

GAO

Report to the Chairman, Committee on
Oversight and Government Reform,
House of Representatives

March 2008

HEALTH-CARE- ASSOCIATED INFECTIONS IN HOSPITALS

Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections

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Highlights of [GAO-08-283](#), a report to the Chairman, Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

According to the Centers for Disease Control and Prevention (CDC), health-care-associated infections (HAI) are estimated to be 1 of the top 10 causes of death in the United States. HAIs are infections that patients acquire while receiving treatment for other conditions. GAO was asked to examine (1) CDC's guidelines for hospitals to reduce or prevent HAIs and what the Department of Health and Human Services (HHS) does to promote their implementation, (2) Centers for Medicare & Medicaid Services' (CMS) and hospital accrediting organizations' required standards for hospitals to reduce or prevent HAIs and how compliance is assessed, and (3) HHS programs that collect data related to HAIs and integration of the data across HHS. GAO reviewed documents and interviewed officials from CDC, CMS, the Agency for Healthcare Research and Quality (AHRQ), and accrediting organizations.

What GAO Recommends

GAO recommends that the Secretary of HHS identify priorities among the recommended practices in CDC's guidelines and establish greater consistency and compatibility of the data collected across HHS on HAIs. HHS generally agreed with GAO's recommendations. In response to comments from the Joint Commission, GAO clarified its discussion of Joint Commission activities; in addition, it incorporated technical comments from the Joint Commission and AOA.

To view the full product, including the scope and methodology, click on [GAO-08-283](#). For more information, contact Cynthia A. Bascetta at (202) 512-7114 or bascetta@gao.gov

HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS

Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections

What GAO Found

CDC has 13 guidelines for hospitals on infection control and prevention, which cover a variety of topics, and in these guidelines CDC recommends almost 1,200 practices for implementation to prevent HAIs and related adverse events. Most of the practices are sorted into five categories—from strongly recommended for implementation to not recommended—primarily on the basis of the strength of the scientific evidence for each practice. Over 500 practices are strongly recommended. CDC and AHRQ have conducted some activities to promote implementation of recommended practices, but these activities are not based on a clear prioritization of the practices. Prioritization may consider not only the strength of the evidence, but also other factors that can affect implementation, such as cost and organizational obstacles. In addition to CDC, AHRQ has reviewed scientific evidence for certain HAI-related practices, but the efforts of the two agencies have not been coordinated.

The infection control standards required by CMS and hospital-accrediting organizations—the Joint Commission and the Healthcare Facilities Accreditation Program of the American Osteopathic Association (AOA)—describe the fundamental components of a hospital's infection control program. These components include the active prevention, control, and investigation of infections. The standards are far fewer in number than the recommended practices in CDC's guidelines and generally do not require that hospitals implement all recommended practices in CDC's infection control and prevention guidelines. CMS, the Joint Commission, and AOA assess compliance with their infection control standards through direct observation of hospital activities and review hospital policy documents during on-site surveys.

Multiple HHS programs collect data on HAIs, but limitations in the scope of information they collect and a lack of integration across the databases maintained by these separate programs constrain the utility of the data. Three agencies within HHS currently collect HAI-related data for a variety of purposes in databases maintained by four separate programs: CDC's National Healthcare Safety Network program, CMS's Medicare Patient Safety Monitoring System, CMS's Annual Payment Update program, and AHRQ's Healthcare Cost and Utilization Project. Each of the four databases presents only a partial view of the extent of the HAI problem because each focuses its data collection on selected types of HAIs and collects data from a different subset of hospital patients across the country. GAO did not find that the agencies were taking steps to integrate data across the four databases by creating linkages across the databases, such as creating common patient identifiers. Creating linkages across the HAI-related databases could enhance the availability of information to better understand where and how HAIs occur. Although CDC officials have produced national estimates of HAIs, those estimates derive from assumptions and extrapolations that raise questions about the reliability of those estimates.

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Abbreviations

ABCs	Active Bacterial Core Surveillance
AHRQ	Agency for Healthcare Research and Quality
AOA	Healthcare Facilities Accreditation Program of the American Osteopathic Association
APIC	Association for Professionals in Infection Control and Epidemiology
APU	Annual Payment Update
BSI	bloodstream infection
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
COP	condition of participation
DRA	Deficit Reduction Act of 2005
DRG	diagnosis-related group
FDA	Food and Drug Administration
HAI	health-care-associated infection
HCUP	Healthcare Cost and Utilization Project
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
MPSMS	Medicare Patient Safety Monitoring System
MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
NHSN	National Healthcare Safety Network
NNIS	National Nosocomial Infections Surveillance
PSI	Patient Safety Indicator
PSO	Patient Safety Organization
SCIP	Surgical Care Improvement Project
SHEA	Society for Healthcare Epidemiology of America
SSI	surgical site infection
UTI	urinary tract infection
VAP	ventilator-associated pneumonia
VRE	vancomycin-resistant enterococci
WHO	World Health Organization

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United States Government Accountability Office
Washington, DC 20548

March 31, 2008

The Honorable Henry Waxman
Chairman
Committee on Oversight and Government Reform
House of Representatives

Dear Mr. Chairman:

According to the Centers for Disease Control and Prevention (CDC), health-care-associated infections (HAI) are estimated to be 1 of the top 10 causes of death in the United States. HAIs, as defined by CDC, are infections that patients acquire while receiving treatment for other conditions.¹ For example, a patient may acquire an infection from bacteria on a device used to treat them, such as a needle or tube to deliver medicine, fluids, or blood. According to CDC, the most common HAIs are urinary tract infection (UTI), surgical site infection (SSI), pneumonia, and bloodstream infection (BSI). Some HAIs can be caused by bacteria that have become resistant to multiple antimicrobial drugs.² One example of such a bacterium is methicillin-resistant *Staphylococcus aureus*, or MRSA, which causes infections that are resistant to treatment with usual antibiotics, including methicillin, and can be serious and potentially life-threatening. MRSA can cause a wide variety of infections, including skin infections, BSIs, SSIs, and pneumonia.

HAIs can be expensive. In 2005 the average payment for a hospitalization in Pennsylvania was over six times higher for patients who contracted a hospital-acquired infection than for patients who did not acquire infections, according to a report by the Pennsylvania Health Care Cost Containment Council.³ A 2007 study of 1.69 million patients who were discharged from 77 hospitals found that the additional cost of treating a

¹In general, HAIs are distinct from community-acquired infections, that is, infections that patients may have acquired before entering the hospital.

²Antimicrobial resistance is the result of microbes changing in ways that reduce or eliminate the effectiveness of drugs, chemicals, or other agents to cure or prevent infections.

³See Pennsylvania Health Care Cost Containment Council, *Hospital-Acquired Infections in Pennsylvania* (Harrisburg, Pa.: November 2006).

patient with an HAI averaged \$8,832.⁴ The costs of HAIs are borne not only by the patients who suffer infections, but also by those who pay for care, such as the Centers for Medicare & Medicaid Services (CMS). According to the American Hospital Association, Medicare paid for over one-third of all hospital costs in 2005.⁵ Hospitals may also incur some of the cost because they are not fully reimbursed for the cost of the extra care attributable to HAIs.

Although not all HAIs are preventable, public and private organizations have established standards and other activities aimed at controlling and preventing them. CMS has established health and safety standards—known as conditions of participation (COP)—with which hospitals must comply in order to be eligible for payment by Medicare and Medicaid and which include the COP for infection control.⁶ Hospitals may choose one of two ways to show that they have met these or equivalent standards: they may be certified by a state agency under agreement with CMS to survey the hospital's compliance with the COPs or they may be accredited by one of two private organizations—the Joint Commission or the Healthcare Facilities Accreditation Program of the American Osteopathic Association (AOA).⁷ Most hospitals are accredited by the Joint Commission.⁸ Other activities within the Department of Health and Human Services (HHS) aimed at addressing the problem of HAIs in hospitals include the development of guidelines by CDC, which contain recommended practices that hospitals may adopt, and several databases in different parts of HHS that contain information about HAIs in hospitals. According to the Institute of Medicine, prevention of HAIs through implementation of

⁴See D. Murphy et al., *Dispelling the Myths: The True Cost of Healthcare-Associated Infections* (Washington, D.C., Association for Professionals in Infection Control and Epidemiology, February 2007).

⁵Medicare is a federal health insurance program that serves over 42 million elderly and certain disabled beneficiaries and pays for health care needs, such as inpatient hospital stays and physician visits.

⁶See 42 C.F.R. § 482.1 (2007).

⁷Section 1865(b)(1) of the Social Security Act also provides that any other national accreditation body that meets certain requirements as determined by HHS may accredit hospitals.

⁸In calendar year 2007, about 81 percent of hospitals were accredited by the Joint Commission, state survey agencies certified approximately 16 percent of hospitals, and less than 2 percent were accredited by AOA. Less than 1 percent of hospitals were accredited by both the Joint Commission and AOA. The Joint Commission was formerly known as the Joint Commission on Accreditation of Healthcare Organizations or "JCAHO."

evidence-based guidelines can lead to improvements in quality of care.⁹ Furthermore, the collection of national data on these infections can provide a benchmark for individual hospitals to gauge their performance and design targeted interventions.

Federal and state lawmakers are also concerned about HAIs and have taken action to reduce them. With the passage of the Deficit Reduction Act of 2005 (DRA),¹⁰ the Congress took steps to revise the way Medicare pays hospitals so that beginning on October 1, 2008, they would not receive higher payments for patients that acquire certain preventable conditions (including any of three HAIs) during their hospital stay.¹¹ The HAI-related preventable conditions that CMS identified in the final regulation implementing subsection 5001(c) of the DRA were UTIs caused by catheters, infections caused by vascular catheters, and mediastinitis following coronary artery bypass graft surgery.¹² According to Consumers Union—a nonprofit organization that has a campaign to stop HAIs—23 state legislatures have enacted laws that require public reporting of hospital HAI rates or HAI-related information.¹³

⁹See K. Adams et al., *Priority Areas for National Action: Transforming Health Care Quality*, Institute of Medicine of the National Academies (Washington, D.C.: The National Academies Press, 2003).

¹⁰Pub. L. No. 109-171, § 5001(c), 120 Stat. 4, 30.

¹¹Under Medicare, hospitals generally receive fixed payments for inpatient stays based on diagnosis-related groups (DRG), a system that classifies stays by patient diagnoses and procedures. Some DRGs take account of certain comorbidities or complications associated with a diagnosis or procedure and pay at a higher rate than would otherwise be paid for the diagnosis or procedure. In a final regulation implementing section 5001(c) of the DRA, CMS identified certain preventable conditions it would not consider as a comorbidity or complication that would lead to the higher payment. See 72 Fed. Reg. 47130, 47200-217 (Aug. 22, 2007). The DRA also requires hospitals to indicate the diagnoses that were present in patients at the time of admission in order for CMS to determine if a preventable condition developed during a patient's hospital stay.

¹²Mediastinitis is inflammation of the area between the lungs (the heart, the large blood vessels, the trachea, the esophagus, the thymus gland, and connective tissues). Additional preventable conditions that will no longer result in higher payments to hospitals include hospital-acquired injuries, such as fractures, pressure ulcers, objects left in the body during surgery, air embolisms, and blood incompatibility. CMS plans to propose additional conditions in the fiscal year 2009 Hospital Inpatient Prospective Payment Systems proposed rule. See 72 Fed. Reg. 47130 (Aug. 22, 2007).

¹³See Consumers Union, "State Hospital Infection Disclosure Laws," available at <http://www.consumersunion.org/campaigns/stophospitalinfections/learn.html>, accessed on March 10, 2008.

In light of congressional activity in this area and concerns you raised about how to prevent or reduce HAIs in hospitals, we examined (1) CDC's guidelines for hospitals to reduce or prevent HAIs, and what HHS does to promote their implementation, (2) CMS's and the accrediting organizations' required standards for hospitals to reduce or prevent HAIs, and how compliance is assessed, and (3) HHS programs that collect data related to HAIs in hospitals, and the extent the data are integrated across HHS.

In general, to conduct our work, we reviewed documents and interviewed HHS agency officials, including officials from CDC, CMS, the Agency for Healthcare Research and Quality (AHRQ), and the Food and Drug Administration (FDA).

To identify CDC's guidelines for hospitals related to HAIs as well as assess their content, we reviewed CDC's infection control and prevention guidelines issued between 1981 and 2007. To determine the extent to which HHS promotes CDC's guidelines, we asked CDC officials about the activities they undertake to promote their guidelines, and we interviewed officials from AHRQ. We reviewed minutes of the Healthcare Infection Control Practices Advisory Committee (HICPAC), a federal advisory body appointed by the Secretary of HHS that provides recommendations to the Secretary and CDC and includes members from government agencies and private organizations.¹⁴ In addition, we interviewed officials from CDC, CMS, FDA, and AHRQ. We interviewed selected experts in the field of infection control, including individuals from private organizations that represent health professionals in infection control and develop materials to support their work, such as the Society for Healthcare Epidemiology of America (SHEA) and the Association for Professionals in Infection Control and Epidemiology (APIC). We also reviewed the World Health Organization's (WHO) guideline on hand hygiene.¹⁵

To determine CMS's and the accrediting organizations' required standards for hospitals to reduce or prevent HAIs and how compliance is assessed,

¹⁴Representatives from the following government agencies are nonvoting members of HICPAC: CDC, CMS, AHRQ, FDA, the National Institutes of Health, and the Health Resources and Services Administration.

