

Department of Health and Human Services

**ACTION PLAN TO PREVENT
HEALTHCARE-ASSOCIATED INFECTIONS**

Agency for Healthcare Research and Quality

Office of the Assistant Secretary for Public Affairs

Office of the Assistant Secretary for Planning and Evaluation

Centers for Disease Control and Prevention

Centers for Medicare & Medicaid Services

Food and Drug Administration

National Institutes of Health

Office of the National Coordinator for Health Information Technology

Office of Public Health and Science

**HHS Action Plan to Prevent
Healthcare-Associated Infections**

Table of Contents

Executive Summary	Page 1
Introduction	Page 7
Prevention: Metrics and Targets	Page 12
Prevention: Prioritized Recommendations	Page 22
Research	Page 29
Information Systems and Technology	Page 46
Incentives and Oversight	Page 57
Outreach and Messaging	Page 82
Coordination, Evaluation, and Conclusion	Page 92
Appendices	

HHS Action Plan to Prevent Healthcare-Associated Infections

Key Abbreviations

AHRQ	Agency for Healthcare Research and Quality
ASPA	Assistant Secretary for Public Affairs
ASPE	Assistant Secretary for Planning and Evaluation
CAUTI	catheter-associated urinary tract infection
CDC	Centers for Disease Control and Prevention
CDI	<i>Clostridium difficile</i> infection
CLABSI	central line-associated bloodstream infection
CMS	Centers for Medicare & Medicaid Services
CoP	Condition of Participation
EHR	electronic health record
FDA	Food and Drug Administration
FHISE	Federal Health Information Sharing Environment
GAO	Government Accountability Office
HAC	Hospital-Acquired Condition
HAI	healthcare-associated infection
HHS	Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
ICD-9	International Classification of Diseases, Ninth Revision
MDRO	multidrug-resistant organism
MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
NHIN	Nationwide Health Information Network
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NNIS	National Nosocomial Infections Surveillance System
ONC	Office of the National Coordinator for Health Information Technology
OPHS	Office of Public Health and Science
POA	present on admission
QIO	Quality Improvement Organization
SCIP	Surgical Care Improvement Project
SSI	surgical site infection
VAP	ventilator-associated pneumonia
VBP	Value-Based Purchasing

HHS Action Plan to Prevent Healthcare-Associated Infections: EXECUTIVE SUMMARY

Background on Healthcare-Associated Infections

The Department of Health and Human Services (HHS) “Action Plan to Prevent Healthcare-Associated Infections” represents a culmination of several months of research, deliberation, and public comment to identify the key actions needed to achieve and sustain progress in protecting patients from the transmission of serious, and in some cases, deadly infections.

Healthcare-associated infections (HAIs) are infections that patients acquire while receiving treatment for medical or surgical conditions. HAIs occur in all settings of care, including acute care within hospitals and same day surgical centers, ambulatory outpatient care in healthcare clinics, and in long-term care facilities, such as nursing homes and rehabilitation facilities. HAIs are associated with a variety of causes, including (but not limited to) the use of medical devices, such as catheters and ventilators, complications following a surgical procedure, transmission between patients and healthcare workers, or the result of antibiotic overuse.

Healthcare-associated infections exact a significant toll on human life. They are among the leading causes of death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002. In hospitals, they are a significant cause of morbidity and mortality.¹ Hospital stays for methicillin-resistant *Staphylococcus aureus* (MRSA) infection have more than tripled since 2000 and have increased nearly ten-fold since 1995.²

Four categories of infections account for approximately three quarters of HAIs in the acute care hospital setting. These four categories are: 1) Surgical site infections; 2) Central line-associated bloodstream infections; 3) Ventilator-associated pneumonia, and; 4) Catheter-associated urinary tract infections. In addition, infections associated with *Clostridium difficile* and MRSA also contribute significantly to the overall problem. The frequency of HAIs varies by location. Currently, urinary tract infections comprise the highest percentage (34%) of HAIs followed by surgical site infections (17%), bloodstream infections (14%), and pneumonia (13%).³

In addition to the substantial human suffering exacted by HAIs the financial burden attributable to these infections is staggering. It is estimated that HAIs incur an estimated

¹ Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160-166.

² Elixhauser A and Steiner C. Infections with Methicillin-Resistant *Staphylococcus Aureus* (MRSA) in U.S. Hospitals, 1993–2005. *AHRQ Healthcare Cost and Utilization Project Statistical Brief* 2007; 35:1-10.

³ Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160-166.

\$28 to \$33 billion in excess healthcare costs each year.⁴ Whereas not all *Staphylococcus aureus* infections are healthcare-associated, healthcare charges for *Staphylococcus aureus* bloodstream infections for Medicare patients exceeded \$2.5 billion in 2005.⁵

HHS Action Plan to Prevent Healthcare-Associated Infections

In response to the increasing threat of HAIs and national and international concern, the Department has composed a Steering Committee of senior-level representatives from the Offices and Operating Divisions of HHS and conducted a number of in-person meetings and conferences with Federal experts. The Department's Action Plan toward the prevention and elimination of HAIs includes goals toward which the healthcare and public health communities have been moving over the past several years. Despite uncertainty about whether there ultimately will be a limit on meeting this goal, the decision to move forward has been embraced by the Steering Committee.

A five-point draft strategy was developed by HHS for the Action Plan and included:

- 1) Establishing an HHS Steering Committee for the Prevention of Healthcare-Associated Infections to develop an Action Plan.
- 2) Beginning to prioritize, in partnership with the HHS Secretary's Healthcare Infection Control Practices Advisory Committee (HICPAC), the significant scientific questions that need to be addressed to move the field forward rapidly and the current 1,200 recommended clinical practices to facilitate rapid implementation amongst healthcare organizations.
- 3) Identifying and exploring policy options for regulatory oversight of recommended practices and providing critical compliance assistance to select hospitals.
- 4) Working to establish greater consistency and compatibility of HAI data through developing standardized definitions and measures for HAIs.
- 5) Striving to build on the principles of transparency and consumer choice to create incentives and motivate healthcare organizations and providers to provide better, more efficient care.

Some of the most prominent clinicians, scientists, and other public health professionals within HHS in concert with key individuals from other federal Departments worked to develop a road-map for addressing this important public health and patient safety issue in the short- and long-term. Five working groups of the HHS Steering Committee met this past year, deliberated on known facts, research needs, and how to prevent HAIs. The primary topics of the five working groups with their respective agency leads were:

- The Prevention and Implementation working group led by the Centers for Disease Control and Prevention (CDC),

⁴ Scott Rd. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention, 2009. Division of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention, February 2009.

⁵ <http://hcupnet.ahrq.gov/>

- The Research working group led by the Agency for Healthcare Research and Quality (AHRQ),
- The Information Systems and Technology working group co-chaired by the Office of the National Coordinator for Health Information Technology (ONC) and CDC,
- The Incentives and Oversight working group led by the Centers for Medicare & Medicaid Services (CMS), and,
- The Outreach and Messaging working group led by the Office of Public Health and Science (OPHS).

The HHS Steering Committee and its sub-groups, which composed the Action Plan to Prevent Healthcare-Associated Infections, accomplished the following:

- Identified metrics with corresponding national 5-year prevention targets
- Identified gaps in the current knowledge of HAIs and created an agenda for current and future research on HAIs
- Recommended standardization of data elements and adoption and use of data and technology standards to track HAIs
- Documented the current regulatory and administrative authority and initiatives/strategies of CMS (working with other HHS Operating Divisions and federal partners) used to prevent and combat HAIs
- Developed a progressive campaign to release and publicize the Action Plan in concert with a number of national partners in the federal, academic, non-profit, and private sectors. This messaging and communications strategy will target a number of audiences using the principles of social marketing and risk communication to also reach the public at large.

Top Ten Messages on HAIs and the Action Plan⁶

- Many healthcare-associated infections are preventable.
- A systemic approach to reducing the transmission of disease can be more effective than disease-specific approaches.
- Developing and supporting basic and translational studies to address the gaps in the science in this field will allow generation of additional strategies to reduce the risks of HAI transmission.
- It will take a strong partnership between federal and local/state governments and communities to truly help prevent HAIs. HHS is committed to this partnership and many of its Operating Divisions are and will be involved.
- The education of best practices for providers and other healthcare personnel is critical to prevent HAIs.
- Specific metrics and national targets have been developed by HHS in concert with national experts on controlling infections.

⁶ That HHS and Collaborators will communicate these to many stakeholders and the public – including healthcare organizations, professional provider organizations, governmental agencies, non-profit public health organizations, and the public.

- Educating patients on HAIs and how to prevent them is a critical part of the national effort.
- An informed media can help promote the education of the American public about the need to prevent HAIs and what HHS and its partners are doing.
- Preventive steps to control and prevent HAIs are cost-effective, save lives, and reduce disability for Americans.
- The time to act on HAIs is now, and HHS and its partners are working closely with providers, health systems, community leaders, and governments to help prevent HAIs.

Priority Recommendations of the Prevention and Implementation Group

- Progress towards 5-year national prevention targets
- Use and improve the metrics and supporting systems needed to assess progress towards meeting the targets
- Consider recommendations, grouped by priority module, outlined for each of the guidelines addressed

Priority Recommendations of the Research Group

- 1) Perform Research Projects to Address Specific Knowledge Gaps (Basic Science, Epidemiology, and Practices)
 - Basic Science
 - Develop strategies for preventing and/or eliminating biofilms associated with medical devices
 - Epidemiology
 - Study the epidemiology of bloodstream infections that occur outside of the hospital
 - Establish the preventability of *Clostridium difficile* infection (CDI) through a regional hospital collaborative intervention
 - Establish the preventability of unnecessary antimicrobial use through a multi-center collaborative intervention
 - Establish the preventability of surgical site infection (SSI) through a multi-center collaborative intervention
 - Practices
 - Assess the effectiveness of the ICU-wide application of a MRSA decolonization strategy
- 2) Perform Research Projects to Enhance the Implementation and Impact of Existing, Evidence-Based Infection Control Practices
 - Investigate the human cultural and organizational barriers to successful implementation of practices at the unit and institutional levels
 - Develop and evaluate novel and automatable strategies for measuring HAIs

- Evaluate and validate standardized post-discharge surveillance methodology
- Develop proxy measures for ventilator-associated pneumonia (VAP) (i.e., acute lung injury) for inter-facility comparisons
- Develop standardized methods for measuring and reporting compliance with broad-based prevention practices (e.g., hand hygiene)

Priority Recommendations of the Information Systems and Technology Group

- Form an Interagency Working Group to enhance the federal capacity to lead a national prevention strategy
- Conduct a comprehensive HAI database inventory to guide future plans for near-, mid-, and long-term integration and interoperability projects and to establish the extent of definitional alignment and data element standardization needed to link HAI data across the nation
- Enhance individual agency systems to extend their coverage or establish new interfaces with other systems
- Accelerate transition to electronic reporting by healthcare facilities to reduce their reporting burden and increase timeliness, efficiency, comprehensiveness, and reliability of the data

Priority Recommendations of the Incentives and Oversight Group

- Improve regulatory oversight of hospitals and CMS oversight of the hospital accreditation program by refining the current method of measuring Accreditation Organization performance, enhancing surveyor training and tools, and adding sources and uses of infection control data
- Continue to incorporate measures of infection prevention and outcomes into Hospital Value-Based Purchasing (VBP) Plan methodology through implementing performance-based payment for hospitals, including measures of infection prevention and outcomes as a basis for payment
- Expand measures in CMS Hospital Compare which improves the quality and transparency of hospital care by increasing public accountability and provides consumers access to important hospital quality of care measures

Priority Objectives of the Outreach and Messaging Group

- Increase support for the HHS Action Plan to Prevent Healthcare-Associated Infections
- Increase knowledge and awareness of key messages and prevention practices among providers, consumers, the media, and general public

Conclusion and Contacts

Healthcare-associated infections are one of the most preventable causes of leading mortality in the U.S. The infections also add a significant economic burden to the healthcare system. The Department, in conjunction with experts, has developed an action plan to help reduce, prevent, and eventually eliminate much of the significant burden to our nation, health systems, communities, and individuals of HAIs.

We strongly encourage you to read the HHS Action Plan to Prevent Healthcare-Associated Infections. For additional details on what is in the Action Plan or on what HHS is doing to address this critical public health issue, please contact the HHS Office of Public Health and Science.

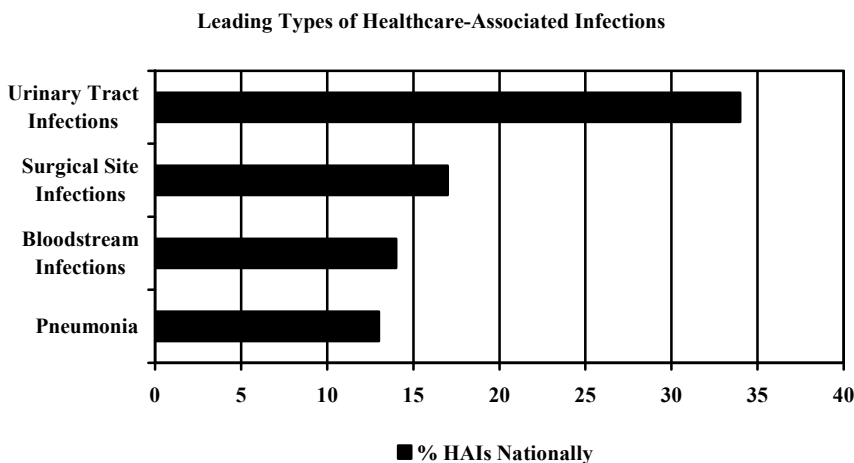
HHS Action Plan to Prevent Healthcare-Associated Infections: INTRODUCTION

Background

Healthcare-associated infections (HAIs) are infections that patients acquire while receiving treatment for medical or surgical conditions. HAIs occur in all settings of care, including hospital acute care units and same day surgical centers, ambulatory outpatient care clinics, and long-term care facilities, such as nursing homes and rehabilitation centers. The infections are associated with a variety of causes, including but not limited to the use of medical devices, such as catheters and ventilators, complications following surgical procedures, transmission between patients and healthcare workers, or are the result of antibiotic overuse. Also, HAI are caused by a variety of infectious agents, including bacteria, fungi, and viruses.

Healthcare-associated infections exact a significant toll on human life. They are among the top ten leading causes of death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002.¹ In hospitals, they are a significant cause of morbidity and mortality. Hospital stays for methicillin-resistant *Staphylococcus aureus* (MRSA) infection have more than tripled since 2000 and have increased nearly ten-fold since 1995.²

Four categories of infections account for approximately three quarters of HAIs in the acute care hospital setting. The frequency of these infections varies by location. Currently, urinary tract infections comprise the highest percentage (34%) of HAIs followed by surgical site infections (17%), bloodstream infections (14%), and pneumonia (13%).³ The chart below indicates the leading types of HAI on a national scale.



¹ Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160-166.

² Elixhauser A and Steiner C. Infections with Methicillin-Resistant *Staphylococcus Aureus* (MRSA) in U.S. Hospitals, 1993–2005. *AHRQ Healthcare Cost and Utilization Project Statistical Brief* 2007; 35:1-10.

³ Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160-166.

In addition to the substantial human suffering exacted by healthcare-associated infections, the financial burden attributable to these infections is staggering. It is estimated that healthcare-associated infections incur an estimated \$28 to \$33 billion in excess healthcare costs each year.⁴ Whereas not all *Staphylococcus aureus* infections are healthcare-associated, healthcare charges for *Staphylococcus aureus* bloodstream infections for Medicare patients exceeded \$2.5 billion in 2005.⁵ The table below illustrates the estimated annual hospital cost per infection by infection site.

Estimated Annual Hospital Cost of Healthcare-Associated Infections by Site of Infection^{6,7}

Major Site of Infection	Total Infections	Hospital Cost Per Infection	Total Annual Hospital Cost (in Millions)	Deaths Per Year
Surgical Site Infection	290,485	\$25,546	\$7,421	13,088
Central Line-Associated Bloodstream Infection	248,678	\$36,441	\$9,062	30,665
Ventilator-Associated Pneumonia (Lung Infection)	250,205	\$9,969	\$2,494	35,967
Catheter-Associated Urinary Tract Infection	561,667	\$1,006	\$565	8,205

Despite the sobering facts, healthcare-associated infections are largely preventable and can be drastically reduced in order to save lives and avoid excess costs. The growing demands on the healthcare system, coupled with concerns of antimicrobial-resistant pathogens and rising healthcare costs, reinforce the imperative to address this issue.

HHS Steering Committee

In recognition of this important public health and patient safety problem, the Department of Health and Human Services (HHS) is presenting a plan to prevent HAIs over the next several years. Successful infection prevention and elimination efforts have been underway for years at the various Operating Divisions of HHS. However, in 2008, HHS began a concerted, Departmental-wide effort to more comprehensively approach the issue. The goal is to marshal the extensive and diverse resources of HHS and collaborate effectively with public and private sector partners to accomplish the large-scale prevention of HAIs.

⁴ Scott Rd. The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention, 2009. Division of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention, February 2009.

⁵ <http://hcupnet.ahrq.gov/>

⁶ Stone PW, Braccia D, Larson E. Systematic Review of Economic Analysis of Health Care-Associated Infections. *American Journal of Infection Control* 2005; 33:501-509.

⁷ Roberts RR, Scott RD, Cordell R, Solomon SL, Steele L, Kempe LM, Trick WE, Weinstein RA. The Use of Economic Modeling to Determine the Hospital Costs Associated with Nosocomial Infections. *Clinical Infectious Diseases* 2003; 36:1424-1432.

In March 2008, the Government Accountability Office (GAO) completed a review of HAIs in hospitals.⁸ The GAO acknowledged HHS-supported efforts and encouraged the Department to further its leadership of addressing HAIs through enhanced coordination of all prevention activities. In particular, the report directed the Department to prioritize existing recommended infection control practices to facilitate their implementation in healthcare facilities. The various information technology systems used to measure HAIs were also highlighted in the report. While there are numerous systems and databases collecting HAI-related data across HHS, the GAO noted a need for greater consistency and compatibility of the data to enhance the information provided, including national estimates of the major types of HAIs.

The Department is committed to protecting the health and safety of all Americans and reducing unnecessary and exorbitant healthcare costs. In response to this important problem, HHS has undertaken several inter-agency initiatives to improve and expand HAI prevention efforts. One of these initiatives was the establishment of the HHS Steering Committee for the Prevention of Healthcare-Associated Infections (Steering Committee).

The Steering Committee included senior-level representatives from the Offices and Operating Divisions of HHS and was chaired by the Principal Deputy Assistant Secretary for Health. The HHS Deputy Secretary charged the Steering Committee with developing an Action Plan to Prevent HAIs. This plan establishes national goals and outlines key actions for enhancing and coordinating HHS-supported efforts. In addition, the plan outlines opportunities for collaboration with external partners to maximize the efforts of all stakeholders.

The Steering Committee utilized a working group structure to accomplish its charge. Each of the five working groups enumerated strategies for accomplishing a portion of the Action Plan:

- The *Prevention and Implementation* group, in partnership with the HHS Healthcare Infection Control Practices Advisory Committee (HICPAC), prioritized existing recommended clinical practices to facilitate implementation in healthcare organizations.
- The *Research* group identified gaps in the existing knowledge base of current infection control practices and developed a coordinated research agenda to strengthen the science for infection control prevention in hospitals.
- The *Incentive and Oversight* group explored opportunities for evaluating compliance with infection control practices in hospitals through required certification processes and identified additional options for the use of payment policies and financial incentives to motivate organizations to provide better, more efficient care.

⁸ United States Government Accountability Office. Health-Care-Associated Infections in Hospitals. GAO-08-283, Washington, DC, April 2008.

- The *Information Systems and Technology* group established a plan to progress towards the standardized measures and data definitional alignment needed to measure HAIs across HHS Operating Divisions and provided opportunities to make the varied HHS data systems interoperable to enhance understanding of HAIs.
- The *Outreach and Messaging* group developed a plan for national messaging regarding HAI prevention to raise awareness among various stakeholder groups across the United States.

Tier One of the Initiative

Given the substantial breadth and depth of HAIs, the Steering Committee decided to concentrate its activities on a first tier of six high priority HAI-related areas within the acute care hospital setting. Surgical site infections, central line-associated bloodstream infections, ventilator-associated pneumonia, and catheter-associated urinary tract infections account for approximately three quarters of HAIs in the acute care hospital setting.⁹ Thus, these four infection categories were included in the initiative's first tier.

In addition, the Steering Committee believed it was important to address an emerging HAI issue, and therefore decided to include two organism specific priorities: *Clostridium difficile*, as well as methicillin-resistant *Staphylococcus aureus* (MRSA) in its first tier efforts. A recent publication demonstrated that *Clostridium difficile* is occurring almost as frequently in the hospital setting as MRSA, impacting resource use and inpatient mortality.¹⁰ MRSA is addressed as a causative organism, given its contribution to the four HAI priority procedures.

While remaining aware of the larger issues regarding HAI prevention, the Action Plan focuses on the setting, procedures, and organisms defined in the first phase. Subsequent stages of the initiative will address additional HAI areas and other types of healthcare facilities (long-term care, nursing homes, ambulatory care settings, etc.).

Key Partnerships

Recognizing that the national prevention of HAIs is a shared responsibility of the government, healthcare industry, and consumers, partnerships are critical to making and sustaining progress in achieving the goals outlined in this plan. As an initial step, the Steering Committee has launched efforts to ensure appropriate stakeholder engagement and input into the development of its Action Plan.

⁹ Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160-166.

¹⁰ Elixhauser A and Jung M. Clostridium Difficile-Associated Disease in U.S. Hospitals, 1993–2005. *AHRQ Healthcare Cost and Utilization Project Statistical Brief* 2008; 50:1-11.

In September 2008, the Department, led by the Centers for Disease Control and Prevention (CDC), convened a meeting of key stakeholders from academia, federal and state governments, consumer groups, etc. with the purpose of soliciting individual input on the setting of national potential prevention targets. At this meeting held in Washington, D.C., foremost experts across the nation identified near- and long-term process and outcome measures for benchmarking progress in the prevention of HAIs.

As this plan begins to be implemented across the nation, HHS will look to its partners to help amplify key messages and the adoption of recommended practices. We can and will accomplish more together, working hand in hand, focused on the end goal of preventing unnecessary infections and their associated consequences.

As with many current and emerging healthcare issues, the success of the nation's healthcare system cannot be measured by the Department's efforts alone. Rather, success in preventing HAIs will be directly dependent on the creation of effective partnerships across the federal government, states, communities, and other private and public organizations to help build and sustain capacity to promote the health and protect the safety of all Americans.

HHS Action Plan to Prevent Healthcare-Associated Infections: PREVENTION – METRICS AND TARGETS

I. Introduction

Ensuring safe healthcare in the United States is an essential part of realizing national goals for a healthy population. The elimination of healthcare-associated infections (HAIs) is an ambitious and challenging goal toward which the healthcare and public health communities have been moving gradually over the past several years. Despite uncertainty about whether there will ultimately be a limit to the extent to which this goal can be achieved, the decision to move toward it has increasingly been embraced.

