ No
☐ Dissemination of policy to personnel	___Yes ___ No	___Yes ___ No
☐ Develop disciplinary procedures for noncompliant staff, if applicable	___Yes ___ No	___Yes ___ No
☐ Enforce mask-wearing provision of the policy, if applicable	___Yes ___ No	___Yes ___ No
☐ Administer influenza vaccine	___Yes ___ No	___Yes ___ No
☐ Development of a system/method to document influenza vaccination receipt outside of the formal employee vaccination program	___Yes ___ No	___Yes ___ No
☐ Review of submitted vaccine exemptions for approval	___Yes ___ No	___Yes ___ No
☐ Communication of personnel with an approved vaccination exemption to unit/department managers who need to wear a mask a	___Yes ___ No	___Yes ___ No
☐ Maintaining records of influenza vaccinations (on-site and off-site)	___Yes ___ No	___Yes ___ No
☐ Communication of influenza vaccination and compliance rates to stakeholders	___Yes ___ No	___Yes ___ No
☐ Management and evaluation of personnel exposed to influenza	___Yes ___ No	___Yes ___ No
☐ Content expert – stays knowledgeable about current influenza recommendations such as infection prevention and control, vaccine supply	___Yes ___ No	___Yes ___ No
☐ Development of a vaccine delay or shortage contingency plan (e.g., distribution plan for available vaccine, PPE considerations, etc)	___Yes ___ No	___Yes ___ No
☐ Coordination of vaccine clinics/access points	___Yes ___ No	___Yes ___ No

d. **Responsibilities for monitoring compliance with skills/techniques included in policy**

☐ Responsibilities are specified for monitoring compliance with influenza vaccination practices

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability defined
☐ Development/maintenance of a process to monitor compliance with influenza vaccination (e.g., vaccinations obtained on-site and off-site)	___Yes ___ No	___Yes ___ No

☐	Development of influenza vaccination compliance goals	___Yes ___ No	___Yes ___ No
☐	Development of methods to measure influenza vaccination/conduct influenza surveillance for healthcare personnel (e.g., National Healthcare Safety Network, state registries)	___Yes ___ No	___Yes ___ No
☐	Development of recognition process for units/areas/departments that meet/surpass compliance goals	___Yes ___ No	___Yes ___ No
☐	Development of process for units/areas/ departments that fail to meet compliance goals	___Yes ___ No	___Yes ___ No
☐	Development of corrective action process for individuals that fail to meet influenza vaccination compliance goals	___Yes ___ No	___Yes ___ No
☐	Monitor compliance with influenza vaccination training/education, as required	___Yes ___ No	___Yes ___ No
☐	Development of process for individuals that fail to meet training/education compliance goals	___Yes ___ No	___Yes ___ No
☐	Development of a process to monitor influenza vaccination supplies to check availability and condition	___Yes ___ No	___Yes ___ No
☐	Routine monitoring of PPE use in individuals granted an exemption, if applicable (e.g., audit surgical mask use)	___Yes ___ No ___ N/A	___Yes ___ No
☐	Results from observational PPE monitoring in individuals granted an exemption are communicated to staff at the unit/area/ department level (e.g., unit/area/ department non-compliance communicated to staff)	___Yes ___ No	___Yes ___ No
☐	Influenza vaccination results (aggregated) are publicized (e.g., posted on a dashboard, scorecard, staff information board, etc)	___Yes ___ No	___Yes ___ No