¹⁵See World Health Organization, *WHO Guidelines on Hand Hygiene in Healthcare (Advanced Draft): Global Patient Safety Challenge 2005-2006: Clean Care Is Safer Care* (Geneva, Switzerland, 2006).

we reviewed CMS's COPs for hospitals and the Joint Commission's and AOA's standards for hospitals and interviewed officials from CMS, the Joint Commission, and AOA. We reviewed CMS's interpretive guidelines, which describe the COPs and provide survey procedures used to determine compliance with them and can be found primarily in CMS's *State Operations Manual*.¹⁶ In addition, we reviewed CMS's revised interpretive guidelines for the infection control COP, which were published in November 2007, during the course of our work.¹⁷ We also reviewed the Joint Commission's and AOA's hospital standards manuals. For the purpose of this report, we refer to the guidance that CMS provides about its COPs in the interpretive guidelines, and that the Joint Commission and AOA provide about their standards in their respective manuals, as "standards interpretations." Our review focused on CMS's infection control COP and the standards the Joint Commission and AOA have in the infection control chapters of their respective manuals. We obtained the following information from each organization: the number of hospitals surveyed by each organization during the first quarter of 2007, and the number of hospitals surveyed by each organization during the first quarter of 2007 that were cited as noncompliant with one of the standards on infection control. Using the data we obtained from these officials, we calculated the percentage of hospitals surveyed by each organization that were noncompliant with at least one infection control standard for the first quarter of 2007. Based on information obtained from and discussions with each organization, we determined that the data CMS, the Joint Commission, and AOA provided to us were sufficiently reliable for the purposes of this report.

To identify HHS programs that routinely collect and maintain in designated databases information that relates specifically to HAIs, we interviewed officials at CDC, CMS, AHRQ, and FDA, and reviewed relevant documents. To describe and assess the programs HHS has that collect data related to HAIs and determine the extent to which the data are integrated, we reviewed agency manuals and other relevant documents that explain the programs that collect the data, examined related publications and data analyses conducted by the agencies based on the data collected, and

¹⁶HHS officials noted that the interpretive guidelines are used by Medicare and Medicaid providers, such as hospitals, critical access hospitals, hospices, nursing homes, and home health agencies, to determine how to implement the requirements in the COPs.

¹⁷Throughout this report, where we refer to the interpretive guidelines for infection control we are referring to the most recent revision.

reviewed HICPAC meeting minutes from March 2004 to June 2007. We also interviewed officials of CDC, CMS, FDA, and AHRQ responsible for each agency's HAI data collection efforts. We obtained data reported from these HAI-related databases, and based on relevant documents and discussion with agency officials we determined that the data were sufficiently reliable for the purposes of this report.

We examined only guidelines, standards, and databases that apply to HAIs in acute care hospitals other than critical access hospitals and did not examine guidelines, standards, or databases that might apply to community-acquired infections or health care workers. We did not independently assess the clinical evidence that supports CDC's infection control and prevention guidelines. We describe CMS's, the Joint Commission's, and AOA's infection control standards, the standards interpretations, and the survey process, but we did not observe the survey process. We conducted this performance audit from January 2007 to March 2008, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

CDC has 13 guidelines for hospitals on infection control and prevention, and in these guidelines CDC recommends almost 1,200 practices for implementation to prevent HAIs and related adverse events. The guidelines cover such topics as prevention of catheter-associated UTIs, prevention of SSIs, and hand hygiene. An example of a recommended practice in the hand hygiene guideline is the recommendation that health care workers decontaminate their hands before having direct contact with patients. Most of the practices are sorted into five categories—from strongly recommended for implementation to not recommended—primarily on the basis of the strength of the scientific evidence for each practice. Over 500 practices are strongly recommended. CDC and AHRQ have conducted some activities to promote implementation of recommended practices, such as disseminating the guidelines and providing research funds. However, these steps have not been guided by a prioritization of recommended practices. One factor to consider in prioritization is strength of evidence, as CDC has done. In addition to strength of evidence, an AHRQ study identified other factors to consider in prioritizing recommended practices, such as costs or organizational obstacles. Furthermore, the efforts of the two agencies have not been

coordinated. For example, we found that CDC and AHRQ both conducted reviews of evidence for HAI-related practices, such as hand hygiene. Although this could have been an opportunity for coordination, an official from the HHS Office of the Secretary told us that no one within the office is responsible for coordinating infection control activities across HHS.

While CDC's infection control guidelines describe specific clinical practices recommended to reduce HAIs, the infection control standards that CMS and the accrediting organizations require as part of the hospital certification and accreditation processes describe the fundamental components of a hospital's infection control program. These components include the active prevention, control, and investigation of infections. Examples of standards and corresponding standards interpretations that hospitals must follow include educating hospital personnel about infection control and having infection control policies in place. The standards are far fewer in number than the recommended practices in CDC's guidelines—for example, CMS's infection control COP contains two standards. Furthermore, CMS and the accrediting organizations generally do not require that hospitals implement all recommended practices in CDC's infection control and prevention guidelines. Only the Joint Commission and AOA have standards that require the implementation of certain practices recommended in CDC's infection control guidelines. For example, the Joint Commission and AOA require hospitals to annually offer influenza vaccinations to health care workers, whereas CMS's interpretive guidelines, or standards interpretations, are more general, stating that hospitals should adopt policies and procedures based as much as possible on national guidelines that address hospital-staff-related issues, such as evaluating hospital staff immunization status for designated infectious diseases. CMS, the Joint Commission, and AOA assess compliance with their infection control standards through direct observation of hospital activities and review of hospital policy documents during on-site surveys.

Multiple HHS programs collect data on HAIs, but limitations in the scope of information they collect and the lack of integration across the databases maintained by these separate programs constrain the utility of the data. Three agencies within HHS—CDC, CMS, and AHRQ—currently collect HAI-related data for a variety of purposes in databases maintained by four separate programs: CDC's National Healthcare Safety Network (NHSN) program, CMS's Medicare Patient Safety Monitoring System (MPSMS), CMS's Annual Payment Update (APU) program, and AHRQ's Healthcare Cost and Utilization Project (HCUP). Each of these databases presents only a partial view of the extent of the HAI problem because each focuses

its data collection on selected types of HAIs and collects data from a different subset of hospital patients across the country. Although officials from the various HHS agencies discuss HAI data collection with each other, we did not find that the agencies were taking steps to integrate any of the existing data by creating linkages across the databases, such as creating common patient identifiers. Creating linkages across the HAI-related databases could enhance the availability of information to better understand where and how HAIs occur. Although none of the databases collect data on the incidence of HAIs for a nationally representative sample of hospital patients, CDC officials have produced national estimates of HAIs. However, those estimates derive from assumptions and extrapolations that raise questions about the reliability of those estimates.

In order to help reduce HAIs in hospitals, we are calling for stronger leadership from HHS by recommending that the Secretary of HHS take action to prioritize prevention practices and improve data about HAIs. In commenting on a draft of this report, HHS generally agreed with our recommendations. In terms of our first recommendation, HHS's comments indicated that CMS welcomed the opportunity to work with CDC to review and prioritize recommendations for infection control and would consider whether to incorporate some of the recommendations into CMS's hospital COPs. HHS's comments also noted that the COPs currently lack the specificity of guidance and recommendations issued by HHS agencies, including CDC's recommendations for infection control. In terms of our second recommendation, HHS's comments acknowledged the need for greater consistency and compatibility of the data collected on HAIs and identified some steps CMS would take to implement this recommendation. HHS also provided technical comments, which we incorporated as appropriate. In response to comments from the Joint Commission, we clarified the discussion of Joint Commission activities; in addition, we incorporated technical comments from the Joint Commission and AOA.

Background

CDC has developed several guidelines for hospitals that describe and recommend practices to prevent or control HAIs, such as hand washing or the use of alcohol-based hand rubs, isolation of infected patients, proper sterilization of equipment, provision of antibiotics to patients before surgery, and annual vaccination of health care workers for influenza. Standards from CMS and hospital accrediting organizations provide a means for assessing hospital compliance with infection control standards that are also aimed at preventing or controlling HAIs.

CDC's Infection Control and Prevention Guidelines

CDC issues both guidelines and guidance relevant to infection control and prevention in hospitals. Guidelines are based on scientific evidence, whereas guidance is usually provisional and limited in its supporting evidence. CDC's infection control and prevention guidelines set forth recommended practices, summarize the applicable scientific evidence and research, and contain contextual information and citations for relevant studies and literature.

Most of CDC's infection control and prevention guidelines are developed in conjunction with HICPAC, an advisory body created in 1992 by the Secretary of HHS. According to its charter, HICPAC provides CDC and the Secretary with (1) advice and guidance on the practice of infection control and strategies for surveillance,¹⁸ prevention, and control of HAIs and related events in health care facilities; and (2) advice on the periodic updating of existing HAI guidelines, the development of new guidelines and evaluations, and other HAI policy statements.¹⁹ HICPAC currently consists of 14 voting members from various infection control disciplines throughout the United States, a designated staff person from CDC, and 15 nonvoting liaison members from government agencies and private organizations.

When CDC and HICPAC select a topic for an infection control and prevention guideline, they begin with internal discussions. After selecting a topic, HICPAC members and CDC conduct research on the topic, which includes identifying and evaluating clinical studies relevant to the topic and developing recommended practices, as appropriate. The draft guidelines are written and reviewed by HICPAC members; circulated to outside experts to validate the content; and sent to other federal agencies for review and approval.²⁰ Afterward, HICPAC members resolve issues

¹⁸Public health surveillance is defined as the ongoing systematic collection, analysis, and interpretation of health data for purposes of improving health and safety.

¹⁹The creation of HICPAC is authorized under section 222 of the Public Health Service Act (codified at 42 U.S.C. §217a). The committee is governed by the provisions of the Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (1972), (codified at 5 U.S.C. App. 2), which sets forth standards for the formation and use of an advisory committee.

²⁰In addition, CDC circulates the draft guideline to experts outside of CDC for comment as part of an Office of Management and Budget initiative to respond to concerns about whether diverse experts and members of the public are provided with sufficient opportunities to comment on influential scientific information or highly influential assessment documents. CDC's infection control and prevention guidelines are considered highly influential documents.

raised during review in face-to-face meetings or conference calls with HICPAC members who wrote the guideline. The approved document is published in the *Federal Register* for a 45- to 60-day public comment period, after which comments are reviewed by HICPAC members. CDC publishes the final guideline in its *Morbidity and Mortality Weekly Report*, on its Web site, or through a professional journal.

CMS's and the Accrediting Organizations' Standards for Hospitals

Hospital compliance with CMS's or the accrediting organizations' standards, including those related to infection control, is assessed on a regular basis. Unannounced on-site surveys, conducted by surveyors from CMS or the accrediting organizations, are a major component in the process by which hospitals' compliance with health and safety standards is assessed. Standards interpretations are given by CMS primarily in its *State Operations Manual*,²¹ which is arranged by COP; by the Joint Commission in its *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*, which identifies rationales and performance expectations that are used to measure each standard and is organized into 11 chapters of safety and quality standards such as "Medication Management" and "Leadership;" and by AOA's standards manual, *Accreditation Requirements for Healthcare Facilities*, which provides explanations for surveyors and the scoring procedures along with its standards and is organized into

32 chapters. Based on the information documented during the survey, surveyors from each organization assess a hospital's compliance with the standards.²² Hospitals are required to correct instances of noncompliance found during the survey. CMS's policy is to survey hospitals every 3 years; however, this policy is contingent on CMS's budget. In fiscal year 2007, CMS set a goal to survey hospitals on average once every 4.5 years, with no more than 6 years elapsing between surveys for any one hospital. Both the Joint Commission and AOA survey hospitals at least once every 3 years.

²¹Appendix A of the *State Operations Manual* contains the COPs for hospitals and is available at http://www.cms.hhs.gov/GuidanceforLawsAndRegulations/08_Hospitals.asp, downloaded on May 14, 2007.

²²As we noted in a previous report, due to the Joint Commission's unique legal status, CMS has limited oversight authority over the Joint Commission's hospital accreditation program. See GAO, *Medicare: CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals*, [GAO-04-850](#) (Washington, D.C.: July 20, 2004).

The Joint Commission has additional components in its standards and survey process. First, it issues National Patient Safety Goals, which are requirements intended to promote specific improvements in patient safety. Officials at the Joint Commission told us that the goals are updated annually and derive primarily from informal recommendations made in the Joint Commission’s safety newsletter, *Sentinel Event Alert*, recommendations from the Sentinel Event Advisory Group, sentinel events reported to the Joint Commission, and a review of the patient safety literature. The goals target problem areas in health care, such as reducing the risk of patient injury resulting from a fall or encouraging patients’ active involvement in their own care. Each goal is reviewed during the on-site survey to determine compliance with it. Second, the Joint Commission conducts several “tracers” as part of its hospital surveys, during which the care provided to selected patients is followed or “traced” through the hospital in the same sequence in which the patient received it. Other requirements that a hospital must meet to be accredited by the Joint Commission include conducting an annual self-assessment of the hospital’s compliance with the Joint Commission standards and submitting data for selected measures of clinical performance, some of which are related to HAIs.

CDC Has 13 Infection Control and Prevention Guidelines Containing Almost 1,200 Recommended Practices, but Activities across HHS to Promote Implementation Are Not Guided by Prioritization of Practices

CDC has 13 guidelines for hospitals on infection control and prevention, and in these guidelines CDC recommends almost 1,200 specific clinical practices for implementation to prevent HAIs and related adverse events. The practices generally are sorted into five categories—from strongly recommended for implementation to not recommended—primarily on the basis of the strength of the scientific evidence for each practice. Over 500 practices are strongly recommended. Within HHS, CDC and AHRQ conduct some activities to promote the implementation of recommended practices, but the activities are not based on clear prioritization of the practices, which may consider not only the strength of the evidence, but also other factors that can affect implementation, such as cost or organizational obstacles.