Although, this process is still imperfect, there continue to be improvements in technologic and procedural capabilities for healthcare delivery and public health surveillance that are gradually bringing us closer to realizing the goal of HAI elimination. The Department of Health and Human Services' (HHS') effort toward this goal is a valuable and timely opportunity to assess which national targets should be addressed first, and what actions should be given the highest priorities in patient care at the bedside, and on the larger scale of communities and health systems. The Action Plan will coordinate where possible and appropriate with existing Departmental efforts, including Healthy People 2020.

The following section will discuss how the proposed national prevention targets were set and how a number of metrics (seven in total) were identified. The metrics should help measure the attainment of these targets to help prevent and control HAIs.

II. Background

In partnership with stakeholders from the medical, public health, and infection prevention and control communities, the Department's Steering Committee for the Prevention of HAIs (Steering Committee) and the Centers for Disease Control and Prevention (CDC) convened a group of scientific experts in HAI prevention and public health in Arlington, VA, on September 25, 2008 in order to provide input on the:

- Development of potential 5-year national prevention targets to be considered for the Action Plan to Prevent HAIs; and
- Identification of potential metrics and systems to assess progress towards these targets.

Participants included representatives from various federal agencies, the Healthcare Infection Control Practices Advisory Committee (HICPAC), professional and scientific organizations, researchers, and other stakeholders. The following is a summary of the outcome of that meeting.

III. Identification of Metrics and 5-year National Prevention Targets

The group of experts was charged with identifying potential targets and metrics for six categories of healthcare-associated infections:

- Central Line-associated Bloodstream Infections (CLABSI)
- *Clostridium difficile* Infections (CDI)
- Catheter-associated Urinary Tract Infections (CAUTI)
- Methicillin-resistant *Staphylococcus aureus* (MRSA) Infections
- Surgical Site Infections (SSI)
- Ventilator-associated Pneumonia (VAP)

By the conclusion of the meeting, a total of 17 potential metrics and associated measurement systems and national 5-year prevention targets were identified. These metrics include both process and outcome measures and covered all six categories of healthcare-associated infections.

The finalized metrics and targets are shown in Table 1 below. (Note: The full list of considered metrics is available in Appendix A). Participants provided input and identified potential metrics using various criteria without attempting to reach consensus. At the meeting the participants divided into six focus groups, based on the six priorities identified earlier. Each of the six sub-groups developed the targets and metrics and brought them forward to the larger group for final discussion.

A sub-set of the HHS Steering Committee reviewed the list of proposed metrics from the meeting participants and identified those metrics that were supported by existing HHS measurement systems. In addition, recognizing the importance of working synergistically with partners, the finalized metrics complement and support existing national metrics and targets identified and/or adopted by key national stakeholder organizations, such as the National Quality Forum (NQF), and many are included in the Society for Healthcare Epidemiologists of America (SHEA)/Infectious Diseases Society of America (IDSA) *Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals*. (Note: The finalized metrics and targets with corresponding metrics from NQF and the SHEA/IDSA *Compendium of Strategies* are listed in Appendix B.) Having shared metrics promotes synergy and efficiency of all organizations working to reduce HAIs.

In the field of infection control and prevention there are a number of abbreviations used by the experts that are often found in the targets and metrics. These abbreviations are:

- ABCs: Active Bacterial Core surveillance
- ADT: Admissions Discharge Transfer
- CLIP: Central Line Insertion Practices
- EIP: Emerging Infections Program
- MDRO: Multidrug Resistant Organism
- NHSN: National Healthcare Safety Network
- SCIP: Surgical Care Improvement Project

Table 1 – Metrics and National 5-Year Prevention Targets

Metric Number and Label	Metric	Measurement System	National 5-Year Prevention Target
1. CLABSI 1	CLABSIs per 1000 device days by ICU and other locations	CDC NHSN; Administrative discharge data¹	CLABSIs per 1,000 device days by ICU and other locations below present NHSN 25th percentile by location type (75% reduction in Stratified Infection Ratio)
2. CLABSI 4	Central line bundle compliance (non-emergent insertions)	NHSN CLIP module	100% compliance with central line bundle (non-emergent insertions)
3. C diff 1	Case rate per patient days; administrative/discharge data for ICD-9 CM coded Clostridium difficile Infections	Administrative discharge data; NHSN MDRO module	30% reduction in the case rate per patient days and administrative / discharge data for ICD-9-CM coded Clostridium difficile Infections NOTE: Preventability of endemic CDI is unknown; therefore, the meeting attendee experts suggested that HHS revisit this target in 2 years as prevention research findings may become available
4. CAUTI 2	# of symptomatic UTI / 1,000 urinary catheter days [Number of UTIs (ICD-9-CM +not present on admission) / (# major surgery ICD-9-CM + urinary catheter ICD-9CM)]*100 discharges	CDC NHSN Administrative discharge data²	25% reduction in the number of symptomatic UTI / 1,000 urinary catheter days 25% reduction in the [Number of UTIs (ICD-9-CM+not present on admission) / (# major surgery ICD-9-CM + urinary catheter ICD-9-CM)]*100 discharges³
5. MRSA 1	Incidence rate (number per 100,000 persons) of invasive MRSA infections	CDC EIP/ABCs	50% reduction in incidence rate of all healthcare-associated invasive MRSA infections
6. SSI 1	Deep incision and organ space infection rates using NHSN definitions (SCIP procedures)	CDC NHSN	Median deep incision and organ space infection rate for each procedure/risk group will be at or below the current NHSN 25th percentile
7. SSI 2	Adherence to SCIP/NQF infection process measures (perioperative antibiotics, hair removal, postoperative glucose control, normothermia)	CMS SCIP	95% adherence rates to each SCIP/NQF infection process measure

¹ Any source that would provide nationally representative hospital discharge coding (i.e., ICD9 or, in the future, ICD10) data, including such sources as the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project, the CDC National Center for Health Statistics or National Hospital Discharge Survey, and those in the Centers for Medicare and Medicaid Services (CMS).

² See above.

³ Zhan C, et.al. Medical Care (in press)

IV. Central Line-associated Bloodstream Infections

Four national 5-year prevention targets and metrics were proposed for central-line associated bloodstream infections (CLABSI). To be consistent with the targets and metrics currently outlined and/or adopted by other national organizations, including the NQF and the SHEA/IDSA *Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals*, the selected targets and metrics listed in Table 1 include one outcome [Metric 1] and one process [Metric 2] metric:

- 1) [Metric1] CLABSI 1: CLABSIs per 1,000 device days by ICU and other locations. [Target1] CLABSIs per 1,000 device days by ICU and other locations below present NHSN 25th percentile by location type (75% reduction in Stratified Infection Ratio).
- 2) [Metric 2] CLABSI 4: Central line bundle compliance (non-emergent insertions). [Target 2] 100% compliance with central line bundle (non-emergent insertions).

Meeting participants discussed several challenges and considerations related to the use of the metrics identified.

- The group focused on ICUs with Metric 1, but proposed that other locations with other specific patient populations could also be used as the sample for the metric. The NHSN is a currently available data source that is designed and validated for this metric. Administrative data might be available as an additional electronic data source in the near future.
- In addition, some participants suggested that standardized algorithms to detect CLABSI be applied to exclude common skin contaminants and other organisms. Participants identified that Metric 2 is challenging because of a lack of an existing data stream. However, the NHSN CLIP module was launched in September 2008.
- Participants suggested several methods of reporting reductions in CLABSIs, including stratified infection ratios, a designated target rate, and a target that is based on performance percentiles within existing data.
- Meeting participants also identified several future needs for CLABSI metrics. These include the need for multiple sampling strategies; better methods to identify changes over time, including assessment, risk stratification, and rates for different risk groups; and a crosswalk gap-analysis across national data sources to understand variables in data sets and data validity.

V. Clostridium difficile Infections

One outcome metric [Metric 3] and 5-year prevention target for the reduction of *Clostridium difficile* infection (CDI) was identified after a review of possible metrics and targets.

- 1) [Metric 3] C diff 1: Case rate per patient days and administrative/discharge data for ICD-9-CM coded *Clostridium difficile* Infections. [Target 3] 30% reduction in the case rate per patient days and administrative / discharge data for ICD-9-CM coded CDIs. (Note: Preventability of endemic CDI is unknown; therefore, the experts suggested that HHS revisit this target in two years as prevention research findings may become available).

The identification of potential metrics was based on current science regarding the feasibility, validity, relevance, and availability of data. In addition to identifying metrics and targets for reduction of *Clostridium difficile* infections (CDI), meeting participants discussed other future needs and challenges summarized below.

- With respect to Metric 3, participants felt that administrative discharge data is potentially valuable for measuring CDI rates, particularly in that it is readily available, nationally representative, and could be used to establish a baseline. However, many also felt that in the future an additional system will be necessary. One possible system is the NHSN MDRO/CDI module.
- More broadly, participants noted that an urgent need exists to evaluate the preventability of CDI in endemic inpatient settings, preferably across a large number of hospitals and the role of patient care environment in transmission of *Clostridium difficile*.
- In addition, they discussed the need for enhanced capability in U.S. hospitals to measure and improve inpatient antibiotic use. One possible initial step is to conduct a survey of U.S. hospitals to identify whether or not an antibiotic stewardship team is in place and, if so, what is the team's purpose and functions at a given institution.

VI. Catheter-Associated Urinary Tract Infections

One specific outcome metric [Metric 4] and an associated target for the reduction of catheter-associated urinary tract infections was identified.

- 1) [Metric 4] CAUTI 2: # of symptomatic UTI / 1,000 urinary catheter days; [Number of UTIs (ICD9+not present on admission) / (# major surgery ICD9+ urinary catheter ICD9)]*100 discharges). This metric includes two possible measurement systems (NHSN or CMS). [Target 4] 25% reduction in the number of symptomatic UTI / 1,000 urinary catheter days; 25% reduction in the [Number of UTIs (ICD9+not present on admission) / (# major surgery ICD9+ urinary catheter ICD9)]*100 discharges.

Several challenges and needs related to the measurement of CAUTIs were identified.

- Participants suggested a comparison of NHSN symptomatic UTI (or available state data collecting similar variables) to administrative discharge data and a review of the UTI definition in non-acute care settings to validate data quality and ensure monitoring of the full burden of CAUTIs. Many experts pointed out current limitations of the UTI definition and proposed that the metric should focus only on bloodstream infections secondary to UTIs.
- In addition, participants suggested that strategies to widely implement “best practices” in the prevention of CAUTIs in a range of settings be developed. Participants felt that these actions would help identify targets and play a vital role in the selection of future metrics.

VII. Methicillin-resistant *Staphylococcus aureus*

One national 5-year prevention target and associated outcome metric [Metric 5] for the reduction of MRSA infections was proposed.

- 1) [Metric 5] MRSA 1: Incidence rate (number per 100,000 persons) of invasive MRSA infections. [Target]: 50% reduction in incidence rate of all healthcare-associated invasive MRSA infections.

Metric 5 is readily available and nationally representative data is available from an existing source. Future needs and challenges related to MRSA measurement are summarized below.

- Participants identified other potential metrics, including a metric measuring the incidence rate of hospital-onset bacteremia based on the NHSN MDRO module. However, the MDRO module is a new component of NHSN without available baseline data. As baseline data is developed and participation in the MDRO module grows, this metric may be considered in the future.
- Participants also felt that a “composite” target to improve sensitivity, reliability, and add confidence that the composite metric reflects reality should be considered in the future.
- The group noted that ongoing evaluation may be needed to determine whether shorter average hospital stays in some healthcare facilities might affect the sensitivity of current measurements of the metric.
- The experts recognized a need to move towards the use of electronic data sources (e.g., laboratory data).

- In addition, while administrative data may be valuable, concerns remain regarding the current administrative data systems' sensitivity and precision in capturing disease related to hospital care. CMS administrative data collected via ICD-9-CM codes have historically been designed and used for reimbursement, rather than public health monitoring, and data is not available for most populations under age 65.
- Other potential next steps identified by the expert participants include implementation of a standardized vocabulary for electronic data capturing of notifiable diseases, antimicrobial susceptibility and clinical data that is used for algorithmic detection of MRSA and other HAIs; evaluation of the need for risk adjustment methods of administrative data from healthcare facilities with patient populations at a disproportionate risk for HAIs; and while the target identified is important, long term efforts may benefit from a broader MDRO prevention effort that would ideally capture both MRSA and other HAIs not currently captured. The steps above were suggested as steps to help improve the quality of MRSA data and assist progress towards the 5-year MRSA prevention targets.

VIII. Surgical Site Infections

Two national 5-year prevention targets and metrics were proposed for surgical site infections (SSI), including one outcome [Metric 6] and one process [Metric 7] metric.

- 1) [Metric 6] SSI 1: Deep incision and organ space infection rates using NHSN definitions (SCIP procedures). [Target] Median deep incision and organ space infection rate for each procedure/risk group will be at or below the current NHSN 25th percentile.
- 2) [Metric 7] SSI 2: Adherence to SCIP/NQF infection process measures (perioperative antibiotics, hair removal, postoperative glucose control, and normothermia). [Target] 95% adherence rates to each SCIP/NQF infection process measure.

Metric 7 consists of five subcomponents which correspond to the SCIP/NQF measures:

- 1) Prophylactic antibiotic received within one hour prior to surgical incision;
- 2) Selection of appropriate prophylactic antibiotic;
- 3) Prophylactic antibiotic discontinued within appropriate time frame after surgery;
- 4) Appropriate post-operative glucose control for surgical patients; and,
- 5) Appropriate hair removal and normothermia.

Numerous other possible metrics and targets were considered in the process of identifying the SSI targets. Participants felt that while the metrics selected may be the best currently available, a number of challenges remain to be implemented for use of these metrics at the national and local levels.

- Participants felt that the validity and feasibility of both metrics needs to be further evaluated, including a cost benefit analysis.
- Use of Metric 6 may require modifications in NHSN data collection, improved tools for collection of denominator data, and standardization of case finding. These improvements to the data collection will require staff and financial resources. Improvements to electronic data systems for surveillance (e.g., the ability to utilize inpatient pharmacy data for surgical site surveillance) should be incorporated into these systems to improve the efficiency and standardization of SSI case finding.
- Other needs identified by participants include harmonization of NQF and SCIP data in order to use the metrics proposed, development of a composite metric to capture performance across the entire spectrum of procedures and risk groups including pediatric SSIs, and re-evaluation of metrics and targets as additional evidence on preventability becomes available.

IX. Ventilator-Associated Pneumonia (VAP)

At this time, no valid outcome or process metric has been identified for VAP.

X. Other Considerations

During the process of identifying national 5-year prevention targets and metrics, a number of considerations, challenges, and next steps to make progress towards meeting the prevention targets were elucidated. These factors are important to consider as recommendations as the proposed targets are further refined and implemented as a part of the HHS effort:

- While it is recognized that the targets and metrics identified as a part of the HHS effort are to be national in nature, some scientific and professional experts commented that it is important that the national measures be linked to bedside actions.
- The refinement of national targets needs further consideration, taking into account existing baselines of data, known interventions, measurement systems to assess progress, and the amount of resources invested.
- There is concern over the potential use of aspirational targets as performance incentives without adequate development of the science base for prevention and feasibility, along with improved measurement systems and increased infrastructure.

- Challenges remain related to resource allocation and workforce development. As HAIs are reduced, the cost of detecting each event will become increasingly great. In addition, the implementation of interventions designed to move towards the target will require resources. While data for some metrics are already being collected, data for others will require additional information to be collected. These new methods of collecting and evaluating data will require staff and financial resources. It is important to limit the additional data collection burden on staff (as much as possible) and healthcare facilities to ensure that the focus of the professionals will be the implementation of prevention interventions that have an impact.
- It is important that existing national data sources identified for metric systems are validated. They need to avoid gaps in data for age groups and other population groups. The feasibility of use of various systems must also be carefully evaluated and used to inform research.
- Process measures data on HAIs is available from multiple sources, including administrative CMS, Quality Improvement Organization (QIO), and CDC data, in addition to data from state organizations and private sector activities. Opportunities exist to improve the use of and explore new uses for this data through linkage, learning, and data validation.
- “Cross-walking” will also be needed between data from systems with direct patient observations, laboratory data, and administrative data.
- Opportunities to move towards electronic data capture and reporting should be evaluated and sought out when possible. Investment in implementation of standards and vocabulary should be considered, along with the development of an enhanced surveillance infrastructure. Collections of data for process metrics often have the potential to be automated. Multiple opportunities to develop and evaluate automated process measures should be considered in the future.
- Development of improved performance measurement methods and systems for such cross-cutting infection control practices as compliance with hand hygiene and contact precautions is needed.
- National efforts to both measure and improve antimicrobial use are needed. These efforts should have a major impact on prevention efforts.
- Overarching targets that measure progress towards important practices and outcomes that indirectly impact HAI prevention should be developed, besides current targets that are fairly disease specific or type-infection specific. Organizational measures, such as nurse/patient ratio, should be explored and considered in developing overarching targets.

- There is a need to leverage and synergize efforts by government agencies, the NQF, the Joint Commission and other accreditation groups, state agencies, and other stakeholders to make an impact on HAI prevention. The identification of metrics and targets is the starting point of a broad effort that relies on the efforts of numerous federal agencies and organizations to reduce HAIs and meet the 5-year prevention targets. These metrics and targets will assist in measuring the impact of these efforts throughout the next five years.

XI. Conclusion and Possible Next Steps

The group also began a discussion as to how the HHS Action Plan could be implemented to achieve the targets. Some key strategies or recommendations for reaching these goals include creating system-improvement programs and extending and improving distribution channels (e.g., states, professional societies, QIOs, health systems). These actions coupled with specific actions related to the metrics and targets would dramatically help prevent HAIs in the United States and reduce both morbidity and mortality.

HHS Action Plan to Prevent Healthcare-Associated Infections: PREVENTION – PRIORITIZED RECOMMENDATIONS

I. Introduction

A 2008 report by the Government Accountability Office (GAO) calls for prioritization of Centers for Disease Control and Prevention (CDC) recommendations for the prevention of healthcare-associated infections (HAIs).

The report emphasized that there are 1,200 such recommendations, accompanied by limited guidance on implementation or prioritization. In response to that report, and as part of the ongoing effort to increase the impact of CDC recommendations, the Department’s Steering Committee for the Prevention of HAIs and the Healthcare Infection Control Practices Advisory Committee (HICPAC) has evaluated and prioritized recommendations from four key CDC guidelines. Prioritized recommendations come from guidelines for the prevention of catheter-associated urinary tract infections (CAUTI), surgical site infections (SSI), intravascular catheter-related bloodstream infections (BSI), and ventilator-associated pneumonia (VAP). The four infection types account for over 80% of all HAI.

These guidelines reflect a range of publication dates and are updated on an ongoing basis. CDC’s guideline preparation process has been updated to ensure that scientific evidence is compiled and evaluated in a consistent, concise, and transparent way.

The guideline for prevention of CAUTI (to be published in 2009) is the first example of this process and includes evidence tables as well as sections on implementation, auditing, and prioritization. As guidelines are updated and healthcare facilities implement recommended practices, priorities will be updated to address current prevention gaps and establish new strategies to address them.

II. Methods

The framework for identifying implementation priorities is based on supporting scientific evidence that a practice is effective/beneficial, recognized gaps in current implementation (i.e., many important practices are fully implemented), synergy with other related practices (i.e., several practices need to be implemented together to have the desired effect), and potential impact. The following process was used for selection of high-priority recommendations from the guidelines for the prevention of CAUTI, BSI, VAP and SSI:

- 1) For each guideline, the pool of recommendations considered for prioritization was narrowed to only those with strong evidentiary support (Category 1A and 1B recommendations). Category 1C recommendations, which include state and

recommendations were considered for prioritization due to the limited number of 1A recommendations for this topic.

Priority Module 1 – Recommendations for Appropriate Pre-Operative Measures

Related HICPAC Recommendations:

- **HICPAC Rec.:** Whenever possible, identify and treat all infections remote to the surgical site before elective operation and postpone elective operations on patients with remote site infections until the infection has resolved (Category 1A)
- **HICPAC Rec.:** Do not remove hair preoperatively unless the hair at or around the incision site will interfere with the operation (Category 1A)
- **HICPAC Rec. :** If hair is removed, remove immediately before the operation, preferably with electric clippers (Category 1A)
- **HICPAC Rec.:** Administer a prophylactic antimicrobial agent only when indicated, and select it based on its efficacy against the most common pathogens causing SSI for a specific operation and published recommendations (Category 1A)
- **HICPAC Rec.:** Administer by the intravenous route the initial dose of prophylactic antimicrobial agent, timed such that a bactericidal concentration of the drug is established in serum and tissues when the incision is made (Category 1A)
- **HICPAC Rec.:** Maintain therapeutic levels of the agent in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room (Category 1A)
- **HICPAC Rec.:** Before elective colorectal operations, mechanically prepare the colon by use of enemas and cathartic agents; Administer nonabsorbable oral antimicrobial agents in divided doses on the day before the operation (Category 1A)
- **HICPAC Rec.:** Use an appropriate antiseptic agent for skin preparation (Category 1B)

Priority Module 2 – Recommendations for Appropriate Intra-Operative Measures

Related HICPAC Recommendations:

- **HICPAC Rec.:** Adequately control serum blood glucose levels in all diabetic patients and avoid perioperative hyperglycemia (Category 1B)
- **HICPAC Rec.:** Keep operating room doors closed during surgery except as needed for passage of equipment, personnel, and the patient (Category 1B)

Priority Module 3 - Recommendations for Appropriate Post-Operative Measures

Related HICPAC Recommendations:

- **HICPAC Rec.:** Protect primary-closure incisions with a sterile dressing for 24 to 48 hours postoperatively (Category 1B)

D. Prevention of Ventilator-Associated Pneumonia

Due to marked severity and high mortality of VAP, this prioritization focuses on the subset of VAP-relevant recommendations within the broader category of healthcare-associated pneumonia prevention. The CDC Guideline for Preventing Healthcare Associated Pneumonia was published in 2003. Additional recommendations included in Module 1 of this prioritization are derived from the 2008 SHEA/IDSA *Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals* and therefore do not carry HICPAC evidence ratings.