4. Enforcement section	
Administration / Governing body	
a. A governance structure is in place to enforce the policy, which may be a component of a broader organization program. For influenza vaccination, this may include: ☐ Committee/task force/working group – to devise and oversee policy, program ☐ Organization goal for influenza vaccination compliance is established ☐ Performance indicators are specified for influenza vaccination compliance ☐ Administrative support is specified for staff compliance with influenza vaccination ☐ Administrative support is specified for the resources needed to carry out an effective influenza vaccination program ☐ Administrative support is specified for dedicated staff time for influenza vaccination-related activities such as participation on committees, training/education, monitoring, and/or enforcement activities, etc ☐	____ Yes ___ No Score: _____
b. The governance structure/administration along with the respective workgroup/committee/task force evaluates data to identify strengths, weaknesses, and develop plans for improvement. For influenza vaccination, this may include: ☐ Evaluation of monitoring for compliance with influenza vaccination expectations ☐ Evaluation of influenza vaccination program and policy (e.g., policy elements and responsible parties; resource review; education gaps) ☐ Evaluation of PPE use in individuals granted an exemption ☐ Conduct root cause analyses / systematic evaluation of audit data to identify 1) incidents/systems that result in failures/barriers to comply and 2) areas that are meeting/surpassing goals; to identify strengths and weaknesses; to develop action plans where gaps are identified ☐	____ Yes ___ No Score: _____
c. Performance considers compliance with the policy. For influenza vaccination, this may include: ☐ Expectations are specified that influenza vaccination compliance is considered/incorporated into the measure of an employee's overall performance	____ Yes ___ No Score: _____
d. Corrective actions/consequences are specified for non-compliance with the policy. For influenza vaccination, this may include: ☐ Corrective actions/consequences are specified for individuals that fail to adhere to the policy/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) ☐ Corrective actions/consequences are specified for managers that fail to enforce the policy/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) ☐	____ Yes ___ No Score: _____
e. Expectations for managers to enforce compliance with the policy are specified. For influenza vaccination, this may include: ☐ Expectations for managers to enforce compliance with all elements of the policy ☐ Expectations for managers or designees to conduct observational practice audits to monitor adherence with appropriate PPE use for individuals granted an exemption ☐ Expectations for managers to provide feedback to staff from observational PPE practice audits for individuals granted an exemption ☐ Expectations for managers to enforce requirements for training and education ☐ Expectations for managers to enforce the process for failing to meet with influenza vaccination compliance goals ☐ Expectations for managers to enforce the process for meeting/surpassing influenza vaccination compliance goals	____ Yes ___ No Score: _____

5. Procedures/protocols	
Protocol/procedure to monitor compliance with policy	
a. Protocol/procedure developed with instructions for how to monitor compliance with skills/techniques specified in policy. For influenza vaccination, this may include: ☐ Protocol developed for vaccine monitoring	____ Yes ___ No Score: _____
Protocol/procedure to comply with policy expectations, requirements	
b. Protocols/procedures developed with instructions for how to comply with specific requirements of the policy. For influenza vaccination, this may include: ☐ Procedure for obtaining vaccination on-site in the hospital ☐ Protocol for submitting written documentation of vaccine obtained outside of the hospital ☐ Process/protocol for submitting a request for vaccination declination ☐ Process/protocol for obtaining/requesting a permissible exception, with timeline ☐ Protocol for individuals granted an exemption (e.g., mask use, etc), if applicable ☐ Plan/protocol for vaccine shortage prioritization ☐	____ Yes ___ No Score: _____

Descriptive information

Total pages:	
Language used is plain/simple, easy to read	____ Yes _____ No
Audience for the policy is clear	____ Yes _____ No
Related policies referenced	____ Yes _____ No
Specify policies referenced	*Specify*:
Attachments/appendices/supporting or related documents referenced: (e.g., dress code [nails, jewelry], exposure control plan)	____ Yes _____ No
Specify attachments/appendices/supporting or related documents referenced	*Specify*:
Number of pages of attachments/appendices:	
Policy owner/sponsor listed	____ Yes _____ No
Specify policy owner/sponsor	*Specify*:
Language used to describe "responsibility" of policy	Open-ended
Approving body/committee listed	____ Yes _____ No
Specify approving body/committee	*Specify*:
Policy includes the date when policy issued (origin date)	____ Yes _____ No
Date of origin	
Policy includes the date when policy last reviewed/approved	____ Yes _____ No
Date of last review/approval	
Key changes to document are specified following each review	____ Yes _____ No
Policy includes all dates policy was revised	____ Yes _____ No
Policy includes the date of next review	____ Yes _____ No
Next review date	
General notes:	