CDC Has 13 Infection Control and Prevention Guidelines, Which Contain Almost 1,200 Recommended Practices, and over 500 of Them Are Strongly Recommended

CDC has 13 infection control and prevention guidelines, which contain 1,198 specific clinical practices that CDC recommends for preventing HAIs.²³ (See table 1.) The hand hygiene guideline, for example, strongly recommends that health care workers decontaminate their hands before having direct contact with patients. The number of recommended practices for each guideline varies. For example, the 2003 guideline outlining environmental infection control practices contains 329 recommended practices, whereas the 2006 guideline for influenza vaccination of health care personnel has 6 recommended practices. The earliest of the guidelines, which was on catheter-associated UTIs, was published in February 1981, and as of December 2007, the most recent, a revision of the guideline for isolation precautions, was published in June 2007.

²³CDC has issued four infection control guidance documents for hospitals: (1) *Infection Control Guidance for the Prevention and Control of Influenza in Acute-Care Facilities*, (2) *Interim Guidance for the Use of Masks to Control Influenza Transmission*, (3) *Respiratory Hygiene/Cough Etiquette*, and (4) *Guidelines on Public Reporting of Healthcare-Associated Infections*. While the title of this fourth guidance document includes the word “guidelines,” CDC officials consider this document to be guidance.

Table 1: CDC’s Infection Control and Prevention Guidelines, with Number of Recommended Practices, Issued between 1981 and 2007

Guideline (issue date)	Total number of recommended practices
1 Guideline for Prevention of Catheter-associated Urinary Tract Infections (1981)	24
2 Guideline for Infection Control in Health Care Personnel (1998)	183
3 Guideline for Prevention of Surgical Site Infection (1999)	63
4 Guidelines for Preventing Opportunistic Infections among Hematopoietic Stem Cell Transplant Recipients (2000)	a
5 Guidelines for the Prevention of Intravascular Catheter-Related Infections (2002)	111
6 Guideline for Hand Hygiene in Health-Care Settings (2002)	42
7 Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program (2003)	b
8 Guidelines for Environmental Infection Control in Health-Care Facilities (2003)	329
9 Guidelines for Preventing Health-Care-Associated Pneumonia (2003)	208
10 Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings (2005)	b
11 Influenza Vaccination of Health-Care Personnel (2006)	6
12 Management of Multidrug-Resistant Organisms in Healthcare Settings (2006)	80
13 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)	152
Total	1,198

Source: GAO analysis of CDC guidelines.

^aFor the purpose of this table, we do not include a count of the recommended practices in this guideline because the guideline is targeted to a specific patient population that not all hospitals treat. However, for the hospitals that do treat such patients, this guideline provides at least another 164 recommended practices.

^bThe practices in these guidelines are not organized in a way that supports counting the total number of practices.

The practices in these 13 guidelines are categorized primarily based on the strength of the scientific evidence, and these categories have changed over time. Basing the categories on the strength of the evidence means that the more highly recommended practices have more and better scientific support indicating their effectiveness than those practices that are not as highly recommended. Seven of the guidelines published between 2002 and 2007 used five categories: (1) strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiological studies; (2) strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale; (3) suggested for implementation by suggestive clinical or epidemiologic studies; (4) additional practices,

including federal, state, and other requirements; and (5) not recommended due to insufficient evidence or lack of consensus regarding efficacy.²⁴ Over 500 practices in these 7 guidelines fall into one of the two strongly recommended categories. Six of the 7 guidelines identify 82 practices that are not recommended, due to a lack of evidence supporting a recommendation. (See table 2.) For example, the 2003 guideline for preventing health-care-associated pneumonia identifies 45 practices that are not recommended. The four guidelines issued between 1981 and 2000 ranked recommended practices into between three and five categories.²⁵ The 2003 guideline on smallpox vaccine and the 2005 guideline on mycobacterium tuberculosis contain recommended practices, but they are not categorized.²⁶

²⁴CDC placed some of the practices in these seven guidelines in two categories.

²⁵Recommended practices related to *Guideline for Prevention of Catheter-associated Urinary Tract Infections* issued in 1981 were categorized as (1) strongly recommended, (2) moderately recommended, and (3) weakly recommended for adoption. *Guideline for Infection Control in Health Care Personnel* issued in 1998 and *Guideline for Prevention of Surgical Site Infection* issued in 1999 used a slightly different four-tier ranking system of (1) strongly recommended and strongly supported by well-designed experimental or epidemiologic studies, (2) strongly recommended based on strong rationale and suggestive evidence, (3) suggested for implementation based on suggestive clinical or epidemiologic studies, and (4) no recommendation or unresolved issue. *Guidelines for Preventing Opportunistic Infections among Hematopoietic Stem Cell Transplant Recipients* issued in 2000 used an evidence-based rating system to determine strength of recommendations and another evidence-based system to determine quality of evidence. Using the first system, the recommendations were categorized as (1) strongly recommended, (2) generally recommended, (3) optional, (4) generally not recommended, and (5) never recommended.

²⁶These two guidelines were created outside of HICPAC by another CDC advisory committee—the Advisory Committee on Immunization Practices—and CDC’s Division of Tuberculosis Elimination.

Table 2: Number of Practices in the Seven CDC Infection Control and Prevention Guidelines That Used the Five Categories, by Category

Guideline	Recommended practices			Total number of recommended practices	Additional practices including federal, state, and other requirements ^a (Category 4)	Not recommended practices (Category 5)
	Strongly recommended and strongly supported (Category 1)	Strongly recommended and supported (Category 2)	Suggested for implementation (Category 3)			
Guidelines for the Prevention of Intravascular Catheter-Related infections (2002)	39	39	33	111	3	8
Guideline for Hand Hygiene in Health-Care Settings (2002)	9	20	13	42	2	2
Guidelines for Environmental Infection Control in Health-Care Facilities (2003)	10	134	185	329	94	16
Guidelines for Preventing Health-Care-Associated Pneumonia (2003)	28	97	83	208	1	45
Influenza Vaccination of Health-Care Personnel (2006)	1	3	2	6	0	0
Management of Multidrug-Resistant Organisms in Healthcare Settings (2006)	2	60	18	80	1	4
Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007)	21	83	48	152	3	7
Total by category	110	436	382	928	104	82

Source: GAO analysis of CDC guidelines.

Notes: CDC has 13 infection control guidelines, of which about half are categorized using the five categories displayed in this table.

^aFor the purpose of this table, Category 4 excludes a count of practices that CDC also classified as recommended. More than 84 percent of the practices in Category 4 are, for example, Occupational Safety and Health Administration workplace standards, building and engineering standards, or administrative plans or procedures.

In general, CDC took an average of about 3 years to develop each guideline—ranging from less than 1 year to 6 years. CDC officials agreed that the amount of time it took to prepare a guideline has been long. CDC reported that it has been developing one guideline that is still in draft form—the Guideline for Disinfection and Sterilization in Healthcare Facilities—for over 7 years.²⁷ This guideline has taken a long time to develop, in part, according to CDC officials, because the agency had to coordinate with other agencies involved in the oversight of disinfection and sterilization products. CDC officials said they were working to reduce the time it takes to develop guidelines by issuing shorter and more focused guidelines.

CDC and AHRQ Have Taken Steps to Promote Implementation of Practices to Reduce HAIs but Lack Prioritization of These Practices to Guide Their Actions

CDC officials identified some activities that the agency has undertaken to promote the implementation of the recommended practices in its guidelines.²⁸ CDC disseminates its infection control guidelines by publishing them in the *Morbidity and Mortality Weekly Report*, posting them on CDC's Web site, and distributing training videos. CDC has also provided some funding support to groups that are developing ways to implement selected recommendations in CDC infection control guidelines. For example, through its Prevention Epicenter Program,²⁹ CDC provided financial support and technical assistance to a study that was assessing the effect of an intervention to prevent catheter-associated BSIs. The researchers reviewed participating hospitals' policies and procedures on a commonly used catheter, updated them to reflect CDC's *Guidelines for the Prevention of Intravascular Catheter-Related Infections*, and implemented an intervention designed to educate staff about the importance of implementing a group of selected recommendations in that

²⁷ CDC has been drafting this guideline since 2000, and CDC officials told us they expected to publish the guideline in 2008.

²⁸ This section addresses efforts to facilitate or encourage implementation of recommended practices, as distinct from requiring hospitals to adopt these practices by incorporating them in the standards set by CMS, the Joint Commission, and AOA.

²⁹ CDC began the Prevention Epicenter Program in 1997 as a way to collaborate with academic institutions to investigate the epidemiology and prevention of HAIs. More information on CDC's Prevention Epicenter Program and other HAI-related activities can be found in app. I.

guideline.³⁰ In a similar effort, CDC provided technical support and funding to the Pittsburgh Regional Healthcare Initiative, which reportedly has demonstrated a 68 percent decline in BSIs over a 4-year period among intensive care unit patients.³¹

AHRQ officials also reported undertaking some initiatives to promote implementation of practices aimed at reducing HAIs. In 2007, AHRQ issued a report that evaluated several strategies, such as clinician and patient education, for possible use in hospitals to increase implementation of specified infection prevention practices related to catheterization, surgical antibiotic prophylaxis, central lines, and ventilator-associated pneumonia (VAP) interventions.³² Although researchers were unable to reach any firm conclusions regarding actionable strategies to prevent HAIs, they identified four strategies worth additional study.³³ In addition, through its Accelerating Change and Transformation in Organizations and Networks program, in September 2007, AHRQ funded several studies to improve the implementation of practices that are known to minimize HAIs and to identify the challenges to implementing those practices.³⁴ The program will implement clinician training at 72 hospitals that is designed to facilitate change in clinician behaviors and habits, care processes, and the safety culture of the participating hospitals. In a document summarizing this initiative, AHRQ acknowledges that the problem is not the lack of

³⁰Studies have demonstrated reductions in HAIs when selected recommended practices are implemented as a group or “bundle.” The Institute for Healthcare Improvement and the Michigan Health and Hospital Association Keystone Intensive Care Unit Project have also employed the bundle approach with success. See P. Pronovost et al., “An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU,” *The New England Journal of Medicine*, vol. 355, no. 26 (2006): 2725–2732.

³¹See C. Muto et al., “Reduction in Central Line-Associated Bloodstream Infections among Patients in Intensive Care Units—Pennsylvania, April 2001–March 2005,” *Morbidity and Mortality Weekly Report*, vol. 54, no. 40 (2005): 1013–1016.

³²See S. R. Ranji et al., *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies, Volume 6—Prevention of Healthcare-Associated Infections*, AHRQ Publication No. 04(07)-0051-6 (Rockville, Md., January 2007).

³³The four strategies were (1) use of printed or computer-based reminders with automatic stop orders to reduce unnecessary urethral catheterization; (2) printed or computer-based reminders to improve surgical antibiotic prophylaxis; (3) active educational interventions with use of checklists to improve adherence to central line insertion practices; and (4) active educational interventions such as tutorials to improve adherence to preventive interventions for ventilator-associated pneumonia.

³⁴According to AHRQ, this program develops and diffuses scientific evidence about what works and does not work to improve health care delivery systems.

knowledge of infection control techniques, but rather the inability to translate the knowledge into social and behavioral changes that can be sustained in health care organizations.

While CDC and AHRQ have taken steps to promote the implementation of practices to reduce HAIs, these steps have not been guided by a prioritization of recommended practices. As WHO has indicated in its hand hygiene guideline, when there is a large number of practices it is important to prioritize them. One factor to consider in prioritization is strength of evidence, which CDC has primarily relied on to categorize its recommended practices. However, a 2001 AHRQ study suggested other factors to consider in prioritizing recommended practices. This study rated 79 patient safety practices—including 22 practices that were related to HAIs—on their potential to improve patient safety. The study examined not only strength of the evidence, but also such factors as

- the potential magnitude of impact of the practice on mitigating patient death or disability,
- the financial cost of implementing the practice,
- the complexity of implementing the practice,
- the organizational and technical obstacles, and
- the risk that other negative consequences could occur if the practice were put into place.

In addition to CDC, AHRQ has reviewed scientific evidence for certain practices related to HAIs, but the efforts of the two agencies have not been coordinated. For example, both agencies independently examined various aspects of the evidence related to improving hand hygiene compliance, such as the selection of hand hygiene products and health care worker education. Although this could have been an opportunity for coordination, an official from the HHS Office of the Secretary told us that no one within the office is responsible for coordinating infection control activities across HHS.³⁵

³⁵ Although HICPAC includes representation from multiple HHS agencies as well as from private organizations, it is not responsible for coordinating the activities of these groups and functions as an advisory body to the Secretary of HHS.

CMS's and Accrediting Organizations' Required Hospital Standards Describe Components of Infection Control Programs, and Compliance with These Standards Is Assessed through On-Site Surveys

The infection control standards that CMS, the Joint Commission, and AOA require as part of the hospital certification and accreditation processes vary in number and content among the organizations, and generally describe the fundamental components of a hospital infection control program, that is, the active prevention, control, and investigation of infections. Examples of standards and corresponding standards interpretations that hospitals must follow include educating hospital personnel about infection control and having infection control policies in place. CMS, the Joint Commission, and AOA standards generally do not require that hospitals implement all recommended practices in CDC's infection control and prevention guidelines. Only the Joint Commission and AOA have standards that require the implementation of certain practices recommended in CDC's infection control guidelines. For example, the Joint Commission and AOA require hospitals to annually offer influenza vaccinations to health care workers, which is recommended in CDC's *Influenza Vaccination of Health Care Personnel* guideline. CMS, the Joint Commission, and AOA assess compliance with their infection control standards through direct observation of hospital activities and review of hospital policy documents during on-site surveys.

Standards for Hospitals on Infection Control Required by CMS and Accrediting Organizations Describe Components of Infection Control Programs

CMS, Joint Commission, and AOA standards for hospital certification and accreditation include standards on infection control. In contrast to CDC's infection control guidelines, which describe clinical practices recommended to reduce HAIs, the CMS, Joint Commission, and AOA standards and their interpretations—which include the performance expectations and explain the standards—describe the fundamental components of a hospital's infection control program, the overall goal of which is the prevention, control, and investigation of infections.

