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State Government Tracking of Hospital-Acquired Conditions

FINAL

Prepared for

Linda A. Radey
Centers for Medicare & Medicaid Services
Office of Research, Development, and Information
Mail Stop C3-19-26
7500 Security Boulevard
Baltimore, MD 21244-1850

Prepared by

Nathan West, MPA
Terry Eng, RN, PhD (c)
Brieanne Lyda-McDonald, MPH
Nancy McCall, ScD
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709

RTI Project Number 0209853.023

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by Nathan West, MPA, Task 4.3 Leader
Terry Eng, RN, PhD (c)
Brieanne Lyda-McDonald, MPH
Nancy McCall, ScD

Federal Project Officer: Linda A. Radey

RTI International

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ACRONYMS USED IN THIS REPORT

AHRQ—Agency for Healthcare Research and Quality
CAP—corrective action plan
CDC—Centers for Disease Control and Prevention
CMS—Centers for Medicare & Medicaid Services
GAO—General Accounting Office
HAC—hospital-acquired conditions
HAC-POA—Hospital-Acquired Conditions—Present on Admission program
HAI—health care–associated infection
HHS—U.S. Department of Health and Human Services
IOM—Institute of Medicine
MS-DRG—Medicare severity diagnosis-related groups
NASHP—National Academy of State Health Policy
NHSN—National Healthcare Safety Network
NQF—National Quality Forum
OIG—Office of Inspector General
PSO—patient safety organization
RCA—root cause analysis
SRE—serious reportable event

EXECUTIVE SUMMARY

Objective

To provide a comprehensive report on the status of State government tracking of hospital-acquired conditions (HACs).

Background

The Deficit Reduction Act of 2005 modified payment for acute care hospitalizations of Medicare fee-for-service beneficiaries if a complicating condition occurred during the hospitalization that could have reasonably been prevented. In response to the legislation, the Centers for Medicare & Medicaid Services (CMS) developed the Hospital-Acquired Conditions—Present on Admission (HAC-POA) program, whereby inpatient prospective payment system cases can no longer be assigned to higher-paying Medicare severity diagnosis-related groups on the basis of preventable complicating conditions that are acquired during the hospital stay. CMS identified 10 HACs as being preventable under accepted guideline-consistent care and targeted these for application of the HAC-POA payment policy. CMS has contracted with RTI International to evaluate the HAC-POA program. The evaluation will seek to answer a broad set of research questions, one of which is what State governments are doing to track HACs.

This report identifies and describes efforts to track and report HACs and other medical errors or adverse events in all 50 States and the District of Columbia. We performed document reviews of information provided on State health department Web sites and annual reports or publicly available databases that capture HAC data. We also met with representatives from both the Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality to ascertain Federal initiatives in State tracking of HACs. Our focus is on the Medicare list of selected HACs, but many State reporting systems track conditions outside the scope of the 10 conditions included in the HAC-POA payment policy. We also discuss the Federal role in these State tracking efforts, because Federal agencies advise and influence what States are doing to track HACs and improve patient safety.

Key Findings

As of March 2010, 26 States and the District of Columbia have enacted legislation to establish adverse event reporting systems. Nineteen of these States have implemented an adverse event reporting system within the last 10 years, with Illinois the most recent (2010).

There are no federal standards for State reporting systems and no uniform list of reportable events or HACs. States are free to designate which events are reportable, but harm is a common denominator for reporting. Fourteen States use the National Quality Forum's list of 28 serious reportable events. Twelve States have identified their own sets of reportable events.

The majority of States publicly report only aggregate-level data on HACs. Six States report both aggregate and facility-specific HAC data. Five States do not offer public reporting.

Most States with legislative mandates for reporting systems hold individual hospitals accountable for their patient care performance. Most often desk audits were performed by the States, but in some cases onsite audits were performed if the determination was made that the hospital did not handle the event appropriately.

Sixteen States use data collected from adverse event reporting systems for both regulatory and quality improvement purposes. Data for quality improvement are used to communicate with other organizations about best practices and patient safety to enhance organizational learning and to improve processes of care.

Thirty-one States have mandated reporting of health care–associated infections. Of those, 21 use or will use the National Healthcare Safety Network as the surveillance system monitoring health care–associated events, including facility-acquired infections and reactions associated with transfusion of blood or blood products.

Just over half the States track at least one Medicare HAC (28 States and the District of Columbia). States vary widely as to the total number of HACs tracked through a State-based reporting system. Eleven States and the District of Columbia track all the Medicare HACs that are part of the National Quality Forum's list of 28 serious reportable events.

Fourteen States and the District of Columbia collect at least six Medicare HACs. No State collects more than 8 of the 10 Medicare HACs.

Conclusion

In the absence of a nationally based mandated reporting system for medical errors and patient safety events, State-based reporting systems serve a significant role collecting and reporting data for the Medicare HACs. Despite the wide variability in terms of what events are tracked and the reporting criteria used, State reporting systems share some common traits. The States use data in similar ways to improve patient safety and employ quality improvement programs, and most of the States provide aggregated public reports. Current Federal initiatives have bolstered HAC reporting activities at the State level, yet there are still overriding concerns surrounding the variability and lack of standardization across State reporting systems. These differences make it unsuitable to identify national incidence and trends for HACs.

SECTION 1
INTRODUCTION

1.1 Brief Background on Hospital-Acquired Conditions and the Role of States to Track and Report Them

The Deficit Reduction Act of 2005 (the Act) modified payment for acute care hospitalizations of Medicare fee-for-service beneficiaries if a complicating condition occurred during the hospitalization that could have reasonably been prevented. Section 5001(c) of the Act requires the Secretary of the Department of Health and Human Services (HHS) to identify complications of care that meet the following three conditions: (1) are high cost, high volume, or both; (2) are assigned to a higher-paying Medicare severity diagnosis-related group (MS-DRG) when present as a secondary diagnosis; and (3) could reasonably have been prevented through application of evidence-based guidelines. In response to the Act, the Centers for Medicare & Medicaid Services (CMS) developed the Hospital-Acquired Conditions—Present on Admission (HAC-POA) program, whereby inpatient prospective payment system cases can no longer be assigned to higher-paying MS-DRGs on the basis of preventable complicating conditions that are acquired during the hospital stay.

To implement this payment change, beginning in April 2008, CMS began requiring hospitals participating in the inpatient prospective payment system to code all *International Classification of Diseases, Ninth Revision* (ICD-9) diagnoses on the inpatient claim as either POA or HAC. Through collaboration with the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and the Office of Public Health and Science, and after extensive public input, CMS identified 10 HACs as being preventable under accepted guideline-consistent care and targeted these for application of the HAC-POA payment policy. CMS has contracted with RTI International to evaluate the HAC-POA program. The evaluation will seek to answer a broad set of research questions, one of which is what State governments are doing to track HACs.