Priority Module 1 – Recommendations for Routine Care of Patients Requiring Mechanical Ventilation

Related Recommendations from 2008 SHEA/IDSA *Compendium of Strategies*

- Use non-invasive ventilation whenever possible
- Use orotracheal rather than nasotracheal intubation when possible
- Minimize the duration of ventilation; Perform daily assessments of readiness to wean from ventilation
- Prevent aspiration by maintaining patients in a semi-recumbent position (30-45 degree elevation of head of bed) unless otherwise contraindicated
- Use a cuffed endotracheal tube with an endotracheal cuff pressure of at least 20cm H₂O and in-line or subglottic suctioning
- Perform regular oral care with an antiseptic solution

Priority Module 2 – Recommendations for Appropriate Cleaning, Disinfection, and Sterilization of Ventilator Equipment

Related HICPAC Recommendations:

- **HICPAC Rec.:** Thoroughly clean all equipment and devices to be sterilized or disinfected (Category 1A)
 - a. Whenever possible, use steam sterilization (by autoclaving) or high-level disinfection by wet heat pasteurization at >158°F (>70°C) for 30 minutes for reprocessing semi-critical equipment or devices (i.e., items that come into direct or indirect contact with mucous membranes of the lower respiratory tract) that are not sensitive to heat and moisture (Category 1A)
 - b. Use low-temperature sterilization methods (as approved by the Office of Device Evaluation, Center for Devices and Radiologic Health, Food and Drug Administration [FDA]) for equipment or devices that are heat- or moisture-sensitive (Category 1A)
 - c. After disinfection, proceed with appropriate rinsing, drying, and packaging, taking care not to contaminate the disinfected items in the process (Category 1A)
- **HICPAC Rec.:** Preferentially use sterile water for rinsing reusable semi-critical respiratory equipment and devices when rinsing is needed after they have been chemically disinfected; If this is not feasible, rinse the device with filtered water (i.e., water that has been through a 0.2 μ filter) or tap water, and then rinse with isopropyl alcohol and dry with forced air or in a drying cabinet (Category 1B)

- **HICPAC Rec.:** Between uses on different patients, clean reusable components of the breathing system or patient circuit (e.g., tracheal tube or face mask) inspiratory and expiratory breathing tubing, y-piece, reservoir bag, humidifier, and tubing, and then sterilize or subject them to high-level liquid chemical disinfection or pasteurization in accordance with the device manufacturers' instructions (Category 1B)
- **HICPAC Rec.:** Between treatments on the same patient clean, disinfect, rinse with sterile water (if rinsing is needed), or dry small-volume in-line or hand-held medication nebulizers (Category 1B)
- **HICPAC Rec.:** Between their uses on different patients, sterilize or subject to high-level disinfection portable respirometers and ventilator thermometers (Category 1B)

Priority Module 3 – Recommendations for Appropriate Maintenance of Ventilator Circuit and Associated Devices

Related HICPAC Recommendations:

- **HICPAC Rec.:** Drain and discard any condensate that collects in the tubing of a mechanical ventilator, taking precautions not to allow condensate to drain toward the patient (Category 1B)
- **HICPAC Rec.:** Use only sterile fluid for nebulization and dispense the fluid into the nebulizer aseptically (Category 1A)
- **HICPAC Rec. :** Use only sterile (not distilled, nonsterile) water to fill reservoirs of devices used for nebulization (Category 1A)

IV. Conclusion

The HHS effort currently underway offers a coordinated strategy that makes the best use of currently available technologic and procedural capacities and drives toward future needs. The focus on measurable progress toward specific national target metrics is both practical and efficient.

In order to achieve those targets, we have provided prioritized modules for implementation at the bedside, realizing that priorities will change and be updated as adherence targets are met and new areas for attention are identified. Although current emphasis is being placed on priorities for implementation, safe and effective healthcare still requires correct adherence to all recommended practices for every episode of care.

HHS Action Plan to Prevent Healthcare-Associated Infections: RESEARCH

I. Introduction

A broad, comprehensive research agenda to support a national effort to prevent healthcare-associated infections (HAIs) needs to address the issue from a number of aspects. Increased understanding of the basic science underlying HAIs and their associated pathogens will be critical for informing prevention efforts. A coordinated research agenda needs to be developed in order to strengthen the scientific understanding of these infections. Research into the epidemiology of HAIs needs to be broadened. Gaps in the existing epidemiologic knowledge base should be identified with corresponding research projects targeted to fill those gaps.

To build upon an expanded understanding of the basic science and epidemiology of HAIs, the effectiveness of current infection control practices in hospitals should also be evaluated. New techniques to prevent HAIs need to be identified. Better implementation of existing practices is needed where the scientific basis for these practices already exists. Interventions that utilize technology to promote HAI prevention and provide clinical decision support, as well as the human and organizational factors affecting adoption of effective interventions in hospitals, need to be studied. Additionally, training grants for clinical HAI researchers could augment the resources addressing these issues.

Specific projects for enhancing the implementation and impact of existing, evidence-based practices can then be identified, prioritized, and executed. Lastly, and perhaps most importantly, completely new and innovative approaches will be needed to combat current and emerging challenges related to these infections.

Thus, the two broad goals of the research portion of the initiative were to: 1) identify gaps in the existing knowledge base of current infection control practices in hospitals and, 2) develop a coordinated research agenda to strengthen the science for infection control prevention in hospitals.

II. Current State of the Art and Identified Gaps in Knowledge and Practice

A. Cross Cutting Issues

In preparation for identifying specific research areas, the working group identified gaps in the existing knowledge base of current infection control practices in hospitals. Several cross-cutting issues emerged:

- 1) Adherence to Current Prevention Recommendations Has Been Suboptimal

Adherence to current prevention recommendations in healthcare settings has been generally suboptimal, even when knowledge of recommended practices is 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.

A better understanding of the barriers to adherence, and strategies to overcome those barriers, are needed to promote improvements such as the following:

- a. The use of technology to improve adherence
- b. Better understanding of human and organizational factors that affect adoption and implementation of effective strategies
- c. Standardized methods (i.e., performance methods) 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 healthcare personnel (e.g., compliance hand hygiene, isolation precautions, environmental cleaning practices) in order to prevent infections

2) Demonstrating Preventability through Multicenter Demonstration Projects Has Proven to Be an Effective Strategy for Influencing the Widespread Adoption of Recommended Practices

Preventability is defined for this purpose as the proportion of all cases of a certain HAI that can be demonstrated as possible to prevent through the careful and concerted implementation of current or existing recommendations and/or guidance.

Recent multicenter demonstration projects involving large numbers of healthcare facilities working collaboratively to decrease HAIs by simultaneously implementing a multifaceted prevention program have been able to demonstrate, through standardized data collection, deep reductions in central-line associated bloodstream infections (CLABSIs) in ICUs.

These projects have answered important questions regarding the preventability of this particular infection type, and have likely directly influenced practice across the United States by setting new expectations for prevention.

Additional prevention demonstration projects involving other targeted infections, such as surgical site infection, *Clostridium difficile* infection, and methicillin-resistant *Staphylococcus aureus*, would be helpful.

3) Limitations in Current Surveillance Strategies Exist and There is a Need to Use Electronic Data in Measuring Processes and Outcomes

A critical component of an effective prevention program is 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 healthcare-associated infection 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 surgical procedures. Such strategies may not capture an important and potentially large proportion of healthcare-associated infections that, although the direct result of care delivered during an inpatient stay or in the ambulatory care setting, have their onset in the community.

Strategies that make use of existing electronic data sources for creating process and outcome measures may have a number of important potential 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 healthcare delivery. More research on the use of electronic data for surveillance of healthcare-associated infections is needed.

4) Multicenter Collaborative Trials to Establish the Efficacy of Preventive Interventions are Needed

In addition to multicenter demonstration projects designed to document preventability using current or existing prevention recommendations, there is a need for additional multicenter collaborative trials that are carefully designed and conducted to establish the efficacy of new preventive interventions and further enhance our understanding of the efficacy of existing interventions.

5) Additional Research is Necessary to Strengthen the Scientific Basis for the Acquisition of Healthcare-Associated Pathogens

The scientific basis for the acquisition (including basic pathogenesis, transmission, and colonization) of numerous healthcare-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.

B. Issues Regarding the Specific Tier 1 Procedures and Organisms

The current state of the art and specific gaps in knowledge and practice across three areas:

- 1) Basic and/or Laboratory Science;
- 2) Epidemiology; and
- 3) Prevention Practices are presented for the following healthcare-associated infections:
 - a. Central Line-Associated Bloodstream Infections
 - b. Surgical Site Infections
 - c. *Clostridium difficile* Infections
 - d. Catheter-Associated Urinary Tract Infections
 - e. Ventilator-Associated Pneumonia
 - f. Methicillin-resistant *Staphylococcus aureus*

1) Central Line-Associated Bloodstream Infections (CLABSIs)

Current State of the Art Practice

Detailed recommendations on the prevention of CLABSIs have been developed by the Centers for Disease Control and Prevention (CDC) and Healthcare Infection Control Practices Advisory Committee (HICPAC).¹ Recent investigations have demonstrated that adherence to recommended catheter insertion practices are usually followed by a dramatic reduction in infection rates, suggesting that the preventable fraction of CLABSIs is large.

Efforts to implement “bundles” of catheter insertion practices have been quite popular in the intensive care setting, and although the rates of adherence are largely unknown, data from the National Healthcare Safety Network (NHSN) suggests that the rate of CLABSIs has been decreasing annually across all ICU types reporting data to that system. Although data suggest that the vast majority of CLABSIs occur outside of the ICU, precise data about catheter use and CLABSI rates in this setting, including among non-hospitalized patient populations, is sparse.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Biofilms and their relationship to the pathogenesis of device-associated infections
 - The prevention of biofilm formation or disruption/removal of biofilms in situ
 - Effective strategies and/or techniques for the early detection of CLABSI and for the differentiation of CLABSI from other bacteremias
- Epidemiology
 - A better understanding of CLABSIs occurring outside the intensive care unit is needed
 - Improved methods for surveillance that allow capture of adverse events associated with catheters regardless of patient location are needed
- Prevention Practices

¹ http://www.cdc.gov/ncidod/dhqp/gl_intravascular.html

- What strategies could be developed to inhibit or destroy biofilms as a means of preventing device-associated infections?
- Use of antibiotic lock solutions: Are they effective? Are there unintended consequences (e.g., antimicrobial resistance)? Are there certain patient populations that should be targeted for this practice?
- What is the impact of daily chlorhexidine bathing on CLABSI rates, and does this practice lead to a shift in pathogens causing CLABSI by selecting for certain gram negative organisms that have intrinsic tolerance or antimicrobial resistance?
- What is the impact of chlorhexidine-impregnated sponge dressings?
- How should antimicrobial-impregnated catheters be optimally utilized?
- How do we optimize post-insertion catheter care?
- How do we assure that catheters are promptly removed when no longer clinically necessary?
- How do we optimize catheter care in non-hospitalized patients?

2) Surgical Site Infections (SSIs)

Current State of the Art Practice

Detailed recommendations on the prevention of SSIs have been developed by CDC and HICPAC.² Overall SSI rates have been relatively stable over recent years, although for some procedures, there has been a shift in pathogens for many cardiac and orthopedic procedures SSI [*Staphylococcus aureus* being the major pathogen, with an increasing proportion caused by Methicillin-resistant *Staphylococcus aureus* (MRSA)]. Adherence to current recommendations on the use of peri-operative antimicrobial prophylaxis is generally suboptimal.³

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Biofilms and their relationship to the pathogenesis of infections following procedures involving implantation of devices
 - The prevention of biofilm formation or disruption/removal of biofilms in situ
 - The role of Nitric Oxide, innate adaptive immune response, cytokines, and endotoxemia in the pathogenesis of SSI
- Epidemiology
 - Surgical care has been shifting to the outpatient setting in recent decades and post-operative inpatient stays are becoming shorter. These trends raise challenges in detecting SSIs, as no standardized methods for post-discharge and outpatient SSI surveillance exist, and common approaches to case finding may be inadequate. There is data suggesting that SSI rates reported to the NHSN may be underestimated. More standardized methods

² http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html

³ Bratzler D, Houck P, Richards C, Steele L, Dellinger EP, Fry DE, Wright C, Ma A, Carr K, and Red L. Utilization of Antimicrobial Prophylaxis for Major Surgery: Baseline Results from the National Surgical Infection Prevention Project. *Archives of Surgery* 2005; 140:174-182.

- for SSI case finding are needed, including those that are exportable beyond acute care to ambulatory care centers.
- There are limitations in current risk-adjustment strategies for comparing inter-facility surgical site infection rates. Better risk adjustment strategies are needed.
 - Most of the current prevention recommendations focus on pre- and intra-operative practices. Some recent data suggest that post-operative care may be important in determining whether or not a surgical incision becomes infected. A better understanding of post-operative risk factors for SSI might lead to an important new approach for SSI prevention.
 - Prevention Practices
 - There is uncertainty as to how the trend towards increasing resistance among staphylococcal infections in cardiac and orthopedic procedures should influence optimal antimicrobial prophylaxis practices (e.g., when should vancomycin be included? Should other agents be used?)
 - The effectiveness of certain pre-operative prevention practices requires further study:
 - Pre-operative bathing with antiseptics;
 - Pre-operative screening for staphylococcal colonization and/or routine attempts to decolonize patients with antimicrobial agents prior to surgery;
 - Role of maintaining intra-and peri-operative normothermia;
 - Role of supplemental oxygenation during surgery;
 - Antimicrobial dosing in obese patients; and,
 - Determining whether antimicrobial strategies are different for surgery as compared with device implantation.

3) *Clostridium difficile* Infection (CDI)

Current State of the Art

As identified by CDC, CDI infection rates have been increasing in recent years, mostly due to transmission of a single, fluoroquinolone-resistant epidemic strain with enhanced virulence characteristics. Prevention strategies primarily focus on optimizing antimicrobial use, and in preventing transmission using basic infection control precautions. Since *Clostridium 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
 - Role of immunity in preventing CDI and the most effective vaccine strategies
 - Evaluate for the presence of metronidazole resistance in *C. difficile* isolates
 - Role of the gut flora, precisely what component of the gut flora, is protective

- Changes in the ecology of gut flora in the setting of cancer chemotherapy and antimicrobial therapy
- Role of proctitis and/or nontoxigenic *C. difficile* in reestablishing gut flora ecology
- Basic biology of the sporulation and germination of *C. difficile*
- Development of valid animal models of *C. difficile*-associated diarrhea (CDAD)
- Roles of Toxin B and binary toxin in pathogenesis
- Epidemiology
 - Better assessments of incidence/burden of CDI in the United States, including setting of onset and in relation to healthcare exposures
 - Methodology for measuring transmission and burden of CDI in non-acute care settings (e.g., long term care facilities)
 - Better understanding of the epidemiology of antimicrobial use in inpatient settings
 - Role of asymptomatic carriers in healthcare transmission is unknown
 - Role of *C. difficile* in neonatal/infant diarrhea
 - Better understanding of the incubation period before CDI develops after *C. difficile* acquisition
 - Relative importance of different sources of *C. difficile* transmission in the healthcare setting (e.g., environment versus healthcare workers) and in relation to CDI burden
 - Better understanding of CDI in the community
- Prevention Practices
 - Develop and assess the impact of a *C. difficile* environmental cleaning bundle, role of sporicidal agents (e.g., bleach)
 - Determine the role of extending duration of contact precautions beyond duration of symptoms in reducing transmission of *C. difficile* in healthcare facilities
 - Define optimal measures to reduce unnecessary antimicrobial use
 - Role of gastric acid suppression

4) Catheter-Associated Urinary Tract Infection (CAUTI)

Current State of the Art

Detailed recommendations on the prevention of UTIs have been developed by CDC and HICPAC.⁴ Between 15% to 25% of hospitalized patients may receive short-term indwelling urinary catheters. In many cases, catheters are placed for inappropriate indications, and healthcare providers are often unaware that their patients have catheters, leading to prolonged, unnecessary use.

An estimate of annual incidence of HAIs and mortality in 2002, based on a broad survey of U.S. hospitals, found that urinary tract infections made up the highest number of infections (> 560,000) compared to other HAIs. Although morbidity and mortality from CAUTI is considered to be relatively low compared to other HAIs, the

⁴ http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html

high prevalence of urinary catheter use leads to a large cumulative burden of infections with resulting infectious complications and deaths. In addition, bacteriuria frequently leads to unnecessary antimicrobial use, and urinary drainage systems may serve as reservoirs for multi-drug-resistant bacteria and a source of transmission to other patients.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Biofilms and their relationship to the pathogenesis of urinary catheter-associated infections
 - The prevention of biofilm formation or disruption/removal of biofilms in situ
 - Effective strategies and/or techniques for the early detection of CAUTI
- Epidemiology
 - Quantification of the contribution of urinary tract infection and bacteriuria to antimicrobial use
 - Role of urinary catheter systems as a reservoir for antimicrobial resistant bacteria and how different types of catheters affect the reservoir composition
 - Quantification of unnecessary urinary catheter use
- Prevention Practices
 - Role of newer catheter materials and technology in prevention of CAUTI
 - Appropriate catheter use in incontinent patients
 - Risks and benefits of periodic use of condom catheters in incontinent male patients
 - Risk of local complications (e.g., skin maceration, phimosis) with the use of condom catheters
 - Appropriate use of urinary catheters to manage skin breakdown in incontinent patients or nursing home residents
 - Role of antiseptics in preventing CAUTI (periurethral cleaning, methanamine)
 - Alternatives to indwelling urethral catheters and bag drainage (suprapubic catheters, urethral stent in bladder outlet obstruction, catheter valves)
 - Optimal methods for preventing encrustation in long-term catheterized patients who have frequent obstruction (catheter materials, irrigation, oral urease inhibitors, methanamine)
 - Use of portable ultrasound in patients with low-urine output to reduce unnecessary catheter insertions or irrigations (in catheterized patients)
 - Use of new prevention strategies in patients requiring chronic catheterization such as bacterial interference

5) Ventilator-Associated Pneumonia (VAP)

Current State of the Art

Detailed recommendations on the prevention of VAP have been developed by CDC and HICPAC.⁵ The National Nosocomial Infections Study (NNIS) database from 1992 to 1997 demonstrated that VAP accounted for 27% of ICU infections in the 112 participating ICUs. By 2008, VAP had become the most common nosocomial infection seen in the intensive care unit in several studies and is one of the major causes of severe healthcare-associated morbidity and mortality among ICU patients.

Unlike most other ICU infection syndromes that have relatively low mortality rates, the mortality rate for ventilator-associated pneumonia ranges in most studies between 20% to 50%. For patients hospitalized in the critical care unit, VAP contributes disproportionately both to poor outcomes as well as to substantially higher costs of care. Current approaches to preventing VAP rely on evidence-based strategies that minimize intubation, minimize the duration of mechanical ventilation, as well as minimizing the risk of aspiration of oropharyngeal pathogens.

Multiple 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 seen with this syndrome.

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Gaps in knowledge about the pathogenesis of VAP lead to inconsistency of both definition as well as diagnosis of the syndrome
 - Biofilms and their relationship to the pathogenesis of ventilator-associated pneumonia
 - The prevention of biofilm formation or disruption/removal of biofilms in situ
 - Better understanding of the contribution of endotracheal tube composition to infection pathogenesis
 - Poor understanding of the role of various host factors in the defense against VAP
 - Evaluation of the effects of mucosal and pulmonary immunity on the prevention of VAP
 - The effect of inflammatory lung injury on the susceptibility to VAP
- Epidemiology
 - Lack of a clear understanding of the relative contributions of the large number of complex and confounding variables/risk factors that influence the development of VAP
 - Need a better understanding of the role of broad-spectrum antimicrobials in the development of VAP caused by multiple-resistant pathogens
 - Relationship of endotracheal tube-induced bacterial sinusitis to VAP
 - Understanding the natural tension between the need for adequate nutrition and the increased risk for aspiration and VAP associated with enteral nutrition

⁵ http://www.cdc.gov/ncidod/dhqp/gl_hcpneumonia.html

- Identify and evaluate proxy measures for VAP (i.e., acute lung injury) for inter-facility comparisons that do not require stringent diagnostic approaches
- Diagnosis
 - No “gold-standard” diagnostic technique
 - Role of diagnostic bronchoscopy with culture
 - Role of various microbiological culturing techniques, including quantitative cultures
- Prevention Practices
 - Role of oral decontamination
 - Role of gastric decontamination
 - Secretion management/role of subglottic suction
 - Role of H-2 blockers and sucralfate
 - Role of positioning the patient
 - Degree to which less-invasive ventilatory support (e.g., CPAP, high oxygen therapy, even iron lung) could reduce the need for positive pressure ventilation via endotracheal tube or tracheostomy and whether this could improve overall outcomes
 - Role of antimicrobial impregnated endotracheal tubes
 - Impact of internal ventilator filters and ventilator breathing circuit filters on the risk of VAP
- Implementation
 - Impact of bundles for improving adherence

6) Methicillin-Resistant *Staphylococcus aureus* (MRSA)

Current State of the Art

Methicillin-resistant *Staphylococcus aureus* (MRSA) remains an important cause of healthcare-associated infections, and is endemic in most US hospitals. In addition to adding to the total burden of *S. aureus* infection, healthcare-associated MRSA infections are associated with increased morbidity and mortality when compared to infections caused by methicillin-susceptible strains. MRSA has also emerged as an important cause of infection in the community. 59% of all purulent skin infections evaluated in U.S. emergency departments are caused by MRSA. MRSA infections, both healthcare- 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 healthcare setting is infected or colonized patients, and that patient-to-patient transmission occurs indirectly via transient carriage by healthcare personnel or through contaminated shared equipment. In 2005, there were an estimated 94,000 invasive MRSA infections in the United States. These were associated with nearly 18,000 deaths. Of these invasive infections, 86% were associated with healthcare delivery, and two-thirds of the healthcare-associated infections had their onset outside the hospital setting.

Although the optimal strategy for prevention and control of healthcare-associated MRSA has not been fully determined, it seems likely that successful control requires a multifaceted approach that may vary according to individual characteristics of a healthcare facility, as outlined in the CDC guidance document “Management of Multidrug-resistant Organisms in Healthcare Facilities, 2006.”⁶

Current Gaps in Knowledge and Practice

- Basic and/or Laboratory Science
 - Effective vaccine target antigens
 - Determinants of colonization/carriage (host, organism, environment)
 - Host determinants in the development of invasive versus soft tissue disease
 - Virulence factors associated with MRSA HAI
- Epidemiology
 - Better understanding of colonization and transmission dynamics within the healthcare setting
 - Are there patient characteristics that influence their risk of serving as a reservoir of transmission?
 - Are there patient characteristics that influence the risk of acquiring MRSA carriage?
 - Better understanding of the inter-relationship of healthcare facilities within a region or system in sustaining transmission
 - Better understanding of the impact of community MRSA emergence on healthcare-associated MRSA infection
 - Preventability of endemic MRSA colonization/infection
 - Better understanding of the epidemiology of healthcare-associated MRSA infections that have their onset outside of hospitals
 - Role of fomites in the healthcare-associated transmission of MRSA HAI
- Prevention Practices
 - What is the impact (both intended and unintended) of suppressing or eradicating colonization for the purpose of either preventing infection in colonized individuals or preventing transmission to others?
 - What is the optimal role for active surveillance for detecting asymptomatic carriage?
 - How can transmission be measured? (i.e., how does a healthcare facility know when it is effectively preventing transmission?)
- Implementation
 - Optimal approach to antibiotic-use controls

III. Criteria for Setting Research Priorities

A criterion-based approach was used to identify a set of research projects that should be given high priority in the near term. Four major criteria were applied when evaluating proposed projects:

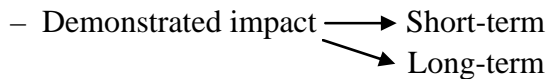
⁶ <http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf>

1) Contribution to Understanding

- Will the project fill a knowledge gap?
Prevalence or Epidemiology: Known/Unknown
Severity: Known/Unknown
Mechanism of Disease or Infection: Known/Unknown
Effectiveness of Present Intervention: Known/Unknown
- What level of evidence will the project yield? Will the evidence likely change behavior?



- Will the project impact be long- or short-term?



- Will the evidence be generalizable?
- Will the project lead to sustainable changes in behaviors, infections, or costs?

