

PART 3: PHASE ONE – ACUTE CARE HOSPITALS

I. INTRODUCTION

While the majority of the burden of health care-associated infections (HAIs) is currently associated with care provided in acute care hospitals, the movement of patients between their homes, community based-settings, outpatient facilities, long-term care facilities, acute care hospitals and other types of facilities occurs frequently. Thus, infection control and the prevention and elimination of HAIs can no longer be compartmentalized within the time from a patient's date of admission to the date of discharge at any one particular facility.

The following chapters are framed as research, information systems and technology, incentives and oversight, and outreach and messaging strategies to reduce HAIs in acute care hospitals. However, the strategies are broadly applicable to multiple types of facilities and can also present a wide-ranging approach to prevent HAIs across the continuum of settings where health care is delivered.

CHAPTER 1: RESEARCH

I. INTRODUCTION

A broad, comprehensive research agenda to support the national effort to prevent health care-associated infections (HAIs) needs to address the issue from a number of perspectives. In this chapter, four categories of scientific investigation are described that complement and build upon one another but require the expertise and efforts of distinct investigators and the coordination of several federal agencies. The four categories are the basic science underlying HAIs, the epidemiology of HAIs, the investigation of infection control interventions, and the implementation science underlying interventions to prevent HAIs.

Attention to all four of these domains of scientific inquiry is important. First, an increased understanding of the basic science underlying HAIs and their associated pathogens is critical for informing prevention efforts. A coordinated research agenda will strengthen the scientific understanding of these infections. Second, research focused on the epidemiology of HAIs needs to be strengthened and broadened. Gaps in the existing epidemiologic knowledge base should be identified, with corresponding research projects targeted to fill those gaps. Third, to build upon an expanded understanding of the basic science and epidemiology of HAIs, infection control interventions must be developed and/or refined and then evaluated. Fourth, for those practices for which the scientific evidence provides strong support, implementation research can provide an understanding of how to accelerate their widespread adoption. For example, studies should be directed to interventions that use technology to promote HAI prevention, such as electronic forms of clinical decision support, and should also focus on the human and organizational factors affecting the adoption of effective interventions in hospitals and other health care settings.

Since the publication of the initial *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* (HAI Action Plan) in 2009, significant investments in all four research areas have been made by the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and the National Institutes of Health (NIH). Funding awards have been made for research to prevent HAIs through both investigator-initiated research and grants and contracts for specific priority projects; these efforts are described in detail below. In addition, career development awards have been made to young investigators to support their HAI-related efforts.

This work has demonstrated that specific projects for understanding the basic science and epidemiology of HAIs and for enhancing the understanding of infection control interventions and their implementation can be identified, prioritized, and executed. However, many challenges remain, and new challenges continue to emerge. To assist in shaping the goals of this national initiative, this chapter will: 1) summarize progress that has been made since the initial publication of the HAI Action Plan, 2) reassess and update the identification of gaps in the existing knowledge base that, once filled, will inform clinical and public health interventions to prevent HAIs, and 3) describe the approach for ongoing assessment of the coordinated federal

research agenda to strengthen the science base for interventions to prevent HAIs in the U.S. health care system.

II. PROGRESS MADE IN HAI PREVENTION RESEARCH, FYS 2008-2011

Four federal agencies, AHRQ, CDC, CMS, and NIH, account for the majority of federal research dollars expended to prevent HAIs. Their respective efforts are unique and reflect their agency mission and specific subject-matter expertise. The section that follows summarizes the HAI research efforts of these agencies in fiscal years (FYS) 2008-2011.

A. Funded Research

AHRQ

In FYS 2008-2011, AHRQ has made substantial funding commitments to support HAI research and prevention. These investments represent the significant growth of an HAI portfolio building on the agency's longstanding focus on patient safety, the prevention of harmful events, and the implementation of programs to prevent harm to patients. The AHRQ HAI portfolio was developed in collaboration with CDC, CMS, and the Office of the Assistant Secretary for Health (OASH), and funding was supplemented in several cases by CDC. A summary of AHRQ's funded HAI projects can be found at <http://www.ahrq.gov/qual/haiflyer.htm>, <http://www.ahrq.gov/qual/haify09.htm>, <http://www.ahrq.gov/qual/haify10.htm>, and <http://www.ahrq.gov/qual/haify11.htm>.

In brief, seven FY 2008 projects were designated to identify and help suppress the spread of methicillin-resistant *Staphylococcus aureus* (MRSA) and related infections. These projects used electronic and administrative data and surveillance and implementation strategies with the goals of reducing the burden of MRSA infections, achieving a better understanding of community-onset and community-acquired MRSA infections, and reducing the transmission of MRSA across health care settings.

In FY 2009, an additional six projects were funded. These projects addressed a broader array of HAI challenges, including MRSA, *Clostridium difficile* infection (CDI), measurement of surgical site infection (SSI), HAI data challenges, and antimicrobial-resistant *Enterobacteriaceae*. In particular, in 2009 AHRQ funded an expansion of the Comprehensive Unit-based Safety Program (CUSP), which is based on the Intensive Care Unit Safety Reporting System developed by the Johns Hopkins University Quality and Safety Research Group in Baltimore, Maryland. CUSP was successfully deployed in the Keystone initiative that reduced central line-associated bloodstream infections (CLABSIs) in over 100 Michigan hospital intensive care units (ICUs).¹ This expansion has reached to all 50 states, added hospitals in states already participating in the program, extended to settings other than ICUs, and broadened the focus to other types of infections, such as catheter-associated urinary tract infections (CAUTIs).

¹ Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine* 2006; 26:2725-2732.

AHRQ's FY 2010 projects built upon and significantly expanded the earlier work. These projects addressed multiple aspects of the HAI problem, ranging from optimizing preoperative surgical prophylaxis to the use of universal glove and gowning practices, and from proactive risk assessment in ambulatory surgery centers to improving infection control in end-stage renal disease (ESRD) facilities. These initiatives were coordinated with activities supported by the American Recovery and Reinvestment Act of 2009, such as those of CDC and state departments of health, to help achieve a coordinated impact on the HAI problem.

In FY 2011 and FY 2012, AHRQ continued to expand on successful projects and programs funded in earlier years. Driven by the enormous success of the CUSP-CLABSI project, the new programs that were funded included the promotion of the nationwide dissemination of the CUSP for CAUTI; development and implementation of a Surgical Unit-based Safety Program, which was an adaptation of the CUSP for the surgical environment to reduce SSIs and other surgical complications; and the development and pilot-testing of a CUSP for prevention of ventilator-associated pneumonia (VAP). Other newly funded projects included the study of interventions designed to reduce infections associated with *Clostridium difficile* as well as MRSA and other multidrug-resistant (MDR) organisms, and novel projects related to the use of work systems factors and changes in the built environment as means to maximize and sustain successful HAI reduction efforts. A new 36-month project will synthesize the results of AHRQ-funded HAI projects carried out in FYs 2007-2010. The twin aims of this last project are to identify and promote the application of effective HAI prevention approaches and to identify gaps in the HAI science base that can be filled with additional research.

CDC

CDC uses its subject-matter expertise in HAI to facilitate a robust portfolio of HAI prevention research. The CDC Prevention Epicenters Program is a network of academic centers with which CDC performs collaborative research on the epidemiology and prevention of HAI. The program has successfully performed research studies across a wide spectrum of topics relevant to the prevention of HAIs, including prevention of bloodstream, surgical, and UTIs, VAP, CDI, and MDR organisms such as MRSA. The program has produced more than 150 peer-reviewed publications on these subjects, including the research that was critical to the development of several novel HAI prevention strategies, such as the use of routine chlorhexidine bathing as an infection control intervention. In addition, the Prevention Epicenters investigators have performed a number of studies that resulted in novel and improved HAI surveillance strategies. A summary of the program's accomplishments can be found at <http://www.cdc.gov/HAI/epiCenters>. In 2011, CDC formed the Safety and Healthcare Epidemiology Prevention Research Development (SHEPherD) program, which provides a mechanism for developing and implementing HAI prevention research on a contractual basis. The SHEPherD Program includes 13 partners uniquely positioned for research in HAI prevention, including academic experts in the field, large networks of health care facilities interested in participating in HAI prevention research, and entities with health care information on large patient populations that can be used to measure longitudinal outcomes of HAIs and the impact of prevention efforts. Over 2,500 hospitals and insurers

covering more than 200 million lives are represented in the SHEPherD program. CDC also uses its surveillance systems, including the National Healthcare Safety Network (NHSN) (<http://www.cdc.gov/nhsn/>) and the Active Bacterial Core Surveillance program (<http://www.cdc.gov/abcs/index.html>), to conduct epidemiologic research that informs prevention efforts and provides estimates of the national HAI burden and trends. CDC also conducts ongoing laboratory research to (1) improve the understanding of epidemiologically important pathogens, (2) confirm and characterize unusual antimicrobial resistance patterns and delineate mechanisms of resistance, and (3) develop optimal methods to decontaminate environmental surfaces and water in health care settings.

From FY 2008 to the present, CDC has used its extensive expertise to advise AHRQ on targeting its congressional appropriations for HAI research. During this time, CDC has developed research proposals that were adopted by and funded through AHRQ research programs, provided technical support to AHRQ personnel and, in some cases, provided supplemental funding for AHRQ research projects. CDC experts continue to provide their primary subject-matter expertise for a number of AHRQ-funded projects.

CMS

CMS is working collaboratively with other federal health agencies on several HAI research initiatives. CMS has worked with AHRQ, CDC, and OASH to evaluate the Hospital-Acquired Conditions (HAC) program, which includes the reporting of Present on Admission (POA) indicators. In addition, CMS, AHRQ, and CDC are collaborating to improve HAI control in ESRD facilities.

NIH

NIH funds a diverse set of projects directly related to HAIs and many more that are focused on studies of the key pathogens involved. A link to all of the funded projects can be found at <http://projectreporter.nih.gov/reporter.cfm>. Search strategies can be devised according to the specific topic of choice (e.g., biofilm, *C. difficile*, MRSA, VAP). (Biofilms are composed of clusters of microorganisms embedded in exuded extracellular materials, called “extracellular polymeric substance” [EPS]. EPS is composed of secreted polysaccharides, protein, and nucleic acids, and is often referred to as “slime.”) Representative projects in 2008 addressed biofilms with Enterococcus and Staphylococcus, animal models with *C. difficile*, and rapid tests for resistance or resistance genes in health care-associated pathogens; rapid detection of bloodstream infection, novel antimicrobials for drug-resistant *C. difficile* enterocolitis, and antimicrobial nanocoating. Representative projects in 2009 addressed antimicrobial resistance and hospital epidemiology and microfluidic devices for point-of-care diagnostics; biofilm growth on functionalized surfaces, imaging of biofilms in urinary catheters, molecular pathogenesis of *Klebsiella* pneumonia, and random hand hygiene prompts. In 2010, representative projects addressed developing treatments for VAP caused by MDR *Acinetobacter baumannii* or *Pseudomonas aeruginosa*, evaluation of exhaled biomarkers in mechanically ventilated patients, development of antibacterial agents and materials, gene regulation of mobility and adherence in bacteria that cause UTIs, and determining whether the risk of peripherally inserted central catheter (PICC)- or PICC-associated CLABSI is

constant over the catheter dwell time in neonates. Representative projects in 2011 addressed the development of novel inhibitors intended for treatment of *C. difficile*; characterizing biofilm infections in postsurgical, trauma, and critically ill patients; and evaluating the unintended negative effects of decolonization regimens on skin and mucosal surfaces with regard to the human microbiome.

Interagency Research Workgroup

The Federal Steering Committee for the Prevention of HAIs Research Working Group directed funding toward addressing current gaps in HAI research, including the monitoring of hand hygiene and of the environment. The hand hygiene project is a technological intervention that includes obtaining feedback through electronic tracing using wireless tracing devices placed on hand hygiene dispensers, employee badges, and in patient rooms. The environmental monitoring project, in collaboration with state health departments, will assess the dynamics of contamination of the health care environment and the role of such contamination in spreading MDR pathogens. The purpose is to assess cleaning and disinfection methods to eliminate or minimize environmental contributions to transmission of these pathogens.

Taken together, the above projects reflect a major commitment to the prevention and control of HAIs in the federal research agenda.

B. Priority Projects

In 2008, the Research Working Group identified priority research projects that addressed gaps in basic science, epidemiology, infection control interventions, and implementation science for the infection types identified in Phase One of the HAI Action Plan. Several of the funded projects described above were designed to address the identified priorities. A description of priority projects proposed in the initial HAI Action Plan appears in Table 5. Where appropriate, the funded projects are indicated. Future updates to this section of the HAI Action Plan will identify additional gaps in knowledge and practice since the original drafting.

III. STATE OF THE ART AND IDENTIFIED GAPS IN KNOWLEDGE AND PRACTICE

A. Gaps in Knowledge and Practice: Cross-Cutting Issues

In preparation for identifying specific research areas, the Research Working Group identified gaps in the existing knowledge base regarding HAIs. Several cross-cutting issues emerged in each area of research, as described below.

Basic Science

Understanding of the Key Pathogens Is Essential

There is an overarching need to facilitate basic research that will enhance our understanding of the key health care-associated pathogens. This knowledge will ultimately lead to better means of diagnosis, prevention, and treatment.

The Acquisition of Health Care-Associated Pathogens Is Poorly Understood

The scientific basis for the acquisition (including basic pathogenesis, transmission, and colonization) of numerous health care-associated pathogens is poorly understood. Many current practices are based on empiric observation. More biologically plausible preventive measures may be derived from additional basic, epidemiological, and translational research.

Further Elucidation of the Role of Biofilms in HAIs Is Needed

Microbial biofilms are of particular interest given their well-documented role in device-associated infections. The mechanisms by which biofilm organisms initiate a disease process are still poorly understood. In addition, it is not known what proportion of device-associated HAIs have a biofilm link, or what role biofilms play in the spread of MDR organisms in the health care setting. An enhanced understanding of biofilms in indwelling medical devices could have a significant impact on HAI rates.

Epidemiology

There Are Limitations in Current Surveillance Strategies

A critical component of an effective prevention program is the use of standardized process and outcome data as a means to inform those responsible for implementing the program and evaluate its impact. Unfortunately, many of the current HAI surveillance strategies are labor intensive and subject to limitations as a result of poor inter-rater reliability in applying standard definitions and variable implementation of case-finding strategies.

In addition, current case-finding strategies are largely focused on identifying infections that are manifested during an inpatient stay or as a result of specific invasive procedures. Such strategies may not capture an important and potentially large proportion of HAIs that, although they are the direct result of care delivered during an inpatient stay or in the ambulatory care setting, have their onset in the community.

Electronic Data for Measuring Processes and Outcomes Are Underutilized

Strategies that make use of existing electronic clinical data sources for creating process and outcome measures may have a number of important advantages, including decreasing the burden of data collection, reducing error introduced by poor inter-rater reliability, and providing the ability to track adverse events longitudinally over the spectrum of a particular patient's receipt of health services. More research on the use of electronic data for surveillance of HAIs is needed.

The Emergence of Antimicrobial Resistance May Require Adaptations to Current Strategies to Prevent HAIs

A recent study found that 16% of all HAIs are caused by multidrug antimicrobial-resistant organisms, half of which are MRSA infections.² The epidemiology of emergent MDR organisms in health care settings must be monitored to allow for appropriate adaptations to current infection control interventions, including antimicrobial prophylaxis, isolation strategies, and screening strategies. These interventions will need to be evaluated and disseminated.

The Role of Vaccines in HAI Prevention Needs to Be Defined

Vaccines are a powerful way to prevent thousands of infections and deaths that occur each year for diseases such as influenza and hepatitis. Currently, there are eight vaccines licensed in the U.S. that target pathogens that can be acquired in health care settings. The appropriate use of these lifesaving interventions needs to be defined.

Infection Control and Prevention Interventions

Multicenter Collaborative Trials Are Needed to Establish the Efficacy of New Prevention Interventions

Multicenter collaborative trials that are carefully designed and conducted are needed to establish the efficacy of new preventive interventions for HAIs and to further enhance our understanding of the efficacy of existing interventions.

Multicenter Demonstration Projects to Establish the Preventability of HAIs Have Influenced the Adoption of Recommended Practices

Preventability is defined as the proportion of all cases of a certain HAI that can optimally be prevented through the careful and concerted implementation of current or existing recommendations and/or guidance.

The degree to which many HAIs are preventable has historically been the subject of debate. However, several multicenter demonstration projects have shown deep reductions in CLABSIs in ICUs. For instance, the Keystone project succeeded in reducing infection rates in over 100 Michigan ICUs by two-thirds over three months.³ Outcomes like this one have been achieved by collaborations involving large numbers of health care facilities simultaneously implementing multifaceted prevention programs and standardized data collection.

These projects have answered important questions regarding the preventability of CLABSIs and likely have directly influenced practice across the United States by setting new expectations for prevention. Additional prevention demonstration projects involving other

² Hidron AI, Edwards JR, Patel J, et al. NHSN annual update: antimicrobial-resistant pathogens associated with HAIs: annual summary of data reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006–2007. *Infection Control and Hospital Epidemiology* 2008; 11:996-1011.

³ Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine* 2006; 26:2725-2732.

targeted infections (such as SSI, CDI, and MRSA) and other targeted sites of care (non-ICU acute care, non-acute care settings) would be helpful.

Attention to Administrative Controls

Administrative controls are known to be of paramount importance for the successful prevention of some healthcare infectious risks (e.g., tuberculosis). The precise role that increasing the effectiveness of administrative controls might play in the prevention of other HAIs (e.g., respiratory virus infections, influenza) needs further delineation.

Attention to Environmental Issues

The environment of health care facilities is a significant element in the prevention of HAIs. There is a need to pay additional attention to projects focusing on environmental issues, including those addressing new technologies and engineering controls, which can potentially affect HAIs.

Antimicrobial Stewardship

There is a need for additional studies to optimize the use of antimicrobial stewardship programs across the range of HAIs. Antimicrobial stewardship refers to a set of coordinated strategies designed to improve the appropriate use of antimicrobials with the goal of enhancing patient health outcomes, reducing resistance to antibiotics, and decreasing unnecessary costs.

Implementation Science

Adherence to Current Prevention Recommendations Has Been Sub-optimal

Adherence to current prevention recommendations in health-care settings has been generally sub-optimal, even when knowledge of recommended practices has been shown to be sufficient. Several lines of evidence suggest that merely increasing adherence to *currently recommended practices* can result in a dramatic reduction in infection rates, at least for some infection types.

Through implementation science, a better understanding of the barriers to adherence, and strategies to overcome those barriers, is needed to promote improvements such as the following:

- A better understanding of the human and organizational factors that affect the adoption and implementation of effective strategies.
- The use of technology to improve adherence.
- The development and use of standardized methods (e.g., performance measures) that are feasible, valid, and reliable for measuring and reporting compliance with broad-based HAI prevention practices that must be practiced consistently by a large number of health care personnel (e.g., compliance with hand hygiene practices, proper technique for inserting a device, isolation precautions, and environmental cleaning practices) in order to prevent infections.

The Interaction of the Varied Recommended Prevention Strategies Is Poorly Understood

Current evidence-based guidelines from CDC recommend several hundred prevention strategies for the various HAIs. At present, the extent to which these strategies interact to produce improved or worse HAI outcomes is poorly understood.

For a given HAI, it is not always clear whether all of the components of a particular evidence-based bundle provide additional incremental improvements in outcomes to justify their inclusion in normal circumstances as opposed to outbreak conditions. For a given setting, it is unclear how aggressive prevention strategies for one HAI will positively or negatively affect the rates of a second HAI. Understanding these relationships will require large, well-designed, multicenter clinical trials.

B. Issues Regarding the Specific Phase One Procedures and Organisms

The Research Working Group solicited input from subject-matter experts at CDC and NIH and from several stakeholder professional societies to describe both the current state of the art and specific gaps in knowledge and practice across four areas:

- Basic and/or Laboratory Science
- Epidemiology
- Infection Control Interventions
- Implementation Science

Summaries are presented for the following HAIs:

- Central Line-Associated Bloodstream Infection
- Surgical-Site Infection
- *Clostridium difficile* Infection
- Catheter-Associated Urinary Tract Infection
- Ventilator-Associated Pneumonia
- Methicillin-Resistant *Staphylococcus aureus* Infection

The listing below has been updated and significantly enlarged since the release of the initial HAI Action Plan.

Central Line-Associated Bloodstream Infection

State of the Art

Detailed recommendations on the prevention of CLABSIs have been developed by CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC).⁴ Recent investigations have demonstrated that adherence to recommended practices for inserting a catheter is usually followed by a dramatic reduction in infection rates, suggesting that the preventable fraction of CLABSIs is large.

⁴ Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines and publications. Available at <http://www.cdc.gov/hicpac/pubs.html>

Efforts to implement “bundles” of practices for inserting a catheter have been quite popular in the intensive care setting, and although the rates of adherence are largely unknown, data from NHSN suggest that the rate of CLABSIs has been decreasing annually across all ICU types that report data to that system. Although data suggest that the vast majority of CLABSIs occur outside the ICU, precise data about catheter use and CLABSI rates in this setting, including among nonhospitalized patient populations, is sparse.

Current Gaps in Knowledge and Practice

- Basic Science
 - Understand the role of biofilms in the pathogenesis of device-associated infections, and quantify the proportion of CLABSIs that are associated with biofilms.
 - Identify effective strategies and/or techniques for the early detection of CLABSI and for the differentiation of CLABSI from other bacteremias.
- Epidemiology
 - Gain a better understanding of the epidemiology of CLABSIs occurring throughout the health care delivery system, with a particular interest in the neonatal ICU (NICU) and outside the acute care setting.
 - Identify improved methods for surveillance of CLABSI, including electronic capture of CLABSI and capture of adverse events associated with catheters regardless of patient location.
 - Develop an improved understanding of the strengths and weaknesses of different denominators to calculate CLABSI rates and simpler ways to capture denominators.
- Infection Control Interventions
 - Determine the efficacy and unintended consequences (e.g., shift in the pathogens causing CLABSI) of daily chlorhexidine bathing on CLABSI rates.
 - Determine optimal strategies for inserting catheters, such as those that rely on intravenous (IV) therapy teams.
 - Determine the optimal use of antimicrobial-impregnated catheters.
 - Develop strategies to limit biofilms as a means of preventing device-associated infections.
 - Facilitate investigation into the optimal strategies for catheter maintenance, which may include determination of the best type of dressing (e.g., chlorhexidine versus standard); the use of antiseptics for cleaning catheter hubs; using antimicrobial lock solutions (the investigation should include the unintended consequences of their use); determining the optimal method of skin antisepsis for the maintenance or insertion of catheters; and the use of needle-less connectors (including their effect on CLABSI rates).
 - Determine how to assure that catheters are promptly removed when no longer clinically necessary.
 - Identify optimal catheter care in nonhospitalized patients.
- Implementation Science
 - Determine barriers to the implementation of prevention bundles for CLABSI insertion; develop CLABSI prevention bundles directly relevant to catheter maintenance; and determine the cost-effectiveness of bundle components.