CMS's infection control COP, the Joint Commission's chapter on infection control, and AOA's chapter on infection control have varying numbers of standards, some of which have been updated more recently than others. (See app. II for CMS's, Joint Commission's, and AOA's infection control standards for hospitals.)

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- CMS's infection control COP contains two standard-level requirements and has not substantially changed since 1986.³⁶ CMS's *State Operations Manual: Appendix A* provides guidance to surveyors in assessing compliance with the COP and explains its intent. CMS issued revised guidance to surveyors for assessing the infection control COP on November 21, 2007, with an immediate effective date.
 - The Joint Commission has 10 infection control standards in the infection control chapter of its manual, the *Comprehensive Accreditation Manual for Hospitals: The Official Handbook*.³⁷ The Joint Commission describes its standards as broad, overarching compliance principles. The Joint Commission manual provides hospitals with information about the accreditation process, including how to comply with the 10 standards in the infection control chapter, and presents a rationale for each standard and "elements of performance," which describe the specific requirements for a hospital to be in compliance with a standard. There are a total of 48 elements of performance associated with the standards in the infection control chapter, ranging from 2 to 8 per standard. In 2006 the Joint Commission began revising its hospital standards, including the infection control standards. These revisions, which the Joint Commission officials described as clarifications to existing standards, will take effect on January 1, 2009.³⁸ The Joint Commission manual also describes other requirements hospitals must meet to be accredited by the Joint Commission, such as the eight National Patient Safety Goals for 2008, one of which relates to HAIs and requires hospitals to (1) comply with the current WHO hand hygiene guideline or CDC hand hygiene guideline³⁹ and

³⁶The infection control COP is found in 42 C.F.R. § 482.42 (2007). CMS officials said that the quality assessment and performance improvement COP, which can be found at 42 C.F.R. § 482.21 (2007), can also affect infection control. The quality assessment and performance improvement COP states that the hospital must develop, implement, and maintain an effective, ongoing, hospitalwide, data-driven quality assessment and performance improvement program that reflects all of the hospital's departments and services.

³⁷Joint Commission officials said that standards in other chapters of their manual could also affect infection control, such as standards in the "Provision of Care" chapter, the "Treatment and Services" chapter, the "Medication Management" chapter, the "Improving Organization Performance" chapter, the "Leadership" chapter, and the "Management of the Environment of Care" chapter.

³⁸Prior to the revisions that will take effect on January 1, 2009, the Joint Commission added a standard requiring hospitals to immunize staff and licensed independent practitioners against influenza. This standard took effect on January 1, 2007.

³⁹Prior to 2008, the Joint Commission's National Patient Safety Goal included only the CDC hand hygiene guideline.

(2) manage as a “sentinel event” all identified cases of unanticipated death or major permanent loss of function associated with an HAI.⁴⁰

- AOA has 51 standards in the “Infection Control” chapter of its *Accreditation Requirements for Healthcare Facilities* manual, which also provides guidance to surveyors in applying AOA’s standards, and these were last updated in 2005.⁴¹ AOA officials also told us they anticipated updating this chapter to reflect CMS’s revised infection control COP guidance.

As a whole, the CMS, Joint Commission, and AOA standards and their interpretations describe similar required elements of hospital infection control programs. Similarities include the following:

- The infection control program is hospitalwide.
- The hospital designates a person or persons as responsible for the infection control program.
- The hospital develops policies to control and reduce infections.
- The hospital educates health care personnel, patients, and family members about infection control.
- The hospital conducts surveillance activities, which include infection-related data collection and analysis.
- The hospital evaluates the effectiveness of infection control activities and modifies or updates the infection control program as needed.

However, there are also differences between the CMS, Joint Commission, and AOA infection control standards and their interpretations. One example is that the CMS and AOA standards specify that the hospital

⁴⁰The Joint Commission defines a sentinel event as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. To “manage as a sentinel event” for this goal is to determine why the patient acquired the infection and why the patient died or suffered serious injury as a result of the infection.

⁴¹AOA officials said that standards in other chapters of their manual could also affect infection control, including the chapters on “Medical Staff,” “Physical Environment,” “Quality Assessment and Performance Improvement,” “Cardiovascular Services,” and “Special Care Units.” The “Medical Staff” chapter describes the activities of the infection control committee, which is required in the “Infection Control” chapter.

should maintain a log of infections and communicable diseases detected at the hospital, whereas the Joint Commission has several standards whose elements of performance state that hospitals should collect infection control surveillance data. Another difference is the extent to which the standards and their interpretations require implementation of practices recommended in CDC's infection control guidelines. The CMS, Joint Commission, and AOA standards generally do not require that hospitals implement all required practices in CDC's infection control and prevention guidelines. While CMS's and the accrediting organizations' standards interpretations make general references to incorporating guidelines into the hospital's infection control activities, only the Joint Commission and AOA have standards that require the implementation of certain practices recommended in CDC's infection control guidelines. The CMS standards interpretations have a more general statement that a hospital with a comprehensive hospitalwide infection control program should adopt policies and procedures based as much as possible on national guidelines. For example:

- As noted previously, a Joint Commission National Patient Safety Goal requires hospitals to implement selected practices in either CDC's or WHO's hand hygiene guideline.⁴² AOA has a standard on hand washing that requires hospitals to have policies and procedures on practices related to hand decontamination and the prevention of HAIs, some of which are also recommended in CDC's guidelines, such as the elimination of artificial nails for staff working in intensive care units. The CMS standards interpretations are more general, stating that hospitals should adopt policies and procedures based on national guidelines that, among other things, address the mitigation of risks that contribute to HAIs by, for example, promoting hand washing hygiene among staff and employees, including use of alcohol-based hand sanitizers.
- Two AOA standards require hospitals to comply with certain practices recommended in CDC's guidelines that reduce surgical site infections and prevent central venous catheter-related infections. The CMS and Joint Commission standards and their interpretations are not as specific. The CMS standards interpretations state that a hospital with a comprehensive infection control program should adopt policies and procedures that

⁴²The selected practices in CDC's and WHO's hand hygiene guidelines are those in the categories of (1) strongly recommended and strongly supported; (2) strongly recommended and supported; and (3) additional practices, including federal, state, and other requirements.

address the mitigation of risk associated with HAIs, including surgery-related infections and device-associated infections. The Joint Commission standards interpretations state that hospitals set goals that include minimizing the risk of transmitting infections associated with the use of procedures, medical equipment, and medical devices and implement methods such as appropriate sterilization techniques to reduce those risks.

- Both the Joint Commission and AOA standards incorporate recommendations from CDC's guideline *Influenza Vaccination of Health-Care Personnel* by requiring hospitals to annually offer influenza vaccinations to health care workers. In contrast, the CMS standards interpretations are more general, stating that hospitals should adopt policies and procedures that address hospital-staff-related issues, such as evaluating hospital staff immunization status for designated infectious diseases, as recommended by CDC and its Advisory Committee on Immunization Practices.

Compliance with Required Infection Control Standards Is Assessed through Observation and Document Review during On-Site Surveys of Hospitals

During on-site surveys, CMS, Joint Commission, or AOA surveyors assess compliance with their respective infection control standards by directly observing patient care, interviewing hospital staff, and reviewing key infection control documents, such as the hospital's infection control plan. In addition, the Joint Commission's surveyors assess compliance with the infection control standards by conducting an infection control system tracer, which is designed to address a hospital's overall system for detecting and preventing infections. Joint Commission officials noted that they foster compliance with the practices for reducing HAIs by using a "systems-based" approach.⁴³ Throughout each on-site survey, CMS, the Joint Commission, and AOA surveyors document noncompliance with the standards that they observe. For example, CMS, Joint Commission, and AOA officials told us that surveyors document observations of poor hand hygiene (e.g., a health care worker not washing his or her hands).

Based on the results of the surveys, CMS and the accrediting organizations assess a hospital's compliance with the infection control standards. CMS, Joint Commission, and AOA surveyors are required to cite all instances of noncompliance. At the end of each survey, CMS surveyors review the observations of noncompliance for each standard and determine whether

⁴³The Joint Commission officials noted that a systems-based approach includes learning the root causes of infections and developing processes to mitigate their recurrence, and uses an epidemiologic approach that includes surveillance, control, and prevention.

to cite the hospital at the condition level or the standard level based on the nature (i.e., severity) and extent (i.e., prevalence) of the noncompliance. A CMS-surveyed hospital is required to develop a corrective action plan within 10 days of receiving a report documenting the noncompliance found during a survey.⁴⁴ The Joint Commission assesses each of the elements of performance that constitute the infection control standards as satisfactory, partially compliant, or insufficient. The entire standard is assessed as not compliant if the hospital has insufficient compliance with any of the corresponding elements of performance or if the hospital is partially compliant with 35 percent or more of the elements of performance. Joint Commission–surveyed hospitals have 45 days from receipt of the survey results to submit a report to the Joint Commission that describes the steps the hospitals took to become compliant with any standards that were assessed as not compliant.⁴⁵ The AOA standards are assessed on a scale from 1 to 4, which varies by standard, where 1 indicates full compliance and 4 indicates noncompliance. AOA-surveyed hospitals have 30 days to report to AOA on the steps they took to become compliant with standards assessed as noncompliant that indicate immediate jeopardy or are at the CMS condition level and 60 days to address other standards assessed as noncompliant. Among the surveys conducted in the first quarter of 2007, 12.6 percent of state-agency-surveyed hospitals, 17.6 percent of Joint Commission–surveyed hospitals, and 22.2 percent of AOA-surveyed hospitals were cited as noncompliant with one of the respective organizations’ standards on infection control.⁴⁶

Between regular surveys, limited information about compliance with the infection control standards may be identified through validation and complaint surveys of hospitals conducted by state survey agencies. State survey agencies conduct validation surveys for CMS on a small number of Joint Commission–accredited hospitals within 60 days of their last Joint

⁴⁴CMS told us that if the hospital is cited at the condition level, surveyors revisit the hospital to determine if the hospital is in compliance with the COPs, including whether the previously cited noncompliance has been corrected. Hospitals that are cited for condition-level noncompliance may lose their ability to participate in Medicare if the noncompliance is not corrected. If a hospital is noncompliant with a standard-level requirement, the state surveyors review the hospital’s corrective action plan to determine if the plan is likely to correct the noncompliance and prevent reoccurrence.

⁴⁵Joint Commission officials told us that a hospital’s failure to submit this report could eventually lead to the loss of accreditation.

⁴⁶During the first quarter of 2007, state survey agencies surveyed 190 hospitals, the Joint Commission surveyed 329 hospitals, and AOA surveyed 9 hospitals.

Commission survey and compare the results of the two surveys.⁴⁷ For example, in fiscal year 2006, state agencies conducted validation surveys at 67 hospitals. State survey agencies conduct complaint surveys in response to complaints made by patients, family members, or health care providers.⁴⁸ In the first quarter of calendar year 2007, state survey agencies conducted 1,119 complaint surveys in 828 hospitals, and infection control deficiencies were found at 3.5 percent of the hospitals.

Information about hospital compliance with infection control standards is generally not publicly reported on Web sites, although the Joint Commission reports compliance with its National Patient Safety Goals on its Web site. It reported that in calendar year 2006, 91.2 percent of the hospitals surveyed that year were compliant with the goal related to implementing CDC's hand hygiene guideline, and 100 percent were compliant with the goal related to managing all identified cases of unanticipated death or major permanent loss of function associated with an HAI as a sentinel event. The rate reported by the Joint Commission in 2006 for adherence to hand hygiene practices was much higher than some studies had reported. For example, in the 2002 *Guideline for Hand Hygiene in Health-Care Settings*, CDC cited several observational studies of health care workers and reported the average adherence across the studies to be 40 percent.⁴⁹ The Joint Commission's surveyors assess this requirement by interviewing and observing hospital employees and would assess a hospital as noncompliant with the requirement if the surveyors observed noncompliance three or more times. Joint Commission officials acknowledged that their assessment mechanism might not sufficiently measure compliance because hospital staff could be on their best behavior when surveyors were present. Joint Commission officials told us they anticipated publishing in 2008 examples of different ways to measure

⁴⁷In a prior GAO report, we recommended that CMS increase the number of validation surveys it conducts to at least 5 percent of all Joint Commission-accredited hospitals. See [GAO-04-850](#).

⁴⁸To evaluate complaints, CMS decides which COP(s) to assess during an on-site survey; the state agency conducts the on-site survey of the identified COP(s); and based on the results of the survey, CMS decides whether a full hospital survey is needed.

⁴⁹Adherence rates in the studies ranged from 5 to 81 percent. CDC notes that the methods used for defining and observing adherence varied by study. See J. M. Boyce et al., "Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force," *Morbidity and Mortality Weekly Report*, vol. 51, no. RR-16 (2002): 1-44.

adherence to hand hygiene as well as tools and training materials that hospitals could use to improve their hand hygiene compliance.

Multiple HHS Programs Collect Data on HAIs, but Lack of Integration of Available Data and Other Problems Limit Utility of the Data

Three agencies within HHS—CDC, CMS, and AHRQ—currently collect HAI-related data for a variety of purposes in four separate databases, but each of these databases presents only a partial view of the extent of the HAI problem. Each database focuses its data collection on selected types of HAIs and collects data from a different subset of hospital patients across the country. Although officials from the various HHS agencies discuss HAI data collection with each other, we did not find that the agencies were taking steps to integrate any of the existing data by creating linkages across the databases such as standardizing patient identifiers or other data items. Creating linkages across the HAI-related databases could enhance the availability of information to better understand where and how HAIs occur. Although none of the databases collect data on the incidence of HAIs for a nationally representative sample of hospital patients, CDC officials have produced national estimates of HAIs. However, those estimates derive from assumptions and extrapolations that raise questions about the reliability of those estimates.