2) Feasibility

- Are resources (human, technologic, technical, etc.) available to perform the project?
- Is there an ability to leverage resources?
- Will the proposed research intervention be scalable to other environments?
- Will the proposed study lead to interventions that could potentially reduce burden?

3) Cost

- Are the costs of the project justifiable for the potential health impact?

4) Impact on Public Health

- Are the project results easily understood and of value to policy-makers?
- Are the impacts of projects on the general public easily understandable?
- Is the impact measured in cost, quality of life, redirected resources, etc.?

IV. Proposed Initial Priority Research Projects

In order to develop a list of the research projects that should be given the highest priority for possible initial investment, the gaps in knowledge and practice outlined in Section II were each considered in the context of the criteria for setting research priorities discussed in Section III.

The following list of high priority research projects emerged from that process and represents a research portfolio that addresses gaps in basic science, epidemiology, practice, as well as each of the priority infection types identified by the HHS Steering Committee for the Prevention of Healthcare-Associated Infections. These initial priority projects should not be construed as sufficient to adequately address all HAI prevention research needs, but rather an *initial step* in what should be an ongoing, long-term approach to research that enables continuous learning of HAI prevention.

The scientific understanding of HAI prevention is rapidly evolving, and therefore the *next steps* in HHS-supported research should be determined after consideration of information and knowledge gained from these initial projects and other ongoing research efforts. These determinations should be made on a rolling basis by an interagency group (see Section V).

Recommendations on Projects:

- Projects that Address Specific Knowledge Gaps (Basic Science, Epidemiology, and Practices)
 - a. Basic Science
 - i. Design and implement broad-based studies that define and clearly delineate the pathogenesis of device-associated infection
 - ii. Develop strategies for preventing and/or eliminating biofilms associated with medical devices
 - b. Epidemiology
 - 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.
 - ii. Establish preventability
 - 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 the NHSN to assess impact

2. Establish preventability of unnecessary antimicrobial use through a multi-center 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.
 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 the NHSN to assess impact.
- c. Practices
- i. Perform a large, cluster-randomized study to assess whether ICU-wide application of a MRSA decolonization strategy is effective at reducing healthcare-associated infection and mortality compared to targeted decolonization strategy guided by active surveillance for MRSA colonization
- Projects Designed to Enhance the Implementation and Impact of Existing, Evidence-Based Infection Control Practices
- d. Multidisciplinary investigation of the human cultural and organizational barriers at the unit and institutional level that inhibit the successful implementation of prevention measures
 - e. Improving measurement to support and evaluate prevention practices
 - i. Perform studies to develop and evaluate novel and potentially automatable strategies for measuring healthcare-associated infections, transmission of epidemiologically important pathogens, and related processes of care using electronic data sources routinely captured during the course of patient care
 - ii. Evaluation and validation of standardized post-discharge surveillance methodology that can be used in both inpatient and ambulatory care settings
 - iii. Identify and evaluate proxy measures for VAP (i.e., acute lung injury) for inter-facility comparisons that do not require stringent diagnostic approaches
 - 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 healthcare

personnel (e.g., hand hygiene, isolation precautions, environmental cleaning practices)

V. Long Term Prioritization, Coordination, and Evaluation of Research Efforts

Highlights of the broad areas of current HAI-related responsibilities for the HHS components involved in the Plan's development are illustrated in Appendix C.

Addressing the longer term research needs for healthcare-associated infections for the nation will require a coordinated effort across the Department and with external stakeholders. Many agencies within the Department such as the Agency for Healthcare Research and Quality (AHRQ), CDC, Centers for Medicare and Medicaid Services (CMS), and National Institutes of Health (NIH) have funded research to address healthcare-associated infections and their underlying causes. However, no mechanism currently exists to coordinate these efforts.

Research on the basic science, epidemiology including risk factors, testing of prevention methods and implementation of evidence-based practices, and effects of payment and coverage policy should be linked, so findings from each area can inform and build upon findings in the other areas. For example, if CDC finds a potential population or setting a risk factor for a healthcare-associated infection, this information could help establish potential priorities for AHRQ-funded research on prevention or implementation of evidence-based practices. Synergies will also emerge, i.e., AHRQ could fund research assessing the effect of a CMS change in payment policy or NIH findings could point toward a potential CDC-funded prevention strategy. This coordination will reduce potential duplication and enhance the impact of each agency's work.

Specifically the following mechanism for coordination is proposed:

The Healthcare-Associated Infections Research Working Group is chartered and meets quarterly. This group would have at least two representatives from AHRQ, CDC, CMS, and NIH and representatives from other HHS Operating and Staff Divisions or federal agencies, as needed. The committee would have three main objectives:

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

The proposed Healthcare-Associated Infections Research Working Group should set up criteria and a plan for evaluation of the HHS research program to address healthcare-associated infections. The evaluation should assess the research program and the projects it has specifically funded. Additionally, the Working Group is committed to the ongoing documentation of HAI research gaps. 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 as well as demonstrate effective interventions. The Research Working Group will set up a priori criteria to evaluate the Department's research program on HAIs and a plan for the timing of evaluation, such as annually. The evaluation of the program should lead to adjustments to the program in subsequent years.

VI. Conclusion and Vision for the Future: Creating a Learning Healthcare System in the United States

The large knowledge gaps that exist in HAI prevention are, in part, the result of barriers to new generation of knowledge that currently exist in U.S. healthcare. In a background paper developed and presented at an Institute of Medicine workshop sponsored Roundtable on Evidence Based Medicine and entitled, "Leadership Commitments to Improve Value in Health Care," Platt and colleagues argue 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.

The authors outline major challenges confronting the development of knowledge to support the learning healthcare system. These include: 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 different organizations interpret the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, Institutional Review Boards' varying interpretations of regulations governing the use of these data for research, and 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.

While knowledge gaps do exist, there is much that has been accomplished. The research plans proposed in this section have begun to identify the gaps in the existing knowledge base of current infection control practices in hospitals, a necessary first step in the process to develop a coordinated research agenda that will strengthen the science for infection control prevention practices in hospitals. It is critical that we understand why adherence to current HAI prevention recommendations has been suboptimal, that we

fully understand the specific limitations that exist in current surveillance strategies, and that we have explored how electronic data can be used to measure process and outcomes.

The proposed research projects address the gaps identified in the basic sciences, epidemiology, practices, and the priority infection types identified in the first phase of the initiative. They lay the foundation for further steps that will be informed by the results of the initial projects and other ongoing research. An ongoing challenge will be the identification of projects that will enhance the implementation and impact of existing evidence-based infection control practices. The Department is committed to collaborating within HHS and with external stakeholders to assess current research methods, funding levels, information technology use, and researcher training and to present solutions to facilitate and accelerate knowledge generation. The overall goal is to support the research required to aggressively combat healthcare-associated infections and protect the safety of all Americans.

HHS Action Plan to Prevent Healthcare-Associated Infections: INFORMATION SYSTEMS AND TECHNOLOGY

I. Introduction

Mounting clinical and public health concerns about healthcare-associated infections (HAIs) compel the healthcare community at large to reexamine the approaches to addressing the prevention of HAIs. Advances in information technology, harmonization of disparate data standards, and capabilities to connect with and integrate multiple data types and sources all create new opportunities for the Department of Health and Human Services (HHS) and other federal agencies to re-think and refine strategies to better focus on improving the national capacity to monitor, measure, and prevent the occurrence of HAIs. HHS and other federal agencies share goals with state agencies, hospitals and other healthcare organizations, healthcare practitioners, accrediting and professional organizations, and the public to take action addressing the prevention of HAIs.

Some such common goals that could be addressed through leveraging advances in state-of-the-art information systems and technology might include:

- 1) Achieve more rapid and more complete detection of HAIs by increasing capabilities to exploit current and future data sources. Efforts would initially use available laboratory data sources and computer-based detection algorithms, but actively work toward the inclusion of data from the clinical record of care. This will be possible only when standard terms for HAIs are used routinely and when automated, intelligent systems are applied to identify HAI indicators among a constellation of clinical findings within electronic data resources.
- 2) Increase the rate of dissemination of reporting data to external HAI surveillance activities performed by quality improvement organization and public health monitoring efforts. This will permit rapid detection of patterns and trends for predetermined or ad hoc sets of demographics, thus creating the opportunity to formulate appropriately targeted tactics and execute early prevention and intervention techniques.
- 3) Provide more comprehensive and timely data to focus prevention efforts and measure their effectiveness at the national level at reducing surgical site infections, central line-associated bloodstream infections, catheter-associated urinary tract infections, ventilator-associated pneumonia, methicillin-resistant *Staphylococcus aureus* infections, and *Clostridium difficile* infections.
- 4) Make available the HAI data for an entire episode of care, e.g., both surgical process-of-care data recorded at the healthcare facility where the patient had his/her operation as well as surgical site infection data recorded at another healthcare facility, such as another hospital or a physician's office, when the

patient seeks care there. Spur the nationwide adoption of electronic health record (EHR) systems that can exchange data interoperably 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) Create an “early warning” mechanism that is context-sensitive to HAI prevention reminders or clinical guidelines, either of which might be triggered automatically by findings or clinical plans or actions that are entered into EHR systems, resulting in point-of-care availability of relevant information that can help guide patient care decisions and documentation, such as decisions about contact precautions designed to prevent 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. The Department recognizes that there are some issues with the current systems, despite notable efforts in this arena by federal agencies.

Previous efforts to pursue integration of federal systems for adverse events reporting have produced mixed results because of the challenges of trying to integrate already-existing data and systems. A proactive strategy to integrate data where it originates, in addition to retrospective integration of different federal systems of reporting, would go beyond addressing data “control and fragmentation” issues in clinical care and begin to capitalize on prevention opportunities in the clinical workflow.

Programs at multiple agencies currently 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. In some cases, the lack of an integrated stream of information creates disconnects and results in loss of potentially important information. In other cases, the databases serve such fundamentally different purposes that productive integration efforts may be virtually impossible.

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, provided 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 data from one system with surgical site infection data from another system, with appropriate protections of personally identifiable health data, could provide new insights into near-term opportunities for prevention and quality-of-care improvement.

In other situations, a longer-term strategy to achieve integration will be needed to enable interoperable data exchanges between separate systems and to leverage the standards-based, electronic record keeping and data sharing that have entered the mainstream of U.S. healthcare. 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. Establishing the Foundation for HAI Data Integration and Interoperability

Critical precursors to achieving HAI data integration and interoperability within HHS and across federal agencies should include:

- Increased visibility and priority given to the measurement and prevention of HAIs, so agency heads will incorporate this as a key objective and important priority into 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 gradual and intentional implementation of system and process changes that utilize 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 healthcare improvement goals.
- Close collaboration with private and other public entities that promote, manage, and implement widely adopted healthcare data and technology standards and 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 which have been advanced by the American Health Information Community (AHIC), the Healthcare Information Technology Standards Panel (HITSP), and 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 (NHIN) 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 NHIN and FHISE initiatives. The Nationwide Health Information Network is a collective set of health information exchanges (HIEs), including providers and several federal agencies that are working together as the NHIN Cooperative to securely exchange healthcare data.

The purpose of the NHIN is to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare. The connection of HIEs is a key step in building a “network of networks,” the NHIN. The Federal Health Information Sharing Environment (FHISE) is a framework to help agencies map their business priorities to information-sharing products and identify what interoperable solutions are currently available and in

future planning. The FHISE framework will help agencies to sift through the enormous amount of information available to identify exactly the information, products, and services needed to address problems.

III. Coordination of Efforts: Interagency Working Group

To meet the information technology needs of a national HAI prevention effort, a well-coordinated effort will be required of the Department. Various agencies across HHS house systems and databases containing HAI-related information. These agencies will need to collaborate to find system integration solutions in order to obtain reliable national estimates of HAIs and a more accurate view of the overall issue.

Thoughtful development and successful implementation of specific interagency projects will be essential to improve national-level HAI monitoring and measurement. A coordinated effort will involve enhanced and consistent communication across the Department. This will allow for problems to be approached in a more holistic fashion rather than in its disparate parts.

Programs in existence or development within one or more agencies should be identified and leveraged to aid in the overall prevention strategy. Also, a coordinated effort will potentially reduce duplication of work and enhance the impact of each agency's contribution to the program.

Specifically, the mechanism proposed to accomplish a coordinated effort would be the establishment of an Interagency Working Group. Implementation of this task will serve as the foundation for accomplishing the remaining tasks outlined in the Action Plan. The Interagency Working Group (or "Healthcare-Associated Infections Information Systems and Technology Working Group") should be chartered and will initially be comprised of at least one representative each from the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and ONC, plus representatives from other agencies as designated. The representatives should have an overarching understanding of their respective agency's HAI-related systems and databases as well as the inter-relationships between these systems. They should also have an in-depth knowledge of gaps in HAI data. Project managers of specific systems within these agencies will serve as technical consultants to the Interagency Working Group. In order to facilitate regular communication, the group will meet monthly.

The Interagency Working Group should focus its attention on specific projects that can be completed with a time horizon of one to two years. The highest priority will be placed on projects that combine data from existing systems to improve capacity at the national level to benchmark progress in reducing HAIs. Near-term efforts to link or share data across systems are likely to require some definitional alignment and data element standardization.

Processes should be established for reconciling differences that would otherwise impede progress in completing high-priority projects. For example, selecting common patient identifiers for use in separate databases may be necessary to link patient-level data that provide a more comprehensive measure of HAIs than is available in any single system.

IV. Work Group Goals, Tasks, and Operational Charter

The goals and tasks for the Interagency Work Group are:

Goal A: 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 to ensure that gaps in the available standards are addressed.

Tasks:

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

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

Tasks:

- 1) Reach agreement on what data are needed to benchmark progress.
- 2) Identify HHS databases that are candidates for integration, with emphasis on the strategic opportunities.
- 3) Complete a business analysis of the integration opportunities that are identified.

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

Tasks:

- 1) Compile an inventory of health information system functional components, e.g., clinical decision support. This can be used to reinforce recommended clinical practices.
- 2) 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 HHS data systems interoperable to enhance understanding of HAIs.

Tasks:

- 1) Express strategic opportunities for integration as use cases that describe data flows and what is required to support them.

To accomplish these goals and tasks, the Interagency Working Group should be guided by an operational charter that describes the Working Group's purpose, scope, authority, participants, roles and responsibilities, and stakeholders.

The operational charter should organize the Working Group's efforts around four major objectives:

- 1) Establish and use an information technology strategy
 - a. Develop an overall information technology strategy to support near-term and long-term HAI data integration while safeguarding data from unauthorized access and use.
 - b. Make decisions regarding specific projects and the scope and boundaries of projects incorporated within a coordinated strategy.
 - c. Establish priorities and provide oversight for interagency system integration projects.
- 2) Communicate with stakeholders
 - a. Formulate a communication strategy to be used both within and external to HHS to ensure the highest degree of understanding of priorities.
 - b. Serve as a point of contact for communication to external stakeholders so HHS efforts are coordinated and linked to a broader national coalition.
 - c. Provide status reports and updates to the overall HHS Steering Committee.
 - d. Identify and serve as a conduit to appropriate points of contact within agencies for data/database information.
- 3) Maintain accountability for the work effort
 - a. Design a set of process measures to monitor progress on achieving goals within the information technology strategy.
 - b. Assist related groups (e.g., the Interagency Healthcare-Associated Infections 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 healthcare-associated infections.
- 4) Minimize reporting burden and maximize information output

- a. Formulate a related strategy to streamline and reduce redundancy in HAI reporting from healthcare facilities and limit additional data collection to ease the reporting burden on stakeholders, specifically hospitals.
- b. Use small pilot studies to determine the effectiveness of information technology solutions for minimizing burden and maximizing output before solutions are disseminated and deployed.
- c. Leverage the availability of healthcare data in electronic form, such as microbiology results data, to automate case detection and enable electronic reporting of HAI data wherever possible.
- d. Establish consistent standards and coordinated data collection methodologies for how stakeholders should submit HAI data to various HHS systems.
- e. 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, etc.). As part of these strategies, develop tools for user data entry which span a broad range of technical capabilities and work flows and take into account special needs in healthcare facilities in rural and underserved communities.

V. HAI Data and Data Inventory

An inaugural project for the Interagency Working Group would be an inventory of HAI data and database resources to guide preliminary analysis and decision-making for near-term and long-term data integration projects. Specifically, an HAI data inventory will establish the extent of definitional alignment and data element standardization needed to link or share HAI data across agencies. It also will provide operational guidance on the steps needed to achieve integration and semantic interoperability of HAI data from multiple databases. The inventory should cover HAI databases regardless of whether integration would involve manual integration with other databases or integration through information exchange. Such an inventory is necessary for and will be used to mobilize health information systems to help reinforce appropriate patient safety recommended clinical practices and to seek strategic opportunities to make varied HHS data systems interoperable to enhance understanding of HAIs.

A comprehensive and consistent set of information about different HAI databases is needed to assess definitions of key concepts across databases, the extent of data element standardization, opportunities to combine data from different HAI databases to provide a unified view for benchmarking purposes, and the prospects for interoperable data communications between HHS systems that can serve to improve understanding of HAIs in terms of risk factors, morbidity, mortality, cost, and prevention. In addition, the inventory should provide the conceptual components of and inform the structural framework for an overarching conceptual model to represent knowledge about HAI.

The information that should be included in the HAI data inventory is broad and complex. It should include data specifications that are already compiled and stored in existing databases and groupings of data based on a set of relationships, and it also will involve access to documents and other information sources that will require special effort to analyze and interpret the metadata. Thus, a well designed and carefully planned project should be done with a commitment of qualified project staff and executive sponsorship with allocation of sufficient resources and the concerted efforts and resourcefulness of HHS personnel who serve as programmatic stewards for HAI databases.

The HAI data inventory should be a systematic collection of information about HAI-specific and HAI-related data currently collected and housed in different databases maintained by HHS and other federal agencies that provide national-level data about risk factors, morbidity, mortality, cost, or prevention of HAIs. Specific information about each database should be tabulated and the results summarized in a report that is sufficiently comprehensive and detailed to guide assessments and decisions about definitional and data element harmonization across multiple databases and domains, to identify opportunities for data integration, and to determine the level of readiness of the organization hosting the needed HAI data sources to engage in interoperable data exchanges.

The HAI databases to be inventoried should include, but are not necessarily limited to the following:

Agency for Healthcare Research and Quality (AHRQ)

- Healthcare Cost and Utilization Project (HCUP) database, nationwide inpatient sample
- Network of Patient Safety Databases (NPSD)

Centers for Disease Controls and Prevention (CDC)

- Active Bacterial Core surveillance (ABCs) database
- National Healthcare Safety Network (NHSN) database
- National Hospital Discharge Survey (NHDS) database
- National Inpatient Sample
- Mortality data files

Centers for Medicare and Medicaid Services (CMS)

- Annual Payment Update (APU) database
- Healthcare Cost Report Information System (HCRIS) database
- Medicare Beneficiary Database
- Medicare Patient Safety Monitoring System (MPSMS) database
- Medicare Provider Analysis and Review (MEDPAR) database

Food and Drug Administration (FDA)

- MedWatch
- Manufacturer and User Facility Device Experience (MAUDE) database

Attributes of each database to be inventoried should include, but are not limited to:

- Purpose(s)
- Reporting incentive(s)
- Geographic coverage
- Temporal coverage
- Data sources
- Frequency of data collection
- Definition of key concepts
- Data elements
- File format
- Documentation
- Privacy protection
- Dissemination
- Access
- Requirements for use
- Data Use Agreement

A detailed plan and timetable should identify all phases, activities, and tasks needed to complete the inventory. It is anticipated that the HAI data inventory would be completed within six months of project kick-off. The objectives of this project should be to deliver a comprehensive and well-characterized inventory of HAI data and source databases in a timely manner. The inventory should be used to help identify near-term and long-term integration projects.

VI. Integrating Sources of Data

Based on the database inventory and deliberations by the Interagency Work Group, decisions should be made about which near-term data integration activities are of the highest priority. 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 HAI data inventory. Caution should be applied when re-purposing data while also focusing attention on filling the most important gaps in HAI data coverage.

One example of leveraging current capacity would be to provide a means to share data between CMS's Surgical Care Improvement Program (SCIP) and CDC's National Healthcare Safety Network (NHSN); specifically, surgical process-of-care data from SCIP can be combined on the facility and patient levels with surgical site infection data from NHSN. In the current environment, fundamental differences in purpose, data requirements, and methods among some systems reduce the prospects for meaningful data linkage or sharing. For example, combining HAI incidence data collected by hospital infection control professionals with HAI incidence data collected from coded hospital

discharge records would have only limited value owing to fundamental methodological differences in case detection. Discrepancies between these two methods of HAI case finding preclude meaningful data mergers: One method involves use of information beyond what is documented in medical records, while the other uses only the coded discharge abstract of medical records.

A sustained and well-coordinated effort will be needed by AHRQ, CDC, CMS, and other federal agencies to develop and implement a long-term action plan for systems integration. Longer-term opportunities exist to create a formal information architecture supporting HAI prevention. This work should be guided and informed by the FHISE and NHIN and should take full advantage of the healthcare 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 would enable data integration and should connect federal systems to the standards-based electronic health record systems (EHRs) that are rapidly emerging. Thorough and ongoing use of standards-based solutions should be developed to reduce or obviate the need for abstracting clinical observations from healthcare 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 Interagency Working Group will face many challenges in its efforts to create a successful environment for 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 the infrastructure needed to share the information nationally. Minimizing HAI data reporting burdens on healthcare facilities is a priority, as is close collaboration with accrediting organizations and healthcare professional organizations. Duplication and other data quality issues must be minimized or eliminated when data are aggregated at the national level. Finally, aggregating data from multiple sources will require agreement on common semantics for the data.

An HAI solution must be requirements driven. An early focus on the data required for specific usages should enable better decisions about information systems and technology. Usage scenarios must be developed for the data. It is anticipated that an informatics solution would be developed in iterative phases. The integration of data from disparate sources might initially target 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 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, maintaining strong linkages to HAI data of interest that are captured by various healthcare systems of origin.

An HAI database of the future should contain metadata and support a standard metadata registry, and would also support a knowledgebase 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 enables aggregation and reuse of data from disparate systems, each of which serves a distinct, primary function as well as a secondary purpose in which data are reported to a central system.

VIII. Conclusion

A well-organized and effective Interagency Working Group, informed in its deliberations and decision-making by a systematic inventory of HAI data and databases and a common information model, can complete the fact finding and analytic work needed to refine plans and define resource requirements for integration of HAI data across existing federal systems. 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.

The Department is strategically positioned to catalyze multi-agency 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 standard-setting for healthcare data and information technology. To the fullest extent possible, efforts to enhance return on investment in federal sources of HAI data should be aligned with the NHIN 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.

HHS Action Plan to Prevent Healthcare-Associated Infections: INCENTIVES AND OVERSIGHT

I. Introduction

The Department of Health and Human Services (HHS), specifically the Centers for Medicare and Medicaid Services (CMS), has a variety of tools within its statutory and regulatory authority to encourage the prevention of healthcare-associated infections (HAIs). These tools can be broadly classified as regulatory oversight, financial incentives, transparency and associated incentives, or some combination of these. CMS also has a number of initiatives within each of these broad categories to combat healthcare-associated infections, and the following describes the various ways in which these tools and initiatives support the nation's efforts to prevent infections.