Policy Evaluation Tool: Whistleblower Policy

Score: 0=nonexistent, 1=cursory, 2=thorough

Section / Policy Element	Score
1. Purpose section	
The purpose provides rationale describing why the subject matter merits formal rules ☐ Purpose of the policy is specified, such as: o Encourage workers to raise concerns o Prevent non-compliance o Instructions for reporting violations, conducting investigations, and protecting workers o Demonstrate commitment and exercise due diligence in seeking to prevent and detect systemic problems and violations of law by developing and sustaining a rigorous Compliance Plan o Provide a road map to the facility's compliance efforts in an effort to prevent non-compliance, including instructions for reporting violations, investigations, and protecting workers ☐ Rationale is specified (e.g., uphold professional and ethical standards in the conduct of their duties/responsibilities; uphold standards of ethics, efficiency, and conduct; provide services pursuant to the highest ethical, business and legal standards) ☐ Desired effects of the policy are specified, such as what the organization hopes to accomplish with this policy and benefits that the policy will deliver to the organization, staff, patients/visitors – such as compliance efforts are designed to: o Strengthen a culture that promotes prevention, detection and resolution of instances of conduct that do not conform to federal and state law and federal, state and private payor healthcare program requirements, regulations, accrediting bodies, the facility's code of conduct and policies o Perpetuate a culture within the Health System that promotes prevention, detection and resolution of instances of conduct that do not conform to federal, state, and local laws and federal, state and private payor health care program requirements ☐	____ Yes ___ No Score: _____
2. Policy section	
a. Specific requirements, behavior, regulations (if applicable)	
The policy provides staff with a clear understanding of requirements, regulations (if applicable), and what constitutes appropriate behavior, including expectations and performance objectives ☐ Organizational rules are clearly communicated (e.g., what to report, how to report violations, how reports will be handled, worker protections) ☐ Timelines for compliance are specified o Reporting o Conducting investigations o Providing resolutions ☐ A timeline for compliance is specified for the person(s) responsible for investigation ☐ A timeline for resolution is specified for the person(s) responsible for investigation ☐ Contact information is specified to inform staff of who to contact with policy-related questions ☐	____ Yes ___ No Score: _____
b. Scope/audience	
The policy outlines the intended audience for this policy ☐ Policy outlines who is expected to comply with policy ☐ Policy complements compliance policies and procedures (such as the Conflict of Interest Policy, the Physician Non-Monetary Compensation Policy, the Physician Personal Services Arrangement Payment Policy, the Federal and State False	____ Yes ___ No Score: _____

Claims Act and Whistleblower Protection Policy, the Physician Contracting Policy and the Medicare Part D Compliance Supplement)	
c. Definitions	
Key concepts and terms are defined. For the whistleblower policy, this may include: □ Staff/healthcare personnel □ Compliance □ Non-compliance □	____ Yes ___ No Score: _____
d. References: scientific rationale / evidence	
References are provided to support policy development, such as: □ Regulations □ Specific federal or state statute(s) □ Federal or state laws □ Standards □ Guidelines/recommendations from relevant governmental agencies, professional associations/groups □ Published literature □ Total:_____ □	____ Yes ___ No Score: _____
e. Expectations are specified for educating healthcare personnel about the policy topic.	
Expectations are specified for educating healthcare personnel about the policy topic. For the whistleblower policy, this may include: □ General compliance education/training addresses topics, such as: o Regulations o Specific federal or state statute(s) o Federal or state laws o Standards o Policies □ Compliance education is integrated into multiple educational opportunities, such as: o New Employee Orientation o Annual training o Unit and department-level education and skills review o Other staff meetings and presentations by request o Periodic communications □ Efforts are made to reach personnel about program, such as email, articles, posters, announcements [*single vs multiple attempts*] o Email o Articles (newsletters, intranet, etc) o Posters (public spaces, staff-only spaces, etc) o Announcements (staff meetings, organization-wide meetings, etc)	____ Yes ___ No Score: _____
f. Expectations for hospital-level strategies	
Expectations for hospital-level strategies for whistleblower/compliance Expectations for reporting □ Expectation that workers have a responsibility, and are expected, to promptly report instances of actual or suspected non-compliance with laws, regulations, and policies of which they become aware □ Expectation of workers to demonstrate commitment, cooperation, understanding of whistleblower policy o Signed document o Specifics for roles (required for all roles?) □ Instructions/process for reporting □ Multiple access points to whistleblower/compliance program o Compliance committee o Access to managers/leaders	____ Yes ___ No Score: _____

