Toward a Safer Health Care System
The Critical Need to Improve Measurement

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It has been more than 15 years since To Err Is Human, the landmark report by the Institute of Medicine (IOM), revealed the substantial morbidity and mortality related to medical errors in the United States. Two recent developments have refocused policy makers on getting patient safety right. The first are data suggesting that deaths associated with medical errors may exceed 400 000 annually, although this number is controversial, with questions about the degree to which medical errors truly caused each of these deaths and how many deaths were attributable to a medical error when death was inevitable. Regardless, medical error is likely a major cause of death and disability in the United States. The second is the Affordable Care Act, which has, through programs like Value-Based Purchasing and Hospital-Acquired Conditions penalties, made patient safety a financial priority for hospitals. While greater focus on safety is a welcome development, there is little reason to believe that added attention alone will lead to safer care. Why? Because the health care industry lacks valid patient safety measures, which are fundamental to improvement. Without these measures, the key ingredient in these efforts is missing: systematic, real-time data on adverse events with timely feedback to clinicians and health care organizations. Without effective measurement and reporting, progress in patient safety will be arduous and slow.

Whether meaningful progress has occurred within patient safety is controversial. The Obama Administration’s internal evaluations suggest modest improvement on a subset of patient safety measures. Despite some questions about these findings, mostly due to a lack of a valid approach to measurement and evaluation, there is no disagreement that policy makers should do more to improve safety measurement.

Journalists and private companies are now beginning to fill the void in measurement left by policy makers. For example, ProPublica, a nonprofit investigative journalism outlet, provoked intense debate with its profile of 17,000 surgeons, using certain readmissions as a surrogate for complications. This follows many federal government efforts to measure safety with a similar approach: using billing data and counting the number of adverse events coded. Identifying complications through billing data can be problematic because hospitals that are diligent about identifying and documenting adverse events may be more likely to be labeled as unsafe, a form of “surveillance bias.” The best organizations may then be labeled as the worst and consequently may receive the largest penalties under pay-for-performance schemes. In the most expensive health care system in the world, the choice should not be between using flawed approaches that penalize the best physicians and hospitals or not measuring adverse events at all.

Federal policy makers, especially the Centers for Medicare & Medicaid Services (CMS), could take 3 steps for meaningful progress. First, CMS needs to eliminate unnecessary, unreliable metrics from government programs and oversee the development of a standardized set of validated metrics. For example, the Patient Safety Indicator (PSI) 90 is a conglomeration of various adverse events of varying importance that rely on administrative data. Administrative data have low validity compared with clinical data (B. D. Winters, MD, PhD, et al, unpublished data, 2015) and are marked by long delays in reaching clinicians, which hampers their usefulness. Instead of focusing on PSIs, CMS instead should focus on the most common and clinically meaningful causes of harm and should use clinical data, not billing data, and monitor and report the validity of the measures. Such an approach will enable hospitals to focus on improving patient safety rather than changing coding, as the current programs have encouraged.

What specific events should CMS focus on? Epidemiologic studies of adverse events find that the most common causes of iatrogenic harm to hospitalized patients are adverse drug events, nosocomial infections, venous thromboemboli, decubitus ulcers, falls, and surgical complications. A recent IOM report also highlights the importance and the burden of diagnostic errors. However, the current national patient safety strategy uses a validated, clinically based approach to measuring only 1 of these, nosocomial infections. The Centers for Disease Control and Prevention (CDC) and its National Healthcare Safety Network have a very good track record of working effectively with professional societies and hospitals on a subset of these infections to develop valid and reliable measures. The CDC’s work has made substantial gains in making hospital care safer, particularly with regard to central line–associated bloodstream infections and surgical site infections. The CMS should work with the CDC to expand this proven model to other types of patient harm.