The Institute of Medicine's landmark *To Err Is Human*, released in 2000, called for a nationwide public mandatory reporting system to identify and learn from medical errors and other adverse events (Institute of Medicine [IOM] 2000). Under the reporting system, State governments would be required to collect standardized information about adverse medical events that result in death and serious harm. Subsequently, the National Quality Forum (NQF) released *Serious Reportable Events in Healthcare* in 2002 (NQF 2002). This groundbreaking document reflected consensus on a list of 28 serious, preventable adverse events that could form the basis for a national reporting system and lead to substantial improvements in patient safety. Since that time, State activity has focused on the development and improvement of reporting systems that can help improve quality and outcomes by identifying system weaknesses, can complement other State functions, and can help safeguard the health care consumer (Rosenthal and Takach 2007). Numerous adverse-events reporting systems are in operation, and there is growing evidence that these efforts have been bringing positive change to the quality of care delivered (Leape and Berwick 2005).

Several States operated mandatory reporting systems before the 2000 IOM report. However, these reporting systems were used primarily to hold providers accountable for their

errors and often involved public disclosure. Confidential, voluntary systems for reporting of medical errors were less common. The IOM report noted that health care providers are often reluctant to report or publicly disclose their medical errors and to participate in related learning efforts out of fear of incurring legal liability or professional sanctions. To address these concerns, the IOM recommended the expanded use of voluntary medical error reporting systems that allow confidential reporting. Partially in response to the IOM report, Congress responded with subsequent legislative acts to encourage and fund voluntary reporting systems.

The Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act) directed HHS to create a list of public or private organizations known as patient safety organizations (PSOs). The Patient Safety Act prohibits the unauthorized disclosure of certain types of data regarding patient safety events that providers send to the PSOs (Government Accountability Office [GAO] 2010). PSOs certify that they will analyze data regarding patient safety events, provide feedback to providers, and develop and disseminate information on ways providers can improve patient safety. To support PSOs and providers in their efforts to develop and adopt improvements in patient safety, the Patient Safety Act directed HHS to create a network of patient safety databases (NPSDs). These databases collect and aggregate nonidentifiable data on patient safety events voluntarily submitted by the PSOs and providers. Patient safety data are aggregated and analyzed nationally. States also responded with a grassroots movement toward public reporting by facility of health care–associated infection (HAI) rates. In 2003, CDC's Healthcare Infection Control Practices Advisory Committee published guidance to States for implantation of HAI public reporting. Currently, 28 States have implemented public reporting laws, 21 of which utilize the National Healthcare Safety Network (NHSN) for their reporting requirements.

More recently, The American Recovery and Reinvestment Act of 2009 (the Recovery Act) authorized $50 million to support States in the prevention and reduction of HAIs. CDC is the Federal agency responsible for distributing the Recovery Act funds to State health departments through cooperative agreements. The HAI Recovery Act will support programs to boost surveillance and prevention of HAIs, encourage collaboration, train the workforce in HAI prevention, and measure outcomes. These efforts are consistent with the recommendations outlined in the *HHS Action Plan to Prevent Health Care–Associated Infections* (Office of Public Health and Science 2009). NHSN will be a primary means of States' collecting data from health care facilities through the Recovery Act agreements. NHSN is a voluntary, secure, Internet-based surveillance system operated by CDC that is open to all types of health care facilities in the United States. CDC currently supports more than 2,600 healthcare facilities that are using NHSN, and 21 States require or will require hospitals to report HAIs using NHSN.

Table 1.1 provides definitions, examples, and sources of various terms frequently referenced in documents relating to tracking and reporting of medical events that may occur in a health care facility setting.

Table 1.1
Frequently used terms relating to medical errors in health care facilities

Term	Definition	Examples	Source
Hospital acquired condition (HAC)	A condition that (1) is high cost or high volume or both, (2) results in the assignment of a case to an MS-DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence-based guidelines.	Foreign object retained after surgery, pressure ulcer Stages III and IV (for a complete list of HACs, see Appendix A).	Centers for Medicare & Medicaid Services: Hospital-Acquired Conditions (HAC) and Present on Admission (POA) Reporting. Available from http://www.cms.gov/HospitalAcqCond/
Health care–associated infection (HAI)	An infection that a patient acquires while receiving treatment for one or more medical or surgical conditions.	Surgical site infection, central line–associated bloodstream infection, ventilator-associated pneumonia, and catheter-associated urinary tract infection.	U.S. Department of Health and Human Services: HHS Action Plan to Prevent Healthcare-Associated Infections: Executive Summary. (n.d.) Available from http://www.hhs.gov/ophs/initiatives/hai/exsummary.html
Serious reportable event (SRE)	Unambiguous, serious, preventable adverse events that concern both the public and health care providers and could form the basis for a national reporting system that would lead to substantial improvements in patient safety. SREs are identifiable and measurable, and their risk of occurrence is significantly influenced by the policies and procedures of health care organizations.	Surgery performed on wrong patient, infant discharged to the wrong person (for a complete list of SREs, see Appendix B).	National Quality Forum: Serious Reportable Events in Healthcare 2006 Update: A Consensus Report. Available from http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare–2006_Update.aspx

NOTE: MS-DRG, Medicare Severity Diagnosis-Related Group.

1.2 Organization of the Report

In the following sections of this report, we present our methodological approach to identifying and summarizing State tracking systems for HACs (***Section 2***), the results of our document review and discussions with CDC and AHRQ (***Section 3***), and a discussion of the role and influence of current Federal initiatives to bolster these reporting systems and future trends for HAC reporting at the State level (***Section 4***).

SECTION 2
METHODOLOGY

2.1 Scope

This report identifies and describes efforts to track and report HACs and other medical errors or adverse events in all 50 States and the District of Columbia (hereafter referred to as States) as of March 2010. Our focus is on the Medicare list of selected HACs, but many State reporting systems track conditions outside the scope of the 10 categories of HACs included in the HAC-POA payment policy. We also discuss the Federal role in these State tracking efforts, because Federal agencies advise and influence what States are doing to track HACs and improve the safety and quality of our Nation's complex health care delivery system.

2.2 Data Collection Approach

Our data collection approach involved three major activities: (1) a thorough document review of existing State tracking reports, databases, and other sources; (2) formal and informal discussions with CDC and AHRQ to ascertain Federal initiatives in State tracking of HACs, and (3) collection and review of publicly available State reports that provide data on HACs.

2.2.1 Document Review

We developed a large inventory matrix that captured reporting system activity for the States. Our information was derived from several sources, including recent HHS Office of Inspector General (OIG) reports describing State adverse event reporting systems and the National Academy of State Health Policy (NASHP) patient safety toolbox (NASHP 2010; OIG 2008). Recent GAO reports on HAI reporting systems and the role of the Patient Safety Act also informed our document review activities. Furthermore, we substantiated information collected from these research efforts by reviewing State health department or hospital association Web sites that provided information on the reporting systems or served as the site for public reporting of HAC data.

