

# Measuring Preventable Harm

## Helping Science Keep Pace With Policy

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**F**OUR YEARS AFTER SORREL KING'S DAUGHTER, JOSIE, DIED from preventable medical errors in 2001,<sup>1</sup> King asked us if her daughter would be less likely to die today. We answered by describing the myriad safety programs in hospitals. She abruptly cut us off. King was not interested in what we were doing. She wanted evidence that Josie and other patients were less likely to be harmed by medical care today, but we could not give her this evidence.

A decade after the *To Err Is Human* report,<sup>2</sup> the global health care community still struggles to state definitively whether patients are safer. Despite rhetoric and work to improve safety, sufficient effort to rigorously evaluate patients has not happened.<sup>3,4</sup> The general public, US Congress, and health care payers demand public accountability and safer outcomes.<sup>5</sup>

Given the desire to measure safety outcomes, why has it been so challenging? The main barrier has been poor investment in the basic science of patient safety. Basic science would allow better understanding of the causes of harm, help in designing and pilot testing interventions to reduce harm, and then robustly evaluate the effects of harm. Great feats such as the sequencing of the human genome and the observation of the blood flow and cell function in the brain have been accomplished. Surely measures of patient safety can be developed.

Most investment and interest in patient safety has been reactive and politically motivated to address egregious, although relatively rare, examples of preventable harm, such as operating on the wrong body part. Other types of preventable harm are more common yet more nuanced. Yet, a dollar is spent on basic and clinical research for every penny spent to ensure patient safety.<sup>6,7</sup>

Without a strong science base, valid and transparent measurement, leadership and accountability, and tenacious political visibility, well-intentioned health systems will continue their struggle to improve patient safety. Most expenditure for patient safety will be neither effective nor efficient. Central to making progress is the ability to distinguish preventable harm from inevitable harm. In this Commentary, we review strategies to make this distinc-

tion, discuss several risks with alternative approaches, and offer suggestions for progress in answering—are patients safer?

### Preventable vs Inevitable Harm

To advance the science of measuring safety outcomes, separating preventable from inevitable harm must be accomplished. In aviation, all fatal crashes are deemed preventable. The implicit idea of preventable harm is that an error occurred that caused harm and if the error were prevented, no harm would have occurred. Health care differs substantially from aviation; despite receiving the best-known medical therapies, some patients will inevitably die or sustain complications. Moreover, what is preventable will change over time. With ever-advancing scientific knowledge and often expensive technologies, what was once inevitable may soon be preventable.

Valid measures of preventable harm require clear definitions of the event (numerator) and those at risk for the event (denominator), and a standardized surveillance system to identify both indicators.<sup>3</sup> If the harm (eg, mortality from acute myocardial infarction or pneumonia) is only partially preventable (as most are), methods to dissect inevitable from preventable harm will be needed.<sup>8,9</sup>

Clinicians have labeled virtually all harm as inevitable for decades. They did so partly because false-positive events (truly inevitable cases labeled as preventable) did not help them learn and improve care. Clinicians often learned alone or with other physicians. They focused more on individual skills rather than on systems or team skills. Such an approach is efficient for physicians; it is very specific (truly inevitable cases labeled as inevitable) but not very sensitive (truly preventable cases labeled as preventable). Although this approach misses many patients who experience preventable harm, those who are identified do provide information. Recent efforts by payers, such as the Centers for Medicare & Medicaid Services (CMS), have gone to the other extreme by labeling all harm as preventable. Ex-

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amples of these efforts include measures of overall hospital mortality,<sup>10,11</sup> global trigger tools,<sup>12</sup> and most of the complications identified by CMS, such as decubitus ulcers.<sup>5</sup> Both approaches have risks and benefits.

### Potential Strategies

Three strategies can be used to tease apart preventable from inevitable harm.

**Assume All Harm Is Preventable: A High-Sensitivity–Low-Specificity Strategy.** First, the CMS approach can be used to assume all harm is preventable and its rates can be monitored directly. This strategy could be appropriate when evidence suggests that most harmful events are preventable. Central line–associated bloodstream infection is a harm that can be validly measured and is largely although not entirely preventable. Unfortunately, most measures of harm are missing one or several of the required validity components, such as clear definitions for the numerator and denominator, a standardized surveillance system, and whether it is largely preventable.<sup>3</sup> Most harms are preventable to some degree, but evidence is lacking about how much. For example, some decubitus ulcers and deep venous thromboses (DVTs) are preventable, but the proportion of preventable harm likely varies by harm type. What proportion of harm should be preventable before policy makers label it preventable?

