PREVENT

HAIs

Healthcare-Associated Infections

Advances in the Prevention and Control of HAIs

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Preface

For over a decade the Agency for Healthcare Research and Quality (AHRQ) has invested in research and implementation projects to prevent healthcare-associated infections (HAIs) in diverse health care settings. AHRQ's commitment to HAI prevention has been expressed in activities within the Agency and through its funding of contracts and grants. In 2011, AHRQ funded IMPAQ International and the RAND Corporation to conduct a synthesis of results of AHRQ-funded HAI projects to identify the major results and lessons learned stemming from AHRQ-funded research, disseminate this information, and identify remaining gaps in the HAI knowledge base. To accomplish these goals, the synthesis draws information from AHRQ-funded project documents (final reports, peer-reviewed literature, and HAI prevention toolkits), in-depth interviews with project leaders, and forthcoming supplements of peer-reviewed infection control journals. In addition, the present volume, Advances in the Prevention and Control of HAIs, is a key information source for the synthesis project and also serves as a valuable dissemination mechanism for methods-related findings and lessons learned. This publication continues AHRQ's highly successful Advances series and focuses on methodological issues associated with the identification, mitigation, and prevention of HAIs, including challenges encountered in the conduct of the studies and how the challenges were overcome.

This volume presents manuscripts developed by AHRQ-funded HAI project leaders who have agreed to share important methodological insights and lessons learned. The volume includes 19 manuscripts organized under two headings. The 11 papers that make up the Development and Implementation of HAI Prevention Practices section discuss methods, challenges, and lessons learned from designing, deploying, and testing HAI prevention practices. The remaining manuscripts fall into the category of HAI Risk Identification for Quality Improvement and focus on HAI surveillance methods and the use of data and technology as a means to improve HAI prevention.

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Advances in the Prevention and Control of HAIs: Setting the Stage

James B. Battles, James I. Cleeman, Katherine L. Kahn, Daniel A. Weinberg

Background

For over a decade, the Agency for Healthcare Research and Quality (AHRQ) has invested in research and implementation projects to prevent healthcare-associated infections (HAIs) in diverse health care settings. AHRQ's commitment to HAI prevention has been expressed in activities within the Agency and through its funding of contracts and grants. In 2011, AHRQ contracted with IMPAQ International and the RAND Corporation to conduct a synthesis of results from AHRQ-funded HAI projects. The goals of the synthesis are to identify and disseminate the major results and lessons learned from AHRQ-funded research, as well as to identify remaining gaps in the HAI knowledge base. To accomplish these goals, the synthesis draws on information from AHRQ-funded project documents (final reports, peer-reviewed literature, and HAI prevention toolkits), in-depth interviews with project leaders, and materials to be presented in forthcoming supplements of peer-reviewed infection control journals. In addition, this volume, Advances in the Prevention and Control of HAIs, is a key information source for the synthesis project and also serves as a valuable dissemination mechanism for methods-related findings and lessons learned.

This publication continues AHRQ's highly successful Advances[a] series and focuses on methodological issues associated with the identification, mitigation, and prevention of HAIs, including challenges encountered in the conduct of the studies and how the challenges were overcome. Complementing this volume's focus on methods, the forthcoming special supplements will present the major results of AHRQ-funded HAI research.

Advances in the Prevention and Control of HAIs presents peer-reviewed manuscripts developed by AHRQ-funded HAI project leaders who have agreed to share important methodological insights and lessons learned. These papers are a form of technology transfer—they provide important methodological details that will facilitate replication of project approaches and results. The information presented here will also assist researchers conducting similar projects because lessons learned are likely to be applicable to other HAI research efforts and to various types of patient safety research and implementation efforts.

[a] For Advances in Patient Safety: From Research to Implementation; Volumes 1-4 (February 2005), go to www.ahrq.gov/advanceps1. For Advances in Patient Safety: New directions and Alternative Approaches; Volumes 1-4 (July 2008), go to www.ahrq.gov/advanceps2.

Organization: Two Major Categories

The volume includes 19 manuscripts organized into two sections. The first section, Development and Implementation of HAI Prevention Practices, includes 11 papers that discuss methods, challenges, and lessons learned from designing, deploying, and testing HAI prevention practices. The second section, HAI Risk Identification for Quality Improvement, presents eight papers that focus on HAI surveillance methods and the use of data and technology as a means to improve HAI prevention.

The articles represent a diverse set of patient cohorts, practice settings, clinical conditions, and intervention types. They include investigations pertinent to patients and staff in ambulatory surgical centers, outpatient dialysis centers, hospitals, hospital intensive care units, long-term care centers, and assisted living settings. Clinical conditions addressed include infections caused by specific organisms (e.g., methicillin-resistant *Staphylococcus aureus* [MRSA], *Clostridium difficile*) as well as specific HAI conditions (e.g., central line-associated bloodstream infection [CLABSI], catheter-associated urinary tract infection [CAUTI]). Despite addressing HAI prevention efforts in different settings and for different HAIs, several themes emerge across these methodological studies.

A prevalent theme is the complexity associated with simultaneously utilizing rigorous, scientifically based methods while assuring flexibility, so that implementation strategies would be responsive to the unique contextual needs of each setting. This complexity has been recognized as one of the key themes of the nascent, but rapidly developing, field of implementation and dissemination science.[1-4] It is reassuring that the manuscripts presented in this volume, which specifically address challenges and opportunities in the implementation of HAI research, highlight the same concerns as those raised in the implementation science literature, which spans a wide spectrum of clinical domains.[5-7] Papers included in this issue vary with respect to the scientific focus of the work, addressing topics such as antimicrobial stewardship, HAI screening in the postoperative period or in long-term care facilities, development of consensus algorithms for antibiotic use, strategies for systematic data collection from primary care providers in community settings, and engineering risk assessment for patient safety events, such as particular types of HAIs. Despite these differences, each paper expresses the importance of tailoring implementation strategies to account for the clinical, cultural, and information technology contexts of sites.

The papers also highlight the importance of study site stakeholders. Health care leaders often serve an important role as potential champions for successful implementation. Many individuals, including subject-matter experts—such as infection preventionists, infectious disease physicians and pharmacists, primary care providers, and nurses—and a wide spectrum of individuals with varied, but relevant expertise—including environmental specialists, laboratory technicians, clinical coders, and information technologists—played important roles aligning the scientific protocol with the local site's culture, budgetary resources, staffing, and information technology capabilities. Researchers documenting their implementation experiences noted the importance of developing and maintaining strong interpersonal relations to facilitate understanding of contextual factors and to assure open communication as implementation challenges emerge. Multiple investigators demonstrated that resources and staffing of the sites can have a major impact on implementation, functioning either as barriers or facilitators.

Investigators implemented education strategies to address gaps between researchers' clinical goals and the clinical realities of study sites. Researchers were challenged to scale their efforts to reasonably match the fiscal constraints of their sites so that the planned design could reflect the scientific design while recognizing the available (or unavailable) site resources. Cultural characteristics of settings varied substantially. Overall, researchers suggest that interventions in settings in which a champion supports the research work better. Settings in which the culture supported asking questions and discussing challenges tended to be more responsive to the needs of researchers.

Investigators noted that site-specific data capabilities varied tremendously across data sources, including traditional paper-based and electronic health records, claims data, and microbiological data. They responded to these differences by paying considerable attention to access to and quality of their data sources. Investigators conducting multi-site studies identified heterogeneity in data as a challenge. Multiple papers collecting data from diverse health care settings highlight the importance of structuring HAI data in a standardized format that would support meaningful data aggregation and analyses, even when faced with the common problems of unusable and missing data. Although some papers in this volume focus on the application of validation methods to entire data sets, others note only limited validation for data they had received and were expected to use. Overall, much consideration was given to the importance of these data attributes in determining the researchers' ability to maintain the project timeline and budget as planned.

Summary

Across all of these manuscripts, a pattern emerges: the studies report on both scientifically grounded findings and practical considerations pertinent to site and patient factors. As a whole, the papers included in this issue consistently highlight the importance of pairing scientific data with qualitative human inputs. Papers feature the need to be flexible and accommodate variations across settings, while also maintaining fidelity in program implementation and systems level intervention.

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Section I. Development and Implementation of HAI Prevention Practices

Advancing the Science of Patient Safety and Quality Improvement to the Next Level

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Abstract

This paper describes our journey to advance the science and practice of patient safety and quality improvement. The journey began with efforts to identify hazards through an incident reporting system called the Intensive Care Unit Safety Reporting System. We quickly found that identifying hazards was merely a first step. We also needed to investigate and learn from these hazards to prevent patient harm. Therefore, we developed the Comprehensive Unit-based Safety Program (CUSP) to identify and learn from local defects and improve teamwork and safety culture. Teams across many units faced common problems, such as healthcare-acquired infections, for which there is empiric evidence on prevention practices, but the evidence is unreliably applied. This discovery led us to develop a model to translate research into practice (TRIP). We combined TRIP with CUSP for the Keystone ICU Project design, with the goal of improving care for adult patients in Michigan intensive care units (ICUs). The resulting dramatic and sustained reductions in central line-associated bloodstream infections (CLABSIs) in Michigan led to a national initiative to reduce CLABSIs across the United States. Applying the perspectives from different academic disciplines helped us learn how this national effort succeeded, an approach we also used to study cardiac surgery-related errors. Still, the CLABSI effort addressed one type of harm, while patients are at risk for over a dozen and care systems relying more on the heroism of clinicians than on safe design. Current efforts include building a quality management infrastructure to support improvement work and defining the skills, resources, and accountability needed at every level of a health system. We are also partnering with patients, their loved ones, and others to eliminate all harms, optimize patient experience and outcomes, and reduce waste. In this trans-disciplinary systems approach, we hope to reduce all harms, improve productivity, and enhance joy for clinicians.

Introduction

Before the renowned *To Err is Human* report,[1] there were isolated studies digging into the problem of medical mistakes.[2] The Institute of Medicine (IOM) report brought urgency and attention to the problem and advanced the theory that system flaws were more to blame than the failures of caregivers.[1] The IOM and other prominent agencies looked to clinicians and researchers for answers, but the science was barely a bud on a branch. The 2013 report, *Making Health Care Safer II*, from the Agency for Healthcare Research and Quality (AHRQ), shows how much the science has matured and how much we still have to learn.[3] This paper reflects on our research group's journey to advance the science of patient safety and quality improvement. We approached the work organically. The work evolved and often germinated new ideas,

projects, or interventions. We grafted experiences and models from other disciplines onto our work, resulting in stronger inferences and robust interventions. All of these contributed to improving the quality of care and patient outcomes.

Reflecting back, we helped advance the science by identifying hazards, establishing a culture of safety, reducing a preventable harm, and moving from one type of harm to all harms (Table 1). Throughout our efforts, we had profound respect for the wisdom of health care workers, especially caregivers; sought to integrate researchers with operational safety practitioners; and used the frontlines of clinical care as our laboratory to harness the wisdom of clinicians, test tools and interventions, measure performance and evaluate success, and acquire new knowledge. We assembled interdisciplinary teams and used transdisciplinary research (team science), in which different disciplines work on common problems through a common conceptual model, to bring a comprehensive perspective to our work.[4]

Table 1. Journey advancing the science of patient safety and quality improvement

Year Started	Description and Funding Source
1999	• Vascular access device policy and training on central line-associated bloodstream infection (CLABSI) prevention practices • Central line insertion cart
2001	• Comprehensive Unit-based Safety Program (CUSP) • Daily goals sheet for intensive care unit (ICU) • Checklist of five evidence-based therapies to prevent CLABSI
2002	• Ventilator-associated pneumonia (VAP) intervention • ICU Safety Reporting System project, funded by the Agency for Healthcare Research and Quality (AHRQ)
2003	• Michigan Keystone ICU project (CUSP, CLABSI, and VAP interventions), funded by AHRQ
2007	• Adventist health systems project (CUSP, CLABSI), funded by the Robert Wood Johnson Foundation
2008	• National program: *On the CUSP: Stop BSI* [bloodstream infection] (CUSP and CLABSI interventions), funded by AHRQ, the Price Family Foundation, and the Sandler Foundation for the Jewish Community Endowment Fund • Locating Error through Networked Surveillance (LENS study in cardiac surgery), funded by the Society for Cardiovascular Anesthesia Foundation
2010	• Cardiac Surgery CUSP Program (Linking operating room [OR], ICU, and floor CUSP teams), funded by AHRQ
2011	• Medication infusion pump usability study, funded by AHRQ • National Program for Surgical Safety (SUSP) and Ventilator-Acquired Complications, funded by AHRQ and the National Institutes of Health
2012	• Systems approach to eliminating all patient harms including harm from disrespectful care (EMERGE Project), funded by the Gordon and Betty Moore Foundation • Fractal quality management infrastructure • Peer-to-peer review

Note: a fractal comprises smaller parts that are similar or identical to the whole object and connected to support and form the whole object.

Identifying Hazards

In 2001, researchers from the Johns Hopkins University, Quality & Safety Research Group, were awarded a grant from AHRQ to build and use an incident reporting system to identify hazards in a cohort of intensive care units (ICUs). This demonstration project was called the Intensive Care

Unit Safety Reporting System (ICUSRS).[5,6] First, we had to develop a system that staff would use to report incidents. We researched existing reporting systems, including the Australian Incident Monitoring Study,[7] to determine how they encouraged self-reporting and what data they found useful. We learned that the aviation safety reporting system (ASRS)[8] was successful because it collected adverse event and near-miss data and used the data to fix systems rather than blame individuals. We included these elements in the ICUSRS. Our project identified factors contributing to incidents and established a network of units to share de-identified data, learn from reports and experiences, and improve care.[9–12]

The ICUSRS was Web-based and accessible from any computer for convenience and privacy (home or work). It was anonymous and confidential (to protect users from perceived or actual punitive actions or liability), voluntary, and integrated with existing reporting systems to avoid duplicate reporting.[13] We collected quantitative and qualitative data to obtain a comprehensive account of the incident. The system went live in July 2002 in three ICUs at the Johns Hopkins Hospital (JHH) and ramped up to 23 ICUs across the United States. We partnered with the Society for Critical Care Medicine, which identified and recruited a geographically diverse group of hospitals and ICUs (adult and pediatric, including medical, surgical, cardiac, and trauma services). Each participating unit assembled an interdisciplinary team to encourage reporting, disseminate feedback, and manage improvements.

The information gleaned from this project benefited the participating ICUs and provided our agenda for further research and intervention. The aggregate data helped sites recognize hazards and change care processes. For example, one site found a large cluster of medication errors when a pharmacist was not present on the unit. The data helped us recognize common hazards, such as inadequate training/education and teamwork.[9–11,14]

As we worked with the participating sites, we discovered that local culture played a major role in whether or not staff reported incidents and/or teams used their data to improve safety. We also found that simply identifying hazards was not enough. We all needed to learn from them to mitigate the risks that would otherwise harm future patients. These insights led to the creation of the Comprehensive Unit-based Safety Program (CUSP).

Establishing a Culture of Safety

Our work in ICUs helped us realize that culture is an integral part of safety and quality improvement. At the same time, a Safety Committee was created at JHH in response to the IOM report.[1] The committee created CUSP to build a culture of safety throughout the hospital.[15–20] CUSP was based on available evidence and expert advice and evolved through trial and adaptation.[21] The committee studied commercial aviation's success with improving and managing errors and high reliability organizations and found industries where employees shared a common commitment to safety. When we started at JHH, frontline clinicians were unsure about the hospital's commitment to safety, and hospital leaders were far removed from the frontlines of care. Recognizing that safety programs must empower frontline staff and provide them with resources to identify, and mitigate risks and that performance and culture vary widely among units, the safety committee designed CUSP as a unit-level intervention to reach all staff and connect them to hospital management.

The original CUSP measured safety culture (pre- and post-intervention), educated staff on the science of safety, partnered units with a hospital executive,[18] and had staff identify safety concerns, implement improvement efforts and document results, and share their learning across the organization.[17] The program was piloted in two ICUs in 2001 as an eight-step program. It continued to evolve as it was implemented and spread to other clinical areas at JHH,[21] and it now comprises five steps.[22] CUSP built a safety infrastructure within units, changed unit culture, and became the platform on which to organize and implement many safety or quality improvement efforts. For example, we were accumulating reports of errors and near misses through the ICUSRS project without a formal process for staff to prioritize their greatest safety concerns and mitigate these risks. To rectify this, we developed a feasible yet scientifically sound root cause analysis tool, called "learning from defects," that staff could use to immediately investigate a defect,[23] and we made this a step in CUSP.

Our defect investigations and sentinel event reports from The Joint Commission repeatedly noted poor communication and teamwork as major contributing factors to all types of adverse events. Teamwork and communication errors quickly became a catch-all term, comprising many types of errors. Thus, we reviewed the literature and looked at specific ways to improve communication and teamwork. We already had a checklist to coordinate and effectively communicate a patient's daily goals during rounds. This checklist was developed in 2001, when an ICU attending physician (PJP) realized that only 10 percent of the nurses or physicians in an adult surgical ICU at JHH understood the goals for their patients at the end of rounds. The checklist was pilot tested in the same ICU, increasing nurse and physician comprehension of daily patient goals to 95 percent.[15] The daily goals checklist became a repository for some safety practices. For example, one item reminds clinicians to remove unnecessary central lines, which is part of the Centers for Disease Control and Prevention (CDC) guidelines for managing existing lines. The checklist was a great success and was modified to fit other clinical areas at JHH,[24,25] and it is now a staple of interdisciplinary rounds and team communication in ICUs across the United States and much of the world.

To help clinicians address their specific teamwork concerns, we gradually assembled a menu of tools from which a CUSP can choose to improve teamwork, communication, or culture, and we made this a program step.[15,16,19,20,24–27] With all of these tools, we identified the need; searched the evidence to see what, if any, interventions were successful; developed tools; and pilot tested them for content validity and feasibility.

Reducing One Preventable Harm: Local, National, Global

While CUSP helps units improve their safety culture and learn from *local* mistakes, we recognized that a different method was needed to mitigate *common* causes of harm, harms with empiric evidence-based practices that were common and standardized enough to be measured as rates. To reduce these types of harms (e.g., bloodstream infection, ventilator-associated pneumonia, surgical site infection [SSI], deep venous thrombosis, and decubitus ulcer), we developed a model for translating research into practice (TRIP).[28] The model was designed for collaborative groups to improve performance over a large cohort of units. Some work is most efficiently conducted by a coordinated scientific body. For instance, it would be ineffective and inefficient for individual units to review evidence on their own and develop performance measures. The TRIP model includes summarizing evidence-based practices into simple, unambiguous checklists; identifying barriers to implementing those practices;[29] measuring

performance (processes and outcomes, if possible); ensuring that all patients reliably receive the checklist items; and encouraging units to locally modify how they implement the checklists.

Our efforts to prevent one type of patient harm—central line-associated bloodstream infection (CLABSI)—began in 1999 at JHH. A convergence of the CDC-sponsored clinical guidelines, JHH epidemiology and infection control efforts, and awareness of high infection rates from central lines—lines we inserted daily—inspired us to reduce these rates. The guidelines recommended effective and feasible clinical practices, yet these practices were not routinely reaching patients. We sought to bridge this gap.

The project to prevent CLABSIs occurred over a 3-year period.[30] It included a mandatory training module (which taught clinicians the infection prevention practices), a central line cart, and a line insertion checklist. Five of the checklist practices related to catheter insertion (wash hands, clean patient skin with chlorhexidine, use full barrier precautions during insertion, avoid femoral vein site, maintain sterile field during insertion), and one described catheter maintenance.

Despite knowledge and a desire to comply with the checklist, physicians faced a major barrier—lack of necessary supplies. We followed the principles of safe design (part of the CUSP training in the science of safety) and created the line cart because clinicians in our surgical ICU had to gather catheter insertion supplies from eight places to comply with the practices. The cart increased checklist compliance rates from 30 percent to 75 percent, but we were still far from 100 percent. Infection rates were cut in half. Therefore, we compiled a checklist of these best practices, which standardized the insertion process and offered an independent check by the bedside nurse to ensure that physicians complied with these practices. When nurses piloted the checklist, physicians resisted being questioned about their practices and often ignored nurses (a warning that to improve safety we must also improve culture). Therefore, we educated all staff about the consequences of suboptimal practices. We empowered nurses to stop non-emergent procedures if a practice was ignored and instructed them to page the ICU attending physician if a resident was noncompliant. With the nursing intervention, compliance increased from 75 percent to 95 percent, and infection rates fell further. Finally, ICU and infection prevention staff investigated every infection as a defect, using a modified version of the original learning from defects tool,[23] to identify ways to prevent the infection. The success of the overall intervention shifted health care from the philosophy that bloodstream infections were inevitable, to the realization that most infections are preventable. Moreover, it identified opportunities to further reduce infections by taking the checklist to the operating room and developing a checklist to improve catheter maintenance practices.

Through the CLABSI project,[31] we established an improvement model that seemed to work and made sense and empowered clinicians: identify an outcome to improve, summarize the evidence to identify interventions that improve the outcome, query frontline staff to identify barriers to complying with the interventions, standardize the process to reliably implement the interventions (e.g., checklist), educate staff about the evidence, have staff implement the interventions in the most seamless way possible in their work area, and evaluate whether interventions were used and improved the outcome. We continue to use this model today to translate evidence into practice.[28]

In 2002, when AHRQ announced a second Request for Proposals (RFP) to improve patient safety, the director of the Keystone Center for Patient Safety and Quality, part of the Michigan

Health & Hospital Association (MHA), approached us about partnering on a grant to improve care in Michigan ICUs. Historically, many quality improvement projects had poor data quality, often lacking standardized definitions and data collection tools, and usually missing volumes of data that exceeded available data, thus limiting the ability to draw inferences.[32,33]

We designed a cohort collaborative in which the Hopkins group provided the technical science (interventions, evidence, data collection tools, and analysis), and the Keystone Center provided project management, recruitment of hospitals, and interaction with improvement teams.[34] To support the large number of participating hospitals and ICUs, we used a theory of change that was practical, yet based on the diffusion of innovation and behavior change.[35,36] Our implementation model included four E's (engage, educate, execute, evaluation) and targeted the three levels of a hospital required to improve care (executive leaders, unit team leaders, and frontline staff).[28]

The project included interventions with evidence supporting their use, including CUSP, daily goals and interdisciplinary rounds, ICU physician staffing,[37,38] our checklist of infection control prevention practices for CLABSI, and another checklist we developed to prevent ventilator-associated pneumonia. CUSP was implemented first, and in parallel with the four E's model,[28] to prepare staff to implement the other interventions. Over 100 ICUs participated in the AHRQ-funded Keystone ICU project from September 2003 to September 2005. The design was a prospective cohort study using a multiple time-series analysis. Our original intent was to conduct a cluster-randomized design in which hospitals would be randomized to receive the intervention early versus late, but few hospitals wanted to be randomized to the control group. Most hospitals believed the intervention would be effective and wanted to implement it. In response, we changed our design to a multiple time series and achieved significant reductions in CLABSIs, though the design lacked a concurrent control group.[39,40]

We established an association between the CUSP/CLABSI interventions and reduced CLABSIs in the Keystone project. A next step, scientifically, was to test this association in a randomized clinical trial to evaluate the effectiveness of the interventions. With a Robert Wood Johnson Foundation grant, we conducted a phased, cluster-randomized trial in 45 hospitals from two Adventist health systems, from 2007 to 2008.[41] In the Adventist collaborative, we added two E's to our organizational change model. *Expand* encouraged teams to spread the program to other units, and *endure* reminded teams to make the intervention a part of routine practice. We also placed greater emphasis on catheter maintenance. The Adventist hospitals decreased their CLABSI rate by 81 percent, an even greater impact than the 66 percent rate reduction achieved in the Keystone project.[39] Importantly, the Adventist collaborative established a causal relationship between the intervention and reduced CLABSIs.

Next, our team recognized that to gain support to spread this intervention broadly, we needed to demonstrate not only that it prevents infections, but that it can be sustained, save lives and money, and be disseminated to other States and types of harm. Sustainability demonstrates whether a successful intervention can become routine practice and engrained in the culture. In a followup analysis, low CLABSI rates were sustained.[39] Moreover, the program improved the safety climate,[42] sustained reductions in VAP,[43] decreased mortality rates,[44] and averted $1.1 million in annual costs per hospital.[45] Despite comparable mortality rates, by the end of the study the mortality rate of a Medicare patient admitted to any Michigan ICU was 10 percent lower than for similar patients in the 11 surrounding States.[44] The intervention was disseminated to Rhode

Island, with similar reductions in CLABSI.[46] The return on AHRQ's $500,000 yearly investment in this 2-year project was unprecedented and led the agency to award additional funding to spread the collaborative project to other States across the United States.

With support from AHRQ, the Price Family Foundation, and the Sandler Foundation for the Jewish Community Endowment Fund, in 2008 we partnered with the American Hospital Association and its research arm, the Health Research Education Trust (HRET), and with the Michigan Keystone Center (MHA), State hospital associations, and many other organizations to implement the collaborative in every State, the District of Columbia, and Puerto Rico.[47]

Hawaii and Connecticut soon replicated the Michigan results.[48-50] Overall, 1,100 hospitals and 1,500 ICUs reduced their infection rates by 41 percent. Moreover, these hospitals achieved a mean rate of one infection per 1,000 catheter-days, a rate deemed impossible before the Michigan work. In Hawaii, the interventions were spread to non-ICUs, and the State leader for the project, from the Healthcare Association in Hawaii, worked with sites to develop tools to reduce rates even further.[48] Also, beginning in 2008 with a partnership with the World Health Organization, the intervention termed "Matching Michigan" was spread to nearly all hospitals in England and Spain and to a sample of hospitals in Peru, Pakistan, and the United Arab Emirates (UAE). The intervention was associated with significant reductions in CLABSIs in Spain, Peru, and Pakistan. The UAE effort is ongoing.

While linking teams in clinical communities[51] explains a large part of the success in reducing CLABSIs, with AHRQ funding we are applying CUSP methods to reduce ventilator-associated complications and surgical complications, other preventable causes of mortality. We realized we needed to link care teams across different service lines within the hospital to improve safety during patient handoffs and remove silos of care. In most hospitals, CUSP teams have had limited interactions with other care areas. Thus, with AHRQ funding, we sought to build on our work of identifying hazards in cardiac surgery[27,52–55] and our work with CUSP/CLABSI by linking CUSP teams within a cardiac surgery product line. We are working with 15 hospitals to create cardiac surgery operating room, ICU, and floor CUSP teams. These teams will link with similar teams at other hospitals and with CUSP teams in different care areas within their own hospital. Although our analyses are still underway, these teams have demonstrated significant reductions in CLABSI, VAP, and SSI and increased teamwork among units.

Beyond One Harm to All Harms

The national CLABSI program provided lessons regarding what it takes to eliminate additional harms: ensure safety through the safe design of systems rather than the heroism of clinicians, build a fractal quality management infrastructure, influence peer norms through peer-to-peer review, and create more valid outcome measures. Despite these successes, the CLABSI work addressed one type of harm, while individual patients are at risk for over a dozen. Harms extend beyond physical harm to harm from disrespectful and undignified care.[56] Yet most hospitals work on only one or two harms, largely because the methods to reduce harm are too burdensome. With generous support from the Gordon and Betty Moore Foundation, we are developing a systems engineering approach with a goal to eliminate all recognized harms (EMERGE Project). For example, ICU patients are at risk for CLABSI, ventilator-associated complications, deep venous thrombosis and pulmonary embolus, decubitus ulcers, delirium and physical deconditioning, and disrespectful care that does not meet their needs, among other harms. There

is a checklist to prevent each of these harms, and when added up, there are nearly 200 interventions required each day to prevent all the harms. Yet there is no information technology (IT) tool that lists these harms and therapies. In the EMERGE project, we will work to create an integrated IT platform to ensure that patients receive all 200 interventions. This approach also applies to outpatients who are similarly at risk for multiple harms.

In addition to improving safety, this approach could significantly improve productivity and reduce health care costs. Health care is the only industry that invested heavily in IT but nearly flatlined in productivity. Today's ICU is likely less safe and productive than it was 30 years ago. It is packed with more devices and alarms, and none communicate. False alarm rates are extremely high in critical care,[57] ranging from 85 percent to 99 percent in one study, and alarm fatigue is a documented problem.[58] In this project, 18 different disciplines are using team science[4] and working with patients, their families, and the private sector to eliminate preventable harm, optimize patient outcomes and experience, and reduce waste.

We also recognized that most devices are designed with little input from clinicians, creating human-machine interface problems and harming patients. With AHRQ funding, we partnered with human factors and systems engineers to evaluate the usability of a ubiquitous medical device, medication infusion pumps. In this study, we determined what users needed to safely operate infusion pumps; the next step is to encourage manufacturers to use our findings[a] to design safer pumps. The opportunities in systems engineering and medical device redesign are enormous.

In addition to systems engineering, we learned that an infrastructure of defined skills, resources, and accountabilities was needed at every level of the health care system to manage and support the improvement work. In addition, each higher level should regularly meet with staff from each lower level to support peer learning and accountability. Improvement of patient safety and quality requires this fractal infrastructure. This quality management infrastructure is grossly underdeveloped in health care; without it, progress will remain slow and arduous.

Informed by the work of the World Association of Nuclear Operators, we are developing tools for peer-to-peer review, in which one provider organization evaluates another, focusing on an outcome (CLABSI), a geographic area (ICU or operating room), or an overall program (quality and safety).[59] Lacking regulatory authority, these reviews focus on learning rather than judging, using validated tools and clinicians, being confidential yet probing.

Finally, health care has too few valid outcome measures, limiting the ability to develop programs to reduce other harms besides CLABSI. No U.S. entity is charged with developing measures, reporting performance data, or housing the data. A health care entity similar to the Securities and Exchange Commission would offer hope that one day, the quality committee of a health system's board could function like an audit committee, with clear goals and valid measures, with skilled staff at all levels of the organization monitoring performance, and with clear accountability and performance monitoring.

[a] Unpublished data, Julius C. Pham, January 2, 2014.

Reflection

In reflecting on our journey thus far, we have learned several things. First, funding was essential to advance the science. Prominent organizations such as the Agency for Healthcare Research and Quality, the Robert Wood Johnson Foundation, the World Health Organization, the Price Family Foundation, and the Sandler Foundation for the Jewish Community Endowment Fund believed in the work and supported our efforts. Medical error is the third leading cause of death, yet Government research funding remains disproportionate to the magnitude of the problem. Second, professional norms are the roots. Clinicians must drive the work and be linked to clinical communities through intrinsic motivation and be energized by peer-to-peer learning to implement the work. Third, all disciplines must be involved to offer a comprehensive perspective on the problems and the solutions. Fourth, science must guide us, and the measures used must be valid. Fifth, we need skilled staff, resources, and accountability at every level to connect the work vertically in the organization and horizontally to clinical communities, clinicians, and other groups. Sixth, health care needs more measures of patient outcomes and costs and an organization similar to the Securities and Exchange Commission to coordinate measure development.[60]

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Strengthening National Efforts to Reduce Healthcare-Associated Infections

Stephen C. Hines

Abstract

National improvement campaigns to reduce healthcare-associated infections (HAI) are demonstrating promising results but still need to become more efficient and effective. The Agency for Healthcare Research and Quality (AHRQ) has funded the Health Research & Educational Trust (HRET) to lead multiple national improvement efforts, including the On the CUSP: STOP BSI campaign that led to a 41 percent relative reduction in central line-associated infections (CLABSI) in participating units. These projects suggest four insights for how to successfully plan and execute large HAI and quality improvement initiatives. First, leaders must recognize not all changes constitute improvements and must carefully assess and foster only the activities causally linked to the targeted outcomes. Second, leaders must recognize that some changes can spread rapidly without a national campaign and must adapt to an external environment that can shift quickly. Third, factors that affect how quickly changes will spread can be identified and leveraged to plan more successful campaigns. Factors that affect which initiatives and parts of the improvement campaign will be rapidly adopted and spread include: environmental factors, ease of implementation, effort required to assess impact, the number of individuals or systems that must participate in the change, and organizational capacity, culture, and competing priorities. These three insights lead to a fourth: leaders of large scale improvement efforts must define their role as managing the effort rather than speeding change implementation. This perspective acknowledges their need to both encourage changes that contribute to reducing patient harms and also to recognize and discourage unproductive or counterproductive changes that may accompany their improvement efforts. These insights are illustrated by examples drawn from the range of AHRQ-funded national improvement campaigns that HRET has led.

Introduction

National health care quality improvement (QI) campaigns are attracting considerable attention from policymakers, payers, and the leaders of health care organizations. Recent efforts—such as the Institute for Healthcare Improvement's (IHI's) 100,000 Lives Campaign and the more focused On the CUSP: Stop BSI (bloodstream infections) initiative funded by the Agency for Healthcare Research and Quality (AHRQ)—presented evidence that a large scale impact is achievable.[1,2] More recent initiatives by AHRQ, the Hospital Engagement Network (HEN) funded by the Center for Medicare & Medicaid Innovation (CMMI) within the Centers for Medicare & Medicaid Services (CMS), and IHI's expanded *Five Million Lives* campaign reflect the belief that large scale improvement efforts are a viable method for substantially improving the quality of American health care.

Along with growing investments in large scale improvement campaigns, there is also substantial discussion about how to overcome the slow pace of spread for many innovations that improve

safety and quality. Berwick has noted that improvements in health have proceeded quite slowly, including straightforward steps to prevent scurvy that took almost 250 years for full implementation.[3] Barth pointed to similar long delays in the widespread implementation of safety devices in cars, estimating it takes about three decades for new safety improvements to become standard on most vehicles.[4] The recognition that the spread of improvements is difficult has been accompanied by research, articles, and even whole conferences devoted to examining how we can speed up the spread of health care improvements.

The Health Research and Educational Trust (HRET) possesses a unique perspective on the opportunities and challenges associated with helping national initiatives to reduce the spread of healthcare-associated infections (HAI) succeed. Under contracts with AHRQ, HRET partnered with the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality and the Michigan Health & Hospital Association Keystone Center for Patient Safety & Quality to lead the national On the CUSP: Stop BSI initiative that expanded a successful pilot project in Michigan into a successful national project that achieved a relative reduction of 41 percent in rates of central line-associated bloodstream infection (CLABSI).[5] HRET leveraged the infrastructure developed through that project to subsequently lead the ongoing AHRQ-funded On the CUSP: Stop CAUTI (catheter-associated urinary tract infection) initiative. In partnership with the University of Michigan and the Michigan Health & Hospital Association Keystone Center for Patient Safety & Quality, that project has reported modest reductions in CAUTI rates, particularly outside the intensive care unit (ICU) setting.[6] Concurrent with these efforts, HRET has partnered with the Kidney Epidemiology and Cost Center at the University of Michigan and Renal Network 11 to develop and conduct a limited pilot test of a change package to reduce vascular access infections in end-stage renal dialysis facilities. Further, in partnership with the Harvard University School of Public Health, HRET is serving as prime contractor on the AHRQ-funded initiative to reduce harms in the ambulatory surgery setting.[a]

These projects, coupled with insights HRET has gained while leading a large HEN for CMS and our ongoing efforts to promote QI in hospitals through the American Hospital Association (AHA)-funded Hospitals in Pursuit of Excellence (HPOE) initiative, have reinforced our belief that national improvement projects have considerable potential to create a safer health care system that delivers higher quality care. But, our experiences have also provided periodic painful reminders that achieving this potential is difficult, sometimes slow, and never possible without constantly adapting our efforts in response to a continuously changing health care landscape.

Efforts to ensure that future initiatives to reduce health care associated infections (HAI) will achieve their intended goals are clearly warranted. However, there is some risk that focusing on methods to speed the pace of implementation may produce unintended and undesirable consequences. We believe these risks can be reduced by reframing goals for spreading HAI reduction strategies and other QI initiatives. An effective strategy should foster the improved management of spread, which includes both increasing the speed with which true improvements are broadly implemented and decreasing or stopping the spread of changes that are not beneficial. This paper draws on our experiences in implementing large-scale HAI QI initiatives to provide four observations designed to support this reframing.

[a] For more information, see www.ahrq.gov/research/findings/factsheets/translating/action12/index.html for the award announcement and http://ascsafetyprogram.org/about-the-program/national-program-team for the program Web site.

Some Changes May Not Lead to Improvement

Health care expends substantial resources on a broad range of change efforts, and most within health care acknowledge that many of these change efforts fail to achieve their intended goals. Although HRET has observed significant improvements in CLABSI rates on one of our projects, other initiatives are producing mixed results. A full taxonomy of types of failures is beyond the scope of this paper, but common failure types include:

- Changes that yield nominal improvements for anyone.
- Changes that produce benefits for some organizations, patients, or units but prove not beneficial for most others.
- Duplicative changes that have no additive benefits.
- Improvements in some outcomes with accompanying harms in others.

Changes that yield nominal improvements for anyone. Many changes are implemented between the bedside and back office functionalities that appear to offer benefits that are never achieved. In some cases, this is because the change fixes something that turns out not to be the true cause of the underlying problem; in other cases, it may be that the solution proved impossible to actually implement or because the change simply did not yield the expected benefit. Frequently, initially promising data may be the result of random variation or other factors that do not persist over time, but efforts to spread sometimes begin before the limitations in the initial results are understood.

HRET began its CLABSI project with a compelling implementation model tested with proven results across the state of Michigan. But because that intervention had multiple components, including clinical fixes and cultural changes, it was impossible to determine whether all of these components were necessary to produce improvement. This prompted ongoing reflection by HRET, our project partners, and AHRQ leadership to attempt to determine whether some of the activities we were promoting were unnecessary dimensions that were correlated with improvement but not causing it. This constant search for the most parsimonious methods to reduce HAI rates is essential to make future QI efforts as efficient and effective as possible.

Changes that produce benefits for some organizations, patients, or units but prove not beneficial for most others. In some cases, changes benefit a specific organization because that organization has a unique problem. In other cases, a solution that is viable in one hospital or unit cannot be replicated elsewhere because the success factors are distinctive and unavailable in most other situations. For example, in several of our projects, engaging with hospitalists proved extremely valuable to achieving HAI rate reductions. However, both our CLABSI and CAUTI projects also included many small and some critical access hospitals that did not employ any hospitalists. These hospitals also improved rates on targeted HAIs, but they did so by making changes quite different from those used in some larger hospitals.

Duplicative changes that have no added benefits. In some cases, multiple changes can produce comparable improvements for a targeted problem. But when some of the changes are already in place, adding others may yield no additional improvement. For example, evidence is good that using a defined QI method such as Lean or Six Sigma can help hospitals improve their quality. But once one method is in place, the additional value of other methods is frequently minimal.

Unpublished data we have examined across several of our large improvement initiatives suggest there is little to distinguish among results achieved by hospitals employing different improvement methods. On the other hand, when hospitals lack any defined method to guide their improvement efforts, they tend to struggle.

Improvements in some outcomes with accompanying harms in others. New drugs and medical technologies provide many examples of this, ranging from thalidomide to silicone breast implants. Although short-term benefits were clearly observable, these were ultimately outweighed by longer term harms.[7,8] In other cases, benefits may prove to be nominal, while financial costs to the health care system are dramatic. Whether the added costs associated with some new drugs and technologies are justified by nominally better results compared to appreciably cheaper treatment options continues to be an ongoing discussion among policymakers. HRET and its partners are addressing this issue in our CAUTI reduction initiatives. Efforts to reduce CAUTI can lead providers to screen for it more extensively. But if these screenings identify asymptomatic bacteriuria that are then treated with antibiotics, antimicrobial resistance, adverse drug events, and increased costs may result. To avoid these risks, HRET and its partners have emphasized avoiding unnecessary catheter insertions and have stressed the importance of removing a catheter as soon as it is no longer needed.

While it may seem obvious that not all changes constitute improvements, each of our improvement projects has required us to carefully assess which changes offer true benefit. The most effective HAI reduction efforts will be those that balance the potential benefits of spreading improvements against the risks associated with using scarce spread resources to promote changes that prove unbeneficial or potentially counterproductive.

Some Changes Spread Rapidly Without National Improvement Campaigns

Many improvements in health care do require substantial time and effort to be broadly disseminated. However, a fixation on issues where spread was difficult and slow can result in inattention to cases where spread was very rapid. Vaccines for polio and small pox spread rapidly in response to widespread public concern about the consequences of contracting these conditions.[1,9] The prescribing of drugs such as Prozac and Thalidomide expanded dramatically in very short periods of time.[10,11] And the use of some medical technologies such as computed tomography (CT) scanners and robotic surgery systems has spread very rapidly in short periods of time.[12,13] In some cases these expansions were enormously beneficial; in others, clinical improvements have been nominal, but the cost impact has been significant.[14,15] In still other cases, the expansions caused great harm to patients they were intended to help.[16]

If all innovations in health care were improvements that spread slowly, then those leading QI initiatives could focus on increasing the speed of improvements throughout the health care system. But sometimes, genuine improvements occur surprisingly quickly. Recently reported dramatic reductions in rates of early elective deliveries (EEDs) required that ongoing efforts to reduce these rates shift rapidly from assuming that most hospitals had significant improvement opportunities to focusing on a much smaller set of hospitals whose rates remained high. Despite occasional successes, such as reductions in EED rates, many potential changes may not yield

benefits to patients. And since some of these changes spread rapidly, effective QI must take into account how to speed some spread efforts and slow or even prevent the spread of other efforts.

On several of our HAI reduction projects, HRET has had to address efforts to endorse and spread very detailed and very long checklists that attempt to comprehensively catalog all that must be done (and not done) in order to prevent avoidable infections. There clearly is an important role for organizations that provide comprehensive summaries of all known infection risks and strategies for their avoidance. HRET works closely with the Centers for Disease Control and Prevention (CDC) and many medical societies that produce invaluable summaries of such risks. Nevertheless, on several projects, participants have converted these summaries into extensive operational checklists consisting of dozens of items that staff are then expected to routinely use in the clinical setting. While these checklists are intuitively appealing (if a short checklist can reduce infections to some degree, then a long checklist will reduce them even more), HRET has benefited from thought leaders such as Atul Gawande[17] and Peter Pronovost[18] who have both argued for the necessity to keep checklists short enough to remember and focused on the factors most likely to have the biggest impact. Success has required recognizing that some changes can spread quickly. Fostering and encouraging rapid changes that are productive, while simultaneously intervening to prevent undesirable changes from spreading, have been important to the success of our projects.

Factors that Impede or Promote the Speed of Spread

In a separate paper under review elsewhere, we have identified factors affecting the speed of spread that fall into four general categories:

- Environmental factors.
- Nature of the innovation.
- Individuals required to embrace the change.
- Organizational factors.

Environmental factors. When people or organizations benefit financially from a change—either through generating revenue, reducing costs, or minimizing legal costs—spread is faster. When regulations mandate a change, adoption is quicker, as it is when there is public awareness of the change's value or there is a champion publicly advocating for the change. But when the environment includes other changes competing for the same resources or any of these other factors are missing, change will be slower or simply not happen. On our CLABSI reduction project, it was appreciably easier to make a financial case to hospitals for why CLABSI prevention is essential. Because the financial burden of treating CAUTI is lower than that of CLABSI, motivating hospitals to reduce CAUTI rates has proven more difficult and may be one reason among many why national CAUTI rates are not declining substantially.

Nature of the innovation. Changes with a strong evidence base that are affirmed by key opinion leaders such as professional societies will spread more rapidly. Moreover, changes that are easier to understand and to successfully implement, as well as changes that produce visible results, will spread more rapidly. Gawande recently contrasted the rapid spread in the use of anesthesia with the slow spread of methods to prevent sepsis, arguing that these differences were attributable to the visible impacts of anesthesia and the invisible impacts of infections leading to sepsis.[19] The

rapid reduction in EED rates provides another such example. Evidence of EED harms was compelling, EED reduction was championed by the Federal Government and opinion leader organizations, and the innovation was straightforward—avoid inducing labor. Efforts to reduce CLABSI also benefited from having a short list of relatively simple changes for which there was good evidence that linked the changes to CLABSI reduction. In contrast, efforts to reduce harms in ambulatory surgery are complicated by very low published rates for harms. When baseline rates are low, it is difficult for participants to see improvements, even when those improvements are taking place.

Individuals required to embrace the change. When a change can be made by an individual, rapid adoption is more common. Drugs and medical technologies may spread quickly because there often are strong financial incentives for their use, and decisions about whether to use them often can be made by single individuals. When changes require coordinated efforts from physicians, nurses, other clinicians, and organizational leadership, spread tends to be far slower and more challenging.[20] Efforts to prevent CAUTI illustrate this challenge. Some patients have a catheter on admission to the hospital; others have one placed in the emergency department. Some of these catheter insertions are medically necessary; others may be driven by convenience or in response to the expressed concerns of the patient or family. A patient may be given a catheter in a general hospital unit to which he or she is admitted or be placed on one in an ICU. Because catheters may be placed by so many staff in so many locations within the hospital and for so many reasons, it has proven much more challenging to help hospitals coordinate a reduction in their rates of unnecessary catheter use.

Organizational factors. When organizations have competing priorities for limited resources, conflicting internal priorities, and a culture that is averse to change, spread will be very slow and difficult. Conversely, when organizations have fewer decisionmakers, aligned internal and external priorities, and a culture with a history of successful innovation, change will be far more rapid.[21,22] HRET has worked with some hospitals on two or more improvement projects, including AHRQ-led efforts to reduce CLABSI and CAUTI and our CMS-funded HEN initiative. Although the analyses we are doing are preliminary, they appear to show that smaller hospitals can make changes more rapidly than larger, more complex organizations. Moreover, hospitals that have been successful (or unsuccessful) on one of our national projects tend to show similar results on others. While not conclusive, these preliminary results do suggest the importance of organizational factors in determining how quickly improvement efforts will spread.

There are no empirical data that quantify the comparative impact of each of these spread factors, but we believe it is very possible for those leading large-scale improvement efforts to make reasonably accurate judgments concerning which potential changes will spread quickly, slowly, or not at all. In general, changes that can be made by individuals or small groups within organizations that are supportive of change, changes that will produce visible improvements to outcomes, and changes that will help make money will almost invariably spread rapidly and with little need for assistance. Conversely, changes linked to multiple factors that impede spread will be difficult or impossible for most providers to successfully implement. This dynamic suggests the value of providing participants with a range of improvement options they can prioritize based on what they perceive will be the most beneficial and easiest to implement within their organizations. Peter Pronovost emphasized the value of providing options and allowing

participants to set improvement priorities on the CLABSI project.[23] We regard this as one of many strategic insights that contributed to the success of that project.

Focus on the Management of Spread

Federal organizations, including AHRQ, CMS and CDC, are all investing substantial resources in supporting national spread campaigns to reduce HAIs and improve health care quality and the efficiency of the health care system. While spreading improvements is a laudable goal, we believe that better results may be achieved if these organizations and the individuals they select to lead these initiatives view their efforts as "managing" rather than "promoting" the spread of innovations. Based on our experiences in leading national HAI reduction efforts, we believe this perspective is optimal because it recognizes that:

- Efforts to promote change entail risks and costs that must be clearly understood, managed, and monitored. If not all changes are improvements and not all changes will be successful, then QI leadership must begin by carefully assessing the evidence for what benefits a potential improvement effort will yield and whether the improvement effort will be viable.
- There are limits to what is achievable and one must operate within these limits. In cases where a change offers substantial benefits but is unlikely to spread because of one or more of the factors noted above, good improvement strategy should focus on changing the underlying factors before investing in improvement campaigns. Changes to financial incentives, regulations, and investments in research that will strengthen the evidence base supporting the innovation may yield much greater benefit than an investment in a premature campaign that is unlikely to overcome strong disincentives to change that are present in the existing system.
- With limited resources, change efforts that have limited benefits will absorb resources that are needed for change efforts that have greater positive impact. Effective leadership of national improvement campaigns should seek to reduce resources being allocated to improvement activities or innovations with marginal benefits because this creates resources that can be reallocated more productively. Investments in medical technologies, data systems, or improvement methodologies that may not benefit patients directly limit investments in other areas where patient benefits may be more pronounced. As a result, effective QI leadership should de-incentivize unproductive change efforts while incentivizing those with the greatest potential value.

If QI leaders frame their goal as "managing" the spread of innovations within health care, they will focus on three issues that currently receive insufficient attention.

Determine Priorities for Spread and Spread Avoidance

Activities designed to promote the spread of improvements frequently are not coordinated with comparable efforts to develop or adjust policies designed to curtail the spread of innovations that are unhelpful or counterproductive. Holistic discussions of both spread and spread avoidance are needed because reducing resources allocated on unhelpful change is critical to the success of efforts to promote positive changes. Across all of our projects, we have found that success

requires helping providers stop doing things that are unnecessary while coordinating and aligning things they are currently doing inefficiently. That assistance creates capacity that can be reallocated to doing new things that directly contribute to HAI reduction.

Adjusting Policies and Regulations that Enhance or Impede Spread

While some efforts are being made to align national improvement campaigns with other policy and regulatory initiatives related to those campaigns, strengthening these efforts will yield better results. For example, if outcomes targeted by a campaign are publicly reported, results of the campaign will be more visible, and the data collection burden will be reduced. Once CMS began requiring hospitals to report CLABSI (and now CAUTI) data into the National Healthcare Safety Network (NHSN), HRET was able to reduce the resources we had been expending to promote data collection. Moreover, once hospital leaders knew public reporting of CLABSI and CAUTI would be coming, leadership engagement became easier as well. Beyond data collection and public reporting, if financial incentives to participate in an improvement effort exist, or if disincentives have been removed, the campaign is more likely to succeed. For example, financial incentives to meet meaningful use requirements are driving hospitals to invest heavily in their health information technology (IT) systems, while the creation of protections for hospitals to discuss and learn from medical errors under the rubric of the patient safety organizations[b] has increased willingness among hospital leaders to talk about issues that would not have been discussed before due to medical liability concerns.

Investing in the Most Viable HAI Reduction Campaigns

Prudent leadership must recognize that some improvements are likely to occur without extensive resources from the government or private philanthropies and should avoid investing scarce resources unnecessarily. Conversely, effective leaders also will recognize that some spread efforts may be extraordinarily difficult and expensive, and so they will channel resources to HAI reduction campaigns that are likely to be more successful at an affordable cost.

Conclusion

Because the number of changes that may benefit the health care system is vast, strategies that focus scarce resources on the promotion of changes with the largest positive impact are essential. We believe that HAI reduction efforts will improve if leaders view their efforts as “managing” the spread of change in health care rather than “promoting” it. Focusing on the management of change calls greater attention to the critical issue of which changes will lead to substantial improvements. It also acknowledges the fact that some changes occur rapidly and independently and encourages an assessment of the factors that will influence how quickly and easily a targeted change is likely to spread. This assessment can lead to strategies that integrate and align a range of change drivers that will help maximize investments in national spread campaigns.

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[b] For more information on patient safety organizations, see www.pso.ahrq.gov.

order 8), National Opportunity to Improve Care in ESRD (HHSA290201000025I, task order 4) and Development and Demonstration of a Surgical Unit-based Safety Program in Ambulatory Surgery (SUSP-AS) to Reduce Surgical Site Infections (SSI) and Other Surgical Complications (HHSA290201000025I, task order 5). The findings and conclusions in this document are those of the author, who is responsible for its content, and do not represent the view of AHRQ. No statement in this report should be construed as an official position of AHRQ or the U.S. Department of Health and Human Resources.

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Development and Implementation of a Consensus Algorithm to Optimize Preoperative Antimicrobial Prophylaxis and Decrease Gram-Positive Surgical Site Infections for Cardiac and Orthopedic Procedures

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Abstract

Surgical site infections (SSIs) are serious adverse events for patients. Rates after cardiac and orthopedic procedures range from 0.4 percent to 5 percent. Over 40 percent are caused by gram-positive organisms, particularly *Staphylococcus aureus*, about half of which are resistant to antimicrobials. Current guidelines and practices for preventing SSIs among high-risk patients vary widely. The aim of the Study to Optimally Prevent Surgical Site Infections (STOP SSIs) was to systematically evaluate existing research, guidelines, and current practice; recommend an evidenced-based bundle of practices (algorithm) for screening, decolonization, and optimizing preoperative antimicrobial selection; and implement the algorithm as a quality improvement initiative in a group of community hospitals to assess its efficacy. A 12-member expert panel advised the project and addressed gaps in the literature and guidelines. The algorithm was implemented into the usual care processes of 20 hospitals in a large national health care system, under the leadership of the corporate infection prevention staff. Lessons learned from implementation included that teams need to allot sufficient time and resources for (1) information technology health care personnel (HCP) to make necessary changes in the electronic health record (EHR) system for standardized data collection and monitoring compliance; (2) educators to develop and conduct programs for initial and ongoing training of all HCP who will use the protocol, including HCP on all shifts, temporary staff, and new staff; (3) project liaisons to develop systems that allow HCP in different service lines to coordinate new activities; and (4) providers to consider and adopt practice changes. Facilitating factors included a strong centralized infrastructure with a common EHR, active involvement of health system leaders and physician champions, and sharing of strategies and solutions among sites to overcome challenges.

Introduction

Surgical site infections (SSIs) are serious adverse events for patients; SSI rates after cardiac and orthopedic procedures range from 0.4 percent to 5 percent.[1,2] Data from over 5,000 SSIs reported to the National Healthcare Safety Network (NHSN) in 2006–2007 revealed that over 40 percent were caused by gram-positive organisms, particularly *Staphylococcus aureus (S. aureus*) organisms or coagulase-negative staphylococci, and about half of the isolates were resistant to antimicrobials (e.g., methicillin-resistant *S. aureus* [MRSA]).[3] Recent studies also found that the percentage of SSIs caused by resistant organisms is increasing.[4,5] A 2010 survey conducted by the Infectious Diseases Society of America Emerging Infections Network found that practices regarding preoperative nares screening for colonization, decolonization, and choice of antimicrobial prophylaxis agents varied dramatically.[6] This practice variation most likely relates

to variation in the results of studies assessing ways to identify and treat patients colonized with *S. aureus* and other patients at high risk of SSI before their operations. The Study to Optimally Prevent Surgical Site Infections, known as "STOP SSIs," was designed to determine if screening for *S. aureus* colonization, decolonizing carriers, and providing MRSA carriers with vancomycin and cefazolin for perioperative prophylaxis would decrease gram-positive SSIs (see Appendix A for the list of participants).

The primary aim of the project's first phase was to systematically evaluate existing research, guidelines, and current practice and to recommend an evidenced-based bundle of practices (algorithm) for screening, decolonization, and optimizing preoperative antibiotic selection. The primary aim of the second phase was to implement the algorithm as a quality improvement initiative in a group of community hospitals and assess whether implementation of the algorithm was associated with reduced rates of *S. aureus* deep incisional and organ space SSIs after select cardiac and orthopedic operations. These procedures were chosen because gram-positive organisms are the most important pathogens causing SSIs in these operations, and these infections can be catastrophic.[7–10] If health care workers understand the factors that influence algorithm implementation, they can create systems and tools that facilitate rapid translation of the evidence into practice. Thus, this project also aimed to identify factors that facilitated or impeded algorithm implementation. This paper reports on the methodology for algorithm development and implementation. The efficacy of the algorithm will be described elsewhere.

Methods

Phase I (August 2010 to August 2011) comprised three concurrent activities: a systematic literature review and meta-analysis; a review of existing preoperative prophylaxis guidelines; and a "call for algorithms" to identify examples of current practices. Phase II (September 2011 to August 2013) activities included site recruitment, training, preparation, and implementation of the evidence-based algorithm in a diverse group of community hospitals. The project leadership team included the principal investigator and co-investigators from an academic medical center, staff members from the coordination center, a quality improvement-related organization, and clinical leadership from the corporate offices of a large national health care system. A 12-member technical expert panel (TEP) composed of nationally recognized cardiovascular and orthopedic surgeons, anesthesiologists, infectious disease specialists, hospital epidemiologists, and medical quality improvement experts advised the investigative team.

Methodology for Algorithm Development

The methodology for conducting the systematic literature review and meta-analysis and associated results was recently published.[11] The investigative team searched the literature using the following data sources to identify relevant studies: PubMed (1995–2011), the Cochrane Database of Systematic Reviews, CINAHL, EMBASE, and clinicaltrials.gov. TEP members were queried to identify relevant English-language guidelines from the United States and Europe. A team member created a summary table of guidelines describing recommendations for preoperative screening, preoperative bathing, nasal decolonization, and selection, dosing, and administration of perioperative antibiotics for prophylaxis relevant to general, orthopedic, and cardiothoracic procedures.

The investigative team disseminated the call for algorithms via Web sites, e-newsletters, letters, blogs, and message boards at professional society meetings from November 2010 through February 2011. The call for algorithms stated that we were seeking "…examples of algorithms, protocols, pathways, policies and procedures, and standing orders that address selection and administration of antimicrobial prophylaxis for cardiac and orthopedic surgery patients. If your organization routinely screens preoperative patients for MRSA, it would be helpful to also include screening and de-colonization algorithms and protocols." Partners in disseminating the call included several medical and nursing surgical and infectious disease-related professional associations.

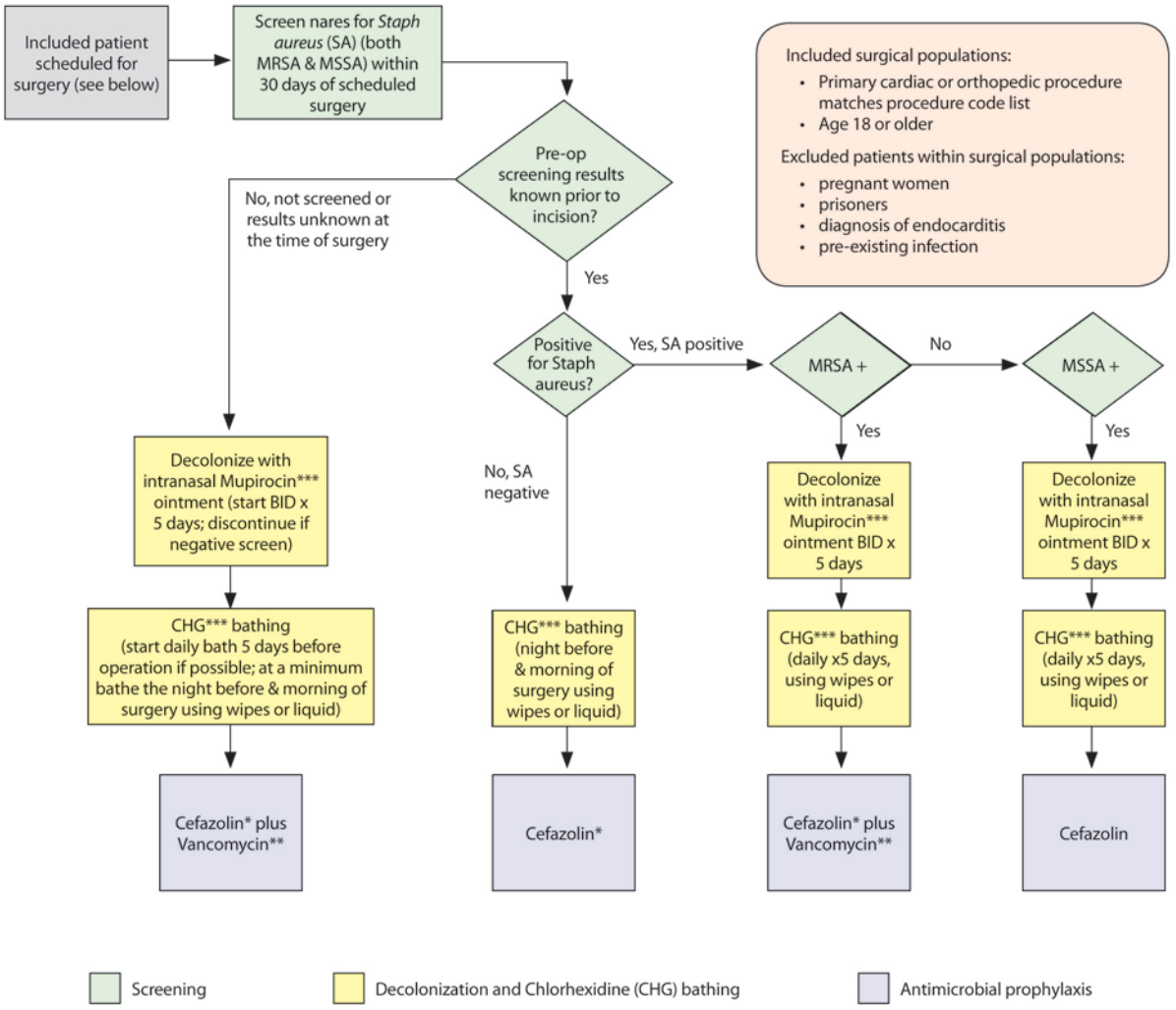
Investigative team members summarized the responses to the call for algorithms and the results of the systematic literature review as an algorithm addressing preoperative screening for *S. aureus*, decolonization of *S. aureus* carriers, and perioperative prophylaxis. They reviewed the algorithm with the TEP and revised it based on TEP members' recommendations (see Figure 1).

