Department of Health and Human Services

ACTION PLAN TO PREVENT HEALTHCARE-ASSOCIATED INFECTIONS

June 2009 Final

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

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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	*Clostridium difficile* 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 *Staphylococcus aureus*
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 Plan[6]

- 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.

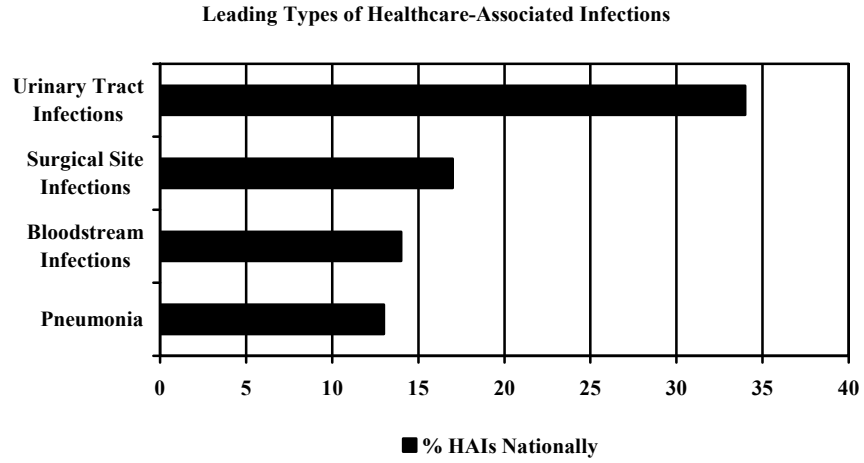
HHS Action Plan to Prevent Healthcare-Associated Infections: INTRODUCTION

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 Jhung 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 data[1]**	**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 data[2]**	**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 discharges[3]**
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 25^{th} 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 our 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

federal regulations regardless of evidentiary support, also were considered. However Category 2 recommendations, without strong evidence to support their efficacy, were not. The prioritization for VAP prevention includes recently compiled recommendations from the Society for Healthcare Epidemiology of America (SHEA)/Infectious Diseases Society of America (IDSA) *Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals* in order to capture practices not included in the 2003 CDC guideline.

2) CDC subject-matter experts in infectious diseases, infection control, and healthcare epidemiology assessed each recommendation for its urgency and relative importance for HAI prevention, the degree to which it is currently implemented by all healthcare facilities (i.e., whether there is a gap in current implementation), and how it is related in healthcare delivery to other recommendations.

3) Recommendations were grouped based on interdependence in implementation. These groupings are referred to as "priority modules."

4) Priority modules, each of which contains interdependent and thematically-related recommendations for clinical practice, were then mapped to relevant recommendations for implementation and auditing.

5) Finally, priority modules were reviewed and refined by an expanded CDC group and by HICPAC.

III. Results

Below are the lists of priority recommendations, grouped by priority modules, for each of the guidelines reviewed for prioritization. Most recommendations correlate with those included in the SHEA/IDSA *Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals.*

Note that topics such as that of hand hygiene, healthcare personnel- and patient-vaccinations, such as those recommended in the guideline for prevention of influenza, and similar overarching requirements are not included below in order to focus on specific recommendations for prevention of each infection type.

A. Prevention of Catheter-Associated Urinary Tract Infections

The CDC Guideline for Prevention of Catheter-Associated Urinary Tract Infections (CAUTI) is being updated in 2008 to expand upon the previous guideline published in 1981. The updated guideline is more concise than previous guidelines and includes new, readily-updateable evidence tables summarizing scientific evidence supporting each recommendation.

In addition, the guideline contains an implementation and audit section. Because of this updated methodology this guideline provides the greatest implementation and auditing detail among the four guidelines.

For prioritization of clinical practices for the prevention of CAUTI, Category 1A, 1B, and 1C recommendations were considered. Category 1C recommendations are required by state or federal regulation, or represent an established association standard, regardless of the quality of scientific evidence used to support the recommendation.