**Adjust for Preventability: A Low-Sensitivity–Low-Specificity Strategy.** A second strategy could use risk-adjustment models to account for preventable vs inevitable harm. These models typically adjust for severity of illnesses, patient demographics, comorbid conditions, and diagnoses. They have a historical presence in measuring intensive care unit mortality and are now used to evaluate overall hospital mortality and mortality in specific conditions. Yet these models appear to motivate little effort to improve care. High performers generally perceive that the models support the high-quality care they provide, whereas low performers generally discredit the models.

Risk-adjustment models poorly correlate in answering the question about preventability due to the nature of observed-over-expected models. Surveillance bias and measurement and random error influence their accuracy.<sup>11</sup> By limiting the population to patients with a specific diagnosis, rather than all hospitalized patients, researchers can develop more accurate risk-prediction models. Unfortunately, as sample size decreases, random error increases. Moreover, it is erroneous to equate a statistically unexpected death with a preventable death. Therefore, methods that use observed-to-expected ratios to estimate preventable harm are likely inaccurate.<sup>11,13</sup>

Another problem with risk-adjustment measures is that they support current performance and maintain the status quo. This approach is far from optimal given that patients on average receive only half the recommended therapies, and estimates of expected deaths account for patient variables not the quality of care received.

**Link Care Received to Outcome: A High-Specificity–Low-Sensitivity Strategy.** The third strategy could link the care received (eg, process) and the adverse outcome measures.<sup>13</sup> If the evidence-based therapy or standard was not rendered or was rendered incorrectly and the patient sustains the adverse outcome, the outcome would be labeled a preventable harm. Health care organizations then could monitor counts or rates of these events and payers could create financial incentives to minimize these events.

For example, because no standardized surveillance for DVT exists, rates are influenced by how intensely clinicians look for this complication. Implementing a screening process for DVT increased these rates 10-fold at one academic institution.<sup>14</sup> Some patients develop these complications despite receiving the best therapy. To identify preventable harm, patients who developed a DVT can be assessed, and those patients who did not receive appropriate prophylaxis or treatment can be identified. This model would reduce the effect of surveillance bias on estimates of preventable harm.<sup>15</sup> For example, if 100 patients developed a DVT and 30 of these patients did not receive appropriate prophylaxis, 30 DVTs would be labeled as preventable. In the model that assumes all harm is preventable, all 100 DVTs would be labeled as preventable.

Although the model that links process to outcome has face validity, it has shortcomings. A precondition of this process-outcome model is that evidence or standards exist regarding therapies that can prevent the harm, but this is not always the case. For example, this method would not capture some harmful events that resulted from poor teamwork or other communication errors.

Given these risks and benefits, science should guide policy. Clinicians and researchers should assume all harm is preventable and determine the extent to which this is true. If research demonstrates that most harm is preventable, payment policy could follow. If research demonstrates that some harm is preventable, policy makers should link process to outcome to identify preventable harm and support research to develop new knowledge regarding how to further mitigate harm. Valid measurement is expensive, and current measures are often not valid and may misinform. Policy makers must determine the cost-effectiveness of measuring different types of preventable harm using various measurement strategies.

### Recommendations for Moving Forward

**Invest in Developing Scalable Measures.** The federal government should invest in the basic science of patient safety to develop scalable measures of preventable harm. That is, measures should be meaningful to clinicians who will use them to improve care and then could be aggregated to the health system, state, and national levels. For example, central line–associated bloodstream infections can be reported at an intensive care unit level or a national level.

**Make Estimates of Measurement Error Transparent.** Current measurement systems are imperfect and more accurate measures will be more expensive than less accurate measures. Tradeoffs must be made between accuracy and costs, and these tradeoffs made transparent. As the stakes increase, the validity, precision, and costs of measures should be publicly reported. This information is unknown for current measures of safety.

**Separate Hospital Efforts to Learn From Policy Efforts to Judge.** Separating hospital efforts that prevent harm from policy efforts that judge performance will be helpful. Hospitals should strive to prevent all adverse events and, in doing so, learn how often harm is preventable. Furthermore, new interventions should be identified to prevent harm. When safety measures are accurate and evidence regarding preventable harm is robust, policy makers can wisely and justly create performance incentives.<sup>5</sup> Efforts undertaken without such evidence may do more harm than good.

## Conclusions

For years, clinicians considered most harm as inevitable. Now, health care and policy organizations have swung the pendulum by suggesting that nearly all harm is preventable. Truth is likely somewhere in between; research is needed to more accurately identify the extent to which harm is preventable. Although clinicians can strive to eliminate all harm, policy makers should be informed by evidence demonstrating what harm is truly preventable. Policy efforts should invest in creating more accurate measures of harm and provide incentives for hospitals to innovate to continually reduce preventable harm. Once health care can accurately estimate the extent to which harm is preventable, policy makers can and should align payment policy. Only if science drives payment policy can health care answer King's

important question, "Are patients safer?" with a resounding and robust yes.<sup>1</sup>

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