2.2.2 Discussions with the Centers for Disease Control and Prevention and the Agency for Healthcare Research & Quality

We held several telephone discussions and met in person with division directors and other key staff within CDC's Division of Healthcare Quality Promotion to gather information on the role of CDC to implement HAI Recovery Act funds, NHSN use at the State level, and HAI prevention plans under way for the States. We also held a telephone discussion with medical officers from AHRQ's Center for Quality Improvement and Patient Safety to understand the role of PSOs and network of patient safety databases.

2.2.3 State Reports of Hospital-Acquired Conditions

We collected State reports, typically in the form of an annual patient safety or adverse event report, from State health department Web sites. We reviewed 21 State reports to determine their serious reportable event (SRE) list (e.g., NQF list or State-defined), their mechanism for collecting the data, and whether the data were reported on individual facilities or in aggregate for all facilities.

2.3 Limitations

The information in this report reflects our findings from the aforementioned document review activities and discussions with CDC and AHRQ staff. We verified that State-level information already collected from NASHP and OIG is still current and that it reflects State mandates currently in place for medical error reporting. However, States' efforts to collect data and report on medical errors, particularly on HACs from the Medicare list, is a fluid and evolving activity, as greater Federal involvement is having an impact on HAC reporting at the State level. We do not guarantee that all findings reflect the most recent and ongoing changes to State tracking of HACs. Future annual reports and updates on State tracking of HACs that are part of this CMS contract to evaluate the HAC-POA program will help address these limitations. Furthermore, our findings assume that States are using the reported information in the manner described by their State reporting system documentation or annual State reports. We did not independently verify the validity of their description of reporting activities.

SECTION 3
FINDINGS

3.1 State Medical Error and Adverse Event Reporting Systems

Table 3.1 presents the findings from our inventory of State governments' medical error and adverse event reporting systems. Our selection of the 27 States presented in the table is consistent with the criteria also used by the NASHP patient safety toolbox and the OIG Report on State Adverse Event Reporting Systems. ***Section 3.1.1,*** following the table, details our methodology.

Table 3.1
General characteristics of State reporting systems

State	Start Date	Reportable Event List	Data Submission Format	Facilities Required to Report
CA	2007	Modified NQF	Manual, to electronic by 2015	General/acute care hospitals, acute psychiatric hospitals, specialty hospitals
CO	1988	State-defined	Manual or electronic	All licensed healthcare facilities
CT	2002	Modified NQF	Manual	General/acute care hospitals, ambulatory care sites
DC	2007	NQF & 1 HAI	Manual	All health care facilities; businesses; any licensee doing health care business, including pharmacies and dental offices
FL	1998	State-defined	Manual or electronic	General/acute care hospitals, ambulatory surgical centers, skilled nursing facilities
GA	2003	State-defined	Manual	General/acute care hospitals, laboratories, dialysis facilities, residential child care facilities, residential mental health facilities, X-ray imaging
IL	2010	Modified NQF	Manual or electronic	Hospitals, ambulatory surgical care centers
IN	2006	NQF	Manual or electronic	Hospitals, ambulatory surgery care centers, abortion clinics, birthing centers
KS	1988	State-defined	Manual	General/acute care hospitals, ambulatory surgical centers, psychiatric hospitals

(continued)

Table 3.1
General characteristics of State reporting systems (continued)

State	Start Date	Reportable Event List	Data Submission Format	Facilities Required to Report
ME	2004	State-defined	Manual	Hospitals, ambulatory surgery care centers, end-stage renal facilities, intermediate care facilities
MD	2004	Modified NQF	Manual	Licensed hospitals
MA	1980	State-defined	Manual	All licensed healthcare facilities
MN	2003	NQF	Electronic	Hospitals, ambulatory surgical centers, regional treatment facilities
NV	2005	State-defined	Manual	Acute care, psychiatric inpatient, and rehab inpatient hospitals; ambulatory surgery care centers; independent ERs; obstetric centers
NJ	2005	Modified NQF	Manual	Acute care hospitals now (all health care facilities to be phased in)
NY	1985	State-defined	Electronic	Hospitals, diagnostic and treatment centers
OH	2007	6 measures chosen from CMS, Joint Commission, NQF, AHRQ (including 5 PSIs)	Manual	Hospitals
OR	2006	Modified NQF	Manual	Hospitals, nursing homes, retail pharmacies, ambulatory surgery care centers, dialysis facilities, birthing centers
PA	2004	State-defined	Electronic	Hospitals, ambulatory surgery care centers, birthing centers, some abortion facilities, nursing homes
RI	1994	State-defined	Manual	Hospitals
SC	1976	State-defined	Manual	Licensed health care facilities
SD	1987	State-defined	Manual	Licensed health care facilities
TN	2000	State-defined	Electronic	Licensed health care facilities

(continued)

Table 3.1
General characteristics of State reporting systems (continued)

State	Start Date	Reportable Event List	Data Submission Format	Facilities Required to Report
UT	2001	NQF, CMS, and Joint Commission for sentinel events	Manual	Health care facilities and hospitals, ambulatory surgery care centers
VT	2007	NQF	Manual and electronic	All hospitals, including State mental health hospitals, excluding Veterans Affairs hospitals
WA	2006	NQF	Manual and electronic	Hospitals, childbirth centers, psychiatric hospitals, correctional medical facilities (ambulatory surgery care centers, July 2009)
WY	2005	Modified NQF	Manual	General/acute care hospitals, ambulatory surgery care centers, home health centers, skilled nursing facilities

NOTE: AHRQ, Agency for Healthcare Research and Quality; CMS, Centers for Medicare & Medicaid Services; ER, emergency room; HAI, health care–associated infection; NQF, National Quality Forum; PSI, patient safety indicator.

3.1.1 General Characteristics of State Reporting Programs

State—Currently 26 States and the District of Columbia have enacted legislation to establish adverse event reporting systems. An adverse event is defined as harm caused by medical management, not related to disease, that causes prolonged hospitalization, a disability at discharge, or both (IOM 2001). All States were inventoried by searching State health department Web sites, State hospital associations, or both to determine which adverse events are reported and which processes are used for collecting and reporting the data.

Year System Began—This column reflects the year the State implemented its adverse reporting system based on State law. Nineteen States have implemented an adverse reporting system within the last 10 years, with Illinois the most recent (2010). Of the 19, 10 have implemented a reporting system within the last 5 years. South Carolina (1976) has the oldest reporting system. The remaining 7 States' systems have been in existence since before 2000.

Reportable Event List—As there are no Federal standards for State reporting systems and no uniform list of SREs, States are free to designate which events are reportable. Despite the lack of a standard list of reportable events, harm is a common denominator for reporting an adverse event. Fourteen States use either the NQF list of 28 SREs or some modification of it. SRE is the term used by NQF to refer to a list of adverse events that should never occur in a health care setting, such as an unintended retention of a foreign object in a patient after surgery. The SREs are organized under six major categories: surgical, product or device, patient protection, care management, environmental, and criminal events (NQF 2006). Twelve States have identified their own unique set of reportable events; 2 States, Ohio and Utah, include

standards from The Joint Commission, AHRQ, NQF, or some combination of these in their list of reportable events.

