



The Challenge of Assessing Patient Safety in America's Hospitals

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Americans expect to receive the highest quality medical care in the world. Over the past few years, the reality of this expectation has been challenged.¹ Highlighting the chasm between the quality of current care and the care that Americans could have, the Institute of Medicine (IOM) issued a call to action to establish a “new health system for the 21st century” that achieves the promise of high quality medical care for Americans. At the forefront of the quality chasm is patient safety.² News coverage of serious medical error events and the 1999 IOM report, *To Err Is Human: Building a Safer Health System*,³ generated enormous public attention around the issue of patient safety within the U.S. health care system. The IOM report estimated that a large number of Americans die each year as a result of preventable medical errors. While the numbers have been disputed,^{4,5,6} there is universal agreement that action is needed to improve health care safety. The IOM report spurred tremendous activity among health care policy makers, professional societies, accreditation organizations, business leaders, and health care providers to implement initiatives to prevent medical errors.

Because the sentinel studies on medical errors were performed in the hospital setting, America’s hospitals are a focal point of many of the initiatives related to patient safety. Groups such as the Agency for Healthcare Research and Quality (AHRQ), the National Forum for Health Care Quality Measurement and Reporting (NQF), and the Leapfrog Group are evaluating and putting forward proposed best practices and potential standards for health care delivery. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Centers for Medicare and Medicaid Services (CMS) and other private and public organizations continue to refine their quality assessment programs. The sheer volume of initiatives and standards in development is tremendous.

At a time when health care costs are escalating, it is important to recognize that the human and capital resource investment necessary to establish or reform systems is very significant. Thus, consideration must be given to the complexity and diversity of U.S. hospitals when establishing standards of care to ensure resources are used wisely to benefit patient safety and quality. Criteria for assessing patient safety would help guide the evaluation of initiatives suggested as potential standards for promoting quality and safety in America's health care system.

The Challenges of Assessing Patient Safety

Reliably and consistently assessing patient safety is important and promotes quality care. But doing so for a diverse set of organizations and communities is extraordinarily

challenging. Hospitals are as diverse as the populations they serve. There are academic hospitals whose primary mission is teaching the health care professionals of tomorrow and performing research to find answers to today's medical problems. There are tertiary care hospitals that provide high-tech, leading edge services for many previously untreatable conditions. There are community-based hospitals that primarily serve the local community's more "typical" inpatient hospital needs (e.g., obstetrics, community-acquired pneumonias). The population served by these hospitals may also differ widely. For example, there are publicly funded hospitals that serve as a safety net for those lacking private medical insurance; hospitals focusing on the elderly or children; rural hospitals that must meet all needs of its population base; and, hospitals specializing in cancer, mental health, or ophthalmology.

Another challenge in initiating programs to improve safety relates to financial resources and manpower shortages. Hospitals differ in their sources of funding and their financial stability. Because resources are limited, hospitals must make wise decisions about how resources are to be allocated. Sometimes it is simply the case that one worthy objective is achieved at the potential expense of another. Careful scrutiny of patient safety initiatives includes balancing the benefits of the initiative against resource allocation. The good news is that there are many low-cost and low-tech changes that hospitals and health care systems can make. When the investment costs are high, however, it is important to ensure that the science behind a proposed change is very strong and that purchasers, policy makers, and other stakeholders understand the resource implications. Although the promise of incentives for hospitals that can successfully implement patient safety programs is certainly an important step toward building better collaboration between the purchasers of health care and America's hospitals, the immediate resources that may be required for some initiatives may be prohibitive for many hospitals, thus precluding the promise of such collaboration. In addition, many areas of the country are facing shortages of physicians, nurses, pharmacists, and other health professionals critical to the operations of a hospital. These shortages create challenges for hospitals seeking to effectively implement significant new initiatives.

Thus, as new patient safety initiatives are proposed and debated they must also be evaluated. Only if such initiatives are feasible, actually undertaken, and in fact work well will they yield optimum care outcomes.

The Need for Criteria for Assessing Patient Safety Initiatives

The purpose of the criteria is to provide an objective means to evaluate proposed quality standards, including the focus of this paper, patient safety standards. Criteria help address the critical questions around assessing the value, efficacy, and appropriateness of proposed standards.