Surgical-Site Infections

State of the Art

Detailed recommendations on the prevention of SSIs have been developed by CDC and HICPAC.⁵ Adherence to current recommendations on the use of perioperative antimicrobial prophylaxis has improved dramatically in hospitals in the U.S. since implementation by hospitals of national performance measures for antimicrobial prophylaxis, and yet SSIs remain an important cause of morbidity and mortality.

Current Gaps in Knowledge and Practice

- Basic Science
 - Gain a better understanding of factors leading to the development of SSIs, transmission in various settings, and optimal modes of prevention, diagnosis, and therapy. Of particular interest is the role of biofilms.
- Epidemiology
 - Develop and standardize methods for SSI surveillance, with a particular emphasis on surveillance after discharge and in ambulatory surgery.
 - Determine postoperative risk factors for SSIs.
- Infection Control Interventions
 - Determine how the resistance of staphylococcal infections to methicillin influences optimal practices for antimicrobial prophylaxis (e.g., when should vancomycin be included? Should other agents be used?).
 - Determine the effectiveness or comparative effectiveness of preoperative prevention practices, including but not limited to:
 - Preoperative bathing with antiseptics.
 - Preoperative screening, decolonization, and choice of antimicrobial prophylaxis in patients colonized with *Staphylococcus aureus* (and determine the unintended consequences of these interventions, such as antimicrobial resistance).
 - Development and use of vaccines for *S. aureus*.
 - Determine the effectiveness or comparative effectiveness of intraoperative prevention practices, including but not limited to:
 - Ultraviolet light.
 - Wound closure techniques (staples versus sutures).
 - Optimal use of a surgical antiseptic scrub.
 - Optimal use of skin-prep solutions (alcoholic chlorhexidine versus alcoholic iodine).
 - Determine the effectiveness or comparative effectiveness of antimicrobial prophylaxis strategies, including but not limited to optimal dosing for obese patients, optimal dosing for device implantation, and intraoperative redosing.
 - Determine the effectiveness or comparative effectiveness of additional perioperative management strategies, including but not limited to:
 - Maintaining intraoperative and perioperative normothermia.
 - Using supplemental oxygenation during surgery.
 - Maintaining optimal perioperative glucose control.

⁵ *Guideline for the Prevention of Surgical Site Infection*. Available at: http://www.cdc.gov/hicpac/SSI/001_SSI.html

- Implementation Science
 - Determine barriers to implementation of current SSI prophylaxis guidelines.

Clostridium difficile Infection

State of the Art

CDI rates have been increasing in recent years, mostly due to transmission of a single, fluoroquinolone-resistant epidemic strain with enhanced virulence. Prevention strategies primarily focus on optimizing antimicrobial use and preventing transmission using basic infection control precautions. Because *C. difficile* spores can persist on environmental surfaces, the role of environmental cleaning is likely to be important.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of CDI, its transmission in various settings, and optimal modes of prevention, diagnosis, and therapy. Logical areas for attention include but are not limited to immunity, gut ecology, toxin biology, and drug resistance.
- Epidemiology
 - Facilitate our epidemiologic understanding of factors related to the development of *C. difficile* in acute care and community-based settings, including the epidemiology of antimicrobial use; the role of asymptomatic carriers in disease transmission; and our understanding of the incubation period between acquisition and onset of infection.
 - Gain an enhanced understanding of the burden of CDI in the United States, including but not limited to an understanding of the relative importance of the setting of onset (particularly community onset) and of health care exposures and the different sources of health care exposures (environment versus health care workers).
 - Develop a methodology for measuring the transmission and burden of CDI in non-acute care settings to assist with reaching the goals above.
 - Determine the role of *C. difficile* in neonatal/infant diarrhea.
- Infection Control Interventions
 - Facilitate research to develop optimal approaches to environmental cleaning of health care settings, such as research on the role of sporicidal agents, determining the best methods for assessing the adequacy of cleaning, and developing and assessing the impact of a *C. difficile* environmental-cleaning bundle.
 - Optimize additional CDI prevention practices to reduce transmission of *C. difficile* in health care facilities by examining such issues as:
 - the optimal duration of contact precautions (following symptomatic infection)
 - the incremental benefit of soap and water over alcohol hand gel
 - the role of hand contamination after glove use
 - Define optimal measures to reduce unnecessary use of antimicrobials.
 - Determine the role of suppressing gastric acid.

- Implementation Science
 - Develop methods to measure and report compliance with the use of personal protective equipment and environmental cleaning.

Catheter-Associated Urinary Tract Infection

State of the Art

Detailed recommendations on the prevention of UTIs have been developed by CDC and HICPAC.⁶ An estimated 15% to 25% of hospitalized patients receive a short-term indwelling urinary catheter^{7,8}; for the elderly, the use of catheters is much higher. In many cases, catheters are placed for inappropriate indications, and health care providers are often unaware that their patients have catheters, leading to prolonged, unnecessary use of these devices.

CAUTIs are the most commonly reported HAI in the US.⁹ Although morbidity and mortality from CAUTI is considered to be relatively low compared with other HAIs, the high prevalence of using a urinary catheter leads to a large cumulative burden of infections, with resulting infectious complications and deaths. In addition, bacteriuria frequently leads to unnecessary use of antimicrobials, and urinary drainage systems may serve as reservoirs for MDR bacteria and as a source of transmission to other patients.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of CAUTI and the optimal modes of prevention, diagnosis, and therapy. A logical area for attention is biofilms.
 - Identify methods to differentiate bladder colonization from CAUTI in patients with catheters.
- Epidemiology
 - Explore the epidemiology of CAUTI and asymptomatic bacteriuria, including incidence, outcomes, and relative contributions to the use of antimicrobials.
 - Identify methods to improve the surveillance of CAUTI, including determining the accuracy of surveillance definitions in select populations (e.g., elderly patients) and developing methods for electronic capture of CAUTI.
 - Study the epidemiology of antimicrobial resistance in uropathogens, considering the role of different urinary catheter systems as reservoirs for resistant bacteria and the presence of resistance to antimicrobial/antiseptic coatings.
 - Quantify the unnecessary use of urinary catheters and its consequences (trauma, encrustation).

⁶ *Guideline For Prevention Of Catheter-Associated Urinary Tract Infections, 2009*. Available at http://www.cdc.gov/hicpac/cauti/001_cauti.html

⁷ Warren JW. Catheter-associated urinary tract infections. *International Journal of Antimicrobial Agents* 2001; 17:299-303.

⁸ Weinstein JW, Mazon D, Pantelick E, et al. *Infection Control and Hospital Epidemiology* 1999; 20:543-548.

⁹ Klevens RM, Edwards JR, Richards CLJr, et al. *Public Health Reports* 2007; 122:160-166.

- Infection Control Interventions
 - Determine the role of newer catheter materials and technology in the prevention of CAUTI (including their role in patient populations most likely to benefit):
 - Antimicrobial and antiseptic-impregnated catheters.
 - Portable ultrasound in patients to reduce unnecessary insertions or irrigations of catheters (in catheterized patients).
 - Define appropriate catheter use in specific circumstances and the risks and benefits of alternative strategies for bladder management (such as condom catheters in male patients). Populations of interest might include patients receiving thoracic epidural anesthesia, incontinent patients, and patients with advanced stage (III or IV) pressure ulcers with incontinence or who reside in nursing homes.
 - Determine the role of antiseptics (e.g., methanamine) in preventing CAUTI.
 - Determine the optimal methods of maintaining meatal hygiene during catheterization.
 - Identify engineering-control strategies (e.g., spatial separation) for catheterized patients to prevent transmission of antimicrobial-resistant urinary pathogens.
 - Further the understanding of catheter management for patients requiring chronic urinary drainage (including the timing and appropriateness of routine catheter changes, alternatives to having an indwelling urethral catheter and bag drainage, methods for preventing encrustation, management of patients with leg bags, new prevention strategies such as bacterial interference, and optimal cleaning and storage procedures for the clean intermittent catheterization technique).
- Implementation Science
 - Identify approaches to limit unnecessary catheter use (both number of insertions and duration).

Ventilator-Associated Pneumonia

State of the Art

Detailed recommendations on the prevention of VAP have been developed by CDC and HICPAC.¹⁰ VAP is a major cause of health care-associated morbidity and mortality among ICU patients.

Unlike most ICU infection syndromes, which have relatively low mortality rates, the mortality rate for VAP in most studies has ranged from 20% to 50%. More recent estimates from studies using multistate modeling suggest that the attributable mortality may be lower, around 8% to 10%.¹¹ For patients in critical care units, VAP contributes disproportionately to poor outcomes and substantially higher costs of care. Current approaches to preventing VAP rely on evidence-based strategies that minimize intubation, the duration of mechanical ventilation, and the risk of aspirating oropharyngeal pathogens.

¹⁰ Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines and publications available at <http://www.cdc.gov/hicpac/pubs.html>

¹¹ Nguile-Makao M, Zahar JR, Francois A, et. al. Attributable mortality of ventilator-associated pneumonia: respective impact of main characteristics at ICU admission and VAP onset using conditional logistic regression and multi-state models. *Intensive Care Medicine* 2010; 36:781-789.

Multidrug-resistant microorganisms are playing an increasingly important role in the pathogenesis of VAP, particularly among infections occurring after the first week in the ICU. These pathogens contribute significantly to the increased costs, morbidity, and mortality associated with this syndrome.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of VAP infection and the determination of the optimal modes of prevention, diagnosis, and therapy. Logical areas for attention include, but are not limited to, immunity, ecology, and biofilms.
 - Evaluate the effect of inflammatory lung injury and trauma on susceptibility to VAP.
- Epidemiology
 - Identify and gain a consensus for a definitional and diagnostic approach to VAP that has adequate test characteristics, is feasible across facilities, and can be used for clinical decision making and, similarly, to gain consensus on a definitional approach that will be useful for surveillance purposes. Specific diagnostic issues may include:
 - Role of diagnostic bronchoscopy with culture
 - Role and importance of various microbiological culturing techniques, including quantitative cultures
 - Role of surrogates for VAP (see next bulleted item)
 - Identify and evaluate surrogate infections for VAP to assess measures of the quality of care for ventilated patients that are objective, simple to gather, amenable to electronic determination, and predict patient outcomes. Measures are needed to allow inter-facility comparisons and for objective evaluation of the impact of prevention measures.
 - Identify the relative contributions of the large number of complex and confounding variables/risk factors that influence the development of VAP, including the role of broad-spectrum antimicrobials in the development of VAP caused by multidrug resistant pathogens.
 - Identify the relationship of endotracheal tube-induced bacterial sinusitis to VAP.
 - Better understand the natural tension between the need for adequate nutrition and the increased risk for aspiration and VAP associated with enteral nutrition solutions.
 - Develop better methods to determine the attributable mortality and attributable length of stay of VAP that take into account the time-dependent nature of the condition.
- Infection Control Interventions
 - Facilitate the determination of optimal care practices for ventilated patients, including positioning, oral care (routine practices, decontamination), secretion management, and acid suppression.
 - Determine the role of novel approaches, such as probiotics, for the reduction of VAP.

- Determine the role of various technologies in the prevention of VAP. This should include examining advances in endotracheal tube design and materials (e.g., antimicrobial impregnated materials), internal ventilator filters and ventilator breathing filters, and less-invasive ventilatory support to reduce the use of positive-pressure ventilation via endotracheal intubation or tracheostomy (e.g., using CPAP [continuous passive airway pressure], high oxygen therapy, iron lung).
- Determine the role of biomarkers (e.g., procalcitonin) in reducing unnecessary antibiotic use in VAP.
- Implementation Science
 - Determine the impact of using bundles of prevention practices on adherence to prevention practices and patient outcomes; define the ideal components of the bundle.
 - Facilitate projects to create precise operational definitions and metrics for prevention practices as well as acceptable contraindications (e.g., head-of-bed elevation — how much, how long, how measured, and for whom?).

Methicillin-Resistant Staphylococcus aureus

State of the Art

MRSA remains an important cause of HAIs, and it is endemic in most hospitals in the U.S. In addition to increasing the total burden of *S. aureus* infection, health care-associated MRSA infections are associated with increased morbidity and mortality compared with infections caused by methicillin-susceptible strains. Furthermore, MRSA has emerged as an important cause of infection in the community. Fifty-nine percent of all purulent skin infections evaluated in U.S. emergency departments are caused by MRSA. MRSA infections, both health care- and community-associated, are generally caused by a very limited number of strains, suggesting that most cases result from direct or indirect person-to-person transmission of MRSA.

It is widely held that the major reservoir for transmission in the health care setting is infected or colonized patients and that patient-to-patient transmission occurs indirectly via transient carriage by health care personnel or through shared equipment that is contaminated. In 2005, there were an estimated 94,000 invasive MRSA infections in the United States, which were associated with nearly 18,000 deaths. Of these invasive infections, 86% were associated with health care delivery, but two-thirds of these HAIs had their onset outside the hospital setting. Recent data suggest that between 2005 and 2008, rates of invasive health care-associated MRSA infection decreased.¹²

Although the optimal strategy for preventing and controlling health care-associated MRSA has not been fully determined, it is likely that successful control requires a multifaceted approach that may vary according to the individual characteristics of a health care facility, as outlined in the CDC guidance document *Management of Multidrug-resistant Organisms in*

¹² Kallen AJ, Mu Y, Bulens S, et al. Health Care–Associated Invasive MRSA Infections, 2005–2008. *The Journal of American Medicine* 2010; 6:641–648.

*Healthcare Facilities, 2006.*¹³ Additionally, there is a growing recognition that the focus of MRSA prevention on individual health care facilities needs to be broadened to incorporate entire geographic regions.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Facilitate research to enhance our understanding of factors leading to the development of MRSA infection, transmission in various settings, and optimal modes of prevention, diagnosis, and therapy. Logical areas for further research include, but are not limited to, biofilms, antimicrobial resistance, ecology, pathogenesis and virulence factors, and immunity.
 - Facilitate development of an effective *S. aureus* vaccine.
- Epidemiology
 - Facilitate research to obtain a better understanding of the colonization and transmission dynamics of MRSA within the health care setting. Logical areas for attention include, but are not limited to, the patient (e.g., characteristics for acquiring MRSA carriage or serving as a reservoir of transmission, the role of colonization of body sites other than the nares); the environment (e.g., fomites), the health care worker, and the role of droplet spread.
 - Facilitate work to understand the epidemiology of MRSA outside the adult ICU (such as in the NICU) and outside and between acute care settings within a geographic region.
 - Further the understanding of the epidemiology of MRSA in the community (both community-acquired and community-onset MRSA and their interaction with health care-associated MRSA).
 - Determine the preventability of endemic MRSA colonization/infection.
 - Improve our current understanding of the strengths and weaknesses of different methodologies for measuring MRSA infections (e.g., discharge data versus active surveillance).
- Infection Control Interventions
 - Facilitate an understanding of the role of various prevention strategies in reducing health care-associated transmission of MRSA. This should include assessments of the unintended consequences of such strategies. Logical strategies include antimicrobial stewardship, improved methods for preventing transmission, and MRSA eradication strategies.
 - Determine the optimal role for using active MRSA surveillance to detect asymptomatic carriage (which patients, what body sites, when, how many cultures?). Facilitate the determination of methods to measure transmission of MRSA within a health care setting.
 - Translate accepted prevention practices to areas outside the adult ICU (such as the NICU and non-acute care settings).

¹³ *Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006.* Available at http://www.cdc.gov/hicpac/mdro/mdro_0.html

- Implementation Science
 - Determine and disseminate optimal approaches to MRSA prevention strategies, such as controls on antibiotic use and using preoperative mupirocin for decolonization in selected procedures.
 - Identify the most effective methods for facilitating coordinated regional prevention activities.

IV. LONG-TERM PRIORITIZATION, COORDINATION, AND EVALUATION OF RESEARCH EFFORTS

HAIs are a major cause of preventable morbidity and mortality in the United States that in total greatly exceeds other causes of preventable mortality, such as the human immunodeficiency virus, or HIV. Nonetheless, funding for the study of HAIs is magnitudes lower than funding for HIV. Addressing the nation's long-term HAI research needs is a complex undertaking that will require a coordinated effort across the federal government and with other stakeholders. Many agencies within HHS, such as AHRQ, CDC, CMS, and NIH, have funded research to address HAIs and their underlying causes. This document outlines a mechanism to coordinate these efforts.

Research on the relevant basic science, disease epidemiology (including risk factors), testing of infection control interventions, implementation of evidence-based practices, and effects of payment and coverage policy should be linked so that findings from each area can inform and build upon findings in the other areas. For example, if CDC finds a potential population or setting to be a risk factor for an HAI, this information could help establish potential priorities for AHRQ-funded research on prevention or implementation of evidence-based practices. Additionally, collaborations will emerge as work progresses (as an example, CMS, working with AHRQ, CDC, and OASH, has been evaluating the effects of the HAC program). This coordination will reduce potential duplication and enhance the impact of each agency's work.

The following mechanism for coordination is proposed:

The Research Working Group is chartered and meets quarterly. This group should be comprised of at least two representatives from AHRQ, CDC, CMS, and NIH as well as representatives from other HHS operating and staff divisions or federal agencies, as needed. The committee has three main objectives:

- Coordinate and prioritize research efforts to reduce HAIs nationwide.
- Design a plan and metrics for evaluating progress within the research domain to address HAIs.
- Serve as a contact point to communicate to external stakeholders on this issue so that HHS's efforts are coordinated and linked to a broader national coalition.

To coordinate and prioritize research efforts, the Research Working Group will prepare an inventory of current HHS research projects and develop a mechanism for exchanging information about these projects to take advantage of potential synergies and reduce needless duplication.

To evaluate progress made in the research domain of the HAI Action Plan, the Research Working Group will conduct periodic assessments of the research program and the projects it has specifically funded. The Research Working Group will set up *a priori* criteria for the evaluation and a plan for the timing of evaluations, such as once a year. Metrics of accomplishment could include documented improvements in care, published articles, dissemination of findings through conferences or other means, or other research products. It is important to note that successful research may demonstrate negative results or bring up more questions in addition to demonstrating effective interventions. The evaluation of the program should lead to adjustments to the program in subsequent years.

To effectively carry out these activities, the Research Working Group will meet quarterly and complete an update of the research component of the HAI Action Plan every two years.

V. CONCLUSION AND VISION FOR THE FUTURE: RESEARCH AS THE FOUNDATION OF A LEARNING HEALTH CARE SYSTEM

The large knowledge gaps that exist in HAI prevention are in part the result of barriers to using the new generation of knowledge that currently exist within U.S. health care. In a background paper developed and presented at an Institute of Medicine's Roundtable on Evidence Based Medicine entitled "Leadership Commitments to Improve Value in Health Care," Platt and colleagues argued that evidence generation, i.e., *learning what works and what does not*, should be established as a normal part of health care in the U.S.¹⁴

At the roundtable, Pratt and associates outlined major challenges confronting the development of knowledge to support the "learning health care system." These included: (1) limited investment for research and development towards understanding how well various strategies work in practice, or how to assure that the right preventive or therapeutic regimen is offered to individuals who need it; (2) difficulty in using much of the existing data, even when it exists in electronic form, because of fragmentation among organizations that control the data, variation in the way that different organizations interpret the Health Insurance Portability and Accountability Act Privacy Rule, institutional review boards' varying interpretations of regulations governing the use of these data for research, and the proprietary concerns of data holders; (3) important limitations in the quality and generalizability of the existing data; and (4) lack of a full understanding of the strengths and weaknesses of the different research methods, ways in which to strengthen them, and the situations in which they are best applied. Meeting these structural challenges will require sustained interest and effort on the part of a coalition of stakeholders within and outside the federal government.

The work of the Research Working Group can perform an important function in facilitating the process of becoming a learning health care system. This chapter summarizes the Research Working Group's work to identify gaps in the existing knowledge base regarding HAIs, which is a necessary first step in the process of developing a coordinated HAI research agenda that will ultimately lead to widespread use of evidence-based infection control and prevention practices in

¹⁴ Platt R. Chapter 9: Clinical Investigators and Evaluators, Leadership Commitments to Improve Value in Healthcare: Toward Common. *National Academies Press*, 2009: 217-236.

the spectrum of health care settings. To do so, it is critical to understand the basic pathophysiology of HAIs, the limitations of our current surveillance methods and the promise of using electronic data for surveillance, the most effective combinations of clinical care and technology to prevent HAIs, and the most effective and efficient methods to improve adherence to current recommendations on preventing HAIs.

Having identified gaps, the Research Working Group has proposed research projects to address the gaps identified in basic science, epidemiology, infection control and prevention, and implementation and on the priority infections identified in the first and second phases of this initiative. In an iterative manner, the work from the HAI Action Plan will address gaps in knowledge and inform the priorities going forward. This framework of progression and iteration from basic science through implementation will be crucial in achieving a learning culture and will complement HHS's commitment to collaboration across the federal government and with additional stakeholders to assess current research methods, funding levels, use of information technology, and training of researchers and to present solutions to facilitate and accelerate the generation and application of knowledge. The overall goal is to support the research required to aggressively combat HAIs and protect the safety of all Americans.

Table 5. Status of Identified Priority Research Projects in the 2009 HHS HAI Action Plan

Domain	2008 HAI Action Plan Project Number	Description	Funded Projects
Basic Science	a. i.	Design and implement broad-based studies that define and clearly delineate the pathogenesis of device-associated infection.	FY 2008 NIH, FY 2009 NIH
Basic Science	a. ii.	Develop strategies for preventing and/or eliminating biofilms associated with medical devices.	FY 2008 NIH, FY 2009 NIH
Epidemiology	b. i.	Perform studies of the epidemiology of bloodstream infections that occur outside of the hospital, including those related to hospitalization. These studies would include an assessment of patient characteristics and risk factors for bloodstream infection that could lead to new prevention strategies.	FY 2008 AHRQ HIT 290-04-0015; FY 2008 AHRQ HCUP HHS290200600009C; FY 2008 AHRQ HCUP 290-04-0005; FY 2008 AHRQ DEcIDE HHS290200600013
Epidemiology	b. ii. 1.	Establish preventability of CDI through a regional hospital collaborative intervention to reduce endemic rates through employment of tiered evidence-based recommendations (e.g., transmission reduction and risk reduction through antimicrobial stewardship), peer-to-peer learning, and standardized electronic collection and feedback of CDI rate data using NHSN to assess impact.	FY 2009 AHRQ ACTION HHS290200600012
Epidemiology	b. ii. 2.	Establish preventability of unnecessary antimicrobial use through a multicenter collaborative intervention. These efforts could include coordinated development and implementation of clinical diagnosis and antimicrobial-use paradigms in the treatment of CAUTI and VAP, as well as in the prevention of SSI (i.e., surgical antimicrobial prophylaxis) with the aim of reducing overall antimicrobial use.	FY 2010 AHRQ ACTION H3; FY 2010 AHRQ ACTION H4; FY 2009 AHRQ PBRN HHS290200710015, HHS290200710013, HHS290200710008, HHS290200710004
Epidemiology	b. ii. 3.	Establish preventability of SSI through a multi-center collaborative intervention to reduce rates. These efforts could include coordinated development and implementation of strategies to implement existing evidence-based recommendations, peer-to-peer learning, and standardized electronic collection and feedback of SSI rate data using NHSN to assess impact.	
Infection Control Interventions	c. i.	Perform a large, cluster-randomized study to assess whether ICU-wide application of an MRSA decolonization strategy is effective in reducing the transmission of HAIs and mortality compared to a targeted decolonization strategy guided by active surveillance for MRSA colonization.	FY 2009 AHRQ DEcIDE HHS29020050031

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Domain	2008 HAI Action Plan Project Number	Description	Funded Projects
Implementation	a.	Support multidisciplinary investigation of the human cultural and organizational barriers at the unit and institutional level (including trustees and senior management) that inhibit the successful implementation of prevention measures.	FY 2010 AHRQ ACTION H10; FY 2010 AHRQ ACTION Mod H17
Implementation	b. i.	Perform studies to develop and evaluate novel and potentially automatable strategies for measuring health care-associated infections, transmission of epidemiologically important pathogens, and related processes of care using electronic data sources routinely captured during the course of patient care.	CMS
Implementation	b. ii.	Evaluate and validate standardized post-discharge surveillance methodology that can be used in both inpatient and ambulatory care settings.	FY 2010 AHRQ HCUP H16
Implementation	b. iii.	Identify and evaluate proxy measures for VAP (e.g., acute lung injury) for inter-facility comparisons that do not require stringent diagnostic approaches.	
Implementation	b. iv.	Develop standardized methods (i.e., performance methods) that are feasible, valid, and reliable for measuring and reporting compliance with broad-based HAI prevention practices that need to be practiced consistently by a large number of health care personnel (e.g., hand hygiene, isolation precautions, environmental cleaning practices).	DHHS

CHAPTER 2: INFORMATION SYSTEMS AND TECHNOLOGY

I. INTRODUCTION

Continuing clinical and public health concerns about health care-associated infections (HAIs) are motivating the health care community at large to redouble its efforts to enhance and extend HAI monitoring, measurement, and prevention. Advances in information technology (IT), the harmonization of disparate data standards, the creation of incentive programs designed to promote the meaningful use of electronic health records (EHRs), and the development of capabilities to connect with and integrate multiple data types and sources have all created new opportunities for the U.S. Department of Health & Human Services (HHS), operating and staff divisions within HHS, and other federal departments and agencies to further develop and refine strategies that focus on improving the national capacity to monitor, measure, and prevent the occurrence of HAIs. HHS and its partners within the federal government share goals with state agencies, hospitals and other health care organizations, health care practitioners, accrediting and professional organizations, and the public to take action that addresses the prevention of HAIs.

Some common goals that leverage advances in state-of-the-art information systems and technology include:

1. *Take full advantage of health care data in electronic form.* Continue progress toward more rapid and complete detection of HAIs by increasing capabilities to exploit current and future data sources. Pathbreaking efforts have used laboratory and other health care data in electronic form, coupled with computer-based detection algorithms, to detect HAIs, but much additional work is needed to leverage these pioneering efforts and capitalize further on the increasing availability of electronic data from the clinical record of care. This will be possible only when laboratory results and clinical observations are expressed routinely using standard terms and when automated, intelligent systems are applied to identify HAI indicators among a constellation of clinical and laboratory findings within electronic data resources.
2. *Build bridges between health care information systems used for infection control and prevention, quality improvement, and patient safety.* Further develop the integration of HAI monitoring and measurement systems with other systems used to monitor and measure health care quality and patient safety. This should include assuring that HAI surveillance and other areas of quality and safety surveillance are complementary and connected in ways that streamline work effort and maximize the benefits for patient care and public health. For example, leveraging meaningful-use public health reporting, or recognizing that an integrated approach will permit rapid detection of patterns and trends for predetermined or ad hoc sets of demographics, will create the opportunity to formulate appropriately targeted tactics and execute early prevention and intervention techniques.
3. *Combine forces with other agencies and organizations.* Enhance capacity at all geographic levels for using more comprehensive, reliable, and timely data as a shared resource for focusing prevention efforts and measuring their effectiveness at the local, state, and national levels in terms of progress toward reducing catheter-associated urinary tract infections (CAUTIs), central line-associated bloodstream infections (CLABSIs),

Clostridium difficile infections (CDIs), methicillin-resistant *Staphylococcus aureus* (MRSA) infections, surgical-site infections (SSIs), and ventilator-associated events (VAE), formerly called ventilator-associated pneumonia (VAP).

4. *Use information systems and technology to link health care records and extend HAI reporting.* Leverage electronic health care records and accountable care organizations (ACOs) in ways that link and make available HAI data for entire episodes of care, e.g., both surgical process-of-care data recorded at the health care facility where the patient had an operation as well as SSI data recorded at another health care facility, such as another hospital or a physician's office, when the patient seeks care there. Promote the continued adoption and meaningful use of EHR systems that can exchange data in an interoperable manner with other systems, which will yield enormous benefits, including new capacity for episode-of-care data collection and more complete measurement and analysis of HAIs.
5. *Apply new tools for putting HAI prevention into practice.* Take full advantage of new investments in clinical decision support (CDS) embedded in EHR systems to provide context-sensitive HAI prevention reminders or clinical guidelines when and where they are needed. The point-of-care availability of relevant information will help guide patient care decisions and documentation, such as decisions about contact precautions designed to prevent the transmission of HAIs.

Improvements in national-level HAI data collection, analysis, and reporting are integral to what HHS and other federal agencies seek to accomplish in a broad-based, national HAI prevention effort. HHS recognizes that there are some issues with the current systems, despite notable efforts in this arena by federal agencies.

As called for in the 2009 iteration of the *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* (HAI Action Plan), HHS and its component operating and staff divisions are pursuing a proactive strategy to integrate data where it originates in addition to developing retrospective integration of different federal systems of reporting. This broad-based strategy goes beyond addressing data "control and fragmentation" issues in clinical care to the meaningful use of EHR systems to streamline HAI reporting and identify and capitalize on HAI prevention opportunities in the clinical workflow.

Programs at multiple agencies collect and report HAI and HAI-related data in separate systems and databases that function, in effect, as "silos," perpetuating singular and isolated paths of information used for making decisions. However, renewed patient safety efforts within HHS and more broadly across federal and state agencies are under way to consolidate and integrate HAI information flows in ways that avoid duplication of effort and disconnects that would otherwise result in loss of potentially important information.

Promoting the linking or sharing of HAI data across systems in a more integrated fashion offers myriad opportunities to yield important benefits for comprehensive analysis and action, given that the safeguards are in place to assure that the merged data are used exclusively for authorized public health purposes and are scrupulously protected from unauthorized access. For example, combining patient-level surgical process-of-care and outcome data from one system with SSI

data from another system could provide new insights into near-term opportunities for prevention and for quality-of-care improvement.

In other situations, pursuing a longer-term strategy to achieve integration is needed to enable interoperable data exchanges between separate systems and to leverage the standards-based electronic record keeping and data sharing that are entering the mainstream of U.S. health care at an accelerating pace. Achieving these longer-term strategies should provide HAI data to multiple agencies with greater efficiency, economy, timeliness, comprehensiveness, and reliability than is currently possible.

II. MAINTAINING THE FOUNDATION FOR HAI DATA INTEGRATION AND INTEROPERABILITY

Critical elements that support HAI data integration and interoperability within HHS and across federal agencies remain:

- Increased visibility and priority given to the measurement and prevention of HAIs, which means that agency heads will incorporate this as a key objective and important priority in their respective strategic plans. The proposed goal is the execution of these strategies in an integrated fashion with federal and external partners.
- Careful planning and close coordination across federal agencies towards implementation of system and process changes that use common data, information, and knowledge models. This should be done to support the prevention of HAIs and all quality-of-care initiatives sharing common strategic goals for health care improvement.
- Close collaboration with private and public partnerships that promote, manage, and implement widely adopted health care data and technology standards, as well as the interoperability standards that have been recognized by the HHS Secretary, to ensure that the business case for prevention of HAIs is included in the development and ongoing maintenance of standards, including efforts to harmonize multiple domains of data.
- Proactive participation in large-scale strategies and other federal initiatives, similar to those that have been advanced by the HHS Office of the National Coordinator for Health IT (ONC). This will help shape the development and implementation of an HAI information architecture that works in conjunction with the Nationwide Health Information Network (NwHIN) and the Federal Health Information Sharing Environment (FHISE) initiatives.

To the fullest extent possible, efforts to improve HAI data integration and interoperability should be aligned with the NwHIN and FHISE initiatives.

The purpose of the NwHIN is to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and health care. The NwHIN is a set of standards, services, and policies that enable the secure exchange of health information over the Internet. A group of federal agencies, health information exchange organizations, and integrated delivery networks (formerly known as the NHIN Cooperative) has participated in the development of the network standards, services, and policies.

III. COORDINATION OF EFFORTS: INTERAGENCY WORKING GROUP

Various agencies across HHS have begun to collaborate, and will continue to do so, to find system integration solutions in order to obtain reliable national estimates of patient-safety adverse events in general, and HAIs in particular, for a more accurate view of the overall issue. With that in mind, the Patient Safety Working Group (PSWG), coordinated by the Agency for Healthcare Research and Quality (AHRQ), serves as a key forum for federal partners to identify and initiate collaborations aimed at integrating HAI monitoring and measurement systems. Further, the PSWG serves as a key federal entity for connecting HAI-related information systems to information systems that provide reporting coverage for a broad array of patient safety incidents and health care-associated conditions.

The thoughtful development and successful implementation of specific interagency projects is essential to improve national-level HAI monitoring and measurement. Coordination of effort, such as seen in the interagency collaboration spawned by the PSWG, will enhance communication and program planning within HHS and between HHS and other federal departments. This is enabling problems to be approached in a more holistic fashion than would be true if disparate parts were addressed.

Programs in existence or under development within one or more agencies will be identified and leveraged under the auspices of the PSWG to aid in the overall prevention strategy. This coordinated effort is reducing duplication of work and enhancing the impact of each agency's contribution to the HAI prevention and, more broadly, patient safety and quality improvement.

The PSWG can answer the call for an interagency working group to coordinate and spur collaborative HAI systems and technology activities. The PSWG is comprised of at least one representative from AHRQ, Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), and ONC, plus representatives from other agencies as designated. The representatives have an overarching understanding of their respective agency's HAI-related systems and databases as well as the interrelationships between these systems. Representatives have an in-depth knowledge of gaps in HAI data. Project managers of specific systems within these agencies serve as technical consultants to the PSWG. In order to facilitate regular communication, the group meets bimonthly.

The PSWG's scope includes specific projects that can be completed within a time horizon of one to two years. A high priority is placed on projects that combine data from existing systems or foster new alignments across systems to improve capacity at the national level to benchmark progress in reducing HAIs.

Processes have been launched for reconciling differences that would otherwise impede progress in completing high-priority projects. For example, a common health care facility identifier across CDC and CMS systems enables HAI data reported to a CDC surveillance system to be reused in CMS's Hospital Inpatient Quality Reporting Program. Also, HAI case criteria and data requirements developed for the CDC surveillance system have been adopted for use in AHRQ's patient safety incident reporting program.

CDC-CMS collaboration enables HAI data submitted by acute care hospitals to CDC's National Healthcare Safety Network (NHSN) to be reported from that system to the CMS quality reporting program. In the Fiscal Year (FY) 2011 Inpatient Prospective Payment System (IPPS) Final Rule, CMS finalized the adoption of two new measures that must be reported by acute care hospitals to the Hospital Inpatient Quality Reporting Program. Specifically, CMS began requiring participating hospitals to report CLABSIs and SSIs to NHSN. In subsequent rulemaking, CMS has adopted additional HAI Action Plan measures for participating hospitals to report to NHSN.

AHRQ-CDC collaboration has enabled HAI definitions and data specifications already used in NHSN to be adopted for use in the common definitions and reporting formats specified by AHRQ (AHRQ Common Formats) for use by health care providers in collecting and submitting standardized information regarding patient-safety events to Patient Safety Organizations, which in turn will submit data to the national Network of Patient Safety Databases.

IV. WORK GROUP GOALS, TASKS, AND OPERATIONS

The goals and tasks envisioned for an interagency work group can be incorporated in the PSWG's operations¹⁵:

Goal A: Maintain and continue to establish definitional alignment and identify standardized data elements that are needed to measure HAIs across HHS agencies and encourage existing federal participation with Standards Development Organizations and the Federal Health IT Standards Committee to ensure that gaps in the available standards are addressed.

Tasks:

- Maintain a comprehensive inventory of existing HAI databases in HHS agencies, including information about data collection, data uses, and data validation.
- Broker agreement on the terms that need to be defined and the set of data elements that need to be specified to measure HAIs.
- Document definitions of terms, value sets, and data elements included in HAI databases in HHS agencies, specifically those needed to measure HAIs.
- Establish definitional alignment and standardization of data elements across HHS agencies, with special emphasis on standardizing health care data already available in electronic form.
- Identify and analyze policy and legal issues and limitations relevant to exchanging data among agencies.

¹⁵ Successful completion of work group goals and tasks is contingent on provision of staff and financial resources.

Goal B: Provide guidance to enable the integration of HAI data from multiple HHS databases for the purpose of benchmarking progress in reducing HAIs.

Tasks:

- Reach agreement on what data are needed to benchmark progress.
- Identify and prioritize candidate HAIs for incorporation into requirements for meaningful use and nationwide state-based reporting.

Goal C: Mobilize health information systems to help reinforce recommended clinical practices for ensuring patient safety.

Tasks:

- Develop a plan for HHS actions that can help move functional components into wider clinical use at an accelerated pace.

Goal D: Seek strategic opportunities to make varied federal data systems interoperable to enhance understanding of HAIs.

Tasks:

- Work with the public, key patient safety policy groups, public-private partnerships, and stakeholders, such as the Health IT Policy Council, CMS, ONC, and the Department of Veterans Affairs, to act on opportunities to incorporate measures to reduce HAIs into meaningful use clinical quality measures. To accomplish these goals and tasks, the PSWG is guided by a shared understanding of the group's purpose, scope, authority, participants, roles and responsibilities, and stakeholders.

The PSWG's work on HAIs should coalesce around four major objectives:

- Use the department's IT strategy.
 - Develop an overall IT strategy to support near-term and long-term HAI data integration and linkages between HAI and other patient-safety information systems, while safeguarding data from unauthorized access and use.
 - Make decisions regarding specific projects and the scope and boundaries of projects that are incorporated within a coordinated strategy.
 - Help establish priorities and provide oversight for interagency system integration projects.
- Communicate with stakeholders.
 - Formulate a communication strategy to be used both within and outside HHS to ensure the highest degree of understanding of priorities.
 - Serve as a point of contact for communication to external stakeholders so that HHS efforts are coordinated and linked to a broader national coalition.
 - Provide status reports and updates to the Information Systems and Technology Working Group of the Federal Steering Committee for the Prevention of HAIs and look for opportunities to inform the relevant working groups and advisory committees across HHS.
 - Identify and serve as a conduit to appropriate points of contact within agencies for data/database information.

- Maintain accountability for the work effort.
 - Design and refine value sets and data definitional requirements for process and outcome measures to monitor progress on achieving goals within the information technology strategy.
 - Assist related groups (e.g., the interagency HAIs Research Working Group) with the design of a set of measures and a plan to improve the measures over time to monitor the nation's performance on reducing HAIs.
 - Work toward the incorporation of HAI measures into appropriate stages for the CMS meaningful use clinical quality measures.
- Minimize reporting burden and maximize information output.
 - Formulate a related strategy to streamline and reduce redundancy in HAI reporting from health care facilities and limit additional data collection to ease the reporting burden on stakeholders, specifically hospitals.
 - Use small pilot studies and work closely with HHS operating and staff divisions such as the CMS Office of Clinical Standards and Quality to determine the effectiveness of IT solutions for minimizing burden and maximizing output before solutions are disseminated and deployed.
 - Leverage the availability of health care data in electronic form, such as data on microbiology results, to automate case detection and enable electronic reporting of HAI data wherever possible.
 - Establish consistent standards and coordinated data collection methodologies for how stakeholders should submit HAI data to various HHS systems.
 - Develop strategies to ensure that end users (i.e., the institutions and individuals entering the data) have adequate access to information technology resources and help-desk functions to support end users in a manner that simultaneously reduces their burden and improves the accuracy of data input (e.g., integrated help functions, error-reporting mechanisms). As part of these strategies, develop tools for data entry by users that span a broad range of technical capabilities and work flows and take into account the special needs of health care facilities in rural and underserved communities.

V. HAI DATA AND DATA INVENTORY

In the fall of 2009, AHRQ contracted with IMPAQ International and the RAND Corporation to conduct an independent evaluation of the HAI Action Plan. As part of the evaluation, the evaluation team inventoried federal HAI data systems and issued a report in June 2010 that included its findings. The federal HAI data systems included in the inventory were AHRQ's Healthcare Cost and Utilization Project, CDC's NHSN, the Active Bacterial Core Surveillance system, the National Health and Nutrition Examination Survey and the National Hospital Discharge Survey; and CMS's Hospital Inpatient Quality Reporting program, specifically the Surgical Care Improvement Project (SCIP) data reported at the Hospital Compare Web site,¹⁶ the Medicaid Analytic eXtract, the Medicare Patient Safety Monitoring System, and the Medicare Provider and Analysis Review.

¹⁶ <http://www.medicare.gov/hospitalcompare/>

The data inventory was designed to (1) profile currently available HHS data systems capable of detecting HAIs, (2) support integration and interoperability projects, (3) support analysis of the strengths and weaknesses of data systems, and (4) reveal gaps in surveillance. Findings from the data inventory helped to clarify the extent of definitional alignment and standardization of data elements among the federal HAI data systems inventoried: substantial differences were found across systems. However, these systems currently serve a variety of analytic purposes and provide data with which to measure a diverse set of HAI and prevention practice metrics.

The 2010 report emphasized fundamental differences between systems that use clinical records for HAI case finding and reporting and systems that use administrative records for the same purposes. Case criteria and data requirements developed for use with clinical data sources reflect the level of detail that is available in entire health care records, whereas criteria and requirements for use with administrative data sources reflect the narrower range of data available in coded summaries of clinical encounters. As a result, the 2010 analysis serves as a reminder that differences between administrative and non-administrative data sources are likely to preclude successful integration between systems that diverge so fundamentally in the records and methods used to identify and report HAI cases. Combining HAI incidence data collected and reported by hospital infection preventionists who use clinical records with HAI incidence data collected from coded hospital discharge records would have limited value because of the fundamental differences in the two approaches to HAI monitoring.

VI. INTEGRATING SOURCES OF DATA

The PSWG provides a forum for deliberations and decisions about which near-term data integration activities are of the highest priority and what are the best processes for accomplishing shared objectives. These decisions should be guided by the understanding of the original business purposes of the data or data groupings and the metadata information available from the data inventory and other sources of information about HAI data systems. Caution should be applied when repurposing data while also focusing attention on filling the most important gaps in HAI data coverage.

An organized, sustained, and well-coordinated effort will be needed by AHRQ, CDC, CMS, ONC, and other federal agencies to continue and extend the work that has begun on the integration of patient safety systems. New opportunities are rapidly emerging to apply new societal investments in systems and new capacity for providing clinical decision support for HAI reporting and prevention. This work should be guided and informed by the FHISE and NWHIN and should take full advantage of the health care technology and data standards that are entering the mainstream of electronic clinical record keeping and reporting.

Using these standards and interoperability specifications to develop, enhance, or modify federal systems enables data integration and should connect federal systems to the standards-based EHRs that are rapidly emerging. Thorough and ongoing use of standards-based solutions should be developed to reduce or obviate altogether the need for abstracting clinical observations from health care records in order to report HAI data to federal agencies. Ideally, clinical data entries describing HAIs will automatically populate HAI reports generated from EHRs.

While this scenario of electronic HAI reporting remains visionary, HHS and other federal agencies are well positioned strategically to help catalyze and coordinate the technical advances needed to make this vision a reality.

VII. CHALLENGES AND OPPORTUNITIES

The PSWG and interagency collaborations face many challenges in their concerted efforts to create a successful environment for the sharing of HAI information among federal agencies.

HAI data owners from a variety of sectors (including state, local, and private) should consider investing in the development and deployment of a common reporting format as well as in the infrastructure needed to share the information nationally. All of these data owners should work within the available processes of existing workgroups, committees, and organizations, e.g., the HIT Standards Committee and the Health IT Policy Council. Minimizing the burden on health care facilities of HAI data reporting is a priority, as is close collaboration with accrediting organizations and health care professional organizations. Duplication and other issues of data quality must be minimized or eliminated altogether when data are aggregated at the national level. Finally, aggregating data from multiple sources will require continued and ongoing agreement on common semantics for the data.

HAI solutions must be driven by requirements. By continuing to focus on the data required for specific uses and user groups, decisions about information systems and technology will be guided by end results rather than tools and processes. Usage scenarios must be documented and updated to assure that specific requirements are met for HAI data. It is anticipated that informatics solutions will continue to be developed in iterative phases. The integration of data from disparate sources might initially target the simple collation of data, in which reports would be retrieved from existing HAI databases “as is” and made available through a shared repository.

A subsequent aggregation phase should involve maintaining and developing common definitions and formats that all HAI databases would use to generate electronic information feeds to the information-sharing environment. An HAI database of the future could be built and maintained using a data model that is harmonized with clinical and administrative domains and maintains strong linkages to HAI data of interest that are captured by various health care systems of origin.

This HAI database of the future should contain metadata and support a standard metadata registry, and it should also support a knowledge base to be used for developing training, guidance, and adjustments to public health policies with respect to prevention of infections. This future database would ideally capitalize on interoperability between federal systems that would enable aggregation and reuse of data from disparate systems, each of which would serve a distinct, primary function as well as a secondary purpose in which data would be reported to a central system.

The Information Systems and Technology Working Group had the opportunity to convene national, state, and local stakeholders at the 2012 HAI Data Summit held in Kansas City, Missouri, to review existing data sources and make recommendations to add efficiencies and enhance the value of the supply chain of HAI data. Topics discussed included the more efficient use of CDC's NHSN and the issue of which elements within NHSN needed to be improved or updated in order for states to share information within the state and up the supply chain to others; consistency in HAI data aggregation, analysis, and reporting; and the importance of data validation and the need for credible and reliable data as we move into an era of increased visibility, transparency, and accountability. Additional information about the 2012 HAI Data Summit is available at the [HHS HAI Initiative page](#).

VIII. CONCLUSION

A well-organized and effective interagency working group, such as the PSWG, that is informed in its deliberations and decision making by a systematic inventory of HAI data and databases and a common information model, can continue the fact finding and analytic work needed to refine plans and define resource requirements for integration of HAI data across existing federal systems. The highest priority should be given to near- and long-term integration projects that will yield new capacity to measure national-level progress in HAI prevention.

HHS is strategically positioned to catalyze multiagency integration efforts and foster close collaboration with other public entities and private sector organizations that have a stake in HAI data or that have lead roles in setting standards for health care data and IT. To the fullest extent possible, efforts to enhance return on investment in federal sources of HAI data should be aligned with the NwHIN and FHISE initiatives. Integrating data from HAI database sources at multiple agencies will require sustained commitment and careful project planning and execution. Successful project outcomes can establish new programmatic collaborations across federal agencies and yield benefits for analysis and action in a broad-based national effort to prevent HAIs.

CHAPTER 3: INCENTIVES AND OVERSIGHT

I. INTRODUCTION

The U.S. Department of Health & Human Services (HHS), specifically the Centers for Medicare & Medicaid Services (CMS), has a variety of tools within its statutory and regulatory authority to support the prevention of health care-associated infections (HAIs). These tools can be broadly classified as regulatory oversight, financial incentives, transparency and associated incentives, or some combination thereof. CMS also has a number of initiatives within each of these broad categories to combat HAIs.

This chapter discusses in detail the various ways in which these tools and initiatives have been used to support the nation's efforts to prevent infections. Section II describes regulatory oversight activities, including conditions of participation, accreditation, and survey and certification. Section III discusses value-based purchasing (VBP) programs and other financial incentives that encourage health care providers in various care delivery settings to report and reduce HAIs. Section IV focuses on transparency and associated incentives, such as Hospital Compare. Section V describes initiatives implemented by CMS, the Centers for Disease Control and Prevention (CDC), state health agencies, and private organizations to prevent and reduce HAIs.

II. REGULATORY OVERSIGHT

A. Introduction

The Conditions of Participation (CoPs) and the Conditions for Coverage (CfCs) are the federal health and safety requirements that hospitals and other providers and suppliers must meet to participate in the Medicare and Medicaid programs. The CoPs/CfCs are intended to ensure that high-quality care is provided to all patients. Compliance with the CoPs/CfCs is determined by State Survey Agencies (SSAs) and by national Accreditation Organizations (AOs). While hospitals are surveyed by SSAs to assess compliance with the CoPs, they are also deemed to have met the requirements in the CoPs if they are accredited by national AOs with accreditation programs approved by CMS. All Medicare- and Medicaid-participating hospitals are required to be in compliance with CMS's CoPs regardless of whether compliance is determined through accreditation or survey.

B. Hospital Conditions of Participation

The Medicare hospital CoPs are the health and safety standards required for the protection of all hospital patients. Revisions to the CoPs require an extensive and, at times, lengthy rulemaking process by CMS that reflects the ever-evolving nature of medicine and patient care, and any revisions must leave a certain degree of latitude to allow for innovations in health care practice that improve the quality of care and move toward the reduction of medical errors and harm to patients. These innovations in patient care, if supported by well-documented research evidence,

most often lead to the issuance of guidelines and recommendations, sometimes referred to as “best practices.” These guidelines and recommendations are issued by federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ), CDC, and the Occupational Safety and Health Administration (OSHA) within the Department of Labor, as well as by nationally recognized organizations. Historically, these federal and private entities have been able to update and disseminate these best practices more quickly than CMS has been able to revise the Medicare health and safety standards through the regulatory rulemaking process.

The hospital Infection Control CoP (42 C.F.R. § 482.42) directly addresses the reduction of HAIs, but the infection control requirements in the CoPs are best understood as a structural framework for hospitals, given the frequently slow process of revision. Thus, the CoP requirements for organizational roles and hospital policies should be used by health systems to integrate nationally recognized infection control standards and best practices into their individual infection control programs and to change their policies and procedures if, and when, the guidelines change.

Additionally, the CMS survey and certification interpretive guidelines for the Infection Control CoP provide a vehicle for a more specific discussion of best practices in infection control for hospitals. The current Infection Control interpretive guidelines contain references to the recommendations of organizations such as CDC, OSHA, the Association for Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, and the Association of periOperative Registered Nurses. The guidelines specifically address special challenges to a hospital’s infection control program, including multidrug-resistant organisms (MDROs), outbreaks of communicable disease, and bioterrorism, and directly refer to current and nationally accepted sources of information for hospitals on these challenges.

The current Infection Control CoP, however, does not specifically address an important concept in infection control and prevention: antimicrobial stewardship. Antimicrobial stewardship, as an area of infection control and prevention, has long been recognized as one of the special challenges that hospitals must meet. During the last several decades, the prevalence of MDROs in hospitals has increased steadily; MDROs are microorganisms that are resistant to one or more antimicrobial agents. Options for treating patients with MDRO infections are very limited, resulting in increased mortality as well as increased hospital length of stay and costs.

C. Accreditation

As mentioned earlier in this chapter, accreditation by a CMS-approved national AO can substitute for a state review by a SSA. If a provider or supplier entity is accredited by an approved AO, CMS may “deem” those entities as having met the Medicare requirements. Accreditation by an AO is voluntary, however, and is not required for Medicare participation. The option to use private accreditation for ensuring provider compliance with Medicare requirements has existed in statute since 1965. A national AO applying for approval of its accreditation program must provide CMS with reasonable assurance that the AO requires accredited health care facilities to meet standards that are at least as stringent as the applicable Medicare CoPs. There are currently seven national AOs that have approval to conduct 15 separate Medicare accreditation programs for hospitals, critical-access hospitals, ambulatory

surgical centers, home health agencies, and hospices. New applications are under review for other types of facilities, including psychiatric hospitals.

D. Survey and Certification

The survey and certification program of CMS is designed to ensure that providers and institutional suppliers comply with the applicable health and safety standards, i.e., CoPs for providers or CfCs for suppliers. Currently, the CMS Survey & Certification Group oversees compliance with these Medicare health and safety standards for more than 271,000 health care facilities of different types, including hospitals, laboratories, nursing homes, home health agencies, hospices, and end-stage renal disease (ESRD) facilities. CMS works with the SSAs and, for certain types of facilities, with approved Medicare accreditation programs of private national AOs to conduct on-site facility inspections for health care facilities that seek Medicare participation. Only certified providers, medical professionals, institutional suppliers, and laboratories are eligible for Medicare payments. In the case of hospitals, Medicaid payments are available only to those hospitals that satisfy the Medicare CoPs. There are approximately 7,200 active SSA surveyors nationwide (about 6,500 full-time equivalents), with roughly 500 dedicated to hospital surveys, and there are three approved private Medicare hospital accreditation programs that are responsible for inspecting over 3,600 of the almost 4,900 hospitals that participate in Medicare.

On November 21, 2007, CMS published a comprehensive update of its interpretive guidelines for the hospital Infection Control CoP. This revision to the hospital interpretive guidelines was made to reflect changing infectious and communicable disease threats as well as current and nationally recognized infection control standards of practice. When deficient practices, such as deficient infection control practices, are identified through a hospital survey by a SSA, the information is captured in a database. Between fiscal year (FY) 2007 and FY 2010, an infection control deficiency was cited in 1.7% to 2.3% of standard hospital surveys conducted by the SSAs and in 0.9% to 1.3% of surveys initiated by a complaint. The database has several deficiency identifiers, or tags, related to various parts of the infection control regulation. With the use of specific tag identifiers for the deficient practice(s), CMS can later analyze the findings for greater insight into problem areas. For example, CMS is able to analyze the hospital deficiency citations for infection control to specifically capture whether the hospital is compliant with having the required designated infection control officer. Typically, hospital complaints have comprised the second-highest volume of complaints received by CMS among all Medicare-certified facility types. When the top allegations for complaints are examined, infection control issues are consistently in the top 12 items.

E. Recommendation and Action Plan for Regulatory Oversight

Consider Proposing Revisions to the Infection Control Condition of Participation (CoP) That Would Address Antimicrobial Stewardship

Effective hospital antimicrobial stewardship programs have mechanisms in place for the early identification of patients with targeted MDROs prevalent in their individual hospital and community, and for the prevention of transmission of such MDROs. When ongoing

transmission of targeted MDROs in the hospital is identified, the infection control and prevention program should use this event to identify potential breaches in infection control practice. CMS should consider whether revisions to the Infection Control CoP would be the best means to encourage hospitals to develop antimicrobial stewardship programs that would improve their internal coordination among all components responsible for the use of antimicrobials. If such revisions to the hospital infection Control CoP are proposed and finalized, CMS should then explore ways of possibly extending antimicrobial stewardship requirements to other appropriate categories of health care facilities as a means of reducing the overall incidence of antimicrobial resistance throughout the nation's health care system.

Updating Guidance

The Medicare hospital Infection Control CoP was first published over 20 years ago. Since then, infections such as the human immunodeficiency virus, severe acute respiratory syndrome, West Nile virus, avian influenza, and methicillin-resistant *Staphylococcus aureus* (MRSA), just to name a few, have emerged and been quickly followed by the development of infection control guidelines that tend to be specific to each emerging infection. Federal agencies and nationally recognized organizations have typically revised these guidelines as needed to keep pace with new developments in providing safe, quality health care and as a way to help hospitals continue to track, monitor, and prevent such diseases.

As new sources of infection and communicable disease present additional challenges to patient care, and as new guidelines are developed to address these challenges and become the standard of practice, Medicare guidance on infection control is modified to reflect these changes. Currently, the Infection Control interpretive guidelines make direct reference to the evidence-based infection control standards of practice established through nationally recognized expert organizations, including CDC. Through annual training, reinforcement of revisions of hospital interpretative guidelines is communicated to approximately one-third of all SSA hospital surveyors each year.

Improve the Quality and Consistency of Surveys Assessing Hospital Infection Control Practices

CMS and selected experts have identified a number of enhancements for regulatory oversight of hospitals as recommendations:

- Incorporate enhancements into the surveyor training program as a means of providing surveyors with illustrative examples of best infection control practices in hospitals.
- Introduce a new infection control surveyor tool to assess the Infection Control CoP.
- Require AOs to also make assessment of infection control a priority focus and to either use the new infection control surveyor tool or develop an equivalent survey process that achieves the same results.

III. VALUE-BASED PURCHASING FINANCIAL INCENTIVES

A. Introduction

CMS is applying the tools within its statutory authority to enhance the quality and efficiency of services provided to Medicare beneficiaries through VBP and related initiatives. These tools include measurement and payment incentives to encourage beneficial interventions and outcomes to improve performance. Using these resources, CMS is working to transform Medicare from a passive payer to an active purchaser of higher-value health care services.

The Preventable Hospital-acquired Conditions (HAC) provision, including the Present on Admission (POA) Indicator Reporting and Hospital Pay-for-Reporting, are hospital-related initiatives that CMS is using to promote increased quality and efficiency of care. In addition, CMS is studying the application of measurement and payment incentives to hospitals through various demonstration projects. CMS has presented an approach to transition from pay-for-reporting to performance-based payment in the Hospital VBP Plan Report to Congress, and the agency has begun the Hospital VBP Program. Finally, CMS has implemented pay-for-reporting that targets physicians and post-acute care settings. Each of these initiatives is discussed below.

B. Hospital-Acquired Conditions (HACs) and Present on Admission (POA) Indicator Reporting

Inpatient Prospective Payment System Incentives

Under Medicare's Inpatient Prospective Payment System (IPPS), hospitals are encouraged to treat inpatients efficiently because they receive a payment based on the patient's Medicare Severity Diagnosis Related Group (MS-DRG), which is based, in part, on the patient's diagnosis and severity of illness. These prospectively determined payment amounts give hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, however, conditions acquired in the hospital, including infections, do not generate higher payments than the hospitals would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications, including infections.

However, complications acquired in the hospital can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may generate an outlier payment. Because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS-DRG classification that took effect for hospital payment in FY 2008, certain conditions can generate higher payments. There are currently 259 sets of MS-DRGs that further divide into two or three subgroups based on the presence or absence of a complicating condition (CC) or major complicating condition (MCC). The presence of a CC or MCC generally results in higher payment.¹⁷

¹⁷ For a detailed discussion of the Inpatient Prospective Payment System Final Rule, please refer to the Fiscal Year 2011 Hospital Inpatient Prospective Payment Rule in the Federal Register, August 16, 2010, pp. 50081, 50092-50094 (<http://www.federalregister.gov/articles/2010/08/16/2010-19092/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>).

The HAC provision is one statutory provision that CMS is using to combat certain health care-associated complications, including infections, in the hospital setting. The Medicare statute requires CMS and the Secretary of HHS, in consultation with CDC, to select at least two conditions that will no longer trigger higher payment when they are acquired during hospitalization. The selected conditions must be: (1) high cost, high volume, or both; (2) assigned to a higher-paying MS-DRG when present as a secondary diagnosis; and (3) a condition that could reasonably have been prevented through the application of evidence-based guidelines.

To identify whether a condition would have been present on admission and thus potentially result in a payment adjustment for a specific claim, CMS decided to require hospitals to submit a “present on admission” (POA) indicator on claims to determine whether diagnoses were present on admission or acquired during hospitalization. On October 1, 2007, CMS began requiring hospitals to submit this information on Medicare claims. The POA indicator is necessary to identify which conditions are acquired during the hospital stay for payment purposes, and this information is also potentially valuable for the broader public health uses of Medicare data.

As of October 1, 2008, Medicare has not been able to assign an inpatient hospital discharge to a higher-paying MS-DRG if a “selected condition” is listed on the claim, was not present on admission, and is the only reason why a discharge would be assigned to the higher-paying MS-DRG. That is, the case will be paid as though the condition was not present. Medicare will continue to assign a discharge to a higher-paying MS-DRG if the “selected condition” is present on admission.

The table below demonstrates how payments are made based on the MS-DRG assignment and the POA status of a single secondary diagnosis under the HAC policy.

Table 6. Payments Based on Medicare Severity Diagnosis Related Group Assignment and Present on Admission Status

Medicare Severity Diagnosis Related Group Assignment (Examples for a single secondary diagnosis)	Present on Admission Status of Secondary Diagnosis	Average Payment
Principal diagnosis: Medicare Severity Diagnosis Related Group 066 <ul style="list-style-type: none"> ■ Stroke without CC/MCC 	--	\$5,347.98
Principal diagnosis: Medicare Severity Diagnosis Related Group 065 <ul style="list-style-type: none"> ■ Stroke with CC example Secondary diagnosis: ■ Injury due to a fall (code 836.4 (CC)) 	Y	\$6,177.43
Principal Diagnosis: Medicare Severity Diagnosis Related Group 066 <ul style="list-style-type: none"> ■ Stroke with CC example Secondary diagnosis: ■ Injury due to a fall (code 836.4 (CC)) 	N	\$5,347.98
Principal diagnosis: Medicare Severity Diagnosis Related Group 064 <ul style="list-style-type: none"> ■ Stroke with MCC example Secondary diagnosis: ■ Stage III pressure ulcer (code 707.23 (MCC)) 	Y	\$8,030.28
Principal Diagnosis: Medicare Severity Diagnosis Related Group 066 <ul style="list-style-type: none"> ■ Stroke with MCC example Secondary diagnosis: ■ Stage III pressure ulcer (code 707.23 [MCC]) 	N	\$5,347.98

Table 6 illustrates the different MS-DRG payments that result when selected HACs are present on the claim. These scenarios are for a single secondary diagnosis only, which is atypical for a hospitalized Medicare beneficiary. The presence of at least one non-HAC CC/MCC on the claim will continue to trigger the higher-paying MS-DRG.

Collaboration and Public Input in the Selection of Hospital-Acquired Conditions

CMS clinical quality experts have worked closely with public health and infectious disease experts from CDC to identify candidate preventable HACs, review comments, and select HACs. CMS and CDC staff also collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on inpatient Medicare claims and on defining the payment implications of the various POA reporting options.

On December 17, 2007, CMS and CDC hosted a jointly sponsored HAC and POA Listening Session to seek individual input from the over 500 organizations and individuals that participated. CMS and CDC received verbal comments during the session and subsequently received numerous written comments. CMS and CDC jointly sponsored a second POA Listening Session in December 2008. CMS has also sought public comment during FY 2007, FY 2008, FY 2009, FY 2010, FY 2011, and FY 2012 IPPS rulemaking. CMS noted that it will be considering additional HAC candidates, including additional infectious conditions, in future rulemaking. CMS expects to continue its collaboration with CDC, other federal health agencies, and stakeholders in the refinement and expansion of the payment provision.

Selection Criteria for Hospital-Acquired Conditions (HACs)

In selecting proposed candidate conditions and in finalizing conditions as HACs, CMS and CDC staff evaluated each condition against the statutory criteria. These criteria limit which conditions can be selected for the HAC payment provision. The first criterion requires that a selected condition is high cost, high volume, or both. The second criterion requires that a selected condition trigger a higher Medicare payment. To do so, a condition must be represented by an ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) diagnosis code that clearly identifies that condition, is designated as a complicating condition (CC) or a major complicating condition (MCC), and results in the assignment of the case to a higher-paying MS-DRG when the code is reported as a secondary diagnosis. That is, a selected condition must be a CC or MCC diagnosis code that would, in the absence of the HAC payment provision, result in the assignment of the case to a higher-paying MS-DRG.

The third criterion requires that a selected condition be considered reasonably preventable through the application of evidence-based guidelines. Guidelines developed by entities such as the Healthcare Infection Control Practices Advisory Committee (HICPAC), professional organizations, and academic institutions were reviewed to evaluate whether guidelines were available that hospitals should follow to prevent certain conditions from occurring in hospitals. The absence of prevention guidelines for many potential candidate conditions, including certain infectious conditions, limits the universe of candidate conditions.

Selected Hospital-Acquired Conditions (HACs) for 2012

Each year since FY 2007, after evaluating proposed candidate conditions against the statutory criteria and considering public comments received during IPPS rulemaking, CMS has finalized categories of conditions to which the HAC payment provision applies. Currently, there are 10 categories of HACs, as described in the list below.

Hospital-Acquired Conditions – The Ten Categories

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Pressure Ulcer Stages III & IV
5. Falls and Trauma:
 - Fracture
 - Dislocation
 - Intracranial Injury
 - Crushing Injury
 - Burn
 - Other Injuries
6. Catheter-Associated Urinary Tract Infection
7. Vascular Catheter-Associated Infection
8. Manifestations of Poor Glycemic Control

- 9a. Surgical Site Infection, Mediastinitis Following Coronary Artery Bypass Graft
 - 9b. Surgical Site Infection Following Certain Orthopedic Procedures
 - 9c. Surgical Site Infection Following Bariatric Surgery for Obesity
 - 9d. Surgical Site Infection Following Cardiac Implantable Electronic Device
 10. Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures
-

Evaluation of Present on Admission (POA) Indicator Reporting

To determine the effectiveness of the HAC program, including POA indicator reporting, on quality of care, CMS is undergoing an independent evaluation that includes the components described below.

Tabulation of Claims

The evaluation includes a tabulation of the reporting of HACs and their POA indicator status from hospital claims. This information was published in the FY 2012 IPPS Proposed and Final Rules with links to additional information. The tabulations revealed that many HACs are relatively rare events and that, for most hospital stays, HACs are reported as POA.

Evidence-based Guidelines for Preventing HACs

The Medicare statute requires that selected HACs be reasonably preventable through the application of evidence-based guidelines (EBGs). An evaluation report identified current EBGs for the 10 selected HACs, one candidate HAC, and seven previously considered candidate HACs. The report will be updated annually.

State Tracking of HACs

The report provides a comprehensive review of the status of tracking HACs by state governments. There are no federal standards for state reporting systems and no uniform list of reportable events or HACs. This report will be updated annually.

Incremental Cost of HACs

Preventable conditions and infections that are hospital-acquired create a significant financial burden for both the Medicare program and Medicare beneficiaries. In FY 2009, CMS spent an additional \$135 million for Part A services on the selected HACs across the episode of care. Among the previously considered candidate HACs, the estimated Part A incremental cost to CMS was \$510 million in FY 2009. For beneficiaries, the Part A incremental cost of the selected HACs was \$17 million across the episode of care and the additional cost of the candidate HACs was about \$63 million.

Future Research

FY 2011 was the second year of the evaluation. In FY 2012, research focused on several areas: determining the accuracy of the POA codes on hospital claims; estimating the readmission rates resulting from HACs; estimating the incremental cost of HACs on Medicare reimbursements and on Medicare beneficiaries, including Part B costs; and

determining whether there are unintended consequences of HACs and what the spillover effects of the Medicare HAC program are on other health care payers.

Enhancements and Future Issues

Each year, through IPPS rulemaking, CMS has the opportunity to consider refinements to the HAC list and potential candidate conditions. This might include the consideration of additional categories of conditions, expansion of existing categories, and reconsideration of conditions that had previously been proposed but not selected. For example, the implementation of ICD-10 (International Statistical Classification of Diseases and Related Health Problems, Tenth Revision) in FY 2014 will provide more specific coding information that would facilitate more precise identification of HACs. Additionally, stakeholders have suggested that waterborne pathogens be considered, that the surgical site infection (SSI) category be expanded, and that ventilator-associated pneumonia (VAP) and *S. aureus* septicemia be reconsidered. The ability to select additional conditions will depend on the development of EBGs such that when those guidelines are followed, the conditions can be considered reasonably preventable. In addition, having the POA indicator as a part of the Medicare claims data will help facilitate identification of additional candidate HACs.

Consumer groups and the media have suggested that infections caused by MRSA and *Clostridium difficile* be selected as HACs for the payment provision. Importantly, these infectious agents are directly addressed in part by the infectious conditions currently selected as HACs. For example, MRSA could be the etiologic agent for a vascular catheter-associated infection (VCAI). However, the current coding for MRSA and *C. difficile* does not differentiate colonization from infection. As the diagnosis coding is refined, the ability to differentiate community from hospital-acquired infections improves, and EBGs for the prevention of infectious agents are defined and enhanced. Accordingly, these infectious agents may be reconsidered as candidates for the HAC payment provision in future rounds of rulemaking.

Beginning in FY 2015, under changes to the Social Security Act made by Section 3008 of the Affordable Care Act, CMS will reduce payment for discharges from hospitals that have risk-adjusted HAC rates in the top quartile of applicable hospitals. In addition, the Affordable Care Act requires the Secretary of HHS to undertake a study and a Report to Congress on extending the HAC-payment policy to other types of providers. The Report to Congress was due during 2012. It would include recommendations for such legislation and administrative action as the Secretary determines are appropriate.

Collection of the POA indicator could provide important information, not only for Medicare payment but also for enhancing public health. Researchers could use POA data from Medicare hospital claims independently or merge it with data from other states or the private sector to explore policy initiatives and refinements, such as for risk adjustment of quality measurement data, tracking the incidence of conditions in the community and in hospitals, or supporting better health care decision making by consumers and professionals.

C. Hospital Pay-for-Reporting

Hospital pay-for-reporting is another approach that CMS has adopted to achieve high quality and more efficient health care. This initiative is designed to equip consumers with quality-of-care information to make more informed decisions about their health care while encouraging hospitals and clinicians to improve the quality of inpatient care. In December 2002, the Secretary of HHS announced a partnership with several collaborators to promote hospital quality improvement (QI) and public reporting of hospital quality information. These collaborators included the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, The Joint Commission, the National Quality Forum (NQF), the American Medical Association, the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons, the American Federation of Labor-Congress of Industrial Organizations, and AHRQ as well as CMS and others.

Initially, subsection (d) hospitals were incentivized to submit data on a starter set of 10 quality measures. Hospitals that did not submit data received a reduction of 0.4 percentage points to their annual payment update (also known at the time as the market basket update) for each of FYs 2005 through 2007. The reduction to the annual payment update has subsequently increased from 0.4 to 2.0 percentage points for FY 2007 through 2014. Beginning in FY 2015, the payment reduction becomes one-quarter of the applicable percentage increase for the fiscal year. For FY 2008, CMS required that hospitals submit data on 27 quality measures, including a number of infection-related measures and encompassing the following conditions or variables: acute myocardial infarction, heart failure, pneumonia, surgical care improvement, 30-day mortality rates for acute myocardial infarction and heart failure patients, and patients' experience of care through the Hospital Consumer Assessment of Health Providers and Systems patient survey.