Electronic or Manual Data Submission—Just under half the States with reporting systems (13) have data submitted manually using paper forms that health care organizations complete and fax to the receiving agency. Four States submit data electronically or via the Internet, and six States have a manual as well as an electronic system. Three additional States will be making the transition to an electronic reporting system at a later date; California is legislated to move to electronic submission by 2015. An example of an electronic reporting system is the New York Patient Occurrence and Tracking System (NYPORTS), the State of New York's secure Internet-based adverse event reporting system. NYPORTS simplifies reporting, streamlines coding, and coordinates with other reporting systems to reduce duplication. The system also allows hospitals to query the database to obtain feedback on their own reporting patterns and compare them with other facilities in the region and the State. Similarly, the Pennsylvania Patient Safety Authority developed the Pennsylvania Patient Safety Reporting System, a secure, Web-based system that permits healthcare facilities to submit reports of serious events and incidents as required by State law.

Reporting Facilities—All 26 reporting States and the District of Columbia delineate the types of health care facilities that must report adverse events. The majority of reporting is focused on reports of adverse events from acute care hospitals, but psychiatric and specialty hospitals are included as well. Twelve States require ambulatory surgical care centers to report adverse events. Five States (Colorado, Massachusetts, South Carolina, South Dakota, and Tennessee) and the District of Columbia require all licensed health care facilities to report adverse events. Independent emergency rooms; pharmacies; and dental, dialysis, home health, and birthing centers are also included in the list of reporting organizations in some States.

Mandatory or Voluntary—Mandatory reporting requires a State to report the State-designated adverse events at an established time and frequency. In some States, failure to report adverse events may result in a monetary penalty against the hospital. Of the 27 States with adverse reporting systems, only Oregon's is voluntary. The other 26 States have mandatory reporting.

3.1.2 Reporting of the Data and Uses Made of the Data

Table 3.2 shows the types of data reported to the state and uses made of the data.

Table 3.2
Reporting of the data and uses made of the data

State	RCA/CAP Reporting Required	Near Misses Reported	Specificity of Publicly Reported Data	Public Report Available	Regulatory or QI Tool
CA	No	No	Aggregate and facility-specific	Yes	Regulatory
CO	Yes	No	Aggregate and facility-specific	Yes	Regulatory and QI
CT	Yes	No	Aggregate	Yes	Regulatory and QI
DC	Yes	No	Aggregate	Yes	QI
FL	Yes	No	Aggregate	Yes	Regulatory and QI
GA	Yes	No	N/A	No	Regulatory and QI
IL	Yes	No	Aggregate and facility-specific	Yes	QI
IN	Yes	No	Aggregate and facility-specific	Yes	QI
KS	No	No	Aggregate	No	Regulatory
ME	Yes	No	Aggregate	Yes	Regulatory and QI
MA	Yes	No	Aggregate and facility-specific	No	Regulatory
MD	RCA review with follow-up with further clinical review	No	Aggregate	Yes	Regulatory and QI
MN	Yes	No	Aggregate and facility-specific	Yes	Regulatory and QI
NV	Yes	No	Aggregate	Yes	Regulatory and QI
NJ	Yes	TBD	Aggregate	Yes	QI
NY	RCA required	Yes	Aggregate and facility-specific	Yes	Regulatory and QI
OH	No	No	Facility-specific	Yes	QI
OR	Yes	Yes	Aggregate	Yes	QI
PA	Yes	Yes	Aggregate	Yes	Regulatory and QI
RI	Yes	No	Aggregate	Yes	Regulatory and QI
SC	Yes	No	N/A	No	Regulatory and QI
SD	Yes	No	N/A	No	Regulatory
TN	Yes	No	Aggregate	Yes	Regulatory and QI
UT	Yes	No	Aggregate	Yes	Regulatory and QI
VT	Yes	No	Aggregate	Yes	Regulatory and QI
WA	Yes	No	Aggregate	Yes	QI
WY	No	No	Aggregate	Yes	Regulatory and QI

NOTE: CAP, corrective action plan; N/A, not available; QI, quality improvement; RCA, root cause analysis; TBD, to be determined.

Root Cause Analysis or Corrective Action Plan Reporting—A root cause analysis (RCA) is a structured process and focused review of systems and processes to identify the causal

or contributing factors underlying an adverse event (AHRQ 2010, OIG 2008). A corrective action plan is developed in response to an adverse event and includes policies and procedures that aim to prevent the future recurrence of the event (OIG 2008). All but four States require an RCA or CAP. Two States, Maryland and New York, require only an RCA.

Near Misses Reported—A near miss is an event that was discovered before it caused harm to the patient (AHRQ 2010). New York, Oregon, and Pennsylvania currently report near misses and New Jersey is considering doing so.

Publicly Reported Data—The content of public reports of adverse events varies across States. California, for example, posts detailed information at the hospital level by specific event. Maryland aggregates hospital data and reports Level I (patient death or serious injury) adverse events in a Maryland Hospital Safety Program Annual Report. Twenty-two States make their data available to the public. The majority (16) report aggregate data; 6 report both aggregate and facility-specific data. Ohio is the only State that reports by facility only. Five States (Georgia, Kansas, Massachusetts, South Carolina, and South Dakota) do not offer public reporting.

Regulatory or Quality Improvement Tool—States use adverse event data for regulatory or quality improvement purposes or both. Most States with legislative mandates for reporting systems (regulatory) hold individual hospitals accountable for their patient care performance. The OIG interviewed State staff from 26 States they identified as having reporting systems, and 23 of those States conducted administrative reviews of data contained in reports (OIG 2008). These adverse event reports most often resulted in desk audits, but in some cases onsite audits were performed if the determination was made that the hospital did not handle the event appropriately. States can potentially use adverse event reports to make licensing decisions for hospitals, although it is rare that a single adverse event report would result in the loss of licensure for a hospital. Data for quality improvement purposes are used to communicate with other organizations about best practices and patient safety to enhance organizational learning and to improve processes of care. The District of Columbia and six States (Illinois, Indiana, New Jersey, Ohio, Oregon, and Washington) use the data only for quality improvement. California, Kansas, Massachusetts, and South Dakota use the data for regulatory purposes. California, for example, conducts an on-site investigation when an SRE indicates an ongoing threat of imminent danger of death or serious bodily harm. Sixteen States use the data for both regulatory and quality improvement purposes.

