A Transformational Effort on Patient Safety

July 2023

DRAFT/PRE-DECISIONAL

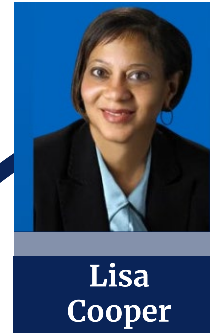
PCAST Reports

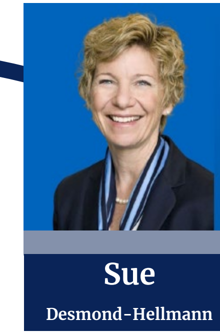
- Established by Executive Order, PCAST is an independent Federal Advisory Committee comprised of individuals from industry, academia, and non-profit sectors
- A PCAST Working Group studies the topic, solicits information from diverse stakeholders, and drafts a report
- To release a report, full Council must make the decision in public, which includes discussion and voting
- Recommendations must reflect the Council's independent judgment, and thus *PCAST reports are not subject to any interagency review or approval process*
- Reports are public, except if classified

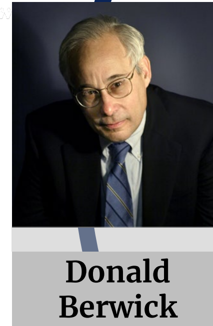
PCAST Working Group

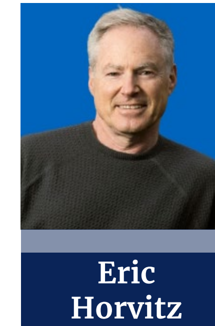
PCAST Members
- Eric Horvitz (Microsoft & Stanford) – *Co-Lead*
- Joe Kiani (Masimo) – *Co-Lead*
- Lisa Cooper (Johns Hopkins University)
- Sue Desmond-Hellmann (Former CEO, Gates Foundation, Former Chancellor UCSF)

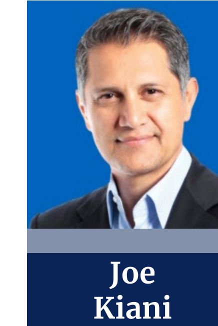
External Members:
- Donald Berwick, MD (Patient safety expert, CMS, Institute for Healthcare Improvement)
- Christopher Hart (Safety systems expert, National Transportation Safety Board)
- Harlan Krumholz, MD (Outcomes research pioneer, Yale University)
- Julie Morath, Nurse (Patient safety expert, Hospital Quality Institute)
- Peter Pronovost, MD (Patient safety expert, University Hospitals Cleveland Medical Center)
- Sue Sheridan (Patient Advocate, Patients for Patient Safety)


Lisa Cooper


Sue Desmond-Hellmann


Donald Berwick


Eric Horvitz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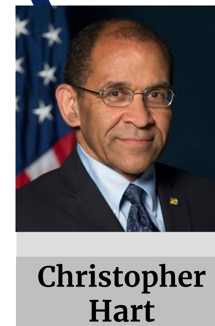
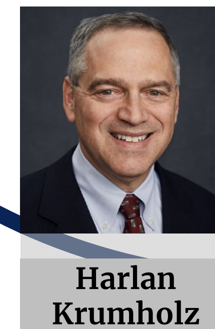
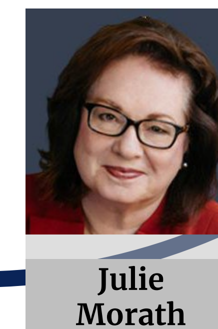
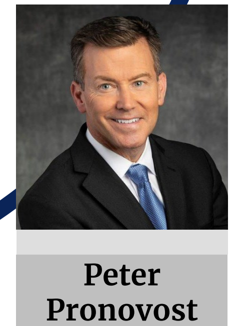

Christopher Hart


Harlan Krumholz


Julie Morath


Peter Pronovost

Background

Patient safety is an urgent national public health issue

- Institute of Medicine, *To Err is Human study (1999)*
- Avoidable errors common & costly

  "…at least 44,000, perhaps as many as 98,000 deaths each year."