Multiple HHS Agencies Collect Different Data on HAIs, but These Data Present Only a Partial View of the Extent of the Problem

Three agencies within HHS currently collect HAI-related data in four separate databases, which were created for a variety of purposes. These are the databases associated with CDC's National Healthcare Safety Network (NHSN), CMS's Medicare Patient Safety Monitoring System (MPSMS), CMS's Annual Payment Update (APU) program, and AHRQ's Healthcare Cost and Utilization Project (HCUP).

The most detailed source of information on HAIs within HHS is the NHSN database.⁵⁰ CDC established the NHSN database in 2005 to combine the

⁵⁰CDC operates other databases that may collect some HAI-related data, but they are not as comprehensive as NHSN. For example, the Active Bacterial Core Surveillance (ABCs) program collects data on six specific bacterial pathogens from 10 designated geographic locations. In 9 of these locations, CDC collects data on the incidence of both community-associated and health-care-associated (including hospital-onset) infections through laboratory results and medical record review. The 9 sites from which CDC collects MRSA data are the state of Connecticut; eight counties in the Atlanta metropolitan area; three counties in the San Francisco Bay area; one county in the Denver metropolitan area; three counties in the Portland, Oregon, metropolitan area; one county in the Rochester, New York, metropolitan area; Baltimore, Maryland; Davidson County (Nashville), Tennessee; and Ramsey County (St. Paul), Minnesota.

data it had previously collected on HAIs through the National Nosocomial Infections Surveillance (NNIS) system with data from two other related databases.⁵¹ CDC instituted NNIS as a voluntary program in the 1970s to assist hospitals that wanted to monitor their HAI rates. CDC analyzed the data submitted by those hospitals—which tended to be disproportionately large hospitals, many of them academic medical centers—in order to provide the hospitals with a benchmark HAI rate against which to compare their own rates. In addition, CDC drew on these data to publicly report aggregate trends in selected HAIs, and it continues to do that with the data being submitted to the NHSN database.⁵² Many of the hospitals that voluntarily participated in the NNIS database have continued to submit HAI data voluntarily to the NHSN database. CDC is working with a number of states implementing mandatory programs for hospitals to submit HAI-related data, using NHSN as the designated mechanism by which hospitals must submit their data.⁵³ As a result, by the end of December 2007, approximately 1,000 hospitals were enrolled in the NHSN database, some of which continued to participate by choice while others enrolled in the NHSN program because of state mandates.⁵⁴

The NHSN program provides hospitals with substantial flexibility to determine the scope of their HAI data collection efforts. Participating hospitals can choose which types of HAIs they will submit data on from among those for which the NHSN program has developed detailed definitions and protocols, including such device-associated infections as central-line-associated BSIs, catheter-associated UTIs, and VAP, as well as procedure-related HAIs such as SSIs and postprocedure pneumonia. Hospitals also choose the specific hospital units (typically different kinds

⁵¹The other two are the Dialysis Surveillance Network database and the National Surveillance System for Healthcare Workers database. The Dialysis Surveillance Network program was a voluntary national surveillance system that monitored BSIs and vascular infections in outpatient dialysis centers. The National Surveillance System for Healthcare Workers program collected information on exposures and infections among health care workers.

⁵²Sections 304, 306, and 308(d) of the Public Health Service Act restrict the disclosure of information reported by hospitals.

⁵³CDC officials reported that, as of December, 2007, 14 states had decided to use NHSN to collect data from hospitals on HAIs for state reporting programs that were either under way or under development. These states require or plan to require their hospitals to both enroll in the NHSN program and authorize CDC to release the hospitals' HAI data to the state.

⁵⁴CDC officials told us that not all of the enrolled hospitals were reporting data to NHSN.

of intensive care units) to monitor for device-associated HAIs and the specific surgical procedures to monitor for SSIs and postprocedure pneumonia. Hospital staff are supposed to follow the detailed definitions and protocols that the NHSN program specifies to identify which patients currently under treatment have developed one of the targeted infections. Hospitals also have to provide at least some HAI data for 6 months of the year to maintain their enrollment in the NHSN program.⁵⁵

The MPSMS database provides CMS with information on national trends in the incidence of selected adverse events among hospitalized Medicare beneficiaries, including a number of different types of HAIs. Beginning with hospital discharges from 2002, CMS has collected these data from the medical records selected for annual random samples of approximately 25,000 Medicare inpatients,⁵⁶ though the list of specific adverse events monitored has varied over time. A CMS contractor receives copies of these medical records after the patients' discharge from the hospital, and the contractor's abstractors⁵⁷ follow CMS's detailed protocols to extract and record specific information on each patient in the sample. These data elements are then entered into algorithms that determine which patients meet CMS's case selection criteria for experiencing the adverse event and for being at risk for the adverse event. For example, the abstractors would determine which of the sampled patients had a central line catheter inserted during that hospital stay and which of those patients had laboratory reports indicating a BSI not present at admission, which together would allow the calculation of the rate of central-line-associated BSIs.⁵⁸ Since 2004, HHS has publicly reported some of the rates of adverse events from the MPSMS database in the *National Healthcare Quality*

⁵⁵States that mandate hospital participation in NHSN could also set their own requirements for the types of infections, hospital units, and procedures reported on, as well as number of months of HAI data required.

⁵⁶The MPSMS sample is a subset of the random sample of patient records that CMS initially selects for the Hospital Payment Monitoring Program, which reviews patient records to estimate Medicare's payment error rate.

⁵⁷We use the term abstractor to indicate persons who are trained to follow a detailed protocol in order to extract specified information in a consistent fashion from the medical records of patients.

⁵⁸The algorithm calculates a rate of central-line-associated BSIs based on the number of patients with central line catheters who did not have an infection when they were admitted to the hospital and who subsequently tested positive for any of 16 designated BSI pathogens 2 or more days after the central line catheter was inserted.

Report and National Healthcare Disparity Report, both of which are issued annually by AHRQ.

The APU program implemented a financial incentive for hospitals to submit to CMS data that are used to calculate hospital performance on measures of the quality of care they provide. The APU program receives quality-related data from hospitals on a quarterly basis for a range of medical conditions and, in 2007, began to require submission of information on three specific surgical infection prevention measures.⁵⁹ Hospitals paid under Medicare's inpatient prospective payment system receive a higher rate of payment if they submit these quality data that address their performance on recommended care practices. During fiscal year 2008, 3,270 hospitals will receive this higher level of payment, which represents 93 percent of hospitals eligible to participate in the APU program.⁶⁰ For patients who underwent specified surgical procedures, hospital staff review their medical records after discharge and, following detailed protocols from CMS, extract and record items of information that relate to three infection prevention practices that are associated with reduced risks of acquiring an SSI: (1) providing antibiotics within 1 hour of the surgery, (2) selecting appropriate antibiotics to prevent surgical infections, and (3) stopping the administration of the antibiotics within 24 hours of the end of the surgery. This information in turn is entered into algorithms that determine what proportion of patients who met CMS's criteria for designation as eligible for these infection prevention measures actually received them. CMS publicly reports these results for each hospital individually on its Web site, Hospital Compare, along with state and national averages for comparison.⁶¹

⁵⁹The Congress created the financial incentives that are implemented through the APU program as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. For more information on the collection and analysis of quality data under the APU program, see GAO, *Hospital Quality Data: CMS Needs More Rigorous Methods to Ensure Reliability of Publicly Released Data*, [GAO-06-54](#) (Washington, D.C.: Jan. 31, 2006), and GAO, *Hospital Quality Data: HHS Should Specify Steps and Time Frame for Using Information Technology to Collect and Submit Data*, [GAO-07-320](#) (Washington, D.C.: Apr. 25, 2007).

⁶⁰Hospitals accredited by the Joint Commission are required to report quality-related data to the Joint Commission quarterly using third-party vendors, who also generally provide these data to CMS. Hospitals accredited by AOA are also required to submit these quality-related data to CMS.

⁶¹The Web site is <http://www.hospitalcompare.hhs.gov>.

AHRQ sponsored the development of the HCUP databases to create a national information resource of patient-level health care data. One of the HCUP databases assembles a sample of patient hospital discharge data from 37 states and converts them to a uniform format that enables the application of AHRQ's 20 Patient Safety Indicators (PSI)—including two that relate to HAIs—to an approximate national sample of all hospital patients.⁶² The two PSIs related to HAIs involve (1) “selected infections due to medical care,” which focuses on infections caused by intravenous lines and catheters, and (2) postoperative sepsis among patients undergoing elective surgery.⁶³ The PSIs are designed to identify patient safety issues by using the kinds of data that are available in hospital discharge data sets—specifically International Classification of Diseases, Ninth Revision (ICD-9), diagnostic and procedure codes, as well as patient demographics and admission and discharge status—and can be used with the HCUP database without collecting any additional information from patient medical records. However, these indicators are intended to be used as quality improvement tools to highlight aggregate patterns, and so they do not identify specific instances of adverse events with a high degree of precision.⁶⁴ AHRQ has posted national estimates for these two indicators—along with the other PSIs—on its Web site, showing the trend from 1994 to 2004.⁶⁵

Two HHS agencies collect, or plan to collect, some limited additional information about HAIs in other HHS databases. FDA obtains data on deaths or serious injuries related to the use of medical devices and stores them in the Manufacturer and User Facility Device Experience Database.

⁶²HCUP encompasses a set of related databases, one of which is the Nationwide Inpatient Sample, which AHRQ has used to generate national estimates for its PSIs. According to AHRQ, the national sample approximates a 20 percent stratified sample of U.S. community hospitals. The sample is approximate because hospitals in the states that do not participate in HCUP are not included in the sample.

⁶³The indicator is limited to patients undergoing elective surgeries to better capture patients for which sepsis is a potentially preventable complication and exclude patients that either had sepsis present on admission or had conditions predisposing them to sepsis.

⁶⁴See K. M. McDonald et al., *Measures of Patient Safety Based on Hospital Administrative Data—The Patient Safety Indicators*, Technical Review 5, AHRQ Publication No. 02-0038 (Rockville, Md.: Agency for Healthcare Research and Quality, August 2002), 76–77.

⁶⁵See <http://www.hcupnet.ahrq.gov>.

A small portion of these adverse events may involve HAIs.⁶⁶ FDA uses these data to identify devices whose safety warrants closer scrutiny, such as might be warranted for heart valves that were not properly sterilized by the manufacturer. AHRQ is developing a database on adverse events, including HAIs, that will assemble data voluntarily submitted by hospitals to multiple Patient Safety Organizations (PSO).⁶⁷ AHRQ officials told us that they planned to disseminate aggregate results derived from the PSOs in an annual report.⁶⁸

Each of the four main HHS databases that currently collect information about HAIs presents only a partial view of the extent of the problem. None of them can provide information on the full range of HAIs, because each focuses its data collection on selected types of HAIs (see table 3).⁶⁹ In addition, none of the databases can address the frequency of even these selected HAIs for the nation as a whole, because each collects data from different subsets of the nationwide population of hospital patients. Although two databases—NHSN and MPSMS—address many of the same types of HAIs, the former provides information only from selected units of hospitals that participate in the NHSN program (which do not represent hospitals nationwide) while the latter provides information only on a representative sample of Medicare inpatients (i.e., MPSMS does not provide information on non-Medicare patients). The APU program does not collect information on patients with HAIs, but instead tracks the implementation of practices intended to prevent SSIs. The other three databases attempt to identify patients who developed infections as a result

⁶⁶FDA receives reports from manufacturers and hospitals regarding these adverse events, including concerns related to disinfection. FDA officials told us that they have received very few reports involving medical devices that might identify contaminated devices that would cause HAIs.

⁶⁷Under the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424, PSOs are entities that collect, aggregate, and analyze confidential information reported by health care providers in part to identify patterns of failures and propose measures to eliminate patient safety risks and hazards.

⁶⁸AHRQ officials plan to release the first such reports once the PSOs become operational, which they expect could occur early in 2009.

⁶⁹CDC officials estimate that approximately 22 percent of HAIs do not fall in the four types of infection currently addressed in whole or part by the four HHS databases—BSIs, UTIs, SSIs, and pneumonia. See R. M. Klevens et al., “Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002,” *Public Health Reports*, vol. 122 (2007): 160–166. These other infections include bone and joint infections; central nervous system infections; cardiovascular system infections; eye, ear, nose, throat, or mouth infections; skin and soft tissue infections; and gastrointestinal system infections.

of their hospital stay using different data sources and varying approaches. The methods employed by the NHSN, MPSMS, and HCUP databases range from concurrent review of patient care as patients are treated in the hospital, to retrospective review of patient medical records after patients are discharged, to analyses of diagnostic codes recorded electronically in patient billing data.

Table 3: Selected Characteristics of HHS Databases That Contain HAI-Related Information

Responsible agency and database	HAI-related data collected	Population for which data are collected	Hospital role in collecting data	Type of HAI information published by HHS
CDC's National Healthcare Safety Network (NHSN)	Infection types <ul style="list-style-type: none"> • central-line-associated BSI • catheter-associated UTI • VAP • postprocedure pneumonia • SSI • MDRO^a • other^b 	Most hospitals report on patients in selected critical care units and those undergoing selected procedures such as coronary bypass surgery and colon surgery.	Hospital staff conduct medical review of signs, symptoms, and laboratory and radiological test results while patient is an inpatient. Hospital staff enter electronic information into database over the Internet.	CDC publishes rate of infection by type of infection and type of hospital unit or procedure for hospitals, in aggregate.
CMS's Medicare Patient Safety Monitoring System (MPSMS)	Infection types ^c <ul style="list-style-type: none"> • central-line-associated BSI • catheter-associated UTI • postoperative pneumonia • antibiotic-associated <i>C. difficile</i> • MRSA • VRE 	National sample of hospitalized Medicare patients.	Hospital staff send a copy of sampled medical records to CMS, which are reviewed by contract abstractors.	AHRQ publishes national-level data on percentage of Medicare patients who experience selected infection types in two annual reports. ^d
CMS's Annual Payment Update (APU) database	Practices to prevent or reduce SSIs <ul style="list-style-type: none"> • providing antibiotics within 1 hour of surgery • selecting appropriate antibiotics to prevent surgical infections • stopping the administration of the antibiotics within 24 hours of end of surgery 	National inpatient population for selected surgical procedures. ^e	Medical record review by hospital staff after patient's discharge. The hospital sends data to a CMS contractor.	CMS posts on a public Web site the proportion of patients receiving recommended practice, by hospital, as well as the state and national average.