Methodology for Implementing the Algorithm and Evaluating Its Efficacy

The investigative team designed Phase II of the project to assess the effectiveness of the algorithm under the conditions of usual practice as a quality improvement initiative rather than as a tightly controlled clinical trial. The team initially proposed to implement the algorithm in a sample of unrelated volunteer sites. However, the infrastructure needed for consistent laboratory testing, dispensing inpatient and outpatient medications and supplies, data collection, and infection surveillance exceeded the original project budget. A team member suggested an alternative of implementing the algorithm in a large national health care system with a centralized institutional review board (IRB), robust computerized information systems and electronic health records (EHRs), and standardized SSI surveillance systems. A partnership with such a system would allow the investigative team to undertake a quasi-experimental study within the time and budgetary parameters outlined in the original contract.

A health care system agreed to implement the algorithm in conjunction with the study because it was planning to launch an enterprise-wide initiative to reduce SSIs and had implemented an initiative for screening nares for MRSA colonization.[12] The health care system's infection prevention leadership, together with team members from the academic medical center and from the coordination center, developed an informational webinar and flyers to introduce the project to over 80 hospitals that performed the procedures of interest. The following criteria were used to determine whether a hospital was eligible to participate: (1) the hospital performed the procedures of interest; (2) the hospital had not already incorporated into its practice all algorithm elements—screening for *S. aureus* carriage, decolonizing carriers with mupirocin and chlorhexidine, and giving MRSA carriers cefazolin and vancomycin for perioperative prophylaxis; hospitals that provided decolonization to both MRSA- and methicillin-susceptible *S. aureus* (MSSA)-positive patients were excluded, but hospitals that provided decolonization only to MRSA-positive patients were eligible for inclusion; and (3) the hospital was able to

The STOP SSIs Algorithm



*May substitute cefuroxime for cefazolin; unconfirmed beta-lactam allergy does not preclude the use of cefazolin. For a confirmed beta-lactam allergy, use vancomycin 15mg/kg (<120 minutes before the operation) in place of cefazolin and add either gentamicin 5mg/kg, or aztreonam 2 Gm <60 minutes before the operation/incision.

**For vancomycin allergy, may use daptomycin (4mg/kg) in combination with cefazolin (if not beta-lactam allergic) for preoperative prophylaxis <60 minutes before the operation/incision. If also beta- lactam allergic, use gentamicin 5mg/kg, or aztreonam 2 Gm <60 minutes before the operation/ incision in combination with the daptomycin. Vancomycin, daptomycin or gentamicin prophylaxis should not be continued after the operation. Cefazolin and aztreonam should be discontinued within 24-hrs. of the operation.

*** Discontinue if patient experiences any side effects or allergic reaction to mupirocin or chlorhexidine gluconate. For the purposes of this algorithm, CHG bathing does not need to continue post-operatively.

Please contact authors for a supplemental document for additional important information on dosing guidance and mupirocin and chlorhexidine use.

Figure 1. Overview of Study to Optimally Prevent (STOP) SSIs Algorithm

provide data on SSIs for at least the 2 years preceding implementation. Health care personnel from interested sites completed an electronic survey, sent by the health care system, about current surgical infection prevention practices. *A priori* power calculations indicated that at least 20 sites would be needed to ensure that the power of the study would be adequate to detect statistically significant differences between the pre- and post-intervention periods.The investigative team trained project liaisons (hospital study coordinators) during a 1½-day in-person meeting in April 2012. The meeting objectives were to share detailed protocol information and to build enthusiasm and relationships among sites and the leadership team. At the meeting, the liaisons developed implementation plans for the multidisciplinary teams at their sites. Training on the second day coincided with a meeting of the investigative team and the TEP, which allowed both liaisons and experts the opportunity to interact face-to-face and to discuss questions that arose during the first day of training. Liaisons and participating hospitals did not receive any direct compensation for their involvement in this project, but they were reimbursed for costs associated with attending training.

The investigative team used several mechanisms to provide ongoing training for health care personnel (HCP) at the sites and to ensure communication with the participants. Representatives from the health care system and the coordinating center developed a modular electronic procedure manual centralized on the health care system's intranet, a site familiar to the liaisons. The modular format allowed team members to update sections as needed. The investigative team conducted frequent (biweekly, then monthly) interactive "coaching call" webinars to answer questions, disseminate study updates, allow sites to discuss challenges and share facilitating strategies, and promote rapid implementation and "hardwiring" of the algorithm. Also, project staff periodically distributed a frequently asked questions (FAQ) document and supported a central electronic mailbox as an additional method of communication.

Implementation of the algorithm required (1) preparatory activities, such as establishing processes for identifying eligible patients, obtaining necessary equipment and supplies, and ensuring local medical staff approval; (2) implementation activities, such as educating patients and obtaining swabs; and (3) maintenance activities, such as ongoing monitoring to ensure consistent adherence to the algorithm. The date of implementation (the "go-live" date) was the date each hospital reported that its systems and processes were operational. During maintenance activities, liaisons were asked to complete a monthly structured review of 10–15 eligible cases to determine if the algorithm was being consistently applied and documented in the EHR. This self-audit was used to identify potential issues and trigger followup activities to address problems. The audit forms were submitted to the coordinating center and reviewed during one-on-one telephone calls between liaisons and project staff.

As described by Berwick,[13] the rate of dissemination of an innovation depends upon three sets of factors: (1) the characteristics of the innovation or intervention itself (e.g., complexity, trialability, relative benefit); (2) the context of implementation (e.g., how the change was implemented, who implemented the change, what planning and training were done, and how open the organizational culture was to change); and (3) the characteristics of the individuals receiving the innovation (e.g., were they innovators and early adopters, or traditionalists requiring strong evidence for change). In this project, the investigative team had information regarding the characteristics of the innovation and the context of implementation but not about the characteristics of those receiving the innovation (beyond the titles and credentials of the

liaisons). To gain additional information about the implementation experience within and across sites, the investigators took notes during coaching calls and calls with individual sites, and they looked for common themes and factors that impeded or enhanced implementation.

The project was reviewed by the IRBs associated with the academic medical center and the coordinating center. The health care system determined that this project was a quality improvement initiative and that the activity the hospitals were undertaking was not considered research with human subjects because there was no interaction or intervention with live humans or their identifiable data for research purposes: the hospitals were doing this on their own for treatment purposes based on the project's merits.[14] The AHRQ liaison to the Federal Office of Management and Budget (OMB) also reviewed the project and approved a clinical exemption for the project.

Results

Guideline Review

The investigative team summarized 19 guidelines for the TEP regarding preoperative screening, preoperative bathing, nasal decolonization, and selection, dosing, and administration of perioperative antibiotics for prophylaxis relevant to orthopedic or cardiac procedures.[1,2,15–31] Of these, eight recommended use of (1) a β-lactam (cefazolin, cefuroxime, or cefamandole) as the first-line agent for preoperative prophylaxis; (2) vancomycin, clindamycin, or a fluoroquinolone for patients with established allergies to β-lactam agents; and (3) vancomycin for patients with known previous MRSA infection or colonization. Most guidelines recommended β-lactams for routine prophylaxis, and one recommended adding gram-negative coverage if vancomycin was used.[1] Three guidelines recommended screening patients' nares, of which only one guideline specifically recommended preoperative screening for MRSA colonization. Two guidelines recommended decolonization of *S. aureus* carriers before the procedure, and one recommended preoperative bathing with an antiseptic soap. One specifically recommended screening patients for *S. aureus* carriage and decolonizing carriers with mupirocin.

Several TEP members were aware that the American Society of Health-System Pharmacists (ASHP) was working with four major professional societies to develop a new consensus guideline regarding perioperative prophylaxis, which was scheduled for release in summer 2011.[18] TEP members who were on the ASHP guideline committee shared their knowledge of the draft recommendations, which helped the investigative team address gaps identified during guideline review.

Call for Algorithms

Forty-eight hospitals submitted information in response to the call for algorithms. Most responses were from infection preventionists, infectious disease physicians, and hospital epidemiologists. The submissions were in the format of policy and procedures (8), standing order sets (15), hospital (local) guidelines (11), flowcharted algorithms (6), and narrative text sent via email (8). Many submissions included more than one format (e.g., policy and order set). Fifteen algorithms were specific to cardiac procedures and 19 to orthopedic procedures; 10 applied to both or did not specify procedures. The majority of the hospitals that submitted algorithms were large (>300 beds) teaching institutions, and all were located in urban areas.

Overall, the algorithms lacked specificity and demonstrated substantial practice variability. Staff at the coordination center could not identify preferred formats or a single widely used algorithm. However, the coordinating center staff's ability to draw conclusions from the call for algorithms was severely limited because information was collected using an unstructured approach; due to regulatory and time constraints, staff could not follow up with respondents. Nevertheless, the investigative team concluded that, given the variation in responses, this project could have substantial benefit by providing evidence-based guidance in a standardized format.

Algorithm

The final algorithm developed in Phase I recommended a bundle of practices: (1) preoperative screening of the nares for both MRSA and MSSA; (2) preoperative chlorhexidine gluconate (CHG) bathing; (3) intranasal mupirocin to decolonize carriers and patients whose screening results were unknown prior to their operation; and (4) cefazolin and vancomycin as perioperative prophylaxis for patients colonized with MRSA or whose screening test results were unknown at the time of the operation (see Figure 1). Details associated with each of the components are available upon request.

Implementing the Algorithm

Initially, 42 hospitals expressed interest in participating in the study, of which 25 completed the followup questionnaire. None of these 25 hospitals had previously implemented all of the practices recommended in the algorithm, although some had applied individual components to their patient populations. Sites had the option of applying the algorithm only to patients undergoing cardiac operations, only to patients undergoing orthopedic operations, or to both patient populations. The 25 eligible sites were sent invitation letters; five hospitals declined participation before the training session because they identified resource constraints, and one withdrew from the project after training but before implementing the algorithm because several key quality staff members left their positions. One additional site joined the project 1 month after the training session. Ultimately, 20 hospitals implemented the algorithm.

All sites were community hospitals that varied in size from 52 to 514 beds, and most were in the South (see Table 1). Nine sites implemented the algorithm for both orthopedic and cardiac procedures, eight implemented it for orthopedic operations only, and four implemented it for cardiac procedures only.

Thirty-one representatives from 19 sites attended the in-person training session. Twelve sites sent two people, of whom three were physician champions. Most liaisons (19) were nurses with advanced degrees or certifications; two were clinical laboratory scientists. Fourteen liaisons worked as infection preventionists, three were directors of surgical services, one was the vice president of cardiovascular services, one was the director of quality and risk management, and one was the manager of the post-anesthesia care unit.

Table 1. Characteristics of participating sites

Hospital	Census Division Region	Location (Rural/ Urban)	Teaching Status	Bed Size (S <100; M 100-299; L >299)	Procedures Included in Implementation (Cardiac/ Orthopedic/ Both)	Date Hospital Implemented Algorithm
1	Mountain	Urban	Non-teaching	M	Orthopedic	6/1/2012
2	New England	Urban	Non-teaching	M	Both	8/1/2012
3	South Atlantic	Urban	Non-teaching	S	Orthopedic	6/18/2012
4	South Atlantic	Urban	Non-teaching	M	Both	6/10/2012
5	South Atlantic	Urban	Non -teaching	M	Cardiac	8/1/2012
6	South Atlantic	Urban	Minor teaching	M	Orthopedic	10/9/2012
7	South Atlantic	Urban	Non-teaching	M	Both	6/25/2012
8	South Atlantic	Urban	Non-teaching	M	Cardiac	8/1/2012
9	South Atlantic	Urban	Non-teaching	M	Cardiac	6/18/2012
10	South Atlantic	Urban	Non-teaching	M	Orthopedic	6/1/2012
11	South Atlantic	Urban	Non-teaching	M	Orthopedic	8/6/2012
12	South Atlantic	Urban	Non-teaching	L	Both	8/1/2012
13	South Atlantic	Urban	Non-teaching	L	Both	Orthopedic on 8/6/2012; Cardiac on 8/22/12
14	South Atlantic	Urban	Minor teaching	L	Orthopedic	7/25/2012
15	West North Central	Urban	Non-teaching	S	Orthopedic	7/15/2012
16	West South Central	Urban	Minor teaching	S	Both	6/15/2012
17	West South Central	Urban	Non-teaching	M	Orthopedic	6/18/2012
18	West South Central	Urban	Minor teaching	L	Both	6/25/2012
19	West South Central	Urban	Non-teaching	L	Cardiac	6/11/2012
20	West South Central	Urban	Minor teaching	L	Both	6/302012

Notes: All were located in urban settings; 15 hospitals were non-teaching, and 5 were classified as minor teaching status. Consolidated Metropolitan Statistical Area (CMSA): Mountain (ID); South Atlantic (FL, GA, SC, VA); West South Central (LA, TX); West North Central (MO); New England (NH). Bed size: Small <100; Medium 100-299; Large >299. American Medical Association teaching status, CMSA, bed size data, and location were obtained from the American Hospital Association Annual Survey Database, FY 2010 edition. All hospitals offered orthopedic surgical services.

During May and June 2012 (the preparation phase), HCP from numerous service lines at each hospital accomplished several important activities (Figure 2): establishing a multidisciplinary implementation team and plans; setting up systems and processes to identify eligible patients; organizing and providing training materials for staff, patients, and physician offices external to the system hospitals when centralized preadmission testing services were not available at the hospital; obtaining medical executive committee approval for new project-specific order sets; working with local information technology staff to ensure that the study-specific charting screens would be available to staff, etc. Although Figure 2 places each activity within a service line, many activities were accomplished by members of different services, and HCP often implemented several tasks in parallel under the coordination and leadership of the site liaison. The corporate investigative team members helped guide HCP through the preparation activities and responded to questions and requests for assistance from individual sites as needed.

To minimize workload for the sites, the algorithm was integrated into usual care processes to the greatest extent possible. Health care system information technology staff developed specific query screens and fields for data entry and integrated them into the EHR. The health care system's supply chain services ensured that necessary supplies and equipment were obtained through the usual supply chain management process.

Given the number and complexity of activities during the preparation phase, several sites needed more time than expected to implement the intervention. As shown in Figure 3, 11 sites reported they had fully implemented the algorithm by the start date of July 1, 2012, and all 20 sites had implemented the algorithm by the end of October 2012.

Examples of challenges and facilitators commonly reported during the first 6 months of the project are described in Appendix B. During the preparation period, the most common challenges were delays in obtaining medical executive committee approval for revised preoperative orders (due to infrequent meetings and full agendas) and obtaining surgeons' commitment to implement the algorithm. Sites also had difficulty establishing reliable processes for screening and decolonizing patients who were admitted through the emergency department for urgent or emergent procedures, bypassing the usual pre-admission process, particularly on weekends and holidays.

The facilitating factors that sites reported most commonly included a corporate physician champion who addressed physicians' concerns regarding specific recommendations in the algorithm and corporate and local technical staff who addressed information technology issues. Additionally, many sites had participated in previous centralized research initiatives, and all sites were screening for MRSA before the project was initiated.

Site Implementation Activities

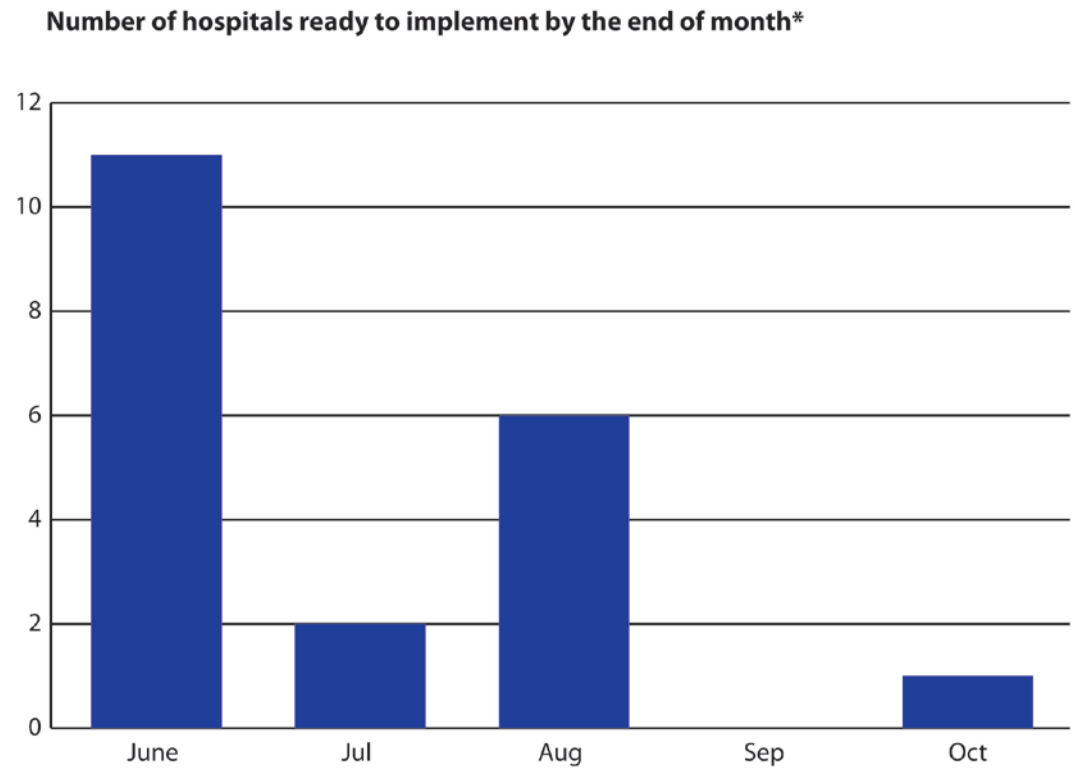
Project liaison and physician champion	Receive protocol training; review materials, ask questions to clarify	Develop local multi-disciplinary implementation team and plan	Revise pre-op orders; obtain medical executive committee approval; facilitate peer adoption of algorithm	Train hospital and outpatient staff on all aspects; retrain as needed; respond to peer questions and concerns	Team develops systems and processes for implementing bundle practices	Collect, submit SSI data (retrospective and prospective)	Participate in group coaching calls and follow up with coordinating center staff	Conduct regular, structured audits; resolve identified obstacles
Outpatient surgical office staff	Set up systems and processes to identify eligible outpatients	Obtain supplies, CHG liquid, mupirocin and equipment as needed	Set up processes for MSSA & MRSA screening 10 to 14 days before operation	Set up processes for receiving lab results and communicating information to surgeons pre-op	Establish process and materials for educating pre-op patients on use of CHG and mupirocin when indicated	Follow up, track, document patient adherence to CHG and mupirocin instructions	Communicate key information to inpatient pre-op health care personnel	Communicate best practices; coordinate across continuum of care
Inpatient nursing and pre-op surgical staff	Set up systems and processes to identify eligible inpatients	Set up processes, equipment for MSSA and MRSA screening of urgent or emergent patients admitted through ED, presurgical, and inpatient admission testing units	Obtain supplies, CHG cloths and warmers, mupirocin	Establish process to administer, document application of pre-op CHG and mupirocin as indicated	Ensure new, weekend, and off-shift staff understand protocol and maintain adherence	Facilitate awareness and adoption of evidence-based practices		
Information technology staff	Health care system IT staff create EHR screens, reports, and document practices; run reports	Standardized screens and reports shared with regional and local IT staff at each site	Standardized screens shared with IT staff at each site; training	Local IT installs updates	Local IT analyst, nurse managers, and educators train staff on new charting screens			
Pharmacy and laboratory staff	Obtain equipment and supplies as needed from supply chain management	Communicate lab results to pharmacy and other health care personnel	Pharmacy reviews new orders against protocol for eligible patient to ensure orders match up with screening results	As needed, assist with renewing or discontinuing mupirocin orders post-op				

Note: For simplicity, this diagram does not show the inter-relationships across service lines or departments and the iterative nature of the activities.

CHG = chlorhexidine gluconate ; ED = emergency department; EHR = electronic health record; IT = information technology; MRSA = methicillin resistant Staphylococcus; MSSA = methicillin sensative Staphylococcus

Figure 2. Site Implementation Activities in the STOP SSIs Project

The sites audited adherence to the algorithm components, which helped the local participants and the investigative team identify opportunities for improvement. For example, project liaisons who investigated adherence issues often found problems with documentation in the EHR rather than failure to apply the algorithm. However, the liaisons had difficulty continuing regular self-audits over time, in part because they had to retrieve information from multiple reports.



*Training occurred in late April 2012; implementation was anticipated July 1, 2012.

Figure 3. Month in which hospitals were ready to implement the project

Discussion

The STOP SSIs project was designed to develop and evaluate an evidence-based algorithm to prevent SSIs associated with gram-positive bacteria. The investigative team identified important challenges and facilitators during both phases of the project. During algorithm development, the team identified few high-quality studies that evaluated practices to prevent these infections. Although numerous groups have pertinent guidelines, none of the guidelines address a full range of preventive measures. Moreover, the algorithms submitted to the investigative team varied substantially in form and content, which indicates that hospital practices for communicating recommended practices, and the practices themselves, are not standardized. Given the lack of standardized guidelines, the investigative team benefited greatly from the TEP members' broad range of expertise and their work with diverse professional societies.

The clinical, technological, and research-related resources of the health care system in which this process improvement project was conducted were essential to rapidly implementing the algorithm at 20 volunteer sites and, thus, to the project's success. Frequent coaching calls helped participants expedite the implementation because they were able to learn about solutions that other participants had found for common obstacles, and they could ask questions of the investigative team. Other quality improvement collaboratives have demonstrated that sharing

tools such as checklists and reminder stickers early in the implementation process allows sites to facilitate rapid change.[32]

Investigative team members noted that they often heard the same challenges repeated during different coaching calls. When they reviewed the minutes of the calls, they expected to find that multiple sites had reported the same challenges. Instead, they found that single sites tended to repeat the same challenge during several calls, indicating that HCP had not resolved the issues. This observation suggests that all hospitals do not have the same ability to overcome challenges, and that some challenges are harder to overcome than others. Future research should assess the factors that limit or enhance a hospital's ability to overcome challenges and the factors that make some challenges very difficult to resolve.

The investigative team relearned the age-old lesson that implementation always takes more time and resources than predicted. In particular, teams need to allot sufficient time and resources for (1) information technology staff to make necessary changes in the EHR to allow data collection and adherence monitoring; (2) educators to develop and conduct programs for initial and ongoing training of all HCP who will use the protocol, including HCP on all shifts, temporary staff, and new staff; (3) project liaisons to develop systems that allow coordination of new activities between the inpatient and outpatient setting, especially when a centralized preadmission testing area is not available; and (4) physicians to consider and adopt the practice changes.

The bundle of practices constituting the SSI prevention algorithm is a complex intervention because it requires patients to follow instructions for treating themselves with a topical antimicrobial agent and bathing with a medicated soap, and it requires collaboration of HCP from multiple disciplines—surgical departments, outpatient offices, inpatient perioperative nursing, preoperative surgical services, postoperative surgical units, infection prevention, information technology services, procurement, pharmacy, and the laboratory. Alexander and Hearld have stated that the implementation of complex interventions must be assessed systematically because the greater the complexity of an intervention, the greater the probability that some components of the intervention will not be implemented fully.[33] In general, implementers assume that the components of an intervention will function as a system to achieve the desired effects. However, if some components are not implemented fully, or if the timing and intensity of the implementation varies by component, then the outcomes do not represent the outcomes of the full "complex intervention." For the current project, the investigative team assumed that all components of the algorithm were essential and that they would act synergistically to reduce infections. To prove this assumption, the investigative team must assess adherence to each algorithm component (screening, decolonization, and appropriate prophylaxis). Future investigators should ensure that they have a mechanism for documenting which components of a complex intervention are implemented, when each component is implemented, and the extent to which the component is implemented (e.g., partially or fully) so that they can assess each component's contribution to the overall outcome.

This project has several important limitations. The investigative team was limited in its ability to collect data about existing algorithms and factors affecting implementation due to regulatory requirements associated with the Government contract. Thus, the investigative team could not collect information about characteristics of the hospitals or programs implementing the existing guidelines, the attitudes of their staff about the guidelines, and the organizational cultures of the

institutions in which the guidelines were implemented. Also, the quality of interpersonal relationships within and between departments, and the skills and experience of the staff championing the initiative, are known to greatly affect the success of implementation.[34] The current study did not have the resources to assess these subtle but important factors related to local culture and level of collaboration. Since the project was conducted within a health care system, the findings may not be generalizable to individual hospitals that do not have access to a similar infrastructure. On the other hand, implementation in a variety of community hospitals may be considered a strength, since these facilities are more like the overall hospital population in the United States than are academic health centers.

Conclusion

The current guidelines regarding prevention of gram-positive SSIs vary as do current practices. Thus, an algorithm that synthesizes current knowledge and expert opinion may help standardize practice and improve patient care. Hospitals in a health care system differed in their ability to implement the evidence-based algorithm for preventing SSIs, despite significant support from the health care system's strong infrastructure. Health care personnel implementing process improvement interventions must have sufficient time and resources to establish new cross-departmental systems that facilitate collaboration, develop essential educational programs, and create the information technology systems needed to support the implementation and assess the results.

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Appendix A. Project Participants

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Appendix B. Commonly Reported Challenges and Facilitators to Implementation of the Algorithm

Category	Examples of Challenges	Number of Unique Sites Reporting a Challenge at Least Once	Examples of Facilitators	Number of Unique Sites Reporting a Facilitator at Least Once
Technology, equipment and supplies				
Availability of equipment and supplies	Delays in receiving equipment for CHG cloths, CHG cloth warmers, or lab to identify MSSA	3–5	Site supplied CHG liquid to pre-op patients before participating in project; site set up a system to deliver CHG cloths to patients	1–2
	Hospitals that did not use PCR experienced delays in getting MSSA results before surgery.	3–5	Participation in project enabled hospitals to justify the funds to purchase PCR equipment	1–2
Electronic health record	Sites that screened patients more than 14 days before surgery manually entered screening results	10 or more	Sites were familiar with documentation from established system MRSA prevention initiatives where look-back period was up to 30 days	10 or more
	Delays in setting up data entry screens and local installation and customization	3–5	Corporate and local IT staff provided technical assistance	3–5
	Communicating results of screening tests performed at community labs was more difficult than communicating the results of tests done in the hospital's lab	1–2	Sites transitioned lab work to a central hospital-based lab	1–2
Personnel				
Turnover of key project personnel	Turnover of nurse managers, pre-admission unit HCP, staff nurses on nursing units	3–5	Standardized procedure documents and archived webinars posted on health system intranet were used to re-educate HCP as needed; site designated a person to answer questions in OR; site created a PowerPoint presentation; designated champions on each floor met monthly; incorporated protocol into orientation for new hires	10 or more
	Turnover of site liaisons	1–2	Trained alternate or co-liaison as backup or assistant	3–5

Appendix B. Commonly Reported Challenges and Facilitators to Implementation of the Algorithm (continued)

Category	Examples of Challenges	Number of Unique Sites Reporting a Challenge at Least Once	Examples of Facilitators	Number of Unique Sites Reporting a Facilitator at Least Once
Turnover of surgeons and other clinicians	Surgical volume decreased when a surgeon left	1–2	New surgeons were highly supportive of project	1–2
	New surgeons or physician assistants missed opportunities to apply algorithm	6–9	Provided one-on-one training as soon as possible	6–9
Physicians and other providers' attitudes/perceptions of algorithm components	Physicians were concerned about nephrotoxicity when using vancomycin for the "unknown group;" that overuse of mupirocin would contribute to mupirocin resistance; about using gentamicin for β-lactam allergic patients	10 or more	One-on-one calls and onsite visits from the health care system physician champion; shared updated consensus guidelines published January 2013	10 or more
			Supportive surgeons expressed desire to apply algorithm to other orthopedic surgical groups	1–2
Temporary staff	Agency staff may not be trained in applying protocol, especially those working weekends, holidays, and nights	1–2	Utilized just-in-time training resources to fast-track care practices	
Site-specific systems and processes				
Documentation of care processes in EHR	Nurses sometimes did not select necessary study screens; not all HCP could document directly in EHR and relied on internal communication	3–5	Liaisons re-educated staff to increase awareness of procedures	
Coordination and communication between surgeons' offices and inpatient preoperative surgical staff	Surgical office staff did not obtain swabs or educate patients about the protocol	1–2	Liaisons traveled to surgeons' outpatient offices to enhance relationships, provide education, and engender embracing of best practices	1–2

Appendix B. Commonly Reported Challenges and Facilitators to Implementation of the Algorithm (continued)

Category	Examples of Challenges	Number of Unique Sites Reporting a Challenge at Least Once	Examples of Facilitators	Number of Unique Sites Reporting a Facilitator at Least Once
Preoperative ordering of mupirocin, CHG baths, and antimicrobial prophylaxis	Order for intranasal mupirocin or for CHG bathing missing	10 or more	Gave pharmacy ownership of mupirocin order process; used a standing order set (e.g., orders part of the "open heart package")	3–5
Process for medical executive committee to approve new orders	Approval of new orders delayed because the committee met infrequently or cancelled meetings	6–9	Physician champion and facility liaison obtained pre-approval from committee chair in anticipation of formal adoption	
Communication of lab screening results to doctors and pharmacy	Surgeons or pharmacy did not receive lab results before the operation	3–5	Daily list of lab results sent to liaison	1–2
Process for identifying and applying the algorithm to patients who need urgent or emergent procedures and bypass the usual preoperative processes	Algorithm not applied to patients that were admitted through the emergency department, from ICU, catheterization lab, etc.	10 or more	Liaisons used reminders, checklists, chart stickers/flags; cardiac catheterization lab obtained swabs; admissions staff notified directors by email of patients coming in for procedures in their areas; nurses printed a checklist that accompanied the patient	10 or more

Appendix B. Commonly Reported Challenges and Facilitators to Implementation of the Algorithm (continued)

Category	Examples of Challenges	Number of Unique Sites Reporting a Challenge at Least Once	Examples of Facilitators	Number of Unique Sites Reporting a Facilitator at Least Once
Process for applying algorithm outside of normal business hours	Health care personnel on nights, weekends, and holidays may be unfamiliar with protocol, resulting in missed opportunities	10 or more	House supervisor called or paged liaison, who then contacted floor nurse; liaison used reminders and checklists	10 or more
Process for postoperative mupirocin orders	Failure to re-order mupirocin post-op when indicated; failure to discontinue mupirocin orders or stop applying mupirocin post-op	6–9	Liaisons and physician champions re-educated physicians, nurse practitioners, and physician assistants; pharmacy monitored screening results; stopped mupirocin as needed	3–5
Process for training existing and new HCP on the protocol	HCP not familiar with algorithm because they were not trained or their training was delayed	3–5	Health care system posted standardized procedure documents and archived webinars on a common intranet; site designated a person to answer questions in OR; site created a PowerPoint presentation; site incorporated ongoing training into annual proficiency testing; manager made a pocket tool for CHG bathing instructions	1

Appendix B. Commonly Reported Challenges and Facilitators to Implementation of the Algorithm (continued)

Category	Examples of Challenges	Number of Unique Sites Reporting a Challenge at Least Once	Examples of Facilitators	Number of Unique Sites Reporting a Facilitator at Least Once
Processes for monitoring and improving adherence to protocol	Continued inconsistent application of algorithm elements	10 or more	Investigative team required sites to submit audit forms periodically and discussed the results with the sites; liaisons provided rewards for HCP (e.g., stars, candy) who applied the algorithm correctly; real-time review of every eligible case when workload/volume permitted; daily (M-F) multidisciplinary team rounds on all orthopedic patients included assessment of compliance with STOP SSI algorithm; surgical care improvement project nurse led efforts to educate nurses and track study patients; liaisons conducted concurrent review; staff in pre-op holding area addressed missing practices on the day of surgery	10 or more
Procedure changes from an excluded procedure to an included procedure during the procedure	Algorithm was not applied because the scheduled procedure was not included (e.g., hip-nailing), but the procedure was changed to an included total hip replacement	1–2	Sites expanded the bundle of practices to apply to all orthopedic procedures that have the potential to be converted to an included procedure	1–2
Organization and external environment				
Physical environment or technology is changed	Adapted to infrastructure changes such as CPOE implementation; construction of new ICUs or operating rooms; conversion of units to different functions	6–9		

Appendix B. Commonly Reported Challenges and Facilitators to Implementation of the Algorithm (continued)

Category	Examples of Challenges	Number of Unique Sites Reporting a Challenge at Least Once	Examples of Facilitators	Number of Unique Sites Reporting a Facilitator at Least Once
Related quality improvement initiatives and policy changes	New universal decolonization policy in the ICU could not be applied to STOP SSI patients; HCP were diverted to other priority issues	3–5	A crosswalk was created to help HCP apply the two protocols appropriately	10 or more
Publication of national guidelines	Publication of a major national consensus guideline on antimicrobial prophylaxis, which was consistent with the algorithm, was delayed more than a year	3–5	The liaisons and clinical champions used the guideline to improve physician adherence to the protocol when it became available midway through implementation	1–2
National public reporting requirements			NHSN 2013 updated SSI followup periods for procedures with implants to 90 days, which is consistent with the followup period for the project; several sites were already reporting SSIs to State agencies	10 or more
Change in department level or C-suite leadership	Turnover led to need for re-education (e.g., CEO, CNO, Co-chair, lab director)	6–9	Liaison provided awareness of evidence-based care practices similar to that for other key HCP	6–9
Change in patient care priorities	Community outbreaks of influenza and fungal meningitis associated with contaminated medication	3–5	Alternative liaisons, colleagues assumed additional responsibilities, reprioritized resources to support the implementation while addressing the other patient care priorities	1–2
Organizational changes	HCP were diverted from project to support the application for trauma center status; changes in organization of nursing staff	1–2		

Appendix B. Commonly Reported Challenges and Facilitators to Implementation of the Algorithm (continued)

Category	Examples of Challenges	Number of Unique Sites Reporting a Challenge at Least Once	Examples of Facilitators	Number of Unique Sites Reporting a Facilitator at Least Once
Patients				
Understanding bathing and decolonization instructions	Limited English proficiency	3 –5	Patient instructions were translated into Spanish; patients were called and reminded; patient education packets were color-coded to indicate the screening test results	3 –5
Adherence to instructions for applying mupirocin and CHG bathing	Outpatients forgot or failed to complete recommended number of baths for various reasons	1–2	Patients were instructed to discontinue bathing when patient's skin was sensitive to CHG or reacted adversely to CHG. Outpatients were called daily for reminders to purchase supplies (if not provided) and perform decolonization	1–2
Out-of-pocket costs for purchasing CHG liquid or mupirocin	High cost for unit-dosed mupirocin	1–2	The health care system approved in-kind contribution to cover the cost of CHG cloths; most hospitals provided CHG free of charge; patients were willing to purchase CHG since it would help them avoid SSIs	3–5
Adherence to filling out pre-op form and bringing it to the hospital when admitted	Patients forgot to bring the forms when they arrived for surgery	1–2	Nurses interviewed patients on day of surgery and documented their adherence; infection preventionists participated in pre-op classes for joint replacement patients	1–2

Abbreviations: CEO = chief executive officer; CHG = chlorhexidine gluconate; CNO = chief nursing officer; CPOE = computerized provider order entry; ED = emergency department; EHR = electronic health record; HCP = health care personnel; ICU = intensive care unit; IT = information technology; MRSA = methicillin-resistant *Staphylococcus aureus;* MSSA = methicillin-susceptible *S. aureus*; NHSN = National Healthcare Safety Network; OR = operating room; SSI = surgical site infection.

Note: Due to limitations in the data collection methodology, the range of numbers represents how many unique sites reported the obstacle or facilitator, not the number that experienced the obstacle or facilitator.

Assessing ICU Staff-Perceived Barriers to Implementation of an Enhanced Carbapenem-resistant *Enterobacteriaceae* Control Intervention

Victoria Parker, Caroline Logan, Brian Currie

Abstract

This paper presents data from an assessment of intensive care unit (ICU) staff-perceived barriers to implementation of an enhanced carbapenem-resistant *Enterobacteriaceae* (CRE) control intervention across all ICUs in three hospitals in a New York City academic inpatient health care network. The enhanced CRE control measure included the initiation of an active CRE surveillance program in all ICU units, with all CRE-positive patients being placed in contact isolation. Active surveillance had not been previously used as an infection control strategy at any hospital or ICU in the health care network. This study was designed to assess ICU staff knowledge of CRE and perceived barriers to implementing the enhanced CRE control intervention. Data collection included pre- and post-intervention interviews of stratified samples of ICU staff (n=30 and n=34, respectively) and a post-intervention online survey offered to all ICU staff (n=205; 19.5 percent response rate). Interviews and surveys included samples of nursing, physician, and physician assistant ICU staff. Responses were used to identify consensus themes in staff perceptions and indicated that awareness of the *Klebsiella pneumoniae* carbapenemase (KPC) variant of CRE as an emerging nosocomial threat was low across all occupational groups at baseline. Staff identified sustained education on the scope of the issue and evidence for interventions as key facilitators in the implementation of new processes. Post-intervention, staff were much more knowledgeable, and they identified the need to also involve ancillary staff and patient family members in educational activities around the new interventions. Results are presented in the context of existing literature to provide insight and guidance to designing and successfully implementing future CRE control interventions.

Introduction

Carbapenem-resistant *Enterobacteriaceae* (CRE) infections have rapidly emerged as a global public health issue. In the United States, the presence of CRE is almost exclusively the result of the emergence and rapid dissemination of the KPC (*Klebsiella pneumoniae* carbapenemase) variant of CRE.[1,2] KPC was first reported in North Carolina in 2001 and, by 2006, had been responsible for a number of well-documented hospital-based outbreaks in the New York City area.[3–7] Over the next 6 years, KPC was noted to have become endemic in New York City hospitals and had rapidly disseminated, both on a national and global basis.[2,8] By 2012, KPC was reported from 42 States; internationally, it was reported from every continent.[2,9] Infections caused by KPC-producing bacteria have resulted in substantial morbidity and mortality because of limited treatment options, and they present significant therapeutic and infection control challenges in health care settings.[2]

Prevention of nosocomial transmission of KPC has surfaced as an emerging priority. A demonstration project funded by the Agency for Healthcare Quality and Research (AHRQ) was

initiated in 2009 at Montefiore Medical Center, in the Bronx, New York, that was designed to assess the impact of implementing Centers for Disease Control and Prevention (CDC) recommendations for enhanced infection control interventions to prevent the transmission of KPC among intensive care unit (ICU) patients. The CDC recommendations were developed in 2006 and updated in 2009.[1,10] The interventions included the use of a rapid molecular test (a polymerase chain reaction [PCR] assay) to drive an active surveillance program to detect KPC-colonized patients, coupled with the rapid institution of contact isolation precautions for all KPC-positive patients. The design and rollout of the intervention included a multidisciplinary planning and implementation team and a focused KPC staff educational program. A pre-post study design was used to evaluate the impact of the intervention, with baseline data collected over a 4-month period and compared to data from a 4-month post-intervention period. The intent was to create a successful, replicable intervention that could be exported to other institutions through the use of a toolkit.

The study design included provisions to assess ICU staff knowledge and understanding of KPC and the need for KPC control interventions, knowledge and acceptance of routine infection prevention practices, and perceived barriers to implementing enhanced KPC screening and control measures. Additionally, the study determined how the intervention rollout and education efforts influenced the adoption of the new KPC intervention. The study was initiated to provide insight and guidance to designing a successful intervention, including identification of potential barriers to implementation that may not have been previously anticipated and addressed in the project planning process. Study results are presented and discussed here.

Methods

Setting

This study was conducted in eight ICUs located in three hospitals in Montefiore Medical Center (MMC), an academic tertiary care hospital network located in the Bronx, New York. The intervention investigations were approved by the MMC Institutional Review Board (IRB), and the activities described in this paper were approved by both the MMC and Boston University School of Public Health (BUSPH) IRBs.

Sample

Stratified staff samples, including key leaders, were chosen from among physician, nursing, and physician assistant staff in all ICU settings for both before and after interviews (n=30 and n=34, respectively), and an electronic survey was sent to all nursing staff, physicians, and physician assistants (n=205) employed in all MMC ICUs during the post-intervention period.

Intervention

After baseline prevalence data had been collected by MMC research staff, the intervention was rolled out during an approximately 1-month period prior to beginning the collection of post-intervention KPC prevalence data. During the intervention phase, ICU nursing staff were trained to take weekly peri-rectal swabs from all patients and from any new admission at the time of arrival into the ICU. Research staff picked up all swab samples daily at 9:00 a.m. Samples were then analyzed, and any positive results were reported to the nurse managers in each ICU by

12:30 p.m. Contact isolation precaution orders were immediately entered into the electronic medical record and implemented.

The intervention rollout was initiated with an extensive educational program that included group meetings with the staff of each ICU. All sessions were timed in the morning to simultaneously capture day and evening staff, and a video presentation was created for off-hour staff who could not be present. Sessions (including the video) were presented by the medical center epidemiologist. They were approximately 50 minutes in duration and included opportunities for open-ended questions and comments. Video participants were encouraged to submit questions and comments via email to the medical center epidemiologist, who responded via email to each participant. Attendance at presentations was mandatory, and compliance was tracked with sign-in sheets.

The educational sessions included a basic overview of the epidemiology and clinical significance of KPC. The importance of asymptomatic colonized patients as a driving force for KPC dissemination was stressed and used as the rationale for initiating an intervention that included an active KPC surveillance program coupled with contact isolation of all KPC-positive patients. Baseline data were used to underscore the fact that the ICUs already had significant KPC prevalence. The intervention was described in its entirety, and the role of each ICU occupational group in the intervention was introduced and discussed. The importance of sampling all patients was stressed. Existing hand hygiene and contact isolation protocols were reviewed, including the need for high levels of adherence by all staff and visitors. The medical center epidemiologist provided contact information for any future questions or for reporting identified problems with the initiative. Placards and signage were provided that presented the intervention workflow and sampling method for future review.

MMC research staff reviewed, on a daily basis, progress toward effective intervention implementation and coached staff to help them successfully achieve each step of the workflow process. This process was particularly helpful in assisting nursing staff to incorporate patient sampling into routine workflow patterns, resulting in complete and timely sampling of all patients. Daily reviews also provided an ongoing opportunity to reinforce KPC awareness and key educational issues, answer staff questions, and identify potential unanticipated problems. After 2 weeks, the intervention process was effectively functional; however daily coaching visits by research staff were continued for an additional 2 weeks to support future intervention sustainability.

Data Collection

Staff were interviewed approximately 11 months before (n=30) and 6 weeks after (n=34) the new KPC screening and precaution guidelines were implemented in all ICUs. A semi-structured interview guide was used that focused on the importance of infection control in the ICU, challenges to it, awareness of KPC, and concerns about caring for patients on contact precautions. A research assistant took detailed interview notes. All interviewees completed a written informed consent form prior to participating in an interview. All interviews were voluntary and were conducted by BUSPH research staff. Participants were promised anonymity and that only aggregate data would be shared with MMC leadership. Baseline interviewees included 14 physicians, 7 nurses, and 9 physician assistants. Post-intervention interviewees included 18 physicians, 10 nurses, and 6 physician assistants.

In addition, a post-intervention survey was sent via email to all 205 physicians, nurses, physician assistants and fellows-in-training employed in the eight ICUs throughout the medical center. The emails contained an anonymous link to a secure online survey (using SurveyMonkey®). The survey was modified from a survey developed at the Columbia School of Nursing to assess nurse adherence to hand hygiene guidance.[11] This survey model was chosen because it had been demonstrated to have acceptable levels of test-retest reliability (0.86) and stability (Cronbach's alpha of 0.80).[11] Potential survey participants were informed that only aggregate data would be shared with MMC leadership. Reminder emails were sent on a weekly basis for 5 weeks, after which the survey was closed to participation.

The survey consisted of 32 questions in five sections and employed 5-point Likert response scales. Sections 1, 2, and 3 contained general statements about the care provided at the respondent's facility, specific unit, and care team, respectively. The last two parts contained specific statements related to the staff's KPC knowledge base and to the implemented KPC prevention and control guidelines. A total of 40 responses were received before the survey closed, for an overall response rate of 19.5 percent. Respondents included 32 nurses, 5 physicians, and 3 physician assistants.

Analysis

The interview notes were independently and systematically reviewed by the research assistant and by one of the principal investigators to identify recurring themes in staff perceptions. Each researcher generated a list of themes that were then compared and combined to generate a consensus list of themes.[12] Survey data were analyzed by combining the "strongly" and "somewhat" responses for each item, resulting in three response categories for each item (agree, neutral, disagree), and frequencies for each were computed. Due to the small size of the occupational groups, no meaningful subanalyses were possible.

Results

Pre-Intervention Interviews

During the pre-intervention interviews, staff identified a number of factors that they considered important facilitators of infection control activities at MMC including:

- Clear interest in activities from top leaders.
- Regular data collection and feedback to staff.
- Development of a "speak up culture" to intercept potential breaches in practice.
- Accountability for those not following current protocols.
- Conveniently placed and consistently available supplies and personal protective equipment.
- Past success with ICU-based multidisciplinary approaches to reduce nosocomial infections (such as implementation of a central line bundled approach to reducing central line–associated bloodstream infections).

They also identified a number of existing problems that they considered barriers to infection control practice, which largely focused on the initiation of contact isolation. These observations included:

- Feeling a need to "do it all" to avoid multiple encounters with patients in contact isolation, resulting in the possibility that patients on contact precaution might get less attention.
- Challenge of educating family members and ancillary staff about contact isolation precautions.
- Difficulty of transferring ICU patients on contact isolation to the next level of care because of the limited number of single-patient rooms.

Awareness of KPC as an emerging nosocomial problem was uniformly low at baseline/pre-intervention across all categories of ICU occupational groups interviewed. While a few were aware of KPC, most were unaware of its dramatic emergence, the clinical implications of KPC infection, or the existence of new guidelines to prevent horizontal transmission of KPC among patients. Interviewees emphasized the importance of providing staff with a clear rationale and evidence for any new procedures to be implemented, offering repeated educational opportunities, having educational materials available for reference at all times, and providing feedback about the results of new efforts as part of existing data reporting processes on "zero target" infection prevention.

Post-Intervention Interviews

During the post-intervention interviews, staff again described their perceptions of implementation facilitators and barriers. Regarding facilitators, interviewees identified a number of thematic elements that had previously surfaced during the pre-intervention interviews. These elements now focused on factors that would enhance compliance with contact isolation precautions for patients who had screened positive for KPC:

- A "speak up culture" that empowered all members of the team to remind others to comply with contact isolation protocols.
- Easy access to personal protective equipment required for contact isolation.
- Consistent unit staffing with individuals familiar with contact isolation protocols.
- Use of dedicated equipment in isolation rooms, including blood pressure cuffs, stethoscopes, etc.

Factors identified as potential barriers to implementation included:

- Presence of non-ICU ancillary staff who would be less aware of the intervention guidelines.
- Presence of patients' family members who would not be familiar with contact isolation protocols.
- Concern with "alert fatigue" with respect to contact isolation signage outside rooms.
- A sense of fatalism about not being able to prevent all patient-to-patient transmission of KPC.

A prominent theme that surfaced was the perception that communication and education would be very important to successful implementation of the KPC intervention. This element of concern extended beyond the ICU staff and encompassed the need to educate ancillary staff who would be entering the ICUs and patients' family members about the seriousness of KPC infections in order to elicit interest and motivation. All interviewees, across all occupational groups, now exhibited a high degree of awareness regarding KPC, including the clinical and infection control implications of KPC infection and colonization. Staff identified the need for comprehensive in-service education, use of visual reminders, and on-site support as important components of a communication strategy for successful implementation of the KPC intervention. Nursing staff identified the collection of peri-rectal swab samples as a sensitive issue and believed that collaboration with nursing staff to ascertain the best way to integrate the sampling process into clinical workflow (both on admission and for weekly surveillance purposes) would be an important determinant of successful implementation of the KPC intervention.

Survey Data

A total of 40 individuals responded to the survey before it closed, for an overall response rate of 19.5 percent. Responses to Parts 1 and 2, which pertained to the care provided at the respondent's facility, suggest that, overall, respondents thought that their facility was committed to high quality patient care and infection control. Key findings are presented in Table 1. Part 3 of the survey addressed the respondent's care team and how the team members do their work. In general, respondents agreed with statements suggesting that care teams work systematically to improve processes of care, but findings from this section also suggest there may be opportunities for the organization to better support this kind of work. Key findings from this section are also presented in Table 1.

The final two parts of the survey, Parts 4 and 5, pertain to respondents' specific knowledge about KPC and the implementation of the new KPC clinical guidelines. Responses indicated that the implementation team was able to successfully educate staff about KPC and develop guidelines that integrated well into existing workflows; however, the findings also provided suggestions for areas of improvement, specifically in ensuring that non-ICU ancillary staff fully understand the guidelines and the rationale for new screening and patient handling processes.

Discussion

Many of the facilitating factors and perceived barriers to implementation of enhanced KPC infection control interventions that ICU staff identified in this study have been previously described in the infection control literature. These factors and barriers relate to the impact of active surveillance and contact precautions on (1) hospital contact isolation capacity and potential "throughput" problems in transferring colonized patients to other clinical units within hospitals, (2) concerns regarding staff and family adherence to contact isolation precautions, and (3) a potential reduction in health care worker–patient contacts, interrupted workflow patterns, and the potential for a negative impact on patient care.[13–17]

Table 1. Post-intervention survey: staff perceptions

Overall perceptions of care quality	Agree or Strongly Agree (%)	Neutral (%)	Disagree or Strongly Disagree (%)
My facility is committed to delivering the highest quality patient care	93	5	3
At my facility, it is a high priority to provide patient care according to evidence-based guidelines	83	10	8
The leadership at my facility places a high priority on improving infection control in our clinical areas	85	8	8
Day-to-day activities demonstrate that patient care quality is important	88	5	8
Approach to quality improvement			
Senior management supports our efforts and helps us obtain the necessary resources and cooperation	64	20	15
Analyzing clinical processes to identify areas for improvement is a regular part of our work	80	5	15
The organization makes sure people have the skills and knowledge to work as a team	65	23	13
When trying to improve performance, we systematically test out new ideas	73	18	10
Knowledge about KPC and KPC infection control guidelines			
Clear and complete information about KPC has been shared with our team	68	13	18
Our team understands the new infection control guidelines specific to KPC	58	23	18
KPC is likely to become as big a threat as MRSA and *C. difficile*	53	33	13
The new guidelines are inconsistent or confusing	42	32	26
Ancillary personnel from outside the unit are not adequately trained on the new guidelines	56	31	13
There was enough education about the new guidelines	39	29	39
Following the new guidelines takes time away from patient care	64	23	13
Our workload is too heavy to follow the new guidelines	61	28	11

Note: *C. difficile* = *Clostridium difficile*; KPC = carbapenemase-producing *Klebsiella pneumoniae*; MRSA = methicillin-resistant *Staphylococcus aureus*.

Given that patients for whom contact isolation precautions are implemented should be placed in single-patient rooms, it is important for each facility to assess the capacity to absorb an increased volume of isolated patients. If availability of single-patient rooms is limited and bed occupancy rates are high, as is the case at MMC, policies should be developed to outline criteria for other placement options, such as cohorting.

Past experience at MMC had already identified delayed transfer of ICU patients resulting from a lack of single-room availability at the receiving clinical unit. Of note, infection control staff were already routinely monitoring transfer of ICU contact isolation patients on a 24/7 basis and were able to identify an appropriate single room for the transferred patient on every occasion. When this issue was raised during the intervention rollout, infection control staff reassured the ICU staff that monitoring would continue, and results would be shared with ICU staff on a regular basis. In fact, the demand for single rooms was lower than anticipated because 16 percent of KPC-colonized ICU patients were already on contact isolation for a different multiple drug-

resistant organism and because there was a significant reduction in the prevalence of KPC colonization of ICU patients post-intervention (7.4 percent vs. 3.5 percent, $p<0.001$).

ICU staff concerns were well placed regarding staff and family adherence to hand hygiene and contact isolation precautions; published observational studies have identified compliance rates of less than 30 percent.[15] Ongoing campaigns at MMC had targeted compliance with both hand hygiene and contact isolation precautions over a 6-year period prior to this study, and these are continuing. Compliance rates were documented via surreptitious direct observation using a standardized tool on all clinical units at irregular intervals, with feedback to clinical staff. Observed rates of compliance in the ICUs during this study consistently ranged from 85 percent to 93 percent.

In spite of documented high rates of adherence, training sessions during the intervention rollout were used to review medical center protocols for hand hygiene and contact isolation and to remind staff about their accountability for their own compliance and for helping to ensure adherence by other staff and patient families. Staff concerns regarding non-ICU ancillary staff adherence to protocols resulted in the extension of group training sessions to respiratory therapy staff and to house staff at the beginning of their ICU rotations.

ICU staff concerns about the negative impact that contact isolation might have on patient care also have been previously documented in the literature. Published reports and small studies have suggested that both ICU and non-ICU patients on contact isolation have fewer health care visits, less patient contact time, half as many attending physician examinations on rounds, increased frequency of depression and anxiety, and decreased satisfaction; they also suffer increased adverse events and experience poorer outcomes relative to control patients not on contact isolation.[13,14,17] However, these studies have had many design issues and invariably have been based on small sample sizes. A more recent report that included large sample sizes from four hospitals confirmed fewer visits and shorter visits for patients on contact isolation, except in ICU units, where the duration of health care worker contact did not vary between contact isolation and non-contact isolation patients in all four study hospitals.[16] This observation was believed to possibly be related to the use of single-patient rooms for all ICU patients; higher proportions of patients on contact isolation precautions in the ICU; the higher acuity of care in the ICU; and the higher nurse-to-patient ratio in ICUs, resulting in the need for less changing of gowns and gloves.[16] Given the uncertainty in the literature and the uncertain clinical significance of observed changes in health care worker interactions with contact isolation patients, it is probably best to sensitize all ICU occupation groups to remain alert for the possibility of potential disparities in the care provided to these patients.

Although the spread of KPC and the need for new approaches to screening and prevention of horizontal transmission in health care settings have been well recognized in the infectious disease and infection control communities, the baseline findings from this study suggest that KPC awareness among intensive care clinicians was much less prevalent. This finding was concerning, given that the KPC epidemic in New York City was more than 10 years old, and that ICU patients carry a high risk for KPC infection. It also underscored the need for repeated, multi-model, continuous education activities to be integrated into the KPC intervention rollout process. Clinicians who had been exposed to such education understood the reason for the new processes and reported commitment to carrying them out. Respondents who had missed some of the education sessions were less clear on the need for the intervention. Our findings also underscore

the need for the implementation process to include clinical staff in problem-solving about how to incorporate new screening steps and infection prevention activities into existing workflows.

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Screening for Surgical Site Infections by Applying Classification Trees to Electronic Data

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Abstract

Automated systems for surgical site infection (SSI) surveillance have been developed and used, but they are rarely tested for generalizability. We sought to develop highly sensitive algorithms for detecting deep and organ-space SSI based on electronic data to flag charts for subsequent clinical review. We developed three electronic algorithms to detect deep and organ-space SSI after coronary artery bypass grafting, total hip and knee arthroplasties, and herniorrhaphies, using a sample of nationwide Veterans Affairs Surgical Quality Improvement Program (VASQIP) data. One algorithm was created using recursive partitioning, while the other two used simpler methods based on abnormal laboratory values or the presence of postoperative microbiology or antimicrobial data. The algorithms were tested against VASQIP data and then assessed for generalization using data from hospitals in three different, external (non-VA) health care systems. Although all three algorithms performed reasonably well at identifying deep and organ-space SSI in the VASQIP test dataset, the recursive partitioning algorithm showed a lower sensitivity than expected. Performance worsened considerably when tested against data from the outside hospital systems, suggesting that the recursive partitioning algorithm was overfit (i.e., did not generalize well to test data samples), despite 10-fold cross validation. The simpler algorithms were more robust, but performance was variable between facilities. The observed variation was primarily due to differences in the data collected and stored in each system. The development of generalizable algorithms to detect SSI using electronic data necessitates careful consideration of the data readily available at most health care systems.

Introduction

The purpose of traditional infection surveillance, performed manually by infection preventionists (IPs), is at least two-fold: (1) to improve situational awareness and (2) to accurately detect trends and differences across times or locations. For the former, it is most useful to have a high sensitivity; for the latter, it is most useful to have a high specificity. IPs have been favored over automated systems for this task because of their adaptability and clinical judgment about the presence or absence of surgical site infection (SSI). Continuing to solely use IPs in this role may appear ideal, but because of increasing time demands, they often cannot devote adequate time to all of their responsibilities.[1–3] Also, the fact that they can and do use clinical judgment can potentially lead to issues concerning intra- and inter-rater comparability and reliability.

Health care systems with electronic health records (EHRs) may improve the efficiency of their SSI surveillance activities (i.e., time spent to find a positive case) and improve case finding reliability by leveraging electronic data. Although many potential approaches exist, the system long employed by Intermountain Healthcare (IH) uses electronic algorithms to screen potential cases and populate more manageable queues of charts for an IP to subsequently review.[4] This approach can capitalize on the IP's superior specificity (i.e., ability to discern the presence of a

true SSI) and may significantly reduce the work burden. When IH initially implemented this scheme, few facilities had the data infrastructure or capacity to replicate its system, but as more facilities employ sophisticated EHRs, more may now be able to implement similar electronic surveillance strategies that are augmented by clinician review.

Completely automated electronic systems can review charts rapidly and without concern for adaptation. There is some evidence to suggest that, in some situations, automated systems may be the instrument of choice.[5] However, these systems can be extremely sensitive to artifacts of data manipulation or changes in clinical practice. Also, automated algorithms are usually limited to using structured data and cannot utilize the same body of information as manual review, such as the information contained within text notes. As a result, the specificity of these systems is typically inferior to manual review.

The purpose of our work was to develop an SSI surveillance tool that detects downstream manifestations of SSI as indicated in electronic data and to implement and test this tool at four disparate health care organizations. We chose to build a two-tiered system: the first tier is run by the automated system, which removes charts where the signal is weak enough to safely exclude; the second tier involves human review on the more difficult cases, where a superior ability to discriminate between signal and noise (i.e., cases and non-cases) can be efficiently applied. We hypothesized that this system would lead to comparable results between health care systems and considerable time savings during surveillance activities.

Methods

Study Sites and Cohort

Our study involved four participating centers: the VA Salt Lake City Health Care System (VASLCHCS), Denver Health (DH), Vail Valley Medical Center (VVMC), and Intermountain Healthcare (IH). The population of interest was all patients who underwent coronary artery bypass grafting (CABG), total hip arthroplasty (THA), total knee arthroplasty (TKA), and abdominal and inguinal herniorrhaphy. These patient populations were chosen because of the relatively high volume of procedures at these centers and the risk of deep and organ-space SSIs. To develop, train, and test our electronic algorithms, we used VA Surgical Quality Improvement Program (VASQIP) data on the outcomes of patients who underwent these procedures from January 1, 2007 through December 31, 2009. These data were selected because of the large volume of data available compared with the other centers and to amass a reasonable number of SSIs for training. We supplemented these data with VA enterprise-wide microbiology, laboratory, admission/discharge/transfer, bar code medication administration, and vitals data from 1 week prior to 30 days after the surgical procedure. Similar external test datasets were developed for each participating center.

Each of the centers had different pre-existing strategies for SSI surveillance. DH and VVMC generally followed National Healthcare Safety Network (NHSN) guidelines and performed traditional manual surveillance. While centers were opportunistic when recording post-discharge, prosthetic-related infections up to a year after surgery, they did not systematically follow up on patients beyond 30 days postoperatively. IH had previously pioneered electronically supported, clinician-managed surveillance systems and uses this modality routinely.[6] The VA uses VASQIP for surveillance, with rules similar to (but not entirely the same as) NHSN. Each of the facilities

pulled the results of routine surveillance based on its own methodologies into databases residing on its own systems. Each of these datasets served as a reference standard representing the status quo. Table 1 shows the procedure and SSI data gathered from the four centers.