3.2 Reporting Health Care–Associated Infections Through the National Healthcare Safety Network and the Health Care–Associated Infections Recovery Act Initiative

The 2009 Omnibus Bill required States receiving Preventive Health and Health Services Block Grant (http://www.cdc.gov/nccdphp/blockgrant/) funds to submit a plan to reduce HAIs. To assist States in responding within the short time required and to facilitate coordination with national HAI prevention efforts, CDC developed a plan template. This template helped ensure progress toward national prevention targets as described in the HHS Action Plan (http://www.hhs.gov/ophs/initiatives/hai/actionplan/index.html), while allowing flexibility to tailor the plan to each State's specific needs. CDC also provides training support and technical assistance to States who will track HAIs using NHSN. The Department received plans for all 50

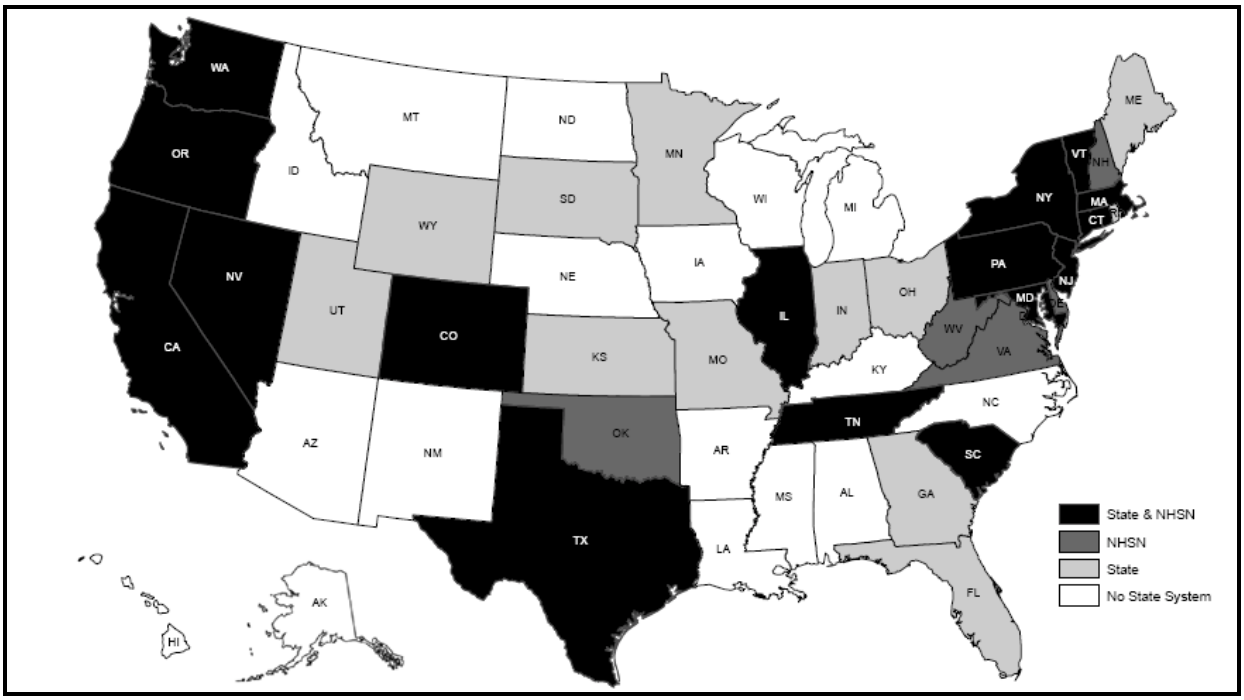
States, the District of Columbia, and Puerto Rico. As of early 2010, State plans are undergoing review at CDC.

Thirty-one States have mandated reporting of HAIs. Of those, 21 use or will use NHSN. NHSN may be used to monitor health care–associated events, including facility-acquired infections and reactions associated with transfusion of blood or blood products. Within the NHSN application, facilities can compare themselves to risk-adjusted, national aggregate data for local quality improvement purposes. The system can also be used by facilities to develop surveillance and analytic methods that allow timely recognition of patient safety problems for prompt intervention. Twenty States do not mandate reporting of HAIs or do not voluntarily report them. Six States—Alaska, Arizona, Indiana, New Mexico, North Carolina, and Ohio—currently have study committees considering whether to mandate HAI reporting.

3.3 Variation in State-Based Reporting Systems

Some States authorize and operate State-based reporting systems that require facilities to report HACs. States vary widely among themselves regarding what HACs are reported through these State-based reporting systems, as shown in ***Figure 3.1***. Many States require the reporting of the NQF list of SREs, whereas others have defined their own list of events including only a portion of the NQF events, and still others include patient safety indicators or HAIs as reportable events. Some States both have a State-based reporting system for medical errors and adverse events and track HAIs separately through NHSN. Beginning in 2011, additional States will fall into this category as more States go “live” with their collection of at least one HAI using NHSN. The map in Figure 3.1 illustrates the different scenarios of States that operate a State-based reporting system for medical errors and adverse events, track HAIs through NHSN, or do both.

Figure 3.1
Reporting system type by State



NOTE: State, State-developed reporting system for medical errors/serious preventable events; NHSN, State uses National Healthcare Safety Network for reporting health care–associated infections.

As the map illustrates, currently 16 States (California, Colorado, Connecticut, Illinois, Maryland, Massachusetts, Nevada, New Jersey, New York, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, and Washington) both maintain a State-based reporting system for medical errors and adverse events and track or will soon track HAIs through NHSN. Nevada and Texas are still in the process of implementing their mandates for HAI reporting. The five States that track HAIs through NHSN, but do not have a State-based reporting system for medical errors and adverse events, are Delaware, New Hampshire, Oklahoma, Virginia, and West Virginia. Twelve States (Florida, Georgia, Indiana, Kansas, Maine, Minnesota, Montana, Ohio, Rhode Island, South Dakota, Utah, and Wyoming) and the District of Columbia maintain a State-based reporting system and do not participate in NHSN. The remaining 17 States (Alabama, Alaska, Arizona, Arkansas, Hawaii, Idaho, Iowa, Kentucky, Louisiana, Nebraska, Michigan, Mississippi, Montana, New Mexico, North Carolina, North Dakota, and Wisconsin) neither track HAIs through NHSN nor maintain a State-based reporting system.