Responsible agency and database	HAI-related data collected	Population for which data are collected	Hospital role in collecting data	Type of HAI information published by HHS
AHRQ's Healthcare Cost and Utilization Project (HCUP) database, Nationwide Inpatient Sample	Infection types <ul style="list-style-type: none"> • postoperative sepsis^f • "infection due to medical care" (focused on intravenous and catheter infections) 	A sample of inpatients in hospitals in 37 states.	HCUP obtains hospital discharge data with ICD-9 diagnostic and procedure codes from statewide data systems.	AHRQ posts on its Web site national-level data on the proportion of patients with ICD-9 codes indicative of the two infection types.

Sources: GAO analysis of CDC, CMS, and AHRQ information.

Notes: BSI is bloodstream infection; *C. difficile* is *Clostridium difficile*; ICD-9 is International Classification of Diseases, Ninth Revision; MDRO is multidrug-resistant organism; MRSA is methicillin-resistant *Staphylococcus aureus*; SSI is surgical site infection; UTI is urinary tract infection; VAP is ventilator-associated pneumonia; and VRE is vancomycin-resistant enterococci.

^aFor patients whose infections are laboratory-confirmed, NHSN collects data on the pathogens identified, and for specified pathogens (including those responsible for MRSA and VRE), the result of any testing of their resistance to specific antibiotics. Participating hospitals have the option to report separately the number of times in a given month that they tested specimens of any of eight specified organisms for resistance to selected antibiotics, as well as the results of those tests. From these data, NHSN produces rates of antimicrobial resistance relative to the number of nonduplicative specimens tested (i.e., excluding multiple tests for the same organism in the same patient). This part of NHSN does not distinguish between MDRO infections acquired in the hospital and community-acquired infections present at admission.

^bHospitals can choose to submit to NHSN data on other types of HAIs, such as skin and soft tissue infections, cardiovascular system infections, and gastrointestinal system infections. CDC does not provide data collection protocols for these types of infections, but they can be entered into NHSN as "custom events" using definitions provided separately by CDC.

^cIn 2007, CMS added catheter-associated UTIs, VAP, MRSA, and VRE to MPSMS and dropped insertion-site infections associated with central vascular catheters, BSIs, and postoperative-associated UTIs.

^dThe two annual reports are *The National Healthcare Quality Report* and *The National Healthcare Disparities Report*.

^eThe three practice measures are assessed for certain categories of surgeries: coronary artery bypass graft; other cardiac surgery; colon surgery; hip arthroplasty; knee arthroplasty; abdominal hysterectomy; vaginal hysterectomy; and vascular surgery.

^fThe rate of postoperative sepsis is computed only for patients undergoing elective surgeries.

The four databases also apply different sets of procedures to ensure the validity of their data, and each set has its own limitations. For the NHSN program, CDC requires participating hospitals to agree to its detailed instructions for identifying patients with HAIs, but CDC currently has no process in place to check how thoroughly and consistently those instructions are followed.⁷⁰ For the MPSMS program, CMS relies on

⁷⁰When the National Quality Forum examined the application of the NHSN criteria for identifying patients with VAP, it found wide variations in the results obtained. According to the National Quality Forum, incidence could range from 4 to 48 percent, depending on which NHSN criteria were selected to diagnose VAP.

internal procedures performed by a contractor that collects the data to routinely monitor the interrater reliability of its abstractors. However, CMS has not assessed the completeness or accuracy of the information in patient medical records that the MPSMS database measures rely on and how that might affect the HAI rates reported by the MPSMS program. CMS requires hospitals that submit APU data to have a small sample of their cases checked each quarter by a CMS contractor.⁷¹ The contractor assesses the accuracy with which the hospital abstracted its APU data from patient medical records. AHRQ's HCUP database relies on ICD-9 codes filed with patient bills.⁷² Many hospitals have their ICD-9 coding periodically checked by outside auditors, but the reason is to determine accuracy for billing purposes, not whether patients experienced HAIs.

Among the four databases, NHSN collects the most clinically detailed information about HAIs, but those data nonetheless have important limitations. Among the strengths of the NHSN database is that it presents detailed information on HAI rates across different types of hospital units and multiple types of HAIs. Moreover, its procedures for identifying patients with HAIs draw on the wider range of clinical information available while patients are still in the hospital, as opposed to retrospective reviews of patient medical records after discharge. On the other hand, the NHSN database is much more limited than any of the other databases in terms of the patient population that it represents. Because the hospitals that submit data either do so by choice or, for a limited number of states, by mandate, this group of hospitals is not representative of hospitals nationwide, as a random sample would be. In addition, the data these hospitals supply do not reflect the experience of many of their patients. For example, the hospitals that participate in the NHSN program report device-related HAIs such as central-line-associated BSIs and VAP for selected hospital units such as different types of intensive care units (e.g., coronary, burn, surgical, medical). In addition, most of the hospitals that participate in the NHSN program report procedure-based HAIs such as SSIs and postprocedure pneumonia for a relatively small number of specific procedures. For example, during March 2007, 225 hospitals

⁷¹Every quarter, CMS draws a sample of five patients for each hospital that submitted data for six or more patients in that quarter.

⁷²Patient bills typically include one principal diagnosis code and multiple other diagnosis codes, which are used in determining the amount of payment that the hospital receives for treating that patient. After the patient has been discharged, hospital staff trained in medical record coding decide which ICD-9 diagnostic codes to enter on the patient's bill based on their review of the patient's medical record.

reported SSIs for colon surgery and 133 did so for coronary bypass surgery, but only 11 hospitals reported SSIs for appendix surgery and 10 for gallbladder surgery.

Available Data Are Not Integrated across Programs to Use Them to Their Full Potential

Although officials from the various HHS agencies discuss HAI data collection with each other, we did not find that the agencies were taking steps to integrate any of the existing data from the four databases that collect HAI-related data. This integration could involve creating linkages between existing data by, for example, creating common patient identifiers in the different databases so that data on the same individuals found in multiple databases could be pulled together, or creating “crosswalks” that could specify in detail how related data fields in the various databases are similar or different. We found that the most extensive exchange of information across the three HHS agencies that collect HAI data occurred through the participation of their representatives in HICPAC. HICPAC generally holds 2-day meetings three times per year, and at each meeting the members from the participating HHS agencies typically provide a summary of their HAI-related activities. Our review of HICPAC minutes from 2004 through 2007 identified numerous instances of officials describing what their own agency was doing to collect HAI data, but we did not find in the HICPAC meeting minutes any evidence that the agencies had taken action to create greater compatibility among the databases or to address gaps in information across the databases. Outside of HICPAC meetings, HHS officials provided other examples of communication and outreach among HHS agencies taking place in relation to various databases. For example, the MPSMS program has a technical expert panel that includes representatives from CDC and AHRQ. Similarly, CMS, CDC, and AHRQ are represented on the steering committee for the public-private Surgical Care Improvement Project (SCIP), which developed the HAI-related measures used in the APU program.⁷³ These group discussions allow agency officials to discuss and explain their different approaches for collecting HAI data, but the focus of these meetings is still on the individual database, rather than on creating linkages from one database to another.

Creating mechanisms for linking data across the HAI-related databases could enhance the availability of information to better understand where

⁷³The SCIP steering committee also includes representatives from the Joint Commission, the American College of Surgeons, and the American Hospital Association.

and how HAIs occur. A case in point concerns information collected by two of the databases on surgical-related HAIs. Approximately 500 hospitals already submit data to APU on surgical processes of care and to NHSN on surgical infection rates for some of the same patients, but these data are not currently linked. As a consequence, the potential benefit of using the existing data to monitor the extent to which compliance with the recommended surgical care processes leads to actual improvements in surgical infection rates has not been realized. Officials at CDC reported that they approached CMS about developing mechanisms for linking NHSN data with APU data. To do this, CDC officials suggested that CDC and CMS agree to collect uniform patient identifiers. Officials at CMS reported that although they recognized the potential benefits of linking the APU data with the data in related HHS databases, CMS is currently focused on managing the expansion of the APU program.

Data Limitations Preclude Development of Reliable National Estimates

HHS cannot use its HAI-related databases to produce reliable national estimates of HAI rates, even for the selected types of HAIs monitored, because none of the databases collect data on the incidence of HAIs for a nationally representative sample of hospital patients. Two of the databases—APU and HCUP—come close to covering a national population for selected HAIs, but the APU database collects data on practices intended to prevent HAIs among surgery patients, not on the number of HAIs that occur. In addition, although the information in HCUP relates to the incidence of some HAIs, its reliance on diagnostic codes recorded in claims data substantially reduces the reliability of that information.⁷⁴ The other two databases—NHSN and MPSMS—collect clinical data on the incidence of selected HAIs, but their data do not derive from a representative sample of the national hospital patient population because NHSN is limited to selected units of participating hospitals that do

⁷⁴See E. R. Sherman et al., “Administrative Data Fail to Accurately Identify Cases of Healthcare-Associated Infection,” *Infection Control and Hospital Epidemiology*, vol. 27, no. 4 (2006): 332–337, and S. B. Wright et al., “Administrative Databases Provide Inaccurate Data for Surveillance of Long-term Central Venous Catheter-associated Infections,” *Infection Control and Hospital Epidemiology*, vol. 24, no. 12 (2003): 946–949. In addition, HCUP’s two HAI-related indicators do not correspond to the infection types usually tracked by hospital infection control programs. Postoperative sepsis would include some, but not all, central-line-associated BSIs, along with other BSIs not related to the insertion of central lines. Infections due to medical care would likewise include central-line-associated BSIs as well as infections caused by other types of catheters and intravenous lines.

not represent hospitals nationwide and MPSMS is limited to Medicare patients. (See table 3.)

Recent concerns about the magnitude of HAIs caused by the drug-resistant pathogen MRSA have further highlighted limitations in HHS's databases for estimating HAI rates. In June 2007, APIC, the professional association for infection control professionals, released the results of a survey it conducted that showed that 46 of every 1,000 patients in those hospitals had tested positive for MRSA.⁷⁵ This was a much higher rate than had previously been estimated by clinicians. The NHSN database has some information about the frequency of MRSA infections, as well as other MDROs, but this information is limited to the subset of patients for whom each hospital submits data, based on the particular hospital units, infection types, and procedures that it has chosen to report to NHSN. Thus, the NHSN database does not provide information on the overall proportion of patients in a given hospital who were found to have a MRSA infection.⁷⁶ The MPSMS program has begun to collect, but has not yet reported, data on the incidence of hospital-acquired MRSA infections within the Medicare inpatient population.⁷⁷ However, a CMS official

⁷⁵Association for Professionals in Infection Control and Epidemiology, "National Prevalence Study of Methicillin-Resistant *Staphylococcus aureus* (MRSA) in U.S. Healthcare Facilities, Executive Summary," released June 25, 2007. See also W. R. Jarvis et al., "National Prevalence of Methicillin-Resistant *Staphylococcus aureus* in Inpatients at U.S. Health Care Facilities, 2006," *American Journal of Infection Control*, vol. 35, no. 10 (2007): 631–637. This figure represents the prevalence of MRSA on a given day in fall 2006, that is, all the known MRSA cases on that day in proportion to the total number of inpatients, across the 1,187 hospitals that responded to the survey.

⁷⁶Another recent study using CDC's Active Bacterial Core Surveillance (ABCs) database found the national rate of invasive MRSA per 100,000 population to be 31.8 in 2005. However, the MRSA rates generated from the APIC survey and ABCs database are not comparable for several reasons. For example, the ABCs program collects data on invasive MRSA, which are cases found in a normally sterile site such as blood and are a subset of the cases of MRSA collected in the APIC survey. In addition, the ABCs database assesses the rate of infections with respect to populations residing in defined geographic areas, rather than at the provider level. The researchers noted that the nine sites in the ABCs database are largely urban areas and that they had no information to establish that the MRSA incidence rates found in those sites reflected the incidence of MRSA in other parts of the United States. See R. M. Kleven's et al., "Invasive Methicillin-Resistant *Staphylococcus aureus* Infections in the United States," *Journal of the American Medical Association*, vol. 298, no. 15 (2007): 1763–1771.

⁷⁷According to AHRQ officials, the MPSMS data to be released in the next *National Healthcare Quality Report*, which AHRQ expects to issue in early 2008, will not include results on MRSA. Those may appear as early as the subsequent *National Healthcare Quality Report*, due in early 2009.

responsible for the program acknowledged that the ability of the MPSMS program to detect patients with MRSA infections is limited by its reliance on retrospective review of patients' medical records.

The varying content and methods used to collect and report data on HAIs for HHS's four databases also preclude HHS from combining data from the databases to produce reliable estimates on either selected HAIs or an overall HAI rate. Even the databases that collect data on the same types of HAIs calculate and report rates in different ways that cannot be reconciled. For example, the MPSMS program reported that 1.7 percent of all the Medicare patients that had a central line inserted in 2004 experienced a central-line-associated BSI. In contrast, the NHSN program reported the mean number of central-line-associated BSIs detected during 2006 by different types of intensive care units, calculated as the number of infections per 1,000 days of central line use. This ranged from 1.5 per 1,000 days in inpatient medical/surgical wards to 6.8 per 1,000 days in burn intensive care units. HHS might be able to develop approaches for linking data across its different databases, such as by developing common data collection methods and specifications or creating crosswalks between the specifications for different databases. However, until that is done, the information on HAI rates from each of the three databases collecting that information stands alone.

