GAO

February 2016

PATIENT SAFETY

Hospitals Face Challenges Implementing Evidence-Based Practices

Accessible Version

GAO Highlights

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Why GAO Did This Study

While millions of Americans benefit from the medical care they receive each year, this care also has the potential to harm patients. Medical care can be unsafe when it leads to adverse events, such as infections. Such adverse events occur even though evidence indicates that some could be reduced or eliminated through implementation of evidence-based patient safety practices.

GAO was asked to review information on the implementation of patient safety practices in hospitals. This report describes (1) key factors that affect hospitals' implementation of evidence-based patient safety practices and their reported effects on adverse events; (2) the types of programs health care payers use to promote hospital patient safety and their reported effects on adverse events; and (3) gaps, if any, that experts identify in the available information on patient safety practices. GAO interviewed patient safety experts and officials from six selected hospitals, six selected insurers, and officials from CMS and AHRQ. GAO selected the hospitals based in part on their performance on certain quality measures related to patient safety and selected the insurers because they operated relevant patient safety programs. The information GAO obtained on the hospitals and insurers is not generalizable. GAO also reviewed literature on the field of patient safety research.

In commenting on a draft of this report, HHS generally agreed with GAO's findings. GAO also received technical comments from HHS and incorporated them as appropriate.

View GAO-16-308. For more information, contact Linda Kohn at (202) 512-7114 or kohnl@gao.gov.

What GAO Found

The six selected hospitals in GAO's study identified three key challenges that affected their efforts to implement evidence-based patient safety practices. Patient safety practices, such as using proper antiseptics, can reduce or eliminate adverse events, which GAO defined as events such as infections that harm patients and result from the medical care patients receive rather than patients' underlying diseases or conditions. Officials from selected hospitals identified the following challenges in implementing patient safety practices:

1) *Obtaining data to identify adverse events in their own hospitals.* According to hospital officials, obtaining useful information on adverse events can be challenging because, substantial time and resources are required to gather the necessary data, among other things.

2) *Determining which patient safety practices should be implemented.* Officials noted that they face challenges identifying which evidence-based patient safety practices should be implemented in their own hospitals, such as when only limited evidence exists on which practices are effective. For example, officials from one hospital told GAO that the hospital tried several different practices in an effort to reduce patient falls without knowing which, if any, would prove effective.

3) *Ensuring that staff consistently implement the practices over time.* Officials from the selected hospitals told GAO that the hospitals face challenges ensuring that hospital staff consistently implement the hospitals' patient safety practices; for example, hospitals must constantly monitor results to detect potential implementation problems.

Officials reported taking various actions to address these challenges, and some reported that their actions led to reductions in adverse events. For example, officials at one hospital noted a 40 percent reduction in certain infections over 1 year after they hired a new infection control nurse.

CMS and selected private insurers have pay-for-performance programs that provide financial incentives for hospitals to improve the quality of their care, including reducing adverse events. CMS, the Agency for Healthcare Research and Quality (AHRQ), and some of the private insurers in GAO's study also have nonfinancial programs to help hospitals improve patient safety that provide technical assistance and other support, such as providing data on best practices found in hospitals, access to peer-led training, and other guidance. AHRQ identified a 17 percent reduction in certain adverse events from 2010 through 2014, which likely resulted from multiple factors.

Patient safety experts GAO interviewed and related literature identified gaps where better information could help hospitals, including information on (1) the effects of contextual factors on the implementation of patient safety practices in different hospitals, (2) detail on the experiences of and strategies used by hospitals that have implemented patient safety practices, and (3) improved techniques for measuring the frequency of certain adverse events.

United States Government Accountability Office

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CAUTI	catheter-associated urinary tract infection
CDC	Centers for Disease Control and Prevention
CLABSI	central line-associated bloodstream infection
CMS	Centers for Medicare & Medicaid Services
CUSP	Comprehensive Unit-based Safety Program
EHR	electronic health record
HAC	hospital-acquired condition
HEN	Hospital Engagement Network
HHS	Department of Health and Human Services
HVBP	Hospital Value-based Purchasing Program
NHSN	National Healthcare Safety Network
VTE	venous thromboembolism

February 25, 2016

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

While millions of Americans benefit from the medical care they receive each year, this care also has the potential to harm patients, as the Institute of Medicine highlighted in its seminal report on patient safety in 1999.[1] Medical care can be unsafe when it leads to adverse events, such as infections, that harm patients and result from the medical care patients receive rather than their underlying diseases or conditions.[2]

Such adverse events continue to occur even though evidence indicates that they could be reduced—and some could be completely eliminated—through implementation of evidence-based patient safety practices.[3] For example, the Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) has assessed the strength of available evidence from research and identified several evidence-

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[1]Institute of Medicine, *To Err Is Human: Building a Safer Health System*, (Washington, D.C.: November 1999).

[2]Institute of Medicine, *Patient Safety: Achieving a New Standard for Care*, (Washington, D.C.: 2004). While the term "adverse events" is sometimes used more broadly to include any undesirable events experienced by patients, throughout this report, we use it to refer to events that harm patients and result from medical care. As such, providers can work to prevent them. Other examples of adverse events include pressure ulcers and adverse drug events.

[3]Department of Health and Human Services Office of Inspector General, *Adverse Events in Hospitals: National Incidence among Medicare Beneficiaries,* OEI-06-09-00090, (Washington, D.C.: November 2010) and P. G. Shekelle, et al., *Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices.* Comparative Effectiveness Review No. 211. (Prepared by the Southern California-RAND Evidence-based Practice Center under Contract No. 290-2007-10062-I.) Agency for Healthcare Research and Quality, AHRQ Publication No. 13-E001-EF (Rockville, MD: March 2013), www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html.

based practices that hospitals can implement to reduce adverse events. Additionally, HHS's Centers for Disease Control and Prevention (CDC) has issued detailed guidelines specifying the patient safety practices that have been shown to minimize the risk of different types of preventable infections resulting from the provision of care at hospitals.

However, even when evidence shows which practices can be effective in reducing or eliminating adverse events, hospitals and other providers must choose how to implement these practices to ensure that all clinicians in the facility consistently follow them over time. In addition, effective implementation strategies may vary according to the circumstances faced by different providers. To help address these challenges, some entities that pay for health care, including the Centers for Medicare & Medicaid Services (CMS) and health insurance companies, have programs intended to promote patient safety efforts among hospitals and other health care providers.

You requested that we study the implementation of evidence-based patient safety practices in hospitals. This report addresses three questions:

1. What key factors affect selected hospitals' implementation of evidence-based patient safety practices and what are their reported effects on adverse events, including related costs?

2. What types of programs do payers use to promote hospital patient safety and what are their reported effects on adverse events, including related costs?

3. What gaps, if any, do patient safety researchers and other experts report in the available information related to patient safety practices?