The widespread publicity surrounding patient safety in this era of consumerism and patients' rights results in tremendous political pressure to "do something." The IOM recommended that patient safety be included in performance standards and expectations for health care organizations. The Quality Interagency Coordination Task Force (QuIC) established by the Clinton Administration proposed assuring that all hospitals participating in the Medicare program implement patient safety programs and that private-sector employers and employees incorporate patient safety into purchasing decisions.⁷ In this time of public "report cards" on hospitals and the creation of contractual requirements and incentives for hospital patient safety programs, it is critical that decision makers have the tools to carefully evaluate what is most important and effective for patient safety.

The pressure resulting from public demands for action on patient safety issues may lead to well-intended calls for new initiatives that, while goal-worthy, may also lead to unintended results. Past history demonstrates that public debate that occurs independently of thoughtful analysis of the medical evidence or assessment of the value of an initiative to patient outcomes can lead to well-intentioned health policy programs that result in unintended consequences.⁸ Within the arena of patient safety, a focus on one specific practice as "the solution" to meeting an objective may distract from evaluation of other effective ways to meet the same objective. A shift of hospital resources and systems to fulfill a new standard may be to the detriment of other initiatives that potentially could yield even greater patient safety benefits for a given hospital. For example, in the area of medication safety, a focus on hand-held decision support devices may overshadow a hospital's other identified needs for more effective dispensing or medication administration systems. It is essential that clear and compelling scientific evidence and effectiveness analysis guide proposed change.

When considering effectiveness, it is important to recognize the resource constraints that are a very real concern in health care. Health care costs are the subject of discussions and debate at the highest levels of government, within the health care community, among business leaders, and among consumers. Every stakeholder in the health care system advocates for improved patient safety, but the tough decision for policy makers is to identify those changes that make the best sense given limited resources. Cost-effectiveness studies are used by health care purchasers to evaluate the "at what cost" question. Health care purchasers, for example, often demand the availability of cost-effectiveness studies before establishing policies on coverage for prescription drugs.⁹ Analogous assessments for patient safety practices would help decision makers determine the most reasonable initiatives to achieve shared patient safety objectives.

In a politically and emotionally charged atmosphere, it is important to utilize the principles of policy development during decision-making processes. Proposed initiatives need to reflect scientific evidence and be the result of a consensus process representing relevant constituencies. And while it is important to expect certain baseline standards of

care, it is also important to provide for flexibility: often there are several equally effective ways to meet a standard's safety objective. Our proposed criteria are designed as a tool to assist policy decision makers, health care purchasers, and the public to carefully evaluate proposed new initiatives that may affect the health care of every American.

Definitions

Because hospital standards in essence define public policy regarding how hospitals must operate, we define a **standard as the minimum level of performance that should be expected of any hospital in America**. This definition helps fulfill one of the principles of American public policy and of the IOM's "six aims"—that of equality or equitability. A standard of care cannot vary because of the gender, ethnicity, geographic location, or socioeconomic status of the individuals cared for by a given hospital. For example, to apply a standard to "private" hospitals and exempt "public" hospitals from the same standard implies a different standard of care for Americans based upon ability to pay. Similarly, standards cannot apply to one geographic region and not to others because of the implication that one region should expect a lower standard of care than the other. Standards also must allow a sufficient degree of flexibility to enable hospitals to employ practices that are most likely to be successful in achieving the standards' objectives.

The objectives of a standard should reflect a clinical outcome (e.g., low rate of morbidity or mortality, low rate of adverse drug events, low rate of hospital-acquired infections). **Hospital quality measures can be outcomes based, but at this point in the science, are usually measures of whether a hospital has a structure or process in place** that is associated with desired outcomes. These measures are not necessarily a measure of clinical outcomes. For example, a quality measure may be the percentage of patients who receive a beta-blocker after a heart attack. A high percentage suggests that the processes of care for heart attack patients are appropriate and may correlate with positive outcomes. However, this measure does not directly assess the clinical outcome (i.e., morbidity or mortality after the event).

