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Keeping Patients Safe: Establishing a National Patient Safety Authority to Reduce Medical Harm

Healthcare services and procedures that cause patients bodily harm are major drivers of excess spending, waste and patient suffering. Though difficult to measure, medical harm—injury resulting from largely preventable events caused by human error in healthcare facilities—is suspected to be the third-leading cause of death in the U.S., despite ongoing work to address patient safety concerns.

An untested strategy with great promise is the establishment of a National Patient Safety Authority (NPSA) to safeguard the interests of patients by monitoring, investigating and promoting health system changes to reduce medical harm events.

What is a National Patient Safety Authority?

In November 1999, the Institute of Medicine documented a staggering number of patient deaths related to preventable medical errors and later advocated for a "fundamental, sweeping redesign of the entire health system." Recent studies have indicated that one in 20 patients are exposed to preventable harm through their interactions with the medical system. Moreover, 12 percent of these harm events were serious or led to death. There has been an appalling lack of progress in reducing medical harm in the two decades following the Institute's call to action—highlighting the need for bold measures.

Patient safety advocates are exploring the creation of an overarching authority to identify and enforce rigorous safety standards for healthcare providers. This strategy is modeled on successful efforts like the Federal Aviation Administration (FAA) and the National Highway Traffic Safety Administration (NHTSA). National oversight provided by these entities has been the catalyst for quantum leaps in airline and traffic safety. For instance, safety standards implemented in 1966 by a precursor to the NHTSA led to the design of new safety features in vehicles and roads, resulting in fewer motor vehicle-related deaths per year by 1970. Meanwhile, the FAA's oversight activities led to a 95 percent decrease in commercial aviation deaths between 1997 and 2018. While the details are still being fleshed out, a National Patient Safety Authority would monitor medical harm events, create patient safety protocols and enforce their adoption in the United States.

Promising practices from existing federal safety authorities can shed light on how to design a National Patient Safety Authority. Specifically, the entity should have the authority to: define harm events; require mandatory reporting; require data alignment; investigate or audit causes of safety or security lapses; make and enforce recommendations; and provide public access to reports and findings.

Defining Patient Harm Events

Defining medical harm events promotes transparency and facilitates the creation of measures that can be used by state-level patient safety authorities and others, making findings reliable and consistent for public audiences. This would allow the NPSA to compare results across different medical facilities and agencies and track changes in medical harm rates over time.

Some existing entities already play a role in defining medical harm events. For example, the National Quality Forum uses a multi-stakeholder process to define "serious reportable events" (also known as "never events") and payers and state authorities have defined other harm events. In addition, the Centers for Medicare and Medicaid Services (CMS) publicly lists its overall patient safety indicators (PSIs), along with a description of specific measures included in their indicators to provide complete transparency.

Data Alignment

The lack of standardized measures is a common critique of the current patient safety reporting process. To ensure the accuracy and efficiency of its data collection process, it will be important for state-level safety agencies to align their data collection efforts with the NPSA. This would involve combining resources and reducing unnecessary spending associated with performing redundant studies. Moreover, standardization would ensure that public reporting is more meaningful to consumers.

An example of a safety authority using a similar strategy is the National Highway Traffic Safety Administration, which worked with the Governors Highway Safety Association to create the Model Minimum Uniform Crash Criteria (MMUCC). The MMUCC outlines measures that should be included in state crash data systems to encourage consistency across state databases. Data collected by states is then used to inform the Fatality Analysis Reporting System, a publicly accessible database that is used by Congress and the NHTSA.

Investigating or Auditing Causes of Safety or Security Lapses

To prevent harm events from reoccurring, it is important to investigate the causes of safety lapses that resulted in patient harm. For example, the Patient Safety Authority (PSA) in Pennsylvania performs its own review of anonymous reports to explore the cause of a safety lapse when it is dissatisfied with a medical facility's investigation.

The National Transportation Safety Board (NTSB) is known as one of the most crucial independent investigative authorities worldwide and its investigations have created a standard for similar agencies. The NTSB investigates almost 2,000 aviation and around 500 other transportation incidents each year. The NTSB's "Go Team" initiates each investigation immediately following an incident and is comprised of individuals who specialize in areas related to the incident, including air traffic control, human performance, airframe structure or weather.

Making Recommendations

Equipped with deep expertise in their area of focus, centralized safety authorities are well-positioned to make recommendations to prevent safety violations and harm events. For example, the National Transportation Safety Board offers recommendations to government agencies at the state and federal levels, along with transportation providers and manufacturers. These recommendations have been used to enact laws intended to reduce safety lapses including laws that mandate positive train control systems, install safety technology on railroad lines, develop FAA regulations that address pilot fatigue and address distracted driving, among others.

Enforcing Regulations

The NPSA could also have the power to issue penalties for not complying with safety regulations. For example, the FAA creates and enforces regulations for aircraft manufacturing, operation and maintenance. Its enforcement

division has the authority to carry out legal action when reporting entities do not comply with its recommendations. Additionally, the Food and Drug Administration (FDA) publishes reports that include recommendations, guidance and enforcement priorities for different industries. The agency has the power to take enforcement action in certain situations. For instance, the FDA's Center for Veterinary Medicine can choose to send a warning letter or proceed with immediate enforcement action when an FDA-regulated product poses a potential threat to public health. Immediate enforcement actions include product seizures and criminal prosecution. The NPSA could explore these and other enforcement tools like financial penalties, limiting providers from Medicare participation and license removal.

Although healthcare enforcement standards exist—for example, those promulgated by licensing agencies and accrediting organizations—few standards focus explicitly on issues of patient safety.

Publicizing Findings from Investigations

A centralized patient safety authority must make its findings available to the public to build trust in the agency's work. Additionally, publicizing safety findings would incentivize healthcare providers to adopt measures to reduce medical harm events and ultimately lead to healthcare quality improvement through three major pathways:

- The change pathway: the use of evidence-based performance measures identifies specific deficiencies in healthcare quality, allowing for improvement in clinical outcomes.
- The reputation pathway: after public disclosure, poor-performing providers are revealed and their reputations are negatively impacted. Concern about public image, through this pathway, incentivizes providers to improve the quality of their healthcare services.
- The selection pathway: consumers choose providers through an assessment of the provider's performance ratings. Providers are therefore incentivized to improve their performance to attract more healthcare consumers.

It is important for this information to be readily available. The FAA and Consumer Financial Protection Bureau (CFPB) require a Freedom of Information Act (FOIA) filing and fee to access their records—a burdensome approach for consumers that we may not want to emulate. Safety authorities that provide more accessible data include the NTSB, which creates final reports that are accessible to the public.

CMS makes selected patient-safety information public, including the frequency of hospital-acquired infections such as central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI) and clostridium difficile infections, through Hospital Compare. Moreover, The Leapfrog Group collects data through its voluntary Leapfrog Ambulatory Survey Center (ASC) survey, which contains information about patient safety. The results are posted for public access in Leapfrog's Compare Hospitals database.

It is important to note that there are concerns about the frequency of consumers' use of patient safety data. Public access and use of patient safety data is low, especially among populations made vulnerable. This may be due to a lack of standardized measures and definitions across hospital reporting datasets. Moreover, data is often presented in a way that is confusing or overwhelming to consumers. When creating a publicly accessible database for the NPSA, these concerns should be addressed to increase the likelihood that consumers will access the NPSA database and make healthcare decisions that could lead to better outcomes.

Summary

Considering limited progress in reducing medical harm in recent decades, bold actions like creating a strong National Patient Safety Authority may be needed to comprehensively address medical harm, improve healthcare quality, increase patient confidence in our health system and reduce wasteful spending. A well-designed National Patient Safety Authority would draw from existing models and evidence to ensure its work is impactful, trusted and accepted by all stakeholders. This new authority could: define safety violations like the PSA; require reporting like the PSA, NTSB and NHTSA; require data alignment like the NHTSA; investigate or audit safety lapses like the PSA, NTSB, FAA and NHTSA; make and enforce recommendations like the FAA and NHTSA; and provide public access without the need to submit an FOIA request like the NTSB.

Note: Citations to the evidence can be found on our website at www.healthcarevaluehub.org/Medical-Harm-NPSA

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