For FY 2009, CMS finalized a total of 29 quality measures, including (1) two new Surgical Care Improvement Project (SCIP) process-of-care measures, and (2) a new outcome-of-care measure, the 30-day mortality rate for pneumonia patients.

For FY 2010, CMS finalized a total of 43 quality measures, including (1) nine AHRQ Patient Safety Indicators and Inpatient Quality Indicators that have been endorsed by NQF; (2) a NQF-endorsed structural measure, participation in a systematic database for cardiac surgery; and (3) three NQF-endorsed readmission measures related to heart failure, pneumonia, and acute myocardial infarction.

For FY 2011, CMS finalized a total of 45 measures, including two new chart-abstracted SCIP measures.

The two new SCIP measures are as follows:

- Postoperative urinary catheter removal on postoperative day 1 or 2.
- Perioperative temperature management.

For FY 2012, CMS is collecting a total of 55 quality measures, including the eight HAC measures, the seven CMS-calculated AHRQ indicators that have been endorsed by the NQF.

The HAC measures related to HAIs include catheter-associated urinary tract infection (CAUTI) and VCAI.

CMS publicly reports on Hospital Compare certain data reported to the National Healthcare Safety Network (NHSN) on quality measures adopted for the Hospital Inpatient Quality Reporting (IQR) Program. Beginning with January 2011 discharges, CMS began requiring hospitals participating in the Hospital IQR Program to report CLABSI measure to NHSN. Beginning with January 2012 discharges, CMS began requiring hospitals participating in the Hospital IQR Program to report SSI and CAUTI data to NHSN.

CMS is also requiring that hospitals use NHSN infrastructure and protocols to report certain Hospital IQR Program measures to NHSN. This information is available at http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf.

In 2013, CMS will begin collecting data on MRSA bacteremia, *C. difficile* infection, and the vaccination of health care personnel against influenza. The data will not be used for purposes of determining whether a hospital met the Hospital IQR reporting requirements until FY 2015.

D. CMS Demonstration Projects

Medicare has a long and successful history of developing program initiatives through its demonstrations. At any given time, CMS has over two dozen demonstrations in its portfolio. The implementation of these demonstrations has frequently provided the agency with practical lessons on policy tradeoffs and objectives, details related to operations of a specific pilot program, and unanticipated issues related to recruiting and engaging demonstration participants. In addition, formal evaluations play a critical part of any demonstration. CMS generally contracts with outside researchers to conduct independent evaluations of each demonstration project. Evaluations are carefully developed, often using randomly assigned control groups and other sophisticated evaluation techniques, to report the results of the demonstrations to CMS and other executive branch leadership, Congress, and the public.

Several demonstration projects conducted by CMS are testing methods to improve the quality of health care. One of the most important is the Premier Hospital Quality Incentive Demonstration, with about 250 hospitals in 38 states in collaboration with Premier, Inc., an alliance that operates a large quality measurement and improvement operation. This demonstration ran from October 2003 through September 2009. The demonstration measured and provided bonus incentives for improving quality of care in five clinical areas, acute myocardial infarction, pneumonia, heart failure, coronary artery bypass graft, and hip and knee replacement, and in SCIP measures. During the six years of operations, the demonstration hospitals improved their quality of care in these six areas by 18.6%, on average.

CMS extended the demonstration for a second three-year period, which ended in September 2009. New quality measures, including all of the SCIP measures, had been added for testing.

The SCIP measures are also included in two related demonstrations, the Medicare Gainsharing Demonstration and the Physician Hospital Collaboration Demonstration. These two

demonstrations were designed to study whether incentives for collaborative arrangements between hospitals and physicians can improve the quality and efficiency of care provided to Medicare beneficiaries. These SCIP measures include the use of prophylactic antibiotics before surgical incisions, the proper selection of antibiotics, proper surgical preparation to avoid infections, and discontinuation of the antibiotics on schedule to reduce antibiotic-resistant bacteria strains. CMS tracks quality of care among participating hospitals to ensure that the demonstration results in improved quality of care.

The SCIP measures are also included in the Acute Care Episode Demonstration to improve inpatient quality of care. Medicare pays up to 15 hospitals in Texas, Oklahoma, Colorado, and New Mexico a “global fee” for selected cardiac and orthopedic procedures. The global fee is a bundled payment for both hospital and physician costs, including the surgeon, consulting physicians or specialists, radiologists, anesthesiologists, and other physicians included in the care of the patient. Participating hospitals and physicians are permitted to use gain-sharing to improve incentives for collaboration. This demonstration is intended to improve internal hospital cost efficiency and quality of care, reduce costs for Medicare, and improve the transparency of information for beneficiaries. Quality will be measured through a series of reported process and outcome measures, including several that focus on surgical infections, such as the selection and administration of antibiotics and the deep sternal wound infection rate.

In all four Medicare demonstrations described above, CMS measures quality of care using available quality measures that will be monitored regularly to track progress toward improving quality. The measurement and evaluation of hospital-acquired infections are an important part of these evaluations, and the Medicare demonstrations program will continue to include hospital-acquired infection measures as they are developed, standardized, available, and made appropriate for use in future demonstration projects.

E. Hospital Value-Based Purchasing Plan Report to Congress

With the 2010 passage of the Affordable Care Act, CMS was able to launch the Hospital VBP program to link hospital payment under the IPPS to hospital performance measures. Section 3001 of the Affordable Care Act authorizes the establishment of a hospital VBP payment program for subsection (d) hospitals under which payments will first be applied beginning with October 1, 2012 discharges.

CMS developed a plan to implement Medicare Hospital VBP in 2006 and 2007. On November 21, 2007, CMS submitted a *Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program* (the Plan).¹⁸ The Plan was built on the current Hospital IQR Program discussed above and establishes a performance-based Medicare IPPS hospital payment adjustment. Under the plan, a portion of the hospital base operating DRG payment would be contingent on actual performance rather than simply on a hospital’s reporting of measurement data.

¹⁸ U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services. Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program. November 21, 2007. Available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf>

Hospital Value-Based Purchasing and the Affordable Care Act

Starting with the FY 2013 Medicare payment determination, hospital performance on measures covering at least five areas (acute myocardial infarction, heart failure, pneumonia, SCIP, and the Hospital Consumer Assessment of Health Providers and Systems Survey) will be used to make payment adjustments under the IPPS to subsection (d) hospitals. Hospital VBP measures must be included in the Hospital IQR Program and publicly reported on Hospital Compare for at least one year prior to the performance period for a given fiscal year VBP payment determination. CMS finalized the initial set of measures, performance periods, and other program requirements for the FY 2013 Hospital VBP Program through rulemaking in the spring of 2011.

Under the Hospital Value-Based Purchasing (VBP) Program, participating hospitals are scored based on the higher of their demonstrated improvement or level of achievement. The Affordable Care Act also mandated a five-year phased approach to link payment to quality under the Hospital VBP Program by increasing the percentage of the base operating Diagnosis Related Group payment at risk from 1% in FY 2013 to 2% by FY 2017. Under Hospital VBP, payments made to high-performing hospitals will generally be larger than those made to lower-performing hospitals. The Hospital VBP Program provides financial incentives to drive improvements in clinical quality, patient-centeredness, and efficiency.

CMS expects that by implementing the Hospital VBP Program, both the measures used to calculate financial incentives for this program and the use of public reporting will continue to evolve. The agency is considering whether to propose for adoption by the program a domain of measurement related to patient safety, which is likely to be expanded over time, to include measures addressing the priority infections previously identified in the 2009 HAI Action Plan. CMS expects to add measures that link higher quality and lower cost to payment, and it intends to focus on patient health outcomes, cost reduction, and HAI measures with significant impact on Medicare beneficiaries and substantial variation among hospitals. The agency added the CLABSI measure to the Hospital VBP program starting with 2015 payment, and it is considering additional outcomes-based HAI measures reported through NSHN as they are adopted for the Hospital IQR Program.

F. Hospital Readmission Reduction Program

In its June 2007 Report to Congress, the Medicare Payment Advisory Commission identified seven conditions or procedures that made up almost 30% of Medicare spending on readmissions. The seven were heart failure, chronic obstructive pulmonary disease, pneumonia, acute myocardial infarction, coronary artery bypass graft surgery, percutaneous transluminal coronary angioplasty, and other vascular conditions. To meet the requirements of the 2005 Deficit Reduction Act related to the Hospital IQR Program, CMS developed readmission measures for four of the seven conditions identified by the Medicare Payment Advisory Commission, including: acute myocardial infarction, heart failure, pneumonia, and percutaneous transluminal coronary angioplasty. Currently, CMS is actively working to develop readmission measures to address the other conditions identified by the Medicare Payment Advisory Commission.

The Hospital Readmissions Reduction Program was established by Section 3025(a) of the Affordable Care Act of 2010 to reduce payment to hospitals, beginning in FY 2013, that have excess readmissions based on the readmission measures endorsed by the National Quality Forum. Currently, these readmission measures pertain to acute myocardial infarction, heart failure, and pneumonia. Under the Hospital Readmissions Reduction Program, the Secretary of HHS shall, to the extent practicable, expand the conditions of readmission measures subject to this payment adjustment beginning FY 2015, as noted below:

“(B) EXPANSION OF APPLICABLE CONDITIONS – Beginning with fiscal year 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in ... to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary ...” Affordable Care Act Sec. 3025(a), adding new Sec. 1886(q)(5)(B) to the Social Security Act.

The Affordable Care Act prescribes a formula for determining the payment reduction, scheduled to begin in FY 2013. The Affordable Care Act limits the reduction to 1% in FY 2013, 2% in FY 2014, and 3% in FY 2015 and subsequent years. Certain adjustments within the Medicare IPPS, such as adjustments for outliers, indirect medical education, disproportionate-share hospital, and low volume, are not taken into account when determining the payment adjustment.

G. Physician Quality Reporting System

The Tax Relief and Health Care Act of 2006 required the establishment of a physician quality reporting system, including an incentive payment for eligible professionals who satisfactorily reported data on quality measures for covered professional services furnished to Medicare beneficiaries during the second half of 2007. CMS initially named this program the Physician Quality Reporting Initiative (PQRI). PQRI was further extended and modified as a result of the Medicare, Medicaid, and State Children’s Health Insurance Program Extension Act of 2007, the Medicare Improvements for Patients and Providers Act of 2008, and the Affordable Care Act of 2010. CMS changed the name of the program to the “Physician Quality Reporting System” in 2011. Through 2014, an eligible professional (or, for 2010 and subsequent years, a group practice) who satisfactorily reports data on quality measures may qualify to earn a Physician Quality Reporting System incentive payment, based on a percentage of the Secretary’s total estimated allowable Medicare Part B charges for covered professional services furnished during a specified reporting period.

Eligible professionals who satisfactorily reported Physician Quality Reporting System quality measures data for 2007 or 2008 could qualify to earn an incentive payment equal to 1.5% of the total estimated Medicare Part B Physician Fee Schedule (PFS) allowable charges for covered professional services furnished during the applicable reporting period selected by them. For 2009 and 2010, the incentive payments for satisfactory payments were equal to 2.0% of the Secretary’s total estimated Medicare Part B PFS allowed charges for covered professional services furnished by the eligible professional (or group practice) during the applicable reporting

period. The applicable quality incentive payments percentages decreased to 1.0% for 2011 and are set at 0.5% for 2012, 2013, and 2014.

Eligible professionals (and group practices) that do not satisfactorily report quality measures under the Physician Quality Reporting System will be subject to a negative payment adjustment beginning in 2015. The payment adjustment starts as a 1.5% reduction in the fee schedule amount for covered professional services furnished during 2015 and increases to a 2.0% reduction for 2016 and each year thereafter.

Since its inception, the Physician Quality Reporting System has grown from a claims-based quality measure reporting program, with 74 quality measures available for reporting by 2007, to a program with several different reporting options from which an eligible professional can select to qualify for a Physician Quality Reporting System incentive payment. Under the 2011 Physician Quality Reporting System, eligible professionals can participate individually by reporting data on the Physician Quality Reporting System quality measures via claims, a qualified registry, or a qualified electronic health record (EHR), or participate as part of a group practice under one of the group practice reporting options (GPRO I and GPRO II). The number of individual quality measures available has increased to nearly 200 measures and 14 measures groups, and there are 26 measures available for reporting under the GPRO I group practice reporting option.

Under the 2011 Physician Quality Reporting System Program, there are six measures that can be reported by eligible professionals that address the reduction of HAIs:

- Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician
- Perioperative Care: Selection of Prophylactic Antibiotic – First- *or* Second-Generation Cephalosporin
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Noncardiac Procedures)
- Perioperative Care: Timely Administration of Prophylactic Parenteral Antibiotics
- Prevention of Catheter-Related Bloodstream Infections: Central Venous Catheter Insertion Protocol
- Perioperative Care: Discontinuation of Prophylactic Antibiotics (Cardiac Procedures)

While additional measures can certainly be developed to address HAIs, it is important to remember that the Physician Quality Reporting System is a physician-based reporting program. Although many eligible physicians practice in a hospital setting, new measures would more likely be structural measures or implemented or collected at the hospital level. For example, a measure could look at how often health care providers wash their hands between patient encounters and following procedures or interventions.

H. Physician Feedback Program and Value-Based Payment Modifier

The Physician Feedback /Value-Based Payment Modifier is a Physician VBP program whose goal is to improve the health outcomes of Medicare beneficiaries and their experience of care by using payment incentives and transparency to encourage higher-quality, more efficiently provided health care services. The Physician Feedback Program was established by Section 131(c) the Medicare Improvements for Patients and Providers Act of 2008, which requires CMS

to provide confidential reports to physicians (and as determined appropriate by CMS, to groups of physicians) that measure the amount of resources involved in furnishing care to Medicare beneficiaries. Information on the quality of care furnished by the physician may also be included. The program has been developed in phases.

Phase One of the program was completed in 2009 with approximately 310 reports sent to randomly selected physicians in 12 metropolitan areas across the United States. Formative testing of the reports with physicians, as well as retrospective analyses of the data used in Phase One, informed CMS's plans for Phase Two of the program.

Phase Two of the program was completed in 2010, with CMS providing reports to 36 group practices and approximately 1,650 individual practitioners affiliated with those groups in the 12 geographic areas identified in Phase One. Phase Two reports also included data on clinical quality of care, in addition to information on total per capita resource use. In addition, CMS provided condition-specific information on per capita resource use for five high-cost, high-volume conditions: congestive heart failure, chronic obstructive pulmonary disease, coronary artery disease, diabetes, and prostate cancer.

In Phase Three of the program, in September 2011, CMS disseminated combined quality and resource use reports to the large medical group practices (each with 200 or more physicians) that participated in the Physician Quality Reporting System Group Practice Option (GPRO-1). CMS chose these medical groups because their quality performance could be compared on the common set of 26 quality measures included in the Physician Quality Reporting System GPRO-1 reporting tool. CMS also compared the group practices on measures of preventable hospital admission for six ambulatory care-sensitive conditions: diabetes, heart failure, bacterial pneumonia, chronic obstructive pulmonary disease, dehydration, and UTI. The resource use section of these reports compared the 35 groups on total per capita cost information as well as per capita cost information on four conditions prevalent in the Medicare population: diabetes, chronic obstructive pulmonary disease, heart failure, and coronary artery disease.

The Affordable Care Act of 2010 contains two provisions relevant to the Physician Feedback program. Section 3003 of the Affordable Care Act continues and expands the confidential feedback program. In December 2012, CMS disseminated Physician Feedback reports to more than 90,000 physicians in nine states and plans to continue to scale up distribution of Physician Feedback reports to physicians nationally in the fall of 2013. Additionally, Section 3003 requires the development of a Medicare-specific episode grouper so that physicians can be compared on episode-based costs of care.

Section 3007 of the Affordable Care Act requires CMS to apply a separate, budget-neutral VBP-based payment modifier to the Physician Fee Schedule (PFS) payment formula based upon a physician's or a physician group's quality of care furnished compared to the cost of that care during a performance period. Quality of care and cost must be evaluated based on a composite of quality and cost measures. The payment modifier applies to the PFS beginning January 1, 2015, for specific physicians and medical groups. By January 1, 2017, CMS must apply the value modifier to the PFS for all physicians and physician groups. In 2013, CMS will implement program parameters for the value modifier through rulemaking.

CMS views Section 3003 and Section 3007 as complementary, as the agency expects the work done for the Physician Feedback program to inform implementation of the payment modifier.

Many of the measures of quality and resource use that CMS employs in other quality programs and measures included in the Physician Feedback reports will be the foundation for the composite measure that CMS will use for purposes of the value modifier. CMS has emphasized in its PFS rulemaking in 2012 and 2013 the connection between the Physician Quality Reporting System and the value modifier. CMS has also placed considerable importance on enhancing the current quality measures for the Physician Quality Reporting System and the Health Information Technology for Economic and Clinical Health Act (HITECH)/EHR Incentive programs by planning to develop outcomes measures that can capture care coordination, transitions of care, and other more complex interactions among providers, such as those related to HAIs. CMS anticipates that it will continue to modify and enhance the composite measures for quality of care and resource use for the value modifier as additional quality and resource measures become available.

The process of developing a value modifier and feedback reports that are fair, meaningful, and actionable for physicians is evolutionary. CMS will emphasize transparency, collaboration with stakeholders, and outreach through physician groups and specialty societies, public listening sessions, and use of the Medicare PFS rulemaking process.

Note: The remainder of this section describes the use of VBP (value-based purchasing) as a tool to combat HAIs in post-acute care settings and through the coordination of care.

I. Quality Reporting for Long-Term Care Hospitals, Inpatient Rehabilitation Facilities, and Hospice Programs

Section 3004 of the Affordable Care Act establishes new quality reporting programs for long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), and hospice programs.

Under the new quality reporting programs established by Section 3004, IRFs and LTCHs have begun required reporting of new and worsening pressure ulcers and CAUTI events. Additionally, LTCHs have begun required reporting of CLABSI events. In October 2012, hospices started collecting data on a Quality Assessment and Performance Improvement structural measure and an end-result outcome pain measure. Hospices began submission of quality data via Web-based data entry on January 1, 2013. Failure to report quality data for a fiscal year will result in a 2 percent payment update reduction for that fiscal year starting in FY 2014. IRFs and LTCHs that participate in quality reporting will report their infection event data to CDC through NHSN, and CDC will report aggregated provider-level data to CMS. IRF quality data for new or worsening pressure ulcers will be electronically reported to CMS through a modified IRF form. LTCH quality data for new or worsening pressure ulcers will be electronically reported to CMS through a newly developed LTCH-CARE (Continuity Assessment Record & Evaluation) data set.

J. Value-Based Purchasing for Skilled Nursing Facilities and Home Health Agencies

Quality measures that target HAIs may serve as the basis of VBP programs for skilled nursing facilities (SNFs) and home health agencies in the future. Currently, quality measures are publicly reported on Nursing Home Compare Web sites. Quality measures publicly reported for SNFs and nursing homes include a prevalence measure of pressure ulcers (among long-stay residents) and the percentage of residents with pressure ulcers that are new or have not improved (among short-stay residents). Both measures of pressure ulcers are reported on the Nursing Home Compare Web site. The percentage of residents who have a UTI and the percentage of residents who have had an indwelling catheter inserted are also reported for long-stay nursing home residents on the Nursing Home Compare Web site. Additionally, the percentage of residents who were appropriately offered the seasonal influenza vaccine and the pneumococcal vaccine are reported for both short- and long-stay residents. Home Health Compare reports several quality measures, including one outcome measure (improvement in UTIs) and two potentially avoidable event measures (development of UTIs and emergent care for wound infections). Measures of how often the home health agencies determined whether their patients received the flu and pneumonia vaccines are also publicly reported. Application of metrics to assess care processes and achievement of avoiding CAUTI, *C. difficile*, and *Staphylococcal* transmission is highly dependent on the development and implementation of cross-cutting measures and data collection mechanisms.

K. Shared Savings/Accountable Care Organizations

Section 3022 of the Affordable Care Act directs the Secretary of HHS to “establish a shared savings program . . . that promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.” The Shared Savings Program is a voluntary program that defines an ACO as a group of health care providers and suppliers that agree to become accountable for the quality, cost, and overall care of Medicare beneficiaries enrolled in the traditional fee-for-service program. The ACO qualifies for shared savings by meeting specific cost and quality benchmarks. On October 20, 2011, CMS finalized the rules for the program.

In accordance with the rule, an ACO may be formed by a variety of different groupings of Medicare-enrolled providers and suppliers, which may or may not include an inpatient facility.

Additionally, there are certain criteria that an ACO must meet to become eligible for the Shared Savings Program, such as agreeing to participate for not less than three years, having a formal legal structure, including sufficient primary care providers for the care of the number of assigned Medicare fee-for-service beneficiaries (not less than 5000 beneficiaries), and defined processes to promote evidence-based medicine.

Accountable Care Organization Performance Assessment and Incentive Payment Model

An ACO qualifies for shared savings by meeting certain quality and cost benchmarks. The Affordable Care Act of 2010 requires that the Secretary determine appropriate measures to

assess the quality of care furnished by the ACO. An ACO must meet quality performance standards established for these measures to be eligible to share in any savings realized. The measures adopted in the final rule to assess quality performance were developed through extensive review of data quality and previously conducted research, internal discussion, engagement of public stakeholders through multiple listening sessions and public comment on the proposed rule, and coordination with national quality organizations.

While maintaining focus on the three-part aim of better care for individuals, better health for populations, and lowering growth in expenditures, the development of quality performance measures is guided by the goal of addressing, as feasible, all six of the aims for quality of care set forth by the Institute of Medicine in 2001. In keeping with these aims, standards for achievement should indicate that an ACO has provided care that is safe, timely, patient-centered, effective, efficient, and equitable.

Under the final rule, if an ACO meets the quality performance standards, savings are realized only if it reduces growth in total Parts A and B per capita costs of the Medicare fee-for-service beneficiary population assigned to that ACO to a level lower than its benchmark average per capita costs. Because HAIs require additional treatment and increase estimated per-beneficiary costs, it is less likely that the ACOs participating in the Shared Savings Program will have savings below the cost benchmark and qualify to receive an incentive payment unless HAIs are controlled in the assigned population.

ACOs that participate in the Shared Savings Program and other ACO initiatives are motivated to reduce HAIs because they will be eligible to receive shared savings only if per capita beneficiary costs are reduced to below the estimated benchmark.

Future Direction of the Shared Savings Program

The statute requires that the Secretary seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both, for the purposes of assessing quality of care. Measures of health care quality, which could include addition or expansion of HAI measures, may be added to the Shared Savings Program over time. In addition, the quality performance standards may be raised in future years, encouraging providers to place more emphasis on improving quality, including the avoidance of costly and preventable HAIs, to qualify for shared-savings incentives.

