NATIONAL PATIENT SAFETY AUTHORITY

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. The stress on the healthcare system from COVID-19 may have further exacerbated these harms due to staffing shortages and burnout.[1] 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.[2] The U.S. has failed to apply its extraordinary technology and information systems to effectively protect its patients and their healthcare workers from harm.

Many organizations have worked to reduce adverse events for over two decades since the IOM report, *To Err is Human*, was published in 1999. The Pittsburgh Regional Health Initiative (PRHI) is one of these organizations. While many other industries can claim steady and impressive improvements in safety, health care cannot. PRHI led a series of conversations in 2019 and 2020 with 120 American leaders in health reform to reach consensus on a new, more substantial, protective approach for patients and workers. The participants agreed that health care lacked an essential component common to other industries: one central independent federal agency focused on patient and provider safety. This has led to a recommendation for a National Patient Safety Authority (NPSA) modelled on the well-established and successful National Transportation Safety Board (NTSB).

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 Secretary of the Department of Transportation must respond to the NTSB's recommendations within 90 days. 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. It is estimated that 80% of the NTSB's recommendations have been adopted.

The COVID-19 pandemic revealed the consequences of this critical flaw in our healthcare safety net: the absence of one *independent* agency entrusted with the responsibility to mount a coordinated, well researched, rapid response and empowered to call on multiple industries to work in concert.

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[1] Office of the Inspector General. (March 2021). Hospitals Reported That the COVID-19 Pandemic Has Significantly Strained Health Care Delivery. OEI-09-21-00140. Available at https://www.oig.hhs.gov/oei/reports/OEI-09-21-00140.asp.
Castellucci, M. (2021). Quality of Care May be Slipping During COVID, Experts Warn. Modern Healthcare. Available at https://www.modernhealthcare.com/safety-quality/quality-care-may-be-slipping-during-covid-experts-warn
[2] Makary, M, et al. (2016). Medial Error—The Third Leading Cause of Death in the US. BMJ, 353 (i2139). Available at https://www.bmj.com/content/353/bmj.i2139

Inspired by James Fallows' query in *The Atlantic*, "Imagine if the National Transportation Safety Board (NTSB) investigated America's response to the coronavirus pandemic,"[3] and the urgency of a pandemic, PRHI and its parent organization, the Jewish Healthcare Foundation (JHF), launched a ***Full Court Press*** **initiative** with its Board and a growing coalition of partners in November 2020 to inform the functions of the NPSA for health care.

The NPSA Policy & Advocacy Coalition was formerly established in February 2021 to advance the creation of an NPSA. The **NPSA Policy & Advocacy Coalition** represents providers, consumers, health plans, patient safety groups, employers and other purchasers of health care, technology companies, foundations, and universities.

The need for an NPSA has surfaced over the last decade, but the pandemic underlined the immediate essentiality of such a body. Other national groups, including the National Academy of Sciences, have called for an independent federal entity with the ability to investigate adverse events and make recommendations in a transparent, non-punitive manner similar to the NTSB.[4]

Proposal for a National Patient Safety Authority (NPSA)

Summary. Harm to patients and healthcare workers across the continuum of care can be reduced using the power of available technologies deployed in other complex, high risk industries. They include advanced analytics and Artificial Intelligence (AI) that use digital data to create more intelligent Healthcare IT systems. Years of investment in health technology have created data sets that can be used to create algorithms that can anticipate and avoid harm by providing timely actionable information to clinicians, automating corrective action, preventing harm before it occurs, and responding vigorously when a crisis emerges.

Our nation routinely deploys powerful, autonomous, intelligent feedback mechanisms to improve public safety relating to transportation, the environment, national security, space travel, and manufacturing. Evidence of this power exists in intelligent systems that safeguard air-traffic control, detect nuclear events and bioterrorism, protect our infrastructure from cybersecurity threats, and assist in safe navigation. These technologies allow NASA to send humans into orbit and hurtle safely to the moon and back, and to send unmanned spacecrafts to explore planets at the edge of the solar system.

It is time to extend such fail-safe technologies to health care, providing medical care without the threat of unanticipated and *preventable* adverse events. The key ingredients and capabilities already exist in health care. Our nation's $30 billion federal investment in Electronic Health Records (EHRs) has led to the digitalization of health care and unlocked **healthcare data** and **AI technology** to convert that data into intelligence. Examples include minimizing the rate of false alarms, detecting clinical deterioration and mortality, identifying postoperative surgical complications, automating surveillance of patient safety risks, anticipating adverse drug reactions, and improving medication reconciliation.[5] **Automation** can also be used to create safe and assured operations and to team with providers and patients in accomplishing patient safety goals.