CDC officials have produced national estimates of HAIs, but those estimates derive from assumptions and extrapolations that raise questions about the reliability of those estimates. Most recently, in 2007, CDC officials published estimates of the aggregate incidence of HAIs and deaths attributable to HAIs in 2002—which included an estimate of 99,000 HAI-related deaths per year.⁷⁸ These estimates rested on two key assumptions. The first assumption was that data from 283 hospitals reporting to the NNIS program (the predecessor program to NHSN) were indicative of hospital rates nationwide, even though the authors acknowledged that the NNIS hospitals were not randomly selected and their rates could differ from those of U.S. acute care hospitals as a whole. The second assumption was that 2002 NNIS data on SSIs could be used to estimate rates for all other types of HAIs, based on the relative frequency of SSIs compared to other types of HAIs observed in a portion of NNIS hospitals during the

⁷⁸R.M. Klevens et al., "Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002," *Public Health Reports*, March–April 2007, vol. 122, 160–166.

1990s.⁷⁹ In 2004, CDC officials announced plans for conducting a national survey designed to collect more up-to-date data on hospitalwide incidence of all types of HAIs in a sample of hospital discharges, but they subsequently decided not to proceed with those plans. CDC officials told us they were developing plans to obtain similar data by adding questions on HAIs to the National Hospital Discharge Survey conducted by CDC's National Center for Health Statistics.⁸⁰ CDC officials said they planned to put questions about HAIs into the National Hospital Discharge Survey starting in 2010. However, CDC officials stated that they planned first to pilot test several different approaches for collecting HAI data through the National Hospital Discharge Survey, and it was too early to say what specific information they would collect through this process.

Conclusions

HAIs in hospitals can cause needless suffering and death. Federal authorities and private organizations have undertaken a number of activities to address this serious problem; however, to date, these activities have not gained sufficient traction to be effective. Current activities at the federal level include guidelines with recommended practices issued by CDC, required standards for hospitals set by CMS, and HAI-related data collected through multiple HHS databases. Private-sector organizations, such as the Joint Commission and AOA, have also set infection control standards for hospitals. With the passage of the DRA by the Congress, hospitals will be encouraged to reduce certain HAIs, because beginning in October 2008 CMS will stop paying hospitals higher payments for patients that acquire them.

We identified two possible reasons for the lack of effective actions to control HAIs to date. First, although CDC's guidelines are an important source for its recommended practices on how to reduce HAIs, the large number of recommended practices and lack of department-level prioritization have hindered efforts to promote their implementation. The guidelines we reviewed contain almost 1,200 recommended practices for

⁷⁹The proportion of NNIS hospitals reporting such comprehensive surveillance data dropped from about half in 1991 to none in 1998, when NNIS stopped collecting these data altogether.

⁸⁰The mission of the National Center for Health Statistics is to collect health statistics in order to guide actions and policies to improve the health of the U.S. population. The National Hospital Discharge Survey is a national probability survey that collects information on the characteristics of inpatients discharged from nonfederal short-stay hospitals in the United States.

hospitals, including over 500 that are strongly recommended—a large number for a hospital trying to implement them. A few of these are required by CMS’s or accrediting organizations’ standards or their standards interpretations, but it is not reasonable to expect CMS or accrediting organizations to require additional practices without a prioritization. Although CDC has categorized the practices on the basis of the strength of the scientific evidence, there are other factors to consider in developing priorities. For example, work by AHRQ suggests factors such as costs or organizational obstacles that could be considered. The lack of coordinated prioritization may have resulted in duplication of effort by CDC and AHRQ in their reviews of scientific evidence on HAI-related practices.

Second, HHS has not effectively used the HAI-related data it has collected through multiple databases across the department to provide a complete picture about the extent of the problem. Limitations in the databases, such as nonrepresentative samples, hinder HHS’s ability to produce reliable national estimates on the frequency of different types of HAIs. In addition, currently collected data on HAIs are not being combined to maximize their utility. For example, data on surgical infection rates and data on surgical processes of care are collected for some of the same patients in two different databases that are not linked. HHS has made efforts to use the currently collected data to understand the extent of the problem of HAIs, but the lack of linkages across the various databases results in a lost opportunity to gain a better grasp of the problem of HAIs.

HHS has multiple methods to influence hospitals to take more aggressive action to control or prevent HAIs, including issuing guidelines with recommended practices, requiring hospitals to comply with certain standards, releasing data to expand information about the nature of the problem, and soon, using hospital payment methods to encourage the reduction of HAIs. Prioritization of CDC’s many recommended practices can help guide their implementation, and better use of currently collected data on HAIs could help HHS—and hospitals themselves—monitor efforts to reduce HAIs. Unfortunately, leadership from the Secretary of HHS is currently lacking to do this. Without such leadership, the department is unlikely to be able to effectively leverage its various methods to have a significant effect on the suffering and death caused by HAIs.

Recommendations for Executive Action

In order to help reduce HAIs in hospitals, the Secretary of HHS should take the following two actions:

1. Identify priorities among CDC's recommended practices and determine how to promote implementation of the prioritized practices, including whether to incorporate selected practices into CMS's conditions of participation (COP) for hospitals.
2. Establish greater consistency and compatibility of the data collected across HHS on HAIs to increase information available about HAIs, including reliable national estimates of the major types of HAIs.

Comments from HHS and Accrediting Organizations and Our Evaluation

We obtained written comments on our draft report from HHS, which appear in appendix III. HHS generally agreed with our recommendations and noted its appreciation for our efforts in developing this report. The comments addressed both of our recommendations.

In terms of our first recommendation, HHS's comments indicated that CMS welcomed the opportunity to work with CDC to review and prioritize recommendations for infection control and would consider whether to incorporate some of the recommendations into CMS's hospital COPs. HHS stated that COPs represent minimum health and safety requirements and the two standards in the infection control COP have a broad reach for assessing a hospital's infection control program. HHS's comments also noted that the COPs currently lack the specificity of guidance and recommendations issued by HHS agencies, including CDC's recommendations for infection control.

In terms of our second recommendation, HHS's comments acknowledged the need for greater consistency and compatibility of data collected on HAIs and identified three actions CMS would take. First, CMS will work with other HHS agencies to evaluate opportunities for consolidating and coordinating national data collection programs. Second, CMS will implement consensus-based measures whenever possible. Third, CMS will require the collection of data that facilitate linkages between databases, including Medicare beneficiary and hospital patient identifiers in the APU program. HHS's comments also noted that CDC has recently begun moving toward greater alignment with CMS.

HHS's comments also noted other activities under way that the department believes would improve the collection of HAI-related data. For example, as part of implementing section 5001(c) of the DRA, hospitals are

required to begin reporting “present on admission” data—diagnoses that are present in patients at the time of admission—in order to determine whether the selected preventable conditions were acquired prior to the hospitalization. We noted this activity in the report, and we believe that it is too early to know the extent of information that will be generated on HAIs or how it will be used by HHS agencies. HHS’s comments also indicated that CMS is evaluating an update to the diagnostic and procedure coding system, which could offer clearer and more detailed information than the current system, and also noted the benefits of employing industry data standards for electronic health care data exchanges to facilitate reporting of HAI-related data to both CDC and CMS. In our report, we did not assess the effect of these activities because they have not been implemented.

We also obtained comments on a draft of this report from representatives of the Joint Commission and AOA. The Joint Commission concurred with our findings that it would be beneficial to have more accurate estimates of HAIs and that prioritization of practices to guide actions in preventing HAIs is a valuable and necessary undertaking. However, it noted that other actions, such as cultural changes in health care organizations, clear strategies for implementation, and a concerted, multifaceted effort by many stakeholders, are needed to reduce HAIs. We agree that such actions are important in reducing HAIs, and that better prioritization of the many recommended practices would facilitate the process the Joint Commission describes. The Joint Commission also provided two comments related to the section of the report that discusses hospital infection control standards. First, it commented that our report places too great a focus on the number of standards, and pointed out the benefit of the Joint Commission’s systems-based approach. It expressed a concern that a reader could perceive that the Joint Commission has fewer expectations for hospitals than CMS or AOA. That was not our intention, and we have modified the report to note the Joint Commission’s systems-based approach to foster compliance with practices to reduce HAIs. Second, the Joint Commission said that the report indicates that their standards are less specific in that they have not adopted certain CDC recommendations, but they noted that many of the CDC guidelines cannot be implemented without additional research or translation into concrete, actionable steps. In the draft, we described some activities being undertaken by CDC and AHRQ to promote implementation of recommended practices to reduce HAIs, including studies funded by AHRQ, and we added a clarification to the text to note the importance of translating knowledge into social and behavioral changes that can be sustained. Furthermore, we believe that

clearer prioritization can help efforts to promote the implementation of practices to reduce HAIs.

HHS, the Joint Commission, and AOA provided technical comments, which we incorporated as appropriate.

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days after its issuance date. At that time, we will send copies of this report to the Secretary of HHS and other interested parties. We will also make copies available to others on request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or bascettac@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.

Sincerely yours,



Cynthia A. Bascetta
Director, Health Care

Appendix I: Other CDC Activities Designed to Reduce or Prevent Health-Care-Associated Infections

In addition to developing infection control and prevention guidelines and recommendations, the Centers for Disease Control and Prevention (CDC) provides leadership in outbreak investigations, surveillance, and laboratory research and prevention of health-care-associated infections (HAI). According to officials, CDC's work in the area of outbreak investigations has led to new knowledge on ways to prevent HAIs. For example, in 2006, CDC investigated an outbreak of eye inflammation that was occurring in patients who recently had cataract surgery at a hospital in Maine. The outcome of this investigation led to the development of recommended practices for cleaning and sterilizing intraocular surgical instruments developed by the American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses.

CDC's surveillance, research, and demonstration projects measure the effect of HAIs, adverse drug events, and other complications of health care. CDC has funded many activities through its Prevention Epicenter Program, which began in 1997 and is devoted to improving the detection, reporting, and prevention of HAIs, antimicrobial resistance, and other adverse events in health care. For example, CDC funded a multicenter trial research project and found that daily bathing with chlorhexidine, an antiseptic, reduces the incidence of methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE),¹ and bloodstream infection (BSI). In addition, CDC has collaborated with three public hospitals in Chicago to develop a clinical data warehouse using the hospitals' information systems, which enabled the hospitals to develop a series of quality improvement strategies to decrease antimicrobial resistance and improve antibiotic prescribing and infection control practices.

Finally, CDC provides direct support and assistance to external groups involved in many HAI prevention activities. CDC has funded and collaborated with the Pittsburgh Veterans Affairs Medical Center to reduce MRSA infections by more than 60 percent in its health care units. The success of this project has led CDC and the Department of Veterans Affairs to initiate similar efforts across all VA hospitals. In addition, CDC is represented on the Surgical Care Improvement Project (SCIP) steering committee. SCIP is a national public-private partnership to reduce

¹VRE are bacteria that have become resistant to vancomycin, an antibiotic used to treat patients infected with bacterial pathogens. VRE can cause urinary tract infections, BSIs, and wound infections.

Appendix I: Other CDC Activities Designed to Reduce or Prevent Health-Care-Associated Infections

surgical complications that is sponsored by the Centers for Medicare & Medicaid Services. CDC told us that they have worked with SCIP to develop quality measures and market the project. Finally, CDC has provided technical assistance to the Institute for Healthcare Improvement, a not-for-profit organization working to improve global health care, in the development of the institute's hand hygiene "bundle" and MRSA infection prevention "bundle" guides.

Appendix II: Centers for Medicare & Medicaid Services' (CMS) Condition of Participation: Infection Control

The conditions of participation (COP) for hospitals, including the infection control COP as well as the survey protocols and interpretive guidelines that accompany the COPs, are contained in Appendix A of CMS's *State Operations Manual*.¹ CMS issued revised interpretive guidelines for the infection control COP on November 21, 2007.²

The COP on infection control (42 C.F.R. § 482.42) (2007) states that

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) Standard: Organization and policies. A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services. The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

¹Appendix A of the *State Operations Manual* is available at http://www.cms.hhs.gov/GuidanceforLawsAndRegulations/08_Hospitals.asp, downloaded on May 14, 2007.

²These revised guidelines are titled "Revisions to the Hospital Interpretive Guidelines for Infection Control" (memo number 08-04) and were effective immediately upon issuance. These revisions are available at <http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR>, downloaded on November 29, 2007.

**Appendix II: Centers for Medicare & Medicaid
Services' (CMS) Condition of Participation:
Infection Control**

In addition, CMS officials said that the quality assessment and performance improvement COP, which can be found at 42 C.F.R. § 482.21 (2007), can also affect infection control.³

³The quality assessment and performance improvement COP states that the hospital must develop, implement, and maintain an effective, ongoing, hospitalwide, data-driven quality assessment and performance improvement program that reflects all of the hospital's departments and services.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

FEB 19 2008

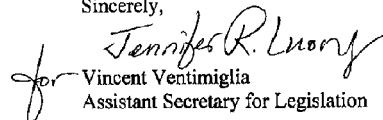
Ms. Cynthia A. Bascetta
Director, Health Care
U.S. Government Accountability Office
Washington, DC 20548

Dear Ms. Bascetta:

Enclosed are comments on the Government Accountability Office (GAO) Draft Report, "Health-Care-Associated Infections in Hospitals: Leadership Needed From HHS to Prioritize Prevention Practices and Improve Data on These Infections" (GAO-08-283).

The Department appreciates the opportunity to review and comment on this report before its publication.

Sincerely,


for Vincent Ventimiglia
Assistant Secretary for Legislation

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS: LEADERSHIP NEEDED FROM HHS TO PRIORITIZE PREVENTION PRACTICES AND IMPROVE DATA ON THESE INFECTIONS" (GAO-08-283).

