newed sense of collegiality, and return to the type of medicine that patients and families want. For patients, coordinated care means more "quality time" with their physician and care team (a patient's advocate in an increasingly complex medical system) and more collaboration in leading a healthy life. And for Medicare, coordinated care represents the most promising path toward financial sustainability and away from alternatives that shift costs onto patients, providers, and private purchasers.

We believe that today's ACO rule is the next step in our shared commitment to a better, more lasting health care system. We look forward to being a trusted partner in our nation's journey toward patient-centered, coordinated care.

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Getting Moving on Patient Safety — Harnessing Electronic Data for Safer Care

Ashish K. Jha, M.D., M.P.H., and David C. Classen, M.D.

More than a decade ago, the Institute of Medicine released its famous report *To Err Is Human*, which set an ambitious agenda for the United States to reduce the number of Americans who were hurt or killed by medical errors and adverse events. In response, a series of new initiatives was launched, including the funding of new research on ways of making care safer and encouragement of programs shielding health care providers from liability if they reported adverse events. Federal agencies set up patient-safety organizations and established ambitious patient-safety goals; accrediting organizations set aggressive patient-safety standards; and providers hired patient-safety officers and implemented numerous patient-safety initiatives.

So what are the fruits of these efforts? Recently, we have received some deeply disappointing news: three studies have called into question whether we've made any progress at all. Landrigan et al. found that rates of injury due to medical error had remained essentially unchanged between 2000 and 2008 at 10 North Carolina hospitals.[1] A report from the Inspector General of the Department of Health and Human Services (DHHS) revealed that Medicare patients experienced substantial harm in U.S. hospitals as recently as 2008.[2] Finally, Classen and colleagues found that almost one in three patients are harmed during their hospital stay and that traditional approaches to measuring adverse events, whether using voluntary reporting or patient-safety indicators, substantially underestimate the events' frequency.[3] If the United States has made progress in patient safety, it has been inadequate.

The primary reason for insufficient progress is the lack of a robust measurement program: there are still no nationally agreed-on methods for systematically identifying, tracking, and reporting adverse events. Here, the patient-safety movement can learn from the quality-improvement efforts that predate it. In the 1990s, emerging evidence suggested that providers were inconsistent in their adherence to evidence-based treatments such as the use of aspirin for patients with acute myocardial infarction. Efforts by the Joint Commission for the Accreditation of Healthcare Organizations to systematically measure performance and give feedback to hospitals, coupled with subsequent efforts to publicly report performance on these measures, led to dramatic improvements in compliance.[4] In the few areas of patient safety that have seen demonstrable improvement (e.g., catheter-related bloodstream infections), the changes are due, at least in part, to robust measurement programs, such as those run by the Centers for Disease Control and Prevention. In other areas, inadequate measures have hindered progress, and patients continue to suffer from the consequences of unsafe care.

Although there is a shortage of good patient-safety metrics, poor-quality measures are plentiful. The best known among these are patient-safety indicators, which use billing data to identify potential complications during a hos-

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pitalization. They generally have poor sensitivity and specificity, and their utility varies with hospitals' billing practices.[3] And because data on them are collected in a post hoc fashion, they fail to engage clinicians at the time of care delivery — and data are generally unavailable to providers for review until years after the care is delivered. In an attempt to make patient-safety measures more visible, the Centers for Medicare and Medicaid Services (CMS) now makes hospital performance data on certain patient-safety indicators publicly available.[5] However, these inadequate measures of safety, even if delivered to hospitals more quickly, are unlikely to engage front-line clinicians in activities that will make care safer.

Another approach to safety measurement has been the use of voluntary (or occasionally, mandatory) reporting of adverse events. These efforts sporadically yield important insights — but generally have very low sensitivity (most adverse events are never reported), which makes it difficult for provider organizations to know whether they're making progress. Finally, some have used the "trigger tools" method, which, though not extensively validated, appears to be sensitive in detecting adverse events.[3] However, this approach, used primarily in research, is resource-intensive to implement and has gained little traction among providers as an ongoing approach to monitoring safety.

