A New Solution to Address the Problem of Medical Errors

Introduction. As Americans suffer devastating consequences from a global pandemic, they also suffer annually and commensurately from preventable medical errors and harm. Our health systems are far from fail-safe. Prior to COVID-19, medical errors were the third leading cause of death in the U.S, contributing to about 250,000 deaths per year. The U.S. fails to apply its extraordinary technology and information system capabilities to protect its patients and their healthcare workers from harm.

The Pittsburgh Regional Health Initiative (PRHI) has worked to reduce adverse medical events for over two decades. After consultation with 120 American leaders in health reform, PRHI now embraces a new, more substantial, protective measure for patients and workers alike.

Inspired by James Fallows' query in the June 29, 2020 *The Atlantic*, "Imagine if the National Transportation Safety Board (NTSB) investigated America's response to the coronavirus pandemic," PRHI and its parent organization, the Jewish Healthcare Foundation, imagined what the outcome would be and proposed the creation of a National Patient (and Provider) Safety Authority (NPSA) modelled on the NTSB.

Proposal for a National Patient Safety Authority (NPSA)

Summary. Harm to patients and healthcare workers across the continuum of care can be dramatically reduced using the power of available technologies deployed in other complex, high risk industries. They include advanced analytics, Artificial Intelligence (AI), and Machine Learning to mine large, existing data sets to anticipate and avoid harm through automated corrective action. The unsatisfactory progress on reducing preventable medical errors, and the deaths resulting from a pandemic for which we were disturbingly unprepared, underline the critical need for a new and bold safety strategy—one that prevents harm before it occurs and responds vigorously when a crisis emerges.

Through a *Full Court Press* effort with its Board Members and content experts, PRHI proposes a National Patient Safety Authority (NPSA), using the well-established and successful NTSB as a model. The NTSB is structured as an independent agency that investigates accidents and proposes recommendations and solutions to prevent the adverse events from re-occurring. The NTSB's solutions often rely on autonomous safety technologies, such as airbags, autonomous slack adjusters, anti-collision equipment, autopilot features, fail-safe thrust reversers, automatic shutoff valves, and autonomous internal inspections and correction devices for pipelines.

Our nation has a history of using powerful, autonomous, intelligent feedback mechanisms to improve public safety relating to transportation, the environment, national security, space travel and external threats to society. Evidence of this power exists in intelligent systems that provide air-traffic control, nuclear event detection, bioterrorism warnings, cybersecurity, and modern navigation assists. These technologies allow NASA to send human beings into orbit and hurtle safely to the moon and back.

It is time to extend fail-safe technologies to health care, where people can then seek medical care without the threat of unanticipated and *preventable* adverse events. The key ingredients exist. Our nation's $30 billion federal investment in Electronic Health Records (EHRs) has unlocked healthcare data and AI technology is available to convert the data into intelligence. Automation is also turning appropriate actions

over to the computer to create safe and assured operations and team with providers and patients, accomplishing human-specified goals and decisions with trust.

Structure and Functions. The NPSA, like the NTSB, would guarantee a data-driven, non-punitive, collaborative approach to protecting patients and providers. **The NPSA would exist as an independent agency at the federal level and interface with HHS agencies** (e.g., CMS, ONC, AHRQ, CDC, FDA, NIH, and ONC) similar to how the NTSB interfaces with the Department of Transportation (DOT) and its Federal Aviation Administration (FAA).

At its core, the NPSA would:

- **Mine big data from EHRs to monitor and anticipate medical errors with AI and Machine Learning technology**
- **Investigate major safety events with NTSB-like "Go Teams"**
- **Create recommendations, including autonomous solutions, to prevent medical errors**

It is possible to perform these core functions with today's technology and data. Seventy-seven percent of quality and safety information can be automated using standard technology and 23% of the information requires natural language processing technology, such as Machine Learning technology. A Patient Safety Organization (PSO) developed a real-time patient safety surveillance system that extracts EHR data, uploads the data to a cloud, applies predictive analytics and clinically validated algorithms to identify and anticipate adverse safety events, and visualizes the information through dashboards. NASA-like command and control centers can then display these dashboards to direct and coordinate actions, execute decisions, and monitor the impact of those actions.

The NPSA's investigative power would be critical to building solutions and alternative scenarios. Like the NTSB, not *every* safety event would require an investigation. The systematic nature, the harm done, and the cost of remediation would trigger a "Go Team" of appropriate experts. Most adverse event investigations would be conducted at the institutional, regional, and state levels. The NPSA would only investigate events with particularly broad or catastrophic impact, novel events (like a pandemic with support from the CDC), or an unusual cluster or trend of anomalous events.

Based on the root causes and findings from the NPSA's investigations, the NPSA would propose recommendations, leveraging autonomous, fail-safe solutions and technologies as appropriate.
For example, the John Hopkins Applied Physics Lab's MDIRA (Medical Device Interoperability Reference Architecture) is guiding stakeholder organizations and the industry in developing interoperable, safe, and secure medical device systems that will deliver advanced and autonomous medical care.

A defined, three-year period of developing and pilot testing the implementation, experimentation research, and evaluation processes of the NPSA would occur before going live. During this period, the NPSA would inventory and select the appropriate technologies to identify and anticipate medical errors, create recommendations to work through legal barriers, and select the patient safety measures and clinically validated algorithms.

Rationale. The nation would benefit from one synchronized, efficient, standardized data collection and analysis system for medical errors and severe threats to patients and healthcare workers. This responsibility is currently spread among federal agencies, a myriad of state and local entities, and independent organizations. This responsibility also relies on antiquated methods, such as retrospective analyses of claims data (e.g., the CMS Patient Safety Adverse Events Composite measure), voluntary self-reported information about adverse events (e.g., AHRQ's network of patient safety databases and PSOs), or manual chart reviews (e.g., the CDC National Healthcare Safety Network, the AHRQ Quality and Safety Review System, and the Medicare Patient Safety Monitoring System). A streamlined approach is necessary to reduce wasteful duplication and inconsistencies, to provide clinicians with a seamless flow of reliable information, and to create a national learning network.

While saving lives, an NPSA would reduce the cost of care (related to litigation, waste, and inefficiency) and alleviate worker burnout by centralizing data collection, enabling autonomous *safety measurement*, real-time *safety monitoring*, *prediction,* and *corrective action.*

Clinicians and providers have long complained about the plethora of quality and safety measures, and redundant manual reporting requirements. The NPSA would relieve this measurement burden for patient safety measures by autonomously mining EHR data and issuing real-time recommendations to inform actions.

Centralizing these functions at the NPSA would avoid the common barrier where only early adopters and high-performing organizations, whose leadership already prioritizes safety, elect to deploy the data monitoring systems. Instead of relying on healthcare systems to opt in and deploy technologies on their own that identify more errors than their current systems are detecting, all the healthcare systems in the U.S. would be able to benefit from the core functions of the NPSA.

The nation has the capability to detect the conditions that precede error, to identify critical risk factors, and to act in time to reduce pain and suffering. Does it have the political will?