II. Regulatory Oversight

A. Introduction

The Conditions of Participation (CoPs) are the federal health and safety requirements that hospitals and other providers must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to ensure that high quality care is provided to all patients. Compliance with the CoPs is determined by State Survey Agencies (SAs) or Accreditation Organizations (AOs). The SAs survey hospitals to assess compliance with the CoPs. Hospitals are deemed to have met the requirements in the CoPs if they are accredited by national accreditation programs approved by CMS. All Medicare- and Medicaid-participating hospitals are required to be in compliance with CMS' CoPs regardless of their accreditation status.

B. Conditions of Participation

The Medicare CoPs are intended to be the minimum health and safety standards required for the protection of patients, and revisions to the CoPs require an extensive, (and, at times, lengthy) rulemaking process by CMS. When revisions are made to these requirements, particular attention must be paid to the ever-evolving nature of medicine and patient care. Moreover, a certain degree of latitude must be left in the requirements to allow for innovations in medical practice that improve the quality of care and move toward the reduction of medical errors and patient harm. 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 come from federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administrations (OSHA) within the Department of Labor, as well as from other

nationally recognized organizations. Historically, these national federal and private entities have been able to disseminate and update these best practices more quickly than CMS has been able to through its regulatory rulemaking process.

The hospital infection control CoP directly addresses the reduction of HAIs. Rather than continually revising the infection control requirements in the CoPs to meet emerging needs, the CoP is most effective serving used as a baseline requirement for hospitals. This COP baseline 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 (discussed in detail in Section II.D), provide a regulatory 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 the CDC, OSHA, and the Association for Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, and the Association of Peri-Operative Registered Nurses. The guidelines specifically address special challenges to a hospital's infection control program, including multi-drug resistant organisms, communicable disease outbreaks, and bioterrorism, and directly refer to current and nationally accepted sources of information for hospitals on these challenges.

C. Accreditation

As mentioned above, accreditation by a nationally-recognized accreditation program can substitute for an ongoing State review. If a provider entity demonstrates through accreditation by an approved national Accreditation Organization (AO) that all applicable Medicare conditions are met or exceeded, CMS may "deem" those provider entities as having met the Medicare requirements. Accreditation by an AO is voluntary and is not required for Medicare participation. The use of private accreditation for ensuring provider compliance with Medicare requirements began in 1965 when Congress granted statutory deemed status for hospitals accredited by The Joint Commission. The statute was later amended to permit deeming for accreditation by national organizations other than The Joint Commission and for categories of providers beyond hospitals. A national AO applying for approval of deeming authority must provide CMS with a reasonable assurance that the AO requires accredited provider entities to meet requirements that are at least as stringent as the Medicare CoPs.

In addition to The Joint Commission's hospital program, hospitals currently have two other accreditation options. CMS has granted hospital deeming authority to the American Osteopathic Association (AOA) and Det Norske Veritas Healthcare (DNVHC). Specifics on each include:

- 1) AOA has had CMS approved hospital deeming authority since 1966 and is approved through September 25, 2009. CMS recently approved DNVHC's application for recognition as a national accreditation program for hospitals, effective September 26, 2008 through September 26, 2012.
- 2) DNVHC's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare CoPs. In addition, the program conducts annual, rather than triennial, surveys to ensure ongoing compliance.

Currently, there are approximately 4,072 Joint Commission-accredited hospitals, which is 83 percent of all hospitals (4,921) participating in the Medicare program. There are approximately 157 AOA-accredited hospitals; approximately half of these hospitals are dually-accredited by the Joint Commission and AOA. In total, over 84% (4,146) of all Medicare-participating hospitals are deemed by these AOs. Hospitals accredited by CMS-recognized AOs, are not subject to routine Medicare surveys by SAs. However, these hospitals are subject to validation surveys conducted by SAs on behalf of CMS in response to allegations of significant deficiencies which, if substantiated, would adversely affect the health and safety of patients.

Recently, Section 125 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) removed The Joint Commission's statutorily-guaranteed accreditation authority for hospitals, to be effective July 15, 2010. At that time, The Joint Commission's hospital accreditation program will be subject to CMS requirements for AOs seeking deeming authority. To avoid a lapse in deeming authority, The Joint Commission must submit an application for hospital deeming authority consistent with these requirements and within a time frame that will enable CMS to review and evaluate their submission.

D. Survey and Certification

The survey and certification program is designed to ensure that providers and suppliers comply with CoPs. CMS works with the SAs to conduct on site facility inspections for the vast majority of facilities that seek Medicare participation. Only certified providers, suppliers, and laboratories are eligible for Medicare or Medicaid payments. Currently, the CMS Survey & Certification Group oversees compliance with Medicare health and safety standards for more than 271,000 medical facilities of different types, including hospitals, laboratories, nursing homes, home health agencies, hospices, and end stage renal disease facilities. There are approximately 7,200 active SA surveyors nationwide (about 6,500 full-time equivalents), with roughly 500 dedicated to hospital surveys.

In FY 2008, CMS successfully trained more than 70% of the hospital surveyors on the new revised hospital interpretive guidelines for infection control (revised

November 21, 2007.¹ The interpretive guidelines are sub-regulatory, or a manual version of how CMS, through the SA surveyors, enforces regulatory requirements, including those associated with infection control. This November 2007 revision to the hospital interpretive guidelines for infection control was updated to reflect changing infectious and communicable disease threats as well as current and nationally-recognized infection control guidelines, best practices, and other resources for hospitals.

When deficiency findings, such as deficient infection control practices, are identified through a hospital or other setting survey, the information is captured in a database. In FY 2007, an infection control deficiency was cited 1% of the time on average. The database has several deficiency identifiers or tags that are related to infection control. 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 breakdown the CoP for infection control into subparta to specifically capture in our database whether the hospital is in compliance with having the required designated infection control officer (which “crosswalks” directly in CMS’s database to A-748).

Hospital complaints have typically been the second highest volume of complaints CMS receives among all the Medicare provider types certified. When the top allegations for complaints are examined, infection control issues are consistently in the top 12 (see Appendix D).

E. Recommendations and Action Plans

Conditions of Participation

The Medicare Hospital Infection Control CoP was first published over 20 years ago. Since then, infections such as HIV/AIDS, SARS, West Nile virus, avian influenza, and MRSA (to name but a few) have emerged and have been quickly followed by infection control guidelines. These tend to be specific to each emerging infection and are issued by nationally recognized organizations. The national organizations have typically revised the guidelines as needed to keep pace with new developments and as a way to help hospitals continue to track, monitor, and prevent such diseases.

However, as new sources of infection and communicable disease present new challenges to patient care, Medicare infection control requirements need to remain flexible and broad enough in their scope so that hospitals are able to incorporate the most current infection prevention and control guidelines into their programs. Shifting toward a more prescriptive regulatory approach (i.e., one that would focus on the prevention and control of specific infections and communicable diseases as would need to be designated in the regulatory text) would be a move backward to a more rigid and process-oriented regulatory structure. It would also be a move away from the more flexible and evidence-based approach that continues to prove a more successful model for reducing harm and improving outcomes for patients. Currently,

¹ www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=2&sortOrder=descending&itemID=CMS1205726&intNumPerPage=10

the Infection Control interpretive guidelines make direct reference to the evidence-based infection control guidelines and recommendations established by nationally-recognized organizations.

The following recommendations would further strengthen the commitment to quality in the prevention of HAIs:

- Require that a hospital ensure that their infection control program follows currently recognized standards of practice as established by national organizations.
- Require that the infection control program be an integral part of the hospital's quality assessment and performance improvement (QAPI) program. While the current Infection Control CoP does require that the hospital-wide quality assurance program address the problems identified by the infection control officer, this revision would more directly link the Infection Control CoP with the equally important QAPI CoP and would require hospitals to pursue a more proactive and innovative approach to infection control through their ongoing QAPI program.

Accreditation

In July 2004, the Government Accountability Office (GAO) made several recommendations to improve CMS oversight of the hospital accreditation program.² The recommendations included modifying the method used to calculate the disparity rate, identifying additional indicators of The Joint Commission's performance, and increasing the validation sample size. CMS' current and planned actions to enhance oversight of hospital accreditation are described below:

- Methodological Changes to Improve Oversight – CMS is assessing differing approaches to refining and improving the current method of measuring AO performance in assuring compliance with the CoPs. CMS secured the services of a contractor in FY 2006 to assist in this endeavor, which is expected to be expanded to address all AOs and all deemed programs. However, a revised approach to performance assessment may also require regulatory revisions.
- Analysis of Complaint Data – CMS is investigating cost-effective approaches to enhancing hospital survey activities, including integration into our overall assessment of the AO's performance, as a result of complaint investigations conducted in hospitals. CMS continues to work with a contractor to explore the utility of the complaint data as a means to assess the performance of the AOs.

Survey and Certification

In the survey and certification area, CMS and experts have identified a number of future enhancements for regulatory oversight of hospitals as recommendations:

² GAO-04-850, *CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals*

- Increase hospital surveyor training on recent revisions of hospital interpretative guidelines to ensure that 100% of dedicated hospital surveyors have the opportunity to be trained on the revised guidelines.
- Incorporate enhancements, which arise from collaborative activities with the CDC, into the surveyor training program as a means of providing surveyors with illustrative examples of best infection control practices in hospitals.
- Conduct a pilot of a surveyor tool. Piloting of a modified version of a CDC-developed surveyor tool for comprehensively assessing infection control practices in ambulatory surgical centers has begun. Depending on the assessment of the pilot experience, CMS may develop another version of the tool that could be employed in the hospital setting. This would require partnership with CDC for applicability to hospital setting.
- Consider instructing surveyors to assess compliance with infection control practices on every hospital complaint survey, in addition to assessing compliance with requirements related to the complaint allegation.
- Consider requiring AOs to also make assessment of infection control a priority focus.
- Partner with the AOs on sharing complaints or survey findings where infectious disease findings occurred.
- Consider joint educational intervention, such as a conference, with the AOs on the subject of infection control compliance. (Note this might be subject to privacy provisions and not be easily implemented.)
- Consider strengthening the relevant sections of the CoPs related to infection control and quality assurance/performance improvement.
- Consider adding a performance/evaluative metric related to hospital acquired infections. This could be accomplished in collaboration with CDC and AHRQ and using systems such as CDC's National Healthcare Safety Network (NHSN).

III. Value Based Purchasing (VBP) 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 value-based purchasing (VBP) and related initiatives. These 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 a more active purchaser of higher value health care services.

The Preventable Hospital-acquired Conditions (HAC) Provision, and Present on Admission Indicator Reporting, and Hospital Pay-for-Reporting are three 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, and CMS has presented an approach to transition from pay-for-reporting to performance-based payment in the Hospital Value-Based Purchasing Plan Report to Congress. Each of these initiatives is discussed in turn below.

B. Hospital-Acquired Conditions and Present on Admission Indicator Reporting

Introduction

The HAC provision is one approach that CMS is using to combat healthcare-associated complications, including infections, in the hospital setting. The Medicare statute requires CMS to select conditions that will no longer trigger higher payment when they are acquired during hospitalization.

CMS selected conditions must be: (1) high cost, high volume, or both; (2) assigned to a higher paying Medicare-severity diagnosis-related group (MS-DRG) when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.

Beginning October 1, 2008, Medicare can no longer assign an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is listed on the claim and was not present on admission. That is, the case will be paid as though the condition were not present. Medicare will continue to assign a discharge to a higher paying MS-DRG if the selected condition is present on admission. However, if any non-selected complicating condition appears on the claim, the claim will continue to be paid at the higher MS-DRG rate.

CMS has also begun collecting a present on admission (POA) indicator 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 HACs for payment purposes, and this information is also potentially valuable for the broader public health uses of Medicare data.

Inpatient Proposed Payment System Payment Incentives

Medicare’s Inpatient Proposed Payment System (IPPS) encourages hospitals to treat patients efficiently. Hospitals generally receive the same payment for stays that vary

in the patient’s length of stay and in the intensity of the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, complications, including infections, acquired in the hospital do not generate higher payments than the hospitals would otherwise receive for uncomplicated cases paid under the same DRG. To this extent, the IPPS encourages hospitals to avoid complications, including infections.

However, complications acquired in the hospital can generate higher Medicare payments. For instance, under the MS-DRGs that took effect for hospital payment in FY 2008, there are currently 258 sets of MS-DRGs that split into two or three subgroups based on the presence or absence of a complicating condition (CC) or major complicating condition (MCC).

If a condition is one of the conditions on the CC or MCC list, the hospital receives a higher MS-DRG payment, unless CMS selected the condition as an HAC and the condition was not present on admission. Medicare continues to assign a discharge to a higher paying MS-DRG if the selected condition is present on admission.

The following table demonstrates how payments are made on average depending on the MS-DRG assignment and the POA Status of a single secondary diagnosis:

MS-DRG Assignment (Examples for a single secondary diagnosis)	POA Status of Secondary Diagnosis	Average Payment
Principal Diagnosis: MS-DRG 066 <ul style="list-style-type: none"> ▪ Stroke without CC/MCC 	--	\$5,347.98
Principal Diagnosis: MS-DRG 065 <ul style="list-style-type: none"> ▪ Stroke with CC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Injury due to a fall (code 836.4 (CC)) 	Y	\$6,177.43
Principal Diagnosis: MS-DRG 066 <ul style="list-style-type: none"> ▪ Stroke with CC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Injury due to a fall (code 836.4 (CC)) 	N	\$5,347.98
Principal Diagnosis: MS-DRG 064 <ul style="list-style-type: none"> ▪ Stroke with MCC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Stage III pressure ulcer (code 707.23 (MCC)) 	Y	\$8,030.28
Principal Diagnosis: MS-DRG 066 <ul style="list-style-type: none"> ▪ Stroke with MCC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Stage III pressure ulcer (code 707.23 (MCC)) 	N	\$5,347.98

This example 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 HAC Selection

CMS clinical quality experts have worked closely with public health and infectious disease experts from the CDC to identify the 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 receive individual input from the over 500 interested organizations and individuals who participated. CMS and CDC received verbal comments during the listening session and subsequently received numerous written comments. CMS has also sought public comment during FY 2007, FY 2008, and FY 2009 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 the CDC, other federal agencies, and stakeholders in the refinement and expansion of the HAC payment provision. As a next step, CMS and CDC intend to jointly sponsor a second HAC and POA Listening Session in December 2008.

HAC Selection Criteria

In selecting proposed candidate conditions and 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 diagnosis code that clearly identifies that condition, is designated as a CC or an 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 a higher paying DRG.

The third criterion requires that a selected condition must be considered reasonably preventable through the application of evidence-based guidelines.

Guidelines developed by entities such as the HHS Secretary's Healthcare Infection Control Practices Advisory Committee (HICPAC), professional organizations, and academic institutions were reviewed to evaluate whether guidelines are available that

hospitals should follow to prevent 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.

In addition, the third criterion requires that a selected condition be considered reasonably preventable when the interventions in the guidelines are followed. The absence of evidence quantifying the extent to which application of evidence-based guidelines results in the prevention of certain conditions, including infectious conditions, also limits the universe of candidate conditions.

Selected HACs for 2009

After evaluating proposed candidate conditions against the statutory criteria and considering public comments received during FY 2007, FY 2008, and FY 2009 IPPS rulemaking, CMS and CDC experts selected 10 categories of conditions to which the HAC payment provision will apply beginning October 1, 2008. The HACs are more precisely defined by specific diagnosis codes (see Appendix E for specific codes).

HACs - 10 Categories of Conditions
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 - Electric Shock
6. Catheter-Associated Urinary Tract Infection (UTI)
7. Vascular Catheter-Associated Infection
8. Manifestations of Poor Glycemic Control
9a. Surgical Site Infection, Mediastinitis Following Coronary Artery Bypass Graft (CABG)
9b. Surgical Site Infection Following Certain Orthopedic Procedures
9c. Surgical Site Infection Following Bariatric Surgery for Obesity
10. Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures

Enhancements and Future Issues

Each year through IPPS rulemaking, CMS will 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, stakeholders have suggested that water-borne pathogens be considered, that the surgical site infection category be expanded, and that ventilator-associated pneumonia and *Staphylococcus aureus* septicemia be reconsidered. The ability to select additional conditions will depend on the development of evidence-based guidelines 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 methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* should 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. 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 evidence-based guidelines for the prevention of infectious agents are defined and enhanced, these infectious agents may be reconsidered as candidates for the HAC payment provision in future rounds of IPPS rulemaking.

Several means to make the HAC payment policy more precise could be considered in the future, including risk adjustment, implementation of a more sophisticated VBP model based on occurrence rates for conditions over time, and adoption of ICD-10. Rather than not paying any additional amount when a selected HAC occurs during hospitalization, payment reductions could be made proportional to the patient's or patient population's risk – the relative likelihood of acquiring a particular condition during hospitalization. This approach may recognize that medical history, co-morbidities, and severity of illness, among other factors, affect the expected occurrence of complications.

The application of a performance-based payment model that incorporates complication rates over time may be a more meaningful, actionable, and fair way to adjust a hospital's payments up or down based on the incidence of HACs (see discussion below in Section III.D.2, entitled, "Hospital Value-Based Purchasing Plan Report to Congress").

The adoption of ICD-10 would provide a better infrastructure for the HAC payment policy. Having more specific coding information would facilitate more precise identification of HACs. The adoption of ICD-10 has been proposed through rulemaking.

Collection of the POA indicator will provide important information, not only for Medicare payment, but also for enhancing public health. Researchers should be able to use POA data for risk adjustment of quality measurement data and to gain insights into the incidence of conditions in the community and in hospitals. The POA data can

be analyzed for only Medicare beneficiaries or can be combined with private sector or state POA data to support broader conclusions. In addition, POA data, including POA data about hospital-acquired infections, could inform publicly reported information to support better health care decision making by consumers and professionals.

C. Hospital Pay-for-Reporting

Another approach CMS has adopted as it transforms the Medicare program from a passive payer towards the goal of being an active purchaser of higher quality, more efficient health care is hospital pay-for-reporting.

This initiative is intended 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 provided to all patients. In December 2002, the HHS Secretary announced a partnership with several collaborators intended to promote hospital quality improvement and public reporting of hospital quality information. These collaborators included the American Hospital Association (AHA), the Federation of American Hospitals (FAH), the Association of American Medical Colleges (AAMC), the Joint Commission on Accreditation of Healthcare Organizations (now called The Joint Commission), the National Quality Forum (NQF), the American Medical Association (AMA), the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons (AARP), the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), AHRQ, as well as CMS and others. In July 2003, CMS began the National Voluntary Hospital Reporting Initiative. This initiative is now known as the Hospital Quality Alliance (HQA): Improving Care through Information.

CMS established a “starter set” of 10 quality measures, used to gauge how well an entity provides care to its patients. Measures are based on scientific evidence and can reflect guidelines, standards of care, or practice parameters. A quality measure converts medical information from patient records into a rate or percentage that allows facilities to assess their performance.

This set includes measures addressing acute myocardial infarction, heart failure, and pneumonia, for voluntary reporting as of November 1, 2003. The 10 quality measures were endorsed by the NQF, a voluntary consensus standard-setting organization established to standardize health care quality measurement and reporting. In addition, this starter set is a subset of measures currently collected for The Joint Commission as part of its hospital inpatient certification program. CMS chose these 10 quality measures to collect data that would: (1) provide useful and valid information about hospital quality to the public; (2) provide hospitals with a sense of predictability about public reporting expectations; (3) begin to standardize data and data collection mechanisms; and (4) foster hospital quality improvement.

Hospitals submit quality data through the secure portion of the QualityNet Web site (formerly known as QualityNet Exchange) (www.QualityNet.org). Data from this

initiative are used to populate the Hospital Compare Website (see discussion in Section IV.B below).

Hospitals that did not submit data received a reduction of 0.4 percentage points to their update percentage increase (also known as the market basket update) for each of FYs 2005 through 2007, establishing an incentive for Inpatient Proposed Payment System (IPPS) hospitals to submit data on the specified 10 quality measures. The reduction to the update has subsequently increased from 0.4 to 2.0 percentage points for FY 2007 and beyond. For FY 2008, CMS required that hospitals submit data regarding 27 quality measures. The quality data collected includes a number of infection-related measures and encompasses the following conditions: 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 HCAHPS patient survey.

CMS will collect a total of 42 quality measures for FY 2010, including: (1) Nine CMS-calculated AHRQ Patient Safety Indicators (PSIs) and Inpatient Quality Indicators (IQIs) that have been endorsed by the NQF; (2) another NQF endorsed measure, Participation in a Systematic Database for Cardiac Surgery; and (3) a heart failure readmission measure.

Specific infection-related measures include:

- Timing of receipt of initial antibiotic following hospital arrival
- Blood culture performed before first antibiotic received in hospital
- Appropriate initial antibiotic selection
- Prophylactic antibiotic received within one hour prior to surgical incision
- Prophylactic antibiotics discontinued within 24 hours after surgery end time
- Surgical Care Improvement Project (SCIP) Infection 2: Prophylactic antibiotic selection for surgical patients
- SCIP Infection 4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
- SCIP Infection 6: Surgery patients with appropriate hair removal

CMS anticipates adopting additional readmission measures as discussed in the FY 2009 IPPS final rule, pending endorsement by the NQF.

The maintenance of measure specifications occurs through publication of the Specifications Manual. Thus, measure selection occurs through the rulemaking process; whereas the maintenance of the technical specifications for the selected measures occurs through a sub-regulatory process so as to best maintain the specifications consistent with current science and consensus. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet web site at www.QualityNet.org.

D. Demonstration Projects

The Medicare Program has a long and successful history of developing program initiatives through its demonstration authority. At any given time, CMS has over three-dozen demonstrations in its portfolio, including demonstrations under development, demonstrations in operation, and demonstrations that are in a close-out phase. The development and implementation of these demonstrations frequently provide the agency practical lessons on policy tradeoffs and objectives, details related to operations of a specific pilot program, and unanticipated issues related to how to recruit and engage demonstration participants.

In addition to these practical design and implementation issues, formal evaluations play a critical part of any demonstration. CMS' Office of Research, Development, and Implementation conducts full evaluations of each demonstration project with help from experts from the research community. 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, the Congress, and the public.

CMS currently has several demonstration projects that are designed to test methods to improve the value of healthcare. One of the most important of these is the Premier Hospital Quality Incentive Demonstration, which includes 250 hospitals in 38 states in collaboration with Premier, Inc., which operates a large quality measurement and improvement operation. That demonstration started in October 2003, and has documented substantial improvements in the quality of inpatient care. The demonstration is measuring and providing 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. In the initial three years of operations, the demonstration hospitals have improved their quality of care in five clinical areas by an average of 16 percentage points.

CMS has extended the demonstration for a second three-year period. CMS added new quality measures for testing, including all of the Surgical Care Improvement Project (SCIP) measures. These measures have just recently been added to the demonstration, so it is too early to determine the extent to which these new measures have shown improvement.

