COMMENTARY

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First, Do No Harm. Second, Measure It.

The patient safety movement can be traced to the 4th century BCE, when Hippocrates uttered those famous words, 'First, do no harm.' In 1854, Florence Nightingale railed against the unsafe patient care in the Crimean War front.[1] In 1910, Ernest Amory Codman implored physicians to study outcomes, remedy errors, and make results public.[2] In 1991, the Harvard Medical Practice Study reported that 3.7% of hospitalized patients suffered an adverse event.[3,4] The 1999 Institute of Medicine report "To Err is Human" estimated there were up to 98,000 deaths annually due to hospital-based medical errors in the United States.[5] Meanwhile, a 2010 study reported an 18% case rate of harm for hospitalized patients.[6] Most recently, a study found a 23.6% rate of adverse events in hospitalized patients, with 7.5% deemed serious.[7]

Twenty-five centuries after Hippocrates, we must ask ourselves if we have made meaningful progress in reducing harm to our patients. While the answer is "yes", the fundamental challenge is that our measurement of harm, while advanced since Hippocrates, is still vastly suboptimal for understanding the true burden of harm, the causative underpinnings, and the impacts of our interventions to reduce it.[8]

We use data about harm in 3 principal ways: to judge or compare, to improve, and to conduct research.[9] Current patient safety data collected for judgement, accountability, or comparison of providers or organizations is lacking in several ways. It is not timely, often lagging by months to years, limiting its usefulness and feeding provider skepticism about its relevance. These data are often driven by the need to submit to publicly reported databases, insurers, or disease/procedure-specific databases.[10] As such, it is often limited to the types of harm important to these entities and not a comprehensive collection of, or even inclusive of, the most frequent forms of harm. This can result in confusion, as multiple, often disparate methods for measurement and reporting of the same type of harm are reported with different outcomes. Furthermore, the focus tends to be on hospital care, limiting our understanding of the problem of harm in the ambulatory and nursing home care environments.[11] Additionally, most of these data sets are either not risk adjusted, are adjusted with models that lack transparency, or lack adequate adjustments for socioeconomic characteristics, making it difficult to truly compare. Finally, this process most often relies on resource-intensive chart review and patient sampling, with complicated statistical analysis done to ensure that the data are representative.[8] This limits the utility of the findings for most hospitals that are not adequately represented in the cohorts, or have the resources and expertise to do their own analysis.

Data for improvement or research suffers from many of these same issues but also lacks the process level measures to understand the root cause of the problem. For example, understanding the frequency of compliance with evidence-based steps for reducing surgical site infections or mortality from sepsis is essential to understanding the necessary changes to fix the problem. Additionally, these methods often use triggers to identify the harm, limiting the types of harm that can be identified, and likely significantly underestimating the true incidence.

To significantly reduce patient harm, we need new data models. These models must have an accurate, timely way to comprehensively measure harm, in all patients, in all settings, in all organizations, in near real time without a dependence on expensive data extraction teams. Ideal data would be risk-adjusted, benchmarked, and expanded to include all forms of harm, not just those that are publicly reported. To effectively identify the root causes of harm, the data should be directly linked to core process measures that help identify the care deficiencies that result in the outcome. Ideally, these combined datasets would also be connected to the consequences of harm such as mortality, prolonged length of hospital stay, readmissions, costs of care, and patient-reported outcomes to best understand the impact of the harm.

Ultimately, another study on the incidence of harm is not the answer. Rather, we need datasets that measure the multitudes of harm in real time, reveal the process measures that led to it, and enable clinicians to make the necessary

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changes to eliminate it. Short of that, we'll spend the next 25 centuries in continued pursuit of Hippocrates' decree.

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