○ Suggestion/mail box ○ Phone number/hotline for reporting ○ Email/website for reporting ○ Anonymous method Expectations for investigating reports ☐ Expectation of workers to cooperate in investigations of any reported violation ☐ Expectation of hospital to have an investigation process in place to conduct investigations ☐ Expectation that those responsible for investigating reports do so in a prompt manner ☐ Expectation that those responsible for investigating reports do so in a discreet manner ☐ Expectation that those responsible for investigating reports provide timely resolutions Expectations for protecting workers ☐ Expectation that workers may report instances of actual or suspected non-compliance in confidence and without fear of retaliation or retribution ☐ Expectation that hospital has a process to assure workers that instances of actual or suspected non-compliance can be reported in confidence and without fear of retaliation or retribution ☐ Expectation that hospital has a process to ensure reports of suspected or actual violations will be kept confidential to the extent possible, with the understanding that confidentiality may not be maintained where identification is required by law or in order to enable the organization or law enforcement to conduct an adequate investigation Expectations for oversight ☐ Expectation for oversight of whistleblower/compliance program operations ☐ Expectation that hospital has designated an employee charged with the responsibility of the development, implementation, communication and monitoring of the whistleblower/compliance program (e.g., compliance officer) ☐ Expectation that hospital has designated a group/body charged with the responsibility of operating the whistleblower/compliance program (compliance committee, board of trustee, other authoritative body) ☐ Expectation that, through a screening process of all prospective contracted and employed applicants, the hospital will not knowingly employ or retain persons with any prior history of non-compliance with laws, regulations and applicable policies as well as exclusion or sanctions from Federal health care programs. A proactive screening process may occur on a regular basis. ○ Intentional or repeated unintentional legal violations, dishonesty, non-disclosures and other acts and omissions (including compliance training sessions) of current employees which violate the letter or spirit of this Compliance Plan are considered equally significant. ☐ Expectation that the hospital has developed compliance program roles and responsibilities related to the governance structure of the program ☐ Expectation that the leadership will hold workers accountable for non-compliance, per policy ☐ Expectation that the leadership will enforce the policy ☐ Expectation that the leadership will report instances of non-compliance externally, as appropriate	____ Yes ___ No Score: _____ ____ Yes ___ No Score: _____ ____ Yes ___ No Score: _____
g. Expectations for behaviors/actions/practices that are required to comply with the policy	