In developing demonstrations, CMS uses the most recent available quality measures wherever applicable, including the SCIP measures, which are included in the two related gainsharing demonstrations. These demonstrations are designed to study whether incentives for collaborative arrangements between hospitals and physicians can improve the quality and efficiency of care provided to Medicare beneficiaries. The demonstrations are intended to provide for parallel incentives for hospitals and physicians, thus improving coordination and quality. Efficiencies will be measured in internal hospital costs, and if the hospitals are successful in reducing their costs, they may share savings with physicians and with clinical staff. Examples of greater efficiencies include providing diagnoses faster and thus reducing length of stay,

improving the turnaround in operating rooms, reducing the use of redundant tests, and the use of innovative products to improve treatment efficiency. CMS is carefully tracking quality of care in participating hospitals to assure that the demonstration results in improved care, and not in any reduced quality. Among the measures of quality are SCIP measures including 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.

The SCIP measures are also included in a key demonstration that is intended to improve inpatient quality of care, the Acute Care Episode (ACE) Demonstration. In this demonstration, scheduled for implementation in early 2009, Medicare will pay up to 15 hospitals in Texas, Oklahoma, Colorado, and New Mexico a “global fee” for cardiac and orthopedic procedures. The global fee is a bundled payment for both hospital and physician costs, including the surgeon, any consultants, radiologists, anesthesiologists, or other physicians included in the care of the patient.

The participating hospitals and physicians will be 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 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 selection and administration of antibiotics and deep sternal wound infection rate.

Thus, in three important Medicare demonstrations that involve inpatient costs and efficiency, CMS has measured the quality of care using available quality measures, and that these measures will be monitored on a regular basis to track progress toward improving quality. If any demonstration hospital were found to be unable to maintain high levels of quality, that participating hospital could be removed from the applicable demonstration. The measurement and evaluation of hospital-acquired infections are an important part of this evaluation, and the Medicare demonstrations program will continue to include HAI measures, as they are developed, standardized, and available for use in the demonstration projects.

E. Hospital Value-Based Purchasing Plan Report to Congress

Introduction

On November 21, 2007, CMS submitted a Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program (the Plan).³ The Plan would build on the current hospital pay-for-reporting program discussed above and establishes performance-based Medicare hospital payment. Under value-based purchasing (VBP), a portion of hospital payment would be contingent on actual performance, rather than simply on a hospital’s reporting of measurement data. The VBP performance measures would include infection rates.

³ www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf

Hospital VBP would provide powerful incentives – both financial and non-financial – for discouraging hospital-associated infections. Payments to higher performing hospitals would be larger than those for lower performing hospitals, providing financial incentives to drive improvement. Public reporting of performance on Medicare’s Hospital Compare website, (discussed below in Section IV) would provide non-financial incentives to encourage hospital performance improvement.

Extensive public input was sought during each phase of plan development. Two Listening Sessions to receive individual input from organizations and individuals were held: the first to discuss the key issues in hospital performance-based payment and a second to discuss design options for the Plan. The Listening Sessions elicited over 100 comments. Comments were also sought during FY 2007, FY 2008, and FY 2009 IPPS rulemaking. In addition, on several occasions, CMS leaders met with leaders from national hospital organizations to discuss issues related to Plan development.

Hospital VBP Performance Assessment Model and Incentive Payments

The performance assessment model is the methodology that would be used for scoring hospital performance on specific measures. Those aggregate scores would then be used to determine an incentive payment. The model evaluates a hospital’s performance on each measure based on the highest of either an attainment score or an improvement score. The improvement score would be determined by comparing the hospital’s current score with its baseline performance.

A hospital’s performance on individual measures would be summed within each measurement domain – such as process of care, outcomes, or patient experience – and then the domains would be weighted and summed to yield the hospital’s total performance score. Using an exchange function, the hospital’s total performance score would be translated into an incentive payment. The source of the incentive payment would be a percentage of the hospital’s base operating DRG payments. Essentially, hospitals would have to earn back a portion of their Medicare payments by performing at a high level or improving their performance.

Hospital VBP Measures

Measures are the foundation of performance-based payment. To qualify for the incentive payment under the Plan, a hospital must report on all measures relevant to its service mix. Measures of various aspects of healthcare quality, such as patient safety, process of care, outcomes, patient experience, efficiency, and care coordination, would be added over time. A subset of the current hospital pay-for-reporting measures would be used for initial implementation, including the current infectious-condition measures related to pneumonia and surgical infection prevention. As measures related to infectious conditions emerge from development and testing, they would be adopted for the VBP financial incentives and public reporting.

Other Issues in the Hospital VBP Plan

The Hospital VBP Plan addresses a number of other issues related to the design and implementation of hospital performance-based payment. The current infrastructure for reporting hospital data would be improved through streamlining the submission process, allowing resubmissions, improving feedback reports, enhancing user support, and strengthening data validation. The Hospital Compare website could continue to serve as the platform for public display of performance results. Given the relative newness of performance-based payment, mechanisms for real-time monitoring and in-depth evaluation would be necessary for timely corrective action of unintended consequences and future enhancements.

Enhancements and Future Issues

CMS continues to refine the Hospital VBP Plan and to test the financial impact that the Plan would have on various types of hospitals if it were implemented. Preliminary tests show that the Plan would reward hospitals that achieve high levels of attainment or improvement, without unintended re-distributional effects.

In implementing the Hospital VBP Plan, the measures for the financial incentive and public reporting would continue to evolve. A patient safety domain of measurement could be expanded over time to include measures addressing the priority infections identified.

F. Recommendations and Action Plan

CMS currently has the statutory authority to adjust hospital MS-DRG payments for selected conditions under the HAC payment provision. CMS has selected catheter-associated urinary tract infection, vascular-catheter associated infection, and certain surgical site infections for non-payment under the HAC provision when those infections are acquired during hospitalization.

Other infections, like ventilator-associated infections, methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*, and other surgical site infections 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 on published literature supporting the conclusion that when the guidelines are followed, the conditions can be considered reasonably preventable.

CMS also currently has the statutory authority to collect and publicly report hospital quality data under the RHQDAPU program. The RHQDAPU program measures compliance with an increasing number of infection prevention and control best practices, including measures developed by the Surgical Care Improvement Project.

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 by August.

CMS has used the experience gained through implementing the HAC payment provision, through the RHQDAPU measurement and public reporting program, and through the various performance-based payment demonstration projects, to inform the development of the Hospital VBP Plan. CMS believes that the Hospital VBP Plan, if the agency had that statutory authority to implement, would be a more sophisticated approach to value-based purchasing than the current HAC and pay-for-reporting approaches. Risk-adjusted rates of infection prevention interventions and outcomes over time for infections like ventilator-associated pneumonia, MRSA, or *C. difficile* could be included to enhance a patient safety domain of measurement, which would count toward determination 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 "rollup measure" or total performance score of the hospital VBP performance assessment model. Scores for the individual infection prevention and outcomes measures, for aggregated infection measures, and for the patient safety domain could be posted on the Hospital Compare website, 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.

Recommendations on how the Hospital VBP Plan methodology could incorporate measures of infection prevention and outcomes:

- Individual measures of infection prevention and outcomes, specified elsewhere in this report, could be scored for hospitals as part of performance assessment.
- Individual infection measure scores could be aggregated into a rollup infection measure for hospitals.
- Individual infection measure scores or a rollup infection measure could be aggregated into a roll up patient safety domain, which could be included in hospitals' total performance scores. Thus, hospitals' financial incentives would depend, in part, on their performance on measures of infection prevention and outcomes.
- Scores for individual measures, roll up infection measures, and the roll up patient safety domain could be reported on Hospital Compare as an infection scorecard for hospitals.

However, even if the Hospital VBP Plan were implemented, elements of the HAC provision and the RHQDAPU program would ideally be retained to serve specific purposes. For example, the HAC payment provision could be better suited for conditions with a very low incidence that cannot be accurately and reliably measured by rates, and the RHQDAPU program's pay-for-reporting approach could be useful for collecting data on measures that are being tested for VBP or that are topped out and no longer provide meaningful differentiation in performance for VBP payment incentives.

The President's FY 2009 Budget proposed the Hospital VBP Plan as a way to enhance the quality and value of Medicare services. In the interim, CMS will continue to consider candidate HACs through rulemaking and will pursue evaluation of promising value-based purchasing strategies through demonstration projects.

IV. Transparency and Associated Incentives

A. Introduction

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

Public reporting enhances accountability in healthcare by increasing the transparency of quality data. Public reporting is designed to create both "indirect" financial and non-financial incentives to improve quality of care. Indirect financial incentives result when public reporting drives patients' choices and, therefore, market share. Non-financial incentives include publicizing performance, reputation, competition, motivation, accountability, and public recognition. Providing reliable quality and cost information empowers not only patients' choices, but also the choices of stakeholders within local and regional communities, as well as nationally. Professionals are more likely to want to join the staffs of high performing hospitals. Choice leads to incentives at all levels and motivates the entire system; improvements take place as providers compete.

B. Hospital Compare

Hospital Compare (www.hospitalcompare.hhs.gov) is a consumer-oriented website that provides information on how well hospitals provide care to their patients with certain medical conditions, including care related to the prevention of 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 various processes of care and outcome measures furthers the goal to improve the quality and transparency of hospital care by giving the public and healthcare professionals better access to important hospital data. These quality measures are meant to be one way to see how well a hospital is caring for its patients.

By making this information available, CMS is meeting two of the Secretary's four cornerstones for Value-Driven Health Care – to measure and publish quality and price

information. Hospital Compare allows consumers to see how hospitals are delivering care to their patients through nationally standardized process of care and outcome measures and cost information for individual hospitals. This information helps educate consumers who are selecting a hospital.

CMS launched the Hospital Compare tool on March 31, 2005. The measures currently reported on Hospital Compare include 10 starter measures and additional measures that many hospitals also voluntarily report to receive their full payment updates (see Appendix F). These measures represent agreement among CMS, the hospital industry, and public sector stakeholders such as The Joint Commission, NQF, and AHRQ. A number of the measures are related to infections: there are three measures related to the prevention of surgical infections, seven measures related to pneumonia care, and one measure related to pneumonia outcomes.

Recently, ten measures from a standardized survey of patient perspectives of their hospital care, known as Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), have also been added to the Hospital Compare site. Public reporting of standardized measures on patients' perspectives of the quality of hospital care encourages consumers and their physicians to discuss and make more informed decisions on how to get the best hospital care, as well as increases the public accountability of hospitals.

The transparency provided by the Hospital Compare tool provides incentives for the entire hospital system. The tool is not only a valuable information resource for patients but also could enhance a hospital's reputation in the community. A hospital performing well on the Hospital Compare site could provide a community reputation that attracts patients, physicians, and staff.

C. Recommendations and Action Plan

Each year, CMS will continue adding additional measures to Hospital Compare. These enhancements are part of HHS' ongoing commitment to increased healthcare transparency. CMS is adding 13 new measures for the FY 2010 program, and retiring one existing measure. The inclusion of these additional measures will encourage hospitals to take steps to make care safer for patients.

As measures are developed for hospital-associated infections related to catheter-associated urinary tract infections, vascular-catheter associated infections, ventilator-associated pneumonia, surgical site infections, methicillin-resistant *Staphylococcus aureus*, and *Clostridium difficile*, they may be added to the Hospital Compare website.

The addition of hospital-associated infection measures to Hospital Compare could increase awareness and educate consumers as well as continue to hold hospitals and other providers accountable for providing better more efficient care.

V. Related Initiatives Addressing Healthcare-Associated Infections

A. Introduction

CMS has undertaken a number of other Medicare and Medicaid initiatives to combat healthcare-associated infections. Within the Medicare program, the Quality Improvement Organizations (QIOs) provide direct provider support for reducing infections. Medicare Part C is applying the Part A hospital-acquired conditions payment policy to Medicare Advantage organizations, which also have quality improvement program requirements that include the prevention and control of infections. The Medicaid program is encouraging States to adopt the Medicare hospital-acquired conditions payment policy and is funding Transformation Grants that include addressing central line infections for premature infants in the Neonatal Intensive Care Unit (NICU).

B. Quality Improvement Organizations

Introduction

The statutory mission of the Quality Improvement Organization (QIO) program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. The QIO Program is a network of organizations staffed with physicians, nurses, technicians, and statisticians – experts in healthcare 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 9th Scope of Work (SOW), which continues for three years beginning August 2008) focuses on four themes: Beneficiary Protection, Care Transitions, Patient Safety, and Prevention. There are also three cross-cutting themes: Reducing Health Care Disparities, Promoting Use of Health Information Technology, and Value-Driven Health Care and a comprehensive set of tasks, roles and responsibilities, progress measures, and an evaluation design.

The following discussion expands on the Patient Safety and Prevention themes, which are more relevant to the healthcare-associated infections focus of this report.

Patient Safety

Patient Safety efforts will reduce patient harm using proven interventions in areas with a record of QIO success in helping 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 healthcare system than an attendant disease process. Work toward these goals will by definition increase the value of healthcare services as it produces higher quality care for Medicare beneficiaries.

QIO activities for the Patient Safety Theme will focus on five topics: improving inpatient surgical safety, heart failure, reducing rates of nosocomial MRSA

infections, improving drug safety, and reducing rates of pressure ulcers and physical restraints in nursing homes as well as pressure ulcers in hospitals. Additionally, nursing homes that have difficulty meeting the CMS survey and certification requirements will be given the opportunity to work with QIOs to assess the areas for improvement and to work on their pressure ulcer and physical restraint rates. QIOs will work with providers to achieve the following: 23,610 fewer restraints, 43,303 fewer patients with pressure ulcers in nursing homes and hospitals, 7,875 fewer MRSA infections, and 14,252 fewer postoperative deaths due to surgical site infection, venous thromboembolic events, or perioperative myocardial infarction.

In CMS' efforts to improve quality and avoid unnecessary costs to the Medicare Trust Fund, the Office of Clinical Standards and Quality (OCSQ), as part of the QIO 9th SOW's Patient Safety Theme, has formed an interagency collaboration with CDC and AHRQ to combat hospital-acquired MRSA. Over the past several decades, the incidence of MRSA infections has grown exponentially. In 1974, MRSA infections accounted for only two percent of the total number of staphylococcus infections; in 1995 it was 22%; in 2004 it was 63%. This rate comes with a mean per patient cost of \$35,367 that is directly attributable to MRSA infections.

The new 9th SOW contract, which began on August 1, 2008, creates an opportunity for hospitals to choose to report on MRSA under the CDC's NHSN Multidrug-Resistant Organism (MDRO) Module and to work with QIOs to reduce infection and transmission rates attributable to MRSA. CDC oversees the NHSN and will soon be launching the MDRO Module, which tracks MRSA infections. All hospitals are encouraged to consider reporting through the MDRO module. Hospitals choosing to participate in the MDRO module will undergo on-line training provided by CDC for the NHSN and the MDRO Module. Hospitals working with the QIOs will receive additional training based on proven effective practices for reducing healthcare-associated MRSA infections and TeamSTEPPS. TeamSTEPPS is a teamwork system which offers a powerful solution to improving collaboration and communications within institutions. Teamwork has been found to be one of the key initiatives within patient safety that can transform the culture within healthcare.

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 healthcare programs, products, policies, practices, community norms, and linkages and will produce higher quality of care for Medicare beneficiaries and 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 (CKD) and 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 will collect a set of measures that involve hospital-acquired conditions. Some of these measures involve infections, including: vascular catheter-associated infection; catheter-associated urinary tract infection (UTI); surgical site infection, mediastinitis, after coronary artery bypass graft (CABG); surgical site infection following certain orthopedic procedures; and surgical site infection following bariatric surgery for obesity. These data will be used in developing and reporting performance metrics for Medicare Advantage (MA) organizations.

CMS will be issuing guidance to MA consistent with original Medicare rules effective October 1, 2008 to not cover specified preventable medical errors that occur at non-contracting hospitals (see discussion in Section III.B above). CMS will also be updating the "MA Payment Guide for Out of Network Payments" to reflect this information for all MA plans.

Medicare Advantage Quality of Care Requirements

The MA quality framework, including quality improvement programs (QIPs), are described in the MA regulations, which currently require MA coordinated care plans to:

- 1) Have QIPs.
- 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 by CMS annually. These standardized performance measures include: HEDIS, CAHPS, and HOS. HEDIS covers measures related to effectiveness of care, access/availability of care, and use of services; CAHPS measures experiences with the care received through the health plan; and HOS measures changes in physical and mental health status.

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

Under the recent Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), beginning in 2011, each MA Private Fee-for-Service (PFFS) and Medicare Savings Account (MSA) plan must have an ongoing QIP that meets the regulatory requirements. CMS is currently developing regulations to implement these new MIPAA quality requirements for PFFS and MSA plans. For 2010, MSA and PFFS plan QI reporting will only apply with respect to administrative claims data.

D. State Medicaid Program Efforts

The implementation of Medicare's hospital-acquired conditions (HACs) payment policy (see discussion in Section III.B above) left many State Medicaid Agencies wondering whether healthcare providers serving dually-eligible Medicaid and Medicare patients would simply attempt to pass through 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.

Consequently, on July 31, 2008, CMS issued a State Medicaid Directors' Letter (SMD). The SMD (#08-004) invited States to submit State Plan Amendments (SPAs) to CMS to conform State Medicaid payment policy to the Medicare HAC payment policy. The letter offered States the option to do nothing, to conform Medicaid payment policy to the Medicare HAC non-payment policy, or to establish a more ambitious "never events" policy that might add any of the 28 "never events" defined by the NQF or other health organization (e.g., CDC) to the Medicare HACs. Some of the "never events" are related to infections, like death or disability associated with the use of contaminated drugs, devices, or biologics; severe pressure ulcers; and burns. The letter encouraged States to consider the entire Medicaid population (not just dual eligibles) in formulating this State payment policy, to clearly link payment with performance.

About 20 of the States had already expressed interest in a "never event" policy and most had expected to use all or some of the 28 NQF "never events" as the basis for their Medicaid payment policies. With the issuance of the new SMD, CMS expects that the majority of States will move to align their Medicaid payment policies with the Medicare HAC policy. Given that many of the HACs deal with hospital-acquired infections, this alignment of Medicare and Medicaid payment policy will send a strong, consistent message to hospitals that federal and state payers expect them to strengthen their infection control programs and prevent all avoidable hospital-acquired infections.

The Neonatal Outcomes Project is another Medicaid infection prevention project that involves the creation and testing of a Protocol for the Prevention and Handling of Premature Births. The project commenced in 2006 and, among other interventions, addresses proper infection control practices in the NICU. At this point, three states have been selected for CMS Transformation Grants to pilot certain of the interventions. These interventions are evidence-based and have been shown to be effective, and the Grants are intended to spread the promising practices into the wider neonatal community to reduce variability in outcomes and improve overall mortality and morbidity statistics for prematurity throughout the nation.

Ohio, which has the first operational Transformation Grant, has as one of its two objectives the infection control intervention, which addresses central line infections in

the NICU. Central line infections are a significant issue in NICUs in Ohio and across the nation, but there is an established protocol to reduce these infections to a fraction of their present level. This protocol was first tested for adults by the Institute for Healthcare Improvement (IHI) in its successful 100,000 Lives campaign. Subsequently, the Perinatal Quality Improvement Panel of California modified the protocol for neonates and, in 2004, published its results (Wirtschafter, NeoReviews, 2004). These results indicated that the neonatal protocol, when properly applied, reduced central line infections to less than half of the previous rate before use of the protocol.

It is expected that the results of these Transformation Grants will demonstrate the effectiveness of these improved infection control techniques for premature infants in the NICU and justify a national effort to introduce these evidence-based methods into routine perinatal practice.

VI. Conclusion

CMS, working with other HHS agencies and various national and local partners, has a number of initiatives and programs to regulate and track HAI infections; and 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 that should influence choices that help diminish and prevent healthcare-associated infections.

HHS Action Plan to Prevent Healthcare-Associated Infections: OUTREACH AND MESSAGING

I. Introduction

As noted in earlier sections, healthcare-associated infections (HAIs) are a significant cause of mortality and morbidity each year in the U.S. To address this important public health and patient safety issue, the Department of Health and Human Services (HHS) will encourage pro-active efforts on behalf of all facets of the healthcare system, as well as consumers, to take important preventive steps.

To this end, HHS will engage in state of the art methods of communication with stakeholders that include providers, purchasers, professional associations, governmental agencies, academia, and the public to raise awareness to the key prevention actions outlined within the plan on or around January 2009.

Communications methods using various channels of communications and state of the art best practices using risk communication and social marketing will include:

- 1) Raising awareness to the importance of addressing HAIs;
- 2) Empowering consumers with tools and knowledge to be effective patient advocates for prevention;
- 3) Helping healthcare professionals focus their attention on preventive steps that will yield the greatest benefits; and
- 4) Sharing the overall progress of the nation in reducing national rates of HAIs.

II. Primary Objective of the Communications Campaign

Reduce healthcare-associated infections by formulating goals and interim benchmarks that aim to:

- Increase dissemination of key messages about practices to prevent healthcare-associated infections to target audiences.
- Increase knowledge and awareness of key prevention practices to reduce healthcare-associated infections among providers, consumers, media, and general public.

III. HHS Secretary's Goal on the Prevention and Elimination of HAIs

The HHS Secretary has issued a call to action to reduce healthcare-associated infections. To do this he has established a plan that the government, the healthcare industry, and

consumers can stand behind to achieve this common goal. Furthermore, HHS aims to empower consumers with information to help to prevent HAIs.

The communication campaign will focus on these mutual goals and the primary objectives outlined above. Some details about the campaign are found below:

A. Proposed Date

January, 2009 HHS Action Plan Released

B. Proposed Theme

Reducing, preventing, and working towards the eventual elimination of the great majority of healthcare-associated infections

C. Target Audiences Include

- 1) Healthcare Provider Groups
 - CEO/ Management/Leadership in the Hospitals
 - Healthcare Workers – Practicing doctors, nurses, etc.
 - Infection Preventionists (IPs) – IPs set hospital policy and are responsible for taking the information to staff in service
 - Hospitalists
 - Allied Health Professionals
 - Janitorial and maintenance workers who could be at risk for acquiring an HAI
 - Quality Improvement Organizations (QIOs). (For additional information, see “Incentives and Oversight” The Centers for Medicare and Medicaid Services (CMS) has just launched a new three-year QIO contract cycle, whereby QIOs will be focusing on infection control in the hospital setting. Their particular focus will be on Methicillin-resistant *Staphylococcus aureus* (MRSA) prevention. {HHS plans to coordinate the communication messaging with the QIOs as part of their inpatient staph-infection prevention/reduction efforts. As background, the QIOs are partnering with specific hospitals in each state, so their reach would be more towards providers than consumers. Each QIO will be able to devise localized methods for communication, in coordination with CMS/HHS’ National Patient Safety Initiative and this campaign. }
- 2) Consumer Groups
 - Patients
 - Caregivers (Including family and friends)
 - Patient Advocacy Groups
- 3) Public Health Community
 - Public health agencies and organizations at the local, state, regional, and federal levels
 - Graduate schools of public health

- Other professional and allied health schools
- Public health laboratories and associations

4) Academia

- Healthcare institutions
- Healthcare instructors
- Curriculum developers

IV. Partnership Development

Recognizing that reducing HAIs nationally is a shared responsibility of government and the healthcare industry, HHS must develop a strong partnership network to amplify prevention messages, promote implementation of recommended practices, and monitor progress at the national, regional, and local level. In addition, consumers can play an important role in advocating for their and other's safe health care. Many of the outreach and messaging activities is currently happening within the various operating and/or staff divisions of HHS. As such, the key focus will be to coordinate and leverage existing agency efforts.