To identify the key factors that affect selected hospitals' implementation of evidence-based patient safety practices and their reported effects on adverse events, including related costs, we interviewed officials responsible for patient safety efforts at six hospitals. We obtained their perspective on how they implemented patient safety practices, the challenges involved, and their approaches for addressing these challenges. We asked officials to describe patient safety practices they implemented at their hospitals, including efforts to address two adverse events that can result from hospital care—central line-associated bloodstream infections (CLABSI), which are bloodstream infections that develop in patients who have a central line, or catheter, inserted into a major blood vessel, and venous thromboembolisms (VTE), which are

blood clots. We chose these conditions because they are targeted by patient safety practices that hospitals are strongly encouraged to adopt, in part because there is strong evidence of the effectiveness of these practices.[4] In addition, we interviewed experts who have published research on patient safety, some of whom noted that CLABSI and VTE have the potential to be completely eliminated in hospitals with effective implementation of patient safety practices. We selected the six hospitals in our review based in part on their performance on measures of CLABSI and VTE rates, as reported by CMS on its Hospital Compare website—where CMS publicly reports individual hospital performance on inpatient quality measures. Specifically, we selected some hospitals that performed better than average on these measures, and some hospitals that performed worse than average. We assessed the reliability of the data CMS reports on these measures by reviewing relevant documentation and interviewing knowledgeable CMS officials, and determined that the data were sufficiently reliable for our purposes. Our selected hospitals also varied in size, from about 190 to over 700 beds, and in location, with one each in California, Indiana, Kentucky, Mississippi, New Jersey, and Texas. When selecting our hospitals, we also considered information obtained from interviews with patient safety researchers; HHS officials; officials from the Joint Commission; officials from organizations focused on patient safety issues, such as the National Patient Safety Foundation; and officials from the American Hospital Association to help identify hospitals that have been more successful in implementing patient safety practices and those that have been less successful. Because these hospitals were not selected as a representative sample, the information obtained from these interviews applies solely to this set of hospitals, and cannot be generalized to other hospitals.

To determine the types of programs that payers are using to promote patient safety and their reported effects on adverse events, including related costs, we interviewed and gathered relevant documents from HHS officials and officials from six private health insurance companies that provide either financial incentives or nonfinancial support to hospitals to promote patient safety practices. We selected these six private health insurance companies because we determined that they operated relevant patient safety programs. While other private insurance companies may also operate similar programs, these six insurance companies were the

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[4]P. G. Shekelle, et al., *Making Health Care Safer II.*

ones that we identified based on information from officials at America's Health Insurance Plans, HHS officials, and review of published research articles. Because these insurance companies were not selected as a representative sample, the information obtained from these interviews applies solely to this set of insurance companies, and cannot be generalized to others. Within HHS, we interviewed CMS and AHRQ officials responsible for agency programs that promote patient safety practices. In our interviews with both HHS officials and officials from the private health insurance companies, we obtained information on how their programs encourage hospitals to implement patient safety practices, how hospitals have responded to these programs, and whether evidence is available on the impact of these programs on adverse events, including related costs. We also asked officials from the six hospitals in our review about their experiences with these programs, when applicable. In addition, we obtained and reviewed other relevant documents, such as published research on the effects of these programs on adverse events, including related costs. When these documents included estimates of the programs' effects, we assessed the reliability of the estimates by reviewing the methodologies used in the studies. As a result, we determined that the estimates included in our report were sufficiently reliable for the purposes of our work.

To determine what gaps, if any, patient safety researchers and other experts report in the available information related to patient safety practices, we reviewed relevant literature and interviewed experts. We focused our literature review on studies that provided a systematic assessment of patient safety research, including both what has been learned and what questions remain largely unanswered. In particular, these studies included systematic reviews of evidence on patient safety practices that AHRQ has sponsored since 2001. To supplement this research literature, we interviewed patient safety experts, whom we identified through their published work and involvement in organizations that focus on patient safety issues. Our analysis was not a comprehensive review of patient safety research, but had a limited focus on hospital implementation of patient safety practices.

We conducted this performance audit from April 2015 through February 2016 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.

Background

HHS, through its various agencies, plays a significant role in providing information to hospitals and other health care providers on evidence-based patient safety practices that can be used to prevent adverse events resulting from medical care. For example, CDC develops and publishes guidelines on recommended evidence-based practices that medical facilities, including hospitals, should follow to avoid adverse events. These guidelines include information on a range of patient safety practices, such as procedures required for effective hand sanitization and the proper techniques for putting on and taking off personal protective equipment, such as gloves and gowns.

Another HHS agency, AHRQ, funds patient safety research, reports on the extent and strength of available evidence supporting a range of patient safety practices and the strategies that hospitals adopt to implement them, and disseminates information and training tools based on this evidence to encourage effective implementation (see Table 1). In 2001, AHRQ published a systematic review of the key evidence supporting patient safety practices that reduce adverse events, and it updated this analysis in 2013.[5] AHRQ's 2013 report included examinations of the frequency and severity of various adverse events, the strength of the evidence on the effectiveness of the patient safety practices that are used to address the adverse events, and issues associated with strategies for implementing those practices. The report also identified 22 patient safety practices that it encouraged hospitals to adopt, 10 of which were strongly encouraged. For example, the report strongly encouraged hospitals to institute policies and procedures to limit the use of urinary catheters and remove them from patients as soon as possible in order to reduce the incidence of catheter-associated urinary tract infections (CAUTI).

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[5]K. G. Shojania, B. W. Duncan, K. M. McDonald, et al., eds. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices.* Evidence Report/Technology Assessment No. 43 (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), Agency for Healthcare Research and Quality, AHRQ Publication No. 01-E058, (Rockville, MD: July 2001) and P. G. Shekelle, et al., *Making Health Care Safer II*.

Table 1: Examples of Patient Safety Practices and Hospital Implementation Strategies

Adverse Event to Be Prevented or Reduced	Examples of Related Patient Safety Practices	Examples of Hospital Implementation Strategies
Central Line-Associated Bloodstream Infection (CLABSI)	Hand hygiene Use of appropriate skin antiseptics Selecting appropriate site for catheter insertion	Checklist for required sterilization procedures Dedicated cart with all appropriate supplies for central line insertion
Venous Thromboembolism (VTE)	Administering preventive anti-clotting medications for higher-risk patients Use of pneumatic compression devices	Automated prescription of anti-clotting medication based on patient risk level as assessed at hospital admission
Catheter-Associated Urinary Tract Infection (CAUTI)	Limiting number of patients receiving urinary catheters Removing catheters as soon as possible	Instituting daily assessment of patient need to retain a catheter Authorizing nurses to remove a catheter without physician approval

Source: GAO analysis of AHRQ information | GAO-16-308

HHS agencies are also responsible for various efforts to measure the quality of care that hospitals provide, including measures of patient safety. For example, CDC administers the National Healthcare Safety Network (NHSN) to track a number of major infections associated with health care, including CLABSI and CAUTI. NHSN provides the reporting infrastructure and standardized definitions that participating hospitals use to collect and report data on the frequency with which these infections occur in their hospitals.

Both CMS and private insurers have initiatives intended to measure and improve the quality of the care provided at hospitals. Many of these initiatives include patient safety measures, such as infections tracked by NHSN, as a subset within the larger group of quality measures they track. CMS collects data on various measures of care quality from hospitals that participate in the Medicare or Medicaid programs. These quality measures are used to indicate the extent to which hospitals are following proper clinical processes, including some processes intended to improve patient safety, and track the outcomes of care experienced by patients, including certain infections and other adverse events. CMS publicly reports information on hospitals' performance on these quality measures, including information from NHSN, on the agency's Hospital Compare website. In some cases, CMS—along with private insurers—uses hospitals' performance on quality measures to adjust the payments made to hospitals for providing care. For example, under its Hospital Value-based Purchasing program (HVBP), CMS increases or decreases its Medicare payments to hospitals based on their performance on certain quality measures, including measures of some adverse events.

Selected Hospitals Took Similar Steps to Address Three Key Challenges and Reported Reductions in Some Adverse Events

Officials from the selected hospitals in our review identified three key challenges in implementing patient safety practices at their hospitals. Hospital officials also reported taking steps to address these challenges, with hospitals reporting that their efforts led to reductions in some adverse events and associated costs.

Selected Hospitals Indicated That Obtaining Useful Data, Choosing Appropriate Safety Practices, and Ensuring Consistency Are Key Challenges to Implementation

Despite differing in characteristics such as size and their performance on CMS quality measures, the six selected hospitals in our study identified the same three key challenges in their efforts to improve patient safety: 1) obtaining data that can be used effectively to identify adverse events, 2) determining which patient safety practices should be implemented at their hospitals, and 3) ensuring that staff consistently implement the practices over time.

Hospitals face challenges obtaining data that can be used effectively to identify adverse events occurring at their hospitals.

Although all six selected hospitals reported making efforts to obtain data on adverse events occurring at their hospitals, such as the rates of infection among their patients, officials reported facing challenges obtaining data the hospitals can use effectively for this purpose.[6] The officials identified two principal reasons for these challenges.

First, most hospital officials indicated that obtaining data on adverse events requires the investment of substantial time and resources in vendors or electronic health record (EHR) systems. Hospital officials from one hospital described having to hire and manage multiple vendors to carry out different data-related tasks. The hospital used one vendor to extract data to meet requirements for reporting to CMS and another vendor to obtain different data for internal purposes, such as monitoring

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[6]The needed data include data on a hospital's performance on various quality measures related to patient safety, including data that can be used to benchmark and compare the hospital with other hospitals.

physician compliance with a new patient safety effort. Officials from another hospital discussed the challenge of obtaining data from different sources to help them identify adverse events. This involved using the hospital's newly implemented EHR system and reconciling that information with data from paper records. Hospital officials also indicated that their EHR systems needed to be updated or that they had to implement a new system to capture data needed to assess patient safety. Some officials mentioned that the data that they were able to obtain from their EHR systems were not always accurate. According to the officials, the hospital had to work with the vendors responsible for the EHR system to determine the cause of the problems and improve the data the system collected.[7]

Second, some hospital officials also emphasized that even when obtained, available data related to patient safety may be too out-of-date to help identify and address recent adverse events at their hospitals. For example, officials from one hospital told us that because the data the hospital collected on adverse events was not timely, the hospital could not use the data to determine whether a new process the hospital had implemented—one to help ensure that certain patients were properly treated with medication to prevent VTE—was successful. As a result, the hospital planned to hire a vendor to more quickly collect and analyze data on adverse events occurring among the hospital's patients. Similarly, some officials noted that although CMS's Hospital Compare website reports on hospital performance on various quality measures, including the rates of certain adverse events, these data are not useful for addressing recent adverse events because they do not reflect current circumstances. According to the Hospital Compare website, the reported performance is based on data for care provided between 10 months and 2 years earlier. An official from one hospital noted that these data can be useful for hospitals to observe their progress over time and to identify long-term trends. However, HHS officials noted that hospitals need to turn

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[7]This challenge is consistent with data reliability concerns related to EHRs that we have previously described. For example, in March 2014, we found that HHS had not fully addressed data reliability issues related to EHRs, such as stakeholders' concerns that quality measure results generated by EHRs were not comparable to results from corresponding quality measures generated by other means, such as when trained professionals manually compile data from patient medical records. See GAO, *Electronic Health Record Programs: Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care*, GAO-14-207 (Washington, D.C.: March 6, 2014).

to other sources to obtain timely information on recent adverse events at their hospitals.

Hospitals face challenges determining which evidence-based patient safety practices they should implement and how best to implement them.

Officials from the selected hospitals told us that after identifying the adverse events occurring at their hospitals, they face challenges identifying which evidence-based patient safety practices the hospital should use to address these events and how best to implement these practices.[8] According to hospital officials, they face these challenges both when limited evidence is available on the effectiveness of the practices and when more extensive evidence is available.

Hospital officials told us that for some adverse events, only limited evidence exists on which safety practices are effective, so hospitals may try to implement different practices without knowing which ones, if any, will work. For example, officials at several hospitals noted difficulties identifying evidence-based practices that can be used to reduce or eliminate patient falls. Officials at one hospital said that they tried several different practices to reduce falls without knowing which would be effective. These practices included giving patients arm bands so staff could identify patients at a high risk of falling, ensuring that bed rails were used consistently, providing bedside toilets, and reducing room clutter. While the hospital officials reported some reductions in falls after these efforts were implemented, the officials were not sure which practices had been the most effective, or what additional practices the hospital could implement to reduce falls even further.

Even when clear evidence-based practices have been identified, these practices typically comprise multiple procedures or behaviors, and so the hospitals we selected often face challenges in choosing from the different options available among the components of these practices. Some hospital officials told us that it can be extremely time-consuming to review the sometimes extensive guidance provided by federal and private sources and then to make an informed choice among the options described.[9] For example, AHRQ and some private organizations have

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[8]Hospitals identify these practices from sources such as CDC. See, for example, http://www.cdc.gov/hicpac/pubs.html. CDC guidance is also communicated to providers through documents produced by professional associations, such as the Association for Professionals in Infection Control and Epidemiology.

[9]Federal resources include CMS's Partnership for Patients while private resources include patient safety guidance documents from the Joint Commission—a health care accreditation organization.

developed "bundles" of evidence-based practices that hospitals can adopt to reduce CLABSIs. These bundles sometimes vary on certain details, such as which type of catheter to use. Hospital officials told us that they often make these choices among accepted evidence-based practice components without knowing what effect these choices may have on their goal of minimizing adverse events. For example, officials at one hospital reported that they used one type of recommended catheter as part of their efforts to prevent CLABSI. The officials later decided to switch to a different type of recommended catheter, and saw a reduction in CLASBI. Similarly, officials at another hospital reported seeing a reduction in CLASBI when the hospital standardized the kind of antimicrobial wash, used to disinfect insertion sites for central lines.

Hospitals face challenges ensuring that hospital staff consistently implement evidence-based practices over time.

Officials from the selected hospitals in our study reported that even after determining which patient safety practices or practice components are most relevant for their hospitals, a key challenge is ensuring that hospital staff consistently implement these practices over time. According to hospital officials, achieving consistent implementation can be challenging because it requires (1) the need to constantly monitor patient outcomes to detect potential problems staff may be having implementing patient safety practices, and (2) the need to convince physicians, in particular, to change their clinical behavior when this behavior is inconsistent with evidence-based patient safety practices.

Officials from all six hospitals reported that one challenge was the need for ongoing monitoring of patient outcomes to detect potential problems staff may be having implementing patient safety practices. Some officials reported initial success in implementing a patient safety practice and reducing adverse events, but also reported that over time these adverse events would become more prevalent due to inconsistent implementation of safety practices. For example, officials from several hospitals noted that for a period of time their hospitals completely eliminated certain adverse events, such as CLABSI and VTE, but then the rates increased. When hospital officials examined the cause of these problems, in many cases they determined that staff were no longer consistently following procedures, such as properly cleaning insertion sites for central lines.

All hospital officials we interviewed also emphasized how challenging it is to convince some staff—in particular, physicians—to change their clinical behavior when such changes are needed to reduce adverse events. According to hospital officials, physicians may be reluctant to adopt a hospital's chosen patient safety practice when those practices differ from those recommended by the physicians' medical specialty organizations.

For example, the organizations may recommend different medications to prevent VTE. Hospital officials also told us that physicians may be reluctant to change their behavior and adopt a hospital's safety practice if physicians have not personally experienced an adverse event with one of their own patients. Hospital officials noted that in general, attending physicians who were not employees of the hospital were more difficult to persuade to change their behavior compared with other physicians.

To Address Implementation Challenges, Hospitals Dedicate Resources and Systematically Involve Staff in Patient Safety Efforts

Officials from all six selected hospitals in our study reported taking steps to address the challenges described above in selecting and implementing patient safety practices. Specifically, hospital officials told us that to overcome these challenges and implement patient safety practices, the hospitals (1) dedicate resources to patient safety efforts, including staff with patient safety expertise, and (2) systematically involve hospital management and staff, including physicians, in patient safety efforts.

Hospital officials told us that dedicating specialized staff with appropriate patient safety expertise helped the hospitals successfully implement patient safety practices. Hospitals reported that these staff, such as infection control specialists, conduct activities such as instructing other staff on patient safety practices, monitoring the implementation of these practices, quickly identifying implementation problems, and taking corrective actions when necessary. While all the hospitals had some staff who perform these functions, some hospitals have more of these staff available. At one hospital, officials told us that these specialists check every central line daily to ensure compliance with evidence-based patient safety practices—checking that insertions are made in the proper locations, checking that insertion sites are properly cleaned, and taking action in response to signs of infection. In addition, hospital officials noted that the specialized staff also help the hospitals identify the most appropriate patient safety practices for their hospitals, determine the most effective implementation strategies, and evaluate these efforts and make adjustments as needed over time.

Another way that hospitals dedicate resources to help implement patient safety practices is by establishing work groups that bring together patient safety specialists and front-line staff to examine specific adverse events or other patient safety problems. For example, one hospital observed an increase in its rates of ventilator-associated pneumonia and assigned a

work group.[10] According to hospital officials, the work group members examined the hospital's adherence to an evidence-based practice for avoiding this type of pneumonia—cleaning ventilator patients' mouths on a daily basis. Specifically, the work group tracked the number of toothbrushes being used for each patient and found that the practice was not being consistently followed. The work group then collaborated with nursing staff to ensure that this practice was performed consistently for each patient. According to officials from some selected hospitals, using work groups is also a way to involve key staff who are not patient safety specialists in decisions about implementing patient safety practices. For example, patient safety specialists and other staff may work together to conduct root cause analyses, which are used to identify and evaluate hospital processes that may have contributed to an adverse event and recommend changes to help prevent future adverse events.

In some cases, hospitals turn to outside partnerships to obtain expertise on patient safety practices. Officials at one hospital noted that they rely on a partnership with a nearby university to help provide needed resources to identify strategies for implementing evidence-based patient safety practices. This partnership engages university staff and students to analyze existing research and identify which strategies work best in different circumstances. The hospital reported that without this partnership it would need to spend a great deal of time reviewing research on which patient safety practices it should implement.

Officials from hospitals that belong to systems of multiple hospitals consistently reported that the systems provide critical resources for the hospitals' patient safety efforts, including access to data on adverse events. For example, the Chief Executive Officer from one hospital—one that consistently reported having no episodes of CLABSI and very low rates of VTE—noted that the larger hospital system provides the hospital with access to an integrated data system with up-to-date data on adverse events, including comparable data from other hospitals in the system that hospital officials use to benchmark their own performance on patient safety. In addition, some hospital officials reported that their hospitals' systems facilitate sharing among hospitals of up-to-date information on effective strategies for improving patient safety. According to hospital

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[10]Ventilator-associated pneumonia is a lung infection that can develop in a person who is on a ventilator, which may occur when germs enter through the ventilator's tube and get into the patient's lungs.

officials, the sharing helps hospitals ensure that their patient safety practices are up to date and identify key challenges hospitals face implementing these practices. In contrast, officials from the hospitals in our study that were not in hospital systems or part of a small system, said it was hard to obtain data on how their patient safety performance compared to other hospitals.

Another way hospitals used resources was for financial incentives though some hospital officials we interviewed noted that hospital staff are generally more motivated by the opportunity to reduce patient harm than by the availability of financial awards. For example, officials at one hospital said that hospitals that improved patient safety could receive funding from their hospital system to support additional patient safety efforts. In addition, officials at some hospitals said that bonuses for executive staff were based in part on meeting goals for reducing adverse events, as well as the hospital's performance on other quality measures. One hospital also provided small bonuses to front line staff for meeting patient safety objectives.

In addition to dedicating resources, officials from the selected hospitals also emphasized the importance of involving management and staff, including physicians, in patient safety efforts. To increase participation of management and staff in patient safety efforts, officials from several hospitals told us that they took certain key actions to promote a hospital-wide "patient safety culture." One action was to increase the prominence of patient safety issues by incorporating patient safety goals into the hospital's overall strategic plan and by reporting on a regular basis to the board of directors information on the hospital's progress in meeting those goals. Some hospital officials indicated that they introduced extensive training for hospital staff on the elements necessary for a strong patient safety culture. These elements include empowering staff at all levels to speak up about potential patient safety concerns, such as observed deviations from established patient safety practices, and setting an expectation that managers and staff respond positively to those concerns. Hospital officials noted that they model and reinforce these expectations on an ongoing basis and also monitor staff engagement on patient safety issues through staff surveys.

Hospital officials described several different strategies for involving physicians in patient safety efforts, which can help to persuade physicians to change their clinical behavior when it is needed to implement evidence-based patient safety practices. Often these strategies involve sharing data with physicians on the effectiveness of the recommended practice.

For example, one hospital implemented a practice to allow only one medication to be used to prevent VTE, and then shared data showing that no VTEs had occurred at the hospital for 3 years under that and another practice. In another example, officials convinced some physicians to implement a set of new practices, while allowing other physicians to continue using their existing practices. Hospital officials then compared data on adverse events among the physicians, which showed that the new practices were safer. According to officials, the evidence was sufficient to convince the remaining physicians to commit to implementing the new practices. Another strategy that hospital officials have adopted is to ask certain physicians to become "champions" for patient safety practices the hospital is implementing. Such physician champions serve as liaisons between hospital managers and other physicians or staff who implement the practices. Hospital officials explained that these champions are key to communicating the importance of changing existing practices when necessary, presenting evidence on the effectiveness of patient safety practices, and responding to concerns.

Hospital officials also told us that they also communicate to staff information on the hospital's performance in meeting its patient safety goals to convey the high priority placed by the hospital on consistently implementing patient safety practices. For example, some hospitals display graphics of relevant adverse events to show specific hospital units' up-to-date performance towards meeting the hospital's patient safety goals. According to officials, displaying these data allow front-line staff in each unit to become more aware of how their own actions help the hospital to meet its patient safety goals. The information also encourages staff to examine if any observed safety problems are caused by inconsistent implementation of patient safety practices, or if other actions might need to be taken. Some hospitals also share data comparing how each hospital unit performs compared to other units of the hospital on measures of patient safety. According to hospital officials, sharing these data helps motivate staff to consistently implement practices over time.

Selected Hospitals Report Reductions in Some Adverse Events

Officials from the selected hospitals reported that effective implementation of evidence-based patient safety practices led to reductions in some adverse events at their hospitals. For example, officials at one hospital noted that after they hired a new infection control nurse, which allowed them to monitor each central line daily, the hospital noticed a 40 percent reduction in CLABSI rates from one year to the next. Officials at another hospital noted that they have not seen a preventable VTE in 3 years since they improved practices for identifying the risk of

VTE among admitted patients, which helps to ensure that patients receive proper preventive treatment based on their assigned risk levels.

The hospital officials we interviewed were less clear on the magnitude of the financial costs associated with achieving these reductions in adverse events. Most officials told us that they did not separately track the costs of implementing patient safety practices because these practices were part of their broader mission to provide high quality care to all of their patients. The officials also indicated that many key staff involved in promoting patient safety did so as part of their overall responsibilities to either administer the hospital's quality improvement program or to serve as front-line clinicians. Some hospitals incorporated their patient safety improvement objectives into even broader efforts to improve hospital effectiveness and efficiency, such as Lean Six Sigma.[11] Such efforts are designed to assist hospitals to become more efficient by redistributing staff and evaluating where processes could become more efficient. At the same time, some officials told us that they believed that any costs associated with implementing related patient safety practices are offset by reducing the number of cases of adverse events such as CLABSI and VTE in their hospitals. Treating such adverse events imposes additional costs on hospitals, for which the hospitals generally do not receive additional payment. For example, one hospital estimated that in a year it had reduced its CLABSI cases from 10 to 6. According to a recent study, treating a patient with CLABSI increases a hospital's costs by about $32,000 per case, so a reduction of 4 cases would result in a savings of about $128,000 for that hospital.[12] However, hospital officials we interviewed generally did not provide specific estimates of the savings associated with their efforts to implement patient safety practices to reduce adverse events.

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[11]Lean Six Sigma is a data-driven approach that attempts to eliminate waste by reducing variation and defects within a process.

[12]V. Stevens, K. Geiger, et al., "Inpatient Costs, Mortality and 30-day Readmission in Patients with Central Line Associated Bloodstream Infections," *Clinical Microbiology and Infection*. vol. 20 (2014).

Payers Offer Financial Incentives but Lack Information on Their Effects, and Some Payers Offer Non-Financial Support That Has Reportedly Helped to Reduce Adverse Events

CMS and the selected private insurers in our study have pay-for-performance programs that provide financial incentives for hospitals based generally on improving the quality of their care, which include measures of adverse events. HHS agencies CMS and AHRQ and some of the selected private insurers also have nonfinancial programs that provide technical assistance and other nonfinancial support to help hospitals improve patient safety.

CMS and Selected Private Payers Offer Financial Incentives Based on Hospitals' Quality Measures, Including Some Measures of Adverse Events, but Lack Information on Effectiveness

CMS and the selected private insurers in our review all have programs that provide financial incentives for hospitals to generally improve measures of the quality of their care, including some specific measures of patient safety, such as measures of adverse events. CMS's HVBP program and its Hospital-Acquired Condition (HAC) Reduction Program—two programs that provide hospitals with financial incentives based on hospitals' performance on various measures of quality—include measures of adverse events. The HVBP program increases or decreases Medicare inpatient payments to approximately 3,000 participating acute care hospitals based on hospitals' performance on a range of quality measures. These quality measures include measures of adverse events, such as rates of CLABSI and rates of CAUTI.[13] In October 2015, we reported that in each of the first 3 years of the HVBP program, most hospitals received a modest payment increase or decrease of less than 0.5 percent of applicable Medicare payments.[14]

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[13]By law, the HVBP program is budget neutral, which means that the total amount of payment increases that it awards to hospitals must equal the total amount of payment reductions applied to other hospitals.

[14]GAO, *Hospital Value-Based Purchasing: Initial Results Show Modest Effects on Medicare Payments and No Apparent Change in Quality-of-Care Trends*, GAO-16-9 (Washington, D.C., October 1, 2015).

CMS's HAC Reduction Program reduces Medicare payments to hospitals with the highest rates of certain adverse events called hospital-acquired conditions, which are medical conditions that patients acquire during hospital stays. These conditions include CLABSI and CAUTI, and the program adds measures each fiscal year to track rates of additional conditions. An August 2015 study of Medicare's pay-for-performance programs found that the HAC Reduction Program reduced Medicare payments by 1 percent for approximately 724 hospitals in fiscal year 2015, resulting in an estimated payment reduction of about $357 million in the first year of the program.[15]

Like CMS, the six private insurers in our study all have pay-for-performance incentive programs that adjust the insurers' payments to hospitals based on the hospitals' performance on a range of quality measures, including measures of some adverse events. In these programs, the formulas used to determine specific payment adjustments—as well as the percentage of payments affected—varies by insurer. Although officials we interviewed from private insurers did not provide information on the amount of the payment adjustments, they estimated that their pay-for-performance programs had the potential to affect between 2 and 7 percent of their payment amounts to a hospital. Officials also reported that for the same insurer these percentages could vary among hospitals, depending on the specific contract between the hospital and insurer.[16]

In some cases, the private incentive programs use the same quality measures and data as CMS, including measures of adverse events. For example, one selected insurer bases its incentive payments on quality measures that CMS publicly reports on its Hospital Compare web site. Officials from this insurer explained that the insurer uses CMS measures and data to reduce the burden on hospitals to report data, given that hospitals already report data on similar sets of quality measures, including measures of adverse events, to multiple organizations. Officials from a second insurer told us that Hospital Compare was a useful tool to

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[15]Charles N. Kahn III, et al., "Assessing Medicare's Hospital Pay-For-Performance Programs And Whether They Are Achieving Their Goals," *Health Affairs*, vol. 34, no. 8 (2015):1281-1288.

[16]In addition to these pay-for-performance programs, insurance company officials noted that their companies do not pay for the costs associated with certain adverse events that are caused by hospital care, such as operating on the wrong limb.

compare hospitals' quality performance because the site offers quality measures, including measures of adverse events, calculated for a large number of patients, whereas the quality data reported for patients insured by a single company can be unreliable due to the relatively small number of patients involved.

In general, neither CMS nor the private insurers in our study have reported data on the extent to which their incentive programs have reduced adverse events or otherwise improved patient safety. As of December 2015, CMS officials indicated that they are in the process of collecting and analyzing data on the effects of the HVBP incentive program, and they expect to report their findings in 2016.[17] However, officials from one of the selected hospitals in our study noted that CMS's HVBP program has had only a modest impact on their general quality improvement efforts—reinforcing existing efforts, instead of spurring new initiatives—which is consistent with information we reported in October 2015.[18] Like CMS, officials from the insurers we interviewed indicated that they have not reported on effects of their financial incentive programs on patient safety; some of the officials told us that they expected the effects to be difficult to measure. Officials from one insurer told us that overall, most adverse events and certain costs of care associated with these events had decreased over the same period of time that the insurer had provided incentives to hospitals to improve quality, but the officials cautioned that it is difficult to determine if these trends are caused by the incentive payments or other factors. Officials from the hospitals in our study did not identify specific impacts that could be attributed to the private insurers' pay-for-performance programs.

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[17]The Patient Protection and Affordable Care Act required that HHS report on the performance of the HVBP program by January 1, 2016. Pub. L. No. 111-148, § 3001(a)(5),124 Stat. 119, 361 (2010).

[18]See GAO-16-9.

HHS and Insurers Provide Technical Assistance and Other Nonfinancial Support to Help Improve Patient Safety and Report That These Efforts Have Reduced Some Adverse Events

In addition to financial incentives, HHS and some of the private insurers in our study have developed programs that provide technical assistance and other nonfinancial support to help hospitals improve patient safety. In general, these programs provide a range of technical assistance and other resources to hospitals, including data on best practices, access to peer-led training, the opportunity to participate in networks or groups of hospitals that collaborate with each other, and other guidance.

For example, CMS's Partnership for Patients was initiated in 2011 as a public-private partnership working to improve patient safety. From December 2011 to December 2014, the program contracted with 26 Hospital Engagement Networks (HENs)—networks of hospitals and organizations at the regional, state, or national levels—to facilitate collaboration among member hospitals to address quality, safety, and affordability issues.[19] According to CMS, the HENs helped identify best practices—including those related to patient safety—and disseminate information on these practices to other hospitals. The HENs also conducted activities such as intensive training programs to help hospitals make patient care safer, implemented systems to track and monitor hospital progress in meeting quality improvement goals, and identified high-performing hospitals and their leaders to coach and share their experiences with other hospitals. According to CMS officials, the agency spent approximately $461 million on the 3-year Partnership for Patients program between 2011 and 2014, and established program goals of reducing certain preventable adverse events—including CLABSI, CAUTI, and VTE—by 40 percent and reducing hospital readmissions by 20 percent.[20] Over 3,700 hospitals participated in the HENs from 2011 to 2014, and according to CMS, these participants accounted for over 70 percent of short-stay, acute care hospitals in the United States.

Another is example is, AHRQ's Comprehensive Unit-based Safety Program (CUSP) which makes information available on strategies that hospitals can implement to prevent certain adverse events, including CLABSI and CAUTI. According to AHRQ officials, CUSP is an organized method for improving patient safety that combines improvement in safety

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[19] According to CMS, the first HEN contracts provided funding from December 2011 to December 2014. In September 2015, CMS awarded contracts to 17 HENs to begin the second major initiative of the program, known as HEN 2.0.

[20] Readmissions refer to when patients return to a hospital within 30 days after being discharged.

culture, teamwork, and communication together with a checklist of proven practices for preventing adverse events. For example, AHRQ has made available on its website a CUSP toolkit that provides hospitals with guidance on strategies for implementing evidence-based patient safety practices. According to AHRQ, the toolkit can be used to address various adverse events, including CLABSI and CAUTI, and includes information on how to encourage shared accountability and teamwork among staff responsible for patient safety, checklists of daily quality goals to help staff manage care, and strategies for improving communication among staff. AHRQ also stated that CUSP efforts include providing technical support to hospitals when they are implementing CUSP strategies, soliciting feedback from participating hospitals, and tracking quality measures among participating hospitals, including measures of adverse events. AHRQ reported about 1,500 hospitals participated in each of the separate CUSP programs to address CAUTI and CLABSI. In addition, AHRQ officials noted that they work with other HHS agencies to incorporate CUSP strategies into other programs, such as Partnership for Patients.

Like CMS and AHRQ, two of the six private insurers in our study also offer nonfinancial support to help hospitals improve care quality, including patient safety. In January 2010, one private insurer in our study, in collaboration with hospital associations and others, established a group of over 180 hospitals to share strategies for implementing evidence-based best practices for improving care quality and patient safety. The areas of focus for this initiative include CLABSI, CAUTI, other infections such as sepsis and ventilator-associated pneumonia, and early elective deliveries.[21] Hospitals involved in this group submit quarterly data to measure their performance in these areas of focus, and the insurer makes these data available to consumers through its web-based provider finder tool. Hospitals in the group deemed successful by the insurer are publicly recognized for their efforts and receive awards. The insurer funded over $6 million for this initiative over the 3 years of this program.

The second insurer includes a provision in its contracts with hospitals encouraging them to collect and share data on the outcomes of their care—including adverse events—as well as information on interventions and other best practices for improving care quality, including patient

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[21]According to CMS, early elective deliveries are associated with increased maternal and neonatal complications for both mothers and newborns, compared to deliveries beyond 39 weeks and deliveries by women who go into labor on their own.

safety. Officials from participating hospitals also have the opportunity to collaborate on the design and implementation of practices intended to improve patient safety.

HHS tracks reductions in adverse events, as well as deaths and costs that are associated with these events. For example, AHRQ identified a 17 percent reduction in certain adverse events from 2010 through 2014, and estimated that this reduction was associated with nearly 87,000 fewer deaths and a savings of approximately $19.8 billion in health care costs.[22] According to AHRQ, the precise causes of the reductions are not fully understood, but the agency notes that they occurred during a period of concerted attention by hospitals to reducing adverse events. Consistent with AHRQ's statement, these reductions are likely the result of multiple factors, rather than being solely the result of any single program. For example, hospital officials we interviewed identified multiple ways in which they were working to improve patient safety, such as tracking patient safety data, employing patient safety specialists, and establishing work groups to examine patient safety issues. According to officials, some but not all of these efforts were influenced by HHS or private insurers' nonfinancial support to hospitals.

HHS and private insurers have also evaluated their programs that provide technical assistance and other nonfinancial support to help hospitals improve patient safety. A preliminary evaluation of the Partnership for Patients program in 2014 found that over the course of the program hospitals reduced deaths and achieved cost savings.[23] According to CMS officials, the agency is working on an updated evaluation of the program. Anecdotally, officials from one hospital in our study that participated in a Partnership for Patients HEN told us that they aligned their hospital's patient safety goals with the goals of their HEN and saw reductions in the adverse events targeted by the HEN each year that the hospital participated. Regarding AHRQ's CUSP program, in 2012, the agency reported reductions in deaths and adverse events among participating

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[22]Agency for Healthcare Research and Quality, *Saving Lives and Saving Money: Hospital-Acquired Conditions Update* (Rockville, MD: December 2015). http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2014.html.

[23]Health Services Advisory Group and Mathematica, *Project Evaluation Activity in Support of Partnership for Patients: Task 2 Evaluation Progress Report* (July 2014).

hospitals that participated in the project on CLABSI.[24] Two of the private insurers in our review also reported that the non-financial support they provided hospitals helped improve quality outcomes, including those related to patient safety. For example, an initiative sponsored by an insurer reported that over three years the participating hospitals had reduced the number of deaths due to sepsis by more than 3,500 and saved an estimated $64 million in hospital costs.[25]

Experts Identified Gaps in Information on Effective Patient Safety Implementation Strategies and Measurement of Adverse Events

Patient safety experts we interviewed and related literature identified three key gaps where better information could help guide hospital officials in their continued efforts to implement patient safety practices. These gaps involve a lack of (1) information about the effect of contextual factors on implementation of patient safety practices, (2) sufficiently detailed information on the experience of hospitals that have previously used specific patient safety implementation strategies, and (3) valid and accurate measurement of how frequently certain adverse events occur.

According to patient safety experts we interviewed and a recent systematic review of existing patient safety research, sponsored by AHRQ, available research—both publicly and privately funded—provides only limited guidance to hospital officials about the contextual factors that can influence which strategies will be the most effective in ensuring consistent implementation of evidence-based patient safety practices in their particular hospitals.[26] Both the experts and the systematic review noted that the effectiveness of a given implementation strategy is often dependent on the specific context or setting in which the strategy is implemented. For example, one strategy that relies on adopting a checklist might prove successful in a hospital that had already developed strong leadership and a high level of team work, whereas adoption of the same checklist might not succeed in another hospital that was less advanced in those areas and therefore less able to ensure that staff consistently follow the checklist.

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[24]Agency for Healthcare Research and Quality, *Eliminating CLABSI, A National Patient Safety Imperative: Final Report* (Rockville, MD: January 2013). http://www.ahrq.gov/professionals/quality-patient-safety/cusp/clabsi-final/index.html.

[25]H. Kun, et al., "Patient Safety First: Phase I Results (2010-2012), Improving Patient Safety and Perinatal Care Across California" National Health Foundation (August 2013).

[26]P. G. Shekelle, et al., *Making Health Care Safer II*.

AHRQ's systematic review highlights the need for more research identifying the organizational characteristics and other factors that make different patient safety implementation strategies more or less effective at particular hospitals. For example, the review identifies a need for more information on how hospitals can minimize adverse events by promoting shared responsibility—and therefore accountability—among the various staff involved in patient care for minimizing adverse events. The review suggests that future reporting of successful patient safety initiatives should include much more detailed descriptions of these key contextual factors to help other hospitals replicate these initiatives.

Regarding the second research gap, experts we interviewed and the related literature pointed out that hospital officials could improve their implementation efforts if they had more detailed information on the experiences of other hospitals that have previously used the same implementation strategies. The experts and literature emphasized that descriptions of the implementation strategies that hospitals have used in the past need to be specified in enough detail so that other hospitals can subsequently determine the extent to which they are following these strategies and implementing each of the specific activities that make up the strategy as it had previously been implemented. In addition, given that specific contextual factors such as leadership and teamwork affect the success of hospitals' efforts to implement evidence-based patient safety practices, AHRQ's systematic review stated that these detailed descriptions of hospitals' implementation strategies need to also include information on the contextual factors that were likely to have influenced their success or failure. In particular, hospitals need a standard way to measure these factors and their impact, so that the information can be communicated to other hospitals seeking to learn from these experiences. Such information could help hospital officials to choose the most appropriate implementation strategies for their hospitals, and help them to monitor the factors that could determine the strategies' effectiveness over time. For example, if there were a standard method for measuring the level of teamwork at hospitals, this information could be used by a hospital to determine whether its current level of teamwork was comparable to the level of teamwork found at hospitals that had successfully implemented a certain patient safety practice. Similarly, for researchers, this more detailed information on the effects of contextual factors would enable them to better understand the circumstances under which different patient safety practices are more or less likely to be effective in reducing adverse events.
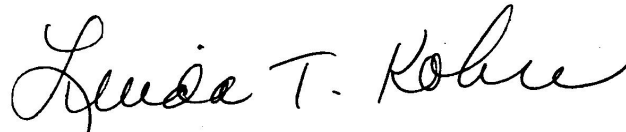
To address the third research gap, the experts we interviewed and related literature call for improved techniques for measuring certain adverse events. The ability to accurately quantify the incidence of adverse events that cause patient harm is critical for hospitals to first identify where they should focus their patient safety efforts and then to monitor the effectiveness of these efforts. However, the experts we interviewed and related literature noted that for many significant types of adverse events, there are no well-defined and broadly accepted measures, which leads to inconsistent assessments of how frequently they occur. For example, there is substantial concern among experts that current measures of the incidence of VTEs only detect a fraction of the VTEs that occur, with significant variation across hospitals. In particular, researchers have found that hospitals that conduct more imaging studies to check for VTEs report higher VTE rates than do hospitals that conduct fewer such studies. This makes comparisons of the reported rates across hospitals less valid. In addition, the relatively low rates reported by hospitals conducting fewer imaging studies provide a potentially misleading signal to officials at those hospitals. Specifically, the low reported rates may lead officials at these hospitals to put less priority on addressing VTEs than they would if they learned that their hospitals' true VTE rates were substantially higher. According to the experts we interviewed and related literature, the development of more definitive measures of adverse events that cause patient harm would provide hospital officials with better information to inform their patient safety efforts. In addition, by demonstrating more clearly the impact of patient safety efforts on reducing patient harm, the improved measures would also help hospital officials win and sustain the support of the front-line clinicians responsible for implementing the patient safety efforts.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for comment. In its comments, HHS generally agreed with our findings. In particular, HHS noted that hospitals face challenges obtaining data to identify adverse events in a timely manner and determining which patient safety practices to implement. HHS also described several initiatives the department has launched to address some of these challenges. For example, the department reported that it plans to test the feasibility of a system that may help provide consistent information on the number of adverse events that occur in individual hospitals, and HHS plans to study whether the system could use data from electronic health records. HHS's comments are reproduced in appendix I. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

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

Linda T. Kohn
Director, Health Care

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

FEB 0 2 2016

Linda Kohn
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Kohn:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"Patient Safety: Hospitals Face Challenges Implementing Evidence-Based Practices"* (GAO-16-308).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

<u>**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)
DRAFT REPORT ENTITLED: PATIENT SAFETY: HOSPITALS FACE CHALLENGES
IMPLEMENTING EVIDENCE-BASED PRACTICES (GAO-16-308)**</u>

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the
Government Accountability Office (GAO) to review and comment on this draft report.

We agree with your note that the conclusions based upon interview of six selected hospitals and
six selected health insurance companies are not necessarily generalizable. However, HHS
recognizes the challenges found by the GAO of: 1) obtaining data to identify adverse events, and
2) determining which patient safety practices should be implemented.

HHS agrees with the importance of contextual factors in implementing patient safety practices as
well as the critical aspects of patient safety culture, teamwork and communications. As such,
HHS has and will continue to develop technical assistance programs that approach the
complexity of change by integrating these key components, in addition to standard tools such as
checklists and protocols. HHS's Comprehensive Unit-based Safety Programs are examples of
successful reductions in adverse events, deaths and costs of care that can result from
implementation of this combined approach. Future programming could include extension of this
approach to other patient safety conditions.

HHS also recognizes challenges hospitals may face in identifying adverse events in a timely
manner and the need for clear definitions of adverse events. HHS has funded development of a
comprehensive patient safety surveillance system, Quality and Safety Review System (QSRS),
that provides a standard set of definitions and specifications for a wide range of adverse events
that occur in the hospital setting based upon HHS's Common Formats for patient safety events.
HHS's Common Formats currently provide standard terms and definitions for reporting patient
safety events, an additional method of measuring adverse events.

As a patient safety surveillance system, QSRS is designed to detect adverse events from a
sample of hospital medical records representing a population of patients and provide reports on
rates of those adverse events for the records reviewed. The scope of QSRS is broad, attempting
to provide information on most all adverse events that occur in hospitals (all-cause harm). For
the most frequently occurring events, QSRS will provide additional detail beyond the fact of
occurrence of the event, e.g., not just fall rates in a specific hospital over a given time period,
but also the percentage of falls that resulted in injury and the percentage of each specific type
of injury.

QSRS will allow collection of comparable performance data over time and across settings using
standard definitions and algorithms to identify events, generate adverse event rates, trend
performance over time, and benchmark performance across institutions. Most importantly, the
standardized definitions and algorithms provide the ability to measure all cause harm, and the
standard specifications ensure that an event identified at one institution (or one department of a
hospital) is the same as one identified elsewhere.

1

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)
DRAFT REPORT ENTITLED: PATIENT SAFETY: HOSPITALS FACE CHALLENGES
IMPLEMENTING EVIDENCE-BASED PRACTICES (GAO-16-308)**

QSRS will enhance and update the Medicare Patient Safety Monitoring system currently
operating at the Centers for Medicare & Medicaid Services (CMS) Central Data Abstraction
Center using medical records currently submitted for quality and audit purposes.

Recognizing hospital's need for their own data to identify adverse events, in 2015 HHS
funded testing of QSRS is a local hospital and health system environment. AHRQ plans to
broaden this testing to refine and improve efficiency for a practical tool. Testing of QSRS in
the hospital and health system setting is providing an opportunity to evaluate the system in
ways not available within the CMS environment. Personnel involved in the care of patients
whose medical records are reviewed will be available to validate results of QSRS review and
suggest changes that would improve the accuracy and efficiency of the system. In addition,
feedback from private sector hospital testing will provide HHS with information on the local
value of the surveillance data and feedback on how this data can be acted on at the hospital
level to prevent the occurrence of adverse events.

HHS also notes the report's mention of hospital challenges with electronic health records and
identifying adverse events. In 2015 HHS funded a feasibility study for automation of QSRS
using data supplied by electronic health records (EHRs). As EHRs evolve, it is anticipated that
QSRS will increasingly be automated to increase the efficiency of identifying adverse events.

The report notes hospital's desire to share up-to-date information on effective
strategies for improving patient safety and for some hospitals' additional need to
obtain data on how their patient safety performance compared to other hospitals.
HHS's Patient Safety Organizations (PSO) are one resource that provides a
mechanism for this type of sharing across hospitals. PSOs can also share patient
safety and quality practice information with other PSOs to further the spread of
learning.

HHS's Hospital Survey on Patient Safety Culture assesses multiple dimensions of teamwork
within and across units as well as openness on communication, especially around adverse events.
Many hospitals using the HHS Hospital Survey on Patient Safety Culture have expressed interest
in comparing their results to other hospitals. In response, HHS has established the Hospital
Survey on Patient Safety Culture Comparative Database. This database is a central repository
for survey data from hospitals that have administered the HHS patient safety culture survey
instrument and allows for comparisons across hospitals on teamwork.

2

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact	Linda T. Kohn, (202) 512-7114 or kohnl@gao.gov
Staff Acknowledgments	In addition to the contact named above, Will Simerl, Assistant Director; George Bogart; Krister Friday; Shirin Hormozi; John Lalomio; and Eric Peterson made key contributions to this report.

Appendix III: Accessible Data

Text of Appendix I:
Comments from the
Department of Health and
Human Services

Page 1	DEPARTMENT OF HEALTH & HUMAN SERVICES
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HOSPITALS FACE CHALLENGES IMPLEMENTING EVIDENCE-BASED PRACTICES (GA0-16-308)

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HHS agrees with the importance of contextual factors in implementing patient safety practices as well as the critical aspects of patient safety culture, teamwork and communications. As such, HHS has and will continue to develop technical assistance programs that approach the complexity of change by integrating these key components, in addition to standard tools such as checklists and protocols. HHS's Comprehensive Unit-based Safety Programs are examples of successful reductions in adverse events, deaths and costs of care that can result from implementation of this combined approach. Future programming could include extension of this approach to other patient safety conditions.

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Page 3

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