Expectations for behaviors/actions/practices that are required to comply with the policy are specified. For the whistleblower policy, this may include: ☐ Expectation that workers are aware of and commit to following processes in place for reporting instances of actual or suspected non-compliance	____ Yes ___ No Score: _____
h. Expectations for monitoring and enforcing adherence to the policy	
The policy outlines expectations for monitoring and enforcing adherence to the policy. For the whistleblower policy, this may include: ☐ Expectations are specified regarding development of monitoring procedures to assist in ensuring that protocols/procedures are followed, such as a work plan that uses a variety of sources and inputs such as: ○ Internal audits to verify adherence to and awareness of the policy/program ○ Surveys to verify adherence to and awareness of the policy/program ○ Staff interviews ○ Voluntary inquiries ○ Past investigations ○ Audits ○ Outside sources such as authoritative publications from the federal government (e.g., OIG, CMS, Medicare Contractors) ○ CMS coverage decisions ○ Special projects ○ Individual requests ○ Compliance hotline ▪ How ▪ By whom ☐ Expectations are specified for regular evaluations of the effectiveness of the whistleblower policy/compliance program ○ How ○ By whom	____ Yes ___ No Score: _____
3. Responsibilities section (indicates which parties are responsible for carrying out policy elements and how policy adherence will be ensured) To ensure staff have the opportunity to be compliant, structural policy elements include parties responsible for carrying out the policy elements and how adherence will be ensured are specified	

a. **Responsibilities for policy maintenance and implementation**

☐ **Responsibilities are specified for maintenance and implementation of the whistleblower policy**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
☐ Development, maintenance, and coordination of a reporting process	___Yes ___ No	___Yes ___ No
☐ Development, maintenance, and coordination of an investigation process	___Yes ___ No	___Yes ___ No
☐ Development, maintenance, and coordination of a policy/program monitoring/audit process	___Yes ___ No	___Yes ___ No
☐ Development, maintenance, and coordination of a policy/program evaluation process	___Yes ___ No	___Yes ___ No
☐ Preparation and dissemination of monitoring/audit summaries	___Yes ___ No	___Yes ___ No
☐ Dissemination of policy to personnel	___Yes ___ No	___Yes ___ No
☐ Development, maintenance, and coordination of materials/information to promote the policy/program	___Yes ___ No	___Yes ___ No
☐ Dissemination of materials/information to promote the policy/program	___Yes ___ No	___Yes ___ No
☐ Monitoring of new laws, regulations, policies, protocols relevant to whistleblower policy/program	___Yes ___ No	___Yes ___ No
☐ Development of compliance program roles and responsibilities related to the governance structure of the program	___Yes ___ No	___Yes ___ No
☐ Development and dissemination of recommendations based on evaluations of reports and investigations to improve care, processes, etc	___Yes ___ No	___Yes ___ No
☐ Communication of results from investigations to the relevant personnel/stakeholders	___Yes ___ No	___Yes ___ No

b. **Responsibilities for training and education**

☐ **Responsibilities are specified for training and education for the whistleblower policy**

____ Yes ___ No

Score: _____

Policy element	Responsibility specified	Accountability specified
☐ Development of policy/program educational/training content [workers, managers, other roles]	___Yes ___ No	___Yes ___ No
☐ Development of policy/program educational/training requirements [workers, managers, other roles]	___Yes ___ No	___Yes ___ No
☐ Development of educational materials such as posters, flyers, other visual aids (to ensure/cue/promote use of appropriate procedure/protocol)	___Yes ___ No	___Yes ___ No

□	Delivery of training and education at orientation [workers, managers, other roles]	___Yes ___ No	___Yes ___ No
□	Delivery of training and education at ongoing intervals (e.g., annually, staff meetings, regular communications such as newsletters, etc) [workers, managers, other roles]	___Yes ___ No	___Yes ___ No
□	Delivery of training and education at orientation [workers, managers, other roles]	___Yes ___ No	___Yes ___ No
□	Delivery of training and education at ongoing intervals (e.g., annually) [workers, managers, other roles]	___Yes ___ No	___Yes ___ No
□	Development of content for audit/monitoring training/education (e.g., how to conduct audits)	___Yes ___ No	___Yes ___ No

c. **Responsibilities for monitoring compliance with protocols/procedures included in policy**

☐ **Responsibilities are specified for monitoring compliance with whistleblower policy**