Electronic Data

We performed a literature review using MEDLINE to identify data elements that were likely to inform a diagnosis of SSI. We selected articles that pertained to the manifestations of SSI that were potentially included in electronic records. We identified leukocyte count, leukocyte differential, fever, procalcitonin, erythrocyte sedimentation rate (ESR), c-reactive protein (CRP), microbiology results, and antimicrobial administration as potential elements to include.[7–20] A significant number of published algorithms also incorporated claims data, but these data were excluded from our algorithm because they often are not available at the time of IP case review.[9,10,12–16,21] Not all of the elements were included in the final algorithm; for instance, although we initially planned to include fever, it was excluded because DH did not record these data through the entire study period.

Algorithm Training and Testing Data

We began by identifying candidate surgeries among VASQIP data from 2007 through 2009. Because VASQIP surgeries are identified by Current Procedural Terminology (CPT) code and not by International Classification of Diseases, Ninth Revision (ICD-9), we built a map between the two vocabularies for the four target surgeries, using the Unified Medical Language System (UMLS) metathesaurus concepts. Included surgeries were identified by both CPT and ICD-9 codes.

VASQIP surveillance is the principal method of SSI accounting at the VA; as such, surveillance is not performed on all surgeries, but rather on a subset. During our study timeframe 63,290 of the target procedures were performed and reviewed in the VASQIP system. This set was divided randomly into two sets for training and testing of the algorithm. Data from VASLCHCS were excluded from the training set because they would later be used in the analysis of our four principal centers.

Table 1. Number of procedures and SSIs between 2008 and 2009 stratified by hospital and type

		DH		IH		VASLCHCS		VVMC	
Surgery		#	%	#	%	#	%	#	%
CABG	Total Procedures	0		1845		78		0	
	sSSI	0		12	0.7	3	3.8	0	
	dSSI	0		7	0.4	0	0.0	0	
	oSSI	0		1	0.1	0	0.0	0	
	Total SSI	0		20	1.1	3	3.8	0	
HERNIA	Total Procedures	898		1059		237		294	
	sSSI	4	0.4	0	0.0	2	0.8	1	0.3
	dSSI	2	0.2	0	0.0	0	0.0	0	0.0
	oSSI	1	0.1	0	0.0	1	0.4	0	0.0
	Total SSI	7	0.8	0	0.0	3	1.3	1	0.3
THA	Total Procedures	268		2810		90		137	
	sSSI	2	0.7	0	0.0	0	0.0	0	0.0
	dSSI	2	0.7	5	0.2	0	0.0	1	0.7
	oSSI	3	1.1	3	0.1	2	2.2	0	0.0
	Total SSI	7	2.6	8	0.3	2	2.2	1	0.7
TKA	Total Procedures	232		7897		163		421	
	sSSI	1	0.4	6	0.1	0	0.0	0	0.0
	dSSI	2	0.9	7	0.1	0	0.0	1	0.2
	oSSI	1	0.4	2	0.0	1	0.6	0	0.0
	Total SSI	4	1.7	15	0.2	1	0.6	1	0.2

Abbreviations: CABG = coronary artery bypass grafting; DH = Denver Health; HERNIA = herniorrhaphy; IH = Intermountain Healthcare; SSI = surgical site infection; TKA = total knee arthroplasty; THA = total hip arthroplasty; sSSI = superficial SSI; dSSI = deep SSI; oSSI = organ-space SSI; VASLCHCS = VA Salt Lake City Health Care System; VVMC = Vail Valley Medical Center.

The VASQIP data included whether a superficial, deep, or organ-space SSI was identified within 30 days of the surgical procedure. For simplicity, we dichotomized this variable to indicate the presence or absence of any SSI type. These data were then linked to potential manifestations of disease. We included electronic markers between postoperative days 4 and 30 because earlier data might indicate that the patient was already infected at the time of operation. Our candidate electronic data elements were leukocyte count, temperature, the sending of a culture, the administration of a systemic antibiotic (inpatient or outpatient), hospital readmission, ESR, and CRP to the presence of SSI. Maximum values during the eligible timeframe were used for laboratory values and vitals.

Algorithm Development

We targeted algorithms with high sensitivity and high negative predictive value that could increase the efficiency of chart review by excluding a large fraction of negative charts. To accomplish the latter while not impeding the former, we investigated methods that would allow interactions between variables. Classification tree and regression tree analysis (CART, also called recursive partitioning) lends itself to the formulation of interacting rules and has been used previously in algorithms to detect SSI.[13] This method is somewhat limited in that it does not analyze interactions along the entire range of variables. Another issue is that, much of the time,

postoperative laboratory elements are missing. Random forest strategies may have advantages when dealing with sets where much of the data are missing, but we thought that for user acceptability it was important to have simple, coherent rules.

We used the function rpart for recursive partitioning in the R software package[22] to develop our algorithms. Initially, we tried to detect all SSI, but because of the lack of sensitivity and inefficiencies when searching for superficial SSI (sSSI), we trained on only deep (dSSI) and organ-space (oSSI) infections. We specified a classification tree and a loss matrix to penalize false negatives. The loss matrix was weighted by the inverse of the prevalence of dSSI and oSSI in the set. The maximum tree-depth was limited to three, and the minimum number of cases in a branch before a split was permitted was three. Any tree that resulted in a change of the complexity parameter (cp) of more than 0.001 was investigated. Effort was taken to prune the tree at the cp that minimized the relative cross-validation error, but when the difference was small and the algorithm was not sensitive enough, values with more splits but slightly higher relative cross-validation errors were accepted.

In addition to the rpart algorithm, we created an “inclusive” algorithm using the presence of any high-normal laboratory value and a “simple” algorithm that looked only for postoperative cultures and antimicrobials. The specific rules for all three algorithms are shown in Table 2.

Each of the hospitals was then sent the data elements necessary for the final algorithm. Actual code scripts were also sent to facilitate algorithm implementation; however, tailoring and adjustments were made to accommodate different data structures at each facility.

For clinical review, we randomly selected up to 50 charts that had been flagged as positive by both the reference standard and the algorithm and up to 50 negatives (false positives by the same standard) for manual review at each center. The reviewer was blind as to the result of routine surveillance as well as to the ratio of positives and negatives. Each chart was classified as to whether an SSI was present and the depth of the SSI. Charts not queued for review by the algorithm were considered negative by the manual review system.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated by comparing the modality’s output against the reference standard.

Human Subjects Research

This study was approved by the institutional review boards at all participating sites, including the University of Utah, IH, DH, and VVMC, as well as by the Research and Development Committee at VASLCHCS.

Table 2. Component rules of the rpart, inclusive, and simple algorithms

CABG
All of the following:
Presence of a postoperative culture
Postoperative antibiotics were given
Maximum postoperative leukocyte count is not less than 11.85
Herniorrhaphy
Either of the following:
Presence of a postoperative culture *and*
Maximum postoperative leukocyte count is not less than 7.78
Absence of a postoperative culture *and* one of the following criteria:
Postoperative antibiotics given *and* any postoperative leukocyte count test drawn
Postoperative antibiotics not given, but the patient had a postoperative admission
Total Knee Arthroplasty
Either of the following:
Presence of a postoperative culture
Presence of a CRP *and* the maximum postoperative leukocyte count is not less than 9.45
Total Hip Arthroplasty
All of the following:
Presence of a postoperative culture
Postoperative antibiotics were given
Maximum postoperative leukocyte count is not less than 7.55
"Inclusive" Algorithm
Any one of the following:
Erythrocyte sedimentation rate greater than 20
Total neutrophil count greater than 5,000/mm3
Total leukocyte count greater than 9,000/mm3
CRP greater than 3mg/dL
Any postoperative antibiotics given
Presence of a postoperative culture
Patient readmitted within 30 days postoperatively
"Simple" Algorithm
Either of the following:
Microbiology test ordered between postoperative days 4 and 30 (inclusive)
Antibacterial prescribed between postoperative days 4 and 30 (inclusive)

Abbreviations: CABG–coronary artery bypass grafting; CRP–c-reactive protein.

Results

Algorithm Training and Testing Performance

For the VASQIP training set, the overall sensitivity of the algorithms (for deep and organ-space SSIs combined) was 93.8 percent, and its specificity was 92.7 percent for all four surgical procedures; the positive and negative predictive values were 5.0 percent and 99.9 percent, respectively. Thus, we anticipated that when an IP reviewed procedures identified by the algorithms, this person would, on average, review 20.1 charts to find each SSI using the

recursive partitioning algorithm, 57.3 charts using the “inclusive” algorithm, and 246.9 if all charts were reviewed.

When the algorithms were applied to the VASQIP test dataset, the overall sensitivity and specificity of the rpart algorithm were 73.1 percent and 92.9 percent, respectively, with a PPV of 3.9 percent and an NPV of 99.9 percent. The performance of the inclusive and simple algorithms was somewhat better and remained stable in both training and test sets.

External Validation

We then applied our electronic algorithm to all surgical procedures that met our prespecified criteria at each principal hospital. The results are shown in Table 3. Overall, the sensitivity was 37.8 percent, the specificity was 94.3 percent, the PPV was 2.0 percent, and the NPV was 99.8 percent.

To investigate the reasons for false alarms by the algorithm at the various sites, we reviewed the false positives identified by the algorithm, as well as the positives identified by routine surveillance. At DH, the study reviewer agreed with all of the cases identified as positive by routine surveillance. Four surgeries were noted to have incorrect ICD-9 codes, indicating that they should not have been included. The study reviewer also identified one superficial SSI and one deep SSI queued by the algorithm but not found in routine surveillance records. At VASLCHCS, four additional deep and organ-space SSIs were identified by the study reviewer in addition to those identified by routine surveillance. At VVMC, all algorithm-identified cases were false positives. At IH, the study reviewer agreed with all positive cases identified by manual surveillance but with none identified by algorithm, except for two cases that appeared to have errors with identifiers.

False negatives were also reviewed at each center to determine the reasons for low sensitivity. At DH, two of the false negatives represented problems with the data pull. One SSI was assigned to the wrong hip replacement in the historical dataset. The hip replacement with infection was not in the dataset. Another procedure identified as having an SSI was actually a hysterectomy. Three surgeries were missed because the SSI occurred more than 30 days postoperatively. One SSI was missed because laboratories were only available from the outpatient setting. One SSI could only have been picked up from emergency department notes. Only two SSIs could have been picked up by electronic data, but they were missed due to the algorithm’s threshold criteria.

Table 3. Accuracy of algorithm at each participating hospital

Accuracy of Algorithm at DH				
		Routine Surveillance		
Algo	SSI	6	71	77
	no SSI	7	1345	1352
	Total	13	1416	1429
Sensitivity				46.2%
Specificity				95.0%
Positive Predictive Value				7.8%
Negative Predictive Value				99.5%

Accuracy of Algorithm at IH				
		Routine Surveillance		
Algo	SSI	9	704	713
	no SSI	16	10857	10873
	Total	25	11561	11586
Sensitivity				36.0%
Specificity				93.9%
Positive Predictive Value				1.3%
Negative Predictive Value				99.9%

Accuracy of Algorithm at VASLCHCS				
		Routine Surveillance		
		SSI	no SSI	Total
Algo	SSI	2	33	35
	no SSI	2	531	533
	Total	4	564	568
Sensitivity				50.0%
Specificity				94.1%
Positive Predictive Value				5.7%
Negative Predictive Value				99.6%

Accuracy of Algorithm at VVMC				
		Routine Surveillance		
		SSI	no SSI	Total
Algo	SSI	0	17	17
	no SSI	3	832	835
	Total	3	849	852
Sensitivity				0.0%
Specificity				98.0%
Positive Predictive Value				0.0%
Negative Predictive Value				99.6%

Abbreviations: Algo = algorithm; DH = Denver Health; IH = Intermountain Health; SSI = surgical site infection; VASLCHCS = VA Salt Lake City Health Care System; VVMC = Vail Valley Medical Center.

At VASLCHCS, only two SSIs were missed. Both occurred in total hip arthroplasties with onset of infection more than 30 days postoperatively. At VVMC, one infection was treated in the outpatient setting, and another was treated at an outside facility. The last infection developed 11 months after surgery and thus was not picked up because it occurred more than 30 days postoperatively.

At IH, 11 of 16 false negatives occurred because the algorithm missed important information in the notes and microbiology. All the data necessary to make an SSI diagnosis occurred after discharge from the initial surgery. In two cases, the reviewer thought that the cases were ambiguous; in another two, the reviewer disagreed that the cases were SSIs. In one case, the reviewer thought that the case was an sSSI rather than a dSSI or oSSI.

Discussion

Our objective was to generate algorithms that would feature high sensitivity and require a low number of charts to review per SSI found; however, we found that our recursive partitioning algorithm had a low sensitivity in the testing set and even poorer performance when tested in outside hospitals. Our simpler algorithms were more robust, which suggests that the recursive partitioning algorithm was overfit (that is, fit too closely to the data, resulting in poor

generalization) to both the sample data and the VA data. Performance was quite variable between facilities.

When SSI rates between facilities are compared, algorithm diagnostic accuracy and reliability must be carefully considered. Usually, routine prospective surveillance or some augmentation of it is used as a reference standard. Routine, manual, prospective surveillance is estimated to have a sensitivity between 30 percent and in excess of 90 percent, with most estimates in the 70 percent to 80 percent range.[7,16,23–25] In addition, the reliability of manual healthcare-associated infection and SSI surveillance has been reported to be less than ideal.[16,26–29] Any comparisons to such standards must take this into account.

Electronic algorithms are frequently reported to have sensitivities in excess of 80 percent.[19,20] Only some of these algorithms have been applied to multiple hospitals, and none of them report individual hospital validation results among hospitals as heterogeneous as the principal hospitals in our study.[7,13,16] Although our recursive partitioning algorithm had high sensitivity on the VASQIP training set, it was notably lower on the VASQIP test set. The pooled sensitivity at the four principal hospitals was only about 40 percent. These results contrast with the high performance seen in other published literature. Specificities and predictive values were relatively stable between our training and testing sets.

The differences in sensitivities that we saw in the recursive partitioning algorithm suggest that the model was overfit at two levels: first, overfitting to the training data, and second, overfitting to the VA data. One study in the literature used the same method to develop algorithms and reported high sensitivities;[13] however, those algorithms were not applied to external data. We expected the sensitivity of the algorithms developed in our study to be high because of success with previously devised algorithms, and because we surmised that it was unlikely that patients with either deep or organ-space SSIs would be absent of both antibiotic therapy and any culture testing for etiologic microorganisms. However, when these algorithms were tested against other hospitals, sensitivity and PPV varied. At VASLCHCS, no improvement in sensitivity over the recursive partitioning algorithm was observed, perhaps due to small numbers. At IH, a relatively large number of false positives were generated; this appears to be largely due to the use of antimicrobials during the postoperative period at this center. At DH, the simple algorithm fared poorly, while the inclusive algorithm fared better, perhaps because the simple algorithm relied more heavily on antimicrobial prescribing, a large amount of which (on the outpatient side) may not be captured by the DH system. This underscores our concern that even more robust "common-sense" algorithms that included elements successful at other institutions still did not generalize well because of institutional differences in data collection and clinical practice.[7,13,16]

The strengths of our study include drawing from VASQIP data to amass a reasonable number of SSIs for training. Also, the use of one-fold cross validation on the VASQIP dataset on an algorithm that was already derived with a 10-fold cross validation and external implementation at other hospitals presents a more realistic picture of algorithm accuracy and its variability. The main limitations of this work are related to three key issues. First is the use of routine, manual surveillance from each facility as the reference standard. Since the accuracy and reliability of manual SSI surveillance performed at different medical centers are thought to be suboptimal, cases identified as true positives at different centers may meet different sets of criteria. Second is the fact that small numbers of SSIs were observed in our four centers, limiting our ability to develop robust algorithms and to obtain an accurate assessment of their performance. The final

issue is the variability in data availability and standardization across the different health care systems.

In the future, improving diagnostic sensitivity while keeping the number of charts needed to review low can only be accomplished by improving the algorithm's ability to distinguish between SSI and other abnormal conditions. This could be accomplished by using procedures more robust to sparse data for algorithm development, incorporating dynamic thresholds for laboratory values and vitals, and enriching the input data by using natural language processing to extract information from text notes. Any electronic algorithm used to compare SSI rates at different centers should undergo extensive testing before operational use.

Lessons Learned

The following key lessons were learned as a result of the work performed in this study, which will help guide future work in this area:

- Generating automated electronic algorithms to detect SSIs across disparate health care systems is complicated by incompatible or missing data and relatively small numbers of true cases.
- The reference standard for SSI surveillance—routine, manual, prospective surveillance—is suboptimal for comparison because of issues with sensitivity and reliability across different centers.
- Advanced methods for algorithm development, including procedures robust to sparse data and natural language processing, will likely be needed to produce algorithms useful for surveillance across disparate health care systems.

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Flexible Interventions to Decrease Antibiotic Overuse in Primary Care Practice: A Report From SNOCAP-USA

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Abstract

Overuse of antimicrobial agents fosters the spread of antimicrobial-resistant organisms, which have become a leading public health threat. The Institute of Medicine has prioritized decreasing the inappropriate use of antibiotics as one of the primary solutions to address the growing problem of antimicrobial resistance. Despite numerous efforts, inappropriate antibiotic prescribing in primary care practices remains common. As part of a large-scale practical trial, a qualitative analysis of key informant interviews was conducted to assess paper-based and electronic implementation methods of antibiotic prescribing clinical decision support tools in primary care clinics. Sensitivity of the intervention to the specific needs of individual practices is necessary to sustaining positive effects in prescribing behavior. While intervention educational materials and decision aids were consistent across practices, implementation included the flexibility to conform to clinicians' preferences and the workflows, policies, and resource limitations of each individual clinic. Key lessons learned include the flexibility to accommodate (1) variability in local antimicrobial resistance and formularies to ensure relevance in almost any primary care practice; (2) ability of practices to modify treatment and diagnostic guidelines within reason, based on contextual factors such as whether practices were part of an integrated system of care and their relative access to diagnostic testing equipment; and (3) availability and recognition of a local antibiotic stewardship champion to answer questions and inform local decisionmaking.

Introduction

Appropriate antibiotic prescribing has long been an issue of great concern to practitioners and policymakers alike.[1] Overuse of antimicrobial agents fosters the spread of antimicrobial-resistant organisms, which have become a leading public health threat.[2,3] Antimicrobial resistance is ultimately associated with poorer clinical outcomes and increased health care costs, much of which can be attributed to complications of antibiotic use.[4,5] The Institute of Medicine has prioritized decreasing the inappropriate use of antibiotics as one of the primary solutions to address the growing problem of antimicrobial resistance.[1]

Research has shown that inappropriate prescribing (wrong indication or indication or use of unnecessarily broad-spectrum agents) may be due to multiple factors. These may include (1) provider knowledge gaps[6,7] or lack of awareness of guidelines;[8] (2) patient demand (perceived or actual);[9–13] (3) difficulty in distinguishing bacterial from viral infections;[14–16] (4) provider or patient perception that a course of antibiotics is the "safest" strategy; (5) time necessary for the provider to explain why antibiotics are not indicated;[17,18] and (6) health beliefs of the provider,[19,20] among others.[7,21] Given the multidimensional nature of this critical problem, a variety of interventions have been designed to improve antibiotic prescribing in the primary

care setting. Such interventions have included dissemination of educational materials to providers and patients, educational meetings and lectures, academic detailing, audit and feedback, guideline development, clinical decision support systems, mass media campaigns, and delayed prescriptions.[22–24]

The selection of the most effective of these interventions to improve the prescribing of antibiotics appears to be condition- and situation-specific.[25] A Cochrane review evaluated 66 studies that met criteria for time series analysis, controlled trials, or controlled pre-post studies. Seventy-seven percent of the studies reported improved outcomes, but no relationship between the type of intervention and the outcome was noted. The authors concluded that lack of a standard study design or direct comparison of interventions limited their ability to recommend specific interventions.[26] In designing an intervention to reduce the inappropriate use of antibiotics in office-based primary care practices, with practical application to a broad variety of settings, a recent assessment of these strategies concluded that multifaceted interventions that include active clinician education combined with clinician decision support systems appear to be the most effective in changing antibiotic-prescribing behaviors.[23]

Indeed, the study demonstrating the largest impact on antibiotic prescribing involved use of clinical decision support (CDS) systems.[27] Because the impact was seen only with the use of CDS, and not with education alone, the success was likely attributable to systematizing and standardizing the decisionmaking process, akin to the "checklist" approach that has shown similar success in infection control initiatives aimed at reducing central line-associated bloodstream infections.[28] Previous studies indicate that clinicians who have been in practice longer and are not involved in medical teaching appear to misuse antibiotics most frequently.[7] CDS tools would likely provide the greatest benefit to those providers, particularly in settings that have limited access to consultation and subspecialty services.[29]

The State Networks of Colorado Ambulatory Practices and Partners (SNOCAP) undertook a study to conduct a pragmatic trial to evaluate the impact of CDS tools in primary care practice. SNOCAP is a practice-based research network that was expanded throughout the USA, in partnership with the American Academy of Family Physicians—National Research Network, to form SNOCAP-USA. This collaboration of practice-based research networks makes it possible to perform this and other related studies to provide practices, policymakers, and patients with actionable information with which to improve care.

In this study, clinical pathways for eight common adult and pediatric infections were developed: nonspecific upper respiratory infection, acute bronchitis, acute rhinosinusitis, pharyngitis, acute otitis media, urinary tract infection, skin and soft tissue infection (cellulitis or cutaneous abscess), and community-acquired pneumonia. Clinics were given binders with hard copies and electronic copies of the CDS tools on the local intranet, with some clinics adopting a combined implementation approach, and others opting for either the binders or the electronic copies. The CDS tools were implemented over a 1-year intervention period.[30] In addition, clinics were provided with patient education materials, and clinic champions were identified who assisted with intervention implementation throughout the study. While the CDS tools did indeed have a positive impact on prescribing behavior change,[30] the use of a mixed methods implementation approach provided valuable qualitative insight regarding the practice-specific dynamics surrounding the successful implementation and use of these tools. One aspect of our inquiry

centered on the need for and value of flexible and adaptive processes to accommodate the needs of local settings.

Methods

After receipt of all required institutional research board approvals, the study was implemented at eight family medicine and internal medicine outpatient clinics in an integrated urban safety net health system in the Rocky Mountain region of the United States. Key informants at each clinic were asked to identify a minimum of one health care provider per site with reasonable knowledge of the clinic's antibiotic prescribing practices. Identified providers at each clinic were then contacted and asked to consent to confidential in-person interviews. Eight providers agreed to participate, representing all eight clinic sites. Six participants represented physician perspectives (MDs), and two participants represented the perspectives of mid-level practitioners (nurse practitioners or physician assistants).

Interviews were conducted by a doctorally prepared qualitative health and behavior scientist over a 2-week period in July 2012. Interviews were conducted at each clinic site in the participant's choice of setting. All interviews were audio recorded, with the recorded data augmented by the investigator's observations made during the interview session. Interviews were conducted in a semi-structured format, according to an interview guide developed by the investigators, which ensured that key topics of interest were addressed with all providers while also allowing for exploration of additional topics and content areas that might emerge during the discussion. Interview topics included providers' awareness of antibiotic stewardship programs in the care setting; how providers were made aware of good antibiotic stewardship practices; what materials and tools were available to help providers in making prescribing decisions and discussing appropriate antibiotic use with patients; patients' perceptions of antibiotic prescribing practices; how providers used available materials in their own care practices; and providers' opinions of, and recommendations for, antibiotic stewardship overall.

Interview data were subjected to analysis through review of written notes and audio recordings. Manual coding and immersive exposure approaches to the data, interview transcripts, notes from the audio recordings, personal observations, and several reviews of all written and audio materials were employed to analyze the qualitative data. Next, an inductive approach using an open, heuristic coding process was taken to identify initial emergent topics mentioned by participants.[31] Individual topics were then further categorized into themes based on the number of participants who mentioned or agreed with reference to a topic. Topics were classified as themes if they emerged in discussion with three or more participants. Identified themes and patterns were then reexamined in context and incorporated into a synthesis of results.[32]

Results

General Awareness and Use of Computerized Decision Support

Primary care providers reported a general awareness of the CDS tools, with the majority of providers reporting themselves and their colleagues as being familiar with both the health system-specific antibiogram and the condition-specific prescribing algorithms provided. Providers reported using the antibiogram and algorithms both for self-education and reference purposes and for guidance at the time of prescribing. Use of CDS tools was reported to be

maintained over time; more than one provider reported having accessed guideline materials to confirm their own knowledge when prescribing for a less frequently encountered diagnosis.

Personal communication methods were widely referenced as a way in which providers initially became aware of CDS tools. Three-quarters of the participants mentioned dissemination in system-based meetings such as grand rounds, departmental meetings, and committee sessions, and half of the participants recalled presentations being made by study personnel at clinic sites and in clinic-based provider meetings. Discussion among colleagues in clinic-based settings and provider meetings were also mentioned by over a third of the participants as a means of promoting awareness, as were informational and review sessions conducted by team leads. No consensus was observed with respect to the means used to inform new providers or residents of CDS tools and associated materials. Two informants indicated that reference information about the CDS tools was included in the educational packets provided to them by clinic supervisors, and two reported making mention of CDS tools during new provider orientation upon employment by the hospital, while two reported dependence on residents' preceptors to share stewardship information. New providers were largely presumed to bear the responsibility for becoming conscious of antibiotic stewardship in clinic practices and health system culture, primarily through asking questions or gaining the information through a perceived emergent awareness and shared community knowledge base.

Email was perceived by the majority of providers as an efficient, effective, and preferred means of disseminating new and updated CDS tools, although a few providers also noted that high volumes of email contributed to some providers exhibiting a tendency to ignore or delete large-group or mass-distribution email messages. The majority of providers also reported acknowledgment of the organization's intranet as an accepted source of information, although this observation was accompanied almost unanimously by a strong perception of the organizational intranet as unwieldy, slow, and difficult to use effectively. It is of note that half of participants specifically identified the sub-site where CDS tools were housed as being easy to access and use, in exception to the perceived general rule.

Clinician and Practice Variation and the Need To Adapt

Providers perceived themselves and their colleagues as generally adhering to prescribing guidelines in concordance with the CDS tools made available. Variations in prescribing practices among primary care providers were attributed to providers' own knowledge as influenced by age, years since completing clinical education, and training background. Several providers noted a willingness to deviate from guideline-based practices in favor of their own clinical judgment and expertise when they disagreed with guideline recommendations, whether for reasons of poor guideline quality or clinical considerations on a case-by-case basis.

Respondents were consistently able to share their clinic-specific challenges to guideline-concordant prescribing, such as availability of certain medications in a clinic dispensary, limited availability of point-of-care diagnostic tests, and barriers to access affecting patients' willingness or ability to return for followup visits. At the same time, the majority of providers were in agreement that the CDS tools were useful and helpful. The guidelines were described as being of good quality, evidence-based, appropriate to the setting, and generally accepted.

Workflow Integration

Paper-based methods were also mentioned by half of the participants. Clinic providers reported actively continuing to use the educational materials in the reference notebooks provided; two clinic providers also described printing and distributing algorithm materials for review and discussion in provider meetings. The availability of provider time during clinic visits was repeatedly noted as a scarce resource and limiting factor, both in general and with regard to the use of antibiotic guidelines; in this connection, participants mentioned the guidelines as easy to access and use, which was perceived as a factor in their value as a reference tool.

Providers expressed strong preference for, and interest in, electronic health record (EHR)-based prompting at the point of prescribing as a way to promote good stewardship practices. Specific suggestions were made for the design of prompts that incorporate informational/educational aspects and recommendations tailored to the active prescription context. For example, such a prompt might be triggered in response to the combination of a diagnosis and a non-recommended medication selection to inform the provider of current resistance patterns and ask whether the provider was aware that an alternate medication was the recommended first-line agent. Providers also recommended the use of electronic methods for guideline updates. In addition, they were cognizant of challenges inherent in maintaining and improving stewardship practices and suggested involving providers as partners in developing new guidelines of interest. It was observed by participants that, in general, sharing appropriate prescribing information in the context of current events or news of interest—such as infectious disease surveillance rates, current resistance rates, or antibiotic cost—would increase provider interest in, retention of, and adherence to recommendations.

Discussion

This intervention was designed with three simple components to be practical and widely generalizable: (1) clinical pathways, (2) patient education materials, and (3) peer champion support. The availability of our clinical pathways in a format adapted to the practice setting (paper or electronic) and widely accessible patient education materials should enable implementation at any primary care practice.

The long-term sustainability of system-wide quality improvement programs is infrequently studied. A systematic literature review published in 2010 identified no studies on the long-term sustainability of such programs.[33] This study provides preliminary insight into the central components of quality improvement initiatives aimed at decreasing antibiotic overuse. Qualitative themes that emerged from the analysis revealed the importance of flexibility in intervention implementation to support sustainability of decreased antibiotic overuse in primary care. Flexible components noted included incorporating information about CDS tools into the provider orientation packets, annual training for providers, and making the tools available at the point of care within the provider's workflow. Other factors were suggested by providers to promote sustainability, such as EHR-based prompting at the point of prescribing, with specific informational/educational aspects and recommendations tailored to the active prescription context (e.g., a prompt that might be triggered in response to the combination of a diagnosis and a non-recommended medication selection). Audit and feedback, not studied as part of this intervention, were also suggested to increase sustained adherence to recommendations. The findings of the present study are supported by the quantitative results yielded in the study by

Jenkins and colleagues,[30] which adopted a flexible implementation approach and demonstrated a positive reduction of antibiotic prescribing for non-pneumonia acute respiratory infections and a reduction in the use of broad-spectrum antibiotics.

Limitations of the present study include the small sample size of providers interviewed and a single, individual interview methodology. Recommendations for further inquiry should include increasing sample size, expanding to include focus groups, and surveying all providers to quantitatively assess factors that support flexible intervention approaches.

Conclusion

The findings of the present study suggest that there is not a one-size-fits-all approach to implementing CDS tools in primary care settings. Key lessons learned include the flexibility to accommodate for:

- Variability in local antimicrobial resistance and formularies to ensure relevance in almost any primary care practice.
- Ability of practices to modify treatment and diagnostic guidelines within reason, based on contextual factors such as whether practices were part of an integrated system of care and their relative access to diagnostic testing equipment.
- Availability and recognition of a local antibiotic stewardship champion to answer questions and inform local decisionmaking.

While electronic implementation is preferred by primary care clinicians, positive outcomes in the reduction of inappropriate use of antibiotics may also be observed with the implementation of CDS guidelines in paper format. CDS tools in primary care settings need to be flexible and respectful of the available resources at the clinic management level.

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Identifying and Aligning Work-System Factors to Mitigate HAIs in Ambulatory Dialysis

Vicki R. Lewis, Lindsey Clark, Raj Ratwani

Abstract

Approximately 5 percent of hospitalized patients suffer a health care-associated infection (HAI), and ambulatory chronic care patients, such as those on hemodialysis for treatment of end-stage renal disease, have seen a 31 percent increase in HAIs. Research in other industries has shown that safe systems are achieved by considering the entire system to enable performance specifications to be met. The sociotechnical systems (STS) model was applied to identify and evaluate factors that lead to HAIs among patients in an ambulatory dialysis unit (ADU). This information was used to recommend and test an intervention for purposively aligning the STS factors to reduce HAIs in an ADU. The framework to apply the STS model was the macroergonomic analysis and design (MEAD) method, an approach used in analyzing complex work systems. The framework is used to understand relationships and interactions within a system that can affect issues such as HAI incidence and intervention efforts. The MEAD method identifies "variances" (nonoptimal situations or misalignments of work-system factors) that occur in the STS domains (external environment, physical environment, technology, people, and organization). Variances within and between domains are then analyzed and appropriate interventions designed. In this paper, we discuss the STS model, the MEAD framework, and the application of the model and framework to identify misaligned work-system factors and the development of an intervention to reduce variances that potentially lead to HAIs in an ADU. In addition, we discuss the challenges encountered and lessons learned in conducting this study.

Introduction

Five percent of hospitalized patients in the United States develop a health care-associated infection (HAI),[1] and ambulatory chronic care patients, such as those on hemodialysis for treatment of end-stage renal disease (ESRD), suffer higher rates. Since 1993 the rate of hospitalizations for ESRD patients due to infection has increased by 31 percent, while all-cause hospitalization rates have decreased.[2]

Identifying the factors that contribute to HAIs is a challenge due to the nature of the health care system. Health care is a complex work system with various interrelated components that interact with one another in a dynamic fashion. Challenges affecting HAI reduction in inpatient settings are exacerbated in outpatient settings because patients are ambulatory and can come into contact with more infection-causing pathogens, both within and outside the care environment.

To analyze and address HAIs within a complex system, it is important to examine the many factors that contribute to HAIs and to implement an inclusive and comprehensive intervention plan. One framework that is particularly well-suited for addressing health care challenges (such as infections) within complex work systems is that of the sociotechnical system (STS) model.[3] STS is an approach to complex organizational work design that recognizes the interaction between people and technology in workplaces. This approach aids in uncovering relationships

and interactions within a system that can affect issues such as HAIs and how interventions work within the system.

Figure 1 illustrates the STS framework as applied to an ambulatory dialysis unit (ADU). In an STS analysis, one must first define the boundaries between the internal environment and the external environment. In the instance of the ADU, the external environment is composed of factors that affect what occurs within the dialysis unit but are outside its control. This includes influences such as policies, legislation and government regulations, equipment suppliers, and the regional demographics of patients. The internal environment is defined as the primary focus of the study and includes four domains:

- **Organizational** factors give insights into the structure of the organization, as well as the mutual relations within the focal unit necessary to accomplish the tasks and achieve the goals of the unit, such as unit policies and procedures, shift schedules, staff-to-patient ratios, work culture, and work values and beliefs.
- **Physical environment** factors include all aspects of the design of the physical space, such as layout and design, chair/bed spacing, air and water quality, work surfaces, resource locations.
- **Technical** factors are the means and methods by which work is performed, such as work processes and procedures, tools, equipment, and software.
- **People** factors are the characteristics and attributes of the individuals who interact with hospital staff, such as clinical staff, environmental services staff, transportation staff, patients, patient family members.

Studying a health care work system from an STS perspective helps to identify the contribution of each of the four domains, both individually and in combination, to unintended outcomes such as HAIs. Solutions can then be developed that address multiple factors within the work system, achieving greater effectiveness and sustainability than solutions that only target one factor. Once the STS model is defined, a method to apply the model is needed that will uncover system relationships in order to develop solutions that address the HAI risk factors present.

The remainder of this paper provides a description of the methods used to apply the STS model—the macroergonomic analysis and design (MEAD) method, as described by Kleiner[3]—in an ambulatory dialysis facility. Several STS models are discussed in the literature (see Carayon[4] for a list of models and the STS components addressed by each). This method was chosen because the STS components described by the MEAD method are applicable to the health care environment and the problem addressed. For example, some models evaluated components such as supply chains or spatial interactions that were not the central focus of this study. There was the added benefit of having one of the MEAD method's authors to advise us in the application of the process. The MEAD method was utilized to identify misaligned work-system factors and to develop an intervention to realign those factors and effectively reduce variance. Kleiner defines a variance as something that significantly affects performance criteria.[3] In this case, a variance may be thought of as any situation that may lead to HAIs in an ADU.

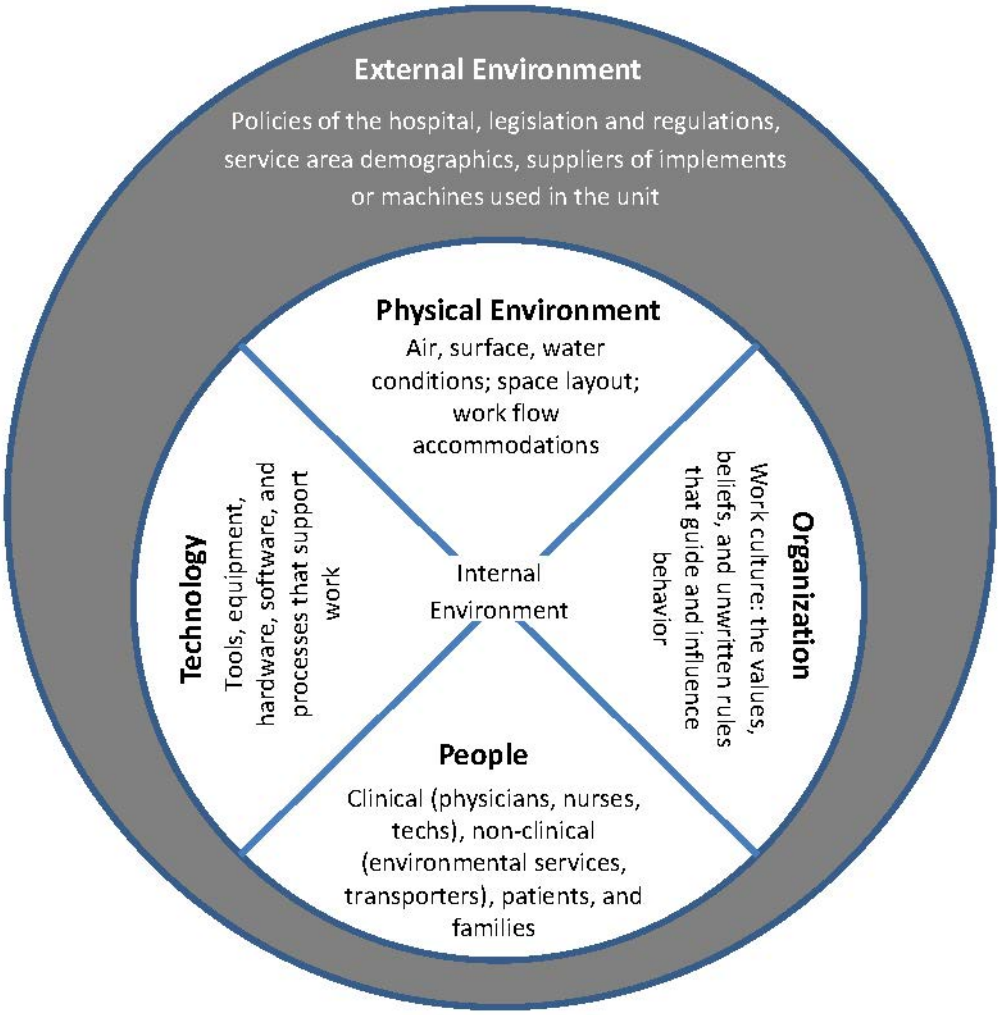

Figure 1. Health care as a sociotechnical system (adapted from Kleiner[3])

The MEAD method was applied to an ambulatory dialysis facility that is the largest not-for-profit dialysis center in the greater Baltimore/Washington, DC region. It is equipped with 54 dialysis stations across three rooms that serve approximately 280 patients and provide more than 3,600 dialysis sessions per month. A discussion of the challenges encountered over the course of this study and lessons learned will also be presented.

Methods

Macroergonomic Analysis and Design (MEAD) Method

The MEAD method facilitates the analysis and organization of data by identifying variances (nonoptimal situations) within STS domains and misalignments between STS domains. MEAD consists of 10 major analyses (Table 1). Phases I through IV are the STS domain initial analyses. Phases V through VIII use the data from the initial domain analyses to determine variances and

Table 1. Sociotechnical systems analysis methods

Phase	Step	Phase	Step
I. Environmental and Organizational Design Subsystems: Initial Scanning	1. Perform Mission, Vision, Principles Analysis 2. Perform System Scan 3. Perform Environmental Scan 4. Specify Initial Organizational Design Dimensions	VI. Personnel Subsystem Analysis: Construct Key Variance Control Table and Role Network	1. Construct Key Variance Control Table 2. Construct Role Network 3. Evaluate Effectiveness 4. Specify Organizational Design Dimensions
II. Technical Subsystem Analysis: Define Production System Type and Performance Expectations	1. Define Production System Type 2. Define Performance Expectations (Performance Criteria) 3. Specify Organizational Design Dimensions 4. Define Function Allocation Requirements	VII. Function Allocation and Joint Design	1. Perform Function Allocation 2. Design Changes to the Technological Subsystem 3. Design Changes to the Personnel Subsystem 4. Prescribe Final Organizational Design
III. Flowchart the Technical Work Process and Identify Unit Operations	1. Identify Unit Operations 2. Flowchart the Process	VIII. Role and Responsibilities Perceptions	1. Evaluate Role and Responsibility Perceptions 2. Provide Training Support
IV. Collect Variance Data	1. Collect Variance Data 2. Differentiate Between Input and Throughput Variances	IX. Design/ Redesign Support Subsystems and Interfaces	1. Design/Redesign Support Subsystems 2. Design/Redesign Interfaces and Functions 3. Design/Redesign the Internal Physical Environment
V. Construct Variance Matrix	1. Identify Relationships Among Variances 2. Identify Key Variances	X. Implement and Improve	1. Implement 2. Perform Evaluations 3. Iterate

methodically identify misalignments in work-system factors. Phases IX and X support the development of the intervention and implementation and illustrate the iterative process to optimize the implementation. A more elaborate description of the goals of each phase may be found in Kleiner.[3,5]

Application of the MEAD Method

Literature Review

In preparation for conducting the MEAD analyses, HAI risk factors were defined to aid in the design of data collection and analysis. A comprehensive literature review was conducted to identify the HAI risk factors that exist within each of the four internal STS domains. In addition, a menu was developed of current interventions related to organizational, technological, people, and environmental aspects to reduce HAIs.[6,7] This process revealed that HAI risk factors and potential interventions are rarely examined across STS domains. For example, articles addressing poor hand hygiene often identified the people domain as the contributing factor to this problem

and suggested interventions that only targeted this factor (e.g., provide reminders to staff to wash their hands). Organizational, technical, and physical environment factors (e.g., availability and location of sinks or other hand washing stations and their relationship to workflow) were typically not addressed in the same article, demonstrating that current interventions may not be sufficient for addressing HAIs in an ADU.

Of the 213 HAI intervention studies reviewed, only one paper addressed all four of the STS factors. In this study, Pronovost and colleagues demonstrated an intervention that reduced catheter-related bloodstream infections to zero at 3 months after implementation and sustained significantly low rates for 16 to 18 months after implementation.[8] Pronovost's team did not use the same STS framework used in this study; however, critical components of that intervention were to "summarize and simplify what to do; measure and provide feedback on outcomes; and improve culture by building expectations of performance standards into work processes," as described by Bosk et al.[9] Closer inspection of the Pronovost et al. study revealed that the authors examined the culture of the organization; they noted needed improvements, involved leadership, took efforts to understand the personnel, redesigned work processes taking the environment into consideration, and acknowledged external environmental pressures, which is similar to using an STS framework. This demonstrates that effectiveness and sustainability of HAI interventions can be achieved when all work-system factors are analyzed.

The literature review determined that the risk factors and potential interventions encompassing all STS domains have scarcely been examined. Therefore, the literature alone could not be used to recommend complete interventions because each study focused on only one STS domain, in one particular type of health care environment. Overall qualities, such as cleanliness of surfaces and tools, proper hand hygiene, and clean air and water are essential across health care environments. However, interventions that work in an ICU may not be applicable within a hemodialysis unit because the acuity of the patients differs, the environment in which the care is provided differs, and the equipment differs. The literature review supported the strategy that designing a successful intervention would require an analysis of each of the STS domains in a health care work system. From this perspective, the team developed a data collection strategy.

Development of Data Collection Methods

Whereas the MEAD method defines the steps for information that should be gathered and for the analysis, it does not specify the methods for data collection. After advice and input were obtained from a Technical Expert Panel representing experts in nephrology, infection prevention and control, nursing, and human factors engineering, the data collection methods were determined. Table 2 shows how each method contributed to a specific domain analysis.

Table 2. Data collection methods for STS domain analysis

Domain Definition and Analysis	Data Collection Methods
External Environment	Document and policy reviews (such as corporate documents, hospital policies, Federal regulatory documents and policies) and open-ended interviews (State regulatory personnel)
Physical Environment and Organization	Open-ended interviews with upper-level management and hospital administration (such as the vice president for medical affairs, chair of nephrology, renal nurse managers, environmental services management)
	Organizational document review of documents pertaining to nursing work structure, patient satisfaction, and overall facility status (such as the facility nursing organizational chart, 2011 dialysis facility report, and recent satisfaction surveys)
	Surface contamination and air quality assessment
Technical and Personnel	Focus groups with frontline dialysis staff and ESRD patients
	Patient chart review to analyze patient population in terms of comorbidities, living situations, vascular access, and recent hospitalizations
	HAI surveillance data collection to understand the most prevalent infections in the unit, identify seasonal trends vs. unexpected peaks
	Work processes observation, including initiating patient treatment, ending patient treatment, monitoring patients, shift-change work process, and cleaning processes.

The external environment (factors outside the ADU's control that affect the ADU work environment) was determined to include the following: external institutions and organizations (e.g., the Maryland Kidney Commission, Centers for Medicare & Medicaid Services), national guidelines and recommendations, patient lifestyle, and patient vascular access determination. Within the organization domain, the main components were identified as the ADU's mission, vision, and values; financial health; unit capacity; policies and procedures; renal team management and structure; environmental services management and structure; quality assurance management and structure; and patient education policies. The physical environment was analyzed in terms of physical layout/design, air quality, water quality, and equipment and resource location. The technical domain was analyzed in terms of work processes and procedures, tools, equipment, and software. The people domain was determined to include clinical staff, environmental services staff, transportation staff, patients, and patient family members.

Results

Discovered Variances

Following data collection across the STS domains, the data were analyzed for emerging themes related to HAI risk factors to determine variances within each domain. Fifty-seven variances were identified across the external and internal environment through the MEAD analysis. Table 3 provides the total number of variances identified for each domain and examples of variances found within each domain. The variances within the people domain represent a large proportion

of the total number of variances identified. Several of the variances overlap with variances from different internal domains, which illustrates the interconnected nature of the STS domains and the importance of considering variance within a holistic context. For example, the physical environment variance that "the physical layout of the oldest treatment area contains barriers that are difficult to work around and creates inefficient workflow patterns" may also be viewed as an organizational domain resource constraint that sufficient resources cannot be procured to remodel and/or add additional facilities. Nonetheless, the critical task is to utilize the MEAD method to thoroughly identify the variances so that variance solutions may be determined by considering options across all of the STS domains. In this case, the layout of the unit was a physical domain variance, and the organizational resources were viewed as a restraint to be considered when developing interventions.

Identification of Work-System Misalignments

The MEAD analyses conducted for Phases V through VIII allowed the team to construct the variance matrix for the ADU (Phase V) and determine where realignments needed to occur. The variances are not weighted, in an effort to identify those that may contribute more heavily to the identified problem, in this case the occurrence of HAIs in an ADU. Instead, each variance is analyzed in terms of its relationship to other variances so that "key" variances can be identified. Key variances are those that have numerous relationships with other variances[3] and are important because they significantly affect performance criteria. In addition, each of the 57 variances was categorized across six HAI risk factors identified in the literature: surface contamination, workflow/work stress, hemodialysis patient-specific risks, feedback, patient education, and standards of care. This process allowed us to decide where to focus our efforts and to determine the scope of the intervention. Table 4 provides an example of the results of this process for surface contamination.

Determining the Intervention

The analysis described in the previous phases informed Phases IX and X. This led to the development of an intervention change package, the AHRQ Systematic Approach for Eliminating Risks (SAFER) Initiative**.** The components of the change package were selected by the ADU management and research team to meet practical criteria—such as personnel, resources, timelines and criteria, and access—that emerged during the MEAD analyses. The ADU management and research team determined that the intervention components must meet the following criteria:

- Linked directly to the risk factors and variances identified.
- Approved by dialysis facility management prior to implementation.
- Achievable and able to be implemented in a reasonable timeframe.
- Sustainable with available facility resources and not reliant upon research funds to maintain.
- Selected to create efficiencies where possible.
- Addressable to the HAIs that are most prevalent in the ADU: vascular access-related bloodstream infections, vascular access site infections, and wound infections.

Table 3. Example variances identified from MEAD analysis

STS Domain (Total Number of Variances)	**Examples of Variances Identified**
External Environment (5)	Complex national guidelines and regulations do not provide instructions and best practices for implementing the suggested recommendations. To meet national guidelines, facilities must independently interpret the recommendations and devise plans for implementation.
	Patients rely on a variety of transportation methods to travel to and from the dialysis unit (family member, nonfamily volunteer, public transportation, private facility transportation such as from a nursing home). Transportation schedules may result in a patient needing to start or end dialysis treatments at different times to meet transportation needs.
	Fistulas and grafts are the preferred vascular access devices for dialysis treatment because they are safer than catheters and have a lower risk for infection.* Multiple external factors contribute to the vascular access device used by a patient, including insurance policies and various pre-existing and incompatible medical conditions.
Organizational (10)	Three patients are scheduled to be put onto dialysis within a 30-minute window for each dialysis shift, yet care providers have a 5-hour treatment shift that allows for more flexibility in putting patients onto dialysis.
	Environmental services (ES) staff members are not an integrated part of the renal team. These staff members serve the entire hospital, with one ES staff member dedicated to each of the three dialysis units. This can contribute to shift delays and disjointed communication between ES and dialysis staff.
	Consolidating quality assurance data is time consuming and difficult. To create a comprehensive report of the data, quality assurance managers must merge information from three separate sources: hospital reports, antibiotic lists, and laboratory reports.
Physical Environment (6)	The physical layout of the oldest treatment area contains barriers that are difficult to work around and create inefficient workflow patterns.
	Patients gain access to treatment areas before their scheduled time or before the staff is ready to receive them. This contributes to a stressful and rushed environment.
	Supplies and equipment are not located in easily accessible areas, and procedures may require staff to make multiple trips to different locations to obtain the needed supplies to put a patient on dialysis.
Technical (8)	Unexpected events while a patient is put onto and taken off of dialysis disrupt the process workflow.
	Work processes do not support early patient wound detection.
	Because of responsibility to other units, it is difficult for ES staff to adapt to unanticipated schedule changes, which may happen for a host of reasons.
People (28)	There is a lack of communication between ES and dialysis unit staff during shift change.
	Staff feels rushed during dialysis put-on, which leads to inconsistent practices.
	Patients are not always aware they have a wound.

*See Centers for Disease Control and Prevention; 2001; www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm

Table 4. Surface contamination-related variances

STS Domain					
Organizational	**Technical**	**People**		**Physical Environment**	**External Environment**
		Staff	**Patient**		
Environmental Services (ES) is not part of the renal team	Availability of ES staff at shift change	Lack of communication between ES and dialysis staff during shift change		Bacteria counts on high-touch surfaces are very high	Patients may introduce contaminants from outside
Inadequate ES staffing for the size of the unit and tasks involved	Availability of ES staff to handle odd start/stop time patients	Knowledge of ES staff regarding types of infections in the unit			

One may note that the criteria do not address the inclusion of only interventions supported by an evidence base; however, evidence-based recommendations and guidelines, such as those issued by the Centers for Disease Control and Prevention (CDC)[10] and the Association for Professionals in Infection Control and Epidemiology (APIC),[11] were considered when selecting components for the change package. For example, the use of an antibiotic ointment for catheter patients was included based on CDC's recommendation; however, the staff's suggestion to have rolling carts for supplies was not included, in order to adhere to APIC guidelines. Nonetheless, while there is a body of evidence that supports interventions to reduce HAI rates in inpatient settings, the evidence base supporting interventions to reduce HAI rates in ambulatory settings is scant.

The reason for the lack of evidence in ambulatory settings is partially driven by the fact that numerous variables influence HAI rates, and these variables are extremely difficult to control in outpatient settings. For this reason, the lack of an evidence base to support interventions in ambulatory settings was not applied as a strict criterion for inclusion in the change package; however, the evidence base was considered to the extent that information was available. Furthermore, the relationship between HAIs and suspected risk factors does not always have an undisputed evidence base. For example, while there is sufficient knowledge regarding the means of transmission of bacteria and correlations between surface contamination and HAI rates, there is not yet clear evidence that reducing surface contamination reduces HAIs in an ADU. Finally, there is not an evidence-based intervention for every variance noted in the ADU. For example, while workflow and work stress were noted as correlated contributors to HAIs in some health care settings, there were no interventions in the literature that specifically addressed this ADU's particular stressors. Therefore, we felt it was appropriate to expand possible interventions to those that addressed the variances and met the other criteria.

Two risk factors were not addressed because the intervention components would not meet these criteria: patient education and standard of care. There was a lack of time and financial resources to provide additional education and training resources to the ADU's highly variable patient population. The recommended intervention components targeting the remaining four risk factors developed by the research team in collaboration with the renal team are discussed below. Table 5 lists the risk factors and recommended interventions.

Table 5. Identified risk factors and recommended intervention components of the SAFER initiative change package (pilot intervention)

Risk Factor	Recommended Intervention
Surface Contamination	Provide dedicated environmental services (ES) resources to the ADU
	Improve communication between dialysis staff and ES staff
	Add antimicrobial materials to high-touch areas
Workflow/ Work Stress	Install transparent privacy film on window between main treatment area and waiting room
	Keep patients out of units until scheduled
Hemodialysis Patient-Specific Risk Factors	Perform foot exams for at-risk patients
	Use antiseptic wipes to clean the patient's arm prior to dialysis put-on
	Use antibiotic ointment at the vascular access exit site for catheter patients
Feedback	Optimize HAI surveillance system for quality assessment
	Post monthly HAI rates in waiting rooms and staff areas

Discussion and Lessons Learned

The MEAD method provides a structured and comprehensive approach to uncover and untangle the HAI risk factors in a busy ADU. The MEAD method offers a number of advantages over previous research efforts. One advantage of the step-by-step, 10-stage process is that it is adaptable to a variety of settings. In addition, since each specific health care setting will have different internal and external environments, the STS perspective allows the mapping of information garnered using the MEAD method to a solid foundation for developing effective and sustainable intervention packages.

There were several lessons learned in the application of the MEAD method that may be noted for future use, including issues related to literature reviews, time and resources needed, the role of the environment (in this case, ambulatory units), and the importance of interpersonal relationships. Each of these areas will be discussed in further detail below.

The importance of the literature review was a key lesson learned that provided the basis of the research team's understanding of the risk factors for HAIs. To prepare for and design data collection and analysis, the time and effort spent preparing a comprehensive literature review was invaluable. Systematically reviewing previous research on this topic allowed the research team to define risk factors for HAIs, which provided the basis for the MEAD analysis.

The immense time and resource commitment that is involved in collecting and analyzing data in the very complex environment of a large ADU was another lesson learned. Once the range of risk factors present in the unit was uncovered and the types of interventions evaluated, it was determined that the list of data collection methods needed to systematically study each STS domain would be more extensive than originally anticipated. However, while conducting analyses of the STS domains and developing interventions to address those domains may be more resource-intensive than many methods that have been used to mitigate HAIs in the past, the advantage of the STS framework is that the application of its methods identifies all of the STS domain factors for which variances, or nonoptimal situations, exist. The necessary alignments for a successful intervention begin to surface, indicating that a set of robust intervention components is necessary to align work-system factors across domains for maximum effectiveness. Considering the great success demonstrated in the work by Pronovost et al., which incorporated

an HAI intervention comprising all of the STS subcomponents,[8] and the high risk and cost of HAIs to society, the rationale for using a comprehensive STS research approach is clear.

Engaging in research in an ambulatory care environment provided another lesson learned, since reducing HAIs in this environment appears to be exponentially more complicated than it would be in an inpatient environment. However, with health care delivery shifting away from inpatient hospital settings and toward a variety of ambulatory and community-based settings, understanding and identifying the challenges to reducing HAIs in ambulatory care is of paramount importance. Vulnerable patient populations rely on frequent and intensive use of ambulatory care to maintain or improve their health. For example, each year more than one million cancer patients receive outpatient chemotherapy, radiation therapy, or both.[12] It is critical that all of this care be provided under conditions that minimize or eliminate the risks of HAIs.[13]

Many aspects of an ambulatory health care environment are difficult to control, and whether an infection is truly health care-associated, simply community-acquired, or patient-driven can be very difficult to define. While an intensive care patient is passive to his or her care, an ambulatory patient potentially can play a vital role in that care. And while the environment of an intensive care unit provides opportunity for control, an ambulatory environment introduces challenges such as patient transportation issues, patient support needs, and seasonal variation in HAI rates that direct how data must be collected and analyzed. Although this may make an HAI rate of "zero" seem daunting, systems models such as STS and methods such as MEAD begin to untangle the complex system components that support and drive tangible solutions.

A final note is that we have maintained the importance of ADU management and staff ownership of the project from its initiation. For example, we regularly share information about the project with ADU management and staff, except for confidential data and materials. While we suggested an initial set of interventions in the context of the variances that were uncovered, these were provided as suggestions. If a member of the ADU leadership did not agree with a recommended intervention, we listened to the ADU leadership reasoning and asked for a suggested alternative that would address the same variance or set of variances. We believe this method yielded a superior intervention change package that, more importantly, had the buy-in of management and staff and was thought to have a higher likelihood of sustainability after completion of data collection for the main intervention.

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Strategies to Reduce Potentially Inappropriate Antibiotic Prescribing in Assisted Living and Nursing Homes

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Abstract

This paper describes and examines the implementation of a quality improvement (QI) program to reduce potentially inappropriate antibiotic prescribing in residential care/assisted living (RC/AL) and nursing homes (NHs) in the context of organizational performance. A QI program that included evidence-based medical provider training related to prescribing, use of a standardized form to communicate signs and symptoms of infection, resident and family education, and ongoing monitoring and feedback and monthly QI meetings was implemented in four RC/AL settings and six NHs in North Carolina. Program fidelity was assessed during monthly team meetings and by medical record review, and facilitators and barriers to implementation were identified by interviews with medical providers and staff. Results were considered in light of both setting types operating as complex adaptive systems. It was challenging to train the numerous medical providers in RC/AL settings, but it was markedly easier to train the NH providers, who championed the QI program. On the other hand, evidence of change in staff practices was more evident in RC/AL, but staff in both settings were receptive to learning the signs and symptoms of infection that need to be communicated to better inform antibiotic prescribing. Change in antibiotic prescribing in RC/AL and NHs can be achieved through better informed and increased communication between long-term care staff and medical providers. By implementing the same QI program in both RC/AL and NH settings, the centrality of the role of the health care supervisor in RC/AL and the need for medical provider endorsement in NHs became clear. Consequently, efforts to change prescribing behavior must be tailored according to the setting.

Introduction

Over 2 million Americans live in long-term care settings, including residential care/assisted living (RC/AL) and nursing homes (NHs).[1,2] Residents in these settings are at greater risk than others of developing infections, due to their age and disability, but the overuse and sometimes inappropriate use of antimicrobials to treat suspected infections has led to the development of resistant organisms, thereby complicating treatment.[3–6] Attesting to the magnitude of the challenge resulting from antibiotic resistance, the World Health Organization calls it one of the three greatest threats to human health and, along with the Centers for Disease Control and Prevention, has issued recommendations targeted to long-term care and other high-risk populations.[7,8]

Numerous strategies have been implemented to address the problem of overprescribing in NHs, including establishing prescribing guidelines,[9] studying the prevalence and incidence of antibiotic use, and designing interventions to improve prescribing. These interventions range from monitoring to complex protocols that provide didactic sessions and performance feedback.

Their goal has been either to reduce a specific type of infection or to increase the appropriateness of the choice of antibiotic; unfortunately, all have had limited success, in part due to insufficient adoption and sustainability.[10–15]

The extent to which change is successfully adopted and sustained in health care organizations depends on a host of considerations, which are reflected in the theory of complex adaptive systems.[16–20] Complex adaptive systems are characterized by diverse, interrelated yet independent stakeholders whose interactions are complex, varied, and unpredictable. Modifications in the system are nonlinear and emerge from learning, adaptation, and self-reorganization.[16,19,20] Based on this framework, interventions to increase appropriate antibiotic prescribing should identify all stakeholders and their interconnections, understand existing practices, maximize communication and collaboration, use influence rather than power, and establish a method for ongoing self-monitoring as the system learns, adapts, and changes over time.[16,19–24] Flexibility in implementation is to be expected as the system evolves, but the intent is to maintain the integrity of the intervention.[21,22]

Based on our understanding of health care organizations as complex adaptive systems, we worked with four RC/AL communities and six NHs in North Carolina to implement a multicomponent quality improvement (QI) program to reduce potentially inappropriate antibiotic prescribing. The effort was grounded in a conceptual model that views the prescribing decision as a result of the interplay between the patient and his/her clinical condition; patient and family knowledge, attitudes, and beliefs regarding the illness and treatment; the structures and care processes in the setting, as well as staff knowledge, attitudes, and beliefs related to the illness and treatment; and the provider, including the characteristics of the medical practice.