3.4 State Tracking of the Medicare List of Hospital-Acquired Conditions

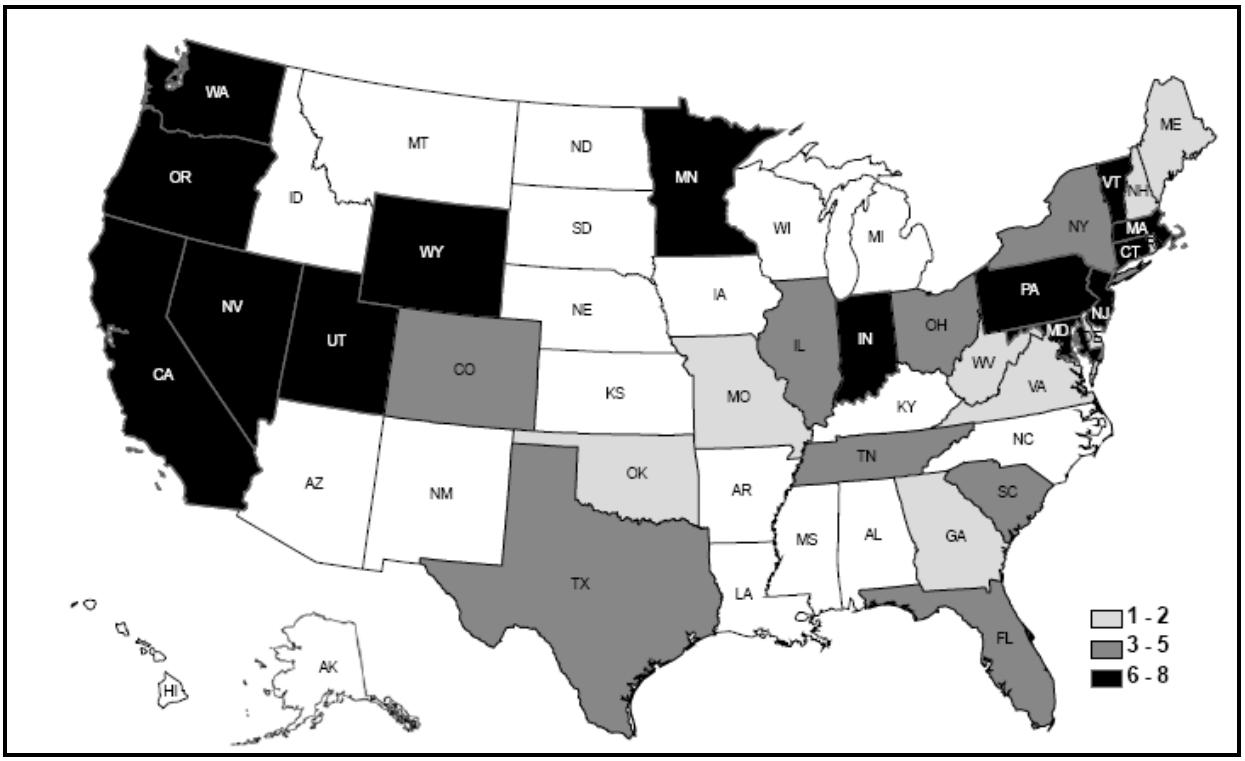
Table 3.3 shows a list of States that track at least one of the Medicare list of HACs. The large majority of States track at least one HAC through a medical error and serious adverse event reporting system authorized and operated by a State government agency. However, more States are beginning to track infection-related HACs through NHSN. Just over half the States track at

least one HAC (28 States and the District of Columbia), as shown in ***Figure 3.2***. States vary widely among themselves as to the total number of HACs tracked through a State-based reporting system. Eleven States and the District of Columbia track all HACs that are part of the NQF's list of 28 SREs. These HACs include (1) foreign object retained after surgery, (2) air embolism, (3) blood incompatibility, (4) Stage III and IV pressure ulcers, (5) falls and trauma, and (6) manifestations of poor glycemic control. These States use the NQF list of SREs or a modified version of that list as the HACs that facilities are required to report.

Outside of these six HAC categories that are also on the NQF list, three of the HAC categories from the Medicare list are HAIs that many States track through various activities. Four States (Connecticut, Nevada, New York, and Pennsylvania) track HAIs through both a State-based reporting system and NHSN, or separate and distinct reporting mechanisms. However, HAIs are more frequently reported through NHSN, because few States have developed their own reporting system for HAIs. Central line–associated bloodstream infections, a subset of vascular catheter–associated infections, are the HAIs most commonly required to be reported through NHSN, with 21 States who are requiring or will require reporting of the infection type. Peripheral line infections, another subset of vascular catheter–associated infections, are not reportable to NHSN. Reporting of surgical site infections is or will be mandated by 14 States through NHSN, whereas only 2 States require reporting of catheter-associated urinary tract infections through NHSN. Many more States plan to begin using NHSN to track at least one HAI as part of their HAI Recovery Act State Plan. These plans are under review by HHS to help understand how State activities can contribute to the HHS HAI goals, identify gaps, and determine means of additional support.

No States collect all 10 categories of selected HACs for the Medicare HAC-POA payment policy, although the District of Columbia and a few States (Connecticut, Massachusetts, New Jersey, Pennsylvania, Vermont, and Washington) do track up to 8 HACs. Only three States—Florida, New York and Pennsylvania—collect deep vein thrombosis/pulmonary embolism as part of their adverse event reporting system. This HAC is an AHRQ-designated patient safety indicator, but the condition is not one of the 28 NQF SREs. States not listed do not track any of the Medicare list of HACs through a State-authorized reporting system or NHSN. It is possible that some reports are submitted through PSOs for certain States and are not listed here. Such reports would not necessarily, or likely, be reported statewide, as individual health care facilities have agreements with a State-designated PSO to voluntarily and confidentially report medical errors.

Figure 3.2
Number of Medicare-listed hospital-acquired conditions reported by States



Of the States that collect HACs from the Medicare list, nine—Delaware, Georgia, Maine, Missouri, New Hampshire, Oklahoma, Rhode Island, Virginia, and West Virginia—collect either one or two. Another eight States (Colorado, Florida, Illinois, New York, Ohio, South Carolina, Tennessee, and Texas) collect between three and five HACs. Although no State collects more than 8 of the 10 Medicare HACs, 14 States and the District of Columbia collect between 6 and 8 HACs. These States are California, Connecticut, Indiana, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, Oregon, Pennsylvania, Utah, Vermont, Washington, and Wyoming.

Table 3.3
State tracking of the Medicare list of hospital-acquired conditions

State	Foreign Object Retained After Surgery	Air Embolism	Blood Incompatibility	Stage III and IV Pressure Ulcers	Falls and Trauma	Manifesta-tions of Poor Glycemic Control	CAUTI	CLABSI/ Vascular Catheter–Associated Infections	Surgical Site Infections	Pulmonary Embolism/ Deep Vein Thrombosis
CA	State	State	State	State	State	State	—	NHSN	—	—
CO	—	—	—	—	State	—	—	NHSN	NHSN	—
CT	State	State	State	State	State	State	—	State, NHSN	—	—
DC	State	State	State	State	State	State	State	State	—	—
DE	—	—	—	—	—	—	—	NHSN	—	—
FL	—	—	—	—	—	—	State	State	State	State
GA	—	—	—	—	State	—	—	—	—	—
IL	State	—	—	—	—	—	—	NHSN	NHSN	—
IN	State	State	State	State	State	State	—	—	—	—
ME	—	—	State	—	—	—	—	State	—	—
MD	State	State	State	State	State	State	—	NHSN	—	—
MA	State	State	State	State	State	State	—	NHSN	NHSN	—
MN	State	State	State	State	State	State	—	—	—	—
MO	—	—	—	—	—	—	—	State	State	—
NV	—	—	—	State	State	State	State	State, NHSN	State	—
NH	—	—	—	—	—	—	—	NHSN	NHSN	—
NJ	State	State	State	State	State	State	NHSN	NHSN	NHSN	—
NY	State	—	—	—	State	—	—	NHSN	State, NHSN	State
OK	—	—	—	—	—	—	—	NHSN	-—	—
OH	State	—	—	State	—	—	—	State	State	—
OR	State	—	State	State	State	State	—	NHSN	NHSN	—