A practice is a structure or process. An example of a structure is the availability of emergency carts in every nursing unit. An example of a process is the opening and checking of the contents of the emergency cart at the start of every nursing shift. A patient safety practice is a type of process or structure whose application reduces the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures.¹⁰ **A safety practice can be thought of as a specific tactic that can be used to achieve the objective of a patient safety standard.** Practices can be simple or complex. Different practices can lead to the achievement of the same objective of a standard. For example, an infection control standard may be a low rate of catheter-related bloodstream infections. The use of maximum sterile barriers during catheter insertion and

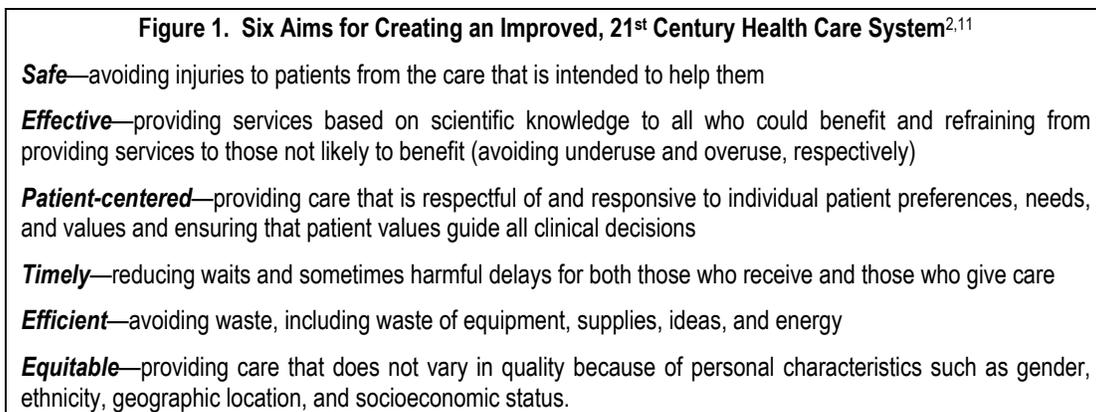
the use of antibiotic-impregnated catheters are both practices that have been shown to reduce catheter-related infections. Thus, either practice (or both in combination) can help an organization achieve this standard.

In this paper, we use the term “patient safety initiative” to refer to quality measures or practices that are being proposed as standards. The universal implementation of a quality measure or safe practice essentially establishes a standard of care. For a quality measure or practice to become a standard, a high degree of evidence must be present to demonstrate that the practice unequivocally stands above all other practices in achieving the objective of a standard. Lacking compelling data that a singular practice is the **only way** to achieve a standard’s quality objective, a practice should not be construed as a standard. In the absence of such data, the standard should allow flexibility in the practices that can be used to achieve the standard.

Criteria

We developed the criteria under the assumption that **for a practice to rise to the level of a standard, it applies to all hospitals**. There are adjunct standards that apply only to specialty care hospitals, such as those for stroke centers or oncology centers. The specialty application of those standards should be clearly stated as such.

Our proposed criteria are consistent with the IOM’s six aims for creating an improved health care system, namely that the system be safe, effective, patient-centered, timely, efficient, and equitable (see Figure 1).



In addition, safety standards (including quality measures or practices proposed for universal or widespread adoption) should meet the following four criteria.

Figure 2. Criteria for Standards

1. **The standard is relevant and appropriate**
 - *Is the standard relevant (meaningful) for all hospitals and the communities that they serve?*
 - *Does achievement of the standard reflect improved quality care?*
2. **The standard was developed using appropriate methodology**
 - *Are the standard and its suggested implementation practice based on accepted evidence?*
 - *Is the standard's suggested implementation practice superior to other implementation practices?*
 - *Were key stakeholders involved in the development of the standard?*
 - *Did the development of the standard incorporate operational feasibility and cost-effectiveness data?*
3. **The standard can be implemented by all hospitals**
 - *Has the standard been implemented and achieved good outcomes across numerous hospitals and hospital types?*
 - *Does the standard allow for appropriate flexibility in achieving the standard's objective?*
4. **The standard promotes continuous quality improvement**
 - *Does the standard assess that outcome objectives are met?*

1. *The standard is relevant and appropriate.*

The safety issue addressed by the standard must be universal, that is, **applicable across hospitals**. Adjunct standards for specialty hospitals must be applicable to all hospitals providing that specialized service. For example, a standard regarding the supervision of medical students that is established for teaching hospitals applies to *all* teaching hospitals in America, but is not applied to non-teaching institutions. Achievement of the standard should **directly reflect improved quality care**. For example, a standard based upon volume, such as the number of surgeries performed, may allow an organization to meet or even exceed the standard, but still have poor clinical outcomes. In this example, the standard's objective is to ensure better outcomes of care. Volume is suggested as a proxy for achieving this objective, but does not really measure the quality of care. Instead, the standard could simply be stated that the hospital demonstrates good outcomes based on the risk-adjusted outcomes of care (e.g., low complication rate from the surgery). The hospital likely will need to implement or maintain multiple good practices to achieve this standard's objective (e.g., practices related to post-operative nursing care, anesthesia care, etc.)

2. *The standard was developed using appropriate methodology.*

The process used to develop standards must be **evidence-based and gain acceptance from all stakeholders**. For standards that involve specific structures or process of care, there must be sufficient evidence that adherence to the standard leads to the desired outcomes and lack of adherence to the standard predictably leads to undesired outcomes. First, the **scientific evidence must demonstrate that the practice is**

effective (i.e., the practice achieves a standard’s desired quality objective). Then, the **scientific evidence must demonstrate that the practice is superior to other practices designed to achieve the standard’s quality objective**. For example, it may be true that the practice of using prophylactic antibiotic X will decrease post-surgical infection rates; however, because the practice of using prophylactic antibiotic Y will also do the same thing, one cannot advocate for antibiotic X as the universal standard for all hospitals. Instead, the standard should define low post-surgical infection rates, which can be achieved by different hospitals using different specific practices (i.e., different, but equally appropriate antibiotic prophylaxis protocols).

A lack of consensus or acceptance from those who are impacted by the standard (e.g., those who must implement the standard, those who must abide by the standard, and those who must fund the initiatives to meet the standard) will result in failure to achieve what often are shared goals. In designing programs for reform, one must take into account the capabilities of those who will implement the program and understand the processes necessary to affect the change. Understanding and predicting how the world will actually behave is essential for policy development. Thus, to minimize unintended consequences of good intentions, all **key stakeholders should be involved with the development** of the standard. In particular, the involvement of individuals familiar with hospital operations is invaluable to help translate research findings into practice. Finally, in an environment of limited resources, one must take a **societal perspective on the costs** of adapting certain safety standards and prioritize accordingly. Thus, standards should be based upon operational feasibility and cost-effectiveness data from pilot studies or demonstration projects.

3. *The standard can be implemented by all hospitals.*

Standards must apply to all hospitals. **Evidence must be assembled to demonstrate that the standard produces the desired outcomes in a variety of hospital settings**. For example, a practice that suggested good outcomes in a teaching hospital and its residents may not yield similar outcomes in a community hospital setting. Thus, the specific practice may be appropriate for teaching hospitals to implement, but a different specific practice may be a more appropriate tactic for non-teaching hospitals to achieve the standard’s objective. To avoid futile implementation efforts, particularly with the most costly initiatives, standards should be based upon not only effectiveness evidence from controlled research settings, but importantly must be pilot tested in **naturalistic settings** so that research outcomes can be replicated with available technologies and resources. For example, standards that specify a particular technology based upon a research study performed with “home grown” computer systems may be difficult to apply to a wider audience that does not have the resources to develop a similar system. Even with the commercialization of similar systems, the commercially-available system should demonstrate performance equivalent to the original research study in a

naturalistic setting. A standard based upon research performed in a setting with Master's-prepared nurses may not be transferable to the majority of hospitals without this level of staff. In addition, and very importantly, given the diversity of hospitals, in the absence of unqualified evidence that one practice is superior to all others, **standards need to incorporate flexibility**, allowing for different practices to achieve the standard.

4. The standard promotes continuous quality improvement.

Application of continuous quality improvement principles should be inherent in the standard. **If a standard is met, the pursuit of performance excellence and outcomes improvement should not cease.** Advocates for patient safety standards should not suggest to providers or consumers that other improvement initiatives are unnecessary simply because a specific standard is met.

With these four criteria, two “filters” are applied to evaluate practices proposed as standards:

- Is the practice feasible to be considered as a standard from an evidence perspective?
- Is the practice feasible *as stated* in a proposed standard for implementation?

A practice may fulfill all the evidence requirements to become a standard (i.e., has greater effectiveness in multiple hospital settings than alternative practices and has demonstrated cost-effectiveness). However, the development team for the patient safety initiative, in converting the practice into a written standard, incorporates tightly prescriptive implementation requirements that make implementation of the initiative, as stated, untenable. In this scenario, the practice appears to be a very good one, but the proposed standard, *as stated*, does not fulfill the criteria to become a standard.

Examples of Application of the Criteria

To illustrate the application of the criteria, we selected examples of practices related to three broad areas of patient safety: medication safety, infection control, and high-risk populations. Within each of these three broad areas, we selected three practices that have been, or have the potential to be, proposed for universal implementation. The practices used for our examples are:

1. Medication safety (objective: reduce adverse drug events)
 - a. Computerized physician order entry (CPOE) linked to clinical decision support systems (CDSS)

- b. Involvement of clinical pharmacists on patient care teams
 - c. Use of unit dose medication distribution systems
2. Infection Control
- a. Use of antibiotic prophylaxis for surgical procedures (objective: reduce surgical infections)
 - b. Use of continuous aspiration of subglottic secretions (objective: reduce hospital-acquired pneumonia in ventilator patients)
 - c. Use of silver alloy urinary catheters (objective: reduce hospital-acquired urinary tract infections)
3. High-risk Populations (objective: reduce morbidity and mortality of high-risk patients)
- a. Use of intensivists to manage intensive care unit (ICU) patients
 - b. Referrals based upon surgical volume for defined surgeries
 - c. Use of prophylaxis interventions for prevention of deep venous thrombosis

For each example practice, we applied the criteria to determine the appropriateness of suggesting the practice as a standard for all hospitals in America.

Methods: Because we evaluated general patient safety practices and not specific standard development initiatives, we can only apply a subset of the criteria. We cannot evaluate the subset of criteria that relates to development aspects that occur when practices are translated into written standards as part of a patient safety initiative. Thus, for our example practices, we apply only the first filter (is the practice feasible to be considered as a standard from an evidence perspective), but not the second filter (is the practice feasible *as stated* in a proposed standard for implementation). Also, for these illustrative examples, we assume that the practices are relevant and appropriate as potential safety standards (Criterion 1) and that the practices will be appropriately incorporated into a continuous quality improvement process (Criterion 4) (i.e., we assume that these two criteria are met). The subset of the criteria that were applied to the example practices is summarized in Figure 3.

Figure 3. Application of Criteria to Illustrative Example Practices

1. The standard is relevant and appropriate	
▪ <i>Is the standard relevant (meaningful) for all hospitals and the communities that they serve?</i>	<i>Assumed met</i>
▪ <i>Does achievement of the standard reflect improved quality care?</i>	<i>Assumed met</i>
2. The standard was developed using appropriate methodology	
▪ <i>Are the standard and its suggested implementation practice based on accepted evidence?</i>	<i>Evaluated</i>
▪ <i>Is the standard's suggested implementation practice superior to other implementation practices?</i>	<i>Evaluated</i>
▪ <i>Were key stakeholders involved in the development of the standard?</i>	<i>Not Evaluated</i>
▪ <i>Did the development of the standard incorporate operational feasibility and cost-effectiveness data?</i>	<i>Evaluated</i>
3. The standard can be implemented by all hospitals	
▪ <i>Has the standard been implemented and achieved good outcomes across numerous hospitals and hospital types?</i>	<i>Evaluated</i>
▪ <i>Does the standard allow for appropriate flexibility in achieving the standard's objective?</i>	<i>Not Evaluated</i>
4. The standard promotes continuous quality improvement	
▪ <i>Does the standard assess that outcome objectives are met?</i>	<i>Assumed met</i>

Our “mini-evaluation” of safety practices for their feasibility to become standards thus consists of the following four key questions:

1. Are the standard and its suggested implementation practice based on accepted evidence? Is there **sufficient evidence for effectiveness** of the practice in achieving the standard’s patient safety objective?
2. Is the standard’s suggested implementation practice superior to other implementation practices? Is there **sufficient evidence for greater effectiveness of the practice than alternatives** in achieving the standard’s patient safety objective?
3. Did the development of the standard incorporate operational feasibility and cost-effectiveness data? Is there a **lack of known implementation issues** (e.g., necessary resources are available and the practice is cost-effective)?
4. Has the standard been implemented and achieved good outcomes across numerous hospitals and hospital types? Is there **evidence of successful transfer to non-research settings** (i.e., good outcomes in non-controlled settings)?

The results of this mini-evaluation will answer the question, “is the practice feasible to be considered as a standard from an evidence perspective?” Figure 4 lists some of the results that may occur with the application of this subset of the criteria.

