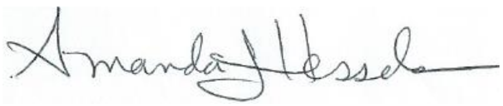
Title Page



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Project Title: Impact of Patient Safety Climate on Infection Prevention Practices and Healthcare Worker and Patient Outcomes

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List of Terms and Abbreviations

Agency for Healthcare Research and Quality (AHRQ)
analysis of variance (ANOVA)
Association of Occupational Health Professionals in Healthcare (AOHP)
Association of Professionals in Infection Control and Epidemiology (APIC)
catheter associated urinary tract infections (CAUTI),
Centers for Disease Control and Prevention (CDC)
central line associated bacteremia (CLABSI)
full time equivalents (FTE)
hand hygiene (HH)
healthcare associated infections (HAI)
Healthcare and Social Assistance (HCSA)
healthcare worker (HCW)
methicillin-resistant *Staphylococcus aureus* (MRSA)
National Institute for Occupational Safety and Health (NIOSH)
National Healthcare Safety Network (NHSN)
National Occupational Research Agenda (NORA)
Occupational Safety and Health Administration (OSHA)
ordinary least squares (OLS)
personal protective equipment (PPE)
registered nurse (RN)
Research to Practice (r2P)

ABSTRACT

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Nearly one in 25 patients has a hospital infection at any given time and one in 25 nurses suffers and blood-borne exposure every year. Basic procedures, termed “standard precautions” may prevent these outcomes, but are not often used by healthcare workers; organizational factors such as perceptions of safety might contribute to adherence. Standard precautions are a fundamental set of actions healthcare workers should take as a primary infection prevention strategy, designed to limit risk of blood-borne infections, other occupational infections, as well as patient healthcare associated infections (HAIs), such as methicillin-resistant *Staphylococcus aureus* (MRSA). Precautions include hand hygiene, use of personal protective equipment, safe use and disposal of sharps, decontamination of environment and equipment, and linen and waste management.

The specific aims were to: 1) describe the direction and magnitude of relationships among patient safety climate and self-reported and observed standard precaution adherence, 2) identify the relationship between standard precaution adherence and blood-borne and other potentially infectious pathogen exposures and HAIs and 3) determine the direct and indirect relationships among patient safety climate, standard precaution adherence, and healthcare worker exposures and HAIs.

This multi-site, cross-sectional study includes survey data on patient safety climate and standard precaution adherence, observational standard precaution adherence data, and existing unit level data on healthcare worker exposures and HAI. The approach included using novel tools and methodology to train hospital based staff on observational surveillance methodology, fostering the NORA Research to Practice (r2P) goals.

A total of 5,285 standard precaution observations and 452 surveys were collected across 43 units in 13 hospitals from 6 states. Data was pooled from these four sources and the analytic approach accounted for other important hospital and nurse factors, to determine whether hospital units with better patient safety climate have better standard precaution adherence and also have better healthcare worker and patient outcomes.

Observed adherence to all categories of standard precautions by all provider categories was 64.4%, and there were significant differences by role of nurse, physician, and ancillary healthcare workers. We identified modifiable features of the safety climate that impede or facilitate the uptake of evidence-based recommendations for standard precaution behaviors, and are associated with better healthcare worker and patient outcomes. A combination of a positive patient safety climate, better standard precaution adherence, and key hospital characteristics, predict HAI and occupational health outcomes, explaining sizeable variance in MRSA (41%), CAUTI (23%), mucotaneous exposures (43%) and needlestick and sharps injuries (38%). Potentially modifiable organizational factors of nurse staffing and Magnet hospital status are important explanatory variables.

Potential implications of this study include developing a model for surveillance methodology and training and generating actionable knowledge for institutional, governmental and academic stakeholders of important and modifiable features of the PSC to improve healthcare worker and patent safety. These breakthroughs also provide future orientation for policy makers to support research that further clarifies and disentangles the factors that meaningfully contribute to high-reliability organizations and positive patient and HCW outcomes.

Section 1 of the Final Progress Report

Significant or Key Findings.

The specific project aims were to: 1) describe the direction and magnitude of relationships among patient safety climate and self-reported and observed standard precaution adherence, 2) identify the relationship between standard precaution adherence and HCW blood-borne pathogen exposure and HAI, and 3) determine the direct and indirect relationships among patient safety climate, observed and reported standard precaution adherence, and HCW and HAI outcomes.

In total, 5,285 (81.1%) of the standard precaution observations and 452 surveys (unit response rate 38.2%), from 43 units in 13 hospitals were used for analyses. The majority of observations included nurses (43.1%), and the most frequent indication observed was hand hygiene (72.6%). Overall standard precautions adherence was 64.4%. In descending order, adherence rates were: (1) personal protective equipment (81.8%), (2) sharps handling (80.9%), (3) linen handing (68.3%) and (4) hand hygiene (58.3%). The aggregate of positive self-reported standard precaution practices were 95.8%, and 77.3% rated unit environment for standard precaution adherence positively. There was no correlation between unit observed adherence and reported adherence (r (41) = (-).024, P = .879).

This project yielded several significant and key findings, the following are the most important results addressing the specific aims. Results of AIM 1 indicate PSC was correlated with both reported and observed adherence. Negative perceptions of the PSC overall and several specific dimensions were correlated more often than positive perceptions with SP adherence overall and specific actions. Results of Aim 2 indicate levels of SP adherence are correlated with MRSA, and specific categories of SP adherence are associated with HAI and occupational pathogen exposures. Results of Aim 3 indicate there are important direct and indirect relationships among dimensions of PSC, HAIs and occupational outcomes. Key PSC dimensions were identified that directly correlate to CAUTI and nurse sharps injuries. Moreover, potentially modifiable variables of nurse staffing and hospital Magnet designation explain substantial variance in the outcomes of MRSA, CAUTI, nurse and all staff mucotaneous and OPIM exposures, and all staff sharps and needlestick injuries.

This study produced four scientific breakthroughs advancing the state of the science in patient and occupational health safety. First, PSC is correlated with higher levels of both self-reported and observed standard precaution behaviors. Secondly, observed adherence to standard precautions is low across all professions and disciplines, and key role distinctions are noted. Thirdly, we identify and document specific standard precaution actions associated with HAI and occupational pathogen exposures. Finally, by employing innovative methods, strategies and approaches to collect and analyze multiple complex sources of data, we identified direct and indirect relationships among patient safety climate, observed and reported standard precaution adherence, and HCW and HAI outcomes. In combination, these results tell us that a positive PSC, better standard precaution adherence, and key organizational characteristics, predict key HAI and occupational health outcomes.

Translation of Findings.

The translation of these breakthroughs at the point of care will be realized through targeted interventions and cross-cutting surveillance methodology that captures risks at the intersection of patient and occupational health and safety. Leaders can identify and implement prevention strategies based on local surveillance data and other organizational information. These breakthroughs also provide future orientation for policy makers to support research that further clarifies and disentangles the factors that meaningfully contribute to high-reliability organizations and positive patient and HCW outcomes.

This project yielded translational and intervention related outputs for healthcare workers and administrators and those in the area of healthcare and infection related occupational safety and health. Major or significant translational research activities, products and outputs include the following:

- Using novel safety climate and standard precaution tools, we conducted national testing to refine and identify applicability of tools for broad use in hospital settings.
- The survey tool was administered to a large sample of nurses and hospitals and identifies organizational features that support a positive safety culture.
- Training modules, including a series of twenty case study vignettes, were developed and pre-tested for content, usability, feasibility, and inter-rater reliability testing by staff nurses and clinical nurse educators.
- Trained hospital liaisons on surveillance methodology for adoption
- With collaborative commitment of national professional organizations we leveraged and created the ability to develop and promote unique observational surveillance tools and methods and expand to other settings.
- Using survey and observational data we identified organizational barriers and facilitators of hand hygiene compliance in a large sample of diverse HCW types and hospitals, and isolated the association to Hai and HCW outcomes.
- We isolated the compliance and use of PPE, relationship with organizational factors contributing to better compliance
- We identify and recommend strategies that may be associated with lower injury rates, such as team based training.
- Disseminated research process and results in real-time to key stakeholders, and are preparing manuscripts for publication.

Findings from this study are also guiding future planning and decision-making (e.g., intervention development) through newly awarded research. Results and efforts from this NIOSH Mentored K01 Award project led directly to the successful application for a project entitled "Simulation to Improve Infection Prevention and Patient Safety: The SIPPS Trial (Agency for Healthcare Research and Quality: 1R18HS026418).

In so doing, translation of this research contributes to: stopping the transmission of infectious diseases in HCSA settings among workers, patients and visitors; promoting safe and healthy workplaces and optimizing safety culture in healthcare organizations; and reducing sharps and mucotaneous injuries and their impacts among all healthcare personnel.

Research Outcomes/Impact.

This project relates to occupational safety and health with regard to improved practices, prevention techniques, surveillance, policy and potential use of technology to collect valuable observational data. Research findings to date have been disseminated widely (locally, regionally, national and international audiences), and target relevant healthcare professionals, key stakeholders, and organizations. We have also developed a Continuing Education (CE) program entitled "Standard Precautions Observation and Safety Climate Tools Research" and training materials for the Standard Precaution Observational Tool (SPOT). Intermediate outcomes include training on project outputs (tools and vignettes) for research data collection, adoption of methods in practice, such as use for real- time real-world surveillance, and integration into policy and procedures (updating hospital standard precaution policies).

Findings from this study can guide future investigations and research in the following ways. Future research might be designed to: a) extend these findings in alternate settings, and b) test if improving modifiable factors reduces incidence, burden, and cost of adverse outcomes. Methodologically, we share lessons learned regarding external factors impacting liaisons' availability, availability and accessibility of nursing staff to complete surveys, and additional training required on observational data tools that required more effort and adaptation than anticipated. Strategies and actions to address obstacles included focused recruitment through local professional organization meetings, in person contact through network and at presentations, and leveraging local site participation along with extending the recruitment and data collection timeline. Efforts to support and communicate with participating sites was also augmented and included regular touchpoints to ensure burden of participation was minimized while study rigor was maintained.

Section 2 of the Final Progress Report - Scientific Report

Significance

Aligned with critical research gaps identified as a priority for the National Occupational Research Agenda (NORA) Healthcare and Social Assistance (HCSA) sector over the next decade, this study addressed NORA second decade strategic goals to: 1) Promote safe and healthy workplaces and optimize safety culture in healthcare organizations; 2) Reduce sharps injuries and their impacts among all healthcare personnel; and 3) STOP transmission of infectious diseases in HCSA settings among workers, patients and visitors.[1] This project was also responsive to the 2013 *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* set by the U.S. Department of Health and Human Services, and the 2015 call to action by the Centers for Disease Control and Prevention (CDC) to reduce the burden of HAI in hospitals using innovative and synergistic efforts.[2,3] This project addressed NORA Research to Practice (r2P) by: *prioritizing* research of the most important occupational health issues, *partnering* with key stakeholders to encourage adoption of research tools and findings, *targeting* an audience to adapt research information products, *fostering* translation of findings into prevention practices and procedures, *disseminating* key research findings using communication science, and *evaluating* data collection methodologies to prevent occupational injury.

Background

This study addresses *three intertwined and important public health problems*: 1) high rates of healthcare worker (HCW) blood-borne pathogen exposures; 2) high rates of patient healthcare associated infections (HAI); and 3) low levels of standard precaution adherence. The HCSA sector covers over 19 million people in the U.S., and 80% are in healthcare industries.[1] Of those, over two million are registered nurses (RNs) comprising the largest sector of the healthcare workforce, 70% of whom work in hospitals.[1,4] Therefore, keeping our healthcare workforce safe, particularly RNs in hospitals, is a national priority.

A critical occupational health and safety issue is exposure to blood-borne pathogens, such as human immunodeficiency, hepatitis B, and hepatitis C viruses through sharps injuries and other modes.[5,6] Recent published data from a survey of the Association of Occupational Health Professionals in Healthcare (AOHP) from 157 hospitals in 32 states identified a sharps injury rate of 28.2 /100 occupied beds; RNs comprised the most impacted occupation, accounting for 42% of all exposures or 3.3/100 RNs.[7] Underscoring the public health importance of these exposures, OSHA requires they are reported under the Needlestick Safety and Prevention Act.[6] An expansion of this regulation is considered this an economically significant priority because these exposures are a largely preventable risk and because of renewed concern with other transmission risks that cause HCW *and* patient infections.[8] A key patient safety indicator and substantial public health problem is HAI,[9-12] affecting approximately 2 million patients annually resulting in 99,000 estimated deaths with attributable costs of $6.7 billion in U.S. hospitals.[13,14]

Although 1 in every 25 RNs suffers an occupational blood-borne pathogen exposure annually and at any given time 1 in every 25 hospitalized patients has an HAI,[3,7,15,16] these numbers may actually underrepresent the burden because <50% of the time HCW report exposures and in <50% of HCW interactions with patients do they follow standard precautions.[17-22] In the U.S., a number of initiatives aimed to improve HCW and patient safety have been broadly implemented in the past decade, largely driven by legislation and mandatory reporting, including targeted “bundles” of infection preventive activities, use of checklists, and safe engineered devices for sharps; despite some initial progress, these adverse events remain too common.[16-18, 23]

Nearly 20 years ago the CDC introduced standard precautions as a primary prevention strategy, the base in a hierarchy of controls designed to protect HCW and patients.[18] Specific standard precaution components include hand hygiene (HH), use of appropriate personal protective equipment (PPE), safe use and disposal of sharps, decontamination of the environment and patient–care equipment, patient placement and linen and waste management.[5] This set of recommended actions is applicable to all providers caring for all patients in all settings.[5]

A recent national survey of infection preventionists and occupational health professionals revealed that the vast majority (82%) believe sharps injuries continue to pose a serious or life threatening risk to HCW, but only 61% believe the Needlestick Safety and Prevention Act achieved what was intended with regulations; respondents cited dedication to an institutional culture of safety as the primary strategy to decrease sharps injuries and body fluid exposures.[24] There is evidence that features of the patient safety climate, such as perceived leadership and management support, organizational support, safety performance feedback, job hindrances, orderliness and cleanliness are related to HCW safety practices, including reported adherence to standard precautions.[23, 25-29]

We recently conducted a systematic review to examine the relationship between patient safety climate and standard precautions and found that despite several high quality studies this topic is underexplored and all studies used different and self-report measures.[30] Direct observation allows for specific individual monitoring of behavior and is the “gold standard” for assessing adherence rates for behaviors such as performing HH, a component of standard precautions.[30-33] Thus, features of the patient safety climate have not been tested in relation to the observed standard precaution adherence or in relation to important HCW and HAI outcomes.

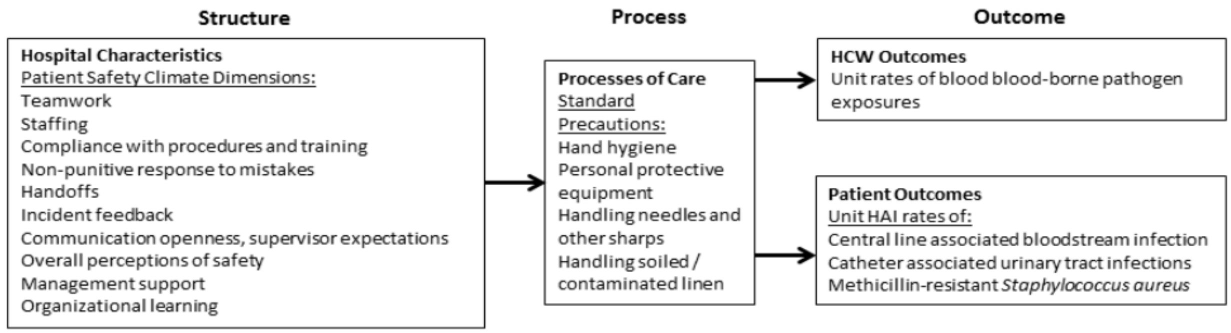
Beyond legislative and mandatory reporting performance drivers, heightening awareness of modifiable features of the patient safety climate may optimize HCW safety practices.[24,47] However, no studies have examined the relationships among observed and reported standard precaution adherence and HCW and HAI outcomes using psychometrically validated tools that account for the features of the patient safety climate. This proposed project is significant because it integrates occupational health and patient safety research and strategies to reduce the burden of adverse HCW and patient outcomes.[1,9,12]

Timely and unique, this project addresses several important gaps in evidence. Innovatively, it stimulates the collective capacity across multiple healthcare institutions and key stakeholder organizations to rapidly generate and translate knowledge to practice. In concert with established collaborative partnerships among NIOSH, AOHP and APIC, this project addresses multiple priority areas with one overarching goal: improved healthcare outcomes for providers and patients alike.

Theoretical and Conceptual Framework

Donabedian’s framework defines quality health care along three basic dimensions: structure, process, and outcomes of care.[34,35] Structure of care is conceptualized as the attributes of the settings in which patient care occurs, including human and material resources and attributes of organizational patient safety climate. Processes of care include the activities involved with the direct provision of care, such as standard precaution adherence. Outcomes of care, such as HCW exposures or HAI rates, are the consequences or results that can be attributed to the structures and processes of care. Based on Donabedian’s framework, both structures and processes of care affect outcomes. Processes of care also mediate the relationship between structures and outcomes. **Figure 1** details the system, process, and outcome features examined.

Figure 1. Conceptual Framework



Specific Aims

Contemporary healthcare demands highly reliable delivery, including the most basic standards of care.[36-39] Hospitalized patients require advanced interdisciplinary clinical care in concert with current technological advancements under highly dynamic circumstances.[40,41] As such, healthcare delivery is an increasingly high-hazard occupation in a high-hazard setting, requiring that HCW have an adaptive skill set to operate under complex conditions.[2,6] Lapses are evident in complications of care, including HCW blood-borne pathogen exposures and patient HAI.[42,43]

In the United States (U.S.), approximately 5.6 million HCW are at risk of exposure to blood-borne pathogens; of these, approximately 385,000 experience a sharps injury annually, or an average of 1,000 per day in hospitals alone, at a rate of 4.0/100 full time equivalents (FTE).[17,44] The majority of these, 56-88%, are preventable.[17,44-46] Nevertheless, despite an immediate and dramatic decrease following passage of the Needlestick Safety and Prevention Act in 2001, rates remain unacceptably high, with HCW sharps injury incidence of 321,907 and blood-borne pathogen exposures of 441,344 annually at a rate of 2.48/100 FTEs.[17,18] Simultaneously, 5-10% of hospitalized patients for whom at-risk HCW provide care acquire one or more HAI; that is approximately 2 million patients, of whom, an estimated 99,000 will die annually.[13,14,47,48] Estimates suggest between 10-70% of HAI are preventable.[13,47]

Standard precautions are a fundamental set of actions HCW should take as a primary infection prevention strategy, designed to limit risk of blood-borne infections, other occupational infections, as well as patient HAI.[5] Components of standard precautions include indications and recommendations for HH, use of appropriate PPE, safe use and disposal of sharps, decontamination of environment and equipment, infectious patient placement, and linen and waste management. These precautions are federally regulated and establish a minimum standard of care for HCW and organizations.[6]

Despite its importance however, adherence to standard precautions remains grossly suboptimal, and is adhered to less than 50% of the time.[19-22] Reasons are not completely clear, though there is evidence that features of the patient safety climate, defined as the group level perceptions, attitudes and shared experiences of the organizational culture of safety may be related to safety practices, including adherence to standard precautions.[23, 25-29] These features include perceived leadership and management support, job hindrances, orderliness and cleanliness. Nevertheless, the relationship between standard precaution adherence and important HCW and patient outcomes is under explored. Consequently, the direct and indirect relationships among the patient safety climate, standard precaution adherence, HCW blood-borne pathogen exposure, and patient HAI remain unknown.

Hence there are three important and longstanding gaps in knowledge: 1) the relationship between recommended and observed practice of standard precautions; 2) if and under what conditions a relationship exists between patient safety climate and standard precaution adherence; and 3) the existence, direction and magnitude of relationships among patient safety climate, standard precaution adherence and HCW and HAI outcomes.

We hypothesized that hospitals that have better patient safety climates also have higher levels of standard precaution adherence and in turn lower rates of HCW exposures and injuries and patient HAI. This NIOSH K01 Mentored Research Scientist Development Award project addressed three specific aims (shown in **Table 1**):

Table 1: Specific Aims and Hypotheses	
Aim	**Tested Hypothesis**
Aim 1: To describe the direction and magnitude of relationships among patient safety climate and self-reported and observed standard precaution adherence	A more positive patient safety climate is associated with greater levels of standard precaution adherence
Aim 2: To identify the relationship between standard precaution adherence and 1) HCW blood-borne pathogen and mucotaneous exposures and 2) HAIs	A greater level of standard precaution adherence is associated with reduced rates of HCW blood-borne pathogen and mucotaneous exposures and HAIs
Aim 3: To determine the direct and indirect relationships among patient safety climate, observed and reported standard precaution adherence, and HCW and HAI outcomes	3.1 A more positive patient safety climate is associated with reduced rates of HCW blood-borne pathogen exposure and injury and rates of patient HAIs 3.2 Standard precaution adherence mediates the relationships among patient safety climate, HCW, and HAI outcomes

Methodology

Research Design

This multi-site, cross-sectional study includes surveys of nurses in U.S. hospital units on patient safety climate and standard precaution adherence, collection of standard precaution observational adherence data on those same units, and aggregation of unit level data on HCW blood-borne pathogen exposures and HAIs.

Sample and Setting

Study sites and liaisons were recruited through the APIC and AOHP research committees through their existing processes. Each organization provided a letter of support and commitment of recruitment assistance. Organizational membership includes the professionals who routinely collect the outcome data of interest and therefore are familiar with the data definitions and surveillance methodology. Each organization has a procedure to contact membership through existing member listserv or email for recruitment and participation in research studies. This method of recruitment was selected as it is already known to members and enhances generalizability by heterogeneity of sites identified and selected.

Hospital inclusion criteria are: 1) use and availability of data following National Healthcare Safety Network (NHSN)[49] and OSHA 300[8] surveillance methodology and definitions, and 2) organizational policies and procedures congruent with the standard precaution behaviors measured using the observational tool. Hospitals meeting criteria were selected based on timing of response and in consideration of maximizing generalizability by geographic region and bed size; one to two adult medical-surgical units per hospital will participate, from up to 50 hospitals. While other unit types are of interest, to limit the potential effect of health care delivery differences across varying patient care settings (e.g., emergency department, intensive care unit) and increase the likelihood of outcome data availability using NHSN definitions, one type, medical-surgical, will be selected.

Inclusion criteria for nurses surveyed about safety climate and standard precautions were an RN who: 1) currently works in a direct care capacity at least 16 hours per week on the selected unit, and 2) has worked on that unit for a minimum of six months. Exclusion criteria were: 1) nurses who are not RNs or 2) do not work in a direct care capacity either currently or for the minimum time to be considered a part of the unit climate (e.g., float nurses, nurses in orientation). Guided by preliminary studies, an experienced mentoring team, and AHRQ survey user's guide the aim was for 60% of full-time equivalent participation per unit.[50] Rationale for selecting RNs to survey was that they comprise the largest sector of the unit level workforce representing patient safety climate and are routinely available, and subject accessibility supports feasibility of this study.

For the observations, the HCW and patients were a convenience sample drawn from those present on the unit the day the observations are conducted following inclusion and exclusion criteria, selection procedures, definitions and instructions. The HCW observed could include any HCW with direct patient contact or contact with the patient's immediate surroundings such as nurses, nursing assistant/aide, medical doctor, or other HCW (e.g., physical therapist, technician, dietician, social worker). Rationale for collecting observational data on HCW other than nurses is that their behaviors may be influenced by the overall patient safety climate of the unit. The data was collected in a manner such that comparisons of adherence by provider type could be drawn. The tool was designed to observe adult patients (21 years of age or older), who are able to understand and speak English and provide permission for the observer to be in the patient room. Patients in acute crisis (i.e., undergoing a rapid response, code or CPR) were excluded. The observation tool contains no identifiable HCW or patient information.

Measures

***Survey on Patient Safety & Standard Precautions*.** This survey measures HCW perceptions of patient safety climate in the hospital unit on which they work, reported adherence to standard precaution practices, and factors that influence that adherence. It is adapted from the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture and Standard Precaution and Safety Climate Surveys, all of which have acceptable psychometric properties.[26,51,52] The unmodified 44-item survey is extensively used nationally to measure 12 dimensions of patient safety climate: supervisor expectations and actions promoting safety, organizational learning, teamwork, communication openness, feedback and communication about errors, non-punitive responses to incidents, staffing, hospital management support for patient safety, handoffs and transitions, and overall perceptions of safety. Items are measured using a 5-point Likert scales so that a 1 represents a low score and a 5 a high score and a composite score per dimension is obtained. The parent tool is reliable (Cronbach's alpha 0.63-0.84) and there is an extensive and explicit Survey User's Guide, including guidance for modifying and administering the tool.[50]

We adapted this tool to include 22 items on which respondents rate their perception of the work environment barriers and facilitators to perform standard precautions using a 5-point Likert scale from "strongly disagree" to "strongly agree", as well as rate frequency of standard precaution behaviors using a 5-point Likert scale from "never" to "always". These items were selected following an extensive literature review, in consultation with my mentoring team, and drawn from two psychometrically sound tools.[26,52] This tool contains no identifiable HCW information Test-retest data of the survey tool indicates moderate test stability at item level by weighted Cohen's Kappa (ĸ= 0.44) and dimension level by intra-class correlation coefficient (ICC 0.49, 95% CI: 0.39-0.57) and internal consistency reliability was demonstrated by Cronbach's alpha (0.52-.89).

Standard Precautions Observation Tool. The tool measures observed HCW standard precaution behaviors in hospital settings and is adapted from the psychometrically sound World Health Organization Hand Hygiene Observation Tool and CDC guidelines.[5,9] This hard copy observation tool is designed to unobtrusively observe HCW encounters with patients. Each form can be used to record up to a total of nine HCW-patient encounters and up 10 standard precaution indications per encounter. These 10 items were selected for inclusion in this tool as they can be clearly defined and unobtrusively observed and represent categories of HH, personal protective equipment, needles or other sharps or soiled linen.[5] Standard precaution adherence is expressed as a percentage per unit.

The patient safety climate results were aggregated to unit level average (an index for unit level patient safety climate). We anticipate approximately 16/unit should be enough to provide reliable estimation for each unit because we will sample 60% of unit RN FTEs. We aim to collect 100-200 observations in each unit. These results were aggregated to unit level average (an index for unit level standard precaution adherence) to provide reliable estimation of precaution adherence score for each unit.

***HCW outcomes*.** Blood-borne pathogen exposure via sharps injuries and/or mucotaneous exposures will be collected using the AOHP EXPOsure Survey of Trends in Occupational Practice tool modified for unit level data. AOHP conducted the first nationally representative blood exposure survey of U.S. hospitals in 2011.[18] This 15-item survey assesses the number of sharps injuries and mucotaneous blood or other potentially infectious material exposures and associated denominator data and has established content and face validity. No identifiable personnel information is collected. These variables are required under OSHA Public Law 91-596 using Form 300 and therefore not considered an additional burden to respondents.[6,18] OSHA has an extensive recordkeeping and training rule under 29 CFR Part 1904 that requires detailed and summary level data on work-related incidents be recorded and reported following explicit definitions and surveillance methodologies.[18] These outcomes were expressed as: 1) sharps injury incidence rate/RN FTE, and 2) mucotaneous exposure incidence rate/RN FTE.

HAI outcomes. Existing HAI data that are measured and collected by trained personnel utilizing CDC NHSN definitions and surveillance methodologies and follow extensive risk adjustment procedures for: 1) central line associated bacteremia (CLABSI), 2) catheter associated urinary tract infections (CAUTI), and 3) hospital-onset methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia were collected.[3,49] These outcome data are expressed as rates following numerator definitions and corresponding location specific denominator data consisting of device days (CAUTI and CLABSI) or patient days (MRSA). Twelve months of data (pre- and post-survey and observational data) were collected to create an average rate per outcome per unit. Most states in the U.S. require hospitals to report HAI rates through NHSN for public reporting purposes and the data are subject to validation procedures to check the accuracy and quality of the data.[49] Therefore, we anticipated high data quality and minimal burden as the sites selected collect this information as part of their routine infection prevention and control department activities.

Potential confounders*.* The analytic models include a number of important hospital and provider characteristics that are potential confounders derived from the HCW data, HAI data or provided by the study site liaison including: 1) hospitals without post graduate medical residents or fellows (non-teaching) distinguished from teaching hospitals; 2) bed size will be stratified as <100 beds, 101-250 beds, and >251 beds; 3) hospitals will be categorized into one of five geographic categories based on U.S. Rural-Urban Continuum Codes of the county where the hospital is located. Additionally, potential nurse confounders that will be collected include nurse skill mix (proportion of RN to licensed practical nurses and others).[18,27,52,53]

Data Collection Procedures

Following IRB approvals administrative permission from each unit management was obtained prior to conducting any observations or administering any surveys. All data were collected between 01/2017 and 10/2018. **Table 2** details the main study variables, data sources, and collection methods.

Table 2: Main Study Variables			
Variable/Source	**Source**	**Method**	**Sample Aim/Time Period**
Observed standard precaution adherence	Observational tool	On-site observation by hospital infection prevention/ occupational health liaison	100-200 observations/unit over 6 weeks
Patient safety climate and reported standard precaution adherence	Safety climate and standard precaution survey	Electronic or pen and paper survey to unit RNs	60% unit RN FTE (~16/unit) over 6 weeks
HCW outcomes	Existing blood-borne pathogen exposure data as defined by OSHA 300	Electronic or pen and paper survey to hospital infection prevention/ occupational health liaison	12 months incidence rate data collected at one time
HAI outcomes	Existing CLABSI, CAUTI and MRSA bacteremia rate data as NHSN defined	Electronic survey to hospital infection prevention liaison	12 months incidence rate data collected at one time

Selection and Training of Liaison Observers. Study site liaisons included infection preventionists, occupational health nurses and clinical nurses identified in collaboration with APIC and AOHP, and hospital leadership. They provided outcomes data and observational data. Liaison inclusion criteria are: 1) at least six months of experience in nursing or conducting HCW infection prevention observations or equivalent training, and 2) availability to be trained on the use of the standard precaution observational tool. Participating site liaisons were given a voucher of $100 to use for professional products in the APIC or AOHP store and an option to enter into an incentive raffle for towards registration fees to an annual educational conference of their choice aligned with the goals of this study.

Study site liaison observers from each hospital received teleconference and/or web-based training on the study procedures and use of the tool by the PI. The training content included the background, design and definitions used in the tool followed by an interactive demonstration using the tool to perform and record observations using a series of case scenarios. A question-and-answer period followed this training for additional clarification prior to use in a live environment. It is anticipated the sessions will last 90 minutes. A series of vignettes previously created and tested in preliminary studies was used to establish inter-rater reliability with the observers in this study. Ongoing support, including needed discussion, clarification, and debriefing critical to ensuring compliance with the protocol and collection of the data was provided. Additionally, scripted procedure guides were developed and used by the site observers. All observers were guided to limit each observation session in a patient room to no more than 60 minutes to limit observer fatigue bias.

Safety Climate and Standard Precaution Survey. Administration of the survey occurred in a time period either preceding or following the observation data collection so that it was contemporaneous, not simultaneous with the observational data to minimize any bias. Following administrative permission from each unit management the electronic survey or pen and paper survey (depending on site preference) was conducted. Unit participation in safety climate and standard precaution survey and observation data collection was designed to be initiated in cohorts of up 10 every two weeks to allow for early identification of any issues and related adjustments in accordance with NORA Research to Practice (r2P) guidance.[1] The survey period per site was 6-8 weeks; a reminders were sent to the staff to complete the survey in two weeks to maximize response rate per unit in accordance with survey user guidelines.[51] The survey information sheet included information containing the goal of the study and elements of informed consent including an explanation of the research, a description of risks and benefits, the assurance of anonymity of the respondent in that there are no identifiers linking the identity and responses of the participant, the right to refuse participation or discontinue participation at any time, contact information for the investigators, and the respective IRB information.

HCW and HAI Outcomes. We requested data that is already routinely collected. Following patient safety climate and standard precaution survey and observational data collection, study site liaisons will be electronically surveyed a subset of OSHA 300/ EXPOsure Survey of Trends in Occupational Practice questions to capture a year of data encompassing six months pre- and post-survey and observational data collection. Similarly, we will request existing unit data on HAI outcome rates that have been collected as per standard hospital procedures utilizing CDC definitions and surveillance methodologies as defined in the NHSN. No identifiable HCW or patient data will be collected.

Analytic Approach

All hospital unit data were aggregated using a random number generated code to assure all four data sources per site are matched in accordance with AHRQ survey procedures.[50] Standard descriptive statistics and techniques were employed to gain familiarity with the distributions and frequencies, as well as checks for and of any missing data or outliers. Bivariate analyses were also conducted to describe relationships among the key variables and include correlations as appropriate. Associations between unit level observed and unit level reported adherence was then explored. By treating the data derived from the safety climate and standard precaution survey as ordinal level values and the unit level data derived from the observational tool as a continuous value (percentage of adherence), associations and differences among dimensions of patient safety climate, reported standard precaution adherence and observed standard precaution adherence were examined using ordinary least squares (OLS) regression, analysis of variance (ANOVA) and t-tests as appropriate.

Multivariable regression analyses. All multivariable analyses were conducted at the hospital unit level of analysis Data from the patient safety climate and standard precaution surveys and observations were pooled with HCW and HAI outcomes data and used to determine whether hospital units with better patient safety climate have better standard precaution adherence and also have better HCW and patient outcomes. To account for hierarchal data structure all data were aggregated at the unit level to yield consistent effect estimates and standard errors. Models included important organizational control variables such as hospital teaching status, bed size, average daily patient census, nursing staffing mix and Magnet designation status[54] as theoretically and empirically indicated following examination of pairwise correlation tests and checks of collinearity

Power. To explore HAI and HCW outcomes using multivariable regression techniques and the probably of a Type 1 error set at 0.05, I estimate that at 80% power to detect a 0.3 partial correlation for the main predictor on the outcome, using a two-tailed hypothesis and controlling for 4 covariates in a random effects model would require a sample of 87 units. I am confident that I have sufficient power and sample given our recruitment aim of 1-2 units from up to 50 hospitals.[55] As with any study that examines rare events achieving sample size may be problematic. Though this study is designed to accommodate up to 100 units the difference in outcomes at the unit level may be nominal. Therefore, and in consideration of the distribution of the outcome data, units may be stratified into quartiles of “bad”, “poor", “good” and “excellent”. Derived from pilot data that included large and small, teaching and non-teaching hospitals, it is anticipated the average number of RN full-time equivalents eligible per unit is 26. The aim of the survey response rate is 60%[51] thus, it is anticipated 16 surveys per unit for up to 1600 surveys will be obtained. The goal of observational data collection will be 100-200 indications per unit, or a maximum of 10,000-20,000 across all sites. The level of significance for all testing was set at $p < .05$. Data was analyzed using STATA/MP13.1 (StataCorp. College Station, TX).

Results

Data-based

In total, 2,139 healthcare worker- patient encounters that included 6,518 standard precaution indications were observed and 500 surveys were collected from nurses on 54 units in 15 hospitals from 6 states. Hospital units that did not submit all three types of data (observations, surveys and outcomes) were excluded from analyses. This yielded a total of 5,285 standard precaution observations and 452 surveys collected across 43 units in 13 hospitals from 6 states used for analyses in results reported below.

Descriptive results. Demographic details of hospitals and nurses are shown in **Tables 3** and **4.** Regarding sites, all hospitals were categorized by Rural-Urban Continuum Codes as located in metro counties; 11 were in counties in metro areas of 1 million population or more and 2 were located in counties in metro areas of 250,000 to 1 million population.

Regarding standard precaution observation data, the majority of observations included nurses (43.1%) and the most frequent indication observed was HH 72.6%). Overall observed standard precaution adherence at the individual level was 64.4%. Overall adherence for nurses was highest (69.1%), followed by the other provider category (62.1%), and lastly physicians (58.4%). In descending order, adherence rates were: PPE (81.8%), sharps handling (80.9%), linen handing (68.3%) and HH (58.3%), (**Figure 2**).

When aggregated for unit level analyses overall adherence was slightly lower at 62.6%. In descending order, adherence rates were: PPE (81.1%), sharps handling (63.2%), linen handing (46.3%) and HH (56.4%). Across the units overall adherence for nurses was highest (69.1%), followed by the other provider category (56.7%), and lastly physicians (46.1%). A one-way ANOVA was conducted to compare the effect of provider role on standard precaution adherence and significant differences were identified [$F(2,116) = 8.75$, $p < .001$]. Differences exist between nurses and physicians ($t(62) = 3.98$, $p < .001$), nurses and others ($t(81) = 2.57$, $p = .01$), but not physicians and others ($t(66) = -1.76$, $p = .08$).

Regarding survey data, the average unit response rate for survey completion was 38.7%. The majority of nurses surveyed (95.8%) reported they often or always perform the 14 precaution practices included in the survey, fewer (77.3%) rated their unit environment positively, or conducive to following standard precautions.

Regarding HAI and occupational rates, HAI incidence was lower than occupational exposure

Table 3. Characteristic of Units (n = 43)

Characteristic	n	%
Magnet Designated		
Yes	28	65.1
No	15	34.9
Teaching Status		
Teaching	28	65.1
Non-teaching	15	34.9
Hospital Ownership		
Private	36	83.7
Public	7	16.3
Hospital Bed Size		
Large (>400)	29	67.4
Medium (216-400)	7	16.3
Small (1-215)	7	16.3

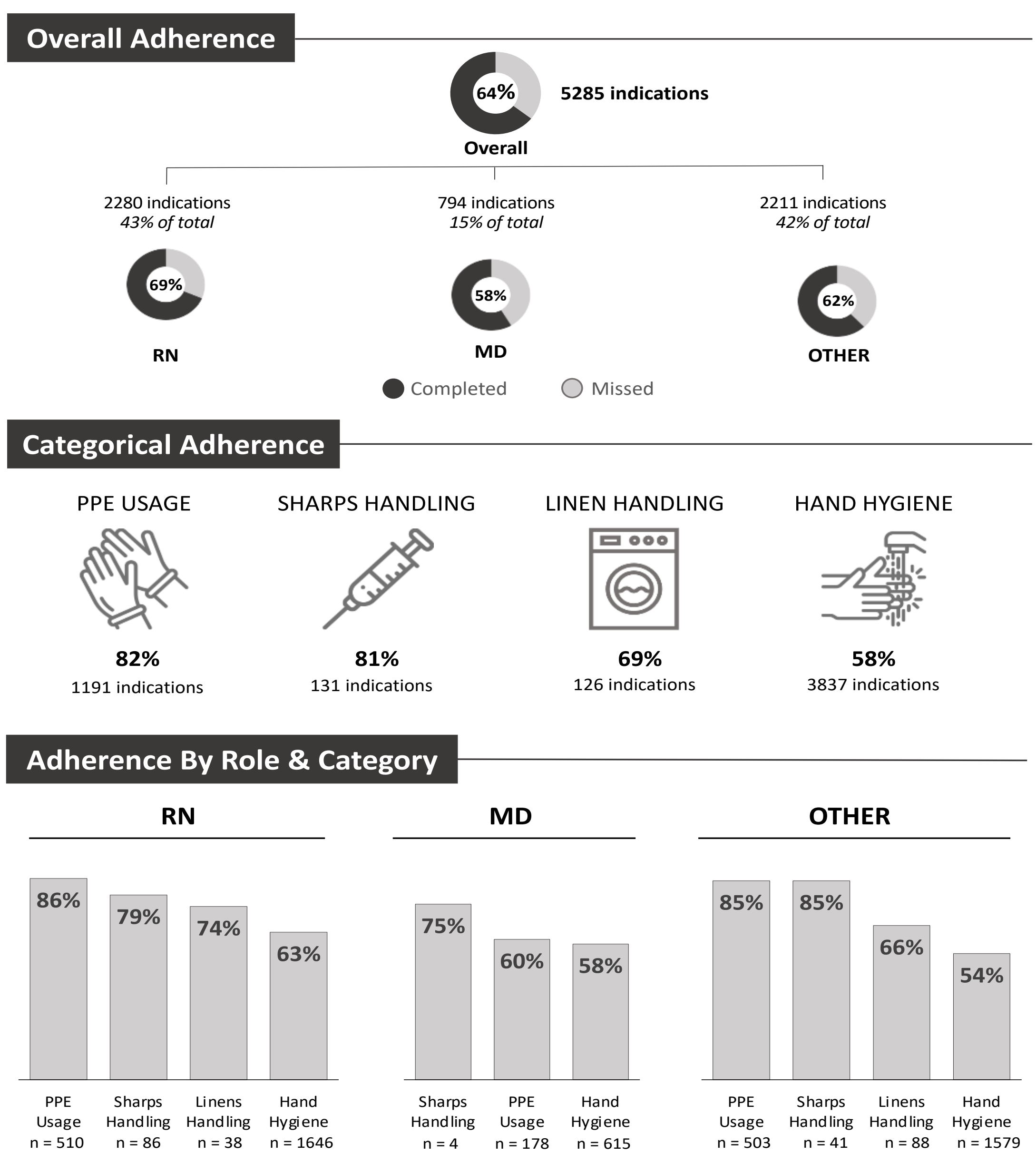
Table 4. Characteristics of Nurses (n = 452)

Characteristic	n*	%
Years in current profession		
0-5	224	49.6
6-10	81	17.9
≥11	138	30.5
Years worked in current hospital		
0-5	242	53.5
6-10	68	15.0
≥11	131	29.0
Primary work unit		
Combined Medical/Surgical	279	61.7
Medicine	48	10.6
Surgery	15	3.3
Pediatrics	17	3.8
Other	72	15.9
Many different units/No specific unit	13	2.9
Years worked on current unit		
0-5	313	69.2
6-10	43	9.5
≥11	86	19.0
Hours worked per week		
≥40 (Full-time)	417	92.3
16-39 (Part-time)	25	5.5

* Numbers may not total 452 due to missing data

incidence. HAI rates in descending order were CAUTI (*M* = 0.76, *SD* = 0.76), CLABSI (*M* = 0.69, *SD* = 1.22), and MRSA (*M* = 0.04, *SD* = 0.08). Regarding occupational exposures and injury rates, the highest rates were observed in needlestick injuries. The needlestick injury rate for all staff was *M* = 12.54 (*SD* = 24.95), and specific to nurses was *M* = 5.35 (*SD* = 5.34). Lower rates of mucotaneous blood or other potentially infectious material exposures were observed for all staff (*M* = 2.30, *SD* = 5.18), and nurses only (*M* = 0.77, *SD* = 1.60).

FIGURE 2. Standard Precautions Adherence Summary



Inferential Results. This project yielded several significant and key findings, the following are the most important results addressing each specific aim.

The following are key results for Aim 1: "To describe the direction and magnitude of relationships among patient safety climate and self-reported and observed standard precaution adherence". A Pearson correlation coefficient was computed to assess the relationship between unit observed adherence and reported adherence and it was not significant (r (41) = -.024, p = .879). There was a positive correlation between patient safety climate in aggregate and reported standard precaution adherence (r (41) = .442, p < .01). Twelve of the thirteen dimensions were independently correlated with standard precaution adherence. Of note, there was a correlation between positive (agree or strongly agree) perceptions of the work environment (that is conducive to the conduct of standard precautions) and reported adherence (r (41) = .435, p < .001). Details are shown in **Table 5**.

Table 5. Associations among Patient Safety Climate Dimensions and Reported Standard Precaution Adherence (N = 43)

Dimension	Mean (*SD*)	r^2	*p* value
Standard Precaution Practice	0.96 (.04)		
Organizational Learning - Continuous Improvement	0.79 (.15)	.522	<.001*
Frequency of Events Reported	0.73 (.17)	.513	<.001*
Feedback & Communication About Error	0.74 (.18)	.504	<.001*
Standard Precaution Environment	0.77 (.12)	.435	<.001*
Management Support for Patient Safety	0.63 (.18)	.402	.01*
Supervisor/Manager Expectations & Actions Promoting Patient Safety	0.78 (.17)	.386	.01*
Teamwork Across Units	0.57 (.17)	.364	.02*
Handoffs & Transitions	0.46 (.16)	.334	.03*
Overall Perceptions of Patient Safety	0.56 (.18)	.333	.03*
Communication Openness	0.67 (.18)	.321	.04*
Staffing	0.43 (.18)	.261	.09*
Teamwork Within Units	0.85 (.12)	.113	.47
Nonpunitive Response to Errors	0.48 (.22)	.070	.66
Composite Safety Score	0.64 (.14)	.442	<.001*

Notes: Patient safety climate measured as composite frequency scores of positive responses (rated 4 or 5)
* = statistically significant at p <.05

Regarding positive perceptions of patient safety climate and observed standard precaution adherence, the relationship was not significant in aggregate. With respect to correlations among categories of standard precaution behaviors and patient safety climate, two dimensions are important to note. First, *Supervisor Expectations & Actions* was significantly correlated with observed RN standard precaution adherence (r = .352, p = .02), indicating unit level positive perceptions of this dimension explained a 12.2% of the variance in higher levels of RN adherence to standard precaution. Second, *Handoffs & Transitions* was significantly, inversely, correlated with observed PPE adherence (r (41) = -.375, p = .01), indicating unit level positive perceptions of this dimension explained a 14.4% of the variance in lower levels of observed adherence to PPE.

Examining the relationships between negative perceptions (e.g., strongly disagree or disagree) of the patient safety climate and observed standard precaution adherence the following findings are of note. First, significant correlations between negative perceptions dimensions of patient safety climate and the aggregate of observed standard precaution adherence were identified: *Supervisor Expectations and Actions* (*r* (41) = -.349, *p* = .02) and *Management Support for Patient Safety* (*r* (41) = -.346, *p* = .02). This indicates that units that negatively rated these dimensions also had lower levels of overall adherence to standard precaution. Second, with respect to correlations among categories of standard precaution behaviors and patient safety climate the following findings are important to note. Three patient safety climate dimensions were associated with HH adherence: *Supervisor Expectations and Actions* (*r* (41) = -.326, *p* = .03); *Management Support for Patient Safety* (*r* (41) = -.321, *p* = .03), and *Staffing* (*r* (41) = -.306, *p* = .04). In addition, negative perceptions of *Frequency of Events Reported* was correlated with lower levels of sharps adherence (*r* (41) = -.374, *p* = .02) and *Management Support for Patient Safety* was correlated with lower levels of safe handling of contaminated linens (*r* (41) = -.426, *p* = .02).

In summary, results of AIM 1 indicate patient safety climate was correlated with both reported and observed standard precaution adherence. Negative perceptions of the patient safety climate (overall and several specific dimensions) were more frequently correlated with standard precaution adherence (overall and specific actions) than positive perceptions.

<u>The following are key results for Aim 2</u>: "To identify the relationship between standard precaution adherence and: 1) HCW blood-borne and mucotaneous pathogen exposures and 2) HAIs." A Pearson correlation coefficient was computed to assess the relationship between the reported standard precaution adherence and HCW exposures or HAI events, findings were non-significant. Similarly, there was no significant association between the aggregate of overall observed SP adherence and HCW exposures or HAI events.

Regarding occupational findings, observed sharps adherence was significantly correlated with all staff mucotaneous exposures (*r* (41*)* = .325, *p* = .03). The OLS regression model demonstrated that observed sharps adherence significantly predicted all staff mucotaneous exposures (β = .32, *t*(41) = 2.19, *p* = .03), explaining a small proportion of variance in this outcome (R^2 = .10, *F*(1, 41) = 4.79, *p* = .03). Examinations of other standard precaution categories and HCW outcomes were non-significant.

Regarding HAI outcomes, when observed SP adherence was examined by quartiles of ("bad", "poor", "good" and "excellent") the association between adherence and MRSA was significant (*r* (41*)* = .326, *p* = .03). And when examined by category of standard precaution actions, the category of HH adherence was significantly correlated with MRSA (*r* (41*)* = .306, *p* = .04). OLS regression models were non-significant.

In summary, results of Aim 2 indicate: a) specific categories of standard precaution adherence were associated with occupational pathogen exposures and HAIs (sharps use and HH respectively), and b) levels of overall standard precaution adherence were correlated with unit level MRSA rates.

<u>The following are key results for Aim 3</u>**:** "To determine the direct and indirect relationships among patient safety climate, observed and reported standard precaution adherence, and HCW and HAI outcomes". Multivariable regression models were conducted to determine if HAI and HCW outcomes could be predicted from the group of standard precaution adherence, patient safety climate, and other independent variables as determined by prior procedures (such as Magnet status, teaching status, licensed bed size, nurse staffing).

Regarding HAIs, the group of independent variables reliably predicted CAUTI [*F*(5, 37) = 2.98, *p* = .02, R^2 = .233] and MRSA [*F*(4, 38) = 2.91, *p* = .03, R^2 = .412] F(4, 95) = 32.39, p < .0005, R2 = .577. Regarding HCW exposures and outcomes, the group of independent variables reliably predicted nurse mucotaneous exposures [*F*(5, 37) = 4.10, *p* = .004, R^2 = .362], all staff mucotaneous exposures [*F*(5, 37) = 3.75, *p* = .007, R^2 = .431], and all staff sharps and needlestick injuries [$F(4, 38) = 5.58$, $p = .001$, $R^2 = .378$]. In these models, the variables that independently added significantly to the prediction of the outcome of interest were Magnet status, nurse staffing, hospital ownership and teaching status. Details are shown in **Table 6**.

Table 6. Multivariable Regression Models for Predictors of Unit HAI and Occupational Outcomes (N = 43)			
CAUTI	**Omnibus *P* = .023*, R^2 = .233**		
Predictors	**β Coefficient**	***SE***	***P* value**
SP Adherence	-.120	.014	.641
Patient Safety Climate	.009	1.19	.952
Magnet Designated Hospital	.082	.336	.607
Teaching Status	.282	.314	.067
Nurse Staffing	.356	.008	.003*
CLABSI	**Omnibus *P* = .357, R^2 = .278**		
SP Adherence	.097	.007	.406
Patient Safety Climate	.194	1.48	.235
Magnet Designated Hospital	-.277	.442	.121
Hospital Ownership	-.419	.812	.101
MRSA	**Omnibus *P* = .034*, R^2 = .412**		
SP Adherence	.042	.000	.727
Patient Safety Climate	.077	.070	.498
Teaching Status	.201	.017	.058
Nurse Staffing	.555	.001	.030*
Nurse needlestick/sharps injuries	**Omnibus *P* = .345, R^2 = .082**		
Predictors	**β Coefficient**	***SE***	***P* value**
SP Adherence	-.103	.048	.541
Patient Safety Climate	.211	5.56	.133
Teaching Status	.240	1.83	.154
Nurse Staffing	-.000	.069	.999
Nurse mucotaneous exposures	**Omnibus *P* = .004*, R^2 = .362**		
SP Adherence	-.167	.017	.401
Patient Safety Climate	-.084	1.22	.406
Magnet Designated Status	-.441	.692	.041*
Licensed Hospital Bed Size	.371	.001	.055
Teaching Status	.258	.333	.014*
All needlestick/sharps injuries	**Omnibus *P* = .001*, R^2 = .378**		
SP Adherence	.266	.198	.074
Patient Safety Climate	.262	28.6	.091
Hospital Ownership	-.577	15.25	.016*
Average Daily Census	-.041	.593	.813
All mucotaneous exposures	**Omnibus *P* = .007*, R^2 = .431**		
SP Adherence	.098	.032	.394
Patient Safety Climate	.217	6.31	.184
Average Daily Census	-.050	.105	.733
Hospital Ownership	-.440	2.82	.037*
Magnet Designated Hospital	-.414	1.43	.004*
Notes: * = statistically significant $p < .05$., Robust regression approach with robust standard errors (SE). standardized Beta coefficients reported. SP = standard precautions. CAUTI = Catheter-associated urinary tract infection. CLABSI = Central line-associated bloodstream infection. MRSA = Methicillin-resistant *Staphylococcus aureus.* Nurse staffing defined as occupied RN full time equivalent.			

Additional findings of interest to healthcare administrators and policy makers include the following. Regarding outcomes, the dimension *Feedback and Communication about Error* and CAUTI were significantly correlated (r (41) = .338, p = .02) and the dimension *Supervisor/Manager Expectations and Actions Promoting Safety* and nurse sharps injuries were significantly correlated (r (41) = .313, p = .04).

A one-way ANOVA was conducted to compare the effect of Magnet status on standard precaution adherence and there was a significant effect of Magnet status on standard precaution adherence in quartiles of “bad”, “poor", “good” and “excellent” [F(1, 41) = 7.61, p = .008]. OLS regression models further demonstrate Magnet status was a significant independent predictor of nurse mucotaneous exposures (R^2 = .16, p = .02), and all staff mucotaneous exposures (R^2 = .21, p = .01), and while significant, explained an inconsequential amount of variance in nurse needle stick injuries (R^2 = .07, p = .04).

Nurse staffing significantly predicted CAUTI (β = .38, t(41) = 3.57, p = .001), explaining a significant proportion of variance in CAUTI (R^2 = .15, F(1, 41) = 12.78, p < .001). Nurse staffing also significantly predicted MRSA (β = .60, t(41) = 2.59, p = .01), and explained a significant proportion of variance in MRSA (R^2 = .36, F(1, 41) = 6.69, p = .01).

In summary, results of Aim 3 tests indicate there are important direct and indirect relationships among dimensions of patient safety climate, standard precaution adherence, HAIs and occupational outcomes. Key patient safety climate dimensions were identified that directly correlate to CAUTI and nurse sharps injuries. Multivariable models identified that the combination of a positive patient safety climate, better standard precaution adherence (as measured by observation), and key organizational characteristics (such as daily census, teaching status) predict key HAI and occupational health outcomes. Moreover, potentially modifiable variables of nurse staffing and hospital Magnet designation explain substantial variance in the multivariable models for outcomes of MRSA, CAUTI, nurse and all staff mucotaneous exposures.

Strategic

The cumulative contributions of this project to NORA Strategic Goals fit under the **HCSA sector** and the **Health Cross Sector: "***Work Organization and Stress-Related Disorders"* and address Goal 1 to "Improve the health and safety of working people through research and surveillance to better understand work organization exposures and their associations with health and safety outcomes"**.** Details are shown in **Table 7**.

Table 7. Contribution Matrix of NORA Sectors and K01 Outputs

Aim	NORA HCSA Strategic Goal	NORA HCSA Intermediate Goal	NORA HCSA Activity/Output Goal	Hessels' K01 Activity/Output
1	#1. Promote safe and healthy workplaces and optimize safety culture in healthcare organizations.	1.4: Promote a culture of safety: Enhance knowledge and skills needed to operationalize a culture of safety.	1.4.1: Identify key safety culture elements. 1.4.2: Develop a safety culture toolkit for hospital settings, including a safety climate survey.	Using novel safety climate and standard precaution tools, conduct national testing to refine and identify applicability for broad use in hospital settings.
		1.5: Promote a culture of safety: Healthcare organizations will institute best-practices management structures in the healthcare sector that best support a strong safety culture.	1.5.1: Identify existing best practices and management structures that best support a safety culture.	The survey tool was administered to a large sample of nurses and hospitals and identifies organizational features that support a positive safety culture.
2,3	#4. Reduce sharps injuries and their impacts among all healthcare personnel.	4.5: Evaluate and improve the utilization of best practices in all healthcare settings to reduce percutaneous injuries.	4.5.1: Identify, recommend and implement sharps injury prevention strategies based on sharps surveillance data and other information or research.	Collecting observational and survey data along with existing exposure data fosters the identification and recommendation of strategies that may be associated with lower injury rates.
		4.1: NIOSH, collaborating with partners, will promote the development and use of surveillance systems that monitor percutaneous injuries among healthcare personnel employed in all healthcare settings		With collaborative commitment of APIC and AOHP, this NIOSH funded K01 project demonstrated the ability to develop and promote unique observational surveillance tools and methods and expand to other settings.
2,3	#5. STOP transmission of infectious diseases in HCSA settings among workers, patients and visitors.	5.4: Improving HH– Investigators/industry will conduct research and development on ways to improve HH compliance.	5.4.4: Design and evaluate methods to overcome barriers to HCW using provided HH resources.	Survey and observational data identify organizational barriers and facilitators of HH compliance in a large sample of diverse HCW types and hospitals.
		5.6: Improving HH to include appropriate glove use – Investigators will examine outcomes of improved HH adherence among HCSA workers.	5.6.2: Assess impact of improved HH compliance on healthcare-associated infection rates. 5.6.3: Assess impact of improved HH compliance on healthcare worker absenteeism or other measures of healthcare worker illness.	Aggregating and analyzing survey and observational data with existing HAI and HCW data, we were able to isolate the relationship among: 1) HH on HAI outcomes and 2) HH, appropriate glove use, and HCW blood-borne exposure and injury.
		5.9: Research and adopt best practices for PPE – HCSA facilities will establish and promote a culture of safety where employer and employee commitment to worker safety in general, and the appropriate use of PPE in particular, are strengthened.	5.9.2: Conduct demonstration projects on PPE compliance and use. 5.9.3: Publish and disseminate broadly the results of these projects to ensure the proliferation of successful PPE strategies. 5.9.5: Develop surveillance of PPE usage to identify priorities, trends and emerging issues associated with the use of PPE in the workplace and use the information to establish a baseline on PPE usage, develop benchmarks and performance measures, sharpen the focus of research efforts and aid in the development of a more effective and active dissemination program.	By collecting valuable survey and observational data we isolated the compliance and use of PPE, relationship with organizational factors contributing to better compliance, trained hospital liaisons on methodology for adoption, and have and continue to publish and disseminate the results of this research project.

DISCUSSION

The overall aim of this project was to determine if hospital units that had stronger patient safety climate also had better adherence to standard precaution practices, and in turn better HAI and occupational outcomes. From this project four important breakthroughs emerge.

First, to our knowledge this study is the first to document features of a stronger patient safety climate were correlated with higher levels of both self-reported and observed standard precaution behaviors. Negative perceptions of patient safety climate, including *Management Support for Patient Safety*, added additional insight into factors that influence standard precaution adherence, indicating it may be as important for administrators to perform a deep dive to authentically “hear” perceptions of all members of the healthcare team to develop successful interventions. Moreover, identifying and targeting interventions to improve perceptions of management support for safety, supervisors expectations and actions, and staffing, may be of particular value when directing efforts to improve adherence to HH, sharps safety and contaminated linen handling.

Secondly, observed adherence to standard precautions, as a set of practices, was low across all professions and disciplines. This was discordant with high levels of reported adherence on the same unit, but consistent with the respondents’ reports of an unfavorable practice environment to perform standard precautions. Hand hygiene adherence was particularly poor across all roles. However, within the remaining standard precaution categories interesting differences in performance by role were noted. Physicians had lower levels of adherence using PPE when indicated as compared to both nurses and other providers. The “other” category of providers, largely comprised of nursing assistants, did not handle contaminated linens safely as compared to nurses, though adherence to sharps safety was higher for the “other” category than nurses. This is surprising as physicians routinely provide hands-on evaluations of patients, which might warrant use of PPE, if by example examining wounds, lesions, or respiratory mucosa. And, by nature of their professional work and scope of practice, nurses handle sharps more often than nursing aides, and aides handle soiled linens more often than nurses.

These findings provide valuable insight into role specific risks and opportunities to improve standard precaution adherence using focused prevention interventions. This may also suggest an entrenched and role-based normalization of deviance; HCW are socialized into the “way we do things here”.[56] Individual HCW should be held accountable for their professional actions, but not in isolation from the system and structural factors that facilitate or impede standard precaution adherence, such as infrastructure and resources, work-flow and work-force, and effective training and enforcement.[57,58] Organizations might leverage these role differences and encourage the high-reliability principles to ‘defer to the expertise of others’, those who are performing well consistently. For example, how might the nursing aide prompt the physician to use PPE when indicated, or the nurse guide the aide to handle contaminated linens without further environmental contamination? Team training and enhanced communication skills will be essential to coalesce our care for patients and fellow HCWs, and developers of these training modalities would be well served to take into consideration role-based hierarchies and needs of educationally disadvantaged HCWs.

Thirdly, the finding that specific categories of standard precaution adherence were associated with HAI and occupational pathogen exposures, independent of overall adherence, points to the direct nature of specific actions that may be necessary for HCWs to provide safe patient care, safely. However, while HH may be important for reducing transmission of MRSA, and sharps safety for reducing overall mucotaneous exposers, these findings do not suggest there is a trade-off of behaviors, as both patient and HCW outcomes are important. These standards were designed in whole to disrupt the chain of infection by controlling the modes of transmission and protecting portals of entry, hence, mastery and practice of one element is insufficient.[5] Thus, while targeting a specific focus area, intervention strategies must be developed in context of the entire set of standard precaution practices.[58] The challenge for health care administrators, industrial hygienists, infection preventionists, and educators however, is creating successful strategies to foster the integration of the high levels of compliance for these distinct behaviors to improve both patient and provider outcomes.

Finally, the multivariable models identified for the first time that in combination a stronger patient safety climate, better standard precaution adherence (as measured by observation), and key hospital characteristics (such as nurse staffing, daily census, teaching status) predict key HAI and occupational health outcomes. These models explain 41% of the variance in MRSA, 23% of the variance in CAUTI, and 43% of the variance in all staff mucotaneous exposures and 38% of the variance in all staff needlestick and sharps injuries. We also identified potentially modifiable organizational factors of nurse staffing and Magnet hospital status as important explanatory variables.

Emerging evidence has identified a relationship between nurse staffing and HAIs, including bloodstream infections, pneumonia and urinary tract infections (with and without a catheter)[59,60] Our study confirms these findings and extends our understanding of the nature and scope in that unit level nurse staffing predicts unit level CAUTI and MRSA rates, independent of patient safety climate and other organizational factors. Literature has also documented that Magnet facilities have better patient outcomes, including lower incidence of HAIs (CLABSI, CAUTI, and MRSA), length of stay, and mortality and reported benefits of increased nurse satisfaction and retention and decreased staff turnover.[53,60-64]

Magnet status characterizes and includes nurse participation in hospital affairs, nursing foundations for quality care, nurse manager ability, leadership, and support of nurses, staffing and resource adequacy, and collegial nurse-physician relations and is measured in part through the nurse practice environment.[65] Thus, the nurse practice environment captures distinct, but similar, constructs to the dimensions of the safety climate.[66] In this study, hospital Magnet status may be considered a proxy measure for nursing practice environment.

Unfortunately, there is a dearth of literature that examines the organizational impact, operationalized by Magnet designation, on needlestick injury and mucotaneous exposures in HCWs. Moreover, sentinel studies, while informative, are limited largely by decades old publication dates, occur prior to the national strengthening of voluntary adverse event reporting systems, or include self-reported incidence of needlestick injuries[53,6,68] In fact, a recent systematic review that examined the impact of hospital Magnet status on patient, nurse and organizational outcomes identified only one article that included needlestick exposures, and this was a business case assessment for small hospitals[64]

This is the first study to our knowledge to document the impact of Magnet designation status on unit level nurse and staff mucotaneous exposure rates. While our study did not identify Magnet status as an independent predictor of HAIs, we generated new evidence of the relationship of Magnet designation and important occupational health outcomes. When these results are considered in context of extant literature, it appears both patients and HCWs benefit in terms of outcomes when seeking care or working in a Magnet designated organization.

This year marks the 20th anniversary of the Needlestick Safety and Prevention Act. Unfortunately, our findings reveal there has been little progress in improvement, and dishearteningly, this issue has garnered little attention in occupational and health services research. Moreover, the focus of published work is largely percutaneous, not mucotaneous, exposures, which is concerning as estimates suggest only 12% of mucotaneous exposures are reported.[69] Findings from this study amplify the recently published *Moving the Sharps Safety in Healthcare Agenda Forward in the United States: 2020 Consensus Statement and Call to Action*, which declares the risk of occupational exposure is greater today than at the time of the initial report and calls to redouble our efforts.[70]

Limitations

This is a cross-sectional study as such though it was possible to show significant relationships among several key variables causality cannot be established. The sample size was smaller than planned and may have been too small to detect meaningful relationships if they existed. Because Magnet status is a journey that takes several years for organizations to attain, it may be that the longer-term, entrenched culture and upstream factors are more predictive of outcomes than the proximate measures of climate, such as that captured in this study. Survey data were only collected from nurses; therefore, we do not know if self-reported and observed adherence data is better aligned for other provider roles. Despite careful planning and observer selection and training, the possibility of a Hawthorne effect exists, therefore actual adherence may be even lower than we report. It is possible that our sample includes hospitals with higher safety awareness and participation in improvement initiatives to decrease HCW and HAI adverse outcomes. Similarly, we are unable to ascertain the duration of a hospitals' Magnet status, and therefore cannot infer a nurse respondents' tenure in the organization indicates exposure to Magnet environment (and if so for how long). Reliance on secondary data from hospital departments may also be a limitation; using established metrics and definitions that are known to the survey respondents should limit any misinterpretation of data. While our models identified important predictors, and explained substantial variance in outcomes, we were limited by sample size on the number of predictors we could include, and by design, did not include all possible important factors for each outcome.

Conclusions

This study produced four scientific breakthroughs advancing the state of the science in patient and occupational health safety. First, patient safety climate is correlated with higher levels of both self-reported and observed standard precaution behaviors. Secondly, observed adherence to standard precautions is low across all professions and disciplines, and key role distinctions are noted. Thirdly, we identify and document specific standard precaution actions associated with HAI and occupational pathogen exposures. Finally, by employing innovative methods, strategies and approaches to collect and analyze multiple complex sources of data, we identified direct and indirect relationships among patient safety climate, observed and reported standard precaution adherence, and HCW and HAI outcomes. In combination, these results tell us that a stringer patient safety climate, better standard precaution adherence, and key organizational characteristics, predict key HAI and occupational health outcomes.

The translation of these breakthroughs at the point of care will be realized through targeted interventions and cross-cutting surveillance methodology that captures risks at the intersection of patient and occupational health and safety. Leaders can identify and implement prevention strategies based on local surveillance data and other organizational information. These breakthroughs also provide future orientation for policy makers to support research that further clarifies and disentangles the factors that meaningfully contribute to high-reliability organizations and positive patient and HCW outcomes. In so doing, this study contributes to: stopping the transmission of infectious diseases in HCSA settings among workers, patients and visitors; promoting safe and healthy workplaces and optimizing safety culture in healthcare organizations; and reducing sharps and mucotaneous injuries and their impacts among all healthcare personnel.

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Additional Items

1. Cumulative Inclusion Enrollment Table.
   Attached

2. Inclusion of gender and minority study subjects.
   N/A

3. Inclusion of Children.
   N/A

4. Materials available for other investigators.
   Data collection materials (observational tool), instructions for use and reduced set of training vignettes have made available to investigators and clinical practitioners. We will make de-identified data from our study available. Researchers interested in replicating our methods and study findings will have full access to the study protocol and analytic methods. The PI is the point of contact for requests. All manuscripts, abstracts, presentations, and chapters developed as a results of this study, including those from outside investigators accessing our research resources, will credit the CDC and NIOSH as the funding source for the data. This process will allow for a central repository and access point for all papers, abstracts, posters, and presentations by any individual or organization using our data. Our plan for resource and data sharing is designed to assure that data generated in this project are made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary information.