In this paper, we describe the adoption and sustainability of that program in the context of organizational behaviors and health care as a complex adaptive system. While the sample was small and the region local, the results have implications for the dissemination of this and similar QI interventions in other RC/AL communities and NHs.

Methods

Based on the conceptual model (Figure 1), the program to reduce potentially inappropriate antibiotic prescribing included four key components: (1) evidence-based training geared to medical providers who prescribe medications for RC/AL or NH residents; (2) use of a standardized communication form for long-term care staff to convey relevant signs and symptoms to inform prescribing; (3) a brochure for residents, their families, and direct care staff to explain the risks associated with the overuse of antibiotics and situations in which antibiotics are not indicated; and (4) ongoing monitoring and feedback in the context of a QI program. In addition, in-service training was provided to all staff so that they were aware of the QI program and sensitized to the importance of antibiotic overuse and resistance.

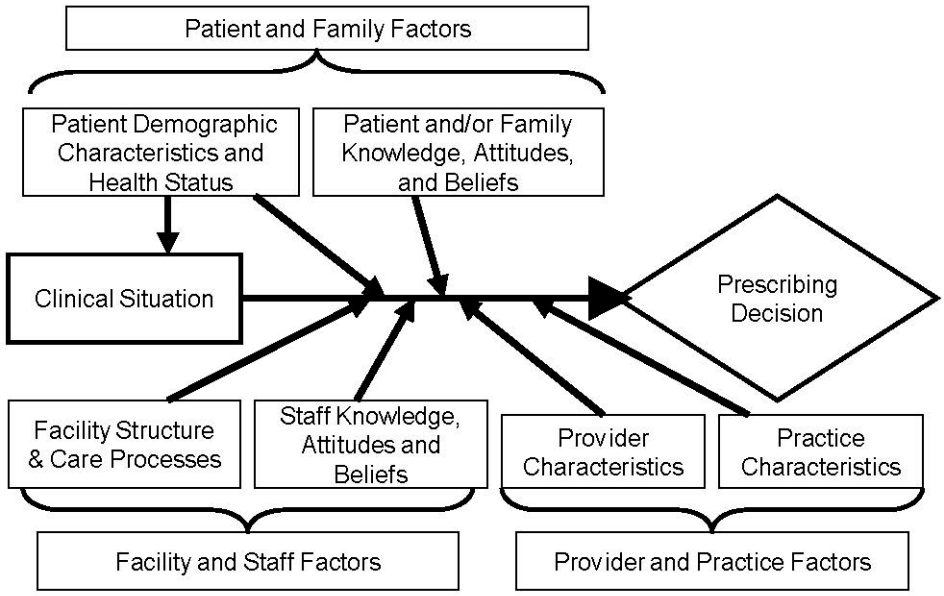

Figure 1. Conceptual model related to prescribing decisions in residential care/assisted living and nursing homes

The project was first initiated in four RC/AL settings and 3 months later in six NHs; in addition, six NHs served as control sites. In the intervention NHs, one provider practice (a group of providers who work together under the auspices of the same corporate entity) served the majority of residents, and the medical directors chose to participate to better inform and reduce their practice's potentially inappropriate prescribing. All settings were located in North Carolina and enrolled in the Collaborative Studies of Long-Term Care. Approval for this work was received from the institutional review boards of the University of North Carolina and Abt Associates Inc., and from the Office of Management and Budget.

Evidence-Based Medical Provider (Prescriber) Training

The content of the prescriber training was based on a comprehensive literature review[5] and consultation with an expert medical panel; in addition, it included baseline data regarding prescribing rates and the extent to which prescribing practices met the Loeb prescribing guidelines.[9] Training began with an overview of the problem of antibiotic resistance and inappropriate prescribing, followed by case-based training on prescribing for urinary, respiratory, and skin infections, as well as situations where antibiotics are often inappropriately prescribed. Guidelines were then presented for selecting an antibiotic. The training was packaged as a five-module, Internet-based program to facilitate later dissemination and adoption. Also, a laminated pocket card was developed that summarized 12 common situations in which systemic antibiotics are generally not indicated. Completion of the five modules took approximately 90 minutes, and trainees involved in the project (individuals who prescribed antibiotics in the study sites) received 10 hours of continuing education credit.

Use of a Standardized Communication Form

Medical provider training addressed the signs and symptoms to be considered according to antibiotic prescribing guidelines. The research team developed a standardized communication form based on these signs and symptoms for completion by long-term care staff to ensure that the provider was informed about the resident's condition. This Medical Care Referral Form (MCRF) was shared in draft form with staff in each setting and modified to meet their needs (e.g., an area was included for providers to record orders). The form also included an area for open-ended text to describe the problem and areas to record vital signs and (if appropriate) information related to a fall, the resident's general health status, and relevant medical history. Some of this information (e.g., related to a fall) was included to increase the suitability of the form for all medical encounters. The form was intended to be used in all instances when contact was made with a medical care provider for anything other than routine care or a followup visit. A 45-minute training session was held with the staff responsible for completing the form, which covered problems of antibiotic overuse and associated risks, use of the MCRF, case studies, and information indicating the extent to which previous prescribing met guidelines.

Resident and Family Education

Recognizing that many lay people consider antibiotics to be the first line of treatment, the research team developed a pamphlet that illustrated common side effects of antibiotics and explained situations where antibiotics are not needed, why a doctor might prescribe an antibiotic when it was not needed, what the patient/family can do to promote better prescribing and recovery, and what the patient/family should not do (e.g., demand an antibiotic). This pamphlet was intended for distribution to all current residents, to new residents at the time of admission, and when hospice was being considered.

Ongoing Monitoring and Feedback and Monthly QI Meetings

A QI team and team leader were identified in each setting, with the intent that this team meet at least monthly. Members of the research team participated in QI meetings, during which they provided updated information about prescribing and the extent to which reported signs and symptoms were meeting guidelines. Team members also discussed the process of prescribing and use of the MCRF and helped to solve problems. Additional QI efforts included in-service education for all staff and training for new staff; distribution of five "practice briefs" related to antibiotic prescribing to all providers and involved long-term care staff; periodic ongoing contact with providers and staff; and education for residents and their families.

Results

Results related to the four methods of the antibiotic prescribing program are summarized separately for RC/AL settings and NHs in Table 1 and described in more detail below.

Table 1. Implementation of the four components of the antibiotic prescribing program, by setting type

Component	Residential Care/Assisted Living (N=4)	Nursing Homes (N=6)
Provider training	Attempted to train 243 providers; 7% completed the training	Attempted to train 9 providers; 7 (78%) completed the training
Standardized form (MCRF) used by long-term care staff	In final month of implementation, presumed infection was documented on the form 25% of the time antibiotics were prescribed*	Overall, the form was used in less than 2% of presumed infections
Brochure for residents, families, and others	Positively received by long-term staff; anecdotal report of use	Positively received by long-term staff and providers; anecdotal report of use
QI program	Barriers to implementation included staff turnover; limited number of supervisory staff; limited number of staff using MCRF; lack of physician involvement; and medical care provision off-site	Barriers to implementation included policy and practices (especially related to the use of the MCRF); resident or family concerns; and staff turnover and resistance to change

MCRF = Medical Care Referral Form; QI = quality improvement

*It is not certain that the form was used for the same prescribing event. A total of 39 antibiotics were prescribed, and 10 forms documented presumed infection; however, some of these forms may not have resulted in an antibiotic prescription.

Evidence-Based Medical Provider (Prescriber) Training

In the four RC/AL settings, 243 medical providers were identified as those who served as the residents' primary care providers or prescribed them medications (e.g., emergency department physicians). All received a letter informing them of the QI project, stressing the important issue of antibiotic resistance, and providing information about and a link to the Web-based training. Due to low uptake (only 11 providers accessed the Web site), the five providers in each RC/AL community who had prescribed the most antibiotics at baseline were offered an honorarium of $250 if they completed the five training modules. In total, 20 individuals (8 percent) began the training, and 16 (7 percent) completed it.

As the time approached to train the NH medical providers, the research team decided to conduct their training on-site, face-to-face, in a 4-hour session. All seven providers in the engaged medical practice attended the training, although two additional providers who treated residents in those NHs did not.

Use of a Standardized Communication Form

Nurses are not uniformly employed in RC/AL settings,[25] and in only one of the four RC/AL sites was completion of the MCRF the responsibility of a nurse; elsewhere, this task was assigned to individuals such as medication aides. Over time, use of the form became common but not always when an antibiotic was prescribed. For example, in the last month of the study, 39 prescriptions for antibiotics were written across the four settings, and the form was completed 40 times; however, only 10 forms (25 percent) indicated the presence of a possible infection, and the majority of the forms (73 percent) were not fully completed. Medical providers wrote a response (e.g., a medical order) on 34 (85 percent) of the forms. Staff in all four settings indicated that the specificity of this form provided them direction and was a great improvement over the one

previously in use, which was essentially an open-ended field in which the staff described the presenting problem.

In the NHs, the staff quickly noted that the form was burdensome and unnecessary for many of their contacts with providers. Here, higher resident acuity translated to more medical encounters, many of which were related to chronic care. Further, the nursing staff were better able to discern the reason for contact than were the RC/AL staff; they were in more frequent contact with the providers, and they regularly documented changes in resident condition in the nursing chart. Consequently, the staff and providers asked that use of the form be limited to times when a resident had a new condition and an infection was suspected. Even with that change, the MCRF was rarely completed (e.g., it was completed for fewer than 2 percent of infections that were treated with an antibiotic). However, nursing staff reported that the form served as a means to sensitize them to the information they needed to compile when communicating with a medical provider.

Resident and Family Education

As planned, a supply of brochures was given to staff in all RC/AL and NH settings; however, other than anecdotal reports, there was no indication that the brochures were distributed. Further, in one RC/AL setting, rather than distributing the brochures, the staff left the brochures on a table. In the NHs, on the other hand, the medical care providers themselves requested that they be given a supply of brochures, so they could distribute them when indicated. Other activities directed toward residents, families, and staff were carried out in the NHs (but not in the RC/AL settings) at the research team's invitation and the administration's request, including presentations made at family night (three occurrences), at a resident council (one occurrence), and at a community health fair (one occurrence).

Ongoing Monitoring and Feedback and Monthly QI Meetings

QI team meetings were held monthly in the RC/AL settings to discuss implementation, barriers, and facilitators. Members of the team primarily included the health care coordinator, medication aides, and the administrator. These meetings were scheduled and attended by the research staff and endorsed by the RC/AL leadership program; however, it is unlikely that the meetings would have occurred absent the research team's initiative. Similarly, because it quickly became evident that the program required active involvement by the research team, a research liaison visited each RC/AL setting on a weekly basis to promote use of the MCRF, answer questions, and address concerns.

Barriers to program adoption identified by RC/AL staff included staff turnover; the limited number of supervisory staff available to train new staff; the limited number of staff qualified/allowed to use the MCRF (because most staff lacked medical training); the lack of physician involvement in the program; and the fact that medical care was typically provided off-site. Overall, program implementation was limited to the time that the health care coordinator was on site.

The QI meetings were also convened monthly in the NHs and attended by research staff. Participants included the director of nursing, the infection control nurse, the staff development coordinator, and often the administrator. During these meetings, clinical and infection control questions were raised and referred to the research team's infectious disease expert or the research

clinicians in attendance. Identified challenges to implementation included NH policy and practices (especially related to the use of the MCRF), resident or family concerns, and staff turnover and resistance to change. Most often, the QI teams reported that the customary practice of reporting orally to on-site providers, or by telephone to off-site providers, was an impediment to the written use of the MCRF. Further, documentation policies often required duplicate recording of the signs and symptoms when staff used the MCRF, a disincentive to its use. However, in every NH, the form was considered to be a helpful informational tool by providing the specific signs and symptoms that are important to report to providers. The QI teams also reported that the informational brochure was helpful to review with residents and families when questions or concerns about the use of antibiotics arose. Further, every team endorsed the goals of the program, the content of the training and educational materials, and the inclusion of multiple stakeholders in the program (i.e., providers, staff, and residents/families).

Change in Antibiotic Prescribing

Despite the limited provider training achieved in RC/AL settings and little use of the MCRF in NHs, both settings evidenced change in antibiotic prescribing. In RC/AL settings, a non-significant decreased trend in potentially inappropriate prescribing was observed and described in a forthcoming paper;[26] and in NHs, a significant reduction in antibiotic prescribing was achieved. These results will be described in forthcoming papers.

Discussion

When conceiving this project to reduce antibiotic use in different settings, we assumed that implementation would be both more and less challenging in RC/AL settings compared to NHs. We assumed it would be more problematic to reach RC/AL providers due to their sheer number and the many practices in which they worked. On the other hand, we assumed it would be easier to effect change in staff practices—most notably through use of the MCRF—because the system is less stringently regulated. Both of these assumptions were borne out, yet change in prescribing practices was achieved, suggesting that RC/AL staff can be active change agents in regard to antibiotic prescribing. In the NHs, however, it was markedly easier to reach the providers but more challenging to change documentation practices. While there was anecdotal evidence that NH staff communication changed, we believe the more certain and likely change agents were the providers themselves because they asked to be involved in the project to better inform their prescribing. In both settings, there was no evidence that residents and families effected change, but that cannot be ruled out.

These findings are consistent with the fact that there is no single point of control in a complex adaptive system.[16] The fact that health care supervisors can influence medical care in RC/AL settings (surmised based on the decreased trend in potentially inappropriate prescribing despite little provider training) is an important finding, especially considering physicians' concerns about the skills of RC/AL staff. In other studies, physicians reported less confidence in the abilities of RC/AL staff compared to those in NHs but indicated that informed communication improved their confidence.[27] At the same time, RC/AL health care supervisors considered clinical care coordination and communication to be an important component of their role,[28] which is consistent with their receptivity to the MCRF. Training RC/AL staff to better communicate with medical providers, as was done with the MCRF, may well be the most

effective way to improve medical care in these settings; further, it may ultimately improve the satisfaction of all stakeholders.[29]

Despite the fact that medical providers are more often on site in NHs (e.g., all NHs have medical directors), it should not be assumed that they are more involved in resident care than are RC/AL primary care providers. In fact, NH physicians have been charged with being "missing in action."[30] Rather, as noted above, we believe the success of the project can be attributed to the buy-in of the involved provider group, rather than their presence in the NH per se. Influential leadership, such as that shown through the NH medical directors' commitment to the goals of the QI program, is more likely to achieve desired outcomes than directives from top management.[16] In terms of training medical providers, the effective 4-hour classroom format could easily be replicated at national meetings, such as the annual meeting of the American Medical Directors Association.

Although fidelity in program implementation is necessary, systems-level interventions require flexibility to accommodate variation across settings.[19,21,23] In this project, the MCRF was modified according to staff request, while still maintaining the integrity of the signs and symptoms related to infections. In future work, completion of the form may be advocated in RC/AL settings, whereas it may best be used as a training and reference tool in NHs; indeed, the nurses clearly indicated that this additional paperwork was burdensome, a lesson important for other QI efforts. Doing so would be similar to how NH staff used the laminated pocket card, which was well received (staff asked for additional copies). In fact, had the project continued longer, the protocol for use of the MCRF would have been changed in this very manner, consistent with current wisdom that adhering to fixed interventions may be short-sighted.[31] It should be noted, though, that while the MCRF was not completed on a consistent basis, review and discussion of the form during QI meetings promoted dialogue about the importance of identifying and managing infections and communicating with providers. Research on intervention implementation highlights the importance of conversation for "sensemaking" and learning, when members of an organization discuss practice change, analyze the process, and strategize how to adapt to modify their practices.[22]

We framed our discussion based on the theory of complex adaptive systems because this theory describes the functioning of both NHs and RC/AL settings. In so doing, it is the only literature of which we are aware that recognizes RC/AL akin to other health care organizations in this regard. While the methods described here are consistent with other systems-level approaches as well and do not fully address all components of the theory, understanding both of these settings as complex adaptive systems provides several important observations and guidance for other QI efforts.

Conclusion

Change in antibiotic prescribing in RC/AL and NH settings may be achieved through better informed and increased communication between long-term care staff and medical providers. However, communication strategies of signs and symptoms must be consistent with the practices of the individual setting. Unless medical providers are more directly involved with RC/AL settings, health care supervisors can and should take an active role in helping to better inform antibiotic prescribing. In NHs, change in practices is more likely to occur when providers themselves are committed to the effort.

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Methodological Challenges Associated With Developing and Implementing Antibiograms in Nursing Homes

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Abstract

Although antibiograms have been observed to improve empiric antibiotic prescribing in hospitals, data on their effectiveness in nursing homes (NHs) are limited. In this study, our objective was to develop and implement antibiograms in three Maryland NHs. Data for antibiogram development were collected via chart review from NH residents during a 6-month period and included residents' characteristics, microbiological cultures, and antibiotic use. Additionally, we identified the primary emergency department (ED) to which NH residents were transferred and reviewed their acute-care charts for admission diagnoses and microbiological and antibiotic data during their first 48 hours of hospitalization. Finally, at each participating NH, an infection control or quality assurance nurse was interviewed as a key informant regarding resources for diagnosing and treating infections. Specific challenges faced in antibiogram development and implementation included identifying facility champions, availability of NH nursing staff and physicians, time required for individual chart review, and low volume of cultures available for antibiogram development. Lessons learned included:

- NHs may have a one-to-one or a one-to-many relationship with laboratories.
- Organisms in NH antibiograms mainly represented uropathogens.
- Incorporating culture data from residents transferred to EDs may not improve the quality of NH antibiograms unless there are sufficient numbers of transfers.
- Implementation of antibiograms in NHs required a significant investment of time and effort, including multiple educational inservices with staff and clinicians.

Development and implementation of nursing home antibiograms based upon chart reviews is possible but time consuming. Additionally, maintenance of the antibiograms requires consistent effort, which may be beyond the limited resources of many NHs. Identifying key, consistent project champions at NHs is important for successful development and implementation.

Introduction

Bacterial infections are a significant cause of morbidity and mortality among older adults residing in nursing homes (NHs).[1–3] Available prevalence data are sparse, but it has been estimated that there are between 1.64 million and 3.83 million endemic infections per year in long-term care facilities, with an annual cost that exceeds $1 billion.[1] These infections, and their associated poor health outcomes, are complicated by the increasing prevalence of antibiotic resistance among pathogens in NH residents, which in turn reduces treatment options and increases the probability of treatment failure.[4] Treatment of infections in NHs is frequently initiated empirically (prior to definitive diagnosis based upon organism identification and

antibiotic susceptibilities) because NHs often have limited resources for timely microbiological identification and antibiotic susceptibility testing. Although aggressive broad-spectrum empiric antibiotic therapy has been associated with improved clinical outcomes among infected patients, use of unnecessarily broad-spectrum antibiotics increases the incidence of antibiotic-associated side effects and creates selective pressure that promotes antibiotic resistance in surviving organisms. On the other hand, narrow-spectrum empiric therapy may not have sufficient coverage for the antibiotic susceptibilities of the infecting organism and, thus, may result in treatment failure and adverse outcomes, leading to increased potential morbidity and mortality.[5,6]

Antibiograms, which present a display of the cumulative antimicrobial susceptibility data of common bacteria isolated from a health care facility, are useful tools to guide empiric antibiotic prescribing.[7] Antibiograms commonly display information structured in a summary table, with bacterial isolates shown along one axis and antimicrobial agents arranged along a second axis, as seen in Figure 1. Percentages in table cells indicate which bacterial organisms are either resistant or susceptible to each agent tested (susceptibility data). Antibiograms utilize clinical culture data from the index facility to delineate the ward- or facility-wide prevalence of antibiotic resistance. Thus, antibiograms help to aggregate and track laboratory results for strains of bacteria that may show decreased susceptibility to certain antibiotics over time. However, the development of antibiograms is labor intensive and requires laboratory and information technology resources. As a result, the use of antibiograms is primarily limited to acute care settings. However, implementation of antibiograms in NHs has the potential to improve antibiotic prescribing for suspected infections and should be considered despite the resource requirements.

Denver Health and Hospital Authority and the University of Maryland, Baltimore (UMB) partnered with the Agency for Healthcare Research and Quality (AHRQ) to (1) determine antibiotic susceptibilities for bacteria isolated in clinical cultures from NH residents in three Maryland NHs; (2) generate NH-specific antibiograms based on the collected data; and (3) develop a toolkit to aid NHs and affiliated laboratories in creating and maintaining NH-specific antibiograms. Further, we assessed whether NH-specific antibiograms could be implemented for use both within the facility and also be transmitted to local emergency departments (EDs) to impact the empiric management of presumed bacterial infections in NH residents. This paper focuses on the methodological challenges associated with meeting these objectives.

GRAM POSITIVE		*Staphylococcus aureus* (4 MRSA)	*Enterococcus sp*
	# of Patients	5	9
Penicillins	Penicillin	0	75
	Ampicillin		100
	Oxacillin	20	
Quinolones	Ciprofloxacin	0	33
	Moxifloxacin	0	
Others	Clindamycin	25	
	Gentamicin	100	33
	Linezolid	100	
	Rifampin	100	
	Tetracycline	100	13
	TMP/SMX	100	
	Vancomycin	100	100
	Nitrofurantoin		100

GRAM NEGATIVE		*Escherichia coli*	*Klebsiella pneumoniae*	*Proteus mirabilis*
	# of Patients	11	4	5
Aminoglycosides	Amikacin	100	75	100
	Gentamicin	82	100	100
	Tobramycin	82	75	80
B-Lactams	Ampicillin	55	0	80
	Ampicillim-Sulbactam		67	
	Imipenem	100	100	
Cephalosporins	Cefazolin	91	75	80
	Cefoxitin	80	100	80
	Ceftriaxone	91	75	80
	Ceftazidime	91	75	80
Quinolones	Ciprofloxacin	36	75	20
Others	Nitrofurantoin	91	33	0
	TMP/SMX	80	75	40

Figure 1. Example of nursing home antibiogram

Methods

Overall Description

We collected antibiotic susceptibility data from 6 months of medical records for three NHs through retrospective chart review at the NHs and at each NH's primary receiving ED/acute care facility. Additionally, we conducted needs assessments in each NH prior to creating and implementing the antibiogram to gather information regarding infection control resources in each facility. The antibiograms were created using WHONET,[a] a free, Windows-based software program that was established for the purpose of analyzing microbiology data by the World Health Organization (WHO) Collaborating Centre for Surveillance of Antimicrobial Resistance, based at the Brigham and Women's Hospital in Boston, MA.[8] Implementation was structured based on NH preferences. We presented the antibiograms to NH staff and physicians during

[a] WHONET Software, World Health Organization. Available at www.who.int/drugresistance/whonetsoftware/en.

several inservices at the facilities. Followup chart review was conducted in the first NH (NH-A), 6 months after the antibiogram was implemented. Key informant interviews were also conducted at NH-A and its related acute care facility to determine usability and usefulness of the antibiogram.

Facility Recruitment

The three NHs were chosen based on location, number of beds, and the facility's prior research experience with UMB (Table 1). NH-A was a rural NH with prior research experience with UMB. This site was chosen in order to work through the methodological and operational challenges of creating and implementing an antibiogram before expanding to two additional NHs. As an initial step, the study team obtained administrative approvals to proceed with the research from each facility's administrator and quality assurance nurse. Institutional review board (IRB) approval was first obtained from UMB for the overall study and then from each NH and acute care facility whose ED received the majority of medical transfers from the identified NH. For institutions without an IRB, the UMB IRB served as the IRB of record.

Table 1. Nursing home characteristics

Characteristic	NH-A	NH-B	NH-C
Number of Beds	118	147	167
Dedicated Short Stay Beds?	Yes	Yes	No
Nonprofit Status	For-profit	Not-for-profit	For-profit
Location	Rural	Urban	Suburban
Median Resident Age	79 years	84 years	72 years
% Female	84	76	59
% Caucasian	86	46	41
% African American	10	51	53
Type of Laboratory Used	Hospital-based	Hospital-based	Private and hospital-based
% Transfers to One Hospital	79	98	48
Charting	Paper-based	Paper-based	Paper and electronic

Medical Record Review

Data were collected via chart review using a standardized form for patients who resided in the NH during a specified 6-month period. Patients were included in the review if they resided at the NH the day chart review began or if they were at the NH within the previous 6 months and provided a clinical culture or were transferred to an acute care hospital for an acute medical reason, such as an infection. The parameters were guided by the information needed to create and evaluate the antibiograms, namely, culture results and transfers to the hospital that may have resulted in cultures.

All the charts were reviewed and data abstracted manually by one of the authors (ACC or JHR) at all three facilities. If a question occurred while abstracting the data, the two reviewers would confer. One NH (NH-C) had portions of its records available electronically, but all information extracted was handwritten to a data collection form. As part of the research, the chart reviewers recorded basic demographic information; type of infections occurring during the 6-month review period; infection treatment; signs and symptoms of infection; antibiotics prescribed; culture

information including dates, antibiotic susceptibilities, and any hospitalizations in the 6-month period; and information about indwelling devices.

The acute care charts of hospitalized residents identified during the NH chart review were reviewed at the affiliated acute care facilities. We reviewed their charts for admission diagnoses and microbiological and antibiotic data during the first 48 hours of hospitalization.

Needs Assessments

We performed a qualitative needs assessment at each NH to examine the NH's organizational structure, particularly as it related to decisions about empiric antibiotic prescribing and to self-perceived concerns about this structure related to diagnosing and treating infections. This assessment was necessary in order to focus the antibiogram implementation phase such that antibiogram usage would meet the needs of staff at the NH and be sustainable. The quality assurance nurse at each NH, who also served as the infection control nurse, was interviewed for this purpose.

Through the needs assessment, we ascertained the handling of microbiological cultures in the NH, including the collection, charting, and result retrieval processes, as well as the estimated frequency with which cultures were ordered. The infection control nurse also provided information about how a resident was transferred to the ED, who made the decision to transfer, and what information accompanied the resident. Finally, the assessment gathered information about the antibiotic prescribing practices within the NH. The infection control nurse provided details about the types of antibiotics available on site, the typical symptoms an empiric antibiotic might be prescribed to treat, and the process used by the nurses to communicate culture results to the prescribing physician responsible for initiating an antibiotic.

Antibiogram Development

Data collected from both the NH and acute care hospital charts were entered into a Microsoft Access 2007 database (Microsoft Corporation, Redmond WA) designed for the project. The study microbiologist then used WHONET to display the data and to compute percentage susceptibilities to each antibiotic for each organism. These percentages were then manually entered into an antibiogram template matrix. Consistent with Clinical Laboratory Standards Institute (CLSI) performance standards, only the results for the first organism-specific positive culture per resident in the time period were included.[9]

Antibiotic susceptibilities were assessed for bacteria found in the NH and the associated acute care hospital independently as well as together. Since only acute care culture data obtained within the first 48 hours of admission were included, and thus likely originated from the transferring facility, we expected to see similar antibiotic susceptibility data in the hospital and NH charts.

Implementation

For each NH, we expected that three antibiograms (NH only, hospital only, NH–hospital combined) would be created based on the chart review data collected at the NH and the hospital (Figure 1). For two NHs, the hospital culture results were not combined with the NH culture results in an antibiogram because there were not enough hospital cultures to substantially

augment the NH culture data. For NH-B, which transferred 98 percent of its residents to the same hospital and had a higher number of patients transferred to the single facility, the hospital cultures added significant information related to pathogen antibiotic resistance to the antibiogram. The combined antibiogram was implemented in this facility.

Implementation in NH-A was a multi-step process. The antibiogram was first circulated to the NH nursing team for feedback on the format of the antibiogram and how best to organize the information. An index card format was agreed upon, with gram-positive results on one side and gram-negative results on the other. We laminated the antibiogram on a 3×5-in. index card so that the antibiogram could be easily carried by physicians and nurses, placed in residents' charts, or posted around the facility. After discussions with the clinical and administrative staff, the NH staff decided to photocopy the antibiogram onto the back of the transfer forms to ensure that the antibiogram traveled with the residents to the ED. The final antibiogram was formally presented via an inservice with NH staff and separately to physicians, administrators, and nurse managers.

In NH-B and NH-C, the same index card format was used for the antibiograms. Multiple inservices were held with NH staff (nurses and administrators) and physicians in each facility to present the antibiograms and to discuss their implementation and utility. The inservices each lasted about 1 hour, during which the antibiogram was presented, and information about antibiogram use and infection control measures was discussed. Results of the initial chart reviews specific to each NH were highlighted during the inservices. These inservices were arranged through the NH administrators or the infection control nurses. Available staff were expected to participate but were not required to do so.

Evaluation

The study period only allowed for complete evaluation of the impact of antibiogram use on antibiotic prescribing and bacterial susceptibility trends at NH-A. Following implementation of the antibiogram, the same data collected at the beginning of the study were collected a second time for the evaluation, including basic demographic information; type of infections occurring during the 6-month review period; infection treatment; signs and symptoms of infection; antibiotics prescribed; culture information including dates, antibiotic susceptibility data, and any hospitalizations in the 6-month period; and information about indwelling devices. Antibiograms were recreated based on the followup data to observe if there were any changes in susceptibilities. Changes in culturing and antibiotic prescribing patterns were also examined.

Research study staff made numerous attempts to interview physicians at NH-A and the associated ED about their use and opinions of the antibiogram. These efforts included multiple telephone calls and emails to the quality assurance nurse at NH-A and to the clinical director at the associated RD. No NH physicians were available to participate, and only one ED physician, who had not seen the antibiogram despite multiple shifts in the ED, participated.

Toolkit Development

A toolkit was compiled for NHs to create antibiograms for their facilities. The toolkit consisted of several components: background information, instructions on obtaining culture data and updating the antibiogram, instructions to supplement the WHONET tutorials, templates for data entry and antibiogram structure, and instructions on entering data from WHONET into the antibiogram. The toolkit was revised with input from the infection control nurse at NH-A, who

planned to update the antibiogram within the year. The toolkit was developed to be publishable online, with the elements downloadable using Microsoft Word and Excel (Microsoft 2003).

Results

All three NHs involved in this study were located in Maryland (Table 1). We consider this group of NHs to be diverse but not necessarily representative of all NHs in Maryland or in other States. The NHs differed in type of location—rural, urban, and suburban—and their populations differed in distribution by sex and race. NH-A and NH-B used the laboratory of the hospital to which they transferred the majority of their residents as the central laboratory that processed their cultures. NH-C used a private central laboratory during the week and a hospital-based laboratory on the weekend. All three facilities employed a full-time nurse who served as both the quality assurance nurse and the infection control nurse.

A total of 623 charts from the three NHs and 216 charts from the three associated acute care hospitals were reviewed. This proved to be the most time-consuming portion of the study. Archived records had to be retrieved for residents who had died or were no longer at the NH. Identifying signs and symptoms related to antibiotic prescribing proved to be the most difficult element of the review in both the NH charts and the hospital charts.

The needs assessments revealed several similarities in culturing practices across all three facilities: urine cultures were by far the most common type of culture ordered, and wound cultures were rarely ordered. Laboratory results were received by fax in all three facilities, and the results were manually entered in the residents' charts.

We were able to create antibiograms for all three NHs. The amount of culture results available for the antibiograms based on our 6-month chart review period was much less than recommended by the CLSI guidelines. However, the facilities were able to see susceptibility data for the few organisms that were included on their specific antibiogram. The antibiograms were successfully implemented in all three facilities using multiple inservices.

Discussion and Project Challenges

There were a number of methodological and operational barriers to overcome in the development of NH-specific antibiograms. These can be broken down into domains corresponding to project development and implementation steps. These steps include facility recruitment, data collection, antibiogram development, antibiogram implementation, and project evaluation (Table 2). Each step provided unique challenges—some foreseeable and some not.

The recruitment of facilities required multiple telephone and email contacts to obtain both administrative and IRB approval. The responsiveness of administrators and contact personnel varied, and it was not uncommon to have to work with several individuals initially before a primary institutional contact was identified. Because this was a research project, IRB approval was required from the university, the NHs, and the acute care facilities. Not all facilities had the same ability to conduct research; for example, one NH required assistance in renewing its Federalwide Assurance for the Protection of Human Subjects (FWA). The overall approval process required between 2 and 5 months for each NH.

Data collection also presented challenges. As was expected, medical chart review was time consuming and required approximately 45 minutes on average for each chart. The amount of time varied, depending on the format (paper or electronic) and the availability of the medical charts. While this study utilized experienced chart reviewers and dedicated research resources, the time required for medical chart review highlights feasibility concerns with regard to dependence on medical chart review by NH personnel for antibiogram creation as part of routine clinical practice.

The needs assessment at the three facilities uncovered some interesting results. First, the NHs had variable relationships both with acute care hospitals and with testing laboratories. NH-B was closely affiliated with a hospital and its laboratory, so their records were consistent. Another facility, NH-C, transferred patients to different hospitals depending on the potential diagnosis (one hospital for medical patients and a different hospital for patients deemed to have a psychiatric problem). In addition, this NH used one laboratory during the week and another on the weekend.

The actual development of the antibiogram required the ability to use WHONET software. While this program is publicly available and relatively easy to use, there is still a learning curve required to become proficient with its use. Additionally, time is required to input the data, which may be challenging for quality assurance nurses who already have multiple roles in the NH. The low number of culture results from the NHs also made it difficult to create antibiograms with truly reliable facility-specific antibiotic susceptibilities. CLSI guidelines recommend including a pathogen on an antibiogram if 30 or more isolates are available. The available NH culture results would not have produced an antibiogram for any facility if this recommendation had been followed, due to the small number of cultures obtained within the 6-month study period. Our microbiologist suggested including an organism if four or more isolates were available. This may have impacted the reliability of the antibiograms. However, even with this smaller number of cultures, facilities would have been able to see susceptibility trends over time. The acute care facility cultures only augmented the NH antibiogram for one NH (NH-B). Looking at data from a longer period of time, perhaps 1 or 2 years as compared to 6 months, might provide more comprehensive culture information. Further, the NHs in this study mainly ordered urine cultures, resulting in antibiograms primarily for uropathogens. Antibiotic susceptibility patterns for other pathogens will be relatively unknown without a change in culturing practices in NHs.

Table 2. Challenges in antibiogram development and implementation

Steps	Challenge/Obstacle	How Resolved and Effort Needed
Facility Recruitment		
Permission to participate	Obtaining administrative approval	Multiple phone and email contacts were required to schedule a meeting to present the project to the appropriate individuals. The nursing home (NH) administrator had to give the final approval, but his/her availability was very limited. For NH-A and NH-C, only one meeting was required; however, for NH-B, multiple phone contacts and two meetings were required, with a span of 2 months between the meetings.
Institutional Review Board (IRB) approval	Conducting research in NHs without IRBs or Federalwide Assurances (FWA) and multiple IRBs for acute care facilities	Approval was obtained from four IRBs. Time for each approval ranged from 1 week to 3 months. Renewing the FWA for NH-C took 6 weeks.
Medical Record Review		
Manual review of NH medical charts	NHs did not have patient infection and culture data available in a format to be shared electronically—mainly paper records.	Baseline chart review took 4 months at NH-A (150 hours, over 1 hour per chart) but decreased to 6 weeks at NH-C (120 hours, about 45 minutes per chart). The followup chart review at NH-A required 6 weeks (85 hours—about 40 minutes per chart).
Manual review of acute care (AC) hospital medical charts	Acute care hospital records were electronic, but the infection and culture variables still had to be abstracted.	Baseline chart review took 3 weeks at AC 1 (40 hours—about 1 hour per chart), 5 weeks at AC 2 (80 hours—about 45 minutes per chart), and 2 weeks at AC 3 (20 hours—about 45 minutes per chart). For the followup chart review at AC 1, 1 week (20 hours—about 35 minutes per chart) was required.
Needs Assessments		
Conducting interview	Scheduling an interview with the quality assurance nurse depended on his/her availability. This person was very busy and not always on site at the NH.	Scheduling this interview required multiple phone and email contacts with the nurse. Only one interview lasting about 1 hour was necessary for the assessment.
NH and laboratory relationships	Two NHs had one hospital laboratory that processed all cultures for the facility. NH-C had two laboratories that processed its cultures. NHs were not always clear whether their affiliated laboratory could produce an antibiogram for their facility.	For a NH to maintain and update its facility's antibiogram, it may consider having its affiliated laboratory create the antibiogram. A poor relationship between the two entities makes this difficult. Dealing with two laboratories increases complications.

Table 2. Challenges in antibiogram development and implementation (continued)

Steps	Challenge/Obstacle	How Resolved and Effort Needed
Antibiogram Development		
Data entry for analysis	Manually abstracted data from medical records had to be entered into a database for analysis.	The study team spent about 45 hours inputting and resolving the handwritten chart review forms.
WHONET software	WHONET software required a learning curve to import data appropriately and to create the antibiogram results as needed.	Study team members learned to create antibiograms in WHONET for the NHs to better inform the toolkit that was developed. This involved following tutorials on the WHONET site as well as using test data to create sample antibiograms.
Clinical Laboratory Standards Institute (CLSI) guidelines for antibiograms	CLSI guidelines suggest a minimum of 30 isolates per organism to be reported in an antibiogram. Nursing homes do not culture to this extent.	Following the recommendation of the team microbiologist, organisms with more than four isolates were included, which can affect the reliability of the results.
Prevalence of urine cultures	Urine cultures were collected far more often than other types of cultures in NHs.	The antibiogram's effectiveness may be strongest with uropathogens.
Contribution of AC cultures to NH antibiograms	For NHs with few monthly transfers to the ED, the culture results from the acute care hospital did not augment the NH antibiograms.	Antibiograms for NH-A and NH-C included only NH cultures and resulted in low numbers of isolates. NH-B had many more isolates because ED cultures were included.
Implementation		
Presenting antibiogram results to NHs	After the antibiogram was created, it took multiple inservices at each nursing home to present the antibiogram to all the interested parties.	At least two inservices were necessary to present the antibiogram at each NH.
Transferring antibiogram to the ED	Each nursing home had to determine a method of transporting the antibiogram with patients to the ED.	NH-A was able to photocopy the antibiogram to the back of its transfer sheet, but this was not possible for the other NHs. The antibiogram had to be sent as a separate document.

Table 2. Challenges in antibiogram development and implementation (continued)

Steps	Challenge/Obstacle	How Resolved and Effort Needed
Evaluation		
Interviewing NH physicians	No NH physician was available to provide feedback about his/her antibiogram use.	10–15 attempted contacts per NH physician were not enough to schedule an interview for this project. Anecdotal input from NH staff suggested that the physicians did use the antibiogram. Evaluation of the medical charts 6 months after the antibiogram was implemented also showed some change in prescribing patterns.
Interviewing ED physicians	One ED physician was available for an interview, but he had not seen an antibiogram from the NH.	Study staff approached ED staff prior to the antibiogram intervention at the NH to alert them that the antibiogram would be sent with the patients. Only ED nurses were available at the time. The ED director also sent a notice to all the practitioners. Since only one ED physician was available to be interviewed, it is not clear if others saw the NH antibiogram. However, evaluation of the ED charts did not show any change in prescribing patterns.

The implementation and evaluation of the antibiograms required multiple inservices and discussions at each NH. The most successful implementation occurred at NH-A, where we were invited to present to the doctors and senior staff at a facility event. As an innovative strategy to improve communication between NHs and their affiliated EDs, the antibiogram was replicated on the back of the transfer sheet that was to accompany any transferred patient. Our ability to evaluate the effectiveness of the antibiogram to improve antibiotic prescribing was limited, due in part to lack of time because of project completion and to difficulty in contacting responsive physicians. The one full-time emergency physician we were able to contact at the acute care facility affiliated with NH-A had not seen the antibiogram, despite working multiple shifts during the 6 months of antibiogram implementation.

This study highlights the challenges in adoption and dissemination of NH antibiograms, as well as the day-to-day challenges associated with communication in clinical settings. Specific challenges included identifying facility champions, availability of NH nursing staff and physicians, time required for individual chart review, and low volume of cultures available for antibiogram development. Lessons learned include the following:

- NHs may have a one-to-one or a one-to-many relationship with laboratories.
- Organisms in NH antibiograms mainly represented uropathogens,
- Incorporating culture data from residents transferred to EDs may not improve the quality of NH antibiograms unless there are sufficient numbers of transfers.
- Implementation of antibiograms in NHs required a significant investment of time and effort, including multiple educational inservices with staff and clinicians.

Conclusion

Through this project, significant barriers to antibiogram development and implementation were identified, including complex nursing home–clinical laboratory relationships and difficulties in ensuring effective utilization of antibiograms. As a research project, the development of nursing home antibiograms based on chart reviews is possible, but it is time consuming and resource intensive. Alternatives to chart review, such as having laboratories affiliated with the NHs create antibiograms as part of their clinical contract, should be considered. Additionally, maintenance of the antibiograms will require consistent effort, which may be beyond the limited resources of many NHs. However, the project also had the unexpected benefit of having NH administrative and clinical staff focus on the issue of empiric antibiotic prescribing practices, which led to increased awareness of the issue of antibiotic resistance. Identifying key, consistent partners will be important for successful development and implementation of risk reduction strategies for healthcare-associated infections.

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Developing the Capacity to Implement Antimicrobial Stewardship: Opportunities for the Future

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Abstract

Multiple initiatives and major campaigns around infection control and environmental cleaning are underway to control healthcare-associated infections (HAIs). However, as new and increasingly resistant strains of bacteria emerge, the problem persists, and additional strategies are necessary. Antimicrobial stewardship programs (ASPs) show promise as one of those additional strategies for addressing HAIs. The ERASE *C. difficile* Project was designed to implement and evaluate ASP interventions, with a focus on reducing *Clostridium difficile* infection *(*CDI) in a mixed-methods study design. ERASE *C. difficile* worked with six hospitals with early ASPs that were recruited by Greater New York Hospital Association (GNYHA)/United Hospital Fund (UHF) on the basis of their successful participation in a prior *C. difficile*-focused collaborative. All six hospitals succeeded in reducing the use of antibiotics targeted by the ASP on one or more measures. However, ASP implementation was typically more complex, faced greater challenges, and took longer than expected. The study showed that using limited case-control methods for antibiotic selection was a feasible, practical, and acceptable approach for facilities to identify potential antibiotic targets for the ASP. Moreover, ASP activities were broader than restrictions on targeted antibiotics. Sites varied by staffing and who carried out ASP roles; however, in all cases ASP activities were multidisciplinary. Many ASPs were implemented with limited, dedicated staff and a prohibition on hiring new staff. These findings suggest that while each hospital needs to tailor its ASP to its unique staffing, resources, culture, and existing practices and relationships, there are common lessons to guide implementation across hospitals.

Background

Reducing healthcare-associated infections (HAIs), especially in hospital settings, is a major health and public health imperative in today's health care environment. HAIs are the most common complication of hospital care and one of the 10 leading causes of death in the United States.[1] New sources of infection and increasingly resistant strains of well-known bacteria are increasing the dangers of HAIs. For example, *Clostridium difficile* infection (CDI) is a serious public health problem that has recently increased in both incidence and severity. From 2000 to 2009, the number of hospitalized patients with a CDI diagnosis more than doubled, from 139,000 to 336,600.[2,3] There are also indications of recent increases in the severity of CDI, including increased complications, with CDI linked to 14,000 deaths in the United States each year and CDI-related mortality rising by 400 percent between 2000 and 2007.[4] Studies have found that, in addition to personal harm to patients, there are major costs associated with CDI, such as longer inpatient lengths of stay and a significant increase in costs both for inpatient care and at 180 days after the initial hospitalization when the CDI occurred.[5,6] The major risk factors for CDI, in addition to advanced age, are exposure to antimicrobials and hospitalization.[7]

Multiple initiatives and major campaigns around infection control and environmental cleaning are underway to control HAIs;[8,9] however, as new and increasingly resistant strains of bacteria

emerge, the problem persists, and additional strategies are necessary. Antimicrobial stewardship targeted to HAI reduction shows promise as a complementary strategy for infections such as CDI, where increased rates are associated with inappropriate antibiotic use. An antimicrobial stewardship program (ASP) is a systematic approach for developing coordinated interventions to reduce the overuse and inappropriate selection of antibiotics and to achieve optimal outcomes for patients in cost-efficient ways. Through both monitoring and, when necessary, altering current antimicrobial prescribing practices, antimicrobial stewardship has been shown to improve patient care, reduce antimicrobial use, reduce pharmacy and overall hospital operating costs, and potentially reduce antimicrobial resistance.[10]

Despite the expanding evidence that ASPs could reduce HAIs, many health care institutions continue to identify barriers to implementing ASP strategies. Many of these barriers are related to obtaining institutional support for these kinds of programs. Stewardship activities involve complex organizational change because they require individuals to alter both the way they work and the way they interact with each other and, thus, require changes in both individual behavior and processes within the organization. Complex organizational change is difficult to accomplish.[11]

In this paper, we profile the experiences of six hospitals in implementing ASPs targeted to reducing CDI in order to offer lessons to other medical centers interested in developing their own ASPs. The six hospitals served as intervention sites in a recent initiative sponsored by the Agency for Healthcare Quality and Research (AHRQ) and supported by the Centers for Disease Control and Prevention (CDC). The initiative, Evaluation & Research on Antimicrobial Stewardship's Effect on *Clostridium difficile* (ERASE *C. difficile)* Project, was led by a collaborative team from Montefiore Medical Center (MMC), the Greater New York Hospital Association (GNYHA)/United Hospital Fund (UHF), and the Boston University School of Public Health (BUSPH).

Methods

Participating Hospitals

The six intervention sites, in four health care systems, are all located in the greater New York region. All are major teaching hospitals, with the number of licensed beds ranging from 396 to 871. Each was recruited by GNYHA/UHF for ERASE *C. difficile* based, first, on the hospital's successful participation in an earlier GNYHA/UHF C. difficile Collaborative to establish basic ASPs;[12,13] second, on its high level of compliance with infection control and environmental practices (but still having high CDI rates); and third, on its commitment to developing its ASP to target CDI reduction further.

Conceptual Framework

Figure 1 provides an overview of the ASP implementation in ERASE *C. difficile* based on an implementation science conceptual model[14] that guided the project. The logic underlying the model is that external facilitation influences the local implementation strategies used by ASP teams to create and implement the clinical interventions undertaken to target antibiotic use. The implementation of the clinical intervention then determines the process outcome, which is measured by reduction in the use of the targeted antibiotics and, over the longer term, by reduction of CDI in the facility. All this work is influenced by the organizational context in

which the implementation efforts take place. The context relationships are shown in Figure 1 with double-headed arrows to signal a potential reverse influence as the implementation strategies and interventions demonstrate success that results in increased organizational support.

In this paper, we focus on the local implementation strategies. The organizational context influences the strategies and the interventions targeted, as discussed below in the sections on local implementation strategies and the lessons learned in the project. The findings in the other model domains, highlighted in the overview of the ERASE *C. difficile* intervention, provide the backdrop for those analyses.

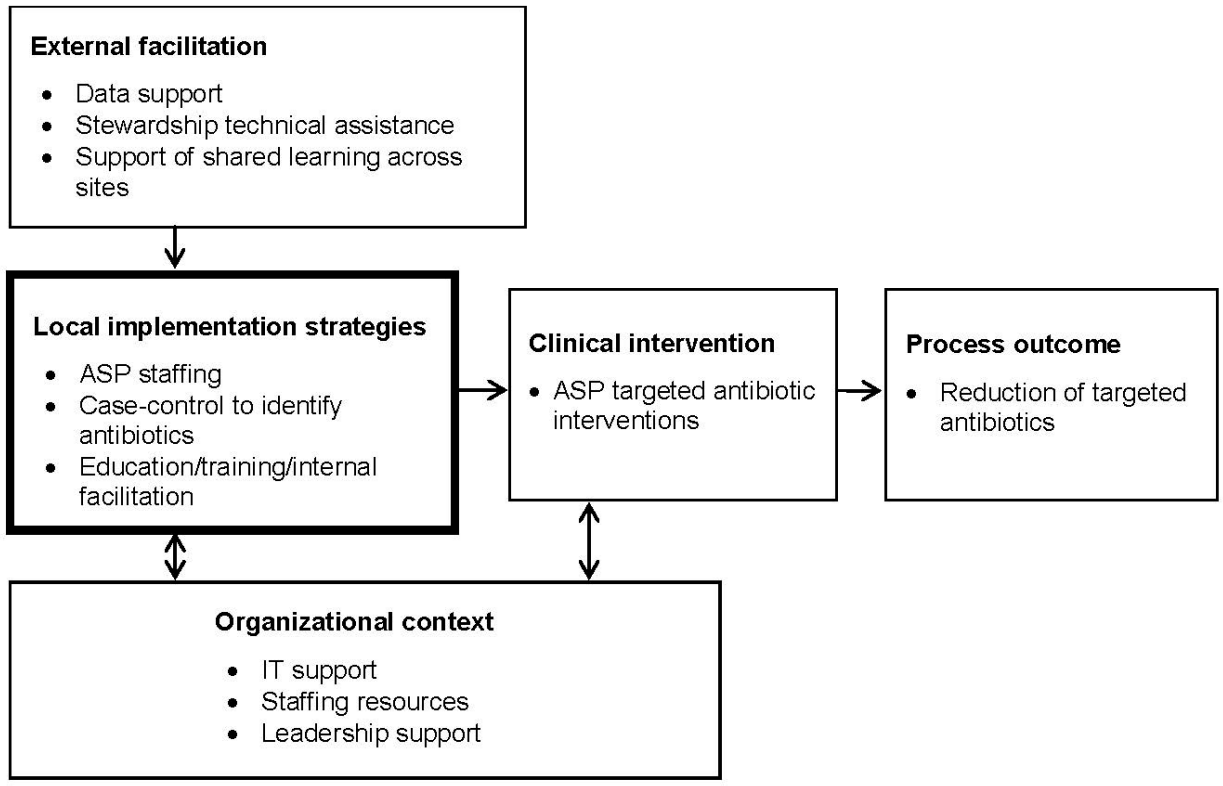

Figure: 1. Implementing antimicrobial stewardship

Data Sources

Data were drawn from four sources, which are discussed below.

Data on antibiotic use. Antibiotic usage data were used for case-control and to assess changes in the volumes of antibiotics targeted in the intervention. Each intervention hospital performed its own limited case-control study on adult (18 years of age or older) inpatients to identify the antibiotics or antibiotic classes associated with CDI (but not to extensively explore other factors associated with CDI). A minimum of 33 CDI cases were obtained from the National Healthcare Safety Network (NHSN) between March 2010 and May 2010. Control cases were adult inpatients free of CDI for 3 months before or after their diagnosis, matched by age (± 5 years) and admission date (± 5 days) to achieve a 2:1 control-to-case ratio. Additional details regarding

the preliminary work performed to determine the best strategies for matching controls, length of time, and data elements needed are reported elsewhere.[15] Odds ratios were used to compare antibiotic use between the case and control groups at each hospital. Statistically significant odds ratios and evaluation of prescription frequency were used to identify preliminary antibiotic targets. Final targets were selected after an internal medication review of prescribing patterns (e.g., who prescribed the drug, for what types of patients, for which diagnoses), which informed the selection of appropriate antimicrobial stewardship interventions. All intervention sites provided data regularly on antibiotic usage, employing a format standardized by MMC and GNYHA. The format was chosen based on the feasibility of extracting antibiotic data from the electronic medical records (EMRs) and informed by interviews with information technology (IT) and ASP staff at each of the sites. Antibiotic consumption was measured with three distinct measures—defined daily dose (DDD), days of therapy (DOT), and number of courses (NOCs) prescribed.[6,16] We examined total antibiotic usage, total target antibiotic usage, total non-target antibiotic usage, and usage for each individual target antibiotic/class.

The measure of implementation effectiveness is based on the usage data. The project team also regularly collected standard data on environmental cleaning, infection control practices, and CDI rates.

Site data on the timing and focus of interventions. Comprehensive qualitative data were collected from each site to identify details about the kinds of ASP strategies implemented within each institution. The data were collected through frequent ad hoc conversations between project team members and the intervention sites, requests from project team members for intervention sites to document the details of their implementation, and individualized meetings between intervention site staff and the infectious disease (ID) physicians on the project team, as well as the project team documentation detailed below. This information was used to develop site profiles of ASP interventions and implementation strategies (summarized in the Appendix), and contributed to the analysis of the implementation process.

Project team documentation. Project team documentation came from two sources. First, GNYHA facilitated monthly conference calls with the intervention sites, during which detailed notes were taken by a project team member on specific project activities from the perspective of the site participants. Second, core project team meetings were held via conference calls regularly throughout the project. The standing agenda included reports about interactions with the hospitals around their data collection and analysis and their activities to implement ASP. Detailed notes provided a running log of project activities, discussion decisions, tasks, and responsibilities. Data from these sources were categorized by type of intervention provided to describe the external facilitation provided and the site implementation processes and to contribute to the analysis of factors that affected implementation.

Group interviews with clinical staff. Project team members from BUSPH with extensive qualitative research experience and no involvement in facilitating the intervention conducted group telephone interviews with members of the ASP team and other involved clinicians at each participating site. Four group interview sessions lasting between 45 and 60 minutes were conducted with staff at the six intervention sites about 6 months after the ASP interventions were introduced; two of the group interviews included staff from two sites within the same system. Group size ranged from 7 to 14, depending on the number of staff involved in ASP implementation in a site and availability to participate in the discussion. Guided by an institutional review board-approved semi-structured protocol, the interviews were designed to explore qualitatively the processes, dynamics, and factors affecting the implementation of the antimicrobial stewardship program, including the challenges the staff faced. Detailed notes of each session, supported by audio recordings, were analyzed qualitatively using a structured analytic framework that provided the initial organization and coding of data. In the framework approach, which was used previously by the BUSPH team in multiple other projects, key constructs from the conceptual model were defined operationally and arrayed as rows headings in a matrix. Narrative evidence about the presence of each construct was recorded for each site in the matrix cells. Data from the interviews were then used to describe the site implementation processes and to identify the factors that affected implementation. A summary of the analyses from these sessions is included in the Appendix.

Overview of the ERASE *C. difficile* Intervention

The six participating hospitals received comparable external facilitation from project team members from MMC, GNYHA, and UHF. The hospitals conducted limited case-control studies, collected data in standard format and provided the data to GNYHA, and implemented ASP interventions targeted to reduce use of the antibiotics identified through the limited case-control studies. All had some success in reducing the use of those antibiotics, as described below.

External Facilitation

The project team provided limited external facilitation to support local implementation. The six intervention sites participated in an in-person kick-off learning session early in the project, monthly conference calls throughout the project, and informal meetings with the project's ID physician. The project team also provided ongoing technical assistance in setting up data files and conducting the case-control activities through the monthly conference calls and through interactions with individual sites by phone, email correspondence, or face-to-face small meetings.

Clinical Intervention to Reduce Targeted Antibiotics

Antimicrobial stewardship begins with the identification of antibiotics associated with HAIs, in this case CDI. Consistent with the ASP approach, all sites conducted limited case-control analyses to identify target antibiotics as planned. Each hospital then selected specific interventions to reduce the use of the target antibiotics at their site. Each facility identified between one and four potential target antibiotics and many potential interventions (see Appendix). Three antibiotics were associated with CDI in some combination at four of the six intervention sites: piperacillin/tazobactam, fluoroquinolones, and cefepime.

As shown in the Appendix, hospitals implemented up to three interventions to reduce the use of these antibiotics, most of which affected the entire hospital, with a back-end audit and feedback approach adopted as a viable intervention at all the intervention sites (i.e., allowing initiation of empiric antibiotic but assisting prescribers in reevaluating the antibiotic choice to potentially stop, narrow the spectrum of, or shorten the antibiotic course based on preset criteria, such as cultures, clinical status, or duration of antibiotics). The hospitals' staggered rollout, with variable time periods to fully implement their interventions, resulted in a total rollout period of approximately 15 months.

Process Outcomes: Reduction of Targeted Antibiotics

Intervention sites were able to reduce at least one of their antibiotic targets on at least one of the measures. The full analyses of ASP reductions in antibiotic use and the impact on CDI reduction are presented in the final project report to AHRQ.[17,18]

Local Implementation Strategies

Despite the relative success of all sites in reducing targeted antibiotics, achieving those levels of success was not easy, and the details of implementation varied across sites. The implementation of the ASP interventions was typically more complex than expected. Guidance for antimicrobial stewardship offers general principles for a program but not a detailed blueprint. There is no one-size-fits-all model nor a single "right way" to structure and carry out the program. ASP activities take place in the context of the larger hospital and health system organization. Typically, ASP programs are expected to demonstrate a strong business case based on cost savings. Organizational factors, such as IT support for ASP and staffing resources available, can affect implementation, serving either as facilitators or as barriers that present challenges to be overcome.

As expected, each hospital tailored the details of its ASP to its unique staffing and culture, existing practices and relationships, and available resources. This section describes the different approaches the participating hospitals used to put the ASP principles into practice. The Appendix presents a profile of the implementation strategies, interventions, and resources for the participating hospitals (information for hospitals from the same system is combined). The next section offers lessons—including frequent challenges—that were common across hospitals.

ASP Staffing

Intervention sites differed in the details of their ASP staffing (see Appendix). However, in all cases, ASP activities were multidisciplinary. Sites varied in whether the leadership of the ERASE *C. difficile* ASP resided primarily in Pharmacy or Infectious Disease. In five sites, ID physicians played the lead role, although with variation in the details of their working relationships with Pharmacy. In the sixth site, an ID-trained clinical pharmacist led the ASP with backup from an ID physician, but the pharmacist primarily drove the ASP together with pharmacy residents. ID fellows and pharmacy residents played important roles in all sites, although in different configurations and with different lengths of rotation. Five of the six sites had ID fellows who participated in the ASP. All sites had pharmacy residents but on limited rotations—two sites had 5-week rotations (one with two residents and the other with four)—so the ASP had access to this resource for only part of the year. All four sites had pharmacists who filled prominent roles in the ASP. Additionally, all sites had ID physicians, but the size of the

departments varied as did the proportion that were on staff versus private physicians who provided their services through consulting. All facilities had an infection control team, with a ratio of no less than one infection prevention and control practitioner (ICP) per 250 beds (but this varied among facilities). The ICPs may have collaborated with the ASP staff, but on the whole they worked in parallel.

Stewardship Activities

Each site's staffing, IT resources, and education and training structures contributed to the interventions that were chosen and implemented at each site to address the antibiotics targeted for reduction, as detailed in the Appendix. While all sites targeted piperacillin/tazobactam, and two of the six sites chose to use audit and feedback to reduce usage, the unique characteristics of each site resulted in very different stewardship activities. For example, one site used data mining software, with one pharmacist guiding the work of residents, who in turn interacted with the medical staff around ID issues. Another site's ASP lead, an ID physician, trained fellows who examined computer-generated lists of data by hand for antibiotic use patterns. This site had a high proportion of consulting IDs, making buy-in of ASP particularly challenging. One system with two sites led by an ID physician and pharmacist used specially trained ID pharmacists to work closely with physicians. These sites devoted extensive resources to education to augment the audit and feedback effort, and they were moving toward formalizing their ASP, using the ASP to drive institutional policy. Each site, in addition, used resources specific to its institution to develop processes that complemented its ASP activities, illustrating the unique characteristics of each site's ASP activities and overall program.

Education, Training, and Coaching

ASP activities had a broader scope than just restrictions on targeted antibiotics. Substantial training and education were needed, first, to highlight the important role of antibiotic restrictions and their interconnectedness to other infection control practices, and second, to explain the stewardship approaches being used and the roles of different professional groups in implementing them. The intervention sites differed in the details of their education approaches, but all used multiple approaches to inform prescribers and clinical staff about the ASP (see Appendix). For example, most sites combined formal lectures, grand rounds, and faculty development forums or guest speakers, with individual conversations, visits to the floors, and coaching in implementing the interventions to reinforce the formal education.

Information System Support

IT software that screens patients for the targeted antibiotics or for other specific criteria for stewardship is a clear implementation facilitator. For example, one site used MedMined® Surveillance Advisor,[19] which was provided by resources from the city hospital oversight system; other electronic ASP surveillance software systems are available. Without investment in these systems, which are costly, the human resources needed to monitor targeted antibiotics are substantial. Participating systems differed in the extent of their systems support, as shown in the Appendix. All sites required substantial IT assistance to extract the data needed for the case-control study and antibiotic usage tracking. Though many sites had EMRs or a computerized physician order entry (CPOE) system, the data typically available were not aggregated or in a format useful to the ASP team. One site had developed an internal template iteratively over several months with its IT team. The template and strategy were ultimately shared with IT staff

at each of the sites, allowing ASP teams to learn from each other about how to physically obtain and leverage their data for the ASP activities that followed data collection. In all cases, managing the data was labor intensive.

Lessons

The experiences of the intervention sites illustrate a number of common lessons about implementing ASP, including both facilitators and challenges to ASP development and success.

The limited case-control methods for antibiotic selection were less complicated than anticipated, but the data burden of antimicrobial targeting was typically heavy. Utilizing limited case-control methods for antibiotic selection is a feasible, practical, and acceptable approach for facilities to identify potential antibiotic targets for ASP. Tools such as an antibiogram can be simple to use and effective in encouraging prescribers to change practice quickly. However, all aspects of acquiring data from ASP activities may be challenging. Obtaining the data in the format needed for the analyses was one of the biggest hurdles the sites faced. Likewise, discerning trends in antibiotic prescribing or simply identifying specific patients to target for ASP activities (i.e., audits) was challenging. Having additional (data mining/data surveillance) software to assist in exploration of clinical information can be helpful, but it always needs to be complemented by an astute ASP member who can interpret and prioritize the results.

Finding strategies where enough of the prescribing could be impacted was difficult. Most sites selected antibiotic targets that were used at a very high rate. However, it was difficult to develop strategies that could address the most highly prescribed antibiotics because they are often prescribed in many different ways, even within one facility (i.e., for different indications, for different populations, and by prescribers of varying types and with varying expertise). For some facilities, limiting the scope of certain interventions was the only feasible option. For example, two sites set up an auditing system to review patients prescribed at least 72 hours of piperacillin/tazobactam. However, it would have been overwhelming to attempt to audit and intervene on all piperacillin/tazobactam at prescribing initiation. Therefore, the ASP teams focused their efforts on services with the highest likelihood of de-escalation of antibiotic use and clinicians' acceptance of the intervention—in these cases, the medical teaching and medical hospitalist non-teaching services. This was a practical strategy, but it was able to impact only a segment (estimated at less than 50 percent) of piperacillin/tazobactam prescribing.

Collaboration among clinical staff strengthens the ASP process. ASP at the clinical level is the heart of the program. Strong stewardship leadership is critical, but the involvement of other staff needs to be considered. ASP does not stand on its own, but rather it must work in partnership with other departments. ASP should complement infection control and environmental cleaning protocols. Involving infection prevention staff and epidemiologists in the interdisciplinary team will strengthen the link between ASP implementation and infection reduction and prevention efforts. The link between ID physicians and pharmacists is critical, and their roles are complementary: pharmacists are needed to fully understand the clinical implications of different antibiotics, and physicians are credible sources in talking with prescribers. Some sites had a long history of close relationships between pharmacy and ID—for example, they round and teach together—while others had to build such relationships. One recommendation for future consideration is to make prescribing a distinct and specialized area of expertise through an integrated ID physician and pharmacist stewardship.

Changing physician practice can be difficult. Often prescribers and house staff are not, initially, fully receptive to being told what to do and how to do it. In most cases, acceptance grows as they learn more about ASP and as relationships with ID and Pharmacy are built and strengthened. A history of antibiotic restrictions and acceptance of those practices usually paves the way for ASP acceptance, but prescribers may not understand ASP at first, even after education. Also, in some cases, additional effort is needed to reduce adversarial positions between prescribers, pharmacists, and ASP and to increase prescriber acceptance of pharmacy residents' recommendations. Resistance is often strongest among private consulting physicians, who are at the hospital less frequently and whose ties are weaker than facility-employed physicians. Communication and education are crucial in the process of gaining prescriber buy-in. Communications with physicians need to come from a credible source and include consistent messages from clinical leaders. Calls from ASP team members can be used for educational purposes as well as a specific communication about the antibiotic in question.

Residents and fellows are important resources for ASP but also bring limitations. All intervention sites relied on ID fellows and/or pharmacy residents to implement the antibiotic restrictions for ASP, but this reliance has shortcomings. First, fellows and residents are only part-time staff, sometimes on very limited rotations, resulting in varying levels of ASP activities from month to month. Even in sites where the pharmacy residents are there for a full year, their time is not dedicated fully to ASP because they have multiple roles and responsibilities. Moreover, postgraduate year 1 (PGY1) pharmacy residents have not yet specialized and therefore may not be interested in ID. Second, when residents are new, physician acceptance of their recommendations is often low. As residents become known to the physicians and gain confidence in working with them, the acceptance of their recommendations increases. It takes time to build confidence and trust; when rotations are short, it is difficult. There was interest among some in changing fellowship and residency rotations to have a longer period, at least 6 months, available for ASP. However, others suggested that this may not be realistic, and that these types of rotations may be more applicable to a PGY2 pharmacy resident specializing in ID.

ASP may require other changes in professional training programs and educational materials. Shifting antibiotic approvals away from ID fellows to the dedicated ASP team (pharmacists and ID physicians) at least for portions of the day may change what has been a cornerstone of many ID fellowship training models. It allows the ID fellows more dedicated time to spend on consults and the ability to do more consults. When the fellows are involved in the approval process during evenings/weekends or as special rotations with the ASP team, their activity is supervised and can become an educational activity. As a result, aspects of the training program may need to be redesigned, including developing lectures/ curriculum for fellows on ASP topics. For other trainees (medical residents, medical students), there may be other advantages to having a small team from ASP taking all calls; it allows for a more consistent approach, provides some continuity for patient care, and allows the interactions to be more educational (there are now individuals whose primary responsibility is to approve antibiotics, rather than relying on fellows to be responsible for this activity, in addition to many others). Educational material may be needed that can be shared with callers regarding their patients and questions.

ASP brings organization and leverage. Having a formal ASP for reducing CDI allows more progress than the individual activities that may have been in place previously. For example, members of one ASP team reported that as ASP became more formalized, there was more organization to the ASP activities, including more specific roles for the pharmacists. The team felt the program had an impact on pushing institutional policies, with more success than before the ASP. The role of microbiology labs in ASP, for example, is illustrated by one site's recognition that when the microbiology laboratory implemented a more sensitive testing algorithm for CDI, the ASP team's input and involvement were welcomed. The ASP team helped educate providers on the proper use and interpretation of the testing, which in turn had implications for prescribing and other clinical practice decisions, including guiding treatment for CDI. This added to clinicians' confidence in the newer, more sensitive CDI methods and discouraged wasteful, repetitive CDI testing. As another example, during the seasonal or H1N1 influenza high activity times, the ASP teams helped clinicians understand the limitations of influenza testing and helped prescribers identify which patients to test and treat with antivirals.

Each hospital needs to prioritize and negotiate the scope of its ASP. The scope of ASP is potentially very broad; there are extensive questions about which responsibilities can realistically be assumed by stewardship. Several sites talked about wanting ASP to be an overarching program that would be more than simply approving drugs and lowering costs. But going beyond prescribing may lead to pushback, though it may also spark thoughtful consideration of procedures. In one site, the ASP committee wanted to perform piperacillin/tazobactam extended infusion therapy as an additional ASP strategy. However, nursing staff resisted because the nursing time required to set up the pumps with each patient would be lengthy as would the time each patient would require with the pump; the end result was believed to be unmanageable. Aside from the question of time and resource commitment, discussion of the recommendation revealed research[20] indicating that the medical outcomes from extended infusion were not quite as convincing as first believed.

Spread and sustainability require organizational support. Support from senior medical center leaders is a clear facilitator for ASP. In two systems, a person was specifically brought in to lead the stewardship initiative, suggesting its priority to the organization. However, in some other sites, clinical ASP leads were stretched thin with little administrative support. In certain other sites, the ASP leads fulfilled that role in addition to all their other duties. More broadly, beyond relying on fellows and residents, most sites had to be creative in finding staff resources.

Making the business case for ASP, usually by demonstrating cost savings, is critical although it may not always be successful. ASP is not always a high priority for senior leaders when it is competing against other initiatives for staff and IT resources. In one case, ASP did not make the capital budget list to obtain needed software applications—even though it could demonstrate a solid business case—because other resource needs were deemed more important.

Conclusion

ASPs offer potential for important benefits for reducing the use of targeted antibiotics that are strategically selected. Simple methods of conducting limited case-control studies are effective in identifying targeted antibiotics. At the same time, intervention implementation was typically more complex than envisioned, with most interventions taking longer to implement than expected. Each facility acknowledged that several supplementary stewardship activities,

including widespread education, were needed to implement the intervention. Gaining necessary approval for plans from committees, obtaining assistance from information technology staff, developing materials, getting buy-in from other prescribers, and educating involved staff about the intervention or intervention modification after pilot testing all served to extend the time required to fully implement the interventions. In some cases, a specific planned intervention had to be scuttled or received lower priority because of the success of other interventions or the need for other stewardship activities. While each participating hospital had to tailor its ASP to its unique staffing, resources, culture, and existing practices and relationships, there are common lessons to guide implementation. For hospitals and systems that want to pursue an antimicrobial stewardship program, the toolkit developed from the ERASE *C. difficile* Project can help guide them through the complexities of implementation.[21]

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Appendix. ASP local implementation strategies, interventions and resources

Site No.	Staffing Details	Education/Training/ IT Resources	Antibiotic Targets and Interventions	Stewardship Activity Details
1 & 6	• ID MD leadership, working closely with Pharmacy. • Residents have ID rotation but do not participate in ASP. • ID fellows participate in ASP for CDI; approve antibiotics on nights/weekends. • Large ID department, all on hospital staff: simple to disseminate ASP information but difficult to standardize prescribing (different teaching services).	**ID MD ASP lead:** • Provides extensive education, supported by informal individual conversations with house staff. Approval calls often lead to case discussions, which furthers education. • Provides education to nurses/nursing attendants to ensure they and prescribers understand interconnectedness of infection control, antibiotic use, and their own roles in those processes. • Works with coaches' interdisciplinary group—nurses, technicians who are not prescribers but serve as champions—to assist with promoting sensible infection control practices on the floors and to support stewardship activities.	**Fluoroquinolones:** Hospital-wide changes to azithromycin restriction to move prescribers away from fluoroquinolones. **PIP/TAZO (and other broad-spectrum empiric antibiotics):** Medicine services audit and feedback (sites 1 [mainly] and 6. Sepsis protocol in ED and Critical Care (site 1).	**Details:** ID MD and PharmD initially trained ID fellow, then trained clinical pharmacists; PIP/TAZO audit mainly on Medicine services. **How done**: • Specially trained ID PharmDs work closely with ID MD; complementary because difficult for PharmDs to approach MDs, hard for MDs to know all dosing specifics that PharmDs do. • Many services unified across sites for ASP. • As ASP is increasingly formalized, more organization in ASP activities and specific role for PharmDs. • ASP pushing institutional policies; harder to establish without ASP. • Interdepartmental collaborations with Intensive Care and Microbiology. • Site-specific details: house staff go between sites; pharmacy systemwide; infection control unified; Microbiology unified under lab at Site 1 with satellites at other locations. **Supporting activities:** • Review by P&T committee, formal medication reviews. • Algorithm preparation. • Extensive educational programs (talks, one-on-one discussions, dissemination materials, train-the-trainer). **Other stewardship activities during timeframe:** • Changes to surgical prophylaxis. • Ongoing work with ED—sepsis, community-acquired pneumonia. • PIP/TAZO extended infusion. • Extensive outreach/education on CDI and antibiotic use

Appendix. ASP local implementation strategies, interventions and resources (continued)

Site No.	Staffing Details	Education/Training/ IT Resources	Antibiotic Targets and Interventions	Stewardship Activity Details
2	• PhD (RPh) leadership with ID/MD backup. • Pharmacy residents on limited rotations; coverage only part of year. • No fellows, viewed by site ASP lead as limiting resources considerably. • Uses medical residents to help with ASP. • ASP committee meets quarterly and reports to P&T committee.	• Weekly grand rounds are ongoing opportunity to discuss ASP. • Guest speakers from ASPs at other facilities. • ASP lead distributes brochures to staff to reinforce learning. **IT:** • CPOE for past 3 years. • As part of electronic system, site uses externally-developed proprietary medication monitoring application that provides certain types of computer alerts, including hard stop for certain antibiotics. Process not controlled by pharmacy; alerts force MDs to think about intended use of antibiotics and thus contain use.	**PIP/TAZO (and other broad-spectrum antibiotics):** Hospital-wide audit of longer antibiotic courses (8-14 days). **Ciprofloxacin:** • Hospital-wide computer prompting for intravenous to oral therapy switches and also asks for reassessment of indications for drug. • Change antibiotic policy/algorithms from Ciprofloxacin for empiric antibiotics for urinary tract infection (UTI) and hospital-acquired pneumonia (HCAP).	**Details:** Audits supported by use of purchased data mining/ data surveillance software. Interventions supported by one PhD (RPh) and chief residents. **How done:** PharmD residents taught monitoring and how to interact with medical staff around ID issues and how to use the software; weekend rotations for both managerial and clinical role. **Supporting activities:** • Preparation of new treatment algorithm for UTI. • Preparation of updated treatment guidelines for HCAP. • Information technology support. • Review by P&T committee. • Extensive educational programs and train-the trainer sessions. **Other stewardship activities during timeframe:** Implemented requirement for indication for antibiotic orders.

Appendix. ASP local implementation strategies, interventions and resources (continued)

Site No.	Staffing Details	Education/Training/ IT Resources	Antibiotic Targets and Interventions	Stewardship Activity Details
3	• ID MD chief provides overall leadership with day-to-day operational leadership by ID MD and clinical pharmacist (driving forces for ASP). • Pharmacy residents on limited rotations—only part of year covered. • ID consultants consist of full-time, part-time, and adjunct ID faculty members.	**ASP lead:** • Trains fellows, including talking with them individually. • Gives lectures, talks on the floor to hospitalist, residents, and attending. • Looks for patterns in prescribing that are then brought to faculty development forum for feedback and review. **Senior ID MD:** • Provides "clinical cover" to assure physicians that changes are not having negative clinical outcomes. **IT:** • Computer system generates daily lists of patients on broad-spectrum agents along with demographic and diagnosis information. • No data mining software; dependent on human followup rather than computer alerts. • Clinicians prefer more targeted information, for example, regular reports that show data specific to their departments.	**PIP/TAZO (and other broad-spectrum antibiotics**): Hospital-wide restriction and audit and feedback.	**Details:** Overall limited resources: part-time pharmacist and ID physician; involvement of ID fellows. Interventions carried out by ID MD, PharmD, and ID fellows. **How done**: • Two ID rounding teams separate from ASP team; all in close physical proximity and work closely; formal discussions via twice weekly meetings/conferences and/or informally in day-to-day conversations. • Junior fellows spend time on floors; carry pager 1 of 4 weeks for consults, emergencies, and antibiotic approvals; discuss appropriateness of requested antibiotic with prescriber and screen for potential problems; month-long turns to (1) review cultures (thus more flexibility for phone consults; and (2) go on floors to track down house staff. • Fellows make recommendations on those cases where ID official consultation is already involved in case (fellows not called if antibiotic approved by ID faculty member); senior personnel readily available for consults. • Fellows carry list of patients and currently prescribed antibiotic; aware of restricted agents; approval number needed for computer entry, and there is a stop on pharmacy end if something is not on approved list. • Audit/review: ID MD and pharmacy make recommendations re: dose adjustment, de-escalation, and early discontinuation of antibiotics as indicated. Interventions made on wide range of antimicrobial agents including cefepime (cefepime increase when PIP/TAZO restricted), carbapenems, fluoroquinolones. **Supporting activities:** • IT support (for paper audit lists). • Review by P&T committee. • Extensive educational programs and train-the-trainer sessions (ID fellows trained to do approval review). **Other stewardship activities during timeframe:** • Use of antibiotic prescribing data. • Select audit/review of other agents (cefepime increase when PIP/TAZO restricted). • Education of newer prescribers on staff.

Appendix. ASP local implementation strategies, interventions and resources (continued)

Site No.	Staffing Details	Education/Training/ IT Resources	Antibiotic Targets and Interventions	Stewardship Activity Details
4 & 5	• ID MD chair works closely with interdisciplinary team (ID MD chair, clinical pharmacy manager, nurse epidemiologists, director of microbiology) that meets regularly to allocate resources, make assignments, and provide coverage when needed. • PGY-1 pharmacy residents with 1-year rotations and 3 ID fellows. ASP done as part of standard training or longitudinal rotation or projects. • The ID MD lead believes his longevity at hospital has permitted establishment of a strong rapport with all other ID MDs.	**Senior ID MD:** • Presents grand rounds on ASP to combined Departments of Medicine and Pharmacy. • Meets with pharmacy personnel on multiple occasions. **Clinical pharmacy manager:** • Provides education for pharmacy residents, other pharmacy staff, and ID fellows. • Prepares educational materials related to ASP and to appropriate antibiotic usage and monitoring for distribution to all institution personnel via Pharmacy newsletter. **ID fellows:** • Present to medical residents at general orientation; do approvals for restricted antibiotic agents that provide another opportunity for education. **Pharmacy residents:** • Required to participate in trainings, readings, and participatory events hosted by Pharmacy Department.	**PIP/TAZO:** Hospital-wide restriction. **Cefepime:** Hospital-wide (sites 4 and 5) audit and feedback and expanded focus in MICU (site 5) (de-escalation).	**Details:** Overall limited resources. Interventions: ID MD, PharmD, and pharmacy residents (limited dedicated time for ASP activities); ongoing prior activities, including highly restrictive formulary, resulted in significant decrease in CDI rates. **How done:** • Pharmacy residents play key role in ASP by conducting prospective audit of target antibiotics with feedback to prescribers; target drugs and antibiotics; review all patients. If difficulty is encountered or suggested intervention is rejected, referred for review to higher level. (i.e., stewardship team oversight). • Pharmacy residents divide stewardship activities by geographic site; residents may be site-specific. • Pharmacy residents' interaction with MDs generally positive; easier when rounding in person, more difficult to suggest intervention by phone; face-to-face interactions facilitate acceptance of recommendations. • Interactions depend on service, MDs, and how they round; walking rounds and sitting rounds have different processes, and topics or concerns are brought up differently. • Residents may make recommendations in different ways: while rounding, from office if not on rounds; recommendations may go directly to the medical resident. Residents may page the stewardship member overseeing if recommendations are not accepted. The stewardship team member may need to reach out to house staff or the teaching attending on behalf of the ASP to influence change in prescribing. • Much of ASP work involves looking at many patients receiving an antibiotic to find the specific patient where an intervention is possible; not being advanced electronically is work intensive and inefficient (despite partial electronic medical record).

Appendix. ASP local implementation strategies, interventions and resources (continued)

Site No.	Staffing Details	Education/Training/ IT Resources	Antibiotic Targets and Interventions	Stewardship Activity Details
4&5 (cont.)		**IT:** • No data mining/data surveillance to identify patients who might benefit from intervention at this time; current process of reviewing broader sets of patients is very time consuming. Pharmacy is on the IT list to develop needed queries for patient clinical information systems; level of priority unclear. Some queries have now been formulated that lay the groundwork for future additional needed lists or IT support. The team may not have all needed IT information.		**Supporting activities:** • Information technology support (for paper audit lists). • Review by antibiotic subcommittee of P&T committee. • Extensive educational programs and train-the-trainer sessions (pharmacy residents), extensive ID MD education/mentoring in ICUs. **Other stewardship activities during timeframe:** • Implemented additional education for house staff. • Implemented requirement for indication for antibiotic orders.

Abbreviations: ASP = antimicrobial stewardship program; CDI = *Clostridium difficile* infection; CPOE = computerized physician order entry ED = emergency department; HCAP = hospital-acquired pneumonia; ID: infectious disease; IT = information technology; MICU = medical intensive care unit; P&T = pharmacy and therapeutics; PGY-1 = postgraduate year 1; PIP/TAZO = piperacillin/tazobactam; UTI = urinary tract infection.

Studying HAI Prevention Efforts to Learn From Experience: Methodological Opportunities and Challenges

Ann Scheck McAlearney, Julie Robbins

Abstract

Central line-associated blood stream infections (CLABSIs) are a leading cause of healthcare-associated infections (HAIs), preventable deaths, and excess health care costs in U.S. hospitals. To address this issue, many hospitals are adopting evidence-based interventions designed to reduce and prevent CLABSIs, but success with intervention implementation has been mixed. Our study was designed to explore the role of management practices in facilitating successful adoption of evidence-based interventions among hospitals participating in statewide CLABSI prevention collaboratives. We completed a multi-site case study investigation including eight hospitals, matched on level of reduction of CLABSI infection rates achieved during their participation in State collaboratives. Over the eight 2-day site visits, we conducted 194 in-person interviews with a mix of clinical and administrative key informants. We found that while our qualitative methodology provided rich insight into factors that affect successful adoption of evidence-based CLABSI prevention standards, we also encountered methodological challenges associated with study design, implementation, and analysis. Taking into account lessons learned—such as the importance of maintaining flexibility and developing an ability to "learn on the fly" during site visits, and being sensitive to the need to manage a large quantity of data and prioritize data analyses—can help guide future studies of HAI prevention and research focusing on implementation of evidence-based interventions. Conducting site visits guided by rigorous qualitative methods is an effective way to study HAI prevention efforts, but future investigations could take into account lessons learned in our study to increase the likelihood that research aims will be achieved.

Introduction

Central line-associated blood stream infections (CLABSIs) are a leading cause of healthcare-associated infections (HAIs), preventable deaths, and health care costs in hospitals.[1,2] In the past decade, the number of CLABSI infections that occur in intensive care units (ICUs) has been reduced significantly due to widespread adoption of evidence-based practices, such as provider education, standardization of processes, and the use of checklists to ensure practice consistency.[1–4] Widespread implementation of these practices has been supported through coordinated quality improvement initiatives at the State and local levels.[5] These efforts have contributed significantly to an estimated 58 percent decline in CLABSIs among patients hospitalized in ICUs in the United States between 2001 and 2009.[5] However, the results have not been uniform; some hospitals have virtually eliminated CLABSIs in their ICUs, while others continue to struggle in their efforts to prevent these infections.[6]

In an effort to better understand this variation and the factors that contribute to hospitals' successful implementation of evidence-based CLABSI prevention practices, we examined whether and how management and organizational factors facilitate successful CLABSI

prevention, an emphasis that has not been considered in the literature. Given the exploratory nature of our inquiry, we used a multi-site case study design and rigorous qualitative methods for this research. We conducted in-depth case studies of CLABSI prevention efforts in eight hospitals to obtain insight into both the facilitators of and barriers to these efforts.

Our study design and methodology constitute an approach that may have applicability for future efforts to study the prevention of CLABSIs and other HAIs. The purpose of this paper is to share insights about the value of this methodological approach for studying HAI prevention in hospitals and to highlight issues that may influence the implementation and impact of this approach. The information and insights we provide should be of immediate use to those involved in efforts to study factors contributing to the success and failures of HAI prevention initiatives, and may have particular value to investigators and policymakers attempting to make sense of the variable levels of success appearing across hospitals, ICUs, and initiatives.

Methods

Case Study Sample

As a first step in designing this study, our research team sought to study organizations that had equal access to similar evidence-based CLABSI prevention guidelines. Consequently, we focused our study on hospitals that had participated in the national, AHRQ-funded project "On the CUSP: Stop BSI" (henceforth referred to as CUSP). This project provided funding for State efforts to disseminate and support implementation of evidence-based CLABSI prevention guidelines.

To minimize differences in timing of CUSP implementation and maximize the opportunity to track related CLABSI outcomes, we decided to study organizations from States that had participated in the first two cohorts of CUSP and completed their participation prior to the commencement of our research. Working with the CUSP project leadership team at the Healthcare Research and Educational Trust (HRET), we identified and selected four States that would (1) provide variation with respect to implementation experience and (2) be most likely to support this research and participate in the study.

Site Selection

To select hospitals for the study, we used CUSP project data that included CLABSI rates and hospital characteristics to categorize hospitals from the four targeted States. We aimed to develop a final sample of "contrasting cases."[7] Thus, we identified pairs of potential sites that had contrasting CLABSI outcomes but were matched on key organizational characteristics (i.e., size, rural vs. urban, teaching status). Our review of the CLABSI outcomes data showed that hospitals indeed had differential CLABSI prevention outcomes, despite following similar evidence-based intervention protocols; we were able to classify hospitals as "good" or "less good" on this basis. In general, the "good" sites had been able to achieve zero CLABSIs and then sustain this rate, except for the occasional anomaly for a few sites during and following CUSP implementation. By contrast, although many of the "less good" sites had reduced CLABSI rates over time, their data trends suggested that they had experienced difficulty reaching zero CLABSIs, had inconsistent results over time, and/or had inconsistent rates across their ICUs. As a final step, we obtained subjective input from State-level CUSP coordinators to confirm that the sites we selected were appropriate for study and would be likely to agree to participate.

Case Study Key Informants

The main source of data for the study was interviews with key informants, conducted during 2-day site visits to each of the case study organizations; all eight site visits were completed between June 2011 and October 2012. At each participating hospital, the research team identified a single contact person and then worked with that person to coordinate the site visit and the key informant interviews. Appropriate key informants were identified by the hospital contact person, guided by a list of target key informants that had been prepared by the research team. Target key informants for each site included executive leaders (e.g., chief executive officers, chief medical officers), managers involved in CLABSI prevention efforts (e.g., ICU directors and nurse managers), and frontline clinicians (e.g., ICU physicians and nurses) and staff (e.g., infection prevention, quality improvement) directly involved in or impacted by these efforts.

Case Study Data Collection

To ensure consistency in the data collection, we used a standard guide to conduct interviews, while recognizing that the specific focus of the questions would vary based on the informant's role in the organization. The interviews included questions about the organization's approach to CLABSI prevention, facilitators of and barriers to these efforts, considerations about sustainability, and lessons learned. The interviews were recorded and transcribed to ensure accuracy and reliability.

Analyses

The primary goal of this paper is to provide insight about the applicability of a qualitative case study methodology to investigate CLABSI prevention; the specific findings from our overall research study will be presented elsewhere. Thus, for the results we report in this paper, members of the research team reviewed project notes and reflected on our experiences conducting the multiple site visits and considered the opportunities, issues, and lessons we learned with respect to applying case study methods to investigate HAI prevention initiatives.

Results

In the sections that follow, we present our findings that highlight the value of the case study approach for investigating CLABSI prevention efforts and identify specific challenges and lessons learned that may be applicable to similar efforts in the future.

Value of Case Study Research

First, our sample of eight hospitals proved to be sufficient and robust, offering a breadth of perspectives and rich insight into CLABSI prevention efforts. As a result, we were able to complete in-depth analyses of the key issues that had been the initial focus of our study and to explore issues that emerged throughout the project. The sample also provided sufficient evidence to support "theoretical replication" of themes across sites, thus enhancing the validity of our analyses and the potential generalizability of our findings.[7]

Second, we found that we reached a point of saturation when conducting our key informant interviews; by the end of each site visit, we were no longer learning any new information from interviews at that site; instead, we were gathering additional evidence that strengthened our findings.[8] As a result, we are confident not only that we spoke with a sufficient number of

informants at each site, but that we spoke with the "right" informants. This finding confirms the robustness of the sample and adds credibility to our conclusions.

Finally, our research was designed to provide flexibility to explore themes that emerged during the course of the site visits, and this indeed occurred. For instance, while we did not initially expect that exploring differences between ICUs would be feasible or informative, we found that this was possible and enhanced our findings. Overall, our use of a semi-structured interview guide permitted us to maintain consistency in our inquiry across sites but also enabled us to be flexible as we sought to explore emergent issues and themes.

Challenges and Lessons Learned

We encountered challenges throughout all phases of this case study research project—particularly around study design, study implementation, and analysis. We present these challenges, and our strategies for overcoming them, as valuable lessons learned that (1) improved the reliability and validity of our findings, and (2) may inform future, similar research efforts. We summarize these challenges and lessons learned in Table 1 and further describe each individually below.

Table 1. Overview of key challenges and how they were addressed, by research phase

Research Phase	Key Challenges	How Addressed
Study Design	1. Selecting States 2. No objective criteria for identifying "good" vs. "less good" sites	• Methods, problems, solutions documented and applied consistently
Study Implementation	1. Securing site participation, reliance on individual site liaisons 2. Determining the "right" key informants 3. Interviewing frontline staff 4. Learning "on the fly" 5. Unexpected variation in sample (CUSP, good vs. less good, organizational match)	• Standardized communication messages, persistence • Flexibility before, during and after site visits • Diligent recording of site visit summaries
Analysis	1. Prioritizing analyses and focus of findings 2. Volume of data and analysis opportunities	• Robust analytic and manuscript development plan

Study Design Challenges

Selecting States. Despite having objective criteria, we quickly realized that subjective factors were equally important in the site selection process. For instance, given that an important factor impacting our research was the ability to successfully recruit States/hospitals to participate in our study, we sought guidance from the CUSP national project office staff (HRET) to identify States that would provide the best fit for our study. As a result, the subjective factors that we considered when selecting States for participation included State-level coordinator receptiveness and willingness to help, competing priorities and initiatives within a State, and perceptions about the level of hospital engagement in CUSP within each State. These factors proved important and

influenced our selection process. One State coordinator expressed reluctance to participate in our project because he did not want to ask the participating hospitals to "do one more thing." Another State coordinator expressed enthusiasm for participating in our project but took nearly a year to follow up and recruit individual hospitals because of competing priorities within the State. We addressed these challenges either by working directly with the State coordinators to resolve them or by circling back to the CUSP national project office staff to consider alternatives.

Defining "good" vs. "less good." Although we initially sought to use CUSP project data to identify "good" and "less good" project sites, we quickly realized that we could not rely on the CLABSI rates alone to identify well-matched hospital pairs that would satisfy our research objectives. For example, while many hospitals in the sample had zero CLABSIs during the 18-month study followup period, many of these hospitals also did not have any infections during the 12-month baseline period. This was due largely to their small size and low patient acuity, which contributed to a relatively low risk for CLABSIs overall. Thus, while these hospitals met the criterion for having "good" outcomes, their experiences were clearly not aligned with our research objective; as a result, hospitals with zero CLABSIs during the baseline period were excluded from participation.

A more detailed analysis of the data on CLABSI rates suggested that hospital size or type could affect both baseline and followup infection rates. For instance, many large academic medical centers had baseline CLABSI rates that were well over five infections per 1,000 line-days, while many smaller community hospitals' baseline rates were lower than two infections per 1,000 line-days. Consequently, we decided first to group the hospitals on the basis of these organizational characteristics and then to select the pairs of "good" and "less good" hospitals from these groupings. We also sought subjective input from State-level coordinators, asking for their perspective about which hospital pairs would be a good match for our study and also would be likely to participate. Our experience highlighted that even when objective data are available, a more purposive selection approach focused on overall study goals may be an important consideration if the aims of a study are to be achieved.

Study Implementation Challenges

Securing site participation. We identified several common challenges in attempting to secure hospitals' participation as case study sites. First, our site contacts were typically individuals who had served as lead representatives for their hospitals' participation in the statewide CUSP project. Although very knowledgeable about the CLABSI prevention efforts at their organizations, they typically were staff-level professionals (e.g., infection control, quality improvement) with little research experience; more importantly, they were not empowered to make a hospital-level commitment to participate in our study. To address this challenge, we developed several communication resources (e.g., a one-page description of the project and the benefits of participation) that our site contacts could use to encourage project participation within their hospitals; these resources were well-received and made a difference with respect to our ability to secure commitments to participate.

Another frequent challenge in securing site participation was related to competing priorities within the hospitals and/or their ICUs. For instance, several of the hospitals that we approached either resisted or delayed participation due to conflicting priorities, such as accreditation

activities, unit-based electronic health record (EHR) system implementation, and other pressing clinical priorities. In nearly all cases, we were able to secure participation by recognizing the importance of these conflicts, being flexible with our timeline, and being politely persistent when reaching out to sites.

Finally, although our research team had institutional review board (IRB) approvals from our own institutions, at least three of the sites required that we obtain approval from their hospital IRBs prior to beginning our research. This created an extra step in the process and resulted in time delays that had to be accommodated in the project timeline.

Identifying the "right" key informants. Although we had a list of target key informants based on job titles, as previously described, we learned that there was considerable institution-specific variation with respect to identifying the "right" informants who would be able to discuss CLABSI prevention efforts. Key considerations included the degree to which the project was a top leadership priority, physician involvement, and the structure and role of professional staff departments such as infection control and quality improvement. As we gained experience across the sites, we modified our list of target key informants, but we also realized that the best strategy was to clearly communicate that we were interested in talking to the "right" informants at all levels and then to defer to the site-based contacts with respect to their judgment and institutional insight about whom we should interview.

Interviewing frontline staff. Because implementation of evidence-based CLABSI guidelines requires significant changes to workflow and clinical relationships, we were very interested in interviewing frontline clinicians and staff. At the same time, we recognized that the clinical demands on these staff would, and should, take precedence over our research. For example, given the intensity of the ICU workload, it was often difficult for frontline nurses to know whether they could spare 30 minutes to speak with us on any given day or to predict a good time to do so. We addressed this challenge by developing a flexible strategy in which the research team would schedule a block of time to complete interviews in a unit-based location (e.g., conference or break room in the ICU). Then, instead of meeting with a predetermined list of individuals, we were available to interview any staff member(s) that unit leaders had identified as having some slack time during our time block. These interviews often took the form of small group sessions in which participants came in and out based on their clinical demands at the time. In general, this flexibility resulted in some trade-offs between depth and breadth of perspectives (e.g., some interviews were shorter than we would have liked), but the research team ultimately concluded that this approach offered an unobtrusive way to successfully obtain perspectives from frontline clinicians.

Two process management strategies contributed to our success in applying this approach. First, the primary interviewer had to be flexible during the interviews, prioritizing questions based on participants' availability. Second, another member of the research team served as a "greeter" for new participants, introducing the project and completing the informed consent process in a side conversation so as not to interrupt the flow of the ongoing interview. While this interview approach might not be possible for all qualitative investigators, the experience of our research team and the adaptability of our individual interviewers enabled us to successfully modify our standard interview protocol and accomplish the aims of our study.

Learning "on the fly." All members of the research team were scholars with doctorate-level training in health care management and had extensive practical and research experience in a variety of clinical settings. While this mix of skills and experience qualified us to conduct our inquiry into the management factors related to successful CLABSI implementation, no member of the team had specific experience related to ICUs or infection control. Therefore, one of the biggest challenges for the team at the outset of our investigation was the clinical nature of the research context and the highly technical focus of many of our informants (e.g., frontline nurses). To prepare for the site visits, we conducted extensive background research to learn about CLABSI prevention and familiarize ourselves with key clinical terms. Yet, once we started the interviews, we realized that there was often a local clinical language and shorthand (e.g., acronyms and institution-specific terms) that we could not have studied or anticipated prior to visiting the individual sites. We managed this challenge in three ways, by: (1) emphasizing at the outset of each interview that we were not clinicians, thus setting the stage for what we might know and not know; (2) asking clarifying questions when necessary for us to effectively conduct our inquiry regarding the organizational dynamics related to CLABSI prevention; and (3) simply listening and learning "on the fly," distilling what was important in the course of the interview and the site visit through repetition and context. For instance, during one of the early site visits, we were introduced to the term "scrubbing the hub," a shorthand term for a specific infection control practice for maintaining central lines. Although we did not fully understand the clinical details of this practice, we asked for clarification and were able to quickly assess that this was an important component of CLABSI prevention efforts and, in some cases, represented a major change in practice. We carried our learning forward when we heard this term being used in many of the subsequent site visits.

Unexpected variation in sample. Despite our best efforts in the site selection process, we encountered unexpected variation among the hospitals in our sample. Most notable was that one of the sites we had selected as "less good" had made a complete turnaround with respect to CLABSI prevention practices by the time of our site visit. Although this site had struggled during the formal CUSP initiative, the hospital had made major changes since its completion. As a result, by the time of our site visit, this hospital appeared to have become a "good" site, based on its own CLABSI outcomes data and insights about the changes made in the intervening months. While our study benefited from the opportunity to learn from a site that had experienced a turnaround in performance with its CLABSI prevention efforts, this finding challenged our "contrasting cases" study design. As a result, we reclassified this site as "good" in all of our analyses, leaving us with three matched pairs and an additional two "good" sites.

We also observed considerable variation in perceptions between, and even within, the study hospitals regarding their role and participation in the CUSP initiative. In some hospitals, and for some informants, project participation was widely recognized and acknowledged; however, in other hospitals, mentioning anything about CUSP resulted in blank stares from many interviewees. This surprising finding challenged our assumption that selecting sites on the basis of CUSP participation would ensure similar baseline levels of access to information and resources regarding CLABSI prevention. We are conducting more in-depth analyses to determine whether there are any systematic differences in CUSP awareness between the case study sites with "good" and those with "less good" CLABSI outcomes.

Analysis Challenges

Focus and priority. Our analytic priority from the outset was to focus on contrasts between the sites with "good" outcomes and those with "less good" outcomes to identify management factors that influence successful CLABSI prevention efforts. However, as with all exploratory studies, some of the most interesting analytic points emerged as the study progressed—for example, issues related to unit-level variation, differences in perceptions based on organizational roles, and differences in implementation of specific practices. While we knew that the study would provide insight about CLABSI prevention efforts, the research team was able to confirm the potential broader applicability of our findings for other HAI prevention and clinical quality improvement efforts.

Quantity of data. With nearly 200 key informant interviews and over 1,500 pages of transcripts representing a wide variety of perspectives from eight different case study sites, the research team has a very robust qualitative database that will support our ability to complete reliable and valid analyses and widely disseminate our findings to relevant audiences. At the same time, the research team faces the (welcome) challenge of managing and making sense of our abundant data; as a result, we have developed a prioritized list of dissemination targets based on project goals, timeliness and potential impact of results, and breadth of scope. While we have not yet published findings from this recently completed study, we have several manuscripts under review and additional analyses underway. Our overarching analytic priority is to identify the factors that differentiate the hospitals with "good" from those with "less good" outcomes and to develop nuanced insight into the factors that support successful CLABSI prevention efforts. From a management perspective, we have had to develop a strong data management system that includes a systematic process for protecting confidential information, efficiently managing data files, and expanding and building the capabilities of our analytic team to support the necessary work.

Discussion and Conclusion

In this paper, we present an important approach to studying factors that influence hospitals' efforts to prevent and reduce CLABSIs. Our qualitative case study methodology produced data that increased our understanding of the organizational factors and management strategies that affect CLABSI prevention efforts. These findings have direct applicability to organizations seeking to prevent CLABSIs but also may provide insight into other similar efforts related to HAIs or other patient safety priorities.

The goal of our paper has been to share what we have learned about the value of this method, the associated challenges, and the "lessons learned." Based on our experience with this research, we believe that our study design and method could be effectively employed by researchers seeking to study the implementation of other evidence-based clinical interventions; further, this approach may be applicable in non-hospital contexts to the extent that consistent clinical guidelines exist and are widely disseminated in those settings. We have highlighted some of the ways in which site visits and qualitative methods can help achieve the aims of HAI prevention research and hope that these insights will be useful for other researchers seeking to pursue this kind of research.

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Section II. HAI Risk Identifiction for Quality Improvement

Building Capacity in HAI Prevention Research: NICHE and the STOP CAUTI Workgroup

Heidi Wald, Angela Richard, Brian Bandle, Regina Fink, Marie Boltz, Sung-Joon Min, Elizabeth Capezuti

Abstract

Catheter-associated urinary tract infections (CAUTIs) are common among frail elders. CAUTI prevention relies on evidence-based nursing practices, few of which have been subject to multisite study. A cornerstone of prevention, surveillance can be used to provide feedback performance improvement. Researchers at the University of Colorado partnered with the Nurses Improving Care of Healthsystem Elders (NICHE) program to create the STOP CAUTI Workgroup to implement and test the impact of electronic surveillance of indwelling urinary catheter (IUC) use and CAUTI rates. Development of the STOP CAUTI Workgroup was based on a modification of the Johns Hopkins Hospital collaborative model, through a process to engage, educate, and establish an administrative framework prior to embarking on the study's execute and evaluate phases. Recruited from among 245 NICHE member hospitals, 20 hospitals completed all steps required to participate in the cluster-randomized controlled trial of audit and feedback in the reduction of CAUTI among hospitalized patients. In this paper, we detail the engage, educate, and establish stages of the project.

Introduction

Hospitalization of older people carries a high risk of iatrogenic events, including pressure ulcers, falls, and hospital-acquired infections.[1] These healthcare-associated conditions (HACs)—increasingly recognized by the larger medical community as unacceptable harms of medical care—are incorporated into quality measurement and value-based purchasing initiatives.[2] Among HACs, catheter-associated urinary tract infections (CAUTIs) have received particular scrutiny. CAUTIs number over 500,000 cases per year in U.S. hospitals, accounting for 80 percent of nosocomial UTIs and 40 percent of all nosocomial infections.[3] CAUTIs result in increased antibiotic use, prolonged hospitalizations, more severe infections, and occasionally death.[4] They are expensive, resulting in a mean additional cost of $589–$656 per hospital stay[4,5] and estimated costs to the U.S. health care system of $424 million dollars annually.

Despite these risks, the use of indwelling urinary catheters (IUCs) in hospitals is commonplace, and evidence exists that their inappropriate use is widespread.[6] An estimated 25 percent of all hospitalized patients have IUCs, and elderly patients are more likely than younger patients to be catheterized and develop CAUTIs.[7] Elderly patients catheterized without a specific medical indication are more likely to die and to have longer hospital stays than those without catheters.[8] CAUTIs and IUCs may result in additional geriatric HACs, such as pressure ulcers and delirium.[9,10]

Concurrent, laboratory-based surveillance is central to CAUTI prevention efforts, but it is resource-intensive. Recent incentives have served to increase surveillance in intensive care units (ICUs).[11] In the absence of data on catheter use and CAUTI rates, hospitals are unable to assess

the impact of prevention initiatives. Electronic health records (EHRs) promise advances in efficiency and standardization of surveillance.[12] However, this approach is untested.

Surveillance is a necessary but insufficient component of an effective infection control program. Evidence-based CAUTI prevention strategies fall into one of three categories: (a) avoidance and alternatives, (b) evidence-based care, and (c) early removal.[13,14] Many of these strategies are poorly adopted.[15] The best single-institution studies suggest that multicomponent interventions can successfully reduce the rates of CAUTIs by 60 to 70 percent.[16,17]

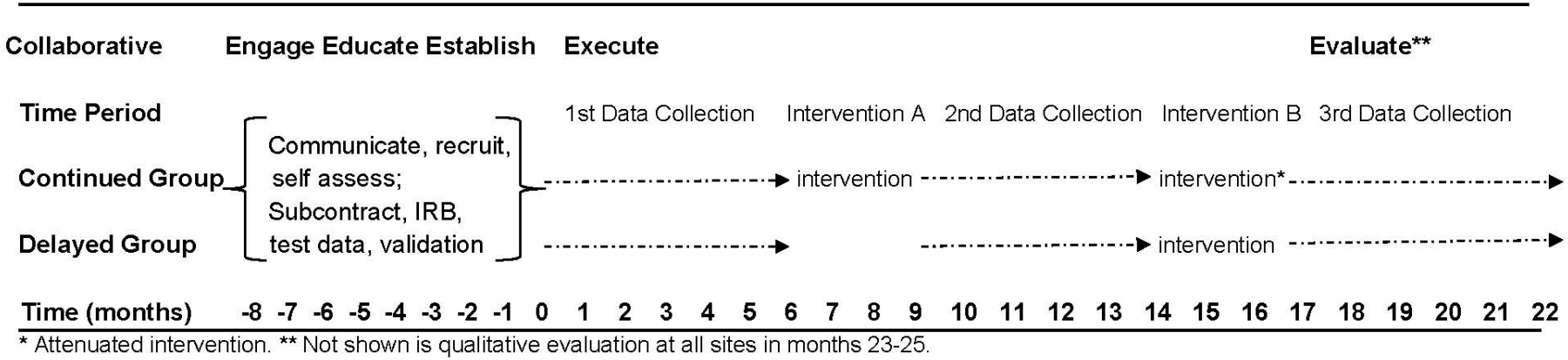
CAUTI prevention strategies highlight the critical role of high-quality nursing care in patient safety efforts. Many HACs are considered nursing-sensitive quality indicators. To successfully combat CAUTI and other HACs, a focus on building gerontological nursing capacity is crucial. Nurses Improving Care of Healthsystem Elders (NICHE) is a national program that provides educational resources to member hospitals about evidence-based geriatric nursing practice, focusing on the reduction of negative outcomes commonly experienced by older hospitalized patients. All NICHE hospitals support a local nurse coordinator.[18] Thus, NICHE is well situated for the conduct of multisite quality improvement research targeted at geriatric HACs.

Approach

Project leaders chose a focus on early IUC removal in at-risk patients as the primary approach to CAUTI prevention because catheter duration is an important modifiable CAUTI risk factor.[19] Audit and feedback of performance measures have been shown to be effective as a quality improvement strategy in health care.[20] We postulated that the audit and feedback of IUC duration and CAUTI rates would lead to reductions in IUC duration and CAUTI incidence. This project, Surveillance and Tracking to Prevent CAUTI (STOP CAUTI), had two aims: (1) to disseminate an electronic method for tracking IUC duration and CAUTI surveillance, and (2) to determine the effect of data feedback care processes (IUC duration) and outcomes (CAUTI). We developed a multi-hospital collaborative within NICHE, the STOP CAUTI Workgroup, and conducted a cluster-randomized, controlled trial of audit and feedback of process and outcome measures in CAUTI prevention. Upon entry into data collection, sites were randomized to continued or delayed intervention. Figure 1 illustrates the project's design and associated timeline.

Substantial evidence exists that collaboratives of care providers designed to collect and share information can be effective in improving health care outcomes.[21] To develop the STOP CAUTI Workgroup, we employed a modification of the Johns Hopkins Hospital collaborative model, which consists of four steps: engage, educate, execute, and evaluate.[22] Because this research study required significant work to prepare for data collection, we added an additional "E," for "establish" (administrative framework).

In this paper, we describe the development of the STOP CAUTI Workgroup with regard to the following activities: engage and educate (recruitment, communication, and self-assessment) and establish administrative framework (contractual and regulatory oversight, validation of key data



* Attenuated intervention. ** Not shown is qualitative evaluation at all sites in months 23-25.

Figure 1. STOP CAUTI project design and timeline

fields and processes). Facilities participating in these activities were positioned to take part in the execute and evaluate steps of the collaborative model—in this case, the cluster-randomized controlled trial of the effect of audit and feedback on IUC use and CAUTI rates among hospitalized patients.

Methods

Engage and Educate

Recruitment

An email call for interested facilities was issued to NICHE hospitals. NICHE coordinators who responded were provided with a detailed project description and invited to participate in an informational webinar. Those who retained a high level of interest were provided with additional information on the project's background, objectives, and timelines and participants' responsibilities. Hospitals agreeing to participate signed a letter of commitment that described in detail the responsibilities of study hospitals and the University of Colorado/NICHE study team.

Communication

Monthly conference calls and webinars provided a forum for exchange of information about the study, support and encouragement for achieving study milestones, education about the study topic and research methods, and facilitation of an esprit de corps among participating hospitals. A study website provided access to study materials and relevant links.[a] The study team maintained active email and telephone communication with NICHE coordinators and other hospital project staff, including participating information technology (IT) personnel. Additional steps to encourage active engagement included followup letters to chief nursing officers and face-to-face lunch meetings at NICHE annual conferences.

Self-Assessment: The STOP CAUTI Current Practice Survey

NICHE coordinators (n=20) were invited, in December 2009, to complete an electronic survey about baseline CAUTI prevention practices. The 25-item survey instrument, informed by an evidence-based literature review,[13,23] was developed in the fall of 2009 and reviewed by an expert panel of nurse researchers, infection preventionists, and a physician prior to pilot testing. The instrument consisted of both quantitative and qualitative questions on IUC care practices including (1) equipment and alternatives to catheters, insertion practices, and maintenance techniques; (2) personnel, training and education, and catheter policies; and (3) documentation, surveillance, and removal reminders.

Respondents were encouraged to gather responses to survey items from relevant sources (e.g., nurses, infection preventionists) prior to completing the survey. They also were asked to send a copy of their hospital's current policies and procedures on IUC placement and management and CAUTI prevention. Email reminders were sent at 2 and 4 weeks post-survey launch. Data were entered into an SPSS database (version 17); survey items and demographics were summarized using descriptive statistics and tests of difference and association.

[a] University of Colorado School of Medicine. NICHE: Nurses Improving Care for Healthsystem Elders. Stop CAUTI. Available at www.ucdenver.edu/academics/colleges/medicalschool/departments/medicine/hcpr/cauti/Pages/default.aspx. Accessed February 5, 2014.

Establish Administrative Framework

Regulatory Oversight, Subcontracts, and Data Use Agreement

The Colorado Multiple Institutional Review Board (COMIRB) approved STOP CAUTI Workgroup activities under an expedited review process for the study coordinating center at the University of Colorado (CU), with waivers of HIPAA (Health Insurance Portability and Accountability Act of 1996) authorization and informed consent. In addition, each STOP CAUTI Workgroup hospital was asked to obtain local IRB review. Several participating hospitals were required to obtain authorization from internal nursing research committees prior to IRB review. The NICHE coordinators' experience with IRB processes varied widely. The CU study team provided technical support to the NICHE coordinators during this process by supplying the COMIRB expedited review application, responding to requests for additional information, reviewing hospital IRB applications, and developing responses to hospital research committee and IRB questions.

In addition, subcontracts were required with CU, the prime contractor, to partially compensate hospitals for time spent on study activities. A template subcontract and budgeting spreadsheet were provided by the study team, and a data use agreement was appended to each subcontract. The study team provided substantial support to NICHE coordinators in moving these processes forward.

Data Collection Protocol

Implementation of the data collection protocol was facilitated by the creation of a detailed data collection manual and webinars for IT personnel from each study site. The protocol specified (a) definitions of data elements, (b) validation procedures for IUC documentation, (c) report creation, (d) manual data collection, and (e) use of the REDCap (Research Electronic Data Capture) Send-it Tool for transmitting data files (a secure Web-based application designed to support data capture for research studies).[24] Individual consultation was provided to IT staff at each hospital on the best methods for extracting EHR data elements and/or obtaining data manually. The STOP CAUTI sites submitted test data files prior to beginning actual data collection. Four sites without EHRs and one site with an EHR that could not provide reports were given detailed procedures for manual abstraction of data.

Validation of Data Elements

Hospitals that extracted data from EHRs were required to validate IUC documentation for each study unit prior to beginning data collection. The audit methodology was detailed in a series of conference calls and in the study data collection manual. The audits, conducted by nursing research or infection control personnel, occurred at the same time each day for a period of 1 to 4 weeks. During this time an auditor queried the EHR for IUC documentation for each patient on the study unit. These findings were compared with a manual clinical assessment, which was considered the gold standard for the validation. The manual clinical assessment consisted of a direct query of the patient's nurse about the presence or absence of an IUC for each patient on a given day. Because nurses provided direct care for IUCs, they generally had visualized the IUC themselves or received sign-out from the earlier shift regarding any voiding or IUC issues. If the nurses did not have knowledge of the IUC information, they generally consulted handwritten notes or the certified nursing assistants, or they returned to visualize the patients themselves.

Hospitals conducted one of two types of audits. For sites where the IUC insertion and removal dates were extrapolated from daily nursing assessments, a validation was performed to verify the accuracy of the daily nursing assessment fields documenting the presence of an IUC. For sites where the catheter insertion and removal dates were directly taken from discrete date fields, the insertion and removal date fields were validated independently.

The nurse report was considered the gold standard test for the presence, insertion, or removal of an IUC. To assess the validity of IUC EHR documentation against the gold standard (Type I validation), we calculated a raw percent agreement. Values 90 percent or greater were considered excellent agreement; 75 percent to 89 percent, good agreement; and less than 75 percent, poor agreement. In addition, we reported sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). To assess the validity of insertion and removal date fields (Type II validation), we calculated raw percent agreement, sensitivity, and PPV. Because these validations were performed only on patients with catheters, specificity and NPV were not reported.

Results

Engage and Educate

Recruitment

Among the 245 NICHE member hospitals, 40 indicated interest, 21 submitted letters of commitment, and 20 completed the steps necessary to enter the study. Table 1 provides details about the STOP CAUTI hospitals and study units. When compared to the typical NICHE hospital, STOP CAUTI sites were not significantly different in terms of bed size, urban setting, teaching status, or ownership status. STOP CAUTI hospitals were more likely than typical NICHE hospitals to have "Magnet" designation (60 percent and 28 percent, respectively; p=.004).

Self-Assessment

The STOP CAUTI baseline practice survey revealed heterogeneity in the use of evidence-based interventions to prevent CAUTI (Table 2). The results were presented at the 2010 NICHE annual conference and are described elsewhere.[25] The same survey was used in subsequent study years to track changes in prevention practices over the course of the study.

Table 1. Characteristics of STOP CAUTI Workgroup hospitals and study units

Characteristic	Value
Hospitals (n=20)	
Staffed beds (mean±SD)	476±253
Size	
Small	5%
Medium	30%
Large	65%
Region	
Northeast	35%
South	20%
Midwest	35%
West	10%
Urban	95%
Ownership	
Not-for-profit	80%
Government	20%
For profit	0%
Teaching	75%
Magnet designation	60%
Electronic medical record	80%
Study Units (n=25)	
Unit Type	
Medical	36%
Med/Surg	16%
Surg	8%
Ortho	4%
Neuro	4%
Ortho/Neuro	16%
Other	16%
Staffed beds (mean±SD)	33±9
Registered nurses (mean±SD)	46±13
Nursing assistants (mean±SD)	18±5

Table 2. Baseline CAUTI prevention practices (n=20)

Prevention Practice	% Employing Practice
IUCs used (most frequent response reported by hospitals)	
Latex	60 used hospital-wide
Silicone	60 used in selected patients
Silver-coated	40 used hospital-wide
Antibiotic impregnated	65 used none
Rubber	35 used none
Temp-sensing	30 used in selected patients
	% responding frequently or always used
Alternatives to IUCs	
Suprapubic catheters	0
Female urinals	5
Straight catheters	20
Condom catheters	25
Bladder scanners	75
Commodes	85
Adjuncts to IUCs	
Securement devices	75
Personnel inserting IUCs	
Registered nurses	100
Medical students	25
Nursing assistants	25
Physicians	30
Residents	35
LPNs	50
Nursing students	70
Routine care of urethral meatus	
Antiseptic	60
Soap/water	35
Routine personal hygiene	5
Documentation of output and IUC	
Electronic	85
Paper	25
Narrative	5
IUC removal triggers	
Yes	45
No	55

*Categories add up to more than 100% because respondents were able to choose more than one response.

Establishment of Administrative Framework

Regulatory Oversight, Subcontracts, and IRB

By August 2010, only 14 of the STOP CAUTI Workgroup sites had completed the IRB processes at their institutions. The six remaining hospitals completed local IRB processes by April 2011. By August 2010, subcontracts were fully executed for only 13 STOP CAUTI Workgroup sites, with the remaining seven hospitals completing this process by May 2011. Navigation of these administrative processes at participating hospitals caused significant delays in entering into data collection.

Data Collection Protocol

Sixteen hospitals employed EHRs from eight different vendors to capture the required study data. Fifteen hospitals were able to provide electronic reports that met the requirements for import into the STOP CAUTI database. Barriers to successful reporting included limited IT resources, difficulty supplying a unique study ID number and unique culture numbers, technical difficulty with the reporting software, difficulty separating text fields from numeric fields, and inconsistency in report layouts. Troubleshooting occurred through one-on-one support, although problems with reporting from one EHR system led to a multisite collaboration that resulted in successful reporting. In some instances, delays in report generation delayed initiation of data collection. For the five STOP CAUTI sites opting to participate using manual data collection, instructions were provided, and a customized Microsoft Excel™ spreadsheet was developed.

Validation of Data Elements

The 15 hospitals providing electronic data reports completed the validation. Five sites conducted validation of daily nursing assessment fields in seven units by determining the agreement between the nursing query and the EHR documentation of IUC presence for each day that each patient was on the unit (Table 3a). A total of 1,929 patient-days and 460 catheter-days were observed. All seven units had excellent nursing query and EHR agreement (95.3 percent–100 percent; CI range 92–100 percent), with 34 discrepancies noted (9.4 percent). The remaining 10 sites validated insertion and removal dates for 359 catheterizations in 13 units (Table 3b). Nine had good or excellent agreement, although the confidence intervals were wide for insertion dates (87 percent–100 percent; CI range 47–100 percent). These hospitals demonstrated good or excellent percent agreement for documented removal dates (78 percent–100 percent; CI range 39 percent–100 percent). Forty-five discrepancies were noted (7.8 percent of insertions and 4.7 percent of removals). After initial audits, hospital J increased completion of day-of-discharge documentation. These data were inclusive of their followup audit only. Hospital L identified major documentation problems requiring manual data collection.

A review of all discrepancies (n=79) demonstrated inaccuracies in insertion documentation (43% percent or removal documentation (35 percent), or were of undetermined cause (22 percent). The most common reasons for discrepancy included time lags (43 percent), missing data (16 percent), charting errors (11 percent), and artifact (8 percent).

Discussion

The STOP CAUTI Workgroup went from concept to reality over the course of 18 months. During that period, the CU research team successfully engaged 20 diverse NICHE hospitals to participate in a complex quality improvement (QI) study. Creating a collaborative fostered efficiency, a sense of shared purpose, and a community of peers addressing the QI challenges of CAUTI prevention.

Lessons were learned in two areas: (a) establishment of administrative processes necessary for project participation, and (b) IT capacity and data validity. While local study coordinators were familiar with QI activities to reduce CAUTIs, few had experience in conducting human subjects research or familiarity with subcontracting processes. The majority of sites were able to accomplish the necessary administrative processes within a few months; however, some sites took more than a year. Individualized assistance was essential in facilitating study coordinators'

ability to navigate unique IRB processes, applications, and requests. In general, frequent communications and the establishment of strong relationships between CU project staff and each of the hospital project teams were key to moving each hospital along in accomplishing the necessary administrative milestones.

In facilities with EHRs, the capacity to report required data fields exceeded expectations. In most instances, IT personnel were able to generate reports based on the data specifications provided. The collaborative STOP CAUTI approach proved particularly useful in troubleshooting reporting difficulty with one EHR system that was shared by four hospitals. Despite this success, there was sufficient variability in reporting that the CU project team needed to customize the import algorithm for nearly every hospital. Data validity was central to the success of this approach.

Although two recent reports in the literature demonstrate excellent agreement between electronic documentation and chart review,[26,27] our validation activity found variability in the accurate documentation of IUC insertion and removal date fields, a validation approach not previously explored. While most of the hospitals had good or excellent documentation of insertion and removal dates, two sites (J and L) had documentation that was poor enough to warrant remediation or alternative data collection strategies. These validation data are limited by the small number of observations at some study sites due to shorter validation periods than stipulated. Longer validation periods would have increased the sample size and the accuracy of our estimates. Because the audits were carried out by clinical personnel at each site, we were unable to confirm that the audit protocols were completed as directed. In particular, we do not know whether the nurse who provided the clinical assessment had primary knowledge of the IUC. If she did not have primary knowledge and looked up the information in the EHR, these validations would be meaningless. An ideal approach might have employed direct observation of daily catheter presence. However, direct observation of insertions and removals would have required levels of staffing that were not feasible. Nonetheless, our experience suggests that hospitals wishing to track IUCs and CAUTIs electronically should periodically demonstrate the accuracy of insertion and removal documentation.

Conclusions

STOP CAUTI Workgroup sites participated in this project for very little compensation because of their affiliation with NICHE and their passion for the topic of CAUTI reduction. This enthusiasm alone was not sufficient to surmount all of the challenges that participation in a QI project of this scope entailed. To successfully embark on future collaborative, multisite QI efforts within NICHE, it would be advisable to build a funded research framework for participating NICHE hospitals that connects directly to research nursing professionals at each site. Despite these challenges, 20 STOP CAUTI Workgroup sites were able to enter into data collection (execute phase) between August 2010 and June 2011. The evaluate phase, with both qualitative and quantitative components, is ongoing.