- Initiatives by hospitals, healthcare organizations, federal agencies (CMS, AHRQ, CDC)
- CMS incentive programs
  - List of hospital-acquired conditions: No payment for additional cost
  - CMS pays 1% less to hospitals at highest quartile for harm
  - Studies: Programs insufficient, e.g., lists covers small percentage of adverse outcomes

Problem Persists

U.S. Department of Health and Human Services
Office of Inspector General

- **OIG Report, May 2022**
  - Adverse outcomes: 23% hospitalized Medicare patients (Oct 2018 data)
  - Avoidable: 50% could be prevented with better care
  - Estimated cost: “100s of millions of dollars.”

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

The Safety of Inpatient Health Care

JANUARY 12, 2023

- **NEJM, Jan 2023**
  - Adverse outcomes: 23.6% of admissions
  - Serious adverse outcomes: 9%
  - Preventable: 22.7% of adverse events

Problem Persists

AHRQ, Dec 2022

- ~6 percent of patients coming to U.S. emergency departments receive incorrect diagnoses
- 7.4 million misdiagnoses & 2.6 million adverse events linked to misdiagnosis per year in the U.S.

BMJ Quality & Safety

- **BMJ, July 2023**
  - >500,000 Americans permanently disabled or die per year because of misdiagnosis
  - 15 diseases account for ~50% of all serious misdiagnosis harms
  - Top 5 account for ~40%

    → Stroke, sepsis, pneumonia, venous thromboembolism, lung cancer

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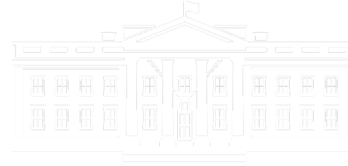

“Despite stunning advances in medical science, we still have important gaps in patient safety.”

- U.S. hospitals rely solely on *voluntary reporting* of adverse events, which *results in substantial undercounting*.
- Considerable variability among hospitals in adverse event rates: some sites at >40% of patient visits.
- Direction: Identify adverse events in EHRs by means of *computerization of triggers* & *leveraging of AI.”*

Directions Forward

Focus areas for recommendations

- Measure adverse events in a reliable & efficient way
- Standardize approaches to identify & focus on preventable adverse events
- Key organizational elements, including safety culture, participation, coordination on safety & quality
- New practices & mitigations via research and urgent leveraging of technical advances

Recommendation 1: **Establish and Maintain Federal Leadership For the Improvement of Patient Safety as a National Priority**

The President should bring immediate attention to the urgent need to improve patient safety and healthcare workforce safety as a national priority, by establishing a White House-led Transformational Effort on Patient Safety that commits to helping solve the critical challenges in the public and private sectors, and direct the Department of Health and Human Services (HHS) Secretary to oversee coordination across HHS agencies including accountability for progress, with public reporting to the President at least annually.

- 1A: **Appoint a Patient Safety Coordinator Reporting to the President on Efforts to Transform Patient Safety Among All Relevant Government Agencies.**
- 1B: **Establish a Multidisciplinary National Patient Safety Team (NPST) and Ensure Inclusion of Persons from Populations Most Affected.**

Recommendation 2: **Ensure All Patients Receive Evidence-Based Solution for Preventing Harm and Addressing Risks**

The President should direct the HHS Secretary, in collaboration with the Department of Defense (DoD), and Department of Veterans Affairs (VA), to require the appropriate federal agencies to develop a list of high-priority harms, evidence-based practices, and system-level mitigation strategies to eliminate harms. As many measures as possible should be generated from real-time automated electronic health data.

- 2A: **Identify and Address High-Priority Harms and Promote Patient Safety Though Incentivizing the Adoption of Evidence-Based Solutions and Requiring Annual Public Reporting Immediately and Quarterly Public Reporting Within 5 Years.**
- 2B: **Create a Learning Ecosystem and Shared Accountability System to Ensure That Evidence-Based Practices are Implemented and Goals for Reduced Harms and Risks of Harm for All Americans are Realized.**
- 2C: **Advance Interoperability of Healthcare Data and Assure Free Access to the Tracking of Harms and Use of Evidence-Based Solutions.**
- 2D: **Improve Safety for All Healthcare Workers and Their Patients Through Supporting a Culture of Patient and Clinician Safety in Healthcare Systems.**

Recommendation 3: **Partner with Patients and Reduce Disparities and Adverse Outcomes**

It is crucial to engage diverse stakeholders in the nation's efforts to reduce harm from unsafe care. This should include partnering and collaborating with patients, families, and communities most impacted by unsafe care. Implementing evidence-based solutions in healthcare settings should include patient-centered approaches and give special attention to long-standing disparities. To address disparities in patient safety, the President should direct the following activities:

- 3A: **Implement "Whole of Society Approach" in the Transformational Effort on Patient Safety.**
- 3B: **Improve Data and Transparency to Reduce Disparities.**

Recommendation 4: **Accelerate Research and Deployment of Practices, Technologies, and Exemplar Systems of Safe Care**

Beyond today's knowledge, it is critically important to accelerate the development and deployment of new technologies, processes, and evidentiary foundations for safe healthcare, so that errors and injuries are minimized. Promising directions include harnessing new practices and technologies for assisting with medication selection and management, improving accuracy of diagnosis, shortening time to diagnosis, monitoring, as well as predictions about treatment effectiveness based on individual characteristics.

- 4A: **Develop a National Patient Safety Research Agenda.**
- 4B: **Harness Revolutionary Advances in Information Technologies.**
- 4C: **Develop Federal Healthcare Delivery Systems' Capacities and Showcase Results as Exemplars for Safer Healthcare.**

Agency Briefings and Feedback

Centers for Disease Control and Prevention

External Experts Consulted

Agency for Healthcare Research and Quality
American Hospital Association
Atlas Research
Centers for Disease Control and Prevention
Centers for Medicare and Medicaid Services
Childrens Hospital of Orange County
Cincinnati Children's Hospital Medical Center
Department of Defense
Department of Health and Human Services
Domestic Policy Council
Food and Drug Administration
Government of the United Kingdom
Imperial College London
Indian Health Service
Institute for Healthcare Improvement
Johns Hopkins University
Kaiser Permanente School of Medicine
Lahey Hospital and Medical Center
Military Health System
National Health Service Improvement
National Quality Forum
New York University Langone Health
Office of Inspector General
Office of the National Coordinator for Health Information Technology
Press Ganey
The Commonwealth Fund
United States Agency for International Development
University of California San Francisco
University of Michigan
University of Pittsburgh School of Medicine
Veterans Health Administration
World Health Organization
Yale University

Feedback/Comments and Response/Incorporation

Conditions of participation (CoP) is too strong of a hammer; would be better to provide positive incentives.	• **Shifted language: Ultimate decisions on CoP in hands of leaders of the *Transformational Effort.*** • **CoP already requires hospitals to "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms."** • Studies: Current defns of HACs capture small fraction of adverse outcomes; voluntary reporting inaccurate; incentives weak. • We recommend review & revision of defns of preventable HAC, new incentives, accountability and reporting/transparency requirements.
What about budgeting for these changes?	• Introduced language on budgeting: Coordinator & HHS director, to engage with the Office of Management & Budget (OMB) to identify resource needs and funding for these activities, • With proposed incentives, Medicare pays increased expense of care for listed HAC *if evidence-based practices in place* (vs today: no pay for additional costs of HAC). • Given high monetary cost of avoidable errors to nation & value of evidence-based practices: expect Medicare cost reductions.

Feedback/Comments and Response/Incorporation

Concern about potential burden on small, safety-net hospitals in poor financial circumstances	• **Introduced language that leads should coordinate on *special needs of specific types of hospitals*.** • **"HHS should provide additional support to hospitals that lack adequate resources such as safety-net hospitals and those serving disproportionately affected populations. "** • **Some benefit with removing CMS penalty of not paying for costs of HACs—if evidence-based practices in place.** • **Given data on disparities in the quality of care: important to bring proven evidence-based practices to underserved areas.**
Concern that quarterly reporting would be too difficult to implement.	• **Moved to annual reporting with goal of shifting to quarterly over five years.**