(continued)

Table 3.3
State tracking of the Medicare list of hospital-acquired conditions (continued)

State	Foreign Object Retained After Surgery	Air Embolism	Blood Incompatibility	Stage III and IV Pressure Ulcers	Falls and Trauma	Manifesta-tions of Poor Glycemic Control	CAUTI	CLABSI/ Vascular Catheter–Associated Infections	Surgical Site Infections	Pulmonary Embolism/ Deep Vein Thrombosis
PA	State	—	State	State	State	—	State, NHSN	State, NHSN	State, NHSN	State
RI	—	—	—	—	State	—	—	—	—	—
SC	—	—	State	—	State	—	—	NHSN	NHSN	—
TN	State	—	State	—	State	—	—	NHSN	NHSN	—
TX	State	—	State	—	—	—	—	NHSN	NHSN	—
UT	State	State	State	State	State	State	—	—	—	—
VT	State	State	State	State	State	State	—	NHSN	NHSN	—
VA	—	—	—	—	—	—	—	NHSN	—	—
WA	State	State	State	State	State	State	—	NHSN	NHSN	—
WV	—	—	—	—	—	—	—	NHSN	—	—
WY	State	State	State	State	State	State	—	—	—	—

NOTE: A dash (—) signifies that the state does not track the condition; CAUTI, catheter-associated urinary tract infection; CLABSI, central line–associated bloodstream infection; NHSN, State uses or will use the National Healthcare Safety Network for mandatory health care–associated infection reporting; State, State-developed reporting system for medical errors or adverse events.

SECTION 4
DISCUSSION AND CONCLUSION

4.1 Greater Federal Involvement in Tracking of Hospital-Acquired Conditions at the State and Facility Level

4.1.1 The Recovery Act, Health Care–Associated Infections, and State Expansion of the National Healthcare Safety Network

The HAI Recovery Act initiative carried out by CDC has prompted a large expansion of State-level reporting of HAIs. Although some States were already collecting data on at least 1 HAI through NHSN or a State-based reporting system, the Recovery Act uses both monetary and technical support to give 49 States, the District of Columbia, and Puerto Rico the opportunity to, at a minimum, build and sustain programs to prevent HAIs. Wyoming was the only State that did not apply for Recovery Act funds. States may also opt to expand surveillance through NHSN reporting and create an NHSN State coordinator role to manage day-to-day operations. Furthermore, States may opt to create, and serve as the lead organization of, prevention collaboratives. One of the primary goals of the Recovery Act for HAIs is to strengthen collaboration between State health departments and health care facilities, and ultimately strengthen partnerships with Federal HHS agencies, to ultimately prevent infections and reduce deaths. The 21 States that already use or have agreed to begin using NHSN for surveillance of HAIs are likely to increase in number as these HAI prevention programs are implemented and gain traction among key State leaders and policy makers.

Patient Safety Organizations and the Patient Safety Act. The Patient Safety Act of 2005 named PSOs as the collectors of confidential, voluntarily reported patient safety events. These PSOs are also intended to be patient safety experts for health care providers and were charged with using the data they gather in the development of strategies to improve patient safety. For its part, HHS was directed to develop a list of PSOs and network of patient safety databases to collect the data into a central location. However, PSOs are not required to submit the data they receive to an NPSD. If they do, the data remain nonidentifiable. Creating the list of PSOs and developing and maintaining NPSDs is under the direction of AHRQ. Details of the role of PSOs, as outlined in the Patient Safety Act, are described in the GAO report on the Act (GAO 2010). PSOs are located throughout the United States and can operate nationwide regardless of their home state.

The PSOs must meet certain requirements to gain authorization to collect patient safety data. To begin with, organizations must certify that they have policies and procedures in place to improve patient safety and health care delivery through the collection of patient safety data, analysis of these data, and development of recommendations for best practices. PSOs also must certify that they will maintain confidentiality and security measures. In addition, these organizations must agree to comply with certain criteria: they must maintain qualified medical professionals on staff and hold contracts with health care providers to store and analyze data. These organizations cannot be units of health care insurers and must disclose financial relationships with contract holders.

At the time it submitted the report to Congress (January 2010), GAO found that very few of the PSOs that they randomly interviewed were collecting patient safety data; they concluded that it is still too early in the process to evaluate the effectiveness of PSOs (GAO 2010). As GAO suggests, this may result from the fact that there was no specific deadline for developing these systems. Also, some organizations are waiting for AHRQ to finalize the format for data collection. It is quite possible that facilities are making preparations or are already providing data to the PSOs on certain conditions from the Medicare list of HACs, but we were not able to confirm this finding because of the strict confidentiality protections and the voluntary basis on which these data are reported. It will be important to continue monitoring the implementation of PSOs within the States and to consider the role these organizations play in the voluntary reporting of HAC data.

4.2 Future Considerations

4.2.1 Previously Considered Candidate Hospital-Acquired Conditions to Be Captured in Future Reports

Although for this baseline State tracking report we did not capture what States are doing to track previously considered candidate HACs, we recommend that future report updates add these activities. In response to the large hospital outbreaks of methicillin-resistant *Staphylococcus aureus* throughout the country in recent years, several States are now capturing data on it through their State reporting systems or other means of tracking infection rates on various HAIs. Another candidate HAC that a few States track as part of their medical error and adverse event reporting system is ventilator-associated pneumonia. Beyond these two HACs, we did not find a significant number of States tracking any other previously considered candidate HACs at this time.

4.2.2 The Patient Protection and Affordable Care Act of 2010

Improving the quality and efficiency of health care is one of the provisions of The Patient Protection and Affordable Care Act signed into law in March 2010 by President Obama (U.S. Congress 2010). Title III, Part I, Section 3001 requires that the Secretary of HHS establish a value-based purchasing program in which incentives will be paid to hospitals each fiscal year, beginning in fiscal year 2013, on the basis of established performance standards to be selected by the Secretary. Establishment of the standards will consider practical experience with the measures involved, historical performance standards, improvement rates, and opportunity for continued improvement. Hospitals will receive value-based incentive payments on the basis of their performance regarding at least five conditions or procedures: acute myocardial infarction, heart failure, pneumonia, surgeries, and HAIs. The value-based purchasing incentives will also be based on hospital scores on the Hospital Consumer Assessment of Healthcare Providers and Systems. Distribution of payments will be based on performance, with the highest-performing hospitals receiving the highest value-based incentive payment. Information on a hospital's performance will be publicly available on the Hospital Compare Web site. Efficiency measures will also be added to the value-based purchasing program in fiscal year 2014 or in subsequent years.