Priority Module 1 – Recommendations for Appropriate Urinary Catheter Use
Related HICPAC Recommendations:

- **HICPAC Rec.:** Insert catheters only for appropriate indications, and leave in place only as long as needed (Category 1A)
- **HICPAC Rec.:** Do not use urinary catheters in patients and nursing home residents for management of incontinence (Category 1B)
- **HICPAC Rec.:** For operative patients, who have an indication for an indwelling catheter; remove the catheter as soon as possible post-operatively, preferably within 24 hours (Category 1B)

Priority Module 2 – Recommendations for Aseptic Insertion of Urinary Catheters
Related HICPAC Recommendations:

- **HICPAC Rec.:** Ensure that only properly trained persons (e.g., hospital personnel, family members, or patients themselves) who know the correct technique of aseptic catheter insertion and maintenance are given this responsibility (Category 1C)
- **HICPAC Rec.:** Insert catheters using aseptic technique and sterile equipment (except as stated in other recommendations where clean technique is appropriate for intermittent catheterization) (Category 1C)

Priority Module 3 – Recommendations for Proper Urinary Catheter Maintenance
Related HICPAC Recommendations:

- **HICPAC Rec.:** Maintain a sterile, continuously closed drainage system (Category 1C)
- **HICPAC Rec.:** Do not disconnect the catheter and urinary drainage system unless the catheter must be irrigated (Category 1B)

B. Prevention of Intravascular Catheter-Associated Infections

The CDC guidelines for Prevention of Intravascular Catheter-Related Infections were published in 2002. Among the infections associated with intravascular catheter use, bloodstream infections (BSI) have severe consequences for patients and are therefore the focus of these prioritized recommendations. However, adhering to recommendations for prevention of BSI will reduce superficial catheter-site infections as well. Due to the

number of recommendations in this guideline, only Category 1A recommendations were considered for prioritization.

Priority Module 1 – Recommendations for Aseptic Insertion of Vascular Catheters
Related HICPAC Recommendations:

- **HICPAC Rec.:** Maintain aseptic technique during insertion and care of intravascular catheters (Category 1A)
- **HICPAC Rec.:** Use aseptic technique including the use of a cap, mask, sterile gown, sterile gloves, and a large sterile drape, for the insertion of central venous catheters (CVC),including for peripherally inserted central catheters (PICC) and guide wire exchange (Category 1A)
- **HICPAC Rec.:** Apply an appropriate antiseptic to the insertion site on the skin before catheter insertion and during dressing changes (Category 1A)
- **HICPAC Rec.:** Although a 2% chlorhexidine-based preparation is preferred, tincture of iodine, an iodophor, or 70% alcohol can be used (Category 1A)
- **HICPAC Rec.:** Select the catheter, insertion technique, and insertion site with the lowest risk for complications (infectious and noninfectious) for the anticipated type and duration of IV therapy (Category 1A)
- **HICPAC Rec.:** Use a subclavian site (rather than a jugular or a femoral site) in adult patients to minimize infection risk for non-tunneled CVC placement (Category 1A)
- **HICPAC Rec.:** Weigh the risk and benefits of placing a device at a recommended site to reduce infectious complications against the risk for mechanical complications (e.g., pneumothorax, subclavian artery puncture, subclavian vein laceration, subclavian vein stenosis, hemothorax, thrombosis, air embolism, and catheter misplacement) (Category 1A)

Priority Module 2 – Recommendations for Appropriate Maintenance of Vascular Catheters
Related HICPAC Recommendations:

- **HICPAC Rec.:** Use either sterile gauze or sterile, transparent, semipermeable dressing to cover the catheter site (Category 1A)
- **HICPAC Rec.:** Promptly remove any intravascular catheter that is no longer essential (Category 1A)
- **HICPAC Rec.:** Replace the catheter-site dressing when it becomes damp, loosened, or soiled or when inspection of the site is necessary (Category 1A)

C. Prevention of Surgical Site Infections

The CDC guideline for Prevention of Surgical Site Infection (SSI) was published in 1999. As such, recent research on SSI is not captured in the guideline. However the recommendations in the 1999 guideline remain important. Recent evidence was reviewed and recommendations that have been called into question based on research published after 1999 were excluded from consideration. Both Category 1A and 1B

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 0.2μ 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 bacteruria 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 endotrachael tube or tracheostomy and whether this could improve overall outcomes
    - Role of antimicrobial impregnated endotrachael 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. The verification code for this document is 267826.

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 facts 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?

– Evidence → Weak
  → Strong → Compliance
  → Non-compliance → Barriers to compliance

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

– Demonstrated impact → Short-term
  → Long-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 exit 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.