The Department appreciates GAO's efforts to ensure that the Centers for Medicare & Medicaid Services (CMS) collaborates with other Health and Human Services (HHS) agencies to--(1) identify and potentially codify infection control practices to prevent health-care-associated infections (HAIs); and (2) develop linkages between the various HHS data collection systems to facilitate the collection and analysis of national HAI data.

As a condition of their participation in the Medicare and Medicaid programs, hospitals must comply with all of CMS's minimum regulatory health and safety requirements, called conditions of participation (CoPs), including the CoP for infection control.

The CoP for infection control requires hospitals to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases and to have an active program for the prevention, control, and investigation of infections and communicable diseases. Hospitals must designate at least one infection control officer to develop and implement policies governing control of infections and communicable diseases. That officer must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel; and maintain a log of incidents related to infections and communicable diseases. Further, each hospital's chief executive officer, medical staff, and director of nursing services is responsible for ensuring that the hospital-wide quality and training programs address problems identified by the infection control officer(s) and for implementation of successful corrective action plans in affected problem areas.

As the GAO report notes, CMS has developed interpretive guidelines for CoPs that describe the CoPs and provide survey procedures. Medicare/Medicaid providers utilize these guidelines to determine how to implement the requirements in the CoPs. The CMS guidelines for the hospital infection control CoP (CMS State Operations Manual, Appendix A: <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1201984&intNumPerPage=10>) reference some of the CDC recommendations that hospitals can use to ensure they are in compliance with the requirements of the CoP. For example, the Guidelines cite the CDC "Guidelines for Prevention and Control of Nosocomial Infections" and "Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities." The Guidelines state that hospitals should provide a safe environment, "consistent with nationally recognized infection control precautions, such as the current CDC recommendations for the identified infection and/or communicable disease...."

Although CMS does not have specific infection control requirements, such as hand hygiene or sterilization standards, we cite noted improper practices that do not follow nationally recognized standards (such as CDC strongly recommended practices) at our standard-level requirement for preventing and controlling infections. In a plan of correction, we would expect a hospital to demonstrate that it had implemented recognized practices to address the improper practices and that it had incorporated the corrective actions into its quality assessment and performance improvement program to ensure sustainability.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS: LEADERSHIP NEEDED FROM HHS TO PRIORITIZE PREVENTION PRACTICES AND IMPROVE DATA ON THESE INFECTIONS" (GAO-08-283).

Thus, although our CoPs have only two standards, the standards have an extremely broad reach when it comes to assessing a hospital's infection control program, and we routinely cite observed infection control breaches, even when such breaches have not resulted in a known infection.

In regard to the collection of HAI data, it is important to note that these data collection programs are designed in some cases for very different purposes. For example, the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program is designed to produce hospital level estimates. Under the RHQDAPU Program, participating hospitals report several infection-related measures. These include SCIP-Inf-1 Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision, SCIP-Inf-2 Prophylactic Antibiotic Selection for Surgical Patients, and SCIP-Inf-3 Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time. These measures are currently publicly reported on CMS's Hospital Compare website. In addition, under Medicare's Quality Improvement Organization Program, selected hospitals receive technical assistance to improve their performance for these and additional measures. The rare nature of selected HAI measures and the current burden of data collection preclude the production of reliable hospital level estimates for these relatively rare events for sampled data. Nevertheless, CMS acknowledges the need for greater consistency and compatibility of the collected data on HAI's.

One advance in the collection of HAI data will occur when we move from the current coding system, ICD-9-CM to an updated system, ICD-10. CMS is currently evaluating this move. Identifying hospital-acquired conditions requires clear and detailed diagnosis codes. The current coding system, ICD-9-CM, is three decades old. It is outdated, and has numerous instances of broad and vague codes. Attempts to add this detail to ICD-9-CM are constrained by a lack of room to expand. This has a negative impact on CMS' attempts to identify cases with a hospital-acquired condition. ICD-10 codes are more precise and capture information using medical terminology used by current medical practitioners. Examples of problems with ICD-9-CM that impact our current effort with hospital-acquired conditions that have been rectified with ICD-10 include the following examples.

- **Pressure ulcers** – We selected pressure ulcers as one of our hospital-acquired conditions. This condition is both high cost and high frequency. There are prevention guidelines for pressure ulcers. Unfortunately, ICD-9-CM does not provide enough detail to clearly identify the exact location, size, or depth of the pressure ulcer. Using trend data, one cannot tell if the pressure ulcer is getting better or worse (increasing in size or depth). ICD-9-CM has nine codes that identify the generic part of the body with the pressure ulcer. It provides no information of the size, depth, or exact location of the pressure ulcer. ICD-10-CM has 60 codes that identify the size, depth, and location of the pressure ulcer.
- **Hospital-acquired Infections** – ICD-9-CM does not have unique codes that identify specific types of bacterial infections which are resistant to antibiotics, such as MRSA infections. MRSA infections are captured through a combination of at least three separate codes under ICD-9-CM. This includes a vague code that captures all types of infections that are resistant to antibiotics.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS: LEADERSHIP NEEDED FROM HHS TO PRIORITIZE PREVENTION PRACTICES AND IMPROVE DATA ON THESE INFECTIONS" (GAO-08-283).

ICD-10 has more detail in each code as to the type and location of the infection. The next draft of ICD-10 will have detailed codes that would indicate whether the patient had a MRSA infection or was colonized with MRSA, but suffering no current infection. The ability to expand ICD-10 to capture detailed information on additional conditions is also one of the strengths of ICD-10.

- **Septicemia** -- CMS is evaluating the selection of septicemia as one of the hospital-acquired condition. ICD-9-CM codes are quite problematic in capturing septicemia cases. Multiple, overlapping codes are required to identify these cases. This makes coding, reporting, and data analysis of septicemia difficult. ICD-10 codes are much improved and clearly identify septicemia cases.
- **Falls and trauma** -ICD-9-CM codes are vague and do not describe whether an injury, such as a leg fracture, occurs on the right or left leg. ICD-9-CM also does not provide information on whether the encounter is for the initial treatment of the fracture or for subsequent care. ICD-10 has detailed codes that identify the nature of the injury, whether it was to the left or right extremity, and whether the treatment is toward a new or earlier fracture. ICD-10 also provides greater detail as to where the injury occurred (e.g., the patient room, corridor, operating room, bathroom). This detail is not present in ICD-9-CM.
- **Foreign body left in after surgery (never event)** – ICD-9-CM has one vague code that captures the fact that a complication developed as a result of a device being inadvertently left in a patient after surgery. ICD-10 codes provides much greater detail and describes the type of complication that results from this never event. The codes describe the type of complication such as an obstruction, perforation, infection, or adhesions. The codes also clearly describe the type of procedure performed that resulted in the device being inadvertently left in a patient, such as an endoscopic procedure or an open procedure. This more detailed information provides a more definitive picture of the nature of the complication resulting from the never event.

There are many other parts of ICD-10 that provide clear and concise codes to capture events and conditions important for health care delivery. ICD-10 has codes that describe under-dosing and over-dosing patients. This information would provide valuable information on patient outcomes. With more precise codes, CMS could add additional hospital-acquired provisions to our proposals.

Another advance in the collection of HAI data is the recent requirement for the collection of Present on Admission data as part of hospital submitted Medicare claims. The Deficit Reduction Act (DRA) required CMS to select certain conditions for which Medicare will no longer pay an additional amount when that condition is acquired during a hospitalization. The DRA further requires that the selected conditions be reasonably preventable through the application of evidence-based guidelines. CMS has closely collaborated with CDC on the selection of these conditions, with particular attention to identifying evidence-based guidelines that are consistent with CDC's recommended practices. Thus, this Medicare payment provision is closely tied to CDC's prioritized practices.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS: LEADERSHIP NEEDED FROM HHS TO PRIORITIZE PREVENTION PRACTICES AND IMPROVE DATA ON THESE INFECTIONS" (GAO-08-283).

As a prerequisite for implementing this Medicare payment provision, the DRA also requires hospitals to begin reporting present on admission (POA) indicator data to identify whether the selected conditions are acquired during a hospitalization. CMS' approach to POA indicator reporting is consistent with the standards set forth in the ICD-9-CM guidelines, which are maintained by CDC. CMS' collection of POA data will generate increased information about hospital-acquired conditions, including infections, which can be used by CDC and others to inform and disseminate reliable national estimates of these conditions.

Finally, CMS, under its Quality Improvement Organization 9th Statement of Work, will include as components of the Patient Safety Theme, measures relevant to health-care associated infections in hospitals. These measures will include a Surgical Care Improvement Project (SCIP) measure on the use of prophylactic antibiotics and a measure on the incidence of Methicillin-Resistant Staphylococcus aureus (MRSA). This work is being conducted in collaboration with CDC.

CMS is committed to ensuring that all patients in Medicare and Medicaid participating hospitals receive quality health care and appreciates the GAO's support in helping HHS achieve that goal.

GAO Recommendations:

In order to reduce HAIs in hospitals, the Secretary should--

1. Identify priorities among CDC's recommended practices and determine how to promote the prioritized practices, including whether to incorporate selected practices into CMS's conditions of participation for hospitals; and
2. Establish greater consistency and compatibility of the data collected across HHS on HAIs to increase information available about HAIs, including reliable national estimates of the major types of HAIs.

CMS Response:

Medicare/Medicaid CoPs are broadly written, minimum health and safety requirements that providers and suppliers must meet to participate in Medicare and Medicaid. As a result, CoPs lack the specificity of the guidance and recommendations issued by HHS agencies, including the CDC recommendations for infection control. CMS continuously evaluates the CoPs for all Medicare/Medicaid providers to determine whether they need to be updated, for example, to reflect more current standards of practice. We welcome the opportunity to work with the CDC to review and prioritize its recommendations. When the recommendations are prioritized, CMS will consider whether to incorporate some of the recommendations into the hospital CoPs.

CMS will take the following actions to establish consistency and compatibility of the data collected across HHS on HAIs:

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS: LEADERSHIP NEEDED FROM HHS TO PRIORITIZE PREVENTION PRACTICES AND IMPROVE DATA ON THESE INFECTIONS" (GAO-08-283).

- (1) Work with other HHS agencies to evaluate opportunities for consolidating and coordinating national data collection programs.
- (2) Implement consensus-based measures definitions, such as using National Quality Forum endorsed measures in the APU program, whenever possible.
- (3) Require collection of data that facilitate linkage between databases, including Medicare beneficiary ID and Hospital patient ID in the APU program.

CMS will be mindful of the burden to hospitals and the need for collecting reliable national level HAI estimates in its national data collection programs. We appreciate the GAO's efforts in developing this report on prioritizing HAI prevention practices and improving HAI data collection.

Page 35, Paragraph 3, Line 1 The GAO draft report states "Although officials from the various HHS agencies discuss HAI data collection with each other, we did not find that the agencies were taking steps to integrate any of the existing data from the four databases that collect HAI-related data."

- Most recently, CDC has taken steps toward definitional alignment with CMS, and CDC has taken steps toward enabling CMS-SCIP data imports into NHSN. Also, the HHS Patient Safety Task Force made efforts toward integrating patient safety reporting to multiple agencies through a common portal.
- In recent years, the Health Level Seven (HL7) data standards organization has developed a XML file format for electronic exchanges of structured clinical documents. The HL7 standard, known as Clinical Document Architecture (CDA), is designed for use in exchange of clinical records, such as continuity of care records and patient history and physical examination findings. The versatility of the CDA standard has led to additional uses, including HIPAA-mandated electronic claims attachments that CMS has developed with HL7 for use in claims processing. All electronic claims attachment documents promulgated by CMS are CDA documents. CDC is using CDA as the file format for information system developers to use in enabling their systems to report healthcare associated infection (HAI) data from hospitals to CDC's National Healthcare Safety Network (NHSN). The clinical, financial, and public health uses of CDA are evidence of the importance this industry standard has already achieved as a specification for data exchanges between disparate systems.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: "HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS: LEADERSHIP NEEDED FROM HHS TO PRIORITIZE PREVENTION PRACTICES AND IMPROVE DATA ON THESE INFECTIONS" (GAO-08-283).

- One important benefit of adopting an industry standard solution for electronic healthcare data exchanges is that it facilitates communication and reuse of data already collected for some other purpose. CDA calls for use of standard healthcare vocabulary in the documents that are exchanged. This requirement is an integral part of enabling interoperability between sending and receiving systems. Another important benefit is enabling technical features for importing files from one system to another and distributing data into the second system's database to be reused for a variety of files that conform to the standard format. For example, CDA documents can be imported and parsed into a database using the same technical features regardless of whether the document carries data about a clinical outcome, such as a healthcare associated infection, or a process of care, such as use of an antimicrobial agent to prevent a surgical site infection.
- This latter benefit points to why adoption of an industry standard file format, in particular CDA, would be advantageous for CDC in its monitoring of HAIs through NHSN and CMS in its monitoring of process of care, such as surgical care, through its CART tool and the Annual Payment Update database. A CDA import function, under development for the NHSN application, will enable CDC's system to be used to import HAI data reported via a CDA document. The same function will lend itself for use in importing a process of care measurement data if those data are conveyed using the CDA file format. The CART tool generates proprietary XML files, i.e., files that do not conform to specifications of a standards development organization such as HL7. At the relatively low cost of converting the proprietary format used in the CART tool to the industry-standard CDA file format, the process of care data collected for the Annual Payment Update database, including Surgical Care Improvement Program (SCIP) data, would be available for importation into NHSN and linkage with the outcome data. In other words, migration to CDA across CDC and CMS systems will enable hospitals participating in both systems to readily combine patient-level process and outcome data.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Cynthia A. Bascetta at (202) 512-7114 or bascettac@gao.gov

Acknowledgments

In addition to the contact named above, key contributors to this report were Linda T. Kohn, Assistant Director; Donald Brown; Shaunessye Curry; Shannon Slawter Legeer; Eric Peterson; Roseanne Price; and Keisha Wilkerson.

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