L. Recommendations and Action Plan for Value-Based Financial Incentives

CMS currently has the statutory authority to adjust hospital MS-DRG payments for selected conditions under the HAC payment provision. CMS has selected CAUTI, VCAI, and certain SSIs for nonpayment under the HAC provision when those infections are acquired during hospitalization. Other infections, like ventilator-associated infections, MRSA, *C. difficile*, and other SSIs may be reconsidered as candidates for the HAC payment policy during future rounds of rulemaking. However, the ability to select additional conditions will depend on the development of evidence-based guidelines and published literature supporting the conclusion that the conditions can be considered reasonably preventable when the guidelines are followed.

CMS also has the statutory authority to collect and publicly report hospital quality data under the Hospital IQR Program. This program measures the compliance of the hospital with reporting an increasing number of infection control and prevention best practices, including measures developed by the SCIP. Adoption of additional measures occurs through rulemaking, which occurs annually with a proposed rule published in the Federal Register in the spring and a final rule published in August.

CMS has used the experience from the HAC payment provision, the Hospital IQR Program measurement and public reporting program, and various performance-based payment demonstration projects to inform the development of the Hospital VBP Program. CMS believes that the Hospital VBP Program is a more sophisticated approach to VBP than the current HAC-based and pay-for-reporting approaches. Risk-adjusted rates of interventions to prevent infection and outcomes over time for infections like VAP, MRSA, or *C. difficile* may be proposed through the rulemaking process to create a patient safety domain of measurement, which will count toward the calculation of a hospital's VBP incentive payment for all DRGs.

Thus, the infection prevention and outcomes measures in the patient safety domain could become a subset of the total performance score of the hospital VBP Program. Scores for the individual measures of infection prevention and outcomes, aggregate infection measures, and the patient safety domain could be posted on the Hospital Compare Web site, along with the scores for the other domains and the total performance score, and could serve as one type of "scorecard" for infection prevention and outcomes.

Note: The next section focuses on public reporting, another tool used by federal health agencies to prevent and reduce HAIs.

IV. TRANSPARENCY AND ASSOCIATED INCENTIVES

A. Introduction

Transparency is a broad-scale initiative intended to equip consumers with information on quality of care to make informed decisions about their health care, while encouraging institutions and clinicians to improve the quality of care. Transparency in health care facilitates improvement of performance, efficiency, and quality by providing facilities and physicians with information for benchmarking.

Public reporting enhances accountability in health care by increasing the transparency of quality data. Providing reliable quality and cost information enhances decision making by patients and stakeholders at the local, regional, and national levels. Professionals are more likely to join the staff of a high-performing hospital. Choice leads to incentives at all levels and motivates the entire system; improvements take place as providers compete. This section provides detailed discussions on federal efforts in addressing HAIs through the public reporting of hospital and physician performance.

B. Hospital Compare

Background

Hospital Compare (<http://www.medicare.gov/hospitalcompare/>) is a consumer-oriented Web site that provides information on how well hospitals provide care to those patients who have certain medical conditions, including care related to the prevention of certain infections. Hospital Compare publicly reports hospital performance data in a consistent, unified manner to ensure public availability of credible information about the care delivered in the nation's hospitals.

The effort to publicly report processes of care and outcome measures furthers the goal to improve the quality and transparency of hospital care by giving the public and health care professionals better access to important hospital data. These quality measures are one approach to evaluate how well a hospital provides care for its patients. By making this information available, CMS is meeting two of the Secretary's four cornerstones for Value-Driven Health Care, that is, to measure and publish quality and price information. Hospital Compare allows consumers to evaluate how hospitals are delivering care to their patients through nationally standardized process-of-care and outcome measures for individual hospitals. This information helps inform consumers who are selecting a hospital for their medical care.

CMS launched the Hospital Compare tool on March 31, 2005. The measures currently reported on Hospital Compare include the measures that are reported under the Hospital IQR Program (Hospital Pay-for-Reporting) and additional measures that many hospitals voluntarily report. A number of these measures are related to infections: three are related to the prevention of surgical infections, seven to pneumonia care, and one to pneumonia outcomes.

Ten questions from a standardized survey of patients' perspectives of their hospital care, known as Hospital Consumer Assessment of Healthcare Providers and Systems, are also reported on the Hospital Compare site. Public reporting of standardized measures on patients' perspectives of the quality of hospital care they receive encourages consumers and their physicians to discuss and make informed decisions on acquiring the best hospital care, and it increases the public accountability of hospitals.

On April 1, 2011, CMS publicly reported eight HAC measures through a downloadable data file with a link on the Hospital Compare site, and on October 13, 2011, these eight measures were incorporated into the main report on Hospital Compare. These measures were selected because Medicare incurs high costs for them or because they occur frequently during inpatient stays for Medicare patients:

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Pressure Ulcer Stages III & IV

5. Falls and Trauma:
 - Fracture
 - Dislocation
 - Intracranial Injury
 - Crushing Injury
 - Burn
 - Other Injuries
6. Catheter-Associated Urinary Tract Infection
7. Vascular Catheter-Associated Infection
8. Manifestations of Poor Glycemic Control

The public reporting on HACs shows the number of times a HAC occurred for Medicare fee-for-service patients between October 2008 and June 2010. The data for the HAC public reporting show that rates for infection were relatively high, with about 45% of hospitals reporting at least one blood or urinary tract infection (UTI) developed during a hospital stay. Nationwide, a blood infection or UTI was reported once for every 3,300 discharges. CMS has also publicly reported these measures on the official CMS Web site (https://www.cms.gov/HospitalQualityInits/06_HACPost.asp) since March 31, 2011.

The public reporting of the HAC measures represents a significant milestone for CMS's efforts in improving the quality of inpatient care for Medicare beneficiaries. For the first time, Medicare patients can see how often hospitals report serious conditions that develop during an inpatient hospital stay and possibly harm them.

CMS also incorporated the following AHRQ Patient Safety Indicators and Inpatient Quality Indicators into the main report of Hospital Compare on October 13, 2011:

- PSI 90 Composite – Patient Safety for Selected Indicators
- PSI 04 – Death Among Surgical Inpatients with Serious Treatable Complications
- PSI 06 – Iatrogenic Pneumothorax
- PSI 11 – Postoperative Respiratory Failure
- PSI 12 – Postoperative Pulmonary Embolism or Deep Vein Thrombosis
- PSI 14 – Postoperative Wound Dehiscence
- PSI 15 – Accidental Puncture or Laceration
- IQI 91 Composite – Mortality for Selected Conditions
- IQI 19 – Hip Fracture Mortality
- IQI 11 – Abdominal Aortic Aneurysm (AAA) Repair Mortality

CMS worked with major stakeholders, like hospitals, consumer groups, employers, payers, and other government agencies, to make HAC data accessible to the public in meaningful, relevant, and easily understood ways that encourage improvement in the quality of health care. In October 2011, CMS incorporated the AHRQ Patient Safety Indicators and Inpatient Mortality Indicators as well as the HAC measures into the Hospital Compare framework. Beginning in FY 2013, CMS will publicly report the AHRQ PSI-90 composite and PSI-04 indicator.

Hospital Compare provides tools to incentivize hospitals to increase transparency at the system level. There is evidence that public reporting affects the reputation of hospitals. Hospital leadership is concerned about reputation, as that may in turn affect staffing, endowments, and other charitable giving (if nonprofit), branding, local political standing, and long-term market share. Having a hospital that performs well on Hospital Compare could strengthen a hospital's reputation, attracting patients, physicians, and clinical staff.

Recommendations and Action Plan for Hospital Compare

Each year, CMS continues to add new measures to Hospital Compare. These enhancements are part of HHS's ongoing commitment to increased transparency in health care. As measures are developed for hospital-associated infections related to VCAI, VAP, MRSA, and *C. difficile*, they may be added to the Hospital Compare Web site. The addition of hospital-associated infection measures to Hospital Compare could increase awareness and educate consumers while continuing to hold hospitals and other providers accountable for providing better and more efficient care.

The transparency provided by setting-specific Compare sites like Hospital Compare could be extended by developing a Compare site that reports cross-setting quality measures for acquired infections regardless of their site of origin. Cross-setting data would support a "systems" approach to reporting on quality and resolving the problem of life-threatening infections that may be difficult to attribute to a particular setting.

C. Physician Compare

Background

Section 10331 of the Affordable Care Act of 2010 requires CMS to establish a Physician Compare Web site by January 1, 2011 that contains information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting System. By no later than January 1, 2013 (and for reporting periods beginning no earlier than January 1, 2012), CMS is required to implement a plan to make information on physician performance publicly available through Physician Compare.

In implementing the Physician Compare Web site, the Secretary shall take several statutory requirements into consideration. In particular, the Secretary is required to establish processes, to the extent practicable, to ensure that (1) the data are statistically valid and reliable and provide an accurate and robust portrayal of performance, (2) provide appropriate attribution of care, (3) give timely feedback on statistical performance, and (4) reflect the care provided to all patients. In addition, physicians must have a reasonable opportunity for prior review of any data made public. Finally, the Secretary is required to ensure patient privacy, seek input from multi-stakeholder groups, and take into consideration the plan to transition to VBP.

To the extent practicable, the performance information on the Physician Compare Web site shall include the following: measures collected under the Physician Quality Reporting System; an assessment of patient health outcomes and the functional status of patients; an

assessment of continuity and coordination of care and care transitions, including episodes of care and risk-adjusted use of resources; an assessment of efficiency; an assessment of patient experience and patient, caregiver, and family engagement; an assessment of the safety, effectiveness, and timeliness of care; and other information as determined to be appropriate by the HHS Secretary. A town hall meeting was conducted in October 2010 to solicit input from stakeholders to inform releases of Physician Compare subsequent to the initial January 1, 2011 release.

Recommendations and Action Plan for Physician Compare

On December 30, 2010, CMS changed the name of the existing Healthcare Provider Directory Web site to “Physician Compare.” This site is primarily a consumer site and can be made to have flexible and logical pathways for consumers. In January 2011, CMS added the names of eligible professionals who satisfactorily reported 2009 Physician Quality Reporting System measures (this would replace the field that indicates whether an eligible professional participates in the Physician Quality Reporting System), which is required by the Medicare Improvements for Patients and Providers Act (2008).

In the spring of 2011, CMS added the names of eligible professionals who were 2009 successful e-prescribers (i.e., electronic prescribers), as required by the Medicare Improvements for Patients and Providers Act. Data will be refreshed monthly, and subsequent releases will occur semiannually.

In July 2011, CMS published the 2012 Medicare PFS (Physician Fee Schedule) proposed rule with a proposed plan for reporting performance information based on 2012 reporting periods at the group practice level when the results are available, including the proposed measures. The Physician Quality Reporting System has two group practice reporting options that could be the source of the information on performance. The Physician Quality Reporting System group practice measures could potentially be supplemented by a limited set of claims-based measures or physician-level measures related to HAIs. Also in June 2011, CMS added the names of eligible professionals who were participating in the EHR incentive program, as required by the HITECH Act of 2009.

In November 2011, CMS published the 2012 PFS final rule with a plan for making performance information based on 2012 reporting periods publicly available, including the measures.

By the fall of 2013, CMS plans to begin reporting performance information for group practices based on 2012 reporting periods.

V. RELATED INITIATIVES ADDRESSING HAIs

A. Introduction

CMS has undertaken a number of other Medicare and Medicaid initiatives to combat HAIs. Within the Medicare program, Quality Improvement Organizations (QIOs) provide direct provider support for reducing infections. CDC has partnered with other federal and state health departments in the surveillance of HAIs and establishing guidelines on prevention. The Medicaid program is encouraging states to adopt the Medicare HACs payment policy. It also funds the Transformation Grants, which include the goal of addressing central-line infections for premature infants in the NICU. Private organizations have also played an active role in consumer education on HAIs and in advocacy.

B. Quality Improvement Organizations (QIOs)

The statutory mission of the QIO Program is to improve the effectiveness, efficiency, economy, and quality of services for Medicare beneficiaries. The QIO Program is a network of organizations staffed with physicians and other practitioners, nurses, technicians, and statisticians — experts in health care quality — with each QIO responsible for a U.S. state, territory, or the District of Columbia. Each of the 53 QIOs is governed by a performance-based cost reimbursement contract. The current contract (the 10th Scope of Work [SOW], which began on August 1, 2011, and continues for three years) focuses on four aims: Improving Individual Patient Care, Beneficiary and Family-Centered Care, Integrating Care for Populations and Communities, and Improving Health for Populations and Communities, while also focusing on the use of learning and action networks to spread and sustain positive results. Within each of these aims, there are cross-cutting themes, including promoting the use of health IT and Value-Driven Care.

The following discussion expands on the patient safety and prevention aims, which are more relevant to this report's focus on HAIs.

Patient Safety

Efforts in patient safety will reduce patient harm using proven evidence-based QI initiatives and tools to improve safety. This work will define improvement in patient safety as the reduction or elimination of patient harm that is more likely a result of the patient's interaction with the health care system than an attendant disease process. Work toward these goals will, by definition, increase the value of health care services by producing higher-quality care for Medicare beneficiaries.

QIO activities for the Patient Safety theme will focus on five topics: reducing CLABSI, CAUTI, SSI, and *C. difficile* infections in hospitals facility-wide; reducing rates of pressure ulcers and physical restraints in nursing homes; promoting best practices in nursing home and other long-term care settings and reducing adverse drug events through the use of a collaborative in partnership with HRSA, and promoting transparency through the Hospital Quality Reporting Program. The role of survey and certification has a strong potential to be

further linked with QI in the 10th SOW. For example, nursing homes that have difficulty meeting the CMS survey and certification requirements will continue to have the opportunity to receive technical assistance from QIOs to assess areas for improvement and to evaluate and improve their performance.

In CMS's efforts to improve quality and avoid unnecessary costs for the Medicare Trust Fund, the Office of Clinical Standards and Quality directs QIO 10th SOW's Patient Safety to work in partnership with national, state, and local stakeholders in order to make a broad impact on HAI reduction rates. For example, CMS specifically partnered with CDC and AHRQ to coordinate HAI reduction programs, such as AHRQ's Comprehensive Unit-Based Safety Program (CUSP) for CLABSI and its CUSP for CAUTI nationwide initiatives in order to harness the power of shared resources and knowledge while avoiding duplicative efforts that can add to the burden of health care providers. In doing this, the QIOs will be able to take advantage of AHRQ-sponsored training sessions on CUSP principles geared toward achieving, spreading, and sustaining rate reductions in hospital-acquired CLABSI and CAUTI in the ICU and non-ICU settings. CMS has taken these and other HAI programs into strong consideration, including their standards, definitions, and targets when determining QIO tasks in this body of work, not only to most strongly align them nationwide but also to deliver a consistent message to those who care for patients.

Facilities working with the QIOs in the 10th SOW will report their CLABSI, CAUTI, and CDI rates to NHSN, which will help track the national picture for this effort. This data will also be available for feedback to facilities with higher infection rates, helping them to target certain performance improvement strategies to the areas of most need. The 10th SOW tries to align with state health departments and encourage partnerships with them; some of the state health departments, through federal funding, are able to establish robust HAI prevention programs. These opportunities to form partnerships, develop work where none previously existed, spread reductions in infections through learning and action networks, and expand the work of infection prevention and reduction both inside and outside of the hospital go beyond what the QIOs could capture alone.

Prevention

Prevention efforts will emphasize evidence-based and cost-effective care proven to prevent and/or slow the progression of disease. Work toward these goals will affect health care programs, their products, policies, and practices, community norms, and linkages between institutions and will produce a higher quality of care for Medicare beneficiaries while yielding significant cost savings. Over time, as disease is mitigated and its progression slowed through preventive measures such as early testing, immunization, and effective and timely intervention, the nation will see a healthier Medicare population emerge. This downstream impact will be most evident in the reduction of chronic kidney disease and a decrease in the rate of progression to kidney failure.

C. Medicare Advantage Efforts

New Reporting Requirements for Medicare Advantage Organizations

As part of the proposed Medicare Part C reporting requirements effective January 1, 2009, CMS has been collecting measures that involve hospital-acquired conditions. Some of these measures involve infections, including VCAI; CAUTI; SSI, mediastinitis, after coronary artery bypass graft; SSI following certain orthopedic procedures; and SSI following bariatric surgery for obesity. These data will be used in developing and reporting performance metrics for Medicare Advantage organizations. These measures are now subject to a yearly data validation audit process.

CMS has issued guidance to Medicare Advantage consistent with original Medicare rules effective October 1, 2008, in which specified preventable medical errors that occur at non-contracting hospitals will not be reimbursed. CMS will also be updating the *Medicare Advantage Payment Guide for Out of Network Payments* to reflect this guidance for all Medicare Advantage plans.

Medicare Advantage Requirements for Quality of Care

The Medicare Advantage quality framework, including QI programs, is described in the Medicare Advantage regulations, which currently require Medicare Advantage coordinated care plans to (1) have QI programs; (2) initiate annual QI projects and report results to CMS on these projects when they submit materials for their routine CMS audits; (3) have a chronic care improvement program; (4) report on annual activity of their chronic care improvement program when they submit materials for their routine CMS audits; and (5) report standardized performance measures specified annually by CMS.

These standardized performance measures include the Healthcare Effectiveness Data and Information Set, the Consumer Assessment of Healthcare Providers and Systems survey, and the Health Outcome Survey. The Healthcare Effectiveness Data and Information Set includes measures related to effectiveness of care, access to/availability of care, and use of services; the Consumer Assessment of Healthcare Providers and Systems Survey includes measures that reflect experiences with the care received through the health plan; and the Health Outcome Survey includes measures that address changes in physical and mental health status.

Under the Medicare Advantage provider selection and credentialing requirements, Medicare Advantage plans are required to contract with providers that meet the credentialing requirements specified in the Medicare Advantage regulations. Included is a requirement that providers must be state-licensed and in compliance with all applicable state and federal requirements.

Under the Medicare Improvements for Patients and Providers Act of 2008, beginning in 2011, each Medicare Advantage Private Fee-for-Service and Medicare Savings Account plan must have an ongoing QI program that meets the regulatory requirements. CMS is currently

developing regulations to implement these new Medicare Improvements for Patients and Providers Act quality requirements for Private Fee-for-Service and Medicare Savings Account plans. For 2010, QI reporting for Medicare Savings Account and Private Fee-for-Service plans will apply only with respect to administrative claims data.

D. Centers for Disease Control and Prevention

While the mission of CDC is broad and encompasses all of public health, the mission of its Division of Healthcare Quality Promotion (DHQP) is highly focused on the prevention of HAIs. Much of the recent success in preventing HAIs, such as reductions in CLABSIs, has been built upon the work of CDC over the last 30 years in learning how to detect, report, and prevent these infections. As a public health agency, CDC is involved in a continuum of activities that provide context for the recent involvement of sister agencies in HAI prevention and that support mutual roles in making HAI elimination a reality.

Epidemiology of HAIs: Identifying Opportunities for Incentives and Oversight and Evaluating Their Impact

CDC leads and assists state health departments in field investigations to understand emerging and established HAIs. Because both the microbes and the health care technology/delivery are constantly evolving, CDC has a key role in identifying new priorities for preventions. In addition to epidemiologists and subject-matter experts, CDC has the only laboratory at the federal level for supporting such field investigations. These intramural resources and expertise make it possible to support states and CMS in developing content-specific guidance, assessment, and measurement tools. In addition, through the use of epidemiologic methods, CDC can quickly evaluate the impact of policy initiatives at both the state and federal levels, including the detection of unintended consequences. One example of such CDC-CMS partnership and collaboration in working with state and local partners is the recent investigation of hepatitis transmission in Las Vegas ambulatory surgical centers in which the method of transmission was quickly identified, patients were notified and tested, and an infection control worksheet was developed for use by state surveyors to prevent additional infections. As described elsewhere in this document, CDC then worked with CMS to pilot the tool in three states before implementing it nationally as part of the state-based CMS certification process. An example of CDC assisting a state to evaluate the impact of an HAI policy initiative is CDC's rendering of assistance to Illinois to help that state understand the impact of a state-mandated prevention strategy for MRSA active surveillance testing to identify and isolate colonized patients.

Surveillance and Measurement of Health Care-Associated Infections: The Yardstick for Incentives and Oversight

An important outcome produced by field investigations and early epidemiologic studies has been the development of standardized case definitions and case-finding techniques. CDC HAI surveillance definitions were first developed in the late 1980s and, along with methods for risk stratification, undergo regular evaluation for necessary revision based upon changes in underlying epidemiology or changes in health care technology. These changes were first

developed for the legacy National Nosocomial Infection Surveillance System (NNIS), which in 2005 was replaced with the Web-based NHSN.

HAIs (outcomes) currently tracked in NHSN include CLABSIs, CAUTIs, VAP, SSI, dialysis access infections, colonization or infection with multidrug-resistant organisms (e.g., MRSA), and *C. difficile* infections. Process measures reported in NHSN include central line-insertion practices, hand hygiene, and compliance with isolation precautions. Whereas NNIS was a solely voluntary system with approximately 300 acute care hospitals, NHSN has grown rapidly with the advent of state mandates for the public reporting of HAIs. As of December 2012, there are approximately 5,200 acute care hospitals enrolled in NHSN. Twenty-nine states and the District of Columbia have mandatory reporting that requires the use of NHSN.

In January 2011, acute care hospitals covered under the IPPS began reporting CLABSIs to NHSN in order to avoid the 2.0% reduction in their CMS update percentage increase (i.e., Hospital Inpatient Quality Reporting Program/pay-for-reporting; see <http://www.qualitynet.org/>). Data on CLABSI rates from this program is reported, by hospital, on the Hospital Compare Web site. Similarly, acute care hospitals covered under IPPS now report SSIs that follow hysterectomies and colon surgeries, and CAUTIs through a similar mechanism via NHSN.

At present NHSN is largely a manual data entry system, but it is moving quickly toward electronic data entry through a standards-based approach known as clinical document architecture (CDA). Working with EHRs and surveillance software vendors, CDAs are being developed to allow clinical and laboratory data as well as admission, discharge, and transfer data that has been electronically captured in hospital systems to be used, via standard HL7 messages and vocabulary, in reporting HAI cases and denominators. Moreover, this electronic data can be leveraged to improve risk stratification. Since the inception of NHSN and with the decades of experience working with the NNIS, CDC has been at the forefront of understanding both modifiable and non-modifiable risk factors for HAIs and how to apply these variables to a reporting system. Because NHSN relies on clinical and laboratory data rather than administrative data, a level of risk stratification for outcome reporting is achievable that cannot be achieved with most other scalable approaches. Again, just as case definitions are being evaluated for accuracy and overall suitability, so are risk-stratification methods now the focus of ongoing research. Once adequate experience with a particular measure is attained and suitability for regional or national reporting is assured, CDC submits the measure to the National Quality Forum for patient safety measure (PSM) endorsement.

Current CDC surveillance definitions that have received PSM endorsement by NQF include CLABSI, CAUTI, SSI, bloodstream infections in hemodialysis patients, and influenza vaccination among health care workers. Because these different infections are risk-adjusted by a large and potentially growing number and variety of factors, a reporting parameter that is both rigorous and flexible is required to allow the “roll up” of measures as envisioned under VBP. The standardized infection ratio (SIR), based upon the concept of the standardized mortality ratio, is just such a measure, as it allows the comparison of performance to historic performance in the same risk strata. Thus a number of different factors can be used to risk-stratify the population under surveillance, and yet SIRs can still be

either compared or “rolled up” across settings. However, because the SIR is a ratio of observed to expected performance, actual movement and overall progress in “getting to zero” may be obscured, and so there may still be a place for also presenting risk-stratified rates where such presentation remains meaningful and yet feasible (i.e., as electronic data capture increases and models for risk stratification become increasingly complex and better at predicting underlying risk, the number of meaningful risk strata will increase).

National HAI Prevention Guidelines and HAI Research: The Foundations for Regulating Structure and Process

The mission of the HICPAC, the only federal advisory committee for HAI prevention practices, includes the development of evidence-based and -graded prevention guidelines for HAIs. Prevention practices with a high evidence grade have formed the basis of highly successful prevention demonstration projects (e.g., CLABSI prevention in ICUs) and national reporting system for process measures (e.g., SCIP). CDC subject-matter experts are not only responsible for shepherding guidelines through the writing and vetting process but are also charged with investigating the epidemiology of prevention practices and their impact on these infections. As either evidence gaps or the need for novel prevention strategies are identified, CDC plays a unique role in performing epidemiologic research to identify new prevention opportunities, early translational research to test novel strategies, or epidemiologic assessment of burden and the likely impact for prioritization. In response to recent U.S. GAO (General Accountability Office) recommendations, CDC is currently performing a formal prioritization of its high-evidence grade recommendations. In addition, where prevention recommendations and evidence for their effectiveness appear to be strong, CDC performs epidemiologic research to assess compliance and works with states and other partners to improve compliance and reduce HAI rates (below). Once it has been demonstrated that groups or collaboratives of hospitals or other providers can reduce the number of certain HAIs through application of HICPAC recommendations, CDC works with CMS to identify the types of incentives and oversight that can motivate more widespread high performance, leading toward elimination of HAIs.

Working with State Health Departments and Other Partners to Eliminate HAIs: Demonstrating That HAIs Are Reasonably Preventable

The successful 64% reduction of CLABSIs in hospital ICUs that were involved in the Pittsburgh Regional Health Initiative was an early example of how CDC works with regional partners in prevention collaboratives. Now, as a result of federal funding to state health departments, CDC is working with over 25 states in conducting HAI prevention collaboratives with acute care hospitals (ranging in number per state from eight to over 50) to prevent CLABSIs, CAUTIs, SSIs, MRSA, and *C. difficile*. These collaboratives work to share best practices for improving compliance with HICPAC high-evidence grade, high-priority (based upon likely impact) or “core” prevention practices. Using NHSN, these collaborative hospitals’ HAI processes and outcomes are measured and fed back to the hospitals and shared in various ways among hospitals. Additional guidance is given by CDC subject-matter experts to include lower-evidence grade (“supplemental”) prevention practices for hospitals or collaboratives that are not achieving desired reductions in HAI outcomes

despite high compliance with core recommendations. Other regional partners in this process include the state QIOs and hospital associations. In this way, CDC is leading partners at the regional level to both demonstrate preventability and reduce overall HAI burdens.

E. Efforts by the States

Efforts by State Medicaid Programs

The implementation of Medicare's HAC payment policy left many state Medicaid agencies wondering whether health care providers serving dually eligible Medicaid and Medicare patients would simply attempt to pass unpaid Medicare bills to Medicaid as a secondary payer. Such action would effectively shift costs to states and, even more seriously, undermine any deterrent effect that the Medicare HAC payment policy would otherwise have.

Section 2702 of the Affordable Care Act required Medicaid to create a regulation similar to the Medicare HAC regulation but which would cover all health care-acquired conditions (HCACs), to be effective on July 1, 2011. Medicaid was directed to review the response of state Medicaid programs to the issuance of the Medicare HAC regulation and to craft a federal law that would prohibit Medicaid payment to states for payments to providers made for incidents defined in the regulation as Provider Preventable Conditions. Obviously, some of these conditions (as in the Medicare regulations) dealt with HAIs.

CMS reviewed the existing policies of the 21 state Medicaid programs that had already developed state regulations on the topic of HCAC. These regulations had already exceeded the scope of the Medicare regulations in the types of conditions covered, the care settings covered, and the populations to which the HCACs applied. Many of the states had already gone beyond the 10 Medicare HACs, the hospital setting, and the population covered by Medicare.

Consequently, CMS adopted an approach that created a federal "floor" for the states that would require all of them to adopt, at a minimum, the 10 Medicare HACs for all hospitals (with the exception of a special clause altering the deep vein thrombosis/pulmonary embolism condition for children and pregnant women) and the three federal national coverage determinations (surgery on wrong patient, wrong surgery, and wrong-site surgery) for all health care providers. This minimum "floor" could be augmented by the states through the states' filing of a State Plan Amendment that would designate such additional "Other Provider Preventable Conditions" (OPPCs) as the state requested and CMS approved. The OPPC can be used by a state to cover all populations, providers, and those conditions that could reasonably have been prevented by the provider.

These State Plan Amendments are presently coming into CMS for approval, and it is likely that many of them will involve infection control issues. Because Medicaid will now require all states to deduct payment for care made necessary by the existing Medicare HACs, those Medicare HACs that involve infection control issues will automatically also become Medicaid HCACs. These, of course, are the HACs that involve CAUTI, SSI, and VCAI in

the hospital setting. The OPPC mechanism will also allow the states to deny payment for outpatient infection-related OPPCs and, assuming that the states follow their previous policies, some of these OPPCs will affect ambulatory surgery centers, SNFs, and physician offices. By this mechanism, it is expected that this new federal regulation will encourage more rigorous infection control practices in the outpatient setting.

National Academy for State Health Policy

In October 2009, the National Academy for State Health Policy convened a roundtable of state and national health policy officials to discuss opportunities for ongoing state-federal collaborations to promote patient safety and QI. In terms of reduction of HAIs, participants in the roundtable reached a consensus that the use of payment strategies that have been shown to encourage the adoption of evidence-based practices to prevent HAIs should be a priority.¹⁹ They agreed that to reduce the potential undesirable consequences of payment strategies, like gamesmanship on the part of providers (e.g., POA coding changes), it is crucial for federal health agencies to provide technical support for actual practice transformation and to reward high-performing states so as to encourage innovations. The participants also agreed that high-level roundtables, environmental scans, and ongoing, regularly scheduled meetings for promoting state-federal coordination are crucial tools and mechanisms for addressing HAIs.

Conference of State Legislatures

The National Conference of State Legislatures released a report in July 2010 that providing analysis of nine state HAI public reporting laws and their implementation.²⁰ These states were Alabama, Colorado, Delaware, Illinois, Massachusetts, New Hampshire, Oregon, Pennsylvania, and Washington. The report attributes successes in HAI reporting to federal leadership in reporting directions and methodologies and to funding from the American Recovery and Reinvestment Act (ARRA) of 2009, which has provided resources for training in reporting, the development of prevention plans, and surveillance tools. The report also discusses the challenges to state-level HAI reporting, including the states' lack of resources to build on existing federal infrastructures (e.g., NHSN), states' lack of mechanisms to enforce mandatory reporting among physician providers, the burden on hospitals to collect data on some of the HAI measures, like SSIs, and electronic data system problems that hospitals have to deal with constantly, like system bugs and crashes and the challenges in setting up digital certificates.

State Departments of Health

The states of Pennsylvania, Illinois, Florida, and Missouri have been pioneers in public reporting of HAIs. Pennsylvania is the first state in which hospitals are required by law to report HAI events. The state's law (Act 52 of 2007) mandates surveillance and reporting of

¹⁹ Buxbaum J. (January 2010) Opportunities and Recommendations for State-Federal Coordination to Improve Health System Performance: A Focus on Patient Safety. *State Health Policy Briefing* (http://nashp.org/sites/default/files/Patient_Safety_1-12-10.pdf, accessed October 15, 2010).

²⁰ Spences A, Sward D, Ward J. (July 2010) Lessons from the Pioneers: Reporting HAIs (<http://www.ncsl.org/documents/health/haireport.pdf> (accessed October 15, 2010).

HAIs. Hospitals are required to report HAIs occurring in all inpatient locations to the Pennsylvania Department of Health (PADOH) through NHSN, and to annually report progress in reducing the occurrences of HAIs in Pennsylvania hospitals.²¹ Since 2008, PADOH has been collecting data on HAIs and reporting these data in real time on NHSN. HHS's efforts to reduce HAIs have been immensely strengthened by funding from the ARRA. The state has one of the largest state-level databases of HAI events in the country, with more than 26,000 reports submitted annually. Pennsylvania has been focusing on CAUTI and CLABSI in its public reporting of HAIs, and recently it added SSIs. For the SSI measure, the PADOH worked with the Statewide HAI Advisory Committee, established under Act 52, and identified six categories, including cardiac surgery, cardiac bypass grafts (single incision and dual incision), hip prosthesis, knee prosthesis, and abdominal hysterectomy. Data validation is conducted by random chart auditing to detect potential CLABSIs. Hospital comparisons are performed using risk-adjusted SIRs. In 2010, 251 hospitals in Pennsylvania submitted data to NHSN continuously over a 12-month period. Between 2009 and 2010, the state saw a 3.4% decline in the occurrence of HAIs.

The PADOH has overcome several major challenges in its efforts to publicly report HAIs in the hospital setting, one of which was to reduce reporting burden by providing technical assistance for the vast majority of the hospitals to report HAI electronically. The department examined and certified commercial EHR surveillance systems, and it incentivized hospitals to report HAI data on NHSN by waiving the requirements for these facilities to report to other statewide pay-for-performance or pay-for-reporting programs. Meanwhile, the department is helping hospitals improve data quality so that the data would allow in-depth analysis of hospital performance in the prevention of HAIs. The department is also working on benchmarking hospital performance on CLABSIs.

Pennsylvania has also launched the public reporting of HAIs in nursing homes. The PADOH requires nursing homes to report 19 HAIs, and it has developed definitions for each condition. Currently, 722 of 732 nursing homes (98.6%) in Pennsylvania report HAI events. Overall, more than 40,000 HAI events have been reported. The state is working with CDC on meaningful public reporting of HAI data.

F. Activities in the Private Sector

Pay for Participation

Pay for participation can be a powerful incentive for provider organizations to participate in the technical assistance programs and activities that are being carried out by AHRQ, CDC, and CMS. In order to further expand the concept of pay-for-participation on the part of third-party payment organizations, HHS is working with state departments of health, state hospital associations, and third-party payment organizations to develop guidelines and recommendations for pay-for-participation programs to be implemented at the state level, programs that would support HAI Action Plan goals. The guidelines would then be

²¹ Pennsylvania Department of Health. (Oct 2011) 2010 Healthcare-Associated Infections (HAI) Report: Q+A (http://www.portal.state.pa.us/portal/server.pt/community/healthcare_associated_infections/14234, accessed October 24, 2011).

distributed to payer organizations across the country for consideration, adoption, and implementation.

Technical assistance is a major component of the HAI prevention strategy for AHRQ, CDC, and CMS. Technical assistance often takes the form of working directly with provider organizations to implement prevention and evidence-based interventions designed to prevent and eliminate HAIs. Participation in technical assistance activities is voluntary; many organizations eagerly participate in these improvement activities, but incentives must be developed to encourage other organizations to use the resources and technical assistance offered.

One of the most successful HAI intervention programs was the Michigan Keystone Project, which focused on the elimination of CLABSI using CUSP. A key component of this statewide effort was a pay-for-participation incentive to Michigan hospitals provided by Blue Cross and Blue Shield of Michigan. The incentive was worth up to 5% of a hospital's inpatient and outpatient reimbursement. Half of the 5% was targeted at quality. The project started out with a pay-for-participation element that had requirements such as attending meetings and conference calls as well as a minimum of 90% completion of the data. If a hospital failed to meet those requirements, it forfeited a portion of the payment.

VI. CONCLUSION

CMS, working with other HHS operating divisions and various national and local partners, has a number of initiatives and programs to regulate and track HAIs. Compliance with these regulations and promotion of the quality-based improvement practices used by CMS in concert with its partners will improve the public's health. Increasingly, these efforts also include more direct sources of information for providers and patients, which should influence choices that help diminish and prevent HAIs.

An advantageous approach to combating the presence of HAIs would be to design an overall framework that acknowledges that infections can, and often do, traverse across all health care settings. This places responsibility on roles that are specific to settings in preventing and mitigating the trajectory of an infection. A comprehensive, system-integrating approach would facilitate quality in patient care and safety as an adjoining goal of *all* inter-dependent units and facilities. Here, *health care* would take on a *systems* framework rather than a singular, insular framework.

A new framework design related to HAIs would eventually lead to a new public reporting framework, allowing the public to assess the *health care system* in which it would prefer to seek care, as this decision relates to the *system's* actions regarding the preventability of HAIs, achievement of better outcomes when an HAI exists, and overall systems-related services to patients. This would allow consumers to predict which facilities work collaboratively as a system to avert infections and their disease course. A shared accountability that would inevitably lead to the use of guidelines, surveillance processes, and financial programs would be in alignment with the overall goals of a health care system that works collaboratively to promote health and

wellness. These efforts would help achieve the ultimate goal of preventive and interventional programs comprised of all types of health care providers that are part of an overarching cooperative consciousness regarding cross-setting culpability for infection. Additionally, this consciousness leads providers to work collaboratively and comprehensively to support infection control management, guideline development, and quality initiatives with an approach that targets how infections truly occur across settings.

CHAPTER 4: OUTREACH AND MESSAGING

I. INTRODUCTION

Effective communication strategies and messages to prevent and eventually eliminate health care-associated infections (HAIs) are essential to achieving the targets and metrics associated with the *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* (HAI Action Plan). Communicating about HAIs, however, presents special challenges, as outreach and messaging strategies must address both the universe of involved parties and such discrete audience segments as health care teams, academic institutions, professional groups, and patients and their caregivers. Similarly, HAI messages must address multiple infections and the multiple, sometimes complex, practices needed to prevent them.

The HAI Action Plan's overall multiphased approach enables the development of strong professional partnerships that help to identify needs and information gaps specific to a variety of audiences. Accordingly, the outreach and messaging strategy reflects considerable guidance from those professional partners as well as from subject-matter experts, regional public health groups, consumer groups, other stakeholders, and members of Congress.

Messages for general and discrete audiences were developed based on communications science principles (e.g., a shared-responsibility approach, communication about risk to affected audience segments) and processes (e.g., formative environmental, audience, and media research, multilevel testing of messages). In particular, environmental research reported in December 2009 revealed that to that point most of the national and state HAI prevention campaigns had targeted health care providers and institutions.²² In contrast, a hallmark of the HAI Action Plan is the national consumer campaign to empower family caregivers as partners in the HAI prevention effort.

The national consumer campaign, which is new to the landscape of HAI communication efforts, focuses on family caregivers in hospital settings, specifically, the largest health-seeking population (adults aged 65+ years) and the largest care-giving population (women aged 40-65 years). Together with underserved populations, these groups are critical recipients and disseminators of HAI prevention messages and reflect the U.S. Department of Health & Human Services' (HHS's) efforts to engage and empower patients and other consumers as partners in preserving health and preventing disease.²³

On April 28, 2011, after the rollout earlier that month of the HHS Partnership for Patients initiative, the Federal Steering Committee for the Prevention of HAIs Outreach and Messaging Working Group met to align plans for the consumer campaign with objectives and planned tactics for the broader initiative. In part because of time and budgetary constraints associated with the contract with Ogilvy Worldwide, the Outreach and Messaging Working Group determined to narrow campaign targets to principal family caregivers and main patient groups,

²² Ogilvy Public Relations Worldwide, environmental scan document delivered to HHS 12/08/09.

²³ For similar efforts, see http://www.cdc.gov/handhygiene/Patient_materials.html, <http://www.ahrq.gov/qual/ptcareria.htm>, www.oneandonlycampaign.org.

namely women aged 40+ years and adults aged 65+. With input from the Partnership, the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and Centers for Medicare & Medicaid (CMS), and after focus-testing by Partnership for Patients stakeholders, HHS determined the final messages to be: (1) Wash or clean hands, (2) Ask questions, (3) Vaccinate against flu and pneumonia, and (4) Ensure safe use of medical devices. To promote these messages, a trifold brochure, a five-panel wallet card, and posters were developed to be mailed to more than 3,700 hospitals actively working to achieve the goals of the Partnership for Patients through 26 Hospital Engagement Networks. HHS will distribute additional hard copies while supplies last as well as electronic files for production by partners.²⁴ The campaign rolled out as a joint OASH-Partnership for Patients activity in November 2011. The HHS Office of the Assistant Secretary for Health, the Office of External Affairs, and Partnership for Patients stakeholders have worked with federal and nonfederal partners to disseminate the materials widely.

The dissemination of HAI prevention messages also relies on the many operating and staff divisions within HHS and, increasingly, newer partners in other federal departments, that play ongoing roles (see Section VI) in developing and communicating health messages to their numerous constituencies and the public. In addition, federal and nonfederal partners are anticipated to substantially broaden the dissemination effort. Powered by traditional and new media applied across multiple audiences, the messages are expected to achieve substantial, sustainable audience penetration.

II. GOALS

Goal 1: Promote and sustain heightened national attention about issues surrounding HAIs among various target audiences, including health care providers, consumers, patients and caregivers, consumer advocacy groups, health professional organizations, media, and the public health community.

Goal 2: Develop rapid communication strategies towards preventing various types of HAIs – catheter-associated urinary tract infections (CAUTIs), central line-associated bloodstream infections (CLABSIs), *Clostridium difficile* infections (CDIs), methicillin-resistant *Staphylococcus aureus* (MRSA), surgical-site infections (SSIs), and ventilator-associated events (VAEs), formerly called ventilator-associated pneumonia (VAP).

Goal 3: Increase both knowledge and practice of key prevention strategies for the various HAIs across and within specific health care settings.

²⁴ Providers may access printed copies of these products by visiting the CMS product-ordering Web site and registering for access to these documents. Go to <http://productordering.cms.hhs.gov>.

III. TARGET AUDIENCE

Table 7 gives a brief overview of the target audiences for HAI prevention as well as the key messages, tactics, and associated materials or products. Some audiences are customary constituents of HHS communications and regular partners in the secondary dissemination of messages. Others were selected specifically to accomplish the outreach goal of maximizing message reach.

Table 7. HAI Target Audiences and Key Messages, Tactics, and Materials/Products

Audience	Audience Sub Segment	Key Messages	Communication Tactics	Materials or Products
Health care providers and provider organizations	<ul style="list-style-type: none"> - Clinicians, including: - Infection preventionists - Hospital epidemiologists - Nurses - Physicians 	<ul style="list-style-type: none"> - Infection prevention is everyone’s responsibility. - Working together, providers and patients can greatly reduce the threat of HAIs. - Team up against HAIs. 	<ul style="list-style-type: none"> - Direct outreach via HHS communication channels - Outreach through professional partners 	<ul style="list-style-type: none"> - HHS HAI and related Web sites, symposia, webinars, and other products - Partner channels and products, e.g., newsletters, webinars - HAI prevention trainings (e.g., HHS <i>Partnering to Heal</i> video, CDC HAI continuing education courses, CDC HAI webinars) - AHRQ Innovations Exchange, HAI interventions: http://www.innovations.ahrq.gov/innovations_qualitytools.aspx?categoryID=54805&taxonomyID=33627 - AHRQ Comprehensive Unit-based Safety Program (CUSP): http://www.ahrq.gov/qual/cusp.htm - AHRQ Common Formats for HAI-related patient safety event reporting: https://psoppc.org/web/patientsafety/version-1.2_documents#Infection - AHRQ toolkit to reduce <i>C. difficile</i> infections through antibiotic stewardship: http://www.ahrq.gov/qual/cdifftoolkit/ - CDC Guidelines: http://www.cdc.gov/hicpac - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs-prevent-hai.html - CDC Prevention Toolkits: http://www.cdc.gov/HAI/prevent/prevention_tools.html - CDC HAI resources: http://www.cdc.gov/hai - CDC hand hygiene resources: http://www.cdc.gov/handhygiene a. AHRQ Morbidity and Mortality Rounds: http://www.webmm.ahrq.gov/ b. AHRQ Patient Safety Organizations: http://www.pso.ahrq.gov/ c. Guidance for Public Reporting of HAIs: http://www.cdc.gov/hicpac/pubReportGuide/publicReportingHAI.html d. National Healthcare Safety Network: http://www.cdc.gov/nhsn/

Audience	Audience Sub Segment	Key Messages	Communication Tactics	Materials or Products
Health care industry	<ul style="list-style-type: none"> - Hospital CEOs - Hospital administrators - Hospital boards 	<ul style="list-style-type: none"> - HAIs occur in all kinds of settings, including hospitals, surgical centers, hemodialysis centers, community clinics, and others. - HAIs impose a substantial economic burden on the health care system. - Encourage accountability, transparency, and patient partnerships. - Team up against HAIs. 	<ul style="list-style-type: none"> - Engage senior leadership through regular, timely information about public reporting, prevention practices, and potential savings in dollars and lives. 	<ul style="list-style-type: none"> - AHRQ Comprehensive Unit-Based Safety Program (CUSP): http://www.ahrq.gov/qual/cusp.htm - AHRQ CUSP Toolkit: http://www.ahrq.gov/cusptoolkit/ - AHRQ toolkit to reduce <i>C. difficile</i> infections through antibiotic stewardship: http://www.ahrq.gov/qual/cdiff toolkit/ - CDC HAI resources: http://www.cdc.gov/hai - CDC Prevention Toolkits: http://www.cdc.gov/HAI/prevent/prevention_tools.html - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs-prevent-hai.html - CDC Guideline: http://www.cdc.gov/hicpac CDC's HAI Tracking System, National Healthcare Safety Network: http://www.cdc.gov/nhsn CDC's HAI as a Winnable Battle: http://www.cdc.gov/WinnableBattles/HealthcareAssociatedInfections/index.html
Health care personnel (including acute care hospitals, ambulatory surgical centers, and ESRD facilities)	<ul style="list-style-type: none"> - Administrative - Food service - Environmental services - All others who work or volunteer in a health care setting 	<ul style="list-style-type: none"> - Infection prevention is everyone's responsibility. - Working together, the threat of HAIs can be greatly reduced. - Team up against HAIs. 		<ul style="list-style-type: none"> - CDC HAI resources: http://www.cdc.gov/hai - CDC dialysis resources: http://www.cdc.gov/dialysis CDC Guidance for Outpatient Settings: http://www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008: http://www.cdc.gov/hicpac/Disinfection_Sterilization/toc.html CDC sharps safety resources: http://www.cdc.gov/sharpssafety CDC injection safety resources: http://www.cdc.gov/injectionsafety CDC hand hygiene resources: http://www.cdc.gov/handhygiene CDC's Safe Healthcare blog: http://blogs.cdc.gov/safehealthcare