Figure 4. Potential Results from Application of Criteria Subset

	Sufficient Evidence for Effectiveness?	Sufficient Evidence for Greater Effectiveness over Alternatives?	Lack Barriers to Implementation?	Evidence of Successful Transfer to Non-Research Setting?
Practice is feasible to become a standard	+	+	+	+
Practice appears feasible as a standard, but should be pilot tested	+	+	+	-
Practice could be a standard, but implementation issues need resolution	+	+	-	-
Practice is feasible to become a standard, but new considerations preclude new implementation (e.g., technology is no longer available)	+	+		+
Practice is promising, but there is insufficient evidence to make it a standard (i.e., it is one of many practices that could be used)	+	-	-	-
	+	-	+	+
	+	-	-	+

To answer these four questions for our illustrative examples, we used an extensive evidence-based review of safety practices performed by the UCSF-Stanford Evidence-based Practice Center (EPC) as commissioned by the Agency for Healthcare Research and Quality (AHRQ).¹⁰ The UCSF-Stanford EPC reviewed the literature for 97 safe practices. They assessed not only whether evidence exists, but also the strength of the evidence. In some instances, there may be evidence that a practice is effective, but there are very few studies. In other instances, there may be many studies that a practice is effective, but the studies are poorly designed. The UCSF-Stanford EPC researchers then rated the strength of the evidence regarding a practice’s impact and effectiveness and identified cost and implementation issues. In “real life,” an assessment of the scientific evidence used by the standard’s development team will need to be performed when evaluating a proposed standard.

Results. Figure 5 summarizes the results of our application of the subset of the criteria to the nine illustrative example practices. The appendix to this report contains the basis for our assessments.

Figure 5. Examples of Applying the Criteria

	Sufficient Evidence for Effectiveness?	Sufficient Evidence for Greater Effectiveness over Alternatives?	Lack of Barriers to Implementation?	Evidence of Successful Transfer to Non-Research Setting?
Medication Safety				
CPOE with CDSS	+	-	-	-
Clinical Pharmacists on Patient Care Teams	+	-	-	+
Unit Dose Medication Distribution Systems	+	-	+	+
Infection Control				
Antibiotic Surgical Prophylaxis	+	+	+	+
Continuous Aspiration of Subglottic Secretions	+	-	-	-
Use of Silver Alloy Urinary Catheters	+	-	+	-
High Risk Population				
Use of Intensivists to Manage ICU Patients	+	+	-	-
Referral Based Upon Surgical Volume*	+	-	+	-
Use of DVT Prophylaxis	+	+	+	+

*Defined surgical procedures only

Among our illustrative example practices, two of the practices (use of antibiotic surgical prophylaxis and use of deep venous thrombosis prophylaxis) are feasible to consider for standards. One practice (the use of intensivists) has strong evidence supporting its use, but currently faces significant implementation issues that cannot be addressed within the hospital system. The remaining practices are good practices with evidence to support their effectiveness, but insufficient evidence to support their elevation to a standard. Each good practice is just one of many practices that can be used by a hospital to achieve patient safety standards. For example, in the broad category of medication safety, CPOE or clinical pharmacists as part of the patient care team should not specifically be advocated as *the* standard of care, but rather should be considered as good practices that could be implemented by a hospital to achieve the safety objectives of medication use standards. In “real life,” the remaining aspects of proposed standards for these practices would need to be evaluated.

Conclusions

There are many good practices with evidence to support their use to help a hospital achieve patient safety standards' objectives. Not all practices, however, are feasible to elevate as standards. Most practices represent one alternative to achieving a standard because there is insufficient evidence that these practices have greater effectiveness than other practices or there is insufficient evidence that the practice will be effective in different settings. For some practices, there are implementation barriers that cannot be addressed by the hospital system (e.g., shortages of trained personnel). In instances where a practice does not fulfill all the criteria, there should be flexibility within the relevant patient safety standard to allow the selection of the specific practice that has the greatest probability for successful implementation by a hospital.

Americans spend more on health care than any other country, and thus, should be able to demonstrate to the world the health care value of those expenditures. Quality standards are an essential part of the U.S. health care system. Hospital standards establish the level of care that all Americans should expect to receive, regardless of where they go to receive their care.

In establishing standards, developers must recognize the power of standards. Standards are health care policies that can affect the lives of every American. This power is not to be taken lightly. In order to ensure that standards are enduring and fair, and not "just the latest fad," standards must be data based, achievable, cost-effective, and reflect the views of all constituencies. There are many important health care practices that lead to good outcomes. Given the diversity of American hospitals, flexibility is critical to allow hospitals to select practices that will allow them to achieve the objectives of patient safety standards. In some cases, these practices will become standards for which hospitals and providers should be held accountable. Careful selection of those improvement efforts that should become standards is important and requires careful analysis and a collaborative effort among key constituencies. The criteria should help aid policy makers, providers and others who are faced with a myriad of voices advocating specific health care practices and structures.

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