How might the CDC expand its efforts on patient safety measurement? The CDC could harness clinical data from electronic health records to develop algorithms for detecting the other leading causes of preventable harm, including adverse drug events, venous thromboemboli, and others (Table). With modest effort, this may be achievable. Even in the 1990s, before the development of sophisticated health information technology systems, this approach was shown to be nearly as sensitive—while far less resource intensive—as manual chart reviews at detecting adverse drug events, such as
agency to play such a role in health care, but it must be efficient, standards, performance is audited and transparently reported, and as the Federal Accounting Standards Advisory Board does for most US hospitals now have electronic health records, there are sensational advances in computing in the past 2 decades and that allergic reactions or nephrotoxicity due to medications. Given the sensational advances in computing in the past 2 decades and that most US hospitals now have electronic health records, there are sufficient data that could be exploited to detect a wide variety of adverse events. With the CDC’s expertise in engaging professional societies, measurement experts, and consumers, these types of measures can be pilot tested and improved over time.

Second, CMS should task an agency with defining standards of what makes good measures and setting accuracy requirements before implementing measures in pay-for-performance and public reporting. Such an agency would serve a similar role for health care as the Federal Accounting Standards Advisory Board does for financial reporting. Under this system, professionals set accounting standards, performance is audited and transparently reported, and journalists report on validated measures, working from a common source of standards. The National Quality Forum is the natural agency to play such a role in health care, but it must be efficient, narrowly focused on high-value metrics, and technically sound. Whatever agency plays this role, it will foster a system in which different payers, clinicians, health care organizations, and even patient groups can reasonably disagree about which measures are most important. But they all should have a common set of sound metrics.

Third, Congress needs to find funding for systems engineering research. There are competing funding priorities, but the payoff for the health care system, including the federal budget, of these investments can be substantial. For instance, the checklist intervention that substantially reduced central line infections was initially supported by a $500 000 grant from the Agency for Healthcare Research and Quality. Complications are expensive, and reducing their frequency can provide significant savings to payers. Reducing complications such as central line infections not only likely saved thousands of lives but also billions of dollars, much of it to the Medicare program. Improving safety depends on having good systems in place rather than on the efforts of individual clinicians. As such, the government—the largest payer in health care—needs to fund practically applicable studies on systems engineering to promote efficient, safe health care.

Despite thousands of deaths each year related to unsafe care, policy actions have not matched the scale of the problem. However, tools are now available to make meaningful progress in safety, starting with systematic collection and dissemination of high-quality, clinically based data. The marketplace is not standing still; organizations that promote public reporting are using available data to make pronouncements about which clinicians and hospitals are safe and unsafe. Some efforts will be better than others, but none of them will be as good as they could be because the metrics they use are only as good as the data going into them. Without standards of accuracy or timeliness, some rating programs will label some of the best clinicians and hospitals as unsafe and some of the neglectful ones as safe, which has the potential to do more harm than good. Better data, valid metrics, and greater transparency represent the best formula for making the United States a world leader in patient safety.

### Table. Common Causes of Hospital Adverse Events and Potential Measures and Data Sources

<table>
<thead>
<tr>
<th>Events</th>
<th>Potential Measures</th>
<th>Data Sources From Electronic Health Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse drug events</td>
<td>Allergic reactions, elevated blood creatinine following nephrotoxic prescription, prescription of antidotes (eg, naloxone)</td>
<td>Order entry, laboratory results, clinical notes for confirmation</td>
</tr>
<tr>
<td>Deep vein thrombosis (DVT)</td>
<td>Rate of postoperative DVT, rate of pulmonary embolism, laboratory abnormalities (eg, elevated D-dimer)</td>
<td>Radiology reports, laboratory results, clinical notes for confirmation</td>
</tr>
<tr>
<td>Falls</td>
<td>Rate of falls among older patients</td>
<td>Nursing notes, clinical notes, radiology reports</td>
</tr>
<tr>
<td>Decubitus ulcers</td>
<td>Rate of decubitus ulcers</td>
<td>Nursing notes, physician notes, nurse-completed single-question ulcer assessment</td>
</tr>
<tr>
<td>Nosocomial pneumonia</td>
<td>Rate of nosocomial pneumonia</td>
<td>Nursing notes, laboratory results, radiology reports</td>
</tr>
<tr>
<td>Diagnostic errors</td>
<td>Rate of missed diagnosis of acute myocardial infarction</td>
<td>Clinical notes, electrocardiogram, laboratory results</td>
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</tbody>
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**ARTICLE INFORMATION**

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**REFERENCES**