Despite these challenges, we currently have an opportunity to turn the tide. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 provides, through CMS, financial incentives for physicians and hospitals to become "meaningful users" of electronic health records (EHRs). EHRs can systematically measure patient safety, turning a laborious, manually intensive, and expensive process of sifting through medical records to identify adverse events into an automated one that is efficient, consistent, and affordable. Although the technology is already available, most EHRs today are not built with this capability in mind — and it won't be easy (or cheap) to retrofit EHR systems later. Without an explicit commitment on the part of EHR vendors to build systems that can systematically track adverse events, most EHRs will fail to do it adequately, if at all. However, the federal government, which creates the meaningful use criteria, could include the ability to effectively measure and report adverse event rates as a "core" requirement of meaningful use. By staking out this ground, CMS can signal to vendors the importance of including such a capability in every EHR sold in the United States. If CMS chooses to use EHR-derived safety measures for public reporting or pay for performance, these metrics will need further validation, a lengthy process, but the agency can expedite the activities needed to ensure that we have validated measures quickly. Even without these additional validation efforts, simply providing better-quality EHR-derived safety data to physicians and hospitals can have a profound effect on patient-safety activities throughout the country.

We recognize that EHR vendors face competing demands, and many advocacy groups are clamoring to have particular functions included in meaningful use. But the $30 billion in taxpayer subsidies for EHR adoption was sold to the U.S. public principally as a way of making health care safer. The current EHR systems, if implemented well, may have a modest effect on safety. Requiring the presence and use of a safety-measurement module for identifying and tracking adverse events would provide a critical signal to providers that monitoring adverse events is essential. Such systems would provide information to hospitals on their performance relative to their peers and their progress toward the goal of causing no harm. Most important, it would allow them to track the effects of their interventions and determine which efforts worked and which ones didn't. Data from such EHR surveillance systems could have patient identifiers removed and be pooled across many sites, which would increase the depth and breadth of the possible analyses and lead to new insight into delivering safer care.

The U.S. health care system is at a crossroads when it comes to ensuring patient safety and earning the trust of the public. Our inadequate progress since *To Err Is Human* is disheartening, but we have an opportunity to right the ship. By making systematic measurement of adverse events a requisite function of the EHRs that are eligible for financial incentives, the federal government can change the way safety is measured and improved throughout the health care system. Without these data, we are likely to repeat our recent experience: good intentions, a lot of effort, and little demonstrable benefit. According to IOM estimates, as many as a million Americans may have died owing to adverse events in U.S. hospitals

over the past decade. We must do better over the next decade. EHRs can improve the safety and culture of U.S. health care, but only if the federal government, as the nation's largest health care payer, demonstrates that it is serious about improving patient safety.

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Evidence-Based Medicine in the EMR Era

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Many physicians take great pride in the practice of evidence-based medicine. Modern medical education emphasizes the value of the randomized, controlled trial, and we learn early on not to rely on anecdotal evidence. But the application of such superior evidence, however admirable the ambition, can be constrained by trials' strict inclusion and exclusion criteria — or the complete absence of a relevant trial. For those of us practicing pediatric medicine, this reality is all too familiar. In such situations, we are used to relying on evidence at Levels III through V — expert opinion — or resorting to anecdotal evidence. What should we do, though, when there aren't even meager data available and we don't have a single anecdote on which to draw?

We recently found ourselves in such a situation as we admitted to our service a 13-year-old girl with systemic lupus erythematosus (SLE). Our patient's presentation was complicated by nephrotic-range proteinuria, antiphospholipid antibodies, and pancreatitis. Although anticoagulation is not standard practice for children with SLE even when they're critically ill, these additional factors put our patient at potential risk for thrombosis, and we considered anticoagulation. However, we were unable to find studies pertaining to anticoagulation in our patient's situation and were therefore reluctant to pursue that course, given the risk of bleeding. A survey of our pediatric rheumatology colleagues — a review of our collective Level V evidence, so to speak — was equally fruitless and failed to produce a consensus.

Without clear evidence to guide us and needing to make a decision swiftly, we turned to a new approach, using the data captured in our institution's electronic medical record (EMR) and an innovative research data warehouse. The platform, called the Stanford Translational Research Integrated Database Environment (STRIDE), acquires and stores all patient data contained in the EMR at our hospital and provides immediate advanced text searching capability.[1] Through STRIDE, we could rapidly review data on an SLE cohort that included pediatric patients with SLE cared for by clinicians in our division between October 2004 and July 2009. This "electronic cohort" was originally created for use in studying complications associated with pediatric SLE and exists under a protocol approved by our institutional review board.

Of the 98 patients in our pediatric lupus cohort, 10 patients developed thrombosis, documented in the EMR, while they were acutely ill. The prevalence was higher among patients who had persistent nephrotic-range proteinuria and pancreatitis (see table). As compared with our patients with lupus who did not have these risk factors, the risk of thrombosis was 14.7 (95% confidence interval [CI], 3.3 to 96) among patients with persistent nephrosis and 11.8 (95% CI, 3.8 to 27) among those with pancreatitis. This automated cohort review was conducted in less than 4 hours by a single clinician. On the basis of this real-time, informatics-