Audience	Audience Sub Segment	Key Messages	Communication Tactics	Materials or Products
Under-represented communities	<ul style="list-style-type: none"> - Spanish-language audiences - Native Americans - Low-literacy audiences - Minority populations - Elderly 	<ul style="list-style-type: none"> - Infection prevention is everyone’s responsibility. - As a patient, it is vital to your health to guard against HAIs. - Working together, the threat of HAIs can be greatly reduced. - Do the WAVE: Wash hands, Ask questions, Vaccinate against flu and pneumonia, and Ensure safe use of medical devices. 	<ul style="list-style-type: none"> - Incorporate HAI messages in ongoing minority outreach activities 	<ul style="list-style-type: none"> - AHRQs “Questions Are the Answer Campaign” main page: http://www.ahrq.gov/questions/ Tips and Tools: http://www.ahrq.gov/questions/tipstools.htm Spanish-language main page: http://www.ahrq.gov/preguntas/ Twenty Tips to Prevent Medical Errors: http://www.ahrq.gov/consumer/20tips.htm - CDC HAI resources: http://www.cdc.gov/hai and patient safety resources: http://www.cdc.gov/HAI/patientSafety/patient-safety.html - CDC hand hygiene materials: http://www.cdc.gov/handhygiene/Patient_materials.html - SHEA/IDSA/CDC Compendium of Patient Guides: http://www.shea-online.org/about/patientguides.cfm
Women aged 40 to 65	<ul style="list-style-type: none"> - Patients - Family caregivers 	<ul style="list-style-type: none"> - Infection prevention is everyone’s responsibility. - Team up against HAIs. - Working together, the threat of HAIs can be greatly reduced. - As a patient or caregiver, it is vital to your own and others’ health to guard against HAIs. - Do the WAVE: Wash hands, Ask questions, Vaccinate against flu and pneumonia, and Ensure safe use of medical devices. 	<ul style="list-style-type: none"> - Consumer outreach campaign 	<ul style="list-style-type: none"> - AHRQs “Questions are the Answer Campaign” main page: http://www.ahrq.gov/questions/ Tips and Tools: http://www.ahrq.gov/questions/tipstools.htm Spanish-language main page: http://www.ahrq.gov/preguntas/ Twenty Tips to Prevent Medical Errors: http://www.ahrq.gov/consumer/20tips.htm - CDC HAI resources: http://www.cdc.gov/hai and patient safety resources: http://www.cdc.gov/HAI/patientSafety/patient-safety.html - CDC hand hygiene materials: http://www.cdc.gov/handhygiene/Patient_materials.html - SHEA/IDSA/CDC Compendium of Patient Guides: http://www.shea-online.org/about/patientguides.cfm

Audience	Audience Sub Segment	Key Messages	Communication Tactics	Materials or Products
Older adults aged 65+ or use “patients” (campaign will target)	Patients	<ul style="list-style-type: none"> - Infection prevention is everyone’s responsibility. - Team up against HAIs. - Working together, the threat of HAIs can be greatly reduced. - As a patient or caregiver, it is vital to your own and others’ health to guard against HAIs. - Do the WAVE: Wash hands, Ask questions, Vaccinate against flu and pneumonia, and Ensure safe use of medical devices. 	- Consumer outreach campaign	<ul style="list-style-type: none"> - AHRQ’s “Questions are the Answer Campaign” main page: http://www.ahrq.gov/questions/ Tips and Tools: http://www.ahrq.gov/questions/tipstools.htm Spanish-language main page: http://www.ahrq.gov/preguntas/ Twenty Tips to Prevent Medical Errors: http://www.ahrq.gov/consumer/20tips.htm - CDC HAI resources: http://www.cdc.gov/hai and patient safety resources: http://www.cdc.gov/HAI/patientSafety/patient-safety.html - CDC hand hygiene materials: http://www.cdc.gov/handhygiene/Patient_materials.html CDC’s Safe Healthcare blog: http://blogs.cdc.gov/safehealthcare - SHEA/IDSA/CDC Compendium of Patient Guides: http://www.shea-online.org/about/patientguides.cfm

Audience	Audience Sub Segment	Key Messages	Communication Tactics	Materials or Products
Medicare quality improvement contractors (e.g., Quality Improvement Organizations [QIOs], ESRD Network Organizations)	<ul style="list-style-type: none"> - Clinicians - Nursing and ancillary care staff in acute care hospitals and dialysis facilities - Hospital “C-suite” executives - Dialysis facility administrators and medical directors (at local and “chain” levels) - State- and locally based hospital or nephrology care associations - Inpatient and outpatient dialysis facilities 	Key messages from campaign that Medicare QI contractors can amplify with their targets: <ul style="list-style-type: none"> - HAIs occur in all kinds of settings, including hospitals, surgical centers, hemodialysis centers, community clinics, and others. - HAIs impose a substantial economic burden on the health care system. - Encourage accountability, transparency, and patient partnerships. - Team up against HAIs. **Messages specific to Medicare QI contractors (to facilities and providers already recruited for QI partnership): - There is always room to improve performance, especially when patient safety is at stake. - Don’t give up — your Medicare QI partner can help support your continued and sustained improvement with reliable, effective tools that supplement what you have already been doing to keep your patients safe. - Medicare QI partners are available to support your continued improvement and to transfer the skills and knowledge your staff needs to sustain gains in improving patient safety. - Gaining buy-in from your leadership team will help spread and sustain your efforts to keep patients safe. 	<ul style="list-style-type: none"> - Outreach to facilities and providers that have already agreed to work with Medicare QI contractors on quality improvement (especially patient safety) goals. - Outreach to local and regional partners that share commitment to patient safety (e.g., state departments of health, patient advocates, state provider associations). - Success stories that demonstrate how other partner facilities and providers have worked to make care safer. - Other QI tools to promote the spread of innovation (e.g., convening learning networks and collaboratives). 	<ul style="list-style-type: none"> - AHRQ Comprehensive Unit-based Safety Program (CUSP): http://www.ahrq.gov/qual/cusp.htm - AHRQ TeamSTEPPS™: http://www.ahrq.gov/teamstepstools/ - AHRQ Common Formats for HAI-related patient safety event reporting: https://psoppc.org/web/patientsafety/version-1.2_documents#Infection - AHRQ toolkit to reduce <i>C. difficile</i> infections through antibiotic stewardship: http://www.ahrq.gov/qual/cdifftoolkit/ - Clinically focused tools designed by AHRQ, CDC, National Kidney Foundation (for dialysis), and other patient safety organizations. - HHS HAI and related Web sites, symposia, webinars, and other products - Partner channels and products, e.g., newsletters, webinars - HAI prevention training, computer-based

Audience	Audience Sub Segment	Key Messages	Communication Tactics	Materials or Products
Public health agencies and organizations at the local, state, regional, and federal levels	<ul style="list-style-type: none"> - State health officers - State epidemiologists - State HAI coordinators - Public information officers 	<ul style="list-style-type: none"> - Role of state and local health departments in HAI prevention - State and local health departments sit at the nexus of health care and the community. - State and local health departments play a key role in promoting prevention of HAIs and helping fill gaps in patient protections for ambulatory and long-term care settings. 	<ul style="list-style-type: none"> - Conference calls - Webinars - Release of key messages - Outreach to partner organizations (e.g., CSTE, ASTHO, NAACHO, NPHIC) 	<ul style="list-style-type: none"> - AHRQ Comprehensive Unit-based Safety Program (CUSP): http://www.ahrq.gov/qual/cusp.htm - AHRQ Common Formats for HAI-related patient safety event reporting: https://psoppc.org/web/patientsafety/version-1.2_documents#Infection - AHRQ toolkit to reduce <i>C. difficile</i> infections through antibiotic stewardship: http://www.ahrq.gov/qual/cdifftoolkit/ - CDC state-based prevention activities: http://www.cdc.gov/HAI/stateplans/HAIstatePlans-map.html - CDC state resources: http://www.cdc.gov/hai/recoveryact - CDC Guidelines: http://www.cdc.gov/hicpac - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs-prevent-hai.html - CDC Prevention Toolkits: http://www.cdc.gov/HAI/prevent/prevention_tools.html

NATIONAL ACTION PLAN TO PREVENT HEALTH CARE-ASSOCIATED INFECTIONS: ROAD MAP TO ELIMINATION
 APRIL 2013

Audience	Audience Sub Segment	Key Messages	Communication Tactics	Materials or Products
Academia (schools of medicine, nursing, pharmacy, public health, et al.)	Health profession students, educators	<ul style="list-style-type: none"> - Teamwork, effective communication and personal accountability help to create a hospital culture of patient safety. 		<ul style="list-style-type: none"> - AHRQ-funded HAI projects: http://www.ahrq.gov/qual/hais.htm - AHRQ Comprehensive Unit-based Safety Program (CUSP): http://www.ahrq.gov/qual/cusp.htm - AHRQ Common Formats for HAI-related patient safety event reporting: https://psoppc.org/web/patientsafety/version-1.2_documents#Infection - AHRQ toolkit to reduce <i>C. difficile</i> infections through antibiotic stewardship: http://www.ahrq.gov/qual/cdifftoolkit/ - HAI prevention training, <i>Partnering to Heal</i>: http://www.hhs.gov/partneringtoheal - CDC Guidelines: http://www.cdc.gov/hicpac - Top CDC Recommendations for Preventing HAIs: http://www.cdc.gov/HAI/prevent/top-cdc-recs-prevent-hai.html - CDC Prevention Toolkits: http://www.cdc.gov/HAI/prevent/prevention_tools.html - CDC HAI resources: http://www.cdc.gov/hai

IV. PARTNERSHIP DEVELOPMENT

Recognizing that reducing HAIs nationally is a shared responsibility, HHS is strengthening and building new partnerships to amplify prevention messages, promote the implementation of recommended practices in hospitals, ambulatory surgical centers, ESRD facilities, and long-term care facilities, and monitor progress at the national, regional, and local levels. To meet the goals of this HAI Action Plan, HHS seeks to partner with all stakeholders, both public and private, that represent the target audiences outlined in the HAI Action Plan. This would include health care system providers, private groups charged with regulatory authority, consumer advocacy groups, research entities, and the like. By sharing information and goals with the Partnership for Patients, HHS is already engaging a multitude of stakeholders in HAI prevention. In addition, individual operating divisions such as AHRQ, CDC, and CMS, among others, provide resources to help inform and empower consumers to advocate for safe health care for themselves and their family members.

Principal partnerships, also depicted in Table 7, include:

- HAI professional organizations that focus on prevention
- National- and state-level hospital associations, and federal, regional, state, and local public health organizations
- Academic institutions, including schools of medicine, nursing, pharmacy, and public health
- Consumer advocacy organizations
- Nonprofit groups interested in the prevention of HAIs

V. EVALUATION

The success of the HHS outreach and messaging effort will be evaluated through a variety of process measures available through HHS and its operating and staff divisions. These measures include:

- Outreach tools and resources:
 - Number of media clips and estimate of impressions and types of outlets
 - Number of people downloading materials from the HHS campaign site, i.e., resources at www.healthcare.gov, HHS HAI Initiative [page](#)
 - Web traffic on HHS campaign site and agency/offices HAI Web sites
 - Number of educational materials (e.g., hard copies) distributed
 - Number of people on HHS, agencies/offices HAI listservs
 - Number of people who have signed up to be on HHS, agencies/offices HAI listservs
 - Number of states that distribute the information to facilities
 - Number of partners that distribute educational materials to membership
 - Number of requests for information and educational resources
- Analysis of social media metrics:
 - Traffic on blogs
 - Comments on blogs
 - Twitter impressions

- Facebook impressions
- Number of sites that syndicate information on content
- Number of partner sites that post links back to HHS HAI campaign site or the HAI sites of agencies/offices
- Educational activities:
 - Number of educational activities conducted each year (e.g., continuing education courses, webinars, and trainings)
 - Number of health care providers educated at each educational activity (e.g., continuing education courses, webinars, and trainings)
 - Number of partners that distribute educational activities
 - Number of groups that are working with the 2009 American Recovery and Reinvestment Act-funded HAI State Plan Collaboratives

VI. ACTIVITIES OF PARTICIPATING HHS OPERATING AND STAFF DIVISIONS AND OTHER FEDERAL AGENCIES²⁵

Each federal agency participating in the outreach and messaging component of the HAI Action Plan campaign plays an important role in communicating appropriate and relevant messages to its constituencies. Listed below are examples of specific HAI-related communications activities organized by each operating or staff division.

A. Office of the Secretary/Office of the Assistant Secretary for Health

- Coordinates a consumer media campaign for the prevention of HAIs.
- Solicits public comment on the HAI Action Plan and develops strategic partnerships for implementation of the plan.
- Develops and communicates training resources to support the elimination of HAIs and promote a culture of safety.
- Works to establish and then disseminates objectives and targets for Healthy People 2020 in its new HAI topic area.

B. Agency for Healthcare Research and Quality

AHRQ's primary goal in messaging and outreach on the topic of HAIs is to convey practical and useful, science-based information that helps the clinical community prevent infections and make care safer for its patients. AHRQ also communicates with consumers on various issues to help them understand how to obtain safe, high-quality health care.

- Promotes research findings and implements programs focused on preventing HAIs through the improvement of quality, safety, efficiency, and effectiveness of health care. Such programs include the national implementation and expansion of the Comprehensive Unit-based Safety Program (CUSP), an initiative proven to reduce HAIs by improving the patient care culture in health care settings through the integration of the effective

²⁵ For a listing of Web-based Federal Resources, please see <http://www.hhs.gov/ash/initiatives/hai/resources/index.html>

application of clinical guidelines, the science of safety, improved communication, teamwork, and leadership.

- Administers a voluntary reporting system to collect patient safety data (including HAIs) through Patient Safety Organizations and sharing data via the Network of Patient Safety Databases.
- Develops market research strategies and messages to better communicate the agency's research agenda on reducing HAIs (CAUTI, CLABSI, CDI, MRSA, SSI, and VAE) in a variety of settings, including hospitals, ambulatory settings, ESRD facilities, and nursing homes.
- Designs and disseminates science-based tools and resources for health care providers and consumers.
- Disseminates the results of HAI research to key stakeholders and develops partnerships using various communications media, including electronic and print newsletters, podcasts, public awareness campaigns, press releases, and social media.
- Tracks the impact of AHRQ research and resources in order to capture and report changes in clinical practice, policy, and patient outcomes through multiple communications venues.
- Collects metrics to highlight the results and effectiveness of AHRQ's communication and dissemination activities.
- Publicizes to the public and the research community the agency's funding opportunities that support research for reducing and preventing HAIs.
- Supports the goals of the Partnership for Patients, including communications and outreach approaches.

C. Centers for Disease Control and Prevention

CDC, through its Division of Healthcare Quality Promotion, develops and implements communications outreach initiatives and messages that emphasize the importance of prevention to eliminate HAIs. CDC's role related to outreach and messaging on the topic of HAIs includes:

- Campaigns and Educational Materials
 - Develops and conducts national campaigns aimed at health care providers and patients/the public to prevent HAIs.
 - Conducts formative research to guide the development of educational materials and campaigns; conducts qualitative/quantitative evaluations to assess the impact of educational materials and campaigns, including the following:
 - *[Get Smart for Healthcare](http://www.cdc.gov/getsmart/healthcare/)*²⁶ (promoting antimicrobial stewardship among clinicians, formerly the 12 Step Campaign to Prevent Antimicrobial Resistance).
 - *[One and Only Campaign](http://www.oneandonlycampaign.org/)*²⁷ (promoting safe injection practices among patients and providers in outpatient settings).
 - *[National MRSA Education Initiative](http://www.cdc.gov/mrsa/mrsa_initiative/skin_infection/index.html)*²⁸ (promoting awareness of MRSA skin and soft-tissue infections among the public/"moms").

²⁶ <http://www.cdc.gov/getsmart/healthcare/>

²⁷ <http://www.oneandonlycampaign.org/>

²⁸ http://www.cdc.gov/mrsa/mrsa_initiative/skin_infection/index.html

- [*Preventing Infections in Cancer Patients*](#) (educates patients and family caregivers about personal prevention of infection and provides resources to ensure safe care in outpatient oncology clinics).
 - [*Hand Hygiene Saves Lives*](#)²⁹ (patient empowerment video, brochures, and posters promoting hand hygiene).
- Media and Electronic Outlets (i.e., press, Web, smart phone applications, etc.), including:
 - Responds to press inquiries from national, regional, and local media outlets on a variety of HAI topics.
 - Works with top-tier media outlets to secure HAI-related articles.
 - Develops and maintains topic pages on HAIs, guidelines, FAQs (frequently asked questions), sheets, etc.
 - Coordinates the [CDC Safe Healthcare blog](#),³⁰ which encourages clinicians and consumers to discuss topics about making health care safer by preventing infections in health care settings.
 - Maintains several HAI Web sites, including <http://www.cdc.gov/hai>, a Web site that provides links to CDC resources, including estimates of HAIs, lists of infectious diseases in health care settings, and information on antimicrobial resistance.
 - Conducts outreach to clinicians through online partners. For example, CDC has joined forces with Medscape to present the [CDC Expert Commentary Series](#),³¹ which is designed to deliver CDC's guidance to Medscape's physicians, nurses, pharmacists, and other health care professionals.

D. Centers for Medicare & Medicaid Services

- Leverages and communicates with relevant groups about payment policies to enhance delivery of quality care. Among these are:
 - Value-based purchasing frameworks that tie accomplishment on quality measures to reimbursement rates for hospital and ESRD services in the Medicare program.
 - Present on Admission Indicator Reporting Policy, which tracks whether certain conditions or patient states have been acquired during an inpatient hospital stay or whether they were community acquired.
 - Hospital-Acquired Conditions (HACs) payment policy, which may prevent hospitals from receiving additional Medicare payment for cases in which one of the conditions involved in the inpatient visit was not present when the patient was admitted to the hospital (e.g., complications arising from infection of the surgical site after coronary artery bypass graft surgery).
 - Incentives (additional program payments) for hospitals and other types of Medicare- or Medicaid-participating providers to report data on clinical quality measures (e.g., Electronic Health Records Incentive Program for Medicare or Medicaid, Hospital Inpatient Quality Reporting Program).

²⁹ <http://www.cdc.gov/handhygiene/>

³⁰ <http://blogs.cdc.gov/safehealthcare>

³¹ <http://www.medscape.com/partners/cdc/public/cdc-commentary>

- Uses cadre of Medicare- and Medicaid-focused quality improvement contractors to communicate with and to activate providers and facilities on evidence-based strategies for continuing and sustaining improvement on patient safety/infection control processes. Examples include:
 - The nation's 53 Quality Improvement Organizations (QIOs), which deliver services locally through a national network of 53 independent organizations located in each of the 50 states, the District of Columbia, Puerto Rico, and the Virgin Islands. QIOs engage providers and practitioners in focused quality improvement initiatives as part of CMS's commitment to ensuring consistent, high-quality health care for Medicare beneficiaries across the country.
 - The nation's 18 End-Stage Renal Disease Networks (ESRD NWs), which oversee the quality of care that patients with ESRD receive and provide technical assistance to these patients and their care providers.
 - External Quality Review Organizations, which perform independent reviews of managed care organizations that provide services for Medicaid beneficiaries at the state level.
- Publicly reports quality data through a suite of Compare Web sites, including Hospital Compare and Dialysis Facility Compare.
- Makes and communicates national coverage decisions that incorporate the best available evidence on medical technologies that improve patient outcomes.
- Sets and communicates minimum health and safety standards that providers and suppliers must meet in order to become Medicare and Medicaid certified, standards that serve as the foundation for improving quality and protecting the health and safety of beneficiaries (i.e., Conditions of Participation, Conditions for Coverage). These standards are enforced through State Survey Agencies and other accreditation bodies (e.g., The Joint Commission). CMS conducts ongoing outreach and provides training to facilities and the survey enforcement bodies about these health and safety standards. (For instance, hospitals are held to specific infection control standards mandating that they must prevent, control, and investigate infections and communicable diseases.)

E. Food and Drug Administration

- Publicly communicates information about antimicrobial drugs, vaccines, diagnostics, and personal protective equipment intended to prevent, reduce, or treat infections.
- Publicly communicates safety information about catheters, ventilators, and other hospital-related medical equipment that might be associated with HAIs; provides guidance about product-specific safety-related issues to manufacturers and health care professionals when needed.

F. Health Resources and Services Administration

- Provides resources to train health professionals and address workforce issues.
- Distributes information on infection control and prevention through various health care systems and facilities.

G. Indian Health Service

- Through multiple venues, provides Native American tribes and communities (patients, staff, and practitioners) with information on infection control and prevention.
- Supports partnerships, involvement, and collaboration among patients, departments, staff, and others within and outside of the agency to prevent and control HAIs.

H. National Institutes of Health

- Supports and conducts biomedical research and research training and disseminates information to public and professional audiences. One area of investigation is the pathogenesis of multidrug-resistant organisms and other pathogens of importance in the health care setting.
- National Institutes of Health (NIH) Clinical Center's Hospital Epidemiology Service directs efforts to prevent hospital-associated infection through a collaborative, coordinated, and continuous process of surveillance, education, and communication founded on current scientific knowledge and consistent with regulatory requirements.
- Intramural investigators who represent NIH in professional societies and on guideline committees directly communicate scientific information used to establish national policies and recommendations for the prevention and management of HAIs.
- Employs multimedia forms of training and guidelines on infection prevention for health care workers at the Clinical Center. The Clinical Center provides patient information on infection control in both English and Spanish.
- Conducts presentations to health care groups on epidemiology matters.
- Provides information on infection control to the NIH Clinical Center staff and patients and to the public through the NIH Health Information Pages,³² and through Medline Plus, a Web-based consumer health information service operated by the National Library of Medicine.

I. U.S. Department of Veterans Affairs

- Facilitates efforts for infection control and prevention through numerous communications mechanisms and across multiple medical care programs whereby infection control and prevention becomes “everyone’s responsibility.”
- Conducts enterprise-wide surveillance for HAI. The U.S. Department of Veterans Affairs is completing development and initiating implementation of an electronic system to support HAI identification and facilities reporting.
- At each Veterans Affairs facility, directly communicates prevention practices to reduce and prevent the spread of antibiotic-resistant organisms, such as MRSA.

³² Can be found at <http://health.nih.gov/category/Infections>.

VII. CONCLUSION

Effective, timely, and targeted communication strategies and messages to prevent and eliminate HAIs are essential to achieving the targets and metrics associated with the HAI Action Plan.

Messages are continuously developed based on the use of research-based tactics to target audiences, such as focus groups and audience segmentation. The messages heavily rely on themes of partnerships among patients, their families, and health care providers for the prevention of HAIs. As such, organizations representing these groups are included in formative research, materials development and message-testing, and targeted or collaborative outreach efforts. In addition, each operating division uses various media modes to deliver these messages, including electronic, print, face-to-face, and social media. For example, in 2011, research-based WAVE (Wash hands, Ask questions, Vaccinate against flu and pneumonia, and Ensure safe use of medical devices) consumer materials, both print and electronic, were developed and disseminated with the assistance of multiple federal and nonfederal partners to more than 3,700 hospitals actively working to achieve the goals of the Partnership for Patients through 26 Hospital Engagement Networks.

As the HAI prevention effort grows, the Outreach and Messaging Working Group continues to formulate and conduct strategic communications activities, disseminate key messages to target audiences, and promote the overall efforts of the Federal Steering Committee for the Prevention of HAIs.