Pivotal to the success of the HAI campaign strategy will be the ability to personalize prevention messages in a way that it can be embraced by all segments of society so as to bring about a shift in prevailing social norms. Some recommendations on the messaging strategy:

- Messages should be tailored appropriately to the audiences that are being targeted (e.g., healthcare professionals and consumers), keeping unique populations and subgroups in mind.
- The messaging should be focused and consistent.
- The messaging should consider the impacts and/or benefits to the target audience, i.e., why they should care, and why it is important they have and use this information.

A. Potential Partners

Partners representing all sectors are encouraged to participate in the HHS Campaign. First tier partners will primarily be those organizations who have been active and/or have synergistic efforts currently underway with their constituencies. Partners should include professional associations for healthcare providers, large hospital systems, associations that deal with infection control and patient safety, health officials (public sector organizations), consumer groups, health care institutions, and other public health organizations.

B. Benefits of Partnering with HHS

Partner assistance and support will help the nation achieve and sustain long-term success in preventing and reducing HAIs. Partnering with HHS offers many benefits, including:

- Public recognition as an HHS partner;
- Scientific expertise of HHS;
- Sharing information and resources with the broad representation of HHS Operating and Staff Divisions;
- Use of HHS educational and promotional materials;
- Use of HHS national media campaign products;
- Improved health and welfare of all Americans;
- Improved quality of patient care; and
- Reduction of unnecessary healthcare costs.

There are many opportunities for partners to get actively involved with the initiative campaign. Suggested recommended actions include:

- Messages should be provided to healthcare consumers/patients.
- HHS and its partners should display posters and other materials in high visibility areas.
- It is important to distribute to healthcare providers detailing sheets reviewing appropriate prevention guidelines.
- Local communities and partners should develop local level appropriate HAI prevention campaigns, including educational products.
- HHS, in conjunction with its regional offices and partnering with state health agencies, should provide assistance to local level campaigns in producing educational materials or sponsoring events.
- It will be critical to deliver presentations on prevention to interested parties. HHS and its partners should actively share information with local media outlets to amplify messages and the importance of addressing the issue.

V. Messaging

The messaging for the overall campaign should be appropriate to the level of the audience and use the principles of risk communication and social marketing. If used by HHS, all messages should have the appropriate level of agency clearance. Other messaging should be developed by HHS and be part of the public domain for shared used by professional groups and audiences.

A. Top Ten Messages for Outreach Strategy

HHS along with its partners should disseminate the following priority messages:

- Many healthcare-associated infections are preventable.
- A systemic approach to reducing the transmission of disease can be more effective than disease-specific approaches.
- Developing and supporting the conduct of basic and translational studies to address the gaps in the science in this field will allow generation of additional strategies that can be used to reduce the risks of HAI transmission.
- It will take a strong partnership between federal and local/state governments and communities to truly help prevent HAIs. HHS is committed to this partnership and many of its agencies are and will be involved.
- The education of best practices for providers and other healthcare personnel is critical to prevent HAIs.
- Specific metrics and national targets have been developed by HHS in concert with national experts on controlling infections.
- Educating patients on HAIs and how to prevent them will be a critical part of the national effort.
- An informed media can help promote the education of the American public about the need to prevent HAIs and what HHS and its partners are doing.
- Preventive steps to control and prevent HAIs are cost-effective and will save many lives and reduce disability for Americans.
- The time to act on HAIs is now, and HHS and its partners are committed to working closely with providers, health systems, community leaders, and governments to help prevent HAIs.

B. Top 5 Campaign Messages

The HICPAC, in partnership with HHS, has developed the top five messages for a healthcare worker and consumer awareness campaign. These messages are consistent with important areas of prevention focus currently identified for HAI. Detailed examples of the following overarching messages can be found under Education and Training Tools at <http://www.cdc.gov/ncidod/dhqp/index.html>.

1. Hand hygiene
2. Healthcare personnel vaccination
3. Patient vaccination
4. Prompt removal of catheters and other devices
5. Antimicrobial stewardship

C. Promotional Activities

The Department will organize national and regional activities to foster implementation of the Action Plan and educate partners about the Campaign's key messages at different levels. HHS will also promote its message through the ten Regional Offices for distribution to states, territories, and communities in their jurisdictions.

1) National

Initial efforts to educate and create partnerships at the national level include:

- HHS participation in national conferences and meetings,
- National Roundtable Discussions with key stakeholders, the media, and national organizations to discuss contributions and support for the Action Plan,
- Dedicated website housing key prevention information (pending resources), and
- The use of social networking sites, Web casts and blogs to disseminate information.

2) Regional

Educational stakeholder meetings plus additional training sessions for providers will be planned and hosted by HHS Regional Offices throughout the country and hosted by Regional Health Administrators.

The purpose of these initial meetings should be to communicate to providers and consumer organizations, and local healthcare providers to garner and advance support for reducing HAIs across the country and will:

- Share and promote the objectives of the Action Plan and campaign,
- Assess any concerns regarding implementation of the plan and campaign,
- Assess levels of acceptance,
- Assess any additional support providers would like to receive, and,
- Provide feedback on a media outreach campaign.

As the effort advances towards implementation, Regional Health Administrators should plan to provide training sessions targeted towards healthcare providers and administrators regarding the recommendations outlined and expressed in the Action Plan. These training sessions will augment any existing prevention activities already occurring at the local level, which were not generated by the Action Plan.

The training sessions will:

- Garner further support in advancing prevention, and
- Translate specific application of the guidelines into practical application.

VI. HHS Assets to Coordinate External Outreach

The following is a snapshot of existing HHS resources and assets that will be mobilized synergistically.

These agency-specific efforts should share information on the HHS Action Plan, share updated prevention information with key audiences, and help improve coordination among the many partners.

Various assets are available across the Department. A preliminary list of available resources for use in the near-term includes:

A. Healthy People 2010 and Healthy People 2020 (in development).

Healthy People 2010 provides a framework for prevention for the Nation. It is a statement of national health objectives designed to identify the most significant preventable threats to health and to establish national goals to reduce these threats.

B. Newsletters and Listservs

- 1) Agency for Healthcare Research and Quality (AHRQ)
 - Agency's Electronic Newsletter (over 31,000 subscribers): www.ahrq.gov/news/enewsix.htm
 - Agency's Patient Safety and Health Information Technology E-Newsletter (over 15,000 subscribers): www.ahrq.gov/news/ptsnews.htm
 - Agency's "Research Activities" newsletter (27,000 subscribers): www.ahrq.gov/research/resact.htm

- 2) Centers for Disease Control and Prevention (CDC)
 - Clinician Outreach and Communication Activity (COCA) Listserv with Newsletter: www.bt.cdc.gov/coca
 - CDC E-mail Blast to CDC Partners (newsletter): www.cdc.gov/Partners
 - Rapid Notification System (RNS): www2.cdc.gov/ncidod/hip/rns/hip_rns_subscribe.html
 - CDC E-cards: www2a.cdc.gov/eCards (Note: Personal e-cards can be sent to different audiences (consumers and healthcare providers) with a message about healthcare-associated infections.)

- 3) Centers for Medicare and Medicaid Services (CMS)
 - Provider Partnership Listserv: Representatives from 124 national provider associations sign up to this listserv after a face-to-face meeting with the Division Director for Division of Provider Information Planning and Development.
 - All Medicare FFS provider types listserv (123,104 subscribers)
 - Additional listservs that target the following groups/topics: Allied health, employers, quality, value based purchasing list (includes The Leapfrog Group and others), health plans, hospitals, cancer, consumer, disability, discharge planners, disease, long term care, pharmaceutical companies, physicians, and rural health lists.

C. Websites

Websites that currently address issues related to or about healthcare-associated infections that will be utilized:

- 1) Agency for Healthcare Research and Quality (AHRQ)
 - Notice on patient safety and medical errors site:
www.ahrq.gov/qual/errorsix.htm
- 2) Centers for Disease Control and Prevention (CDC)
 - HAI Website: www.cdc.gov/ncidod/dhqp/healthdis.html
 - Morbidity and Mortality Weekly Report (MMWR) Website:
www.cdc.gov/mmwr/weekcvol.html (To reach health professionals and health departments, include a “Notice to Readers” about HAIs)
 - CDC Web Features: www.cdc.gov/Features/PediatricColdMeds (Could write a feature and link to other HHS sources of info on HAIs)
 - Emerging Infectious Diseases (EID) Journal:
www.cdc.gov/ncidod/EID/announc.htm (Could post announcement and links to reports or meetings on the EID website)
- 3) Centers for Medicare and Medicaid Services (CMS)
 - Technical information about Hospital Acquired Conditions and Present on Admissions Medicare policies: www.cms.hhs.gov/HospitalAcqCond

D. Podcasts

- 1) Agency for Healthcare Research and Quality (AHRQ)
 - Radiocasts/podcasts via AHRQ's Healthcare411:
<http://healthcare411.ahrq.gov/>
- 2) Centers for Disease Control and Prevention (CDC)
 - Website: www2a.cdc.gov/podcasts/player.asp?f=7953 (Can create a podcast and link to other HHS sources of info on HAIs)

E. Meetings/Conference Calls/Conferences

- 1) Centers for Disease Control and Prevention (CDC)
 - Clinician Outreach and Communication Activity (COCA):
www.bt.cdc.gov/coca (Conference calls that offer free CME to participants)
 - Healthcare Infection Control Practices Advisory Committee (HICPAC):
www.cdc.gov/ncidod/dhqp/hicpac.html (Liaisons representing American College of Occupational and Environmental Medicine, American Hospital Association, American Healthcare Association, Advisory Council for the Elimination of Tuberculosis, Association of Perioperative Registered Nurses, Association of Professionals of Infection Control and Epidemiology, Consumer’s Union, Council of State and Territorial

Epidemiologists, Joint Commission, and Society for Healthcare
Epidemiology of America)

F. Media Listservs

HHS will utilize a Media listserv to email “news” updates to reporters, regionally and nationally, and will include usage of the following:

- AHRQ's Media /Reporters listserv
- CDC Division of Media Relations: www.cdc.gov/media/archives.htm (DMR has a broad listserv of reporters as well as list of reporters who cover CDC and some specific for HAIs)
- Office of Public Health and Science (OPHS)

G. HHS Products

Operating Divisions, including AHRQ, CDC, and CMS, have already produced materials which should be added to the Website.

- AHRQ: Table containing AHRQ products
- CDC: Table containing CDC products
- CMS: Two different fact sheets listed under CMS Website

H. HHS Products in Development

- Consumer brochure
- Posters for healthcare providers
- Buttons for healthcare providers
- Provider fact sheet
- “Top Ten Bill of Rights” laminated cards for consumers
- HHS Website on HAI, hosting information, linking to products, materials, conferences etc.
- CMS fact sheets which contain an overview description of Hospital Acquired Conditions and Present on Admission (currently being updated and should be available shortly)

VII. General Timelines for Projected Late Winter/Early Spring 2010 Launch

- Pre-Event Media Advisory/Press Release: Issue in advance of the event
- Post-Event News Release: Issue news release summarizing the event after the event
- Media Roundtables: To continue the momentum across the country and engage the media, consumers and other stakeholders
- News Conference: To announce the launch of the media campaign
- On-site Media Room/Media Avail: Depending on details of the event, establish on-the-ground media support (media room or media availabilities)

- Radio and Television PSAs: To be released the day of campaign launch

VIII. Conclusion

The Department is committed to disseminating the Action Plan widely and will be working with its Regional Offices and many partners in broadcasting state of the art messaging that will help prevent and eliminate (to the greatest extent possible) healthcare-associated infections.

HHS will continue to focus its efforts on developing an effective strategy for building strong nationwide support for the plan to reduce the incidence of HAI. Utilizing a two tier, regional and national approach, the messages will be developed targeting both healthcare providers and consumer groups.

Messages will be disseminated via HHS resources including list servs, websites, and conference calls, as well as through the vehicles of communication provided through the partnership organizations.

HHS Action Plan to Prevent Healthcare-Associated Infections: COORDINATION, EVALUATION, AND CONCLUSION

Coordination of Efforts

The success of a national healthcare-associated infection (HAI) prevention effort will require effective coordination within the Department of Health and Human Services (HHS) and between the Department and external stakeholders. A synchronized effort will involve consistent communication between all the agencies involved in the initiative. This enhanced communication will allow for problems to be approached in a more holistic fashion rather than in its disparate parts. Initiatives in existence or development within one agency can be identified, targeted, and leveraged to aid in the overall prevention of these infections.

Various agencies within HHS currently fund efforts related to prevention, research, information technology infrastructure, communication, and incentives to prevent HAIs. However, there has been no official mechanism to lead and align these efforts in a cohesive manner, reduce duplication, and capitalize on potential synergies to increase overall impact. As specific examples of potential coordination, the Centers for Medicare and Medicaid Services (CMS) could plan to introduce incentives into the payment system and could coordinate research on the effects of implementing payment policies with the Agency for Healthcare Research and Quality (AHRQ) and/or Centers for Disease Control and Prevention (CDC) or research projects could be aligned between the National Institutes of Health (NIH), CDC, and AHRQ.

The mechanism proposed to institutionalize this coordinated effort is the establishment of an Interagency Steering Committee or “Steering Committee for the Prevention of Healthcare-Associated Infections.” The formation of the Steering Committee will enable implementation of the Action Plan and provide a context for measuring progress in achieving the Action Plan’s goals.

Effective partnership with other segments of the federal government and private sector stakeholders will be essential to the success of the initiative. The Steering Committee will seek to leverage the resources within and external to HHS to successfully implement the Action Plan.

At a minimum, objectives of the Steering Committee will include:

- 1) Coordination of efforts across prevention, research, information technology infrastructure, incentives and oversight, and public messaging and outreach to reduce HAIs nationwide.
- 2) Establish criteria and develop a plan to evaluate the Department’s progress in reducing HAIs nationwide. As part of evaluating the effort, designate a set of

primary measures to track HAIs and formulate a plan to further develop these measures over time.

- 3) Serve as a contact point to communicate to external stakeholders on this issue so the Department's efforts are harmonized and linked to a broader national coalition.

The following structure is proposed:

- 1) The Steering Committee will be chaired by the Principal Deputy Assistant Secretary for Health. It will initially be comprised of at least one member from AHRQ, CDC, CMS, the Food and Drug Administration (FDA), NIH, the Office of the Assistant Secretary for Public Affairs (ASPA), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Office of the National Coordinator for Health Information Technology (ONC), and the Office of Public Health and Science (OPHS).
- 2) The Steering Committee will meet at least quarterly.
- 3) The Steering Committee Chairmanship and membership will be reassessed annually starting in 2010.

The Steering Committee may elect to form working groups to address specific topics or implement project plans as determined. The work of these groups will be overseen and coordinated by the Steering Committee. The working groups may be convened at any time and for the duration deemed best by the Steering Committee.

Measuring Success

The proposed "Steering Committee for the Prevention of Healthcare-Associated Infections" will establish criteria and formulate a plan for evaluation of the national prevention effort. The evaluation criteria may include national measures of infection rates as well as assessment of specific programs and projects initiated by the Department and coordinated by the Steering Committee.

Input from and partnership with external stakeholders will be valuable to the accurate measurement of the nation's progress in preventing HAIs. Measures and measurement plans in use or development by other segments of the nation will be harmonized with those of the Steering Committee.

The Steering Committee will evaluate progress towards the national prevention of these infections annually. Regular updates will be requested from Steering Committee members and key external stakeholders regarding current and planned activities related to HAI prevention. These inventories will be used for ongoing monitoring, coordination, and evaluation of efforts. Results from the regular assessments of the initiative will lead

to adjustments to the program and issuance of Action Plan revisions in subsequent years. Updates to the Action Plan will be formulated and released on an annual basis.

Conclusion

The Department has a long and proud history in steadily and substantially improving the health and welfare of Americans. Despite this progress, HAIs continue to take a significant toll on human life. As shared in the introduction, it is estimated that there are 1.7 million HAIs in hospitals each year, which result in approximately 99,000 deaths and an estimated \$28 to \$33 billion in additional healthcare costs. The good news is that many of these deaths can be prevented through increased awareness and implementation of recommended infection control practices. For these reasons, the prevention of HAIs is a top priority for the Department.

The Steering Committee for the Prevention of HAIs focused its efforts on the development of an Action Plan. This endeavor provided an unprecedented opportunity to gather the various HHS Offices and Operating Divisions to bring the Department's extensive resources to bear on this critical patient safety issue. In addition, the opportunity to collaborate with external stakeholders has helped us all achieve significant and sustainable success. The work is not complete, but will continue to require the concerted and focused effort of all involved, for the end result of helping to create a healthier America.

**HHS Action Plan to Prevent Healthcare-Associated Infections:
 APPENDICES**

Appendix A

Metric Number and Label	Metric	Measurement System	National 5-Year Prevention Target
1. CLABSI 1	CLABSIs per 1,000 device days by ICU and other locations	NHSN Administrative discharge data¹	CLABSIs per 1,000 device days by ICU and other locations below present NHSN 25th percentile by location type (75% reduction in SIR)
2. CLABSI 2	Laboratory detected bacteremia per 1,000 patient days	ADT/lab System Data Streams	50% reduction in laboratory detected bacteremia per 1,000 patient days
3. CLABSI 3	CLABSIs per 100 patient months	NHSN Administrative discharge data	50% reduction in CLABSIs per 100 patient months
4. CLABSI 4	Central line bundle compliance (non-emergent insertions)	NHSN CLIP module	100% compliance with central line bundle (non-emergent insertions)
5. C diff 1	Case rate per patient days and administrative/discharge data for ICD9 coded Clostridium difficile Infections	NHSN MDRO module and Administrative discharge data	30% reduction in the case rate per patient days and administrative / discharge data for ICD9 coded Clostridium difficile Infections NOTE: Preventability of endemic CDI is unknown; therefore, the experts suggested that HHS revisit this target in 2 years as prevention research findings may become available
6. C diff 2	Contact precautions	NHSN MDRO module	100% compliance with contact precautions
7. C diff 3	Appropriate hand hygiene practices	NHSN MDRO module	100% compliance with appropriate hand hygiene practices
8. CAUTI 1	Rate of BSI secondary to UTI / 1,000 patient days	NHSN	50-75% reduction in the rate of BSI secondary to UTI / 1,000 patient days
9. CAUTI 2	# of symptomatic UTI / 1,000 urinary catheter days	NHSN	25% reduction in the number of symptomatic UTI / 1,000 urinary catheter days

¹ Any source that would provide nationally representative hospital discharge coding (i.e., ICD9 or, in the future, ICD10) data, including such sources as the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project, the CDC National Center for Health Statistics or National Hospital Discharge Survey, and those in the Centers for Medicare and Medicaid Services (CMS).

	[Number of UTIs (ICD9+not present on admission) / (# major surgery ICD9+ urinary catheter ICD9)]*100 discharges	Administrative discharge data	25% reduction in the [Number of UTIs (ICD9+not present on admission) / (# major surgery ICD9+ urinary catheter ICD9)]*100 discharges ²
10. CAUTI 3	(Urinary catheter days / patient days)*100	NHSN	50% reduction in (urinary catheter days / patient days)*100
11. MRSA 1	Incidence rate (number per 100,000 persons) of invasive MRSA infections	CDC EIP/ABCs	50% reduction in incidence rate of all healthcare-associated invasive MRSA infections
12. MRSA 2	Incidence rate (number per 1,000 patient days) of hospital-onset MRSA bacteremia (hospital wide)	NHSN (starting 2009)	50% reduction in incidence rate of hospital-onset MRSA bacteremia (hospital wide)
13. MRSA 3	Number of hospitalizations with non-present on admission MRSA bacteremia/pneumonia/sepsis Number of hospitalizations with non-present on admission MRSA not otherwise specified (NOS)/pneumonia/sepsis	NHDS Administrative discharge data	25% reduction in hospitalizations with non-present on admission MRSA not otherwise specified (NOS)/pneumonia/sepsis 90% of facilities with fewer “hospitalizations” with non-present on admission MRSA not otherwise specified (NOS)/pneumonia/sepsis than predicted (i.e. model prediction)
14. SSI 1	Deep incision and organ space infection rates using NHSN definitions (SCIP procedures)	NHSN	Median deep incision and organ space infection rate for each procedure/risk group will be at or below the current NHSN 25 th percentile
15. SSI 2	Adherence to SCIP/NQF infection process measures (perioperative antibiotics, hair removal, postoperative glucose control, normothermia)	CMS SCIP	95% adherence rates to each SCIP/NQF infection process measure
16. VAP 1	VAP rate, ventilator utilization (vent days), intermediate outcome – duration of ventilation	NHSN definitions	Track performance, no national target
17. VAP 2	VAP process bundle: Continuous assessment of head of bed elevation; Daily oral care and daily assessment of readiness to extubate and sedation levels	Direct local observation	100% compliance with each metric in the VAP process bundle within 2 years

² Zhan C, et.al. Medical Care (in press)

Appendix B

Metric Number and Label	Metric	Measurement System	National 5-Year Prevention Target	NQF Measures³	Compendium Measures⁴
1. CLABSI 1	CLABSIs per 1000 device days by ICU and other locations	CDC NHSN; Administrative discharge data⁵	CLABSIs per 1000 device days by ICU and other locations below present NHSN 25th percentile by location type (75% reduction in SIR)	CLABSI rate: CLABSI rate for ICU and high-risk nursery (NRN) patients	CLABSI rate
2. CLABSI 4	Central line bundle compliance (non-emergent insertions)	NHSN CLIP Module	100% compliance with central line bundle (non-emergent insertions)	Central line bundle compliance (hand hygiene; maximal barrier precautions upon insertion; Chlorhexidine skin antiseptics; Optimal catheter site selection; Daily review of line necessity with prompt removal of unnecessary lines.)	1. Compliance with CVC insertion guidelines as documented on an insertion checklist 2. Compliance with documentation of daily assessment regarding the need for continuing CVC access. 3. Compliance with cleaning of catheter hubs and injection ports before they are accessed. 4. Compliance with avoiding the femoral vein site for CVC insertion in adult patients.
3. C diff 1	Case rate per patient days; administrative/discharge data for ICD9 coded Clostridium	CDC NHSN MDRO module; Administrative discharge data	30% reduction in the case rate per patient days and administrative/discharge data for ICD9 coded		CDI rates should be calculated according to the recently published recommendations. (Rates for healthcare onset,

³ NQF Endorsed Measures for Healthcare-Associated Infections (<http://www.qualityforum.org/pdf/reports/HAI%20Report.pdf>)

⁴ SHEA/IDSA “Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals” (http://www.cdc.gov/ncidod/dhqp/HAI_shea_idsa.html)

⁵ Any source that would provide nationally representative hospital discharge coding (i.e., ICD9 or, in the future, ICD10) data, including such sources as the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project, the CDC National Center for Health Statistics or National Hospital Discharge Survey, and those in the Centers for Medicare and Medicaid Services (CMS).

	difficile Infections		Clostridium difficile Infections. NOTE: Preventability of endemic CDI is unknown; therefore, meeting attendee experts suggested that HHS revisit this target in 2 years as prevention research findings may become available.		healthcare facility associated; community onset, healthcare facility associated; community associated; indeterminate onset; unknown; and recurrent CDIs)
4. CAUTI 2	# of symptomatic UTI / 1000 urinary catheter days [Number of UTIs (ICD9+not present on admission) / (# major surgery ICD9+ urinary catheter ICD9)]*100 discharges	CDC NHSN Administrative Discharge data	25% reduction in the number of symptomatic UTI/1000 urinary catheter days 25% reduction in the [Number of UTIs (ICD9+not present on admission) / (# major surgery ICD9+urinary catheter ICD9)]*100 discharges ⁶	Catheter-associated urinary tract infection rate for intensive care unit patients.	Rates of symptomatic CAUTI, stratified by risk factors (age, sex, ward, indication, and catheter-days)
5. MRSA 1	Incidence rate (number per 100,000 persons) of invasive MRSA infections	CDC EIP/ABCs	50% reduction in incidence rate of all healthcare-associated invasive MRSA infections		Overall prevalence or prevalence density of MRSA colonization and/or infection
6. SSI 1	Deep incision and organ space infection rates using NHSN definitions (SCIP procedures)	CDC NHSN	Median deep incision and organ space infection rate for each procedure/risk group will be at or below the	Surgical site infection rate: Deep wound and organ space infections as a result of elective surgery to include	Surgical site infection rate

⁶ Zhan C, et.al. Medical Care (in press)

			current NHSN 25th percentile	coronary artery bypass graft (CABG) and cardiac surgery; hip or knee arthroplasty; colon surgery; hysterectomy (abdominal and vaginal); and vascular surgery.	
7. SSI 2	Adherence to SCIP/NQF infection process measures (perioperative antibiotics, hair removal, postoperative glucose control, normothermia)	CMS SCIP	95% adherence rates to each SCIP/NQF infection process measure.	Cardiac surgery patients with controlled postoperative serum glucose; Surgery patients with appropriate hair removal; Prophylactic antibiotics received; Prophylactic antibiotics selection; Prophylactic antibiotics discontinued	Compliance with Centers for Medicare and Medicaid Services antimicrobial prophylaxis guidelines.