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[3] Fallows, J. (2020). Imagine if the National Transportation Safety Board investigated America's response to the coronavirus pandemic. The Atlantic. Available at https://www.theatlantic.com/politics/archive/2020/06/how-white-house-coronavirus-response-went-wrong/613591/

[4] National Academy of Sciences. (2012). Health IT and Patient Safety: Building Safer Systems for Better Care. Available at https://essentialhospitals.org/wp-content/uploads/2014/07/IOM-report-on-EHR-and-Safety.pdf

[5] Chiou, E et al. (2020). Role of Artificial Intelligence in Patient Safety Outcomes: Systematic Literature Review JMIR Med Inform, 8(7). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414411/

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

At its core, the NPSA would:

- **Support agencies in monitoring and anticipating adverse events with AI and Machine Learning technology**
- **Identify significant harm and then conduct investigations of the adverse events**
- **Create recommendations, including autonomous solutions, to prevent medical errors**

Supporting Autonomous Data Mining

The NPSA would support HHS agencies and the VA in adopting technology to autonomously mine **adverse events**—medical errors that lead to patient injury or harm—where they happen, including outside of hospitals. This technology could mine existing adverse events and indicators, such as Never Events,[6] the IHI Global Trigger Tool indicators,[7] healthcare-acquired infections reported to the CDC National Healthcare Safety Network,[8] the CMS Patient Safety Composite Measure[9] (a subset of the AHRQ Patient Safety Indicators[10]), and the AHRQ Common Formats, which define incidents, near misses, and unsafe conditions for AHRQ's Network of Patient Safety Databases.[11]

It is possible to perform these core functions with today's technology and existing data sources. 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.[12]

For example, a Patient Safety Organization (PSO), Pascal Metrics, developed a **real-time patient safety surveillance system** that extracts EHR data, uploads the data to a cloud, identifies the IHI Global Triggers, applies predictive analytics and clinically validated algorithms to anticipate adverse safety events, and visualizes the information through dashboards potentially housed in NASA-like **Command and Control Centers**.[13]

[6] Available at http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx
[7] Available at http://www.ihi.org/resources/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx
[8] Available at https://www.cdc.gov/nhsn/index.html
[9] Available at https://qualitynet.cms.gov/inpatient/measures/psi/resources
[10] Available at https://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec_ICD10_v2020.aspx
[11] Available at https://www.pso.ahrq.gov/common-formats/overview
[12] Clinovations Government + Health. (2018). Feasibility of the Partial Automation of Data Abstraction for the Quality and Safety Review System. AHRQ Publication No. 18-0034-EF. Available at https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/qsrs/qsrs-final-report-feasibility-508.pdf
[13] Classen, D, et al. (November 2018). An Electronic Health Record–Based Real-Time Analytics Program For Patient Safety Surveillance And Improvement. Health Affairs, 37(11). Available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.0728.

Conducting Investigations

The NPSA's investigative power is critical to building solutions and alternative scenarios. The mission is to eliminate major harms one by one by uncovering the root cause(s). Operating with specific guidelines (much like the NTSB), an NPSA can prioritize which adverse events and patient-reported incidents require an in-depth, multi-disciplinary national investigation and which could be investigated regionally and locally through partner organizations.

Adverse events that create serious harm across systems would trigger a "Go Team" of appropriate experts, including human factor engineers. Many adverse event investigations would be conducted at the institutional, regional, and state levels. During the investigations, the NPSA could assemble additional data to inform their investigations.

Similar to the NTSB's investigations,[14] information from the NPSA's report on the findings from the investigation would not be admissible into evidence or used in a civil action for damages resulting from a matter mentioned in the report.

Recommending Solutions

Based on the root causes and findings from the NPSA's investigations, the NPSA would propose recommendations to prevent the adverse events from re-occurring.

The NPSA could draw on existing evidence-based practices (e.g., the patient safety practices reviewed in AHRQ's Making Healthcare Safer series)[15] and make recommendations for wider scale deployment of autonomous, fail-safe solutions and technologies as appropriate. For example, clinical decision support algorithms have improved early identification of sepsis[16] and provided advanced warning of cardiopulmonary arrest to trigger Rapid Response Teams.[17]

There are also examples where government is setting bold objectives for the private sector. For example, MDIRA (Medical Device Interoperability Reference Architecture) created a technical framework to guide the development of interoperable, safe, and secure medical device systems to deliver autonomous medical care.[19] The National Emergency Tele Critical Care Network (NETCCN) also includes plans for closed loop autonomous control of medical devices like infusion pumps and ventilators.[18] It is part of the U.S. Army's TATRC program called Technology in Disaster Environments.

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[14] 49 U.S. Code § 1154(b)
[15] AHRQ. Comparison Tables for Making Healthcare Safer Reports. Available at https://www.ahrq.gov/research/findings/making-healthcare-safer/comparison.html
[16] Henry, KE, et al. (2015). A Targeted Real-Time Early Warning Score (TREWScore) for Septic Shock. Science Translational Medicine, 7(299). Fleuren, LM, et al. (2020). Machine Learning for the Prediction of Sepsis: a Systematic Review and Meta-Analysis of Diagnostic Test Accuracy. Intensive Care Med, 46..
[17] Kia, A, et al. (2020). MEWS++: Enhancing the Prediction of Clinical Deterioration in Admitted Patients Through a Machine Learning Model. Journal of Clinical Medicine, 9(2). Available at https://doi.org/10.3390/jcm9020343
[19] Available at https://secwww.jhuapl.edu/mdira/documents
[18] Available at https://secwww.jhuapl.edu/mdira/

Interfacing with HHS Agencies. The NPSA's core functions to investigate adverse events and issue recommendations are designed to complement the patient safety work of HHS agencies and the VA.

Supporting Autonomous Data Mining

The NPSA's function to *partner* with HHS agencies to autonomously collect and mine adverse events is designed to support the existing data collection work across AHRQ, CMS, and CDC in response to the current data collection challenges cited by the US Government Accountability Office (GAO)[20] and the Office of the Inspector General (OIG).[21] The AHRQ draft report notes the future potential of ML technology and distributed data sets.[23]

To help alleviate these challenges and build on developments, such as the AHRQ Quality and Safety Review System (QSRS), the NPSA would help agencies select autonomous data collection systems to reduce duplication and inconsistencies, provide clinicians with a seamless flow of reliable information, and display real-time information via visual dashboards or Command and Control Centers.

Conducting Non-Punitive NTSB-Like Investigations: A Unique Role

Currently, the NPSA's non-punitive investigation function is not part of any federal or state agency's role.

Issuing Recommendations with a Feedback Loop

The NPSA would send their recommendations and solutions to agencies and the industry based on the root causes of the adverse events that the NPSA investigates. HHS would use its complementary functions (examples listed below) to act on the recommendations, sending a response to the NPSA within 90 days, similar to how the NPSA interfaces with the DOT.

- **AHRQ's complementary functions:** fund patient safety research, review the evidence of patient safety practices, certify the Patient Safety Organizations, implement the NPSD, and disseminate information and tools to translate the practices into action, among other leading roles.

- **CMS' complementary functions:** publicly report patient safety indicators on Hospital Compare, use value-based payment programs (e.g., the Hospital-Acquired Condition Reduction Program and the FY 2023 Hospital Value-Based Purchasing Program), survey, provide technical assistance to providers through programs like the Quality Improvement Organizations, and create other rules and regulations.

[20] US Government Accountability Office. (2016). Patient Safety: Hospitals Face Challenges Implementing Evidence-Based Practices. GAO-16-308. Available at https://www.gao.gov/products/gao-16-308
[21] Office of the Inspector General. (2019). Patient Safety Organizations: Hospital Participation, Value, and Challenges. OEI-01-17-00420. Available at https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000239.asp
[23] AHRQ. (2021). Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine. Available at https://pso.ahrq.gov/sites/default/files/wysiwyg/strategies-to-improve-patient-safety_draft-report.pdf

Demonstration Period. A defined, **three-year period** of developing and pilot testing the implementation and evaluation processes of the NPSA would occur before going live. During this period, the NPSA would inventory and select the adverse event indicators and the technologies to identify and anticipate the adverse events.

Rationale. The nation would benefit from a single independent agency solely focused on reducing and preventing adverse events in health care. This responsibility is currently spread among federal agencies, a myriad of state and local entities, and independent organizations. While saving lives, an NPSA would reduce the cost of care (related to litigation, waste, and inefficiency) and alleviate worker burnout by supporting autonomous *safety measurement* and *corrective actions*.

Making these functions at the federal level would enable all the healthcare systems in the U.S. to benefit from the core functions of the NPSA. This would avoid the common barrier where only early adopters and high-performing organizations, whose leadership already prioritizes safety, elect to invest in patient safety surveillance systems, dedicate resources for multi-disciplinary investigations, and adopt corrective actions.

Modern technology and analytics provide the capability to detect many of the conditions that precede error, to identify critical risk factors, and to act in time to reduce pain and suffering. The pandemic revealed with drama and urgency the need for an agency tasked with the responsibility to ensure that these actions are standardized and executed with haste. The NPSA Policy & Advocacy Coalition has assembled to advance this mission.