Policy element	Responsibility specified	Accountability defined
☐ Development, maintenance, coordination of compliance monitoring – how and when monitoring will be carried out (e.g., methods, frequency, data collection/compilation, data summaries)	___Yes ___ No	___Yes ___ No
☐ Monitor adherence with policy components	___Yes ___ No	___Yes ___ No
☐ Development/maintenance of processes for reporting instances of non-compliance	___Yes ___ No	___Yes ___ No
☐ Development/maintenance of processes for investigating reports of non-compliance	___Yes ___ No	___Yes ___ No
☐ Development/maintenance of processes for protections for workers that report instances of non-compliance	___Yes ___ No	___Yes ___ No
☐ Development/maintenance of a process for communicating with a complainant about the status of the complaint	___Yes ___ No	___Yes ___ No
☐ Development/maintenance of a process for a written record of the report including corrective action and/or assessment of errors	___Yes ___ No	___Yes ___ No
☐ Development/maintenance of corrective action/disciplinary process	___Yes ___ No	___Yes ___ No
☐ Monitoring compliance with whistleblower policy training/education requirements	___Yes ___ No	___Yes ___ No
☐ Development and dissemination of recommendations based on evaluations of reports and investigations to improve care, processes, etc	___Yes ___ No	___Yes ___ No
☐ Communication of results from investigations to the relevant personnel/stakeholders, as appropriate	___Yes ___ No	___Yes ___ No

____ Yes ___ No

Score: _____

4. Enforcement section

Administration / Governing body

a. A governance structure is in place to enforce the policy, which may be a component of a broader organization program. For the whistleblower/compliance program, this may include:

☐ Committee/task force/working group – to devise and oversee policy, program

☐ Administrative support is specified for staff compliance with whistleblower/compliance program

☐ Administrative support is specified for the resources needed to effectively carry out the whistleblower/compliance program

☐ Administrative support is specified for dedicated staff time for whistleblower/compliance-related activities such as participation on committees, training/education, investigations, monitoring, and/or enforcement activities, etc

☐

____ Yes ___ No

Score: _____

b. The governance structure/administration, along with the respective workgroup/committee/task force evaluates data to identify strengths,

____ Yes ___ No

Score: _____

	weaknesses, and develop plans for improvement. For the whistleblower/compliance program, this may include: □ Expectation to monitor to ensure compliance with whistleblower/compliance policy □ Review and evaluation of compliance monitoring efforts (e.g., audits) □ Evaluation of the program/policy (e.g., policy elements and responsible parties; resource review; education gaps) □ Systematic evaluation of audit data to identify systems that result in failures/barriers to comply; to identify strengths and weaknesses; to develop action plans where gaps are identified □ Review and evaluation of feedback on whistleblower/compliance program reports/investigations □ Make recommendations such as changes to policies/procedures to prevent recurrence	
c.	Performance of personnel/worker considers adherence to the policy. For the whistleblower/compliance program, this may include: □ Expectations are specified that adherence to the policy is considered/incorporated into the measure of an employee's overall performance □ Expectations are specified that adherence to the policy is a condition of employment □	____ Yes ___ No Score: _____
d.	Corrective actions/consequences are specified for instances of non-compliance with the policy. For the whistleblower/compliance program, this may include: □ Disciplinary action is considered for personnel who fail to make reports in a timely manner □ Corrective actions/consequences are specified for those found to have violated the policy, by role: • Medical staff (providers with privileges) • Non-medical staff (nursing, ancillary, etc) • Board members • Contractors, etc □ Corrective actions include steps are taken to prevent recurrence – including modification of the whistleblower/compliance program, as appropriate □ Corrective actions/consequences are specified for individuals that fail to adhere to the whistleblower/compliance protocols/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) □ Corrective actions/consequences are specified for managers that fail to enforce the whistleblower protocol/procedures outlined in the policy (e.g., warnings, formal reprimands, penalties, disciplinary action) □ Corrective actions/consequences are regularly summarized and communicated/reported to the governance structure (e.g., compliance committee) □ Appropriate personnel (e.g. Compliance Officer) will take appropriate steps to remediate the violation, if an investigation reveals that there has been non-compliance with laws, regulations, or other provisions of the policy/program. □ Any individual who retaliates against another individual who has reported a violation in good faith or who, in good faith, has cooperated in the investigation of a violation is subject to discipline, including termination. □	____ Yes ___ No Score: _____
e.	Expectations for managers to enforce compliance with the policy are specified. For the whistleblower/compliance program, this may include: □ Expectations for managers to enforce compliance with all elements of the policy □ Expectations for managers or designees to conduct monitoring/audits to ensure and assess compliance □ Expectations for managers to enforce requirements for training and education □ Expectation that managers promote policy adherence, foster communication, encourage compliance	____ Yes ___ No Score: _____