Appendix D

Top 5 Hospital Allegations for Complaints & Incidents, CY2005 to CY2008

TOP 5 HOSPITAL ALLEGATIONS FOR COMPLAINTS & INCIDENTS

Ranking	Allegation	# Allegations
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CY2008 to date (01012008-08182008)

1	Quality of Care/Treatment	2426
2	Restrain/Seclusion - Death	2074
3	Resident/Patient/Client Rights	1205
4	Nursing Services	832
5	EMTALA	826
13	Infection Control	216

CFY2007

1	Quality of Care/Treatment	4103
2	Resident/Patient/Client Rights	2225
3	EMTALA	1346
4	Nursing Services	1157
5	Resident/Patient/Client Abuse	631
11	Infection Control	405

CY2006

1	Quality of Care/Treatment	3677
2	Resident/Patient/Client Rights	2101
3	EMTALA	1517
4	Nursing Services	1105
5	Resident/Patient/Client Abuse	608
12	Infection Control	314

CY2005

1	Quality of Care/Treatment	3872
2	Resident/Patient/Client Rights	3240
3	EMTALA	1483
4	Nursing Services	1139
5	Resident/Patient/Client Neglect	705

Source: QIES Workbench 8/21/2008; ACTS; Pennsylvania
Complaints and incidents are combined for this report

Note: Includes data for the State of Pennsylvania



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Appendix E

Hospital Acquired Conditions, Including Codes, Selected for October 1, 2008

HAC	CC/MCC (ICD-9-CM Codes)
1. Foreign Object Retained After Surgery	998.4 (CC) 998.7 (CC)
2. Air Embolism	999.1 (MCC)
3. Blood Incompatibility	999.6 (CC)
4. Pressure Ulcer Stages III & IV	707.23 (MCC) 707.24 (MCC)
5. Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Electric Shock	Codes within these ranges on the CC/MCC list: 800-829 830-839 850-854 925-929 940-949 991-994
6. Catheter-Associated Urinary Tract Infection (UTI)	996.64 (CC) Also excludes the following from acting as a CC/MCC: 112.2 (CC) 590.10 (CC) 590.11 (MCC) 590.2 (MCC) 590.3 (CC) 590.80 (CC) 590.81 (CC) 595.0 (CC) 597.0 (CC) 599.0 (CC)
7. Vascular Catheter-Associated Infection	999.31 (CC)
8. Manifestations of Poor Glycemic Control	250.10-250.13 (MCC) 250.20-250.23 (MCC) 251.0 (CC) 249.10-249.11 (MCC) 249.20-249.21 (MCC)
9a. Surgical Site Infection, Mediastinitis Following Coronary Artery Bypass Graft (CABG)	519.2 (MCC) And one of the following procedure codes: 36.10–36.19

HAC CC/MCC	(ICD-9-CM Codes)
9b. Surgical Site Infection Following Certain Orthopedic Procedures	996.67 (CC) 998.59 (CC) And one of the following procedure codes: 81.01-81.08, 81.23-81.24, 81.31-81.38, 81.83, 81.85
9c. Surgical Site Infection Following Bariatric Surgery for Obesity	<i>Principal Diagnosis</i> – 278.01 998.59 (CC) And one of the following procedure codes: 44.38, 44.39, or 44.95
10. Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures	415.11 (MCC) 415.19 (MCC) 453.40-453.42 (MCC) And one of the following procedure codes: 00.85-00.87, 81.51-81.52, or 81.54

Appendix F

Hospital Compare Measures as of October 1, 2008

Acute Myocardial Infarction (AMI) – Heart Attack	Aspirin at Arrival
	Aspirin Prescribed at Discharge
	ACE Inhibitor or Angiotensin Receptor Blocker (ARB) for Left Ventricular Systolic Dysfunction
	Adult Smoking Cessation Advice/Counseling
	Beta-Blocker Prescribed at Discharge
	Beta-Blocker at Arrival
	Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival
	Primary Percutaneous Coronary Intervention (PCI) within 90 Minutes of Hospital Arrival
	AMI 30-day Mortality
Heart Failure (HF)	Discharge Instructions
	Evaluation of Left Ventricular Systolic Function
	ACE Inhibitor or Angiotensin Receptor Blocker (ARB) for Left Ventricular Systolic Dysfunction
	Adult Smoking Cessation Advice/Counseling
	HF 30-day Mortality
Pneumonia (PN)	Oxygenation Assessment
	Pneumococcal Vaccination
	Blood Culture Performed in the Emergency Department Prior to Initial Antibiotic Received in the Hospital
	Adult Smoking Cessation Advice/Counseling
	Initial Antibiotic Received within 6 Hours of Hospital Arrival
	Appropriate Initial Antibiotic Selection
	Influenza Vaccination
	PN 30-day Mortality
	Surgical Care Improvement Project (SCIP)
Prophylactic Antibiotic Selection for Surgical Patients	
Prophylactic Antibiotics Discontinued within 24 Hours After Surgery End Time	
Surgery Patients with Recommended Venous Thromboembolism (VTE) Prophylaxis Ordered	

HHS Action Plan to Prevent Healthcare-Associated Infections 06222009
 Section 11: Appendices

	Surgery Patients Who Received Recommended Venous Thromboembolism (VTE) Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)	Communication with nurses
	Communication with doctors
	Responsiveness of hospital staff
	Pain management
	Communication about medicines
	Discharge information
	Cleanliness of hospital environment
	Quietness of hospital environment
	Overall rating of hospital
	Willingness to recommend hospital
Children's Asthma Care	Use of relievers for inpatient asthma
	Use of systemic corticosteroids for inpatient asthma

Appendix C – Current HHS HAI-Related Research Responsibilities (AHRQ, CDC, CMS, and NIH)

	AHRQ	CDC	CMS	NIH
Basic Discovery		Biofilms, resistance mechanisms		Vaccines, biofilms, studies of pathogenesis (intramural and extramural)
Surveillance	At a population level, using hospital inpatient and outpatient administrative databases	National Healthcare Safety Network (NHSN), Active Bacterial Core Surveillance, new measure development and validation, e-surveillance, electronic medical record capture		Electronic healthcare epidemiology surveillance system currently being installed at the NIH/Clinical Center
Epidemiology	Population-based epidemiologic studies (longitudinal trends, population risk associations)	Outbreak response, molecular epidemiology, other epidemiologic studies (burden estimates, risk factors, etc.)		Intramural studies in a unique clinical research hospital setting
Etiology		Identification of emerging pathogens through surveillance and outbreak response		Funding for clinical studies, basic studies characterizing new and/or emerging pathogens
Prevention Efficacy/Effectiveness		Prevention demonstration projects, intervention studies, investigation of novel/innovative prevention strategies		Proof of principle studies (intramural), comparative trials (extramural)
Prevention Implementation	Within organizations, systems of care, institutions, primary care networks	Prevention demonstration projects, prevention collaboratives, behavioral epidemiology, education, promotion	Through quality reporting, payment incentives, and special Quality Improvement Organization (QIO) programs	Clinical studies, including comparative trials (intramural and extramural)
Guidelines	Generate the evidence base for further guideline development	Healthcare Infection Control Practices Advisory Committee (HICPAC) produces evidence-based guidelines and related guidance; Maintain consistent case definitions in guidelines and NHSN		Research contributions to inform Public Health Service guidelines, society-sponsored guidelines, etc.

AH	RQ	CDC	CMS	NIH
<p>Treatment</p> <p>Comparative Effectiveness</p> <p>Implementation</p>	<p>Comparative effectiveness of treatments</p> <p>Within organizations, systems of care, institutions, primary care networks</p>	<p>Comparative effectiveness of prevention strategies</p>	<p>Comparative effectiveness through information from coverage with evidence development</p>	<p>Comparative trials (intramural and extramural)</p>
<p>Quality/Safety of Healthcare</p>	<p>Patient Safety Organizations, measurement tools for baseline and evaluation and quality improvement, training, data collection</p>	<p>NHSN as a system to track infections; Develop baseline through measurement, training, and data collection; NHSN as a quality improvement tool</p>	<p>Through quality reporting, payment incentives, and special QIO programs</p>	<p>Developed and implemented electronic occurrence reporting system and ongoing clinical quality/performance measurement/performance improvement program at the NIH/Clinical Center</p>
<p>Efficiency and Costs</p>	<p>Improved quality and reduced costs, avoidable admissions and re-admissions (HAIs)</p>	<p>Cost estimate studies, assess impact, assess unintended consequences of prevention initiatives and policies related to HAI prevention</p>	<p>CMS does not pay for certain hospital-acquired infections</p>	

Appendix G – Stakeholder Feedback and Revisions to the Original Draft Metrics and Targets

Comments on the initial draft metrics published as part of the HHS Action Plan to Prevent Healthcare-Associated Infections in January 2009 were solicited and reviewed. While comments ranged from high level strategic observations to technical measurement details, overall commenters encouraged established baselines, both at the national and local level, use of standardized definitions and methods, engagement with the National Quality Forum (NQF), raised concerns regarding the use of national targets for payment or accreditation purposes and of the validity of proposed measures, and would like to have both a target rate and a percent reduction for all metrics. Commenters varied on the aggressiveness of the national targets, with some expressing concern that these targets were overly ambitious while others were concerned that the targets were not ambitious enough. Furthermore, commenters emphasized the need for flexibility in the metrics, to accommodate advances in electronic reporting and information technology and for advances in prevention of healthcare-associated infections (HAIs), in particular ventilator-associated pneumonia. Finally, some commenters expressed concern that the proposed process measures included in the HAI metrics do not have demonstrated correlation with reduced HAIs.

To address comments received on the Action Plan Metrics and Targets, proposed metrics have been updated to include the proposed source of metric data, baselines, and which agency would coordinate the measure. To respond to the requests for percentage reduction in HAIs in addition to HAI rates, a new type of metric, the standardized infection ratio (SIR), is being proposed. Although metrics using infection rates are NQF endorsed, the Department of Health and Human Services (HHS) staff will work with NQF to address future consideration by NQF of the SIR for endorsement. Below is a detailed technical description of the SIR.

To address concerns regarding validity, HHS is providing funding, utilizing Recovery Act of 2009 funds, to the Centers for Disease Control and Prevention (CDC) to support states in validating National Healthcare Safety Network (NHSN)-related measures and to support reporting on HHS metrics through NHSN. Also, most of the reporting metrics outlined here have already been endorsed by NQF and for population-based national measures on methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile*. Work to develop hospital level measures will be conducted in the next year utilizing support to CDC through funds available in the Recovery Act.

Finally, to address concerns regarding flexibility in accommodating new measures, reviewing progress on current measures, and incorporating new sources of measure data (e.g., electronic data, administrative data) or new measures, HHS and its constituent agencies will commit to an annual review and update of the HHS Action Plan Targets and Metrics. The process for annual review and update will include representatives from appropriate federal agencies, state and local health agencies, scientific and clinical experts on HAI prevention and performance measurement, healthcare providers, professional organizations, accreditation organizations, consumer groups, and other key stakeholders. The first meeting to review measures and provide updates will tentatively be held in late 2009 or early 2010.

HHS Action Plan to Prevent Healthcare-Associated Infections 06222009

Section 11: Appendices

Metric Number and Label	Original HAI Elimination Metric	HAI Comparison Metric	Measurement System	National Baseline Established (State Baselines Established)	National 5-Year Prevention Target	Coordinator of Measurement System	Is the metric NQF endorsed?
1. CLABSI 1	CLABSIs per 1,000 device days by ICU and other locations	CLABSI SIR	NHSN Device-Associated Module	2006-2008 (proposed 2009, in consultation with states)	At least 50% reduction in central line-associated bloodstream infections in ICU and ward-located patients	CDC	Yes*
2. CLIP 1 (formerly CLABSI 4)	Central line bundle compliance (non-emergent insertions)	CLIP Adherence percentage	NHSN CLIP in Device-Associated Module	2009 (proposed 2009, in consultation with states)	100% adherence with central line bundle	CDC	Yes†
3a. C diff 1	Case rate per patient days; administrative/discharge data for ICD-9 CM coded <i>C. difficile</i> Infections	Hospitalizations with <i>C. difficile</i> per 1,000 patient discharges	Hospital discharge data	2008 (proposed 2008, in consultation with states)	At least 30% reduction in hospitalizations with <i>C. difficile</i> per 1,000 patient discharges	AHRQ or CDC	No
3b. C diff 2 (new)		<i>C. difficile</i> SIR	CDC NHSN MDRO/CDAD Module LabID‡	2009-2010	Reduce the facility-wide healthcare facility-onset <i>C. difficile</i> LabID event SIR by at least 30% from baseline	CDC	No
4. CAUTI 2	# of symptomatic UTI per 1,000 urinary catheter days	CAUTI SIR	CDC NHSN Device-Associated Module	2009 for ICUs and other locations 2009 for other hospital units (proposed 2009, in consultation with states)	Reduce the CAUTI SIR by at least 25% from baseline in ICU and other locations	CDC	Yes*

HHS Action Plan to Prevent Healthcare-Associated Infections 06222009

Section 11: Appendices

5a. MRSA 1	Incidence rate (number per 100,000 persons) of invasive MRSA infections	MRSA Incidence rate (healthcare-associated)	CDC EIP/ABCs	2007-2008 (for non-EIP states, MRSA metric to be developed in collaboration with EIP states)	At least a 50% reduction in incidence of healthcare-associated invasive MRSA infections	CDC	No
5b. MRSA 2 (new)		MRSA bacteremia SIR	CDC NHSN MDRO/CDAD Module LabID [‡]	2009-2010	Reduce the facility-wide healthcare facility-onset MRSA bacteremia LabID event SIR by at least 25% from baseline	CDC	No
6. SSI 1	Deep incision and organ space infection rates using NHSN definitions (SCIP procedures)	SSI SIR	CDC NHSN Procedure-Associated Module	2006-2008 (proposed 2009, in consultation with states)	Reduce the admission and readmission SSI [§] SIR by at least 25% from baseline	CDC	Yes [¶]
7. SCIP 1 (formerly SSI 2)	Adherence to SCIP/NQF infection process measures	SCIP Adherence percentage	CMS SCIP	To be determined by CMS	At least 95% adherence to process measures to prevent surgical site infections	CMS	Yes

* NHSN SIR metric is derived from NQF-endorsed metric data

† NHSN does not collect information on daily review of line necessity, which is part of the NQF

‡ LabID, events reported through laboratory detection methods that produce proxy measures for infection surveillance

§ Inclusion of SSI events detected on admission and readmission reduces potential bias introduced by variability in post-discharge surveillance efforts

¶ The NQF-endorsed metric includes deep wound and organ space SSIs only which are included the target.

Understanding the Relationship between HAI Rate and SIR Comparison Metrics

The Original HAI Elimination Metrics listed above are very useful for performing evaluations. Several of these metrics are based on the science employed in the NHSN. For example, metric #1 (CLABSI 1) for CLABSI events measures the number of CLABSI events per 1,000 device (central line) days by ICU and other locations. While national aggregate CLABSI data are published in the annual NHSN Reports these rates must be stratified by types of locations to be risk-adjusted. This scientifically sound risk-adjustment strategy creates a practical challenge to summarizing this information nationally, regionally, or even for an individual healthcare facility. For instance, when comparing CLABSI rates, there may be quite a number of different types of locations for which a CLABSI rate could be reported. Given CLABSI rates among 15 different types of locations, one may observe many different combinations of patterns of temporal changes. This raises the need for a way to combine CLABSI rate data across location types.

A standardized infection ratio (SIR) is identical in concept to a standardized mortality ratio and can be used as an indirect standardization method for summarizing HAI experience across any number of stratified groups of data. To illustrate the method for calculating an SIR and understand how it could be used as an HAI comparison metric, the following example data are displayed below:

Risk Group Stratifier	Observed CLABSI Rates			NHSN CLABSI Rates for 2008 (Standard Population)		
	Location Type	#CLABSI	#Central line-days	CLABSI rate *	#CLABSI	#Central line-days
ICU	170	100,000	1.7	1200	600,000	2.0
WARD	58	58,000	1.0	600	400,000	1.5
$\text{SIR} = \frac{\text{observed}}{\text{expected}} = \frac{170 + 58}{100000 \times \left(\frac{2}{1000}\right) + 58,000 \times \left(\frac{1.5}{1000}\right)} = \frac{228}{200 + 87} = \frac{228}{287} = 0.79 \quad 95\% \text{ CI} = (0.628, 0.989)$						

* defined as the number of CLABSIs per 1000 central line-days

In the table above, there are two strata to illustrate risk-adjustment by location type for which national data exist from NHSN. The SIR calculation is based on dividing the total number of observed CLABSI events by an “expected” number using the CLABSI rates from the standard population. This “expected” number is calculated by multiplying the national CLABSI rate from the standard population by the observed number of central line-days for each stratum which can also be understood as a prediction or projection. If the observed data represented a follow-up period such as 2009 one would state that an SIR of 0.79 implies that there was a 21% reduction in CLABSIs overall for the nation, region, or facility.

The SIR concept and calculation is completely based on the underlying CLABSI rate data that exist across a potentially large group of strata. Thus, the SIR provides a single metric for performing comparisons rather than attempting to perform multiple comparisons across many strata which makes the task cumbersome. Given the underlying CLABSI rate data, one retains the option to perform comparisons within a particular set of strata where observed rates may differ significantly from the standard populations. These types of more detailed comparisons could be very useful and necessary for identifying areas for more focused prevention efforts.

The national 5-year prevention target for metric #1 could be implemented using the concept of an SIR equal to 0.25 as the goal. That is, an SIR value based on the observed CLABSI rate data at the 5-year mark could be calculated using NHSN CLABSI rate data stratified by location type as the baseline to assess whether the 75% reduction goal was met. There are statistical methods that allow for calculation of confidence intervals, hypothesis testing, and graphical presentation using this HAI summary comparison metric called the SIR.

The SIR concept and calculation can be applied equitably to other HAI metrics list above. This is especially true for HAI metrics for which national data are available and reasonably precise using a measurement system such as the NHSN. The SIR calculation methods differ in the risk group stratification only. To better understand metric #6 (SSI 1) see the following example data and SIR calculation:

Risk Group Stratifiers		Observed SSI Rates			NHSN SSI Rates for 2008 (Standard Population)		
Procedure Code	Risk Index Category	#SSI [†]	#procedures	SSI rate [*]	#SSI [†]	#procedures	SSI rate [*]
CBGB	1	315	12,600	2.5	2100	70,000	3.0
CBGB	2,3	210	7000	3.0	1000	20,000	5.0
HPRO	1	111	7400	1.5	1020	60,000	1.7
$\text{SIR} = \frac{\text{observed}}{\text{expected}} = \frac{315 + 210 + 111}{12600 \times \left(\frac{3.0}{100}\right) + 7000 \times \left(\frac{5.0}{100}\right) + 7400 \times \left(\frac{1.7}{100}\right)} = \frac{636}{378 + 350 + 125.8} = \frac{636}{853.8} = 0.74 \quad 95\% \text{ CI} = (0.649, 0.851)$							

[†] SSI, surgical site infection

^{*} defined as the number of deep incision or organ space SSIs per 100 procedures

This example uses SSI rate data stratified by procedure and risk index category. Nevertheless, an SIR can be calculated using the same calculation process as for CLABSI data except using different risk group stratifiers for these example data. The SIR for this set of observed

data is 0.74 which indicates there's a 26% reduction in the number of SSI events based on the baseline NHSN SSI rates as representing the standard population. Once again, these data can reflect the national picture at the 5-year mark and the SIR can serve as metric that summarizes the SSI experience into a single comparison.

There are clear advantages to reporting and comparing a single number for prevention assessment. However, since the SIR calculations are based on standard HAI rates among individual risk groups there is the ability to perform more detailed comparisons within any individual risk group should the need arise. Furthermore, the process for determining the best risk-adjustment for any HAI rate data is flexible and always based on more detailed risk factor analyses that provide ample scientific rigor supporting any SIR calculations. The extent to which any HAI rate data can be risk-adjusted is obviously related to the detail and volume of data that exist in a given measurement system.

In addition to the simplicity of the SIR concept and the advantages listed above, it is important to note another benefit of using an SIR comparison metric for HAI data. If there was need at any level of aggregation (national, regional, facility-wide, etc.) to combine the SIR values across mutually-exclusive data one could do so. The below table demonstrates how the example data from the previous two metric settings could be summarized.

HAI Metric	Observed HAIs			Expected HAIs		
	#CLABSI	#SSI [†]	#Combined HAI	#CLABSI	#SSI [†]	#Combined HAI
CLABSI 1	228			287		
SSI 1		636			853.8	
Combined HAI			228 + 636 = 864			287+853.8 = 1140.8
$\text{SIR} = \frac{\text{observed}}{\text{expected}} = \frac{228 + 636}{287 + 853.8} = \frac{864}{1140.8} = 0.76 \quad 95\% \text{ CI} = (0.673, 0.849)$						

[†] SSI, surgical site infection