Table 3. Validation of indwelling urinary catheter data fields

A. Validation of daily documentation of indwelling urinary catheter (Type 1)

Hospital	Unit	Days	Patient-days	Catheter-days	Discrepancies	% Agreement *(% CI)*	Sensitivity	Specificity	PPV*	NPV **
A	1	10	308	71	4	98.7 *(97, 99.7)*	.99	.99	.96	1.00
B	1	12	221	37	2	99.1*(97, 99.9)*	1.00	.99	.95	1.00
	2	12	234	89	11	95.3 *(92, 98)*	.97	.95	.92	.98
C	1	11	310	104	0	100 *(99, 100)*	1.00	1.00	1.00	1.00
D	1	10	274	50	6	97.8 *(95, 99)*	.92	.99	.96	.98
	2	10	311	66	9	97.1 *(95, 99)*	.89	1.00	.99	.97
E	1	10	271	43	2	99.3 *(97, 99.9)*	1.00	.99	.96	1.00
Totals						**Range**				
5	**7**	**75**	**1929**	**460**	**34**	**95.3-100**	**.89-1.00**	**.95-1.00**	**.92-1.00**	**.97-1.00**

B. Validation of insertion and removal dates of indwelling urinary catheter (Type 2)

Hospital	Unit	Days	Catheters	Insert/Removal Discrepancies	Insertion Date % Agreement	Insertion Sensitivity	Insertion PPV*	Removal Date % Agreement *(CI)*	Removal Sensitivity	Removal PPV*
F	1	10	39	6/2	88 *(73, 96)*	.97	.90	94 *(80, 99)*	1.00	.94
G	1	10	21	1/2	95 *(76, 99.9)*	.95	1.00	85 *(55, 98)*	.85	1.00
	2	10	19	1/0	95 *(74, 99.9)*	.95	1.00	100 *(66, 100)*	1.00	1.00
H	1	29	71	2/0	97 *(90, 99.7)*	.97	1.00	100 *(95, 100)*	1.00	1.00
I	1	31	47	0/0	100 *(93, 100)*	1.00	1.00	100 *(93, 100)*	1.00	1.00
J	1&2	14	10	0/2	100 *(66, 100)*	1.00	1.00	78 *(39, 97)*	.78	1.00
K	1	15	23	1/0	94 *(72, 99.9)*	.94	1.00	100 *(83, 100)*	1.00	1.00
L	1	15	38	10/11	71 *(48, 89)*	.75	.94	64 *(45, 81)*	.69	.91
M	1	10	21	2/0	90 *(70, 99)*	.91	1.00	100 *(83, 100)*	1.00	1.00
N	1	6	34	2/0	94 *(80, 99)*	.94	1.00	100 *(90, 100)*	1.00	1.00
P	1	7	15	2/1	87 *(60, 98)*	.87	1.00	93 *(68, 99.9)*	.93	1.00
	2	6	8	1/0	88 *(47, 99.7)*	.88	1.00	100 *(54, 100)*	1.00	1.00
Totals					**Range**					
10	**13**	**178**	**359**	**28/17**	**71-100**	**.75-1.00**	**.90-1.00**	**64-100**	**.69-1.00**	**.91-1.00**

* Positive predictive value.
**Negative predictive value.

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Using Claims Data to Perform Surveillance for Surgical Site Infection: The Devil Is in the Details

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Abstract

Increasingly, investigators and regulatory agencies are using billing claims data to identify healthcare-associated infections (HAIs) for quality improvement initiatives. We use hernia repair as an example to investigate methodological strategies for surgical site infection (SSI) surveillance and the effect of variation in coding of anatomical surgical site by provider and facility on SSI incidence. Using commercial insurer claims data, we conducted a retrospective cohort study of enrollees aged 6 months to 64 years with ICD-9-CM procedure or CPT-4 codes from facility and/or provider claims for umbilical, inguinal/femoral, and incisional/ventral hernia repairs, between 2004 and 2010. SSIs occurring within 90 days after hernia repair and before a subsequent surgery were identified by ICD-9-CM diagnosis codes. Supporting evidence for operations included UB-92 revenue codes and CPT-4 codes for pathology, mesh, and administration of anesthesia. A total of 181,811 hernia repair procedures were initially identified based on distinct procedure dates more than 7 days apart. The number of distinct procedures was reduced to 140,632 after removing procedures with no supportive evidence for operation, operations in medically complicated patients, complicated hernia operations, operations coded for more than one hernia site or unclassified, and operations performed at the time of an SSI. The incidence of SSIs was compared according to the stringency of identification of the hernia site. When agreement between the provider and the facility classification was required to define the hernia site, the incidence rates of SSI after incisional/ventral, inguinal/femoral, and umbilical hernia repairs were 4.11 percent (715/17,390), 0.45 percent (352/77,666), and 1.16 percent (288/24,917), respectively. By contrast, the incidence rates after hernia repair at the three sites were 3.29 percent (199/6,041), 0.53 percent (56/10,573), and 1.41 percent (57/4,045) for procedures with discordant coding and facility/provider-only information. Use of administrative data to identify SSI requires a thorough methodological approach to accurately identify and characterize surgical procedures, particularly when surgical factors are important risk factors for infection.

Introduction

Using claims data to determine the incidence of surgical site infection (SSI) after surgical procedures requires accurate identification of both infections and the surgical procedures. Many of the studies describing the use of administrative or claims data to perform SSI surveillance have focused only on the accuracy of International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) diagnosis codes to identify the infections, with varying results, depending on the surgical procedures studied and the diagnosis codes used to indicate infection.[1–8]

Few investigators have validated the accuracy of ICD-9-CM procedure and Current Procedural Terminology, 4th edition (CPT-4®) codes to identify and characterize surgical procedures. This information is critical to accurately determine the denominator of at-risk procedures in the calculation of SSI incidence.[9–14] The relative lack of studies validating the coding of surgical

procedures may be due to the perception that procedures are more accurately coded than diagnoses.[15]

The overall goal of our study was to determine the incidence of SSI among procedures performed in inpatient hospital and ambulatory surgical centers (both hospital-based and free-standing centers), using claims data from a large U.S. private insurer. We developed a rigorous algorithm to identify procedures in order to ensure the accuracy of the calculated incidence of infection. We use the identification of unique hernia repair procedures as a complicated example, since these procedures can occur repeatedly within an individual; and classification of the procedures by site of repair is important because the incidence of SSI likely varies by anatomic site.[16–19] In this study, it was important to characterize the anatomic site of hernia repair, since our ultimate goal was to compare SSI rates according to the location where surgery was performed. We assumed that this location would vary, based on the anatomic site of the hernia. We expected that incisional hernia repair would more likely be performed in an inpatient hospital setting than would inguinal, femoral, or umbilical hernia repairs. Therefore, it was important to develop methods to accurately characterize the anatomic site of the hernia in order to compare SSI rates within hernia types across the three types of facilities.

Methods

Data Source

We conducted a retrospective cohort study using the HealthCore Integrated Research Database™ (HIRD), which contains longitudinal claims data from 13 WellPoint-owned Blue Cross and/or Blue Shield health plans located in the Southeast, Mid-Atlantic, Eastern, Central, and Western regions of the United States. Data in the HIRD include all fully adjudicated claims submitted for reimbursement from providers, facilities, and outpatient pharmacies and are linked to health plan enrollment information.

Fully insured members enrolled in a health plan that included, at a minimum, medical coverage of hospital and physician services were eligible for selection into the study cohort. Members with an ICD-9-CM diagnosis code or prescription claim that indicated HIV-positive status at any time during the study period were not eligible for entry into the cohort because HIV status could not be disclosed due to privacy considerations. Members who were likely to have incomplete data also were not eligible. These included members enrolled in a plan with hospital coverage only, since up to 60 percent of SSIs are identified and managed in the ambulatory setting;[20] members enrolled in a plan that reimburses providers through capitated, rather than fee-for-service payment, since utilization data are likely incomplete;[21] and members enrolled in multiple plans at the time of the surgery of interest. Operations on members whose insurance coverage ended on the day of hernia repair were excluded because ascertainment of subsequent SSI would not be possible. Medical claims were restricted to paid claims.

The research data for this study contained up to five ICD-9-CM diagnosis codes and five ICD-9-CM procedure codes per claim. Inpatient facility claims also included Uniform Billing (UB-92) revenue and Healthcare Common Procedure Coding System (HCPCS) codes, while ambulatory facility and provider claims included CPT-4 and HCPCS codes. Service dates were available for lines with CPT-4 codes, but exact procedure dates were not available from inpatient facility

claims, which included only the first service date (interpreted as the inpatient admission date) and the last service date (i.e., the discharge date).

Hernia Repair Patient Population

We initially identified hernia repair surgeries among members eligible for cohort entry (n=171,140 members, each with one or more hernia procedures) and aged 6 months to 64 years, from January 1, 2004 through December 31, 2010, using ICD-9-CM and CPT-4 procedure codes from inpatient and ambulatory facilities (other than home health agencies) and provider claims for incisional/ventral, inguinal/femoral, and umbilical hernia repairs (Table 1). The hernia repair patient population was further refined by excluding operations likely to have erroneous claims for hernia repair, complicated procedures and operations in patients considered medically complicated, and procedures in which the surgery date and/or classification of the hernia site could not be determined from the available information in the claims (Figure 1).

Table 1. ICD-9-CM procedure and CPT-4 codes used to identify hernia repair

Operative Category	Laparoscopic		Open	
	ICD-9-CM	CPT-4	ICD-9-CM	CPT-4
Incisional/ ventral	53.62, 53.63 54.21* + (53.51, 53.61, 53.59, 53.69)	49654–49657	53.51, 53.61, 53.59, 53.69	49560, 49561, 49565, 49566
Inguinal/ femoral	17.11–17.13, 17.21–17.24 54.21* + (53.00–53.05, 53.10–53.17, 53.21, 53.29, 53.31, 53.39)	49650, 49651	53.00–53.05, 53.10–53.17, 53.21, 53.29, 53.31, 53.39	49500, 49501, 49505, 49507, 49520, 49521, 49525, 49550, 49553, 49555, 49557
Umbilical	53.42, 53.43 54.21* + (53.41, 53.49)	49652, 49653	53.41, 53.49	49580, 49582, 49585, 49587

*Required that 54.21 be on the same claim as the open hernia ICD-9-CM procedure code.

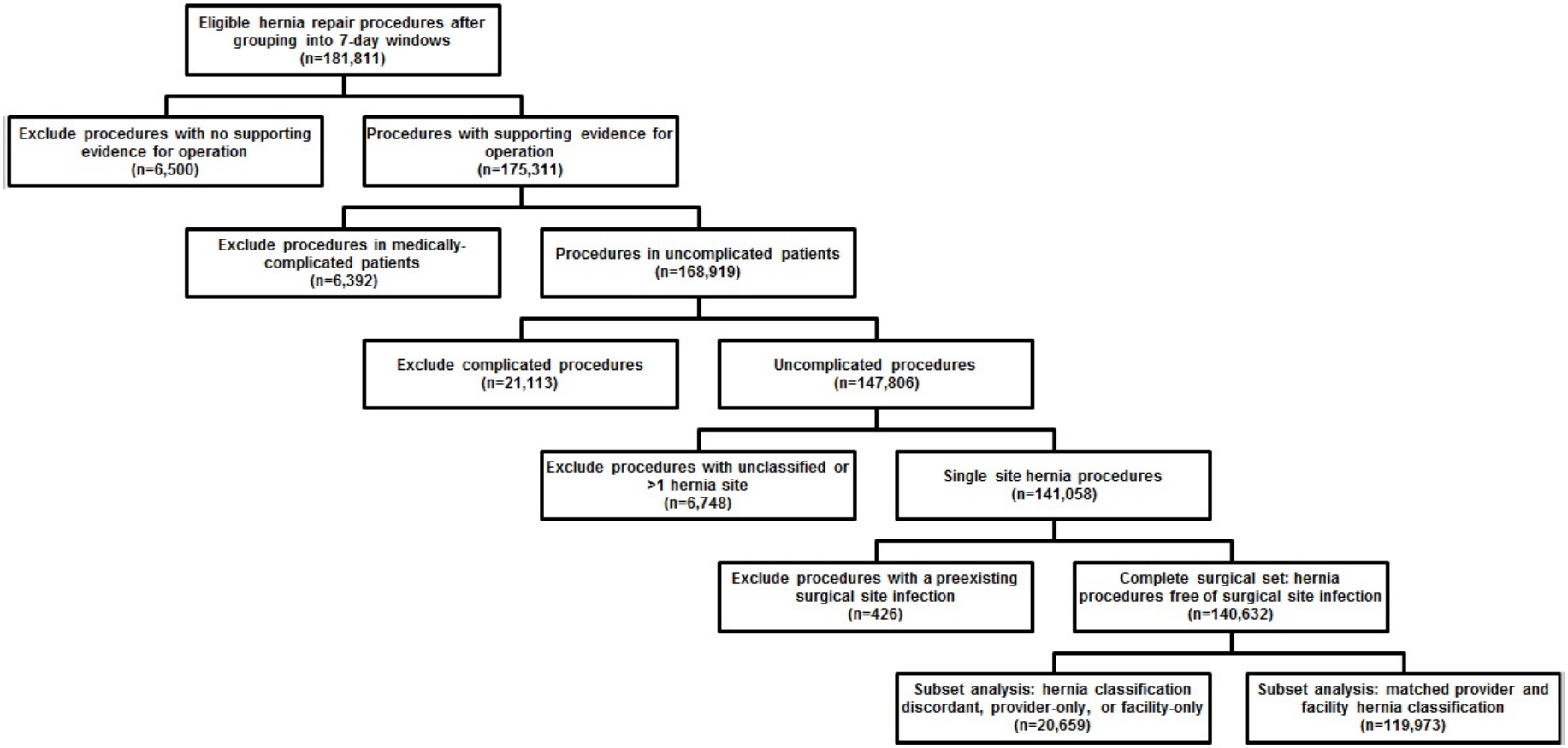

Figure 1. Claims data algorithm for classification of hernia repair

Problem Claims

We created an algorithm to identify "problem claims." Problem claims were those that contained CPT-4, HCPCS, or UB-92 revenue codes truncated to four digits and populated in the fields reserved for ICD-9-CM procedure codes. This error apparently occurred during processing of certain types of non-inpatient facility claims (authors' unpublished observations). Claims in which a hernia procedure code was present only on one line on a single claim, with no other claims on the same date, were also classified as problem claims.

Complicated Patients and Operations

The primary aim of this study was to estimate the risk of SSI among hernia procedures, depending on the surgical facility type. For this reason, we excluded hernia repair procedures performed in medically complicated patients, who would be very unlikely to undergo surgery in an ambulatory setting. These patients would have unique risk factors that would put them at higher risk of SSI compared with other patients. The medically complicated patient category included persons coded for cancer or chemotherapy, or with end-stage renal disease, from 30 days before to 7 days after the hernia procedure. Hernia repairs in persons with septicemia between 7 days before to 1 day after the hernia procedure date were excluded because those individuals had preexisting systemic infection. We also excluded hernia repairs in persons with motor vehicle accidents, abdominal compartment syndrome, or gunshot wounds coded on the same line as the hernia repair (Table 2).

In addition, we excluded complicated hernia repair procedures performed at the time of or after another surgical procedure during the same admission. The rationale for this exclusion is that these procedures would be complex, and if an SSI developed, it would not be possible to determine the attributable surgery. Additional surgical procedures were identified using CPT-4 and ICD-9-CM procedure codes for an operative procedure on the National Healthcare Safety Network (NHSN) list of procedures for SSI surveillance, including hernia sites not included in this study (epigastric, lumbar, spigelian, and omphalocele).[22] We also used CPT-4 codes for a variety of abdominal surgeries that are not part of the NHSN list, or are included in the NHSN list only as ICD-9-CM procedure codes, to exclude additional abdominal procedures performed before the hernia during the same admission or on the same day as the hernia repair (Table 2). We expanded the identification of other abdominal procedures through the use of CPT-4 codes for two reasons: first, because the majority of other surgical procedures performed before or at the time of hernia repair involved the abdomen, and second, to define more accurately the date of the other surgical procedure, since the research database did not contain procedure dates for ICD-9-CM procedure codes. We did not want to exclude procedures that occurred after the hernia repair because they may have been performed as a result of a complication of the hernia operation. The ability to more precisely date the additional procedures using CPT-4 codes with their associated service date was thus very important.

Table 2. Codes used for surgery exclusion and as evidence for surgery

	CPT-4 or HCPCS Codes	ICD-9-CM Procedure Codes	UB-92 Revenue Codes	ICD-9-CM Diagnosis Codes
Codes Used for Hernia Repair Exclusion				
Abdominal surgery codes	43279–43425, 43600–43659, 43770–43999, 44010–44130, 44133, 44136–44139, 44155–44158, 44211–44238, 44345, 44346, 44602–44900, 44950–45170, 45395–45505, 45540–45825, 46260–46288, 47010, 47100–47142, 47370, 47400–47460, 47560, 47561, 47570, 47579, 47700–47999, 48105–48160, 48520–48548, 49203–49220, 49255–49329			
Non–study hernia codes (epigastric, lumbar, spigelian, omphalocele)	49540, 49570, 49572, 49590, 49600, 49605, 49606, 49610, 49611			
Cancer				140.0–172.9, 174.0–209.36, 209.70–209.79
Chemotherapy	96400–96549, J9000–J9999, Q0083–Q0085	99.25	0331, 0332, 0335	V58.11, V58.12, V66.2, V67.2
End-stage renal disease				585.6, V45.1, V45.11, V45.12, V56.0, V56.1, V56.2, V56.8
Septicemia				038.0–0.38.9, 790.7
Motor vehicle accidents				E810.0–E825.9
Abdominal compartment syndrome				729.73
Gunshot wounds				E922.0–E922.3, E922.8, E922.9, E928.7, E965.0–E965.4, E97.0, E979.4, E985.0–E985.4
Codes Used as Additional Evidence for Hernia Repair Surgery				
Anesthesia	00750, 00752, 00830, 00832, 00834, 00840, 00860			
Pathology	88302			
Surgical mesh (individual codes)	C1781, S2077, 49568			
Surgery-related revenue codes			201, 360, 361, 369, 370, 379, 490, 499, 963, 964, 975	

Finally, we also excluded the remaining hernia repairs performed on or after day 3 of an inpatient hospital stay (with admission date considered day 1) because these patients would not have had the opportunity for surgery in an ambulatory facility.

Characteristics of the Surgery

Establishing the date of surgery and classifying the hernia site were fundamental to the analysis of the study. Operations lacking these surgical characteristics based on the claims were excluded.

Establishing the Surgery Date and Use of Supporting Evidence for Surgery

Hernia repair dates within 7 days were collapsed into a single surgery date because of the potential inaccuracy in dates, particularly on provider claims.[23] In addition to the procedure codes in Table 1, CPT-4 code 49659 (unlisted laparoscopy procedure, hernioplasty, herniorrhaphy, herniotomy) coded by a provider was included as supplemental information to refine the surgery date when none of the CPT-4 codes in Table 1 were used by a provider.

When there was more than one date within 7 days that coded for hernia repair, we compared facility and provider surgery dates and incorporated supplemental claims evidence from other unique providers. We used these supplemental claims, which included anesthesia and pathology, along with claims for surgical mesh, to determine the most likely surgery date. For hernia repairs coded only by a provider or by a facility, we required additional evidence that an operation actually took place, including anesthesia, pathology, or surgical mesh codes or a surgery-related UB-92 revenue code (Table 2). If no additional evidence existed for facility-only or provider-only claims, the surgeries were excluded. Because procedures coded using ICD-9-CM procedure codes lacked an exact service date, the hernia repair date from the inpatient facility stay defaulted to the admission date. We therefore prioritized the service date from the provider (when available) to assign the surgery date, together with the supplemental information from other unique providers.

After determining the most likely hernia surgery date within the 7-day window, further steps to define the exact date of operation were performed based on the hospital length of stay and the number of days between multiple hernia repair dates. This allowed us to further consolidate dates that appeared to refer to the same hernia procedure. We consolidated multiple hernia surgery dates within inpatient admissions of more than 4 days, since it was unlikely that more than one hernia repair procedure took place during a single admission.

Classification of Hernia Site

We classified the hernia repairs as incisional/ventral, inguinal/femoral, and/or umbilical, based on the ICD-9-CM procedure and CPT-4 codes from the provider and facility (Table 1). If claims were available from both a provider and a facility, and the classification of hernia site differed, we prioritized the site and approach (i.e., laparoscopic vs. open) coded by the provider because the information coded by the performing surgeon should be more accurate. We excluded hernia procedures when the provider coded for a laparoscopic hernia repair with an unlisted site (CPT-4 code 49659) and the facility coded for an open hernia repair of a specified site, since both the hernia site and the technique were unclear. If the final hernia categorization involved more than one site (i.e., if the provider coded for more than one site or the surgery was coded only by a

facility that coded for more than one hernia site), we excluded that surgery since it would be a more complex procedure and could not be classified to a single site.

Identification of Primary Outcome—Surgical Site Infection

SSIs first recorded from 2 to 90 days after eligible surgeries were identified using ICD-9-CM diagnosis codes from inpatient and ambulatory facilities and provider claims. We excluded claims with locations that were not consistent with a provider diagnosis (e.g., laboratory, patient's home), as well as claims with CPT-4 codes for pathology services (88104–88399), because the diagnosis codes on those lines may have been indicators of tentative or "rule-out" diagnoses.

The codes used to identify SSI included the standard postoperative wound infection codes (998.5, 998.51, 998.59, 996.69) plus codes for peritonitis (567.2–567.29, 567.9) and retroperitoneal infection (567.3–567.39). In accordance with the NHSN definition of SSI,[22] a diagnosis code of cellulitis of the trunk (682.2) or unspecified site (682.9) on the same claim as a CPT-4 code for incision and drainage (10060, 10061, 10180, 11005, 11008, 49020, 49021, 49040, 49041, 49060, 49061) was considered evidence of SSI. Because the ICD-9-CM diagnosis code 682.9 refers to cellulitis and abscess at an unspecified site, it was used as an indicator of SSI only if it met one of the following criteria: if it was on the same claim line as an abdomen-specific CPT-4 procedure code (11005, 11008, 49020, 49021, 49040, 49041, 49060, 49061), or if it was coded by the surgeon who performed the hernia repair on the same claim as a non-abdomen-specific CPT-4 code for incision and drainage (10060, 10061, 10180).

The date of onset of SSI was defined according to the timing and location of diagnosis. For SSI newly coded by an inpatient facility during the original operative admission, we assigned the date of SSI to the discharge date if the difference between the discharge and admission date was greater than or equal to 2 days. For SSI diagnosed during a subsequent inpatient admission, the date of SSI onset was assumed to be the date of hospital admission. For SSI diagnosed initially in an ambulatory setting, the onset date was defined as the first service date with an ICD-9-CM diagnosis code for SSI.

ICD-9-CM diagnosis codes for SSI from 30 days before to 1 day after surgery were considered preexisting infection. Infections coded on the day of or the day after surgery were considered preexisting because the development and diagnosis of SSI due to hernia repair requires a minimum of 1 day; therefore, infections coded within 1 day of surgery most likely represent prevalent infection. We excluded hernia repairs if a preexisting SSI was identified.

The observation period for development of SSI was through 90 days after surgery, with earlier censoring for the end of insurance enrollment, a subsequent hernia repair, or another abdominal surgery. For subsequent surgeries, we censored 1 day after the subsequent surgery to be consistent with our algorithm that SSI coded the day after a surgical procedure is preexisting and can be attributed to the previous surgery. Non-abdomen-specific ICD-9-CM diagnosis codes for infection (e.g., 998.59) were not classified as SSI if they were first coded after a subsequent non-abdominal NHSN surgery within 90 days.

The incidence of SSI within 90 days of surgery by hernia site was compared using the chi-square test. All data management and statistical analyses were performed using SAS v9.2 (SAS Institute Inc., Cary, NC).

Results

A total of 181,811 hernia repair procedures were initially identified during the 7-year period examined in this study, based on distinct procedure dates more than 7 days apart. The number of distinct procedures was reduced to 140,632 (termed the “complete surgical set,” see Figure 1) among 135,907 patients, after removing procedures with no supporting evidence for operation (n=6,500), procedures in medically complicated patients (n=6,392), complicated hernia procedures (n=21,113), hernia repairs coded for more than one site or unclassified (n=6,748), and hernia repairs performed at the time of an existing SSI (n=426).

Of the 140,632 hernia repair procedures, a total of 119,973 (85.3 percent) procedures in 116,572 patients had an exact facility and provider match for both the hernia site and the approach; this group formed a subset for further analysis (Figure 1). Of the remaining 20,659 hernia repair procedures, 6,398 (4.5 percent of the complete surgical set) had discordant information from the provider and the facility regarding the hernia site and/or use of laparoscopy; in these cases the provider information was used to characterize the procedure. A total of 6,404 (4.6 percent of the complete surgical set) hernia procedures were defined by information from the facility only, and 7,857 (5.6 percent of the complete surgical set) were based on information from the provider(s) only. Of the complete surgical set, 23,431 (16.7 percent) procedures were classified as incisional/ventral hernia repairs, 88,239 (62.7 percent) as inguinal/femoral hernia repairs, and 28,962 (20.6 percent) as umbilical hernia repairs. Among the subset of 119,973 hernia repair procedures with matched facility-provider classification, 17,390 (14.5 percent) were classified as incisional/ventral hernia repairs, 77,666 (64.7 percent) as inguinal/femoral repairs, and 24,917 (20.8 percent) as umbilical hernia repairs.

A total of 1,667 incident SSIs were identified after the 140,632 hernia surgeries, for an overall SSI rate of 1.19 percent. The incidence of SSI was 3.90 percent (914/23,431) after incisional/ventral, 0.46 percent (408/88,239) after inguinal/femoral, and 1.19 percent (345/28,962) after umbilical hernia repairs. The incidence of SSI within 90 days was significantly lower in unmatched incisional/ventral hernia procedures compared to the incidence following procedures in which provider and facility coding agreed on the site and approach (3.29 percent SSI in unmatched incisional/ventral hernia repair vs. 4.11 percent SSI in incisional/ventral hernia repair with concordant facility-provider coding, p=0.005). For both inguinal/femoral and umbilical hernia repairs, the calculated incidence of SSI was higher in unmatched procedures compared to procedures with concordant coding of the site and approach of repair, although the differences were not statistically significant (Table 3).

Table 3. Comparison of SSI rates by classification of hernia repair

	Matched Provider/Facility Classification n=119,973		Discordant Classification or Provider/Facility Only n=20,659		
Hernia Site	SSI n (%)	Total procedures	SSI n (%)	Total procedures	p
Incisional/ventral	715 (4.11)	17,390	199 (3.29)	6,041	0.005
Inguinal/femoral	352 (0.45)	77,666	56 (0.53)	10,573	0.277
Umbilical	288 (1.16)	24,917	57 (1.41)	4,045	0.168

Discussion

In many studies using claims data, ICD-9-CM procedure codes alone, or a combination of ICD-9-CM procedure and CPT-4 codes from both facility and provider claims data, are used to identify surgical procedures in inpatient facilities. In the majority of these studies, detailed algorithms to identify surgical procedures are not provided. Detailed methods to identify procedures are very important in performing surveillance for healthcare-associated infections (HAIs) because attribution of infection to the surgery requires that the surgery actually occurred and that it took place before the infection. Therefore, rigorous methods to identify surgical procedures and to determine the most likely procedure date are essential if claims data are to be used reliably for HAI surveillance.

Using the example of hernia repair, we developed systematic strategies to increase the likelihood that a surgery actually took place; to refine the surgery date, taking into account the possibility of repeated surgeries within an individual; and to characterize the anatomic site of surgery. These steps are important components of SSI surveillance after all surgical procedures, in particular, ensuring that a procedure took place (to avoid overpopulating the denominator with non-procedures) and refining the surgery date (to ensure that only incident infections are identified). The steps we performed to refine the surgery date and to increase the likelihood that a surgical procedure took place reduced the number of hernia repair procedures by 3.6 percent (6,500/181,811). This reduction removed duplicate or non-surgeries from the denominator. The number of hernia procedures was reduced by an additional 14.7 percent when we required complete agreement between the provider and the facility regarding the hernia surgery site and approach.

We determined some of the methodological steps necessary to clean the data from experience and the literature, whereas others were developed after working with the commercial insurer data. Determining the correct denominator for surgical procedures is straightforward when detailed clinical information is available (e.g., operative log), but it can be more challenging when claims data are used. For example, procedure codes can sometimes be included on preoperative or postoperative medical claims, complicating identification of the surgery date. The accuracy of ICD-9-CM procedure codes to identify specific surgical procedures is less than 100 percent, and thus inpatient facility dates may not always correspond to a surgery date for the procedure of interest. The lack of procedure dates from inpatient facilities made it necessary to develop an algorithm to calculate the most likely surgical date, particularly when the surgery took place during a hospitalization lasting more than a few days. Determining the correct surgical date is also important to discriminate between preexisting infections and SSIs attributable to the procedure.

By requiring agreement in coding of anatomic site and approach from the provider and the facility, the likelihood of accuracy of classification will likely be higher, since the coding by providers and facilities is performed independently. The requirement for concordant information regarding the classification of procedures should therefore lead to more accurate estimates of the incidence of SSI. Although the NHSN does not stratify hernia SSI rates based on anatomic location, we suspected, based on the published literature,[17,24] that incisional/ventral hernia surgeries would have a higher incidence of SSI compared to inguinal hernia, which was confirmed. We found that the incidence of SSI following incisional/ventral hernia repair was higher when we required provider and facility coding agreement, and the incidence of SSI for umbilical and inguinal/femoral hernia repair decreased when we required provider and facility concordance. We suspect that some of the discordant incisional/ventral hernia repairs involved other anatomic sites (e.g., inguinal), and thus the SSI incidence was lower for these imprecisely coded procedures. In the case of the discordant inguinal/femoral and umbilical hernia repairs, it is possible that some of the imprecisely coded procedures were actually incisional/ventral repairs, and thus the SSI incidence was higher for the discordant procedures than for the umbilical procedures with matched facility and provider coding.

By definition, the use of claims data for SSI surveillance involves secondary analysis of the data collected for billing purposes. Therefore, some data elements that are important for SSI surveillance, such as procedure dates, may be less important for reimbursement and, as a result, may be less accurate or coded with less detail. There is also the potential for misclassification of diagnoses and likely undercoding of SSIs, particularly minor infections during the 90-day global surgical reimbursement period for providers.[25] Thus our calculations for the incidence of SSI after the three types of hernia repair are likely underestimates of the true infection rates after these procedures.

Some authors have concluded that billing and claims data cannot be reliably used for HAI surveillance, including SSIs.[4,26] We believe that use of careful and methodical strategies to deal with the inconsistencies in claims data and algorithms tailored to specific surgical procedures, such as we have described for hernia repair, will improve the accuracy of ICD-9-CM diagnosis codes to identify true SSIs. Claims data cannot be approached as simple data that can easily be mined to identify infections. Rather, the individual datasets must be carefully analyzed to determine the extent of missing information (e.g., not all ICD-9-CM diagnosis and procedure codes submitted for reimbursement may be provided by the data source) and how this missing information affects the determination of type of procedure, procedure date, and infection. Comparison of facility and provider surgical coding can provide insight into strategies to identify surgical procedures more accurately. Knowledge of the billing and claims processes is important to understand how and when SSIs are coded. Clinical knowledge is also important when specific features of the surgical procedure are potentially associated with risk of SSI, as we determined for the anatomic site of hernia repair. We believe that the use of claims data for surveillance of SSIs requires the development of algorithms based on clinical knowledge of the surgical procedures and infection, together with a thorough analysis of the claims data, to expose problems and issues that may impair accurate identification of the procedures and SSIs. Only by subjecting the data to careful scrutiny can methodological strategies be developed to overcome the inconsistencies of claims data.

Conclusions

HAI surveillance based on claims data requires methodological approaches to identify both the infections and the denominators as accurately as possible. In the case of SSI, accurate identification of surgical procedures is essential to avoid overpopulation of the denominator with implausible events. We developed a systematic algorithm using complete claims data containing both ICD-9-CM procedure and CPT-4 codes from facilities and providers to exclude procedures that were unlikely to have been performed. We believe that more thorough approaches such as these are essential to determine accurate rates of SSI using complex claims data.

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Turning Unstructured Microbiology Culture Data Into Usable Information: Methods for Alerting Infection Preventionists in a Health Information Exchange About Multidrug-Resistant Gram-Negative Bacterial Infections

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Abstract

Recent outbreaks of carbapenem-resistant gram-negative bacteria (CRGNB) among hospitalized patients have elicited national attention and underscored the danger of healthcare-associated infections. Whenever patients visit more than one hospital, a multidrug-resistant organism (MDRO) may spread. Within hospitals, spread is also a scourge. Therefore, our goal is to build a regional system that parses laboratory microbiology culture data to make the data usable for decision support and then alerts hospitals when a patient with a history of MDRO is admitted. The previous methicillin-resistant *Staphylococcus aureus*/vancomycin-resistant enterococci (MRSA/VRE) alert system in our region relied on hospital infection preventionists (IPs) to enter data; our new system uses microbiology culture data generated in the normal course of health care at more than 25 hospitals. We cull the microbiology data from the Health Level Seven version 2 (HL7v2) messages that hospitals send to a health information exchange. The principal informatics problem is that for microbiology data, more than for simpler types of laboratory results data, most of the messages are not structured in standard HL7v2 format by the sending hospitals. We therefore built an HL7v2 correction engine that deals with incorrect message structure and/or content in order to generate new, standardized microbiology content, which we append to the existing message. The engine uses natural language processing and other methods to parse key data elements needed for infection control alerts: organism, antibiotics tested, minimum inhibitory concentrations, susceptibility interpretation, body source of the culture, and health care facility where drawn. These standardized data elements can then be integrated into enhanced email alerts to IPs. We solicited suggestions from IPs in various hospitals across the State regarding how they would like to receive information and which organisms to include. We subsequently will evaluate the perceived utility of the alerts, the rate and timeliness of the use of isolation, and the geographic patterns of gram-negative MDRO infections.

Introduction

Recent outbreaks and deaths caused by multidrug-resistant gram-negative “superbugs” among hospitalized patients in the United States have elicited national attention and have underscored the danger posed by these infections.[1] In the past year, new, multidrug-resistant strains of carbapenem-resistant *Enterobacteriaceae* (CRE) have appeared at an accelerating rate. Of the 37 strains of CRE in the United States, 15 have been discovered since July 2012, which prompted a February 2013 Centers for Disease Control and Prevention (CDC) advisory encouraging health care providers to “act aggressively to prevent the emergence and spread” of these bacteria.[2] In 2013, the Chief Medical Officer of England warned of a dystopian future: Antibiotic resistance

"is a growing problem, and if we don't get it right, we will find ourselves in a health system not dissimilar from the early 19th century."[3] The focus of this project is on *gram-negative* multidrug-resistant organisms (MDROs), but from the beginning we worked to ensure that our methods would generalize to *gram-positive* MDROs, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE), or to any other bacteria for which alerts may be desired in the future.

The increasing prevalence of gram-negative rods (GNR) that are MDROs has been documented worldwide. Carbapenem resistance was preceded by increasing recognition, over the past 10–15 years, of extended-spectrum beta-lactamase production among *Enterobacteriaceae* (ESBL-E). In France, the national infection control program found that from 2003 to 2013, while the incidence of MRSA declined (from 0.72 to 0.41 per 1,000 patient days), the incidence of ESBL-E climbed alarmingly (from 0.17 to 0.48 per 1,000 patient days).[4] Increasing rates of ESBL-E among urinary tract[5,6] and bloodstream[7,8] pathogens have been documented in many nations. Based on U.S. surveillance data reports to the CDC, the prevalence of multidrug-resistant *Klebsiella pneumonia* and *Escherichia coli* increased from 7 percent in 2000 to 13 percent in 2008.[9] Beyond the *Enterobacteriaceae*, beta-lactamase production is one of the key mechanisms underlying multidrug resistance in other gram-negative organisms, such as *Pseudomonas aeruginosa*[10,11] and *Acinetobacter baumannii*.[12]

In a general sense, the epidemiologic understanding of GNR MDROs is beginning to parallel that of MRSA. Early in the history of MRSA, it was considered a problem centered primarily in hospitals and intensive care units (ICUs); with time, community-associated disease came to the fore.[13] Similarly, it now is increasingly understood that a substantial minority of GNR MDROs arise in the outpatient setting, and that many of the affected patients have no healthcare-associated risk factors.[14] From 2006 to 2011, there was a 10-fold increase in the rate of carriage of ESBL-producing *E. coli* among healthy adults in Paris.[15] A recent (2010) analysis of diapers documented what was probably transmission from one child to another of ESBL-producing *E. coli*;[16] almost 3 percent of healthy preschool children were colonized, as were 8 percent of children of the same age at Uppsala University Hospital in Sweden. Among international travelers studied by the Weill Cornell travel medicine clinic in New York City during 2009–2010, 28 percent acquired ESBL-E overseas and imported it into the United States.[17]

Because people can carry GNR MDROs in their gastrointestinal tracts asymptomatically for months or even years, they can bring these bacteria into hospitals upon admission. After discharge from a university hospital in Paris (based on data from 1997 to 2010), the median time to clearance of ESBL-E (based on rectal screening results) was 6.6 months; based on the high rate of readmission while still colonized, the authors recommended that "screening for ESBL-E and contact isolation precautions at hospital readmission are advisable for all patients identified as testing positive for ESBL-E infection during an earlier hospital stay."[18] Substantial rates of inter-hospital spread of *Clostridium difficile*[19] and MRSA[20] have been documented in California. A study of five hospital systems in the Indiana Network for Patient Care (INPC) reported that in 10 percent of hospitalizations, the admitting hospital was not aware of the patient's previous history of MRSA at a different institution; as a result, in a 1-year period there were 3,600 inpatient days in which contact isolation was indicated but not ordered.[21]

In light of the growing danger of GNR MDRO outbreaks caused by patients who carry these organisms into the hospital, we drew upon our experience (since 2007) delivering alerts when

patients with a history of MRSA or VRE are admitted to the major hospitals in Indianapolis, IN. In this paper, we describe the development of a new alert system for GNR MDRO.

Methods

Overview

With sponsorship from the Agency for Healthcare Research and Quality (AHRQ), we are developing a new system with these aims, to: parse microbiology culture data from more than 25 hospitals (in 12 hospital systems) in a regional health information exchange; check whether patients being admitted to hospitals have a history of GNR MDRO anywhere in the system; and send email alerts to notify local infection control personnel when a patient with a history of GNR MDRO is newly admitted.

Indiana Network for Patient Care

The INPC is a leading operational regional health information exchange, formed in 1994 by Regenstrief Institute and the five major hospital systems in Indianapolis.[22] Its primary purpose is clinical data exchange to improve the quality and efficiency of health care; a secondary purpose is research.[23] In 2002, the INPC was the site of an early randomized trial that examined the value of data shared across institutions for patients in emergency departments.[24] The INPC has stored more than 1 billion data elements, and since 2009, the number of hospital systems has expanded beyond the original five to more than 25 (though not all send microbiology data). The microbiology culture parsing and email alert system described in this paper is built on the newer INPC infrastructure in Oracle; the MRSA/VRE registry and alert system that preceded it was built on the legacy Virtual Address eXtension (VAX) INPC database, which is being phased out.

Existing MRSA/VRE Registry and Alert System

Beginning in 2007, Kho and colleagues built a MRSA/VRE registry and alert system into the original five INPC hospital systems.[21,25,26] Seven new variables were embedded in the INPC for infection preventionists (IPs) to enter information about patients infected or colonized with MRSA or VRE. Then, whenever a patient is admitted to a hospital in the original set of five hospital systems, the INPC's receipt of the Admission, Discharge, and Transfer (ADT) Health Level Seven (HL7) message initiates an automated process that checks the MRSA/VRE registry. If the patient's registry status shows MRSA or VRE infection or colonization that has not been "cleared" through a subsequent data entry by an IP, an automated email alert is sent to the IP at the admitting hospital. In this way, the MRSA/VRE system helps hospitals place patients into contact isolation sooner and also facilitates better monitoring of infection rates in the region and the spread of MRSA and VRE between hospitals.[21]

New Microbiology Culture Data Processing and Alert System

In light of the growing danger of GNR MDRO outbreaks caused by patients who carry these organisms into hospitals, we began building a new system that would, among other purposes, notify hospitals when a patient with a history of GNR MDRO is being admitted. The MRSA/VRE registry relied upon IPs to enter data. Our new system is designed to avoid this manual data entry step. The new design parses, and then stores in a usable format, microbiology culture results data generated in the normal course of health care and sent to the INPC in HL7

format. There were two additional reasons why the new microbiology culture data processing and email alert system was needed: the INPC's more than 20-year-old VAX database was in the process of being decommissioned in favor of a new INPC schema in Oracle; and the expansion of the INPC to additional hospital systems afforded an opportunity to provide microbiology alerts to new hospitals. The new message parser is designed for use within the overall HL7 message processing infrastructure developed by Regenstrief Institute, the Health Open Source Software (HOSS) pipeline. The microbiology data then are stored in an infection control database schema, the Regional Electronic Infection Control Network (REICON) database, which is modeled exactly on the main INPC database schema. We can therefore use INPC concepts ("dictionary terms") and concept mapping tables.

The Informatics Problem With Microbiology Culture Data

The principal informatics problem is that for microbiology data, more than for simpler types of laboratory results data, most of the messages are not structured in standard HL7v2 format by the hospitals that send data to the health information exchange (INPC). When the data (in the inbound HL7 Observation Result [ORU] messages) are not structured according to the HL7 standard, the existing INPC can store the data only as text "blobs." The blobs are human-readable in the electronic medical record and therefore are useful for clinicians taking care of patients one at a time. But because the blobs are not structured, they cannot serve as the basis of an automated program that would check the database to see if the patient has ever had a microbiology culture positive for GNR MDRO (or for gram-positive bacteria such as MRSA or VRE, or for any other culture result).

HL7 Correction Engine (the "REICON Transform")

We therefore built a microbiology HL7v2 correction engine, which deals with incorrect HL7 message structure and/or content in the inbound ORU messages that contain microbiology culture data. The engine generates new, standardized microbiology content that we append to the existing ORU HL7 message. This process is an enhancement to the existing methods that the INPC uses (in many cases only partially) for parsing ORU HL7 messages that contain microbiology culture data. The new engine uses natural language processing and other methods to parse the six key data types and elements needed for infection control alerts: the organism, the antibiotics tested, the minimum inhibitory concentrations of the antibiotics, the susceptibility interpretation for each antibiotic, the body source from which the patient's culture was drawn, and the health care facility where it was drawn. In addition, we look for a seventh data type: evidence that an assay for ESBL or CRE was positive. These standardized data elements can then be stored in the INPC schema in Oracle and, as structured data, can subsequently be integrated into enhanced email alerts to IPs whenever a patient with a history of GNR MDRO is admitted to a hospital. The GNR MDROs are our initial focus for alerts, but we designed the new parser to deal with any bacterial culture; therefore, it could be applied to MRSA, VRE, and other infections in the future. It will be necessary to deal with MRSA and VRE once the existing VAX-based MRSA/VRE registry is shut down.

As a first step, we obtained a dataset consisting of all inbound ORU HL7 messages from a 2-month period. These messages were culled downstream from a Regenstrief "pre-processor," which, as one of its functions, adds Logical Observation Identifiers Names and Codes (LOINC®) codes to the messages. We wrote a LOINC-code filter to separate the microbiology culture

messages from all other laboratory results. For inclusion in this project, we selected the top 12 hospital systems based on microbiology message volume. As of 2012, these 12 hospital systems included 27 hospitals plus some smaller facilities. They extend from northernmost to southernmost Indiana. The five hospital systems in the original MRSA/VRE registry are included; therefore, the 12 hospital systems reflect an expansion of the infection control network both phylogenetically (to gram-negative organisms) and geographically (beyond the Indianapolis area).

Evaluating HL7 Patterns and Building a Library of Concepts

A vital step was to thoroughly study a large batch of the messages from each of the 12 hospital systems. By scrutinizing the structure and content of the HL7 messages that each institution sent to the INPC, we identified the "canonical forms"—the main patterns—that each institution was using. We analyzed how these patterns deviated from the HL7 standard. We then wrote programs to address these patterns. The programs use a combination of two natural language processing (NLP) methods—the REX (Regenstrief Extraction) tool developed by Dr. Friedlin,[27] and the open-source General Architecture for Text Engineering (GATE) software[28]—plus additional Java steps to extract relevant content and to generate the corrected HL7 structure, which we append to the messages.

With regard to the content within the HL7 messages, we built an empirical library of all of the variants (including abbreviations and misspellings) of organism names, antibiotic names, body sources, and hospital building names/abbreviations found in the hospitals' messages. Our process maps the wide variety of nonstandardized content in the incoming messages (e.g., among bacteria: "Prt mirabilis," "Acinetobacter baum./haemol.," "Ec faecalis"; among antibiotics: "Piperacillin/T," or brand rather than generic names) into information that the decision support engine can act upon. We also use the open-source software Organism Tagger,[29] but our own library for variant names of bacteria goes beyond what Organism Tagger can address. Where applicable, we map to existing concepts in the Regenstrief dictionary.

As an addition to INPC's exception browser tool, we are building in warnings for exceptions. Exceptions are situations when, despite all of the mappings and processes developed thus far, there is an incorrect or unexpected value (e.g., an unrecognized value for the organism or the antibiotic, or an incorrect value of minimum inhibitory concentration or the susceptibility interpretation sent by the hospital). Our team will review these exceptions as they are generated to give us a sense of the volume of exceptions and to help us plan for the long-term sustainability of our enhanced microbiology processing. During the development phase, we have been analyzing the exceptions as we analyze the large batches of messages in order to enhance the parsers.

A Dictionary Term for Gram-Negative Superbug

When the REICON engine appends standardized microbiology content to the existing ORU HL7 message, it also evaluates that content against criteria, developed in consultation with the IPs, for five categories of GNR MDRO (Table 1 [see Appendix for a listing of organisms in each category]). If the criteria are met, an additional data element (GNR_MDRO) is written into the REICON database. GNR_MDRO stores which of the five "rules" was met and which version of the rules was applied. Because the criteria will evolve, our approach will enable investigators in future years to see which criteria were applied in any given period.

Table 1. Five rules for labeling, in REICON, a bacterium as a GNR MDRO

Rule	Organism Category*	Definition
1	*Enterobacteriaceae*	Confirmed production of an extended-spectrum beta-lactamase (ESBL)
2	*Enterobacteriaceae*	Confirmed carbapenemase production
3	*Pseudomonas aeruginosa*	Resistant to three or more classes of the following: • Aminoglycosides (Gentamicin, Tobramycin, or Amikacin) • Fluoroquinolones (Ciprofloxacin or Levofloxacin) • Carbapenems (Imipenem or Meropenem) • Beta-lactams (Piperacillin/Tazobactam or both Ceftazidime and Cefepime)
4	*Acinetobacter baumannii*	Resistant to three or more classes of the following: • Aminoglycosides (Gentamicin, Tobramycin, or Amikacin) • Fluoroquinolones (Ciprofloxacin or Levofloxacin) • Carbapenems (Imipenem or Meropenem) • Beta-lactams (Ampicillin/Sulbactam or both Ceftazidime and Cefepime)
5	Other gram-negative bacterium not listed above	Resistant to all antibiotics tested, excluding colistin or tigecycline

*For the list of organisms in each category, see the appendix.
Note: GNR = gram-negative rod; MDRO = multidrug-resistant organism

ADT Hospitalization Messages and Master Patient Index Look-Up

We had to adapt to the new Oracle environment what we had in the VAX environment: a procedure that takes inbound ADT messages for hospitalizations and compares the patient identifiers with those in the INPC master patient index, to determine whether the patient being admitted has any medical record numbers (MRNs) in any other INPC institution. Then, using all of the newly admitted patient's MRNs, the REICON database is searched for any history of GNR MDRO. At the suggestion of the IPs, we do not limit the look-back period in querying for a history of GNR MDRO.

Automated Email Alerts

The emails being developed for the IPs at the admitting hospital include these key elements: organism, antibiotics tested, minimum inhibitory concentrations, susceptibility interpretation, body source of the culture, and health care facility where drawn. A disclaimer notes that the alerts were generated by an automated process and encourages the IPs to validate the results before acting upon them. At the request of the IPs, we include, in the email's subject line, an abbreviation for which rule applies: (1) ESBL-E, (2) CRE, (3) Pseudomonas, (4) *Acinetobacter*, or (5) Other. Not all of the hospital systems are interested in all five rules. If a hospital's policy is not to isolate patients with ESBL-positive *Enterobacteriacea*, its personnel can save time by not opening emails marked "ESBL-E."

Evaluation

In future work, we will evaluate the perceived utility of the alerts, the rate and timeliness with which isolation is used, and the geographic patterns of gram-negative MDRO infections.

Because the “live” email alerts will require some time to accumulate prospectively, we are also using the results of our retrospective message processing to analyze how many patients with a history of GNR MDRO were subsequently admitted to any of the 12 hospital systems. In that way, we can model how many email alerts would have been generated in a retrospective timeframe. We also have begun planning a study of cost effectiveness to estimate whether REICON might, by increasing the rate and/or timeliness of isolation, reduce the spread, sequelae, and costs of GNR MDROs.

Results

We have processed a batch of 20 million ORU HL7 messages in order to extract, structure, and store the microbiology data. We also have written a 21-page deployment guide (not included here). Our message processing pipeline is summarized in Figure 1. The top panel depicts, in its long rectangle, the processing of ORU messages, with the HL7 correction engine described above (the “REICON Transform”) as the center box. The bottom panel depicts, in its long rectangle, the processing of ADT messages to determine (in the “Decision Support” box) whether the patient being hospitalized is one who previously had ORU data for a GNR MDRO. A forthcoming paper will report our initial retrospective results in depth.

Discussion

Both microbiology data informatics and infection control notification are taking place amid larger-scale shifts in the hospital marketplace and in the health information exchange environment. Some hospitals are being acquired by others or are being brought into a larger hospital network. In some cases, these shifts increase the efficiency of our work; in other cases, they may create extra work. When one small hospital joined a larger network (one of the original five), we got an efficiency boost, in that some of the methods already developed for the larger network were immediately applicable to the new hospital joining it. By contrast, when another small hospital was acquired by a larger network, the hospital decided to keep its HL7 message processing and interfacing with the INPC distinct from that of its new network, at least for a few years.

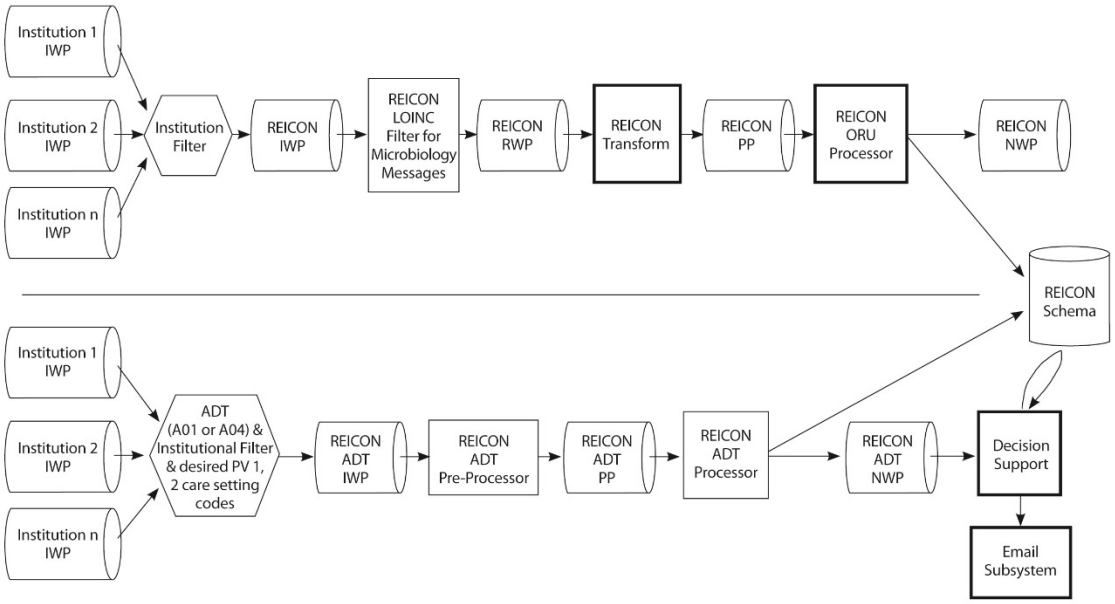

Figure 1. REICON message processing

At the health information exchange level, within the past 2 years Indiana Health Information Exchange (IHIE), Inc. (which now runs the main INPC) employed a subcontractor, AT&T/Covisint, to process inbound HL7 messages from the INPC hospitals. As a result, the REICON project works with a separate stream of HL7 messages (a copy of the actual messages). This situation was part of the reason that we decided to create a separate REICON database to be housed separately but with the same schema as the main INPC.

This project underscores a key informatics principle: When dealing with many hospitals, the wide variety of electronic medical records (EMRs) and other information technology (IT) infrastructure that they use, and the wide variety of (often not fully standardized) HL7 message structure and content that they deliver, generate much complexity in message parsing. The relationship between the number of hospitals and the complexity of work is not linear, it is exponential. For this reason, it is always essential to study the message patterns at the outset, to help shape the subsequent coding as efficiently as possible. In one of our programmers' words, "If you've seen one [hospital] interface, you've seen one."

Microbiology data are particularly challenging because one culture result may contain multiple layers of results (body source, organism, susceptibility), many antibiotic assays, and additional elements such as ESBL and CRE. Even readers familiar with these complexities may be unaware of the variability in some seemingly straightforward data elements. The hospital facility where a culture was drawn, or where a patient is being admitted, is sometimes represented in HL7 messages as one of an alphabet soup of abbreviations that requires detective work to decode.

It is important, of course, to collaborate with the IPs (the end-users) in designing the system and to be flexible. Hospital systems are always re-evaluating their definitions of what constitutes an MDRO. A year ago, the criteria for MDRO *Enterobacteriaceae* at one of the larger hospital

systems were [{resistant to Ceftazidime or Ceftriaxone} and/or {confirmed production of an ESBL}] or [{resistant to Imipenem or Meropenem} and/or {confirmed carbapenemase production}]. Subsequently, the hospital system restricted the rules to just ESBL or carbapenemase. It is desirable to build decision support structures that facilitate future revisions of the rules (and the addition of new organisms and rules).

We also found that it was not always necessary to create a new process for functions that the REICON project had not used before. Occasionally, by examining existing tools and infrastructure in the HOSS pipeline (the exception browser) or the INPC database (its concept dictionary), we found a way to tailor a solution that had already been written.

Conclusion

Although there are many methodological challenges in building a flexible microbiology data processing, storage, and alert system for IPs, the results may contribute to epidemiologic understanding of the patterns of gram-negative (and ultimately other) MDROs across a wide region. The email alerts may make some contribution to reducing the emergence and spread of these dangerous bacteria.

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Appendix

List of Organisms from Table 1

Enterobacteriaceae

Escherichia
- Escherichia coli, E coli, E coli O157:H7
- Escherichia vulneris
- Escherichia hermannii
- (or other species)

Klebsiella
- Klebsiella pneumoniae
- Klebsiella oxytoca
- (or other species)

Enterobacter
- Enterobacter sp
- Enterobacter cloacae
- Enterobacter species
- Enterobacter aerogenes
- Enterobacter agglomerans
- (or other species)

Proteus
- Proteus mirabilis
- Proteus vulgaris
- (or other species)

Serratia
- Serratia marcescens
- (or other species)

Citrobacter
- Citrobacter freundii
- Citrobacter koseri
- (or other species)

Salmonella
- Salmonella (any species)

Shigella
- Shigella (any species)

Yersinia
- Yersinia (any species)

Morganella
- Morganella (any species)

Providencia
- Providencia (any species)

Hafnia
- Hafnia (any species)

Edwardsiella
- Edwardsiella (any species)

Other gram-negative bacteria not listed:

Pseudomonas (where the species is not aeruginosa)
Acinetobacter (where the species is not baumannii)
Stenotrophomonas maltophilia
Burkholderia cepacia (or other species)
Legionella pneumophila
Campylobacter jejuni (or other species)
Moraxella catarrhalis
Branhamella catarrhalis
Haemophilus influenzae (or other species)
Vibrio cholerae (or other species)

Detection of Methicillin-Resistant *Staphylococcus aureus* (MRSA) From Multiple Body Sites of Residents at Long-Term Care Facilities

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Abstract

Accurate determination of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization status can be an important part of any infection control strategy to limit the exposure of MRSA-free residents of long-term care facilities (LTCFs) to these pathogens. The nares are the most commonly sampled body site and the most frequently positive body site for the organism. We compared nasal polymerase chain reaction (PCR) to culture of the nares and four other body sites for detection of MRSA colonization to determine if the nares are still the preferred body site to be tested or if other sites should be included. The study population consisted of asymptomatic, infection-free residents at three LTCFs. A double-headed swab was used to collect nasal samples, and single swabs were used to collect oral, axilla, perineum, and perianal samples. Each swab was plated onto BBL™ CHROMagar™ MRSA (CM). When *S. aureus* was recovered, identification was confirmed with the Staphaurex® agglutination test. Pulsed-field gel electrophoresis (PFGE) analysis was performed on MRSA isolates recovered from each positive body site. After plating, one of the paired swabs from each nasal specimen was used to perform the BD GeneOhm™ MRSA achromopeptidase (ACP) assay, and the second swab was used for the Cepheid Xpert® MRSA test. Both PCR assays were performed according to the manufacturers' instructions. A total of 291 residents qualified for the study, and 26 (8.9 percent) residents had at least one body site culture positive for MRSA. Twenty-one of 26 (81 percent [95 percent CI, 76 percent to 85 percent]) residents were PCR positive in the nares; of the five that were PCR negative, three had positive perianal samples, and two had positive perineum samples. Our results suggest that nasal PCR testing captures 81 percent of those colonized with MRSA. If greater capture is desired, additional body sites should be considered for testing.

Introduction

The long-term care facility (LTCF) is a part of the U.S. health care system that presents unique challenges for infection prevention and control. Many residents of LTCFs are vulnerable older adults who are unable to manage independently in the community. They require a range of care, from minimal assistance with activities of daily living to total dependence upon health care personnel. In addition, there are many opportunities for direct interaction among residents, visitors, and health care personnel during group activities and at mealtimes, both in common activity areas and in dining rooms. An important goal of the LTCF is to find effective ways of minimizing the healthcare-associated infection risk while still maintaining the desired interactive lifestyle for these residents, who call the facility their home.

A major challenge in health care organizations today is the spread of drug-resistant bacteria. When residents of an LTCF are admitted to an acute care hospital, they are at risk of becoming

colonized and then returning to the LTCF with these organisms. Because it is hard to impose "contact isolation" precautions that restrict resident movement in a home-like living environment, there is considerable risk for the spread of these organisms. To better protect older adults, it is important for hospitals and LTCFs to collaborate on ways to prevent the spread of these organisms in both facilities. We developed a research and demonstration project to create a model of interfacility communication and cooperation between hospitals and LTCFs to facilitate infection prevention and control by developing LTCF-tailored interventions that reduce infection risk in older adults while maintaining their desired lifestyle. The prevention of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization and disease is the program model proof of concept. Our hypothesis for the study is that one can safely remove the colonization risk from nearly all MRSA-negative residents in a way that does not interfere with the desired lifestyle and thereby reduce their risk of MRSA clinical infection.

Colonization prevalence is an important measure for the success of this program, and accurate determination of colonization status is therefore an important part of the strategy. The nares is the most commonly sampled body site and is the most frequently positive body site for the organism, but not all MRSA carriers harbor MRSA in their nose. Studies have found that the throat and the rectum may provide additional information about true colonization status,[1–3] but past studies that have mixed reports of infected and non-infected individuals do not provide an accurate description of colonization sites in the asymptomatic, non-infected person. Our hypothesis was that testing the nares alone, using real-time polymerase chain reaction (PCR), is sufficient in long-term care because this approach led to a 70 percent reduction in clinical disease in our acute care hospitals.[4] Therefore, as part of our study, we sampled the nares and four other body sites of 300 non-infected residents at three LTCFs to investigate if sampling the nares is sufficient for determining MRSA colonization. We compared nasal PCR to the culture of all five body sites to determine if nasal PCR is sufficient for surveillance or if other body sites need to be included.

Methods

Sample Collection

Samples were collected from residents of three LTCFs from March 15, 2011 to February 22, 2012. The LTCFs are within 15 miles of each other and are served by two different health care systems. Residents selected for the study were able to give written consent and did not have an active infection with MRSA. They were selected from non-dementia units including, but not limited to, assisted-living and hospital/surgical rehabilitation floors.

To obtain consent, the residents were approached by a member of the research team. Research personnel wore street clothes with no lab coats so as not to give the impression of medical authority (i.e., did not look like a nurse or doctor) that would arouse feelings of coercion on the part of the resident. Research personnel read the consent form to the resident; if the resident orally agreed to be sampled and could sign his or her name and the date on the consent form, the investigator proceeded. If at any time the resident asked the researcher to stop, the collection process was discontinued.

Five body sites were sampled for culture: nose, throat, axilla, perineum, and perianal area. Nasal samples were collected using a double-headed swab with Liquid Stuart's transport media

(Copan) because two swabs were needed to perform PCR and culture. PCR was only done on the nares, since the test is Food and Drug Administration (FDA)-approved only for that use. The swabs were pre-moistened with the transport media prior to collection, for ease of sample collection, following protocol in our acute care hospital. Single swabs with Liquid Stuart's transport media were used to collect throat, axilla, perineum, and perianal samples. FDA-cleared PCR tests are not available for these sample sites; therefore one swab was sufficient for culture testing. Non-nasal swabs were not pre-moistened prior to sample collection. All samples were immediately transported to the laboratory and processed within 8 hours of collection.

Laboratory Testing

Each body site swab was plated onto BBL™ CHROMagar™ MRSA (CHROMagar). After plating, one of the paired swabs from the nasal specimens was used to perform the BD GeneOhm™ MRSA ACP assay, and the second swab was used for the Cepheid Xpert® MRSA test. Both nasal swab samples were destroyed after the PCR tests were performed, and so no sample existed for broth enrichment culture. For consistency, the other four body site swabs did not receive broth enrichment culture. The CHROMagar cultures were read at 24 and 48 hours. Mauve colonies found growing on the plates were isolated to blood agar, and *S. aureus* identification was made by performing a Staphaurex® agglutination test (Remel, Lenexa, KS). *S. aureus* colonies that were mauve on CHROMagar were considered to be MRSA.

The nasal samples were tested for MRSA by two different PCR assays, the BD GeneOhm assay and the Cepheid test. Both assays were performed according to the manufacturers' instructions. Sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) were determined for each PCR method, with positive culture of any single body site as the gold standard.

MRSA isolates recovered from each body site were typed by pulsed-field gel electrophoresis (PFGE) using *SmaI* restriction enzyme as previously described.[5,6] The patterns were identified on BioNumerics version 6.6 (Applied Maths Inc., Austin, TX) using a dendogram generated by the unweighted-pair group method with arithmetic mean based on Dice coefficients, where optimization and band position tolerance were set at 0.8 percent and 1.2 percent, respectively.[6,7] A similarity coefficient of 80 percent was selected to define the patterns. Assignment of pulsotype was correlated by comparison to the published literature.[8,9]

Results

A total of 302 residents were enrolled in the study, and 291 qualified for analysis. The 11 residents who were disqualified included 5 who were mistakenly sampled twice, and 6 whose written consent was deemed invalid by the institutional review board. The results for the residents tested, by LTCF, are shown in Table 1.

Table 1. Residents tested during study period, by long-term care facility

	MRSA Culture Negative (all body sites)	≥1 Culture Positive with MRSA	Total Residents Tested	Percent Positive Residents Tested / (95% confidence interval)
LTCF 1	90	20	110	18% / (12%–26%)
LTCF 2	101	3	104	2.9% / (1%–-8%)
LTCF 3	74	3	77	3.9% / (1%–11%)
Totals	265	26	291	8.9% / (6%–13%)

Twenty-six (8.9 percent) residents had at least one body site that was culture positive for MRSA, with a total of 63 culture-positive body sites. The number of cultures positive at each body site is listed in Tables 2 and 3. More than two-thirds (69 percent) of the 26 culture-positive residents were positive at two or more body sites. Of note, 21 of the 26 (81 percent) culture-positive residents were MRSA nasal PCR positive. Of the five that were not PCR positive, three were culture positive from the perianal region, two were positive from the throat, two were positive from the perineum, and none had a positive axilla culture. Overall, 13 of the 26 culture-positive residents were positive from their perianal site, 15 were positive from the throat, 11 from the perineum, and 3 from the axilla.

Table 2. Culture of multiple positive body sites vs. BD GeneOhm™ MRSA ACP assay and Cepheid Xpert® MRSA PCR test

Culture Positive Body Site	BD Nasal PCR Positive (n=21)	BD Nasal PCR Negative (n=5)	Cepheid Nasal PCR Positive (n=20)	Cepheid Nasal PCR Negative (n=6)
Nasal	20	1	19	2
Throat	13	2	14	1
Axilla	3	0	3	0
Perineum	9	2	9	2
Perianal	10	3	10	3

Table 3. MRSA culture-positive colonization of residents in three long-term care facilities, by body site

No. of Sites with MRSA Carriage	No. of Residents	Nares	Throat	Axilla	Perineum	Perianal
0	265	0	0	0	0	0
1	8	5	1	0	1	1
2	6	4	4	0	1	3
3	6	6	4	1	3	4
4	5	5	5	1	5	4
5	1	1	1	1	1	1

The sensitivity, specificity, PPV, and NPV for each of the nasal MRSA PCR tests are given in Tables 4 and 5. Culture of MRSA from any of the five body sites sampled was used as the reference standard for a positive patient. When the BD GeneOhm assay was used, 21 of 26 (81 percent) MRSA-colonized residents were detected. The results were similar with the Cepheid test: 20 of 26 (77 percent) of residents colonized with MRSA were detected. A total of seven

residents had at least one nasal PCR test negative; five had negative results for the BD GeneOhm test, and six for the Cepheid test.

Table 4. BD GeneOhm™ MRSA ACP assay versus all culture sites

	Any Body Site Culture Positive	All Body Site Cultures Negative	
PCR Positive	21	34	p=0.42
PCR Negative	5	231	
Sensitivity	81%		
Specificity	87%		
Predictive Value Positive	38%		
Predictive Value Negative	98%		

Table 5. Cepheid Xpert® MRSA PCR versus all culture sites

	Any Body Site Culture Positive	All Body Sites Culture Negative	
PCR Positive	20	5	p=0.36
PCR Negative	6	256*	
Sensitivity	77%		
Specificity	98%		
Predictive Value Positive	78%		
Predictive Value Negative	98%		

*Four tests were invalid, and results could not be provided.

The results of the strain typing of the 63 MRSA isolates are depicted in Figure 1. Analysis of the strain typing revealed eight different groups of related isolates that were arbitrarily designated as Groups 1–8. Group 1, with five residents, represents the USA300 pulsotype (community-associated MRSA), and Group 2, with 14 residents, is the USA100 pulsotype (the most common healthcare-associated MRSA clone). An additional five residents had strain types that had PFGE patterns similar or closely related to the USA100 pulsotype. One resident had a MRSA strain that resembled EMRSA-15 (the epidemic MRSA strain that has spread from the United Kingdom to several countries in Europe and Asia but is rarely detected in the United States) when compared to published PFGE images (Figure 2).[10,11] This strain type was recovered from the resident's nose, throat, perineum, and perianal area (the axilla did not grow MRSA). No other resident harbored this strain during this study. Two residents had one different strain type each among their MRSA isolates. Of the five residents that were nasal culture negative, no one strain type predominated in the other body sites.

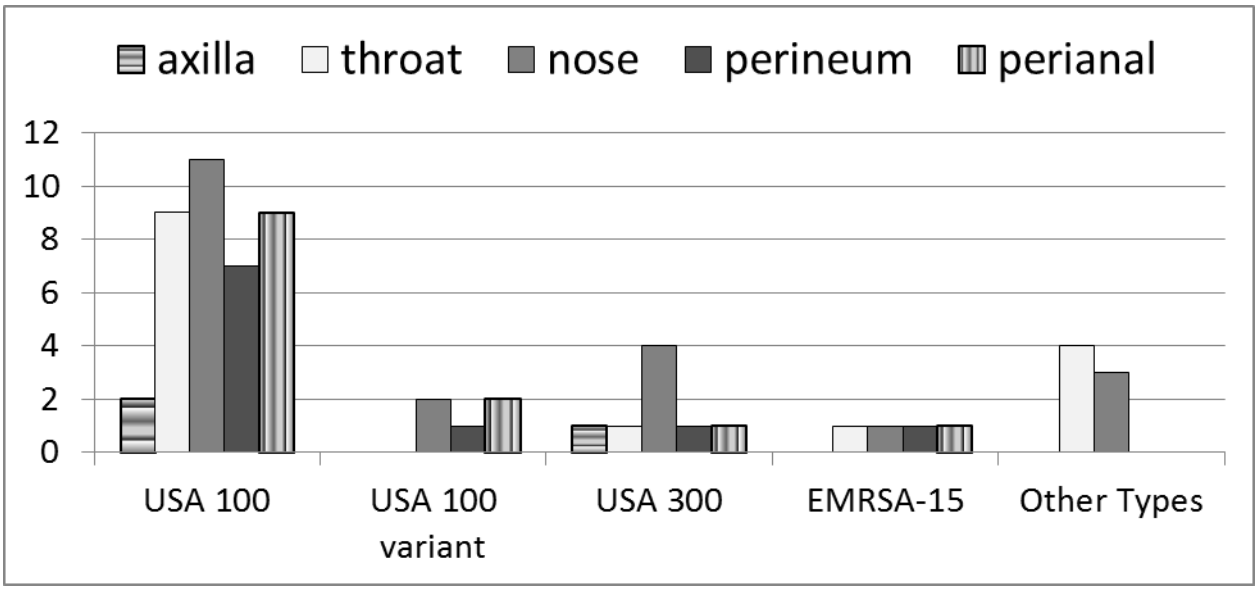
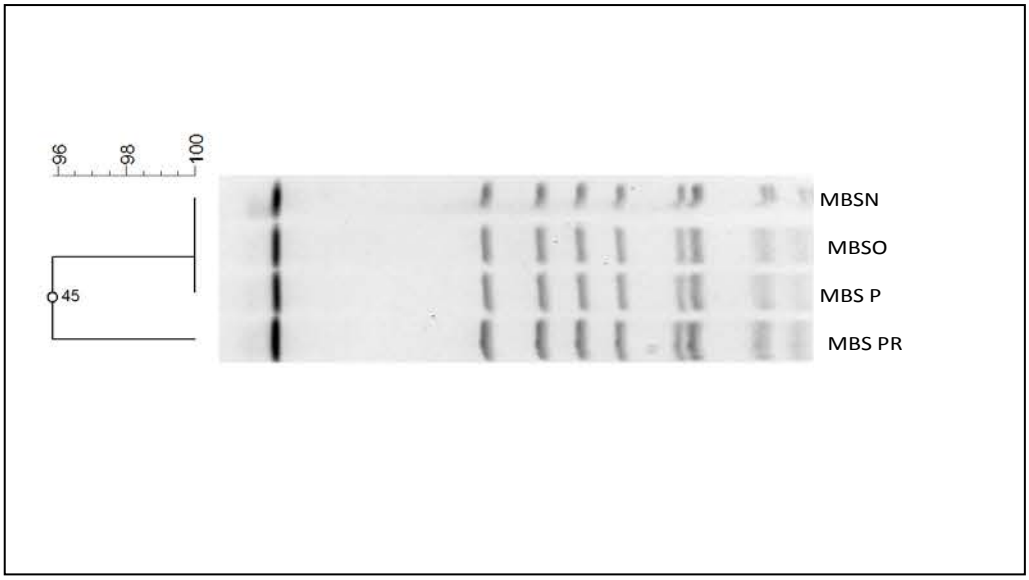


Figure 1. Pulsed-field gel electrophoresis pulsotypes of the 63 MRSA isolates at three long-term care facilities



Notes: MBS=multiple body site, N=nasal, O=oral (throat), P=perineum, PR=perianal.

Figure 2. Pulsed-field gel electrophoresis image of long-term care facility resident's strain resembling EMRSA-15

Discussion

In our health care organization, as in many others, real-time PCR is used to determine the MRSA nasal colonization status of a patient. Tests for nasal colonization with MRSA at an LTCF may also be conducted with PCR, and it was therefore added to the study to make the results applicable. Our results suggest that if we had only performed nasal PCR on the 291 residents in this LTCF population, we would have missed 19 percent of those colonized with MRSA, and that additional sampling with culture is needed to capture all those colonized with MRSA. Upon examination of our data, a good choice for additional sampling in this population might be the culture of the perianal region. In the case of the five residents who were nasal PCR negative with the BD GeneOhm test, three were positive in the perianal area. Likewise, in the six residents that were nasal PCR negative with the Cepheid test, three were positive in the perianal area. Only the nasal PCR and perianal culture combination gave a MRSA colonization rate close to 90 percent.

These findings are similar to Eveillard et al., who also showed that nasal and perirectal sampling captured more than 90 percent of those colonized; however, their study was conducted at a 600-bed teaching hospital rather than at an LTCF.[2] Mody and colleagues found that only 65 percent of the residents from 14 nursing homes were nasally colonized with MRSA.[1] Of those not colonized in the nose, perianal/groin samples and throat samples added approximately the same number of additional positive cultures. However the authors reported that adding just one body site, either perianal/groin or throat, would not achieve a colonization rate greater than 90 percent, and more than two sites would have to be sampled to achieve it. Interestingly, in our investigation and the Mody study,[1] the throat offered no distinct advantage in combination with the nose as some have suggested.[12,13] In addition, our study set included only uninfected individuals, providing an accurate description of colonization sites in the asymptomatic, uninfected person. The Mody and Eveillard studies included infected as well as asymptomatic patients.[1,2]

The predominant MRSA clonal type in this population of 291 non-infected LTCF patients was USA100. We did not detect many USA300 strains. Reports suggest that USA300 can evade detection because it is not a predominant nasal colonizer.[14] However, in contrast to these reports, of the five residents who were colonized with the USA300 type, four were found to harbor their MRSA strain only in the nose, and the nasal PCR test was positive for all four residents. This discrepancy may be due to the fact that we excluded clinically infected residents in the study. Interestingly, Shurland et al. found similar results with a study of residents in extended care facilities from one health care system. Eighty-four percent of USA300 MRSA-colonized residents had anterior nares colonization, whereas 86 percent of residents with non-USA300 strains were nasally colonized, and this difference was not significant.[14] Unlike our study, however, this study included residents with areas of skin breakdown.

One of the challenges in this investigation was the recruitment of subjects. Our study population was limited to 300 residents, a subset of the LTCF population, where we sought to enroll only residents who could give informed consent and were able to sign the consent forms. This excluded the dementia units. Also, an important consideration in the choice to exclude dementia units was to avoid the risk of undue stress on the residents. Five swabs were used to collect the various samples, and residents might become upset if they saw long, white swabs coming close to their body, especially personal areas like the groin or rectum. Moreover, it might be difficult for these residents to be moved if they were wheelchair bound. On the other hand, they might be

combative and not allow anyone to get near the area to be sampled. Still another reason to exclude residents with dementia is the need to involve individuals with power of attorney to sign a consent form. This would require more communication time than speaking directly to a resident. There might also be additional time and expense if forms needed to be handled through the mail.

Another challenge in the recruitment of subjects was their physical availability and mental alertness. Residents were consented mid-morning to afternoon because they were dressed and alert at this time. We found that this time period fostered a successful conversation with the resident, and the consent process went smoothly. However, it was during this time period that the residents were highly mobile and were often gone from their rooms. They could be participating in activities in other parts of the building or even outside the facility, making recruitment difficult. We found that the best time to find residents in their rooms was immediately before or after a meal. Research personnel had to arrange their visits to coincide with these timed events. In addition, we found it helpful to have two research personnel travel together to collect the samples. Often residents needed assistance during the sample collection, so the second person could aid in supporting the resident while the samples were collected.

To avoid potential problems while collecting samples at the LTCF, we found it helpful to have a good rapport with the LTCF personnel responsible for infection control (preferably a dedicated infection preventionist). This person was key to providing ongoing communication to the LTCF staff about the study and acted as a liaison with research personnel for any problems that arose. We relied on the guidance of these individuals because they are the experts when it comes to the framework of their facility, and the execution of the project had fewer problems because we had these study champions. We received no complaints from the residents or health care personnel about the study process.

This study had some limitations. One was the lack of the broth enrichment culture as part of the culture process. It is possible that there would have been more positive cultures had broth enrichment been used. Unfortunately, there was not a nasal swab sample left over for broth enrichment because both swabs were used for the PCR tests. The other potential limitation was the exclusion of the dementia unit. If this population of patients had a higher MRSA colonization rate than the population tested, it could have provided additional positive samples.

There were several lessons learned from this study. Having a good working relationship with the infection preventionist and the leadership staff at the LTCF afforded a smooth path to working with the residents and the health care workers. Knowing the activity patterns of the residents helped to maximize study personnel time and increased sample collection rates. Residents were often at doctors' appointments, physical therapy, or unit activities between meals, so those were time intervals to be avoided for sample collection. Interacting with residents immediately before or after breakfast was very successful. Knowing peak mental and physical fitness time of the day for the residents allowed for less confusion and more willingness to participate in a study.

More than one sample type will likely need to be collected if greater than 90 percent colonization status is to be achieved; for our population, the nose and perianal region represented the best combination. PCR can be a useful test methodology for nasal screening in LTCFs, although test systems vary in sensitivity and specificity. However, in our acute care hospitals, which have a comprehensive MRSA control program, we only test the nares and have achieved a 70 percent

reduction in clinical disease using this approach.[4] Thus, if colonization and disease in long-term care are reduced using nasal PCR testing, approximately an 80 percent level of capture may be sufficient.

Conclusion

Accurate determination of MRSA colonization status is an important part of any infection control surveillance strategy that has a goal to limit the exposure of non-colonized individuals to this pathogen. In our study the nose proved to be the site most colonized with MRSA, with nasal PCR capturing 81 percent of all those colonized with MRSA. Of interest in this study was that while the two PCR tests had similar sensitivity for the LTCF population, one had superior specificity, which resulted in significantly fewer false positive tests being reported when the Cepheid assay was used (Tables 4 and 5; $p < 0.001$). To capture more than 90 percent of all colonized residents, sampling the nares and additional sites is necessary. Since we used nasal PCR alone to reduce MRSA disease in our acute care facility,[4] this level of detection may be sufficient; but if successful control is not achieved in the LTCF setting using nasal swab PCR alone, then the testing of additional body sites should be considered.

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An Electronic Card Study of Treatment Strategies for Community-Acquired Methicillin-Resistant *Staphylococcus aureus* (CA-MRSA)

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Abstract

We describe the use of electronic health record (EHR) data to develop, distribute, provide followup, and analyze results in a study that developed and tested sustainable, guideline-consistent treatment strategies for community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA). Of the many applications of EHRs, one example is the enhanced capabilities for collecting patient-specific data within practice-based research networks (PBRNs). Historically PBRNs utilized physical "card" studies to collect information from clinicians at the point of care. Using the EHR-linked datasets available through eNQUIRENet, cases of certain skin or soft tissue infection (SSTI) were identified on a nightly basis. The research team then used internal email systems to invite clinicians to take part in evaluations of the cases. The email included links to internal Web sites and online evaluations. Evaluation data were then linked back to de-identified EHR data. To study clinical decisionmaking related to SSTI, we successfully developed a reliable, Health Insurance Portability and Accountability Act of 2009 (HIPAA)-compliant method of using EHR data to guide tailored data collection. We showed that data could be collected by clinicians and patients and be linked electronically to researchers in remote locations. Electronic card studies offer a new and useful tool for performing enhanced clinical research and for developing and launching practice-based guidelines. Removal of clinician error in initiating the survey and in selecting the proper survey improves results. A better understanding of response rates is obtained than in traditional card studies because all cases can be identified, and providers do not have to remember to initiate data collection.

Introduction

Community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA) is a significant public health concern; it has the potential to develop quickly into an invasive skin infection and cause other life-threatening complications. Despite the relatively low prevalence of skin and soft tissue infections (SSTIs) in primary care,[1] *S. aureus* is the most common pathogen causing SSTIs.[2] In response to this public health problem, the Centers for Disease Control and Prevention (CDC) convened an expert panel and published recommendations and a clinical algorithm/flow sheet for outpatient management of CA-MRSA.[3] The feasibility and uptake of the CDC guidelines in busy primary care settings were previously unknown. Thus, a request for task order was commissioned by the Agency for Healthcare Research and Quality (AHRQ) and awarded to SNOCAP-USA to further the understanding of CA-MRSA and to develop and test real-world, sustainable strategies consistent with the CDC guidelines, using a practical trial approach.[4,5]

Although the CDC guidelines for treatment of SSTI have been widely disseminated, they are primarily based on expert opinion because there are few empirical data on which to base treatment decisions. It is still not the norm for SSTI treatment to account for CA-MRSA[3] or to follow CDC recommendations. Such findings may be interpreted as demonstrating substandard

care from a clinician who is either not familiar with or not following the established guidelines or may represent logical clinical decisionmaking in an understudied area. Practice-based research networks (PBRNs) have been studying this kind of phenomenon since their inception, often discovering that the "evidence-based guidelines" were not well-suited for primary care or that they were not applicable to specific patients in primary care due to other comorbidities, life expectancy, patient preferences, and other factors.[4,6,7]

Overall, the CA-MRSA project sought to develop and evaluate sustainable, guideline-consistent treatment strategies for CA-MRSA by working with the primary care clinicians and infectious disease consultants in two health care organizations. Specifically, we sought to evaluate MRSA management decisions for specific SSTI cases of interest in real time. To evaluate whether providers were able to provide care concordant with the CDC guideline for MRSA,[8] encounter-related data were extracted from electronic health records (EHRs) and used to inform an online survey that was presented to the clinicians—an approach that could be generalized to other areas of clinical inquiry and expanded to better inform policy and clinical decisionmaking.

The method was based on the traditional PBRN study method of "card studies," which are observational studies that collect discrete, patient-level survey data at the point of care.[9] Card studies are particularly suitable for collecting patient-level information for disease-specific conditions that may be uncommon. In a standard card study, the data collection instrument is a long, thin card designed to fit in a pocket and be carried around and completed in less than 60 seconds as the clinician provides care. Card studies have been a popular tool in practice-based research for many years.[10] Although the original card studies were typically simple convenience samples, subsequent designs have progressed in terms of the scope of the data collected, the sources of data, and the collection methods. Card studies remain a popular research tool and are often used in PBRNs to understand clinical decisionmaking around selected conditions, to gain a better understanding of the incidence and prevalence of conditions in primary care, and to provide pilot data for subsequent studies. Card studies have played a significant role in developing new standards of care for conditions including miscarriages, headaches, and otitis media, and they provide a better understanding of care processes.[4,6,7,11] The ability to extract existing clinical data from EHRs offers an opportunity to rethink the traditional card study approach.

To learn about the clinician decisionmaking process, we designed a survey using EHR data to inform the data collection process and to incorporate the data collection into the clinicians' workflow. The result was a novel "electronic card study" informed by data from the EHR. The study used multiple data sources including EHRs, manual chart audits, patient-reported outcomes, and provider-reported clinical decisionmaking processes. Data from each source were stripped of patient identifiers, with the exception of dates of service, and linked together for analysis. This paper describes the development, use, and potential benefits and limitations of an electronic means to collect feedback from clinicians about their clinical decisionmaking near the point of care, an approach that could be applied to the study of many other infectious diseases or other clinical care processes.

Methods

The CA-MRSA study was conducted in eNQUIRENet (formerly DARTNet), a federated network of standardized EHR data and other clinical information from multiple organizations

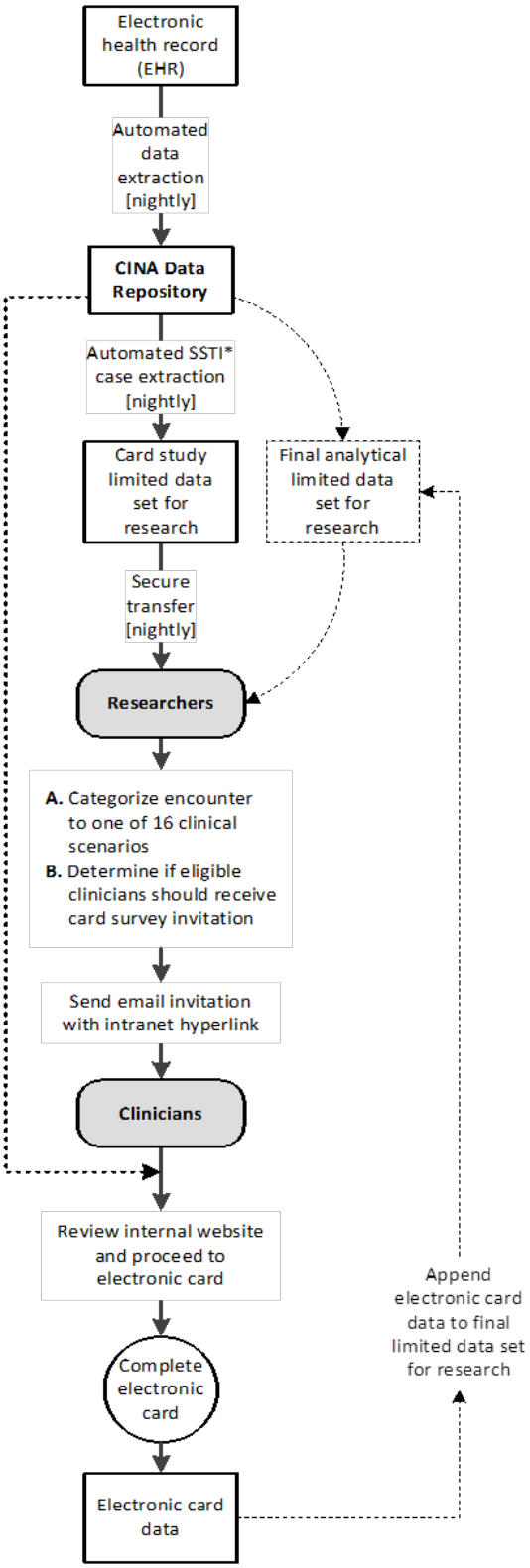
across the United States.[12,13] The EHRs and clinical information systems reside in member practices and are linked through a secure Web-based system so that they can be searched and queried as one large database while maintaining the privacy and confidentiality of patient data. The CA-MRSA study was designed to collect data through data extraction from the participating health systems' EHRs. Our intent was to extract EHR data to see if clinicians were providing guideline-concordant care and then to ask them about the care they provided as close to the point of care as possible. We linked clinicians' decisionmaking considerations with a limited dataset extracted from each organization's EHR system. For example, the dataset contained information about which medications were prescribed and whether a procedure was performed. The rationale for why the clinicians chose the prescribed medications and the reasoning behind the decision to perform a procedure were collected via the electronic card study. Data elements from these sources were merged using a common random identifier to form a comprehensive record of the encounter that included which treatments were chosen and why.

Two health care systems independently reviewed the CDC guidelines for the treatment of SSTIs, including ambulatory treatment for CA-MRSA, and developed interventions to promote guideline-concordant care. The intervention included a ready-made tray/kit for incision and drainage procedures, a patient information handout, provider MRSA education, and patient home care instructions.[3] SSTIs were identified and care processes were tracked using EHR data. During the intervention phase, both organizations contacted patients seen for SSTIs 2 weeks after the index visit, to collect patient-reported outcomes concerning resolution or the need for further care outside the clinical organization. Directed chart audits were used to determine guideline-concordant care for selected conditions that could not be extracted as discrete data elements from the EHR (for instance, extent of erythema around an abscess). To better understand clinicians' decisionmaking, a total of 19 primary care clinicians from 16 primary care practices in the two organizations were asked to participate in an electronic card study activity. Figure 1 shows the data flow for the electronic card study.

Data Extraction

A limited dataset containing information about SSTI encounters from both participating organizations was sent via secure FTP to the research team each night for analysis. The limited dataset was generated by QED Clinical, Inc. (dba CINA, Dallas, TX), a software company that provides clinical decision support and registry services to clinics irrespective of which EHR system they use. Every night, at each location, an automated process extracted data from the client's EHR and other data sources (such as practice management systems), standardized the data, and placed them into a proprietary clinical data repository housed on a server behind the client's firewall. For this study, CINA set up a second automated process to search the clinical data repository nightly for encounters during which an ICD-9 code for SSTI was used (680.x, 681.x, 682.x). For encounters where such a diagnosis code was used, a limited dataset was generated and sent via secure FTP to the research team. The limited dataset included patient age, diagnosis codes, culture records, procedure records, and prescription records, but no direct patient identifiers.

Figure 1. Data flow for electronic card study



Note: CINA is the decision support software vendor
SSTI = skin and soft tissue infections

Encounter Categorization and Survey Invitation

Each morning, the research team reviewed the new encounter records to determine if the providers of record should be invited to complete an electronic card and, if so, to determine which evaluation option the provider would receive. To determine provider eligibility, we checked whether the provider of record had consented to participate in the study. If the provider had consented for the card study, it was further determined if he/she had any outstanding evaluations. We also checked whether the encounter was the patient's first in which an SSTI diagnosis code was used within a time window. If the provider had consented to participate and had no evaluations outstanding, and the encounter was the patient's first in the last 30 days with an SSTI ICD-9 code, the encounter was eligible for an evaluation. The research team analyzed the data to categorize each encounter into one of 16 different clinical scenarios, each of which was evaluated differently:

- Child (yes or no).
- Culture performed (yes or no).
- Procedure performed (yes or no).
- Antibiotics prescribed (yes or no).

After encounter eligibility was determined and the encounter was categorized, an invitation to complete an electronic survey was sent to the provider via email. Invitation emails containing a hyperlink to an intranet Web site were sent to providers of record 1–3 days after the encounter.

Internal Web Site

The hyperlink in the invitation email took providers to a Web site running on their organization's server. The Web site tapped into clinical information stored in the clinical data repository to display information intended to refresh the provider's memory regarding the encounter to be evaluated. It displayed patient identifiers related to the encounter, including name and date of birth—enough information for the provider to go into the EHR to review the patient's records. A unique random encounter identification number generated by CINA for this study was embedded in the invitation email hyperlink and used to link to data about the clinical encounter and display information about the patient to the provider. This Web site was behind the organization's firewall and was therefore inaccessible to anyone outside the organization. Logic behind the internal Web site read the information embedded in the hyperlink to generate a customized link to the specific online evaluation for the selected clinical scenario.

Online Survey

The hyperlink on the internal Web site took the provider to the online evaluation tool and contained information about the clinical scenario (e.g., a child with an SSTI who had a procedure performed and antibiotics prescribed, but no culture done). The information embedded in the link was used by the survey (set up using CheckBox [Watertown, MA]) to prepopulate certain fields in the data table and to determine which set of questions to present to the clinician. The unique random encounter identification number was also transmitted via the link so that the responses to the evaluation could be linked back to the limited dataset.

Results

We successfully developed a reliable, HIPAA-compliant method of using EHR data to guide tailored data collection concerning clinical decisionmaking related to SSTIs. Encounters were categorized into one of 16 different clinical scenarios, and the research team decided whether or not to send the invitation to evaluate the encounter via the card study. The decision to send an invitation was based on whether the clinical data indicated a new SSTI episode and whether the provider of record had consented to participate and had a recent prior invitation to which they had yet to respond. The research team triggered 157 electronic cards, which resulted in a response rate of 70.7 percent. Upon receipt of the invitation email, the clinicians clicked on the link, which took them to an intranet Web site that displayed specific information about the encounter and a link to the electronic card study. On average, the clinicians completed the evaluations in 3.5 days.

The electronic card study helped to clarify several areas of interest from the electronic data pulls. For instance, the rate of incision and drainage procedures seemed low, 10.3 percent at baseline and 4.7 percent during the intervention across organizations. This was partly explained through chart audit, where it was apparent that not all procedures were billed. Greater understanding, however, came from the card study, where it became clear that in many cases the abscess had already spontaneously drained and the need for a procedure had been alleviated. Another area where the card study helped elucidate the quantitative findings was related to obtaining cultures. Again, the culture rates appeared low from the electronic data, 17.1 percent across organizations at baseline and 14.2 percent during the intervention period. In this case, a number of clinical decisions in combination helped clarify the findings, including the disease processes that fell into specific diagnostic codes; the lack of material to culture, such as in smaller, spontaneously drained lesions; and the overall lack of clinical utility in culture results. In fact, in followup interviews driven by the card study results, responding clinicians could identify no instances of culture results altering clinical care. Thus, there was little evidence to encourage greater use of cultures for SSTIs.

Discussion

Advantages and Limitations of Electronic Card Studies

Although traditional card studies have been successful in large part because of their simplicity, they also have significant limitations that would not have made their use possible in the CA-MRSA study. Electronic card studies have the potential to address many of these limitations and to offer advantages that are not possible using a paper card methodology. Paper card studies require provider recall and initiation based on patient-eligibility criteria, which can sometimes be complex or of low prevalence, and thus not all cases are captured. Since the initiation of the electronic card is done by the researcher or preset software, this issue is reduced. In addition, the traditional cards cannot be tailored to different clinical scenarios. Electronic card methodology allows the research team to customize the cards sent to the clinicians, to collect only the data appropriate for the clinical scenario. Also, all cases can be captured because researchers are no longer reliant on providers to select the right survey or to complete the survey. Another advantage of the electronic card study is that it can be directly linked to the patient's record. The providers are shown details of the patient's visit prior to completing the card to help refresh their memory of the case. The paper cards, on the other hand, rely on the provider to accurately match

the card to the specific patient. Speed is another advantage of the electronic cards. Electronic cards can be sent to the researchers for review on a daily basis and do not require the practice to mail the cards.

In the present study, without information from clinicians near the point of care, many of the findings would most likely have been interpreted as indicative of very poor guideline concordance. These findings might have been attributed to poor underlying knowledge and overall clinical care. Our understanding of the decision processes could have been supplemented by interviews, where hypothetical situations were posited, but it would be difficult to know how well the answers tracked with actual patient experiences. Using the near-point-of-care electronic card study approach, clinicians were asked to respond based on an actual clinical case. We believe these answers are more likely to represent the breadth of the decision processes that occur when translating guidelines into clinical care.

Although the advantages of electronic card studies are numerous and far outweigh the limitations, there are limitations that warrant discussion. One major disadvantage is the additional upfront set-up time required by the use of EHR linkages. It takes a significant amount of time to develop the data extraction, transfer, and preliminary analysis processes and to set up the data collection tool. Once the system is in place, however, it can be easily modified and reused for future studies with minimal cost. Another concern is that several issues were discovered in the accuracy and timeliness of the data capture itself. For example, culture records were slow to appear in the EHR. Also, certain procedures were not captured consistently in the EHR and were difficult to locate within the system. In addition, some antibiotic prescriptions were still handwritten and were not captured reliably in the EHR. However, the electronic card study system detected that the data were missing and asked the provider, in the evaluation, to verify the missing information.

Conclusion

There is great potential for future electronic card studies. Lessons learned from this study confirm that the use of the EHR to capture data allows clinicians and researchers to perform real-time automated card studies using a much larger sample size than was previously thought possible. Further, electronic cards can be tailored to match very specific criteria designed by researchers. Logical areas where this approach could add to current clinical knowledge include reasons for low rates of human papilloma virus (HPV) immunizations and reasons for not including HPV testing during cervical cancer screening; reasons antibiotics were prescribed for acute (most likely viral) infections; antibiotic use and choices in treating otitis media; reasons for low rates of screening for human immunodeficiency virus; and many other concepts. Electronic cards can even be generated for completion by patients for clinical purposes and then be used secondarily for research.[14] The approach developed for this study can be generalized and expanded to more areas of inquiry and more clinics to even better inform policy decisions.

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A Participatory Research Approach to Reducing Surgical Site Infections (SSIs): Development of an Automated SSI Surveillance Tool

Lucy A. Savitz, Susan L. Moore, Walter Biffl, Connie Price, Heather Gilmartin

Abstract

Healthcare-associated infections (HAIs) have a significant impact on health care quality and cost. Four health care delivery systems collaborated in a participatory research approach to enhance surgical site infection (SSI) detection and surveillance for selected procedures through use of an automated tool. A planned mixed methods approach was used to model risk factor data available from electronic medical records, conduct algorithm testing and validation, and incorporate structured feedback from surgeons and infection control nurses with regard to tool acceptance and implementation. A version of the tool was tested on a retrospective cohort to assess performance versus surveillance through manual chart review. The tool achieved 100 percent sensitivity in detecting SSIs previously identified and 72 percent specificity in detecting SSIs meeting National Health Safety Network guidelines. At an estimated manual review burden of 20 minutes per chart, a time savings of 456 hours through algorithmic surveillance was calculated. Although these results are promising, IPs were reluctant to depend solely on such a tool for surveillance; however, tool use for real-time detection was deemed desirable. Strategies such as the algorithm developed and tested in this study show potential to both improve efficiency and reduce cost without compromising quality.

Introduction

The persistent problem of mitigating healthcare-associated infections (HAIs) has plagued hospitals both here and around the world. Numerous attempts at improving the quality and safety of care over the years have provided only temporary improvements with minimal impact. For this project, we used a participatory research approach to yield a clinically relevant toolkit that could be implemented in a variety of delivery system settings.[1]

Prevention of adverse events is both a longstanding problem that has plagued hospitals around the world and a priority for the Center for Medicare & Medicaid Innovation's (CMMI), through its Partnership for Patients initiative (http://innovation.cms.gov/initiatives/Partnership-for-Patients/). Under this initiative, U.S. hospitals were expected to reduce healthcare acquired conditions (HACs) by 40 percent and readmissions by 20 percent by the end of 2013. Hospital Engagement Networks (HENs)[a] are charged with reducing four HAIs that fall within CMMI's targeted HACs, including surgical site infections (SSIs). Intermountain Healthcare leads one of the HENs, and a Denver Health (DH) subject matter expert, Dr. Connie Price, has been working through this initiative with hospitals across the United States to reduce SSIs. Some of the biggest challenges facing partner HEN hospitals in reducing SSIs include a resource-constrained environment and multiple, competing quality and safety initiatives. This paper describes our efforts to provide meaningful research results with high operational utility in reducing SSIs.

[a] Hospital engagement networks (HENs) are one component of the Partnership for Patients, a Centers for Medicare & Medicare Services (CMS) initiative. Over 3,700 hospitals are participating in 26 HENs around the country.

The purpose of this project was to explore opportunities for enhancing the detection and surveillance of inpatient-acquired SSIs for four target procedures—herniorrhaphy, coronary artery bypass graft (CABG) surgery, and hip and knee arthroplasty (including primary total arthroplasty, primary hemiarthroplasty, and revision procedures). The objective was to create and implement an algorithmic process for predicting and/or identifying those patients at risk for an SSI, using electronic risk factor data newly available through enhanced data repositories and accessible by hospital systems with electronic medical records (EMRs). Specific details of the quantitative modeling work are reported elsewhere.[2] The project was based on a longstanding HAI detection trigger system built and administered by investigators at Intermountain Healthcare since the mid-1980s.[3] The project presented an opportunity to (1) update this work, (2) directly engage clinical perspectives from the fields of surgery and infection prevention on currently excluded risk factors important to such models, and (3) assess the impact of such a tool when implemented in the work environment of infection prevention staff.

Investigators from multiple delivery systems came together to provide the most representative results and generalizable tools. Collaborating delivery systems were DH (a safety net hospital located in Denver, CO), Intermountain Healthcare (a large, nonprofit, integrated delivery system based in Salt Lake City, UT), and the Salt Lake City Veterans Affairs (VA) Medical Center (a VA hospital located in Salt Lake City, UT). Representativeness was further extended by including the Vail Valley Medical Center (a rural community hospital located in Vail, CO), a DH partner.

Methods

This participatory research effort was intentionally designed as a multiphase, sequential mixed methods study with iterative tasks, whereby one level of inquiry informed the next. Active involvement of delivery systems in research is intended to accelerate the uptake of research results and build trusting relationships that support a foundation for longer term studies.[4] Further, the objectivity of outside observation, balanced with the richness of end-user knowledge, has been shown to enhance validity and foster credibility from both a rigorous research perspective and a clinical relevance perspective. Foundational work in establishing priorities for comparative effectiveness research have further shown the need to actively engage end users in the full spectrum of such research.[5]

Our mixed methods approach embraced the participatory research paradigm—answering relevant questions that address problems and priorities experienced in these settings.[6] Participation was considered at every stage of the research process.[7,8] The research team comprised health services researchers, infectious disease physicians, a surgeon, and an infection preventionist (IP). This interdisciplinary team identified relevant research questions, designed the study, and established an analytic plan in collaboration with the AHRQ Task Order Officer, Dr. Kendall Hall, together with a team of subject matter experts from the Centers for Disease Control and Prevention (CDC). The CDC team included Dr. Sandra Barrios-Torres, Dr. Teresa Horan, and Dr. Jonathan Edwards. Throughout the project, broader end-user perspectives were engaged via three focus groups conducted in sessions ranging from 1 to 2 hours with six surgeons (one group) and 13 infection control nurses (two groups; eight participants in group one and five participants in group two). A manual open, heuristic coding process was used to identify topics and themes from focus group data. Results from the surgeons' focus group were used to gain insight into how tool dissemination and adoption might be promoted among surgeons and inform

the selection of common risk factors for analysis. Detailed input was codified by data analysts in testing the developed tools at each of the four participating health care delivery systems, with adjustments made to accommodate different data structures where necessary.[2] Finally, feedback from end users obtained through the two nurses' focus groups was used to produce a supporting user guide and implementation manual.

We used a planned mixed methods approach for this project. The Office of Behavioral and Social Sciences provides a review of best practices in mixed methods studies.[9] More recent work by Zhang and Creswell[10] focuses on the mixing procedures, whereby "Mixing in mixed methods is more than just the combination of two independent components of quantitative and qualitative data." Although there are alternative mixing procedures delineated by the authors, our connected approach relied on blending qualitative and quantitative data such that the research connected the qualitative and quantitative portions of the project. Connected mixed methods studies connect the qualitative and quantitative portions of a project in such a way that one approach builds on the findings of the other approach.

We began by employing a modified Delphi process with six surgeons attending the 5th annual Academic Surgical Congress in San Antonio, TX to identify risk factors for improved identification of SSIs. In particular, we were interested in expanding risk factors currently under consideration by hospital surveillance systems. This expert consensus exploration of risk factors was coupled with an in-depth focused group discussion with the same surgeons. The participating surgeons were recruited through professional networking to participate in the risk factor exploration and focus group discussion, both of which took place in person at the conference, adjacent to a session on SSIs. Results from both the rank ordering (i.e., Delphi) and in-depth discussion were used to inform quantitative modeling. A union set of 33 common risk factors identified and ranked by surgeons' discussion and confirmed as electronically available in participating institutions' data systems was used in modeling. Markov chain Monte Carlo multiple imputation was used to account for missing data values. Independent association between potential risk factors and SSI was determined through univariate regression. Binary logistic regression was used to evaluate a variable relationship with SSI occurrence. The final model included risk factors with a probability of < 0.05 or that contributed to the predictive value of the model.[1] Electronic algorithms were created to detect both deep and organ-space SSIs, using both recursive partitioning and simplified methods based on abnormal laboratory values or the presence of postoperative microbiology or antimicrobial data. Figure 1 depicts the classification tree algorithm structure, showing the identification of positive values through compact logic.[1] Algorithm development, training, and testing are discussed in detail in a separate paper in this report.[2]

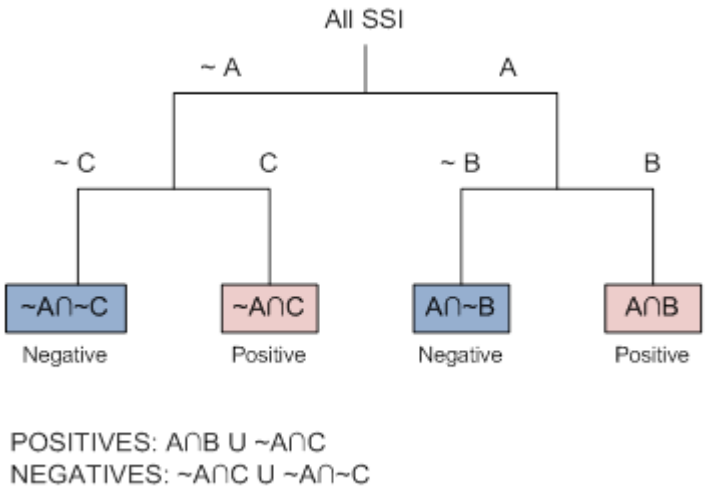

Figure 1 Classification Tree Algorithm Identification

Source. Price CS, Savitz LA. Improving the Measurement of surgical site infection risk stratification/outcome detection. Final Report (Prepared by Denver Health and its partners under contract 290-2006-00-20). AHRQ Publication No. 12-0046. Rockville, MD: Agency for Healthcare Research and Quality; March 2012. Available at http://psnet.ahrq.gov/resource.aspx?resourceID=25139. Accessed March 26, 2014.

Note: A, B, and C indicate conditions. Operators are represented as follows: NOT by the ~ symbol, INTERSECTION by the ∩ symbol, and UNION by the U symbol.

Following conclusion of the quantitative data analysis, including updated risk factor modeling at the surgical procedure level, we conducted two focus groups with infection control nurses to learn about the e-detection tool developed in this study, talk about SSI surveillance and the challenges that individual IPs face in their institution, and discuss implementation and changes in the standard surveillance process that could be facilitated through the use of the electronic tool. The first nursing focus group was conducted in Denver, CO, with five participants recruited from among members of the Mile High Chapter of the Association for Professionals in Infection Control, and the second nursing focus group was conducted in Salt Lake City, UT, with eight participants recruited from hospitals in the Intermountain Healthcare system. The feedback we received from the focus groups provided an understanding of the challenges institutions would confront in implementing an automated surveillance tool in their care delivery system and informed development of a manual for implementation. Testing of the tool in multiple delivery system settings identified a shared perspective that the tool would reduce the work burden associated with chart abstraction, allowing providers to focus their work effort on high-risk cases for SSI prevention.

Challenges were addressed throughout the testing, and the tool was re-worked for maximum applicability for the diverse settings and EMRs. Data were pooled across the four health care system settings to conduct quantitative analyses. Interviews with programmers were used to document effort time and the source of data. These findings, along with the data from the focus

groups, were documented and used in developing a user toolkit to support adoption outside the delivery system settings in which the study was conducted.[b]

Results

The DH infection prevention team sought to further adapt, tailor, and validate the electronic detection algorithm created for use in everyday surveillance of SSIs at DH, in order to reduce the burden of chart review while identifying a high percentage of SSIs. Prior to implementing the electronic tool, infection prevention personnel manually reviewed all charts for SSI surveillance purposes based on culture results. DH tested the tool in its integrated system to determine whether it would be possible to reduce cost associated with chart review hours by staff, while maintaining and/or improving the quality of their SSI surveillance efforts. The mandate for the algorithm's application was to maximize sensitivity at the expense of specificity, while realizing a meaningful reduction in chart review burden.

To test the sensitivity of the tool, DH's Infection Prevention Data Manager generated a retrospective cohort of procedures, including associated SSIs as defined by National Health Safety Network (NHSN) guidelines, using DH surveillance data from 2007-2010. The procedures reviewed included hip and knee arthroplasty, abdominal and vaginal hysterectomy, spinal fusion, craniotomy, and herniorrhaphy. The modified algorithm identified 804 procedures (37 percent of total charts for that time period) for review. The percentage of total procedures identified for review varied by procedure type from 15 percent of herniorrhaphy to 62 percent of craniotomy. After manual review by infection control staff, the modified algorithm was determined to have achieved 100 percent sensitivity in detecting SSIs previously identified through traditional surveillance and 72 percent specificity in detecting SSIs meeting NHSN definitions, validated on 4 years of DH's manual SSI surveillance data using NHSN methodology.

Over this 4-year period, 1,375 unnecessary chart reviews could have been avoided without sacrificing detection of a single SSI using the modified surveillance algorithm. Assuming 20 minutes per chart for traditional manual review, a time savings of 456 hours, or 57 full (8-hour) days of chart review, could have been realized using the modified algorithm for surveillance of SSI in hip and knee arthroplasty, abdominal and vaginal hysterectomy, spinal fusion, craniotomy, and herniorrhaphy at DH.

The major constraint to this additional project involved the DH programmer's time, which was required to pull the SSI data into a standardized format. Pooled data were analyzed by current staff whose time was covered by the AHRQ project budget. Making the business case for uptake of the automated surveillance program was a key feature of this work. While promising quantitative results in identifying SSIs using the automated module were found, the perceptions of infection prevention professionals from our focus groups have been instrumental in providing additional support for the decision to implement and institutionalize this automated surveillance system. In summary, the IPs present at the Denver focus group expressed a desire for a free electronic surveillance tool that could enhance current surveillance methods and provide support for the validity of current findings, while providing an opportunity for real-time notification of

[b] This toolkit is available in the Resources section, under the Surgical Site Infection subsection as AHRQ Report of the Intermountain-led Hospital Engagement Network (HEN) Web site at www.henlearner.org.

at-risk patient events if the department would be able to respond in a timely manner. The IPs were hesitant to consider the electronic tool as the sole method for HAI surveillance, mostly due to the high risk of false-positives and the challenges with interpretation of HAI definitions in diverse populations. The sustainability of an institutional surveillance program was noted to be person-specific. The benefit of an electronic surveillance tool that could push data to the IP department was deemed a bonus; the data could be pushed to the department to allow real time surveillance at all times

Discussion

One of the strengths of our research approach was to rigorously differentiate between risk factors for and manifestations of SSI, using a mixed methods approach with engaged delivery system investigator participation. Risk factor data can supply additional information to data systems to improve performance, but use of such data could also curtail any analysis of risk from surveillance systems using the algorithm. We anticipated that the main characteristics that would facilitate its acceptability were a high sensitivity and a low number of charts that would need to be reviewed per identified SSI.

Our approach sought to capitalize on the superior specificity of human reviewers, the growing wealth of electronic data, and the speed of automated systems. If charts are reviewed in roughly 20 minutes,[11] and the fraction of SSI among procedures is roughly one percent,[12] then 33 hours of review could be anticipated for every SSI found. If electronic tools could effectively remove 80 percent of charts, then only 6.6 hours would be spent for every SSI found. The impact of such savings may be large. The Virginia requirement for statewide detection/reporting would require 160 IPs at a cost of $11.5 million. More than 50 percent of IP time is spent at the desk[13]—time that could be applied to implementation, education, and other effective activities. A noted limitation of the tool is the need for an integrated EMR system that ideally would include postoperative visits and outpatient pharmacy and laboratory data. In addition, the algorithm requires the time of information technology specialists to build and maintain it. This could be a challenge for institutions that do not have strong advocates for the infection prevention program.

Conclusion

Our surveillance tool has the potential to maximize the work environment of infection prevention staff, moving them from their desks to the units where they can focus on the activities that prevent infections. Further, the surveillance system provides cognitive surveillance support to the human element of traditional practice (i.e., chart review, available electronic data, using “shoe leather”). The advantages of automated surveillance programs include:

- Provide quality assurance for current practice.
- Reduce the burden of chart review.
- Identify patterns of infection that might suggest opportunities for process improvement/reengineering to enhance quality and safety.
- Enhance the work environment for infection prevention staff.
- Meet mandatory, hospital-wide reporting of SSI for value-based payments.
- Use a publicly available electronic surveillance tool vs. an expensive, proprietary data mining surveillance tool like Theradoc™ or Medimined® that can cost up to $150,000, require a separate server, and have continuing maintenance/upgrade fees.

Patient safety improvement strategies, such as the surveillance algorithm developed and tested in this study, leverage electronic data, freeing up clinical resources (e.g., the reduced need for chart review and abstraction in this study). Such approaches provide critical tools for simultaneously reducing cost and improving quality.

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Issues Regarding Identification of Urinary Catheter Use From Medical Records

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Abstract

Urinary catheters often are placed unnecessarily, used without physician awareness, and associated with a very common and expensive complication—hospital-acquired catheter-associated urinary tract infection (CAUTI). In this paper we describe our experience in developing, implementing, and analyzing a retrospective, comprehensive medical record review regarding urinary catheter use and identification of urinary tract infections as CAUTIs. We share the results of urinary catheter use measures to illustrate the complexity in identifying catheter use in medical records that are being used to generate quality measures for comparing hospitals. We also discuss our experience involving resident physicians as collaborators in an opportunity for learning about patient safety research. Additionally, we share our experience related to maintaining compliance with the Accreditation Council for Graduate Medical Education (ACGME) resident duty work hour regulations.

Introduction

Catheter-associated urinary tract infections (CAUTI) are among the most common healthcare-associated infections,[1,2] with each having potential to cause life-threatening bacteremia and sepsis.[3] With an average of one in five hospitalized patients having urinary catheters (UCs),[3] UCs are a common and often avoidable hazard to patients because they are often placed unnecessarily[4,5] and used without physician awareness,[6,7] and may remain in use for prolonged periods,[4,8] with each day increasing the risk of infection.[3] Hospital-acquired CAUTI easily met criteria as a high-volume,[1] expensive,[3] reasonably preventable[9,10] condition for which hospitals could no longer receive additional payment after the October 2008 implementation of the Hospital-Acquired Conditions (HAC) Initiative.[11,12] Of note, this removal of payment for HAC began as a Medicare policy, yet rapidly expanded to many other payers, including Medicaid programs[13] and Blue Cross Blue Shield[14] nationwide. Hospital rates of hospital-acquired CAUTI have been publicly reported on Medicare's Hospital Compare Web site since 2011, as required by the Affordable Care Act of 2010.[15]

Although not paying extra for hospital-acquired CAUTIs seems like a simple concept, the HAC Initiative's implementation is complex.[11,12] For a urinary tract infection (UTI) to be identified as a nonpayable, catheter-associated UTI, the claims data submitted for payment must include, in addition to the UTI diagnosis code, the ICD-9-CM [International Classification of Diseases, 9th Revision, Clinical Modification] code 996.64 for "infection and inflammation due to an indwelling urinary catheter." Both the UTI and catheter-association codes need to be identified as hospital-acquired conditions by a mandatory variable that requires all diagnoses to be identified as hospital-acquired or present-on-admission.[11,12] If these codes are not assigned accurately and completely for each UTI diagnosis listed, the hospitals may receive extra payment by default.[16] Similarly, inaccurate or incomplete description of CAUTI events in claims data may lead to inaccurate public reporting.[17]

Despite high expected rates of CAUTIs from epidemiology and surveillance studies,[1,2] CAUTI rates from claims data are extremely low; many hospitals have reported zero CAUTIs despite reporting UTI rates similar to those of other hospitals. The reason for this is the lack of use of the catheter-associated code.[17,18] Rare use of the catheter-associated code has been demonstrated before[17] and after[18] the HAC Initiative. Because hospital coders (who generate claims data) are required by Federal guidelines[19] to obtain diagnoses as described in "provider" notes written by physicians, nurse practitioners, and physician assistants, we hypothesized that UTIs were not being described as catheter-associated in provider notes either because the providers were unaware of UC use, or because they did not recognize or describe UTIs as catheter-associated UTIs.

To further understand why the catheter-association code is rarely used, we performed a post-policy, retrospective, comprehensive medical record review to describe and quantify how UC use and catheter-association for UTIs are documented in different medical record types. The purpose of this paper is to share the challenges and lessons learned in the development, implementation, and analysis of this study. We share the results regarding UC use measures to highlight the complexities in detecting UC use in medical records, which are used to generate device-associated quality measures for comparing hospitals. We also share our experience involving resident physicians as collaborators in learning about patient safety research as medical record abstractors, along with our experience related to maintaining compliance with the Accreditation Council for Graduate Medical Education (ACGME) resident duty work hour regulations.[20]

Methods

Design

We conducted a retrospective medical record review for a random sample of 295 adult hospitalizations, with discharges from the University of Michigan Health System (UMHS) in the first 12 months (October 1, 2008 to September 30, 2009) after the HAC Initiative's implementation. Our sample was generated by the UMHS Clinical Information and Decision Support team by first identifying all hospitalizations with UTI as a secondary diagnosis (i.e., not the primary reason for admission) in the administrative discharge data (i.e., claims) within the chosen time period (requested in four quarters). The random sample of hospitalizations for medical record review regarding catheter use was then selected using a random number generator. This project was reviewed and approved by the University of Michigan Institutional Review Board. The study included two types of data: medical records from each hospitalization and the accompanying claims data.

Data Sources

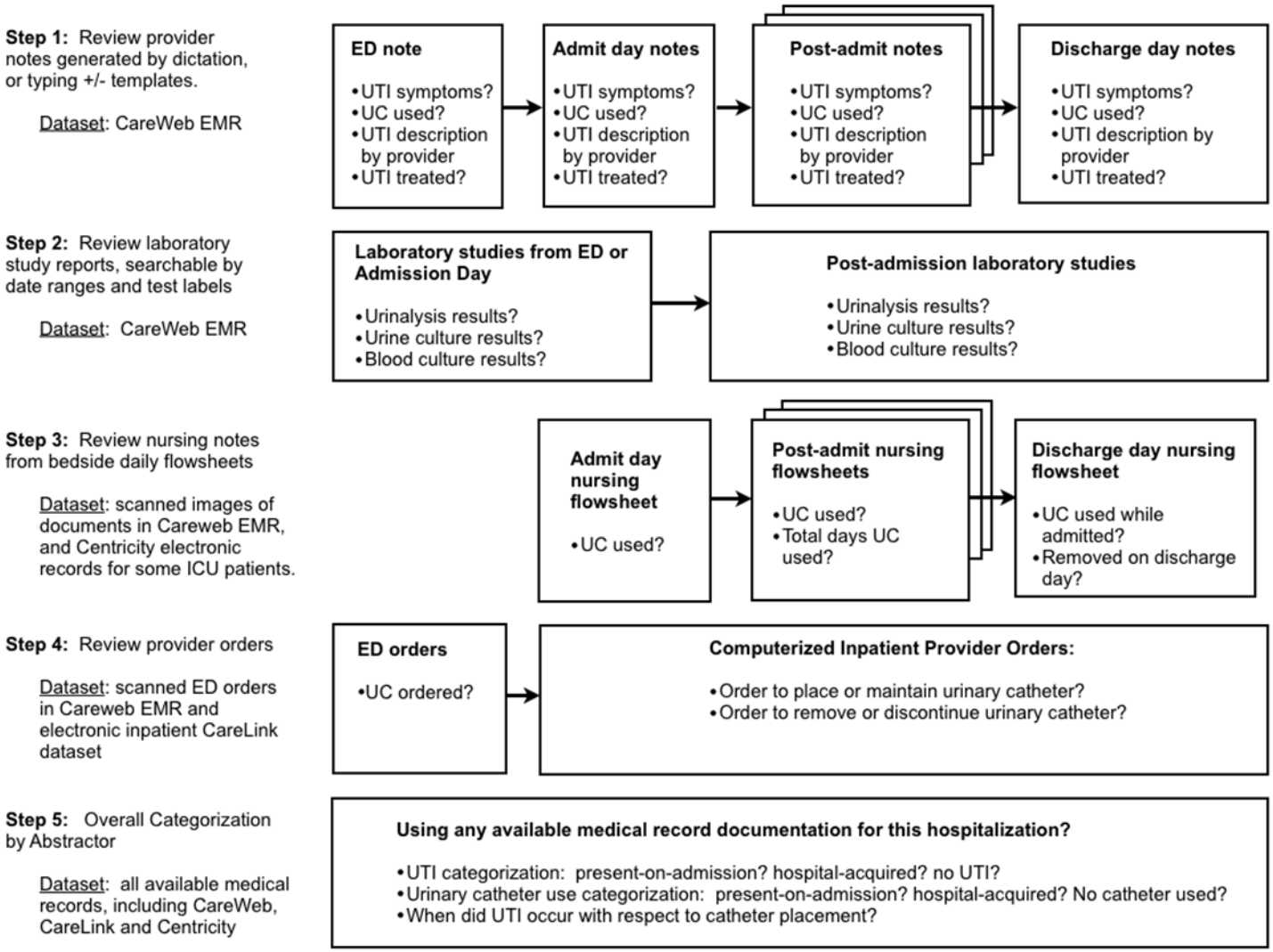
Comprehensive Medical Record for Hospitalization

This retrospective medical record review was performed from May 2009 to May 2011, a period in which hospitalization records were all accessible electronically but used different computer systems and methods, depending on the type of documentation. Provider notes were entered by dictation or typing into an electronic medical record (EMR) system called CareWeb; nurse notes were usually scanned into CareWeb from paper bedside flowsheets; emergency department (ED) provider orders were scanned-in documents; inpatient orders were recorded in the computerized provider order entry (CPOE) system called CareLink (implemented April 2008); and test results

were searchable in CareWeb. Figure 1 illustrates the type and sequence of document review performed. To facilitate a systematic review of these document types, an electronic survey-generating tool was adapted to serve as a guide to remind reviewers how to locate each type of documentation, to require responses to specific questions (Appendix, Table A-1) about the documentation regarding catheter use (all UC types: Foley, intermittent straight catheter (ISC), nephrostomy, suprapubic, and external, as defined in Appendix, Table A-2) and association with UTIs. Skip logic allowed the abstractor to skip questions not relevant to a particular record (e.g., ED-related questions if there was no ED course). Abstractors also answered some questions using any available hospitalization records regarding catheter use and UTI development. Though beyond the scope of this paper, data were collected regarding documented UTI symptoms and laboratory data in a manner to permit categorization of UTIs by various diagnostic criteria.[9,10]

We chose resident physicians as abstractors because we thought this project would be an excellent opportunity for residents to learn about patient safety research, and because resident physicians had the medical and practical expertise and experience needed to review all required documents.

The principal investigator (JM) met with the internal medicine residency program director to request involvement of residents; it was decided the abstractor positions could serve as internal "moonlighting" opportunities for two second-year residents in good academic standing whose rotation schedules in the project's timeline were expected to have a few hours each week available within the ACGME duty hour restrictions.[20] "Moonlighting" describes work opportunities where licensed residents can earn income beyond their resident salary. Residents were limited to working 80 hours per week (including internal moonlighting[20]) and were provided at least one 24-hour day in 7 days that was free from all clinical, educational, and administrative duties. Residents were required to log all work hours (including moonlighting) into an electronic system called MedHub, and a detailed protocol was followed regarding submission of work hours for review to the residency program and the graduate medical education (GME) office. The physician-abstractors underwent 4 hours of data collection training; they provided feedback that was incorporated into the final abstraction tool. They also completed the University of Michigan's Program for Education and Evaluation in Responsible Research and Scholarship. Residents met with JM periodically during and after completing the medical record abstraction to share their experience and challenges. After completion of the abstractions by resident-physicians using the electronic tool, a third physician (JM) re-abstracted provider notes to assess details of the language used to describe UC use and catheter association for UTIs; this was necessary after clarification from our hospital coders regarding the type of language required in provider notes to prompt application of the catheter-association code to UTI diagnoses in claims data.



Notes: EMR=electronic medical record; ED=emergency department; UTI=urinary tract infection; UC=urinary catheter

Figure 1. Comprehensive medical record review flow diagram

In addition to being an organized, complete, and reproducible review of the medical record, the abstraction process was designed to be flexible to accommodate the resident physicians' schedules. The physician-abstractors accessed the medical records electronically (using the same data security standards that they used daily in accessing the records for patient care) and were guided by the password-protected, encrypted electronic tool to systematically review and answer questions from the medical record regarding UC use and UTI development. Abstractors were provided a list of medical record numbers and discharge dates (in password-protected, encrypted files), each linked to a new chart review number (based on abstractor and review number), to identify the hospitalization record in the abstracted data file. To optimize use of abstractor time and data security, the abstraction was designed specifically to collect only categories of data (such as UC use and UTI development), without any patient or hospitalization identifiers.

Administrative Discharge Abstract (Claims Data)

After completion of all medical record abstractions, claims data were requested. Claims data included all diagnosis and procedure codes applied by the hospital coders to request payment for the hospitalization after the patient was discharged, as well as routine patient demographics. Claims data also included the new mandatory variable required by the HAC Initiative,[12] which required all diagnoses to be identified as hospital-acquired or present-on-admission. Comorbidity variables[21] were generated from the claims data using comorbidity software (version 3.4) from the Agency for Healthcare Research and Quality (AHRQ). By inclusion criteria, all hospitalizations were for adults not admitted to obstetrics, whose claims data included at least one UTI code as a secondary diagnosis from the 10 diagnosis codes chosen for nonpayment in the HAC Initiative[12] (i.e., 112.2, 590.1, 590.11, 590.2, 590.3, 590.80, 590.81, 595.0, 597.0, 599.0). There were two potential indicators of UC use in claims data: (1) the 996.64 catheter-association code to identify UTIs as CAUTIs and (2) inclusion of an ICD-9-CM procedure code for insertion (57.94) or replacement (57.95) of an indwelling urinary catheter. Of particular importance, UC procedure codes are applied only when UCs are placed by physicians; however, nurses place the majority of UCs.

Statistical Analysis

Descriptive summary statistics are reported. Data management tasks for the abstracted data in survey format were performed using SPSS, version 18 (SPSS Inc., Chicago, IL). The merged dataset of abstracted medical record data with claims data was analyzed using Stata/MP, version 12.1 (StataCorp, College Station, TX). Thirty records were reviewed by both physician-abstractors to assess inter-rater reliability using the kappa statistic. A random number generator was used to select one record from each of the 30 duplicate abstracted records to be included in the analytic sample.

Results

Hospitalization Characteristics

In all, 295 records were requested for this sample, but one hospitalization had been converted to an outpatient visit after our original sample was created and therefore did not have accompanying inpatient claims data. Our random sample of 294 hospitalizations (for 289 unique patients, including 5 patients with 2 hospitalizations in the sample) that included a secondary

diagnosis of UTI had the following characteristics: 193 (65.7 percent) were for women; mean age 63 years (range: 22–98), median length of stay 7.5 days (IQR 1–16, range 1–84), including 181 (61.6 percent) with Medicare; and 21 (7.1 percent) deaths while admitted. Common comorbidities included renal failure (23.5 percent), chronic lung disease (16.7 percent), paraplegia (11.2 percent), other neurologic diseases (13.3 percent), diabetes (10.2 percent), and heart failure (9.5 percent). A total of 163 (55.4 percent) patients had ED evaluations before admission.

Measures of Urinary Catheter Use

Urinary Catheter Use Documented in Provider Notes

Table 1 summarizes the quantitative measures of UC use from provider notes reviewed for each time period in the hospitalization, including ED course, admission day, post-admission days (defined as day after admission until day before discharge), and discharge day. Examples of evidence of UC use in provider notes included (1) patient interview information, such as "Foley since surgery 4 days ago" or "complains Foley hurts"; (2) exam findings, such as "bilateral nephrostomy tubes are present"; (3) provider's review of tests, such as "urinalysis from Foley has bacteria"; and (4) provider's assessment and plan, such as "UTI, due to Foley" or "ISC every 6 hours if no void." References to remote UC use (e.g., "patient required Foley catheter temporarily after prostate surgery in 2005") were not included in this measure. Overall, provider notes identified 184 patients (63 percent) with at least one provider note describing UC use (as current use or ordered, or by mention of patient having a catheter-associated UTI).

Although not quantified in this study, the detailed abstraction of language used in provider notes to describe catheters and catheter association for UTIs suggested some patterns of provider documentation regarding catheters. It was not unusual for the first mention of a UC in provider notes to be in a consultant note well into the hospitalization. Consultation notes commonly describing UCs were from physical medicine and rehabilitation, the wound/ostomy care team, urology, and geriatrics; catheter placement was often requested in nephrology consultation notes for obtaining 24-hour urine volumes and test results. Unexpectedly, infectious disease consultations did not frequently comment regarding ongoing UC use as part of the assessment if it was not related to the reason for consultation. Primary managing teams, whose notes often mentioned UC use, included hospitalists and intensive care teams, usually in a dedicated section of the note for devices; highly structured notes (that appeared to have been typed using a template) seemed more likely to mention UC use. Some provider notes with dedicated device sections included vascular lines (such as central venous catheters) without noting UCs in use by nursing flowsheets. In this sample, providers from the anesthesia teams managing surgical intensive care unit (ICU) patients seemed the most reliable documenters of UC presence or absence. If UC use was mentioned once in a provider note, it commonly was mentioned on a recurring basis. Sometimes this appeared to be by exact copying of text from one day's note to another; at other times it appeared to be due to increased awareness of UC use after it was first noted.

Table 1. Urinary catheter (UC) use as documented throughout hospitalization course

Type of documentation	Time Period of Hospitalization			
	ED Course N=163, 55.4%	**Admission Day** N=294, 100%	**Post-Admission Days** N=294, 100%	**Discharge Day** N=294, 100%
Provider Notes describing UC use Overall, provider notes identified **184** (63%) hospitalizations with UC use.	ED providers described UC use for 31 of the 163 hospitalizations with an ED course.	Admitting providers described UC use for 91 (31%) hospitalizations.	Post-admission provider notes described UC use for 164 hospitalizations.	Provider notes on discharge day described UC use during 62 (21%) hospitalizations. Provider notes describe expected post-discharge UC use for 28 (10%) hospitalizations.
	106 (36%) of patients had UC use mentioned in provider documentation for ED course or admission day.			
Nursing documentation of UC use Overall, bedside nursing flowsheets identified **212** (72%) hospitalizations with UC use.	Not available to review	Nurses noted UC use for 143 (49%) hospitalizations on bedside flowsheet on admission day.	Nurses noted UC use for 204 (69%) hospitalizations by bedside flowsheet on post-admit days.	Nurses noted UC use for 91 (31%) hospitalizations by bedside flowsheet on discharge day, with 28 (9.5%) UCs removed on the discharge day.
		By nursing inpatient flowsheets (available for 289 [98%] hospitalizations), 212 hospitalizations had ≥1 UC from day of admission until discharge including 180 (61%) Foley UCs, 63 (21%) ISCs, 5 (2%) external UCs, 9 (3%) nephrostomy UCs, 5 (2%) suprapubic UCs.		
Provider orders regarding UCs Overall, provider orders regarding UC identified **222** (76%) hospitalizations with UC orders.	ED providers ordered UCs for 24 hospitalizations, including 18 Foley UCs and 6 ISCs.	Using the inpatient electronic CareLink order system (all orders from admission to discharge): • Providers submitted UC orders regarding UC placement or maintenance for 211 (72%) hospitalizations, including 176 (60%) Foley UC orders, 103 (49%) ISC orders. • Providers submitted orders to discontinue UCs for 149 (51%) of hospitalizations. • 215 hospitalizations with UC use were identified by having an inpatient provider order to place/maintain or discontinue a UC. CareLink orders were available to review for 294 (100% of sample) hospitalizations.		
Claims data indicators of UC use Overall, claims data codes identified **25** (8%) hospitalizations with UC use.	• ICD-9-CM 996.64 (catheter-associated inflammation/infection due to an indwelling UC): listed for 20 hospitalizations • ICD-9-CM codes 57.94 (insertion of indwelling UC) or 57.9 (re-insertion of indwelling UC): listed for 5 hospitalizations			

Abbreviations: ED=emergency department; UC=urinary catheter (any type unless specified); ISC=intermittent straight catheter UC ICD-9-CM=International Classification of Diseases, 9th Revision, Clinical Modification.
Notes: Post-admission course is defined as time period after admission day but before discharge day.
Claims data contain diagnosis and procedure codes describing the entire episode of care (ED course through discharge)

Urinary Catheter Use Documented in Nurse Notes

Evidence of UC use in nurse notes primarily came from daily flowsheets monitoring fluid intake and output (often with abbreviations such as a circled "F=300," meaning 300 cc urine output in Foley catheter bag) and periodic assessments of continence devices. Overall, nurse notes identified 212 hospitalizations with at least 1 day's record indicating UC use, including 143 (49 percent) on admission day and 204 (69 percent) on post-admission days. On discharge day, nurse notes indicate that 91 (31 percent) patients had UCs used on the day of discharge, including 28 percent with the catheter removed on the day of discharge.

Urinary Catheter Use Documented in Provider Orders

ED providers ordered UCs impacting 24 hospitalizations, including 18 Foley catheters and 6 ISC orders. By the inpatient CPOE orders, 211 hospitalizations had orders to place (including "as needed" ISC orders), maintain, or discontinue UCs, including 176 hospitalizations with Foley catheters and 103 with ISC orders. Overall (with a kappa of 0.9), 222 (76 percent) hospitalizations were noted to have at least one UC order by either an ED or inpatient provider.

Urinary Catheter Use Documented in Administrative Discharge Abstract (Claims Data)

Claims data contained the ICD-9-CM catheter-association code 996.64 for 20 (6.8 percent) hospitalizations, including 11 with diagnosis codes describing hospital-acquired catheter-associated UTIs. ICD-9-CM procedure codes for inserting or replacing indwelling urinary catheters were listed for five hospitalizations. Overall, claims data identified 25 (8 percent) hospitalizations with UC use identified by either the catheter-association or catheter placement codes.

Frequency of Provider Identification of UTIs as CAUTIs

Given the rare use of the catheter-association code 996.64 by hospital coders to describe UTIs as CAUTIs in claims data, and the requirement for hospital coders to obtain diagnoses such as UTI for claims from provider notes, we evaluated the language used by providers in their documentation to describe UTIs as catheter-associated or not. From conversations with our hospital coders, physicians needed to clearly describe the UTI as being catheter-associated; it was not sufficient to describe a UTI and catheter use individually, such as "UTI, plan: remove Foley." Coders look for specific provider language such as "UTI due to catheter," "UTI due to Foley," or "catheter-associated UTI." In our sample, providers used language indicating that UTIs were catheter-associated for 22 (7.5 percent) hospitalizations, as categorized in Table 2. Of note, for 5 of these 22 hospitalizations, the discharge summaries had addenda that included a clarification regarding a diagnosis of catheter-associated UTI, including 4 hospitalizations for which the addenda accounted for the only mention of a catheter-associated UTI in the provider notes.

Table 2. Language in provider notes (for 22 hospitalized patients) to describe catheter-associated UTIs

Phrases used by providers to describe CAUTIs	Number* of patients for whom phrase was used
The phrase "catheter-associated UTI or "catheter-associated urinary tract infection" or "UTI due to catheter" was used	4
Abbreviation "CAUTI" or "CA-UTI" or "CA-urinary tract infection" was used	0
Provider documented the word "Foley" in association with a UTI diagnosis, such as "UTI due to Foley"	13
Provider specifically mentioned another type of urinary catheter in association with UTI (such as "UTI due to nephrostomy" or "suprapubic catheter UTI"	6

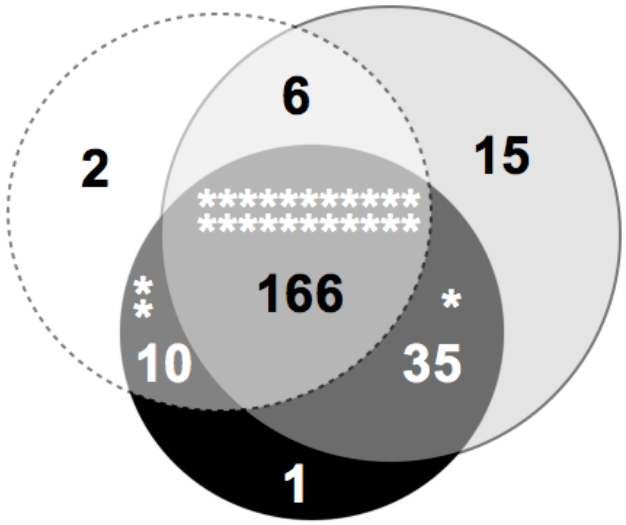
*Numbers sum to 23 because for one patient with provider-described CAUTI, two different types of phrases were used to describe CAUTI in the medical record.
Note: CAUTI=catheter-associated urinary tract infection; UTI=urinary tract infection.

Variations in Identification of UC Use by Type of Documentation

As Figure 2 illustrates, the four different documentation types identified slightly different patient groups as having UC use. Overall, 235 (80 percent) hospitalizations in the sample were identified as having UC use by at least one of the four types of documentation, with 166 hospitalizations identified by provider notes, nurse notes, and provider orders and 22 hospitalizations identified by all four documentation types including claims data.

Discussion

Our single-site study found that the majority (80 percent) of hospitalized patients discharged with a secondary diagnosis of UTI had evidence of UC use in the medical record. Completing this comprehensive medical record review was resource intensive and time consuming (requiring an average of 1 hour per hospitalization) and required expertise in accessing, navigating, and reviewing clinical documentation fragmented across multiple EMRs. Reviewing provider notes and nurse bedside flowsheets was the most resource-intensive activity. Reviewing UC use by provider orders in the CPOE system was simpler and identified the most hospitalizations (n=222, 76 percent) with UC use; however, some provider orders included "as needed" criteria and so may not reflect actual catheter use. Given that our CPOE system was relatively new and that UCs had previously been placed without physician orders[6] or awareness,[7] we were pleasantly surprised that 207 (94 percent) of all 220 hospitalizations (see Figure 2) with evidence for UCs in provider or nurse notes did have a provider order involving UCs. Nurse notes identified 212 (72 percent) patients with UCs, which reflected actual catheter use because nurses documented their tasks performed using the UC (such as amount of urine noted in a Foley catheter bag, or urine obtained using an ISC). Electronic systems for nurse documentation (such as Centricity Clinical Information View [GE Medical Systems, 2002], whose use has since expanded at UMHS) can be queried in less time; still, any electronic entry by busy clinicians should validated due to possible inaccuracies from default responses and copy/paste issues. In summary, except for reviewing provider orders, reviewing the multiple inpatient medical record documentation systems for catheter use was akin to hunting for a needle in a haystack due to the sheer volume of records requiring manual review and inconsistent documentation of UC use in provider notes.



Type A: Provider notes mentioned urinary catheter use (any type), N=184 hospitalizations

Type B: Inpatient nursing notes indicated urinary catheter use (any type), N=212 hospitalizations

Type C: Provider orders involving urinary catheters (any type), N=222 hospitalizations

Area overlapped by (A+B+C): 166 hospitalizations had urinary catheter use indicated by provider notes & nursing notes & provider orders

Type D: Hospitalizations identified with urinary catheter use by claims data, N=25 hospitalizations. Each white asterisk represents 1 of the 25 hospitalizations with urinary catheter use by claims data.

Notes:

1. Amount of circle overlap is not to scale, to permit ease of reading numbers in various sections.
2. Area of (A or B or C or D): 235 hospitalizations were identified with urinary catheter use by at least one of the 4 documentation types.
   - 22 hospitalizations were identified with urinary catheter use by all 4 documentation types (A+B+C+D).
3. Of 220 of all patients with urinary catheter use by either provider notes (area A) or nurse notes (area B), 207 (94%) had a provider order (seen in area C) involving a urinary catheter.

Figure 2. Venn diagram of urinary catheter use indicated by four types of documentation: provider notes, inpatient nurse notes, provider orders, and claims data

This study has some important limitations, primarily the fact that only one academic medical center was examined, using a modest number of hospitalizations. However, the rare use of the catheter-association code in our sample is similar to low rates seen in statewide and nationwide claims data.[17,18] This study was not designed to determine why provider notes rarely describe UTIs as catheter-associated. Informal queries with some of our physicians (residents and hospitalists) suggest two reasons: (1) providers are unaware how strictly their documentation is reviewed by hospital coders selecting diagnosis codes to describe UTIs, and (2) in comparison to a patient's other medical problems requiring treatment, catheter use or UTI may be a lower priority for the time dedicated to documentation. Because UMHS providers have no personal disincentive for describing CAUTIs in their notes, we do not believe providers intentionally avoided describing UC use or catheter association for UTIs.

The resident physicians' experience and insights were invaluable to this project, particularly given the complexities of the EMRs. Both abstractors enthusiastically expressed that it was an excellent opportunity to learn about patient safety research, including device use, device-associated complications, and implications of physician documentation. One abstractor stated, "In short, this project was a far more effective patient safety curriculum than many other residents had available to them." The residents also stated that their experience was advantageous in their application to competitive fellowships and described how the project impacted their career interests:

- "I don't think it can be stressed enough how useful this experience was to me … the project helped to fine tune my career interests. I plan to make quality and process improvement a large part of my career."
- "My involvement in this project … was an important stepping stone in both clarifying and strengthening my interest in quality improvement and advancing my career in that direction."

These physicians also appreciated the "moonlighting" opportunity to help supplement their income while also contributing to their education:

- "We had the benefit of being engaged and inspired by our own faculty while participating in meaningful research, while simultaneously supplementing our income at a time when dollars matter."
- "For many … time spent as a house officer is period of relative financial desperation. The pressure to augment income is strong. To have the opportunity to do it while simultaneously performing meaningful work and learning about something relevant is a gift."

However, resident involvement in this project was not without challenges. Although we anticipated that hiring residents would be somewhat more complicated than other abstractors, given resident schedules and ACGME duty hour regulations,[20] we did not anticipate the tremendous complexity of the review process required before the resident could be paid. Compared to other moonlighting options, this project was more complex to administer because the work was performed on a very flexible schedule, with the amount of time spent in one "shift" varying from 15 minutes to several hours. The process for submitting timesheets to release

payment required several modifications to address unexpected challenges. The finalized process was as follows:

1. Resident entered the time worked into an electronic system called MedHub.
2. Resident submitted "moonlighting" paper timesheet with the days/hours worked to the research team "moonlighting supervisor" (JM) to review, sign, and enter the research account code from which payment would come.
3. The supervisor sent the signed timesheet to the residency program office for review.
4. Residency program office reviewed, queried if needed, approved, signed the timesheet, and returned it to the supervisor.
5. The supervisor submitted the completed timesheet to the GME office.
6. The GME office also reviewed the duty hours for compliance and, if there were no discrepancies, submitted the approved timesheet to payroll to generate payment from the research account.

Several steps involved time limitations as to when the process had to be completed to progress to the next stage. Other challenges included delays in timesheet approval due to unexpected reports of "discrepancies" (even though a work hour violation had not occurred) such as:

1. Work recorded in the paper timesheet in minutes did not exactly match the duty hours recorded in MedHub (which rounded to 30-minute blocks).
2. MedHub would not allow recording of moonlighting hours on residency vacation days, generating discrepancies between the paper timesheets and electronically recorded hours.
3. Need for duty hour assessors (particularly with staff changes) to recognize that moonlighting hours could be contiguous with usual resident work hours (e.g., performing medical record reviews from 5 p.m. to 7 p.m. after working an 8 a.m. to 5 p.m. residency shift).

Without a doubt, the most important challenge that residents faced was stress from responding to multiple queries regarding these work hour "discrepancies," with potential for their participation ending or pay denials while the research team, residency office, and GME office addressed each new issue that arose. Fortunately, despite these unexpected and time-consuming challenges, the medical record review process was completed, with the resident-physicians paid in full before completing their residency.

Conclusion

In summary, this single-site study involving a comprehensive medical record review of patients discharged with a UTI diagnosis found that although UC use remains very common in this patient population and was documented routinely by nurses and in the electronic orders, it was more difficult to detect in provider notes, which are the primary data source that hospital coders review to generate the claims data. Although provider notes often commented on the use of UCs, providers rarely described UTIs specifically as catheter-associated diagnoses using the text that hospital coders require to describe UTIs as CAUTIs in claims data. This likely explains why so few UTIs are identified as CAUTIs in claims data, despite the fact that CAUTIs remain a common hospital-acquired infection. This significant problem with identification of catheter-

association for UTIs in claims data supports the recent decision, in June 2013,[22] to use CAUTI rates from surveillance data collection reported to the National Healthcare Safety Network (and also to Hospital Compare) instead of CAUTI rates from claims data as the measure for comparing hospital performance by complication rates and assigning financial penalties, beginning in October 2014. However, hospital rates of CAUTI from claims data are still being publicly reported on Hospital Compare (as of August 2013), despite the results of this study in combination with others,[17,18] indicating that claims data are not a reliable data source of either UC use[23] or identification of CAUTI events.[17,18]

We conclude by sharing some principles and lessons learned from conducting this project.

- Urinary catheter use remains a common risk factor for many hospitalized patients and was most frequently documented in this medical record review by electronic orders (which required little time or resources to review) and nurse flowsheets (whose review was time intensive in this study because of the use of scanned bedside flowsheets, but could be simplified using electronic nurse data entry systems).
- Physicians rarely describe UTIs with language specific enough to be interpreted by hospital coders as being catheter-associated UTIs, despite often acknowledging UC use in notes.
- Research tasks (such as this comprehensive medical record review) can be designed to be flexible, educational, inspiring, and rewarding opportunities for resident physicians. However, involving resident physicians as moonlighting collaborators has some unique challenges that may be more difficult to address as ACGME duty hour requirements evolve over time.

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Appendix

Table A-1. Examples of questions in the electronic tool to guide medical record review

Section: Emergency Department Provider Notes in CareWeb Please go to CareWeb "Documents" → "CareWeb Docs" for this hospitalization, and answer the following questions using notes labeled "ED NOTE" and "CONSULT-ED."
Is there emergency provider documentation (ED NOTE or CONSULT-ED) for this hospitalization? o Yes o No (if No, tools skips to questions regarding Inpatient Admission notes)
According to documentation available in these ED provider notes, please indicate what information supported that this patient has a urinary tract infection (UTI) at the time of admission to the hospital from the ED? **Please check ALL that apply.** o Vital signs T>100.4 F or >38 C, with no other recognized cause than UTI* o Patient/caregiver report of fever or chills/rigors+ o Urinary complaint of dysuria, frequency, or urgency* o Suprapubic tenderness or costovertebral angle pain or tenderness*† o Altered mental status, malaise or lethargy† o New or worsening incontinence** o For spinal cord injury patients: increased spasticity or autonomic dysreflexia† o Urine described as malodorous or discolored** o Abnormal urinalysis (UA) known to ED team: no details given o Abnormal UA: positive leukocyte esterase or nitrite* o Abnormal UA: pyuria (≥10 WBC/mm^3 or ≥3 WBC/HPF of urine)* o Abnormal UA: microorganisms seen on Gram stain of urine* o Positive urine culture known to ED team: no details given o Positive urine culture: ≥10^5 CFU/mL with ≤2 species of bacteria* o Positive urine culture: ≥10^3 and <10^5 CFU/mL with ≤2 species of bacteria* o Positive urine culture: <1000 CFU/mL yeast o Positive urine culture: ≥1000 CFU/mL yeast* o Positive blood culture for gram-negative infection o Positive blood culture, other organism o ED provider listed UTI as a problem or suspected diagnosis for this admission†† o ED provider initiated/continued empiric antimicrobial treatment for suspected or confirmed UTI†† o NONE, no information in ED provider notes supports UTI diagnosis was suspected or possible o Other information supporting UTI diagnosis, not listed above (such as radiology test supporting infection, or culture from non-urine fluid or tissue*): ☐

* Part of 2009 Centers for Disease Control (CDC)[10] criteria for identifying symptomatic urinary tract infections, when interpreted in context of patient age and whether urinary catheter in place currently or in past 48 hours.

† Part of 2009 Infectious Diseases Society of America (IDSA)[9] criteria for identifying symptomatic urinary tract infections when interpreted in context of catheter type, specimen collection type, and whether urinary catheter is in place currently or in past 48 hours.

** Other common criteria that physicians use to identify urinary tract infections

†† Criteria hospital coders can use as evidence of UTI documentation in provider notes †

Table A-1. Examples of questions in the electronic tool to guide medical record review (continued)

What kind of urinary catheter was being used at the time of presentation to the ED?

- o NONE, no evidence a urinary catheter was being used at the time of presentation to ED
- o Foley: indwelling trans-urethral catheter
- o Suprapubic: indwelling bladder catheter, not trans-urethral
- o Nephrostomy tube: indwelling, into kidney or ureter
- o External catheter: "condom" catheter for male patient
- o Intermittent straight catheter (ISC) use
- o Urinary catheter in use, but cannot determine type from ED note
- o Other urinary catheter in use: _____

Section: CareWeb Lab results

What were the URINALYSIS results when collected as part of the ED or inpatient admission work-up? *Urinalysis test codes are usually: UA, UMIC, UMAC. When using the search function, please search codes individually. Please check ALL that apply.*

- o Urinalysis not collected in ED or as part of admission work-up.
- o Urinalysis results were NOT suggestive of UTI (no leukocyte esterase, no nitrite, no WBCs, no WBC casts, no microorganisms)
- o Positive leukocyte esterase
- o Positive nitrite
- o Pyuria (≥10 WBC/mm^3 or ≥3 WBC/HPF of urine)
- o Microorganisms seen on Gram stain or urine
- o Other (please specify): _____

What were the urine culture results when collected as part of ED or inpatient admission work-up? *Urine culture test code is usually URCC. Please include results for both bacteria and yeast growth from urine culture. Please check ALL that apply.*

- o No urine culture was collected as part of ED or inpatient admission work-up
- o Urine culture results had NO growth
- o Positive urine culture of ≥10^5 CHF/mL with no more than 2 species of bacteria in sample tested
- o Positive urine culture of ≥10^3 and <10^5 CFU/mL with no more than 2 species of bacteria in sample tested
- o Positive urine culture: <1000 CFU/mL yeast
- o Positive urine culture: ≥1000 CFU/mL yeast
- o Other (please specify):_____

Section: Review of CareWeb "Imaged Documents" for this Hospitalization

Refer to "UMHHC Chart – Inpatient Chart – Orders (Patient Care/Diagnostic/PCA/Epidural/PN/ATF": this is where you find physician orders for ED course.

	Yes	No	Not applicable, no ED course for patient
Were orders given for a urinalysis (UA/"dip")?	o	o	o
Were orders given for Foley catheter insertion?	o	o	o
Were orders given for condom catheter placement?	o	o	o
Were orders given for straight catheter use?	o	o	o
Were orders given for suprapubic catheter placement or use?	o	o	o

Table A-2. Urinary catheter type definitions

Catheter Type	Urinary catheter description
Foley catheter	The Foley catheter is an **indwelling** trans-urethral urinary catheter that is a flexible plastic tube passed through the urethra into the bladder to drain urine from the bladder to be collected in a urine storage bag. This catheter can be placed either for temporary use (hours–days) or prolonged use (weeks–months). These catheters are most often placed by nurses but occasionally are placed by physicians (such as urologists) when placement is challenging for anatomic reasons. Most Foley catheters are used for short periods of time while a patient is hospitalized or having an outpatient procedure, but some patients with chronic medical issues have Foley catheters in place at home, outside of the hospital. "Foley" catheters are named for Dr. Frederic Foley, the urologist who designed them.
Intermittent straight catheters (ISC)	Intermittent straight catheters (ISC) are **non-indwelling** catheters that are stiffer plastic tubes passed through the urethra into the bladder to drain urine from the bladder. Unlike the Foley catheter, the ISC does not remain in the bladder; instead, it is used to periodically empty the bladder and is in place for only a few minutes (removed after flow of urine ceases), using a technique of "in-and-out" catheterization of the bladder. Patients may require use of an ISC only on an as-needed basis (such as in a full bladder requiring drainage once while perioperative medications make spontaneous bladder emptying difficult). Other patients require multiple catheterizations using an ISC per day on a scheduled basis (such as in patients with chronically enlarged prostates). ISC catheters are most often placed by nurses but can also be placed by patients performing self-catheterization.
Nephrostomy catheter	A nephrostomy catheter is a type of **indwelling** catheter that is a flexible tube that is placed through the skin into the kidney to drain urine that cannot be urinated through the bladder due to a blockage in the ureter tubes, which drain urine from the kidney to the bladder. Nephrostomy tubes are placed by surgical physicians or interventional radiologists, most often in operating rooms. Nephrostomies can be placed temporarily (for example, to drain urine until a kidney stone is removed) or can be placed for long-term use, including in patients being discharged home.
Suprapubic catheters	A suprapubic catheter is a type of **indwelling** catheter that is a flexible tube surgically placed through the skin into the bladder to drain bladder urine that for anatomic or practical reasons cannot be managed by another type of catheter. This catheter can be the same as a Foley catheter, but it is named suprapubic to designate its location. Suprapubic catheters are initially placed and changed as needed by physicians, but after the patient has had a suprapubic catheter in place for a while, it can be changed by a nurse or the patient.
External "condom" catheters	An external catheter is a **non-indwelling** urine collection device that consists of a flexible tube and urine storage bag (similar to a Foley catheter) attached to the patient by a condom that is fit over the penis. Although similar devices have been tested for female patients, currently external catheters are used primarily in male patients. This type of catheter is used when there is a need for urine collection, but the patient has no difficulty releasing urine from the bladder. External catheters are also commonly known as "Texas catheters" because they are often manufactured in Texas.
Other urine collection devices that are **NOT catheters** include: **Urostomy**: a surgically created opening in the abdominal wall to allow drainage of urine from the kidneys and ureters into the surgically created new pathway (called an **ileal conduit,** created using a small segment of bowel) to reach the opening on the skin. Urine is collected from the opening into a "pouch," which is a type of plastic bag attached to the skin by an adhesive, changed periodically to empty the urine.	

Using Socio-Technical Probabilistic Risk Assessment (ST-PRA) to Assess Risk and Improve Patient Safety and Reliability in Health Care Systems

Anthony D. Slonim, Ebru Bish, Laura Steighner

Abstract

Health care during hospitalization has become more complex. With this complexity comes additional patient risk that may lead to patient safety events. These events usually occur infrequently, but when they do, they can be catastrophic for patients. Common approaches for analyzing serious or sentinel events in health care include root cause analysis (RCA), which is retrospective in nature and has a number of limitations. Hospitals are also required to prospectively perform a failure modes and effects analysis (FMEA) annually on one high risk event. The FMEA process also is not without limitations. In this paper, we describe an approach to prospectively analyze potential serious and sentinel events by using a tool known as socio-technical probabilistic risk assessment (ST-PRA). This tool, used in several other industries, has seen some moderate success in health care for analyzing risks related to blood transfusions, medication errors, and infections. The major benefits of this tool, in contrast to other available tools, are that it is prospective, accounts for combinations of risk failures, and is both quantitative and qualitative in nature. Unfortunately, because of its complexity, the tool is still used primarily in the research domain and has not yet made its way into mainstream quality improvement efforts.

Introduction

Socio-technical probabilistic risk assessment (ST-PRA) is a tool that incorporates risk estimates from the literature and uses experiential estimates from health care providers to estimate risks in rare health care outcomes. The tool examines single point failures and failure combinations, thereby allowing investigators to design interventions to reduce risks associated with the performance of process steps in a health care procedure. The tool is most useful for very rare, high-risk events and has been used in health care for a variety of problems ranging from blood transfusion infection risks to medication errors.[1,2] For example, for blood transfusion infection risks, the tool helps not only to assess risk with the highest likelihood of error, but also points to important efforts to mitigate those infection risks.[3]

This paper summarizes the model building steps of ST-PRA, including data collection, literature review, database analysis, the use of technical experts, building ST-PRA fault trees, sensitivity analyses, and designing an intervention. It concludes with a discussion of the strengths and limitations of ST-PRA modeling as a tool aimed at improving patient safety.

Methods

Probabilistic risk assessment (PRA) is an engineering tool developed in the 1970s to quantify risks and identify threats to the safety of nuclear power plants.[4] Subsequently, it has been applied in settings ranging from aerospace to manufacturing to natural disasters.[5,6] PRA is a systematic tool that prospectively identifies a system's risk points. It utilizes quantitative and qualitative

data to “map” the risks associated with adverse outcomes. PRA is thus a hybrid between qualitative process analysis techniques and quantitative decision-support models.[7] PRA involves a detailed deductive method that utilizes logical relationships and probability theory to construct a model (“fault tree”) of how risk points interact with one another and either individually or collectively combine to contribute to the adverse outcome.

ST-PRA expands the basic PRA model by accounting for human performance.[8] Most quality and patient safety work involves the interactions of people, systems, and technology, which are all accounted for by the ST-PRA methodology. The challenge with ST-PRA is determining the probabilities associated with breakdowns in human performance that contribute to adverse outcomes.

The process mapped by an ST-PRA model incorporates both internal and external process factors and can disentangle the impact of factors that are related to individuals from those that are related to institutions or the system. In this way, ST-PRA addresses what has previously been described as a major limitation of isolated database analyses where interactions of different-level processes occur simultaneously. To ensure that ST-PRA captures all possible process factors, it is important to use several data sources in building the process map. Next, we describe the data sources used for this purpose.

Data Sources

A variety of data types (i.e., quantitative or qualitative) and sources are used in the development of ST-PRA fault tree models. Each source informs the data collection effort for other sources in an iterative fashion: information gleaned during a literature review can inform the analysis of databases; similarly, information collected during site visits, technical expert interviews, or focus groups can inform additional data analyses and literature searches.

Literature Review

A literature review can assist in identifying the potential risk factors associated with a patient safety event. The literature also provides discrete probability estimates and ranges for inclusion in the models and sensitivity testing.

Readily available search engines, including PubMed, the Cochrane Collaborative, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL), can be used for data collection. As with any literature review, keyword search terms can assist in better understanding the literature on the topic under study. The intent of the literature review is to ensure that relevant work is incorporated into the risk models. Potential articles are reviewed for relevance. For example, often an entire article will be reviewed only to identify a single probability estimate for a specific content area (e.g., the compliance of health care providers with hand washing). The reference lists may also be reviewed to ensure that the review is as inclusive as possible. General inclusion and exclusion criteria for an article’s inclusion in the literature review need to be established.

A grey literature review can also provide important information. This category includes Web-based presentations, articles, and white papers that can be accessed through Google, Google Scholar, and Bing Internet. The project team and technical experts may provide additional sources of information. A targeted search of Web sites known for improvement efforts or

standards of care can identify information on general or specific risks relevant to the model. Examples of potentially helpful organizations are Agency for Healthcare Research and Quality (AHRQ), Institute for Healthcare Improvement, Robert Wood Johnson Foundation, Centers for Medicare & Medicaid Services (CMS), and The Joint Commission.

All relevant literature should be entered into a database to assist with the creation of a bibliography and to support the specific risk estimates in model building.

Database Analysis

Discharge databases are important for studying health care problems in a variety of settings. The Healthcare Cost and Utilization Project (HCUP) series of datasets provide information on inpatient (National Inpatient Sample [NIS]), emergency department (State Emergency Department Databases [SEDD]), and ambulatory surgery settings (State Ambulatory Surgery Databases [SASD]). Subsets of the HCUP datasets (e.g., Kids' Inpatient Database [KID] for children) can also provide population-specific data. Analyzing quantitative information from these datasets provides occurrence rates and risk probabilities for model development.

Site Visits

The third data source involves site visits that allow the exploration of patient care and the identification of risks in actual practice settings. Site visits also provide an opportunity to determine the boundaries of the risk modeling exercise. Each site visit represents a different context where different processes, errors, and risks may be identified. Site visits should be conducted in locations where complementary information regarding the process can be gathered. A semi-structured protocol ensures consistency in data gathering across sites. Site visits may consist of several activities that serve to inform the socio-technical elements of the ST-PRA models. Our research team has found the following activities valuable for this purpose: a review and comparison of policies and procedures; informal exploratory interviews with a selection of six to eight staff from the participating setting; and a comparison of the process flow across sites, noting differences in policies and procedures, facility characteristics, and other relevant issues, as necessary.

Technical Expert Panel

A technical expert panel (TEP) can provide valuable information to guide the ST-PRA modeling. TEP members should represent expertise that ensures comprehensive coverage of the relevant issues. Often, only a few meetings are necessary, and specific guidance can be achieved through the review of documents. The first meeting should orient TEP members to the study's objectives and the ST-PRA methodology and gather feedback on the ST-PRA's focus. A second meeting can be used to review the draft fault tree model and solicit feedback on areas for improvement. A third and final TEP meeting can be used to (1) review the ST-PRA modeling results, (2) identify the highest risk basic-level events and event combinations (cut sets), and (3) inform the design of an intervention.

Developing the Fault Tree Model

A fault tree is a graphical depiction that conjoins risk estimates associated with a specific outcome of interest. The initial development of the fault tree incorporates information collected via the four major data sources previously described, to identify the risks associated with an

adverse outcome. Iteratively, the model can be refined and revised to ensure that it has face validity with technical experts who understand the procedure under study. In this section, we detail the steps involved in developing a fault tree model, as depicted in Figure 1. For additional information on this topic, the reader is referred to a detailed clinical example of an ST-PRA for blood product infections,[1] which highlights how the top-level event and contributing factors are organized.

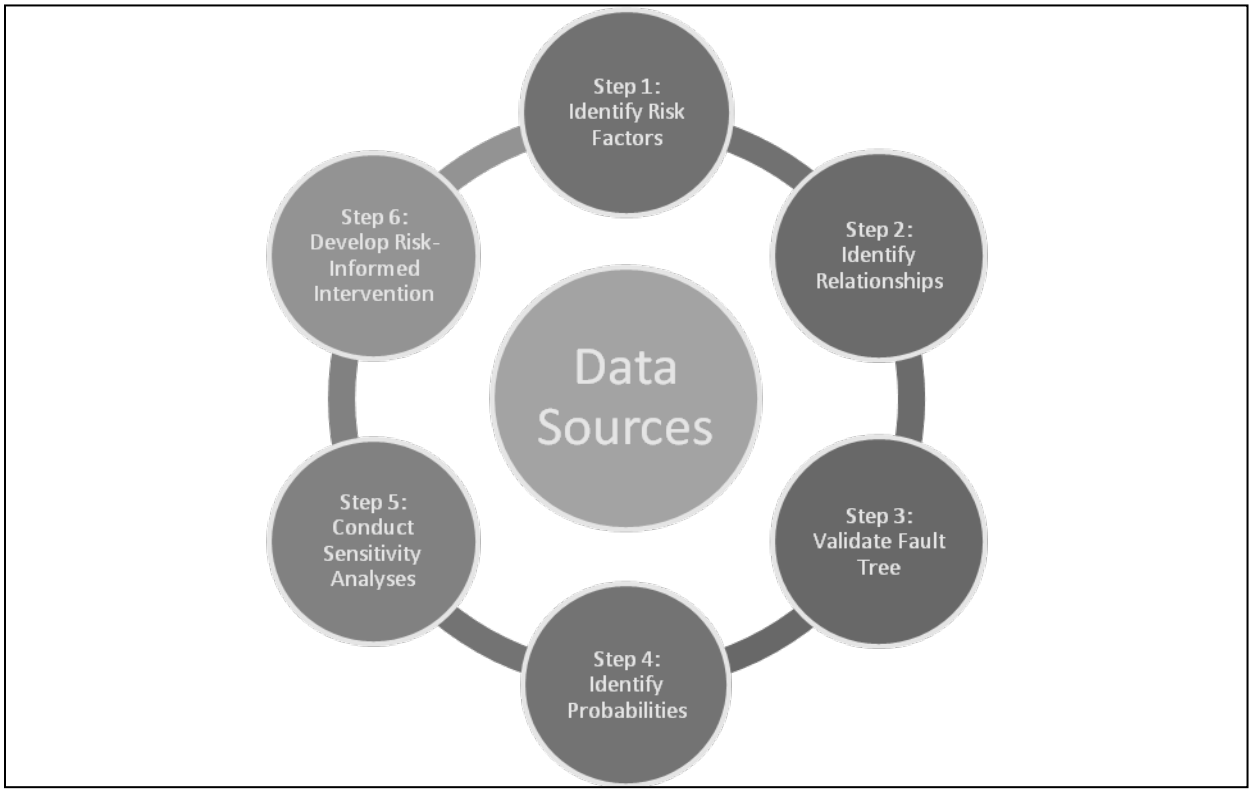

Figure 1. Steps involved in developing the fault tree model

Step 1: Identify All Factors Contributing to the Outcome of Interest

After determining the outcome of interest (also known as the "top-level event"), the first step involves identifying the risks that contribute most to the outcome. The objective is to identify a comprehensive list of variables (also known as "basic-level events") that contribute risk within the model and potentially lead to the outcome.

An initial list of basic-level events is created based on the major risk factors recognized in the literature. This list can be augmented by studying the process maps developed from the site visits and identifying points of failure in the processes (e.g., communication failure between health care professionals). Finally, based on discussions with TEP members, basic-level events can be added or deleted from the list, as appropriate. When additional basic-level events are considered for inclusion in the fault tree, a targeted literature review using these basic-level events as key search terms should be conducted to provide additional support for their inclusion.

Step 2: Identify the Dependencies and Interactions Among the Risk Points

The research team must consider how the basic-level events are connected to the result in the top-level event. For many of these basic-level events, this process is straightforward. For example, it is clear that contamination of surgical equipment contributes additional risk at the basic-event level, which can lead to a higher frequency of surgical site infections.

The research team uses an approach that incorporates the risk point estimates by considering each of the basic-level events along different components of the process under study. By creating a logic model and isolating the basic-level events in each part of the process, the face validity and overall interpretability of the model is improved by the relevant stakeholders. It is also a useful method for incorporating the data gathered from the site visits where the patient's care is detailed in independent process flow maps. These flow maps allow the team to visually inspect the numerous interactions of the process across providers and care settings, tending to make what may be very complex interactions more easily understood in the model under study.

As a preliminary step, specific parameters are established to guide the development of the model's framework and the relationships among the risk points. Parameters allow fault tree designers to home in on a top-level event and the numerous characteristics that may contribute to the outcome of interest. For example, investigators may consider limiting the project's scope to specific parts of the process or time limits (e.g., 30 days after hospital discharge).

Once the model's scope is appropriately defined, the relationships (i.e., dependencies and interactions) among the multiple risk points are studied to understand their contribution to the outcome. This is where clinical judgment, the results of the database analysis, the site visit process maps, and the input from the TEP are critical. Using these inputs, the identification of multiple connections and combinations associated with the occurrence of the outcome can be determined. For example, a patient-level factor (e.g., diabetes) is identified from the literature, a staff-level factor (e.g., wearing artificial nails) is specified in a hospital policy, and an organization-level factor (e.g., preoperative screening) is identified by the technical experts. These connections may be further enhanced by targeting additional literature searches to patient-level and staff-level factors that have been studied by other researchers.

The relationship between the basic-level events and the top-level event is established next. The fault tree uses "gates" to demonstrate the logic for joining all the basic-level events into an organized model that contributes to the outcome. The two major types of gates are "AND" gates (i.e., the output event occurs if all the input events connected to the AND gate occur) and "OR" gates (i.e., the output event occurs if at least one of the input events connected to the OR gate occurs). In combination, the basic-level events, modeled in the fault tree along with the AND gates and OR gates, produce a descriptive, hierarchical flow diagram of the process and the outcome under investigation. For the AND gates, the probabilities of the input events are multiplied together; for the OR gates, the probabilities of the input events are added together, with the overlap subtracted to prevent double counting the gate if both failures occur simultaneously. Figures 2 and 3 present examples of AND and OR gates, respectively.

Step 3: Validate the Fault Tree Model

Once the model is developed, the TEP reviews it and provides feedback on the connectivity and logic of the basic-level events with the top-level event. The model is then revised based on this

feedback. To address specific questions that need further clarification, focused interviews and additional literature searches can be used. The goal of this validation step is to confirm that the logical relationships built into the fault tree are representative of the system and processes under study.

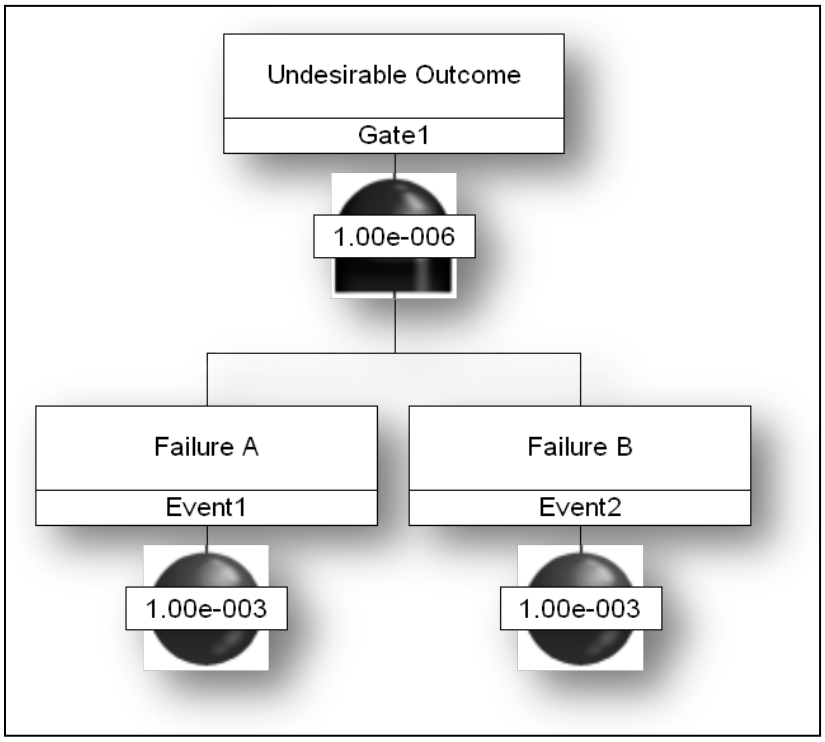

Figure 2. Example of an AND gate

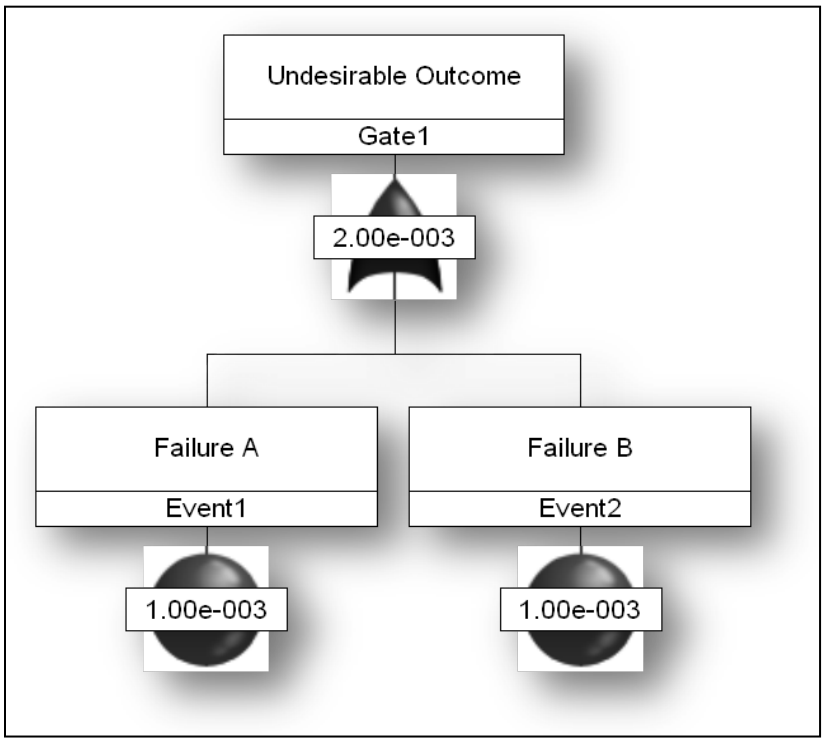

Figure 3. Example of an OR gate

Step 4: Identify the Likelihood of the Basic-Level Events in the Fault Tree

The assignment of probabilities to each basic-level event in the fault tree occurs next. If available, information from the literature review provides a starting point for probability estimates of the basic-level events. When gaps exist, additional and more focused literature reviews or interviews may be necessary to estimate these probabilities. When technical experts' estimates are relied on, these estimates are targeted in the study's subsequent sensitivity testing.

Once probabilities are assigned to the basic-level events, the fault tree is modeled using Relex™ (Relex, Inc., Voronezh, Russia), a software package that calculates the remaining probability estimates for all intermediate and top-level events, using the logical relationships previously specified. This process leads to a probability estimate for the top-level event and the major risk points in the process (also known as cut sets) that are developed as the next step of the study.

Step 5: Conduct Sensitivity Analyses of the Fault Tree Model

Because some of the model's probabilities are based on imprecise information from the databases, highly variable literature, or technical expert estimates, the use of sensitivity analyses can improve the model's reliability. The sensitivity analysis can be considered a series of grounded "what if" tests to study the robustness of the ST-PRA model. These analyses begin by examining the "base case" and then varying the basic-level event probabilities across a range of values to determine whether the combinations of the major events cause a change in the likelihood of the top-level event. These analyses involve identifying the minimal cut sets, defined in the next section, for the base case and for variations of the base case (obtained by

modifying the probabilities) to study the robustness of the fault tree model. This process enables the identification of an intervention with the greatest likelihood of mitigating the risk of the top-level event.

Minimal cut sets. Cut sets are unique event combinations that lead to the occurrence of the top-level event. A cut set is considered a "minimal cut set" if, when any basic-level event is removed from the set, the remaining events are collectively no longer a cut set; that is, a minimal cut set is defined as a critical path through multiple failure points. By identifying the different cut sets associated with an event, the model can be reconsidered after removing specific failure points or system components as a result of implementing an intervention or series of interventions designed to reduce the rate of occurrence of the top-level event. The minimal cut sets are identified through the software, using the underlying logic depicted in the AND/OR gates. The software then combines basic-level event probabilities to identify the paths, based on the conditional probabilities of event combinations. The minimal cut sets with the highest risk for the top-level event are then listed in descending order of priority.

Sensitivity analysis. A sensitivity analysis focuses on events with large probability variations and varies these probabilities in the base case within the ranges suggested by the literature. When a probability estimate is unavailable, an anchor estimate can be obtained from technical experts. For example, questions that arise from a process failure with relevance to pediatric patients can be referred to specific TEP members with expertise and professional experience in pediatrics. This estimate can then be considered the anchor estimate for the sensitivity analysis, which examines the range of intervals from 25 percent to 75 percent around the provided probability estimate.

For example, hand washing is a common approach to prevent the spread of bacteria and would be expected to have a positive impact on preventing healthcare-associated infections. The literature indicates that the hand-washing compliance rates for non-operating-room (OR) staff range between 40 percent and 90 percent. The hand-washing compliance rates for the OR staff are consistently higher and less variable, approximately 75 percent to 90 percent. In the sensitivity analysis, the conditional probability for non-OR hand-washing compliance can be varied across the range of 40 percent to 90 percent to understand the impact of hand washing on mitigating the occurrence of a healthcare-associated infection. Sensitivity analyses ensure a model's accuracy even if basic-level event probabilities were grossly inaccurate at the beginning of the modeling exercise. If the same contributors are identified after the sensitivity analyses, the model's integrity can be ensured, or the model can be reworked if the contributors are found to be different.

The fault tree model is examined for each variation of the base case where the outcome of the top-level event is modified. The top five minimal cut sets can be run to understand how and if they change beyond the base case.

Developing a Risk-Informed Intervention

One of the most important goals is to develop an intervention with the greatest likelihood of mitigating the risk of the outcome under consideration. There are three major steps to developing a risk-informed intervention: (1) conduct criticality analyses to inform the selection of an

intervention, (2) identify the target event(s) for the intervention, and (3) design interventions to mitigate the risks associated with the target event(s).

Conduct a Criticality Analysis

Importance measures rank the most significant risks based on their contribution to the top-level event as a means of improving system performance. These measures help to assess the risk's criticality by its absolute risk, its relative importance within the model, or its frequency in the model. Commonly used relative importance measures include the criticality, Birnbaum, and Fussell-Vesely measures. These measures anchor an individual risk estimate within the context of the model's other risks. For example, the Birnbaum measure ranks the risks based on the relative contribution of individual component failures in a system; the Fussell-Vesely measure is a linear indicator of risk that accounts for the fractional contribution of a risk element to the total system for all scenarios under study based on the failure of an individual component. Alternatively, the criticality measure is a measure of absolute risk, which identifies the independent risk contribution of a basic-level event. For example, assuming that the top-level event occurs, the criticality of basic-level event A is the probability that the top-level event is a result of basic-level event A, thereby indicating the fundamental components of a system's liability. The importance measure selected depends, in part, on the type of model and the purpose of the modeling exercise.

Identify Event(s) Targeted for Intervention

The criticality analysis provides a foundation for understanding the basic-level events with the highest probability of contributing to the top-level event. However, the real power of ST-PRA stems from the event combinations and probabilities that identify critical paths leading to the occurrence of the top-level event. Using both the criticality analysis and cut sets to identify the intervention ensures that the selected intervention will have the greatest impact of reducing the top-level event.

To be successful, it is also important to consider the ease of implementation, the likelihood of achieving substantive improvement based on the intervention, and the level of effort necessary to effectively implement the intervention within an existing system. As with other quality improvement efforts, the most feasible intervention is the one that combines ease of implementation, has the greatest likelihood to yield an impact, and is the most resource conservative.

Design the Intervention

Based on the model's results, an intervention aimed at a specific event and the major components of the cut set is developed. When designing an intervention, it is important to look for opportunities where the intervention can be hardwired into the care system. Such an intervention should focus on aspects that the provider can control (as opposed to the patients' compliance), should be integrated into the care process, and should include redundant steps to minimize single point failures.

During the design, the investigative team considers both the results from the sensitivity analyses and information gleaned through the site visits. These results tend to identify major processes within the system under study that can impact how care is provided. The model can be used and

revised in real time, depending on the impact achieved with the proposed intervention on reducing the likelihood of the top-level event.

Discussion

Strengths shared between the more traditional PRA and the ST-PRA methodology include the following features:

- Provides a broad perspective, including contextual elements such as operating procedures, system, and human factors, to the risk model.
- Is proactive, identifying the possible adverse events before they actually occur, thereby enabling the decisionmaker to introduce targeted interventions for preventing these events from occurring.
- Models complex interactions and dependencies among the multiple risk points that may lead to the adverse outcome, using logical relationships and Bayesian probabilities.
- Allows the uncertainty associated with error rate estimates to be incorporated into the model through sensitivity analysis.
- Allows an assessment of risk and a prioritization of risk reduction interventions based on sequences that have the highest probability of occurrence, providing a roadmap of targeted interventions.
- Is dynamic in that PRA (and ST-PRA) can incorporate new estimates of probability as they are available.

The incremental value of the ST-PRA methodology lies in its capacity to consider both individual contributors of risk and unique combinations of risks that contribute to the adverse outcome, by incorporating both quantitative and qualitative data into the models. This modeling process creates a real world experience, which can be tested using the sensitivity analysis to ensure the scientific integrity of the tool and the ultimate results. Finally, the ST-PRA model also serves as a living document that can be modified as new risk information is acquired either through direct observation or through improved methods for studying the environment.

Despite these important strengths, notable limitations should be acknowledged. First, the quantitative estimates from datasets are limited because these data often fail to include the more granular risk estimates important for creating the risk models. As improvements in the SASD, NIS, and SEDD datasets occur, additional information regarding the care context will allow further refinement of this research. Second, the lack of integrated data systems, linking patients between care contexts such as between the emergency department and inpatient settings, significantly limits the ability to inform the model with real risk estimates across transition points of care. Finally, a common criticism of any modeling exercise such as ST-PRA is that the model will not be a “real world” representation of the process, but instead will involve some simplifying assumptions. Nonetheless, a careful use of quantitative estimates from the literature, and the modeling of the *in vivo* process flows contribute to a realistic understanding of the system under study. When combined with the sensitivity analyses, which ensure that the risk estimates and conclusions are supported across a range of values, the modeling effort can be made more robust.

Conclusion

The use of ST-PRA as a modeling tool to identify patient safety risks in a variety of contexts is an important method for advancing the understanding of risk and reliability in health care. The models can be refined as new information becomes available and as improvements in care are realized through interventions. Additional effort to make the ST-PRA methodology more accessible for use outside the research domain is a critical next step.

Although ST-PRA adds value over other existing risk assessment tools such as RCA and FMEA, the current fault tree software, Relex™, is difficult to use and not well understood by health care quality improvement teams. Until probability and fault tree analyses can be performed using more user-friendly and readily available software tools, ST-PRA will remain out of the reach of health care providers. The authors recommend that additional efforts be invested to make ST-PRA more accessible to enable the improvement of system design and the reduction of risks associated with the delivery of health care.

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