☐ Expectation that managers are accessible to employees who wish/seek to report ☐ Expectation of managers to enforce the policy	
f. Expectations for staff to enforce compliance with the policy are specified. For the whistleblower policy, this may include: ☐ Expectations that all staff are responsible for their own conduct ☐ Expectations that all staff are responsible for adhering to the policy ☐ Expectations for all staff members to role model expected practices ☐ Expectation all workers to cooperate with policy/program monitoring activities	____ Yes ___ No Score: _____
5. Procedures/protocols	
Protocol/procedure for skills/techniques	
a. Protocol/procedure developed with instructions for workers on how to report instances of suspected or actual non-compliance with the policy: ☐ Guidance on when to elevate the situation – such as use of a chain-of-command structure (e.g., discuss with supervisor first…) ☐ Specifications for worker to be prepared to provide as much information as possible, specifics (date, time, location, situation) ☐ Mechanism(s) for reporting: o Verbal report to supervisor/manager o Phone number/hotline/website/email address o Suggestion/mail box o Anonymous method o Other:_____ b. Protocol/procedure developed with instructions for handling/documenting reports c. Protocol/procedure developed with instructions for investigating reports of violations d. Protocol/procedure developed with instructions for protecting workers that report violations e. Protocol/procedure developed with instructions for a written record – including corrective actions / assessment of errors f. Protocol/procedure developed with instructions for disciplinary actions g. Protocol/procedure developed with instructions for handling retaliation situations	a.____ Yes __ No Score: _____ b.___ Yes __ No Score: _____ c. ___ Yes __ No Score: _____ d.___ Yes __ No Score: _____ e.___ Yes ___ No Score: _____ f.___ Yes ___ No Score: _____ g.___ Yes ___ No Score: _____ Overall sense of punitive vs. assessment of problem: _____
Protocol/procedure to measure compliance with policy standards	
h. Protocol/procedure developed with instructions for monitoring adherence to the policy. i. Protocol/procedure developed with instructions for evaluating the policy	h.___ Yes __ No Score: _____ i.___ Yes ___ No Score: _____

Descriptive information

Total pages:	
Language used is plain/simple, easy to read	____ Yes _____ No
Audience for the policy is clear	____ Yes _____ No
Related policies referenced	____ Yes _____ No
Specify policies referenced	*Specify*:
Attachments/appendices/supporting or related documents referenced:	____ Yes _____ No
Specify attachments/appendices/supporting or related documents referenced	*Specify*:
Number of pages of attachments/appendices:	
Policy owner/sponsor listed	____ Yes _____ No
Specify policy owner/sponsor	*Specify*:
Language used to describe "responsibility" of policy	Open-ended
Approving body/committee listed	____ Yes _____ No
Specify approving body/committee	*Specify*:
Policy includes the date when policy issued (origin date)	____ Yes _____ No
Date of origin	
Policy includes the date when policy last reviewed/approved	____ Yes _____ No
Date of last review/approval	
Key changes to document are specified following each review	____ Yes _____ No
Policy includes all dates policy was revised	____ Yes _____ No
Policy includes the date of next review	____ Yes _____ No
Next review date	
General notes:	