The law also provides an annual fiscal year payment adjustment to qualifying hospitals as an incentive for reducing HACs beginning with fiscal year 2015. Inpatient hospitals with high

volumes of HACs will have the amount of payment for discharges reduced to 99% of the amount of payment that would otherwise apply. This reduction will be applied to hospitals that are in the top quartile relative to the national average of HACs during the applicable period as determined by the Secretary of HHS. The Secretary is also required to establish and implement an appropriate risk adjustment methodology.

The law also requires the Secretary to conduct a study of expanding HAC regulations to other facilities under the Medicare program under Title XVIII of the Social Security Act, including rehabilitation hospitals, long-term care hospitals, hospital outpatient departments, skilled nursing facilities, ambulatory surgical centers, and health clinics. The study will include an analysis of the impact of such policy on the quality, safety, and cost of care under the Medicare program. A report to Congress on the results will be submitted no later than January 1, 2012. Although no Federal mandate in the legislation requires reporting of HACs, these provisions of the law heighten the awareness of the need for stronger patient safety protections in health care facilities, and more States may consider legislative acts or regulations that establish mandatory or voluntary reporting systems in response to Federal action.

4.3 Conclusion

In the absence of a nationally based mandated reporting system for medical errors and patient safety events, State-based reporting systems serve a significant role in collecting and reporting data for the Medicare HACs. Twenty-six States and the District of Columbia track at least one HAC through a State reporting system. Another 21 States track at least 1 infection from the Medicare list of HACs through NHSN. These systems appear to have great variability in terms of what events are tracked; what the reporting criteria are; and what other information accompanies the report, such as the requirement for the facility to perform RCAs and CAPs or to report near misses. Despite these inconsistencies across States, there are common traits among State reporting systems. The States use data in similar ways to improve patient safety and employ quality improvement programs within health care facilities. Most of the States also provide public reports; data are provided in aggregate to protect individual facilities from potential litigation or sanctions of medical professionals. Also, only one State with a State reporting system collects the event data on a voluntary basis. All other States with a reporting system have mandates in place to collect the data.

Current Federal initiatives have bolstered HAC reporting activities at the State level, yet there are still overriding concerns surrounding the variability and lack of standardization across State reporting systems. These differences make it unsuitable to identify national incidence and trends for HACs. Reporting formats vary substantially from State to State; underreporting of HAC data makes it problematic to make any significant inferences or to track improvement over time. The passage of health care reform did not mandate or provide national guidelines for reporting systems to collect more standardized information on HACs, but the law does call for stronger patient safety protections in the health care settings. In our estimation, more States may as a result take action to implement reporting systems for patient safety events.

REFERENCES

Agency for Healthcare Research and Quality (AHRQ): Glossary. Retrieved March 22, 2010, from http://www.psnet.ahrq.gov/glossary.aspx.

Government Accountability Office (GAO): Patient Safety Act: HHS is in the process of implementing the act, so its effectiveness cannot yet be evaluated. GAO-10-281. 2010. Available from http://www.gao.gov/new.items/d10281.pdf.

Institute of Medicine (IOM): To Err Is Human: Building a Safer Health Care System. Washington. National Academy Press, 2000.

Institute of Medicine (IOM): Crossing the Quality Chasm: A New Health System for the 21st Century. Washington. National Academy Press, 2001.

Leape, L.L., and Berwick, D.M.: Five years after To Err Is Human: What have we learned? JAMA 293:2384-2390, 2005.

National Academy for State Health Policy (NASHP): Patient Safety Toolbox. 2010. Available from http://www.nashp.org/pst-welcome.

National Quality Forum (NQF): Serious Reportable Events in Healthcare 2006 Update. Washington. National Quality Forum, 2006.

National Quality Forum (NQF): Serious Reportable Events in Healthcare: A Consensus Report. Washington. National Quality Forum, 2002.

Office of Inspector General (OIG): Adverse Events in Hospitals: State Reporting Systems. Washington. U.S. Department of Health and Human Services, 2008.

Office of Public Health and Science: HHS Action Plan to Prevent Healthcare-Associated Infections. 2009. Available from http://www.hhs.gov/ophs/initiatives/hai/infection.html.

Rosenthal, J., and Takach, M.: 2007 Guide to State Adverse Event Reporting Systems. Portland, ME. National Academy for State Health Policy, 2007.

U.S. Congress: P.L. 111-148. Patient Protection and Affordable Care Act. 2010. Available from http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf

APPENDIX A
MEDICARE LIST OF HOSPITAL-ACQUIRED CONDITIONS

The CMS list of HACs is divided into 10 categories. Effective October 1, 2008, CMS no longer pays a higher reimbursement for hospitalizations complicated by these categories of conditions that were not POA.

Hospital-Acquired Condition

1. **Foreign object retained after surgery***
2. **Air embolism***
3. **Blood incompatibility***
4. **Pressure ulcers (stages III and IV)***
5. **Falls***
   - A. Fracture
   - B. Dislocation
   - C. Intracranial injury
   - D. Crushing injury
   - E. Burn
   - F. Electric shock
6. **Manifestations of poor glycemic control***
   - A. Hypoglycemic coma
   - B. Diabetic ketoacidosis
   - C. Nonkeototic hyperosmolar coma
   - D. Secondary diabetes with ketoacidosis
   - E. Secondary diabetes with hyperosmolarity
7. **Catheter-associated urinary tract infection**
8. **Vascular catheter–associated infection**
9. **Deep vein thrombosis/pulmonary embolism associated with**
   - A. Total knee replacement
   - B. Hip replacement
10. **Surgical site infection**
    - A. Mediastinitis after coronary artery bypass graft
    - B. Associated with certain orthopedic procedures involving the
      - a. Spine
      - b. Neck
      - c. Shoulder
      - d. Elbow
    - C. Associated with certain bariatric surgical procedures for obesity
      - a. Laprascopic gastric bypass
      - b. Gastroenterostomy
      - c. Laparoscopic gastric restrictive surgery

*****One of the NQF's 28 SREs in health care.

SOURCE: Fiscal Year 2009 Final Inpatient Prospective Payment System Rule, 73 Fed. Reg. 48434, 48471 (August 19, 2008).

APPENDIX B
NATIONAL QUALITY FORUM LIST OF SERIOUS REPORTABLE EVENTS

Surgical Events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately post-operative death in an ASA Class 1 patient

Product or Device Events

- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient elopement (disappearance)
- Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

Care Management Events

- Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy
- Artificial insemination with the wrong donor sperm or wrong egg

Environmental Events

- Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient of any age
- Sexual assault on a patient within or on the grounds of the healthcare facility
- Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility