



REPORT TO THE PRESIDENT A Transformational Effort on Patient Safety

Executive Office of the President
President's Council of Advisors on
Science and Technology

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EXECUTIVE OFFICE OF THE PRESIDENT
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20502

President Joseph R. Biden, Jr.
The White House
Washington, D.C.

Dear Mr. President,

Doctors, nurses, and other healthcare staff are passionate, dedicated professionals who care deeply for the patients in their care. Nonetheless, dangerous and preventable events continue to occur at surprisingly high rates. According to recent data, in the United States, Medicare patients suffer an adverse event in one out of four hospitalizations. One third of those adverse events are serious, including catastrophic outcomes.¹ Consistent with observations noted in other areas of health care, adverse outcomes disproportionately impact people from groups historically experiencing social marginalization, widening gaps in healthcare disparities.²

Concern about errors is not new, yet progress in addressing our rates of adverse health outcomes has been unacceptably slow.³ Not all harm is preventable; however, significant progress has been made in understanding and developing evidence-based practices to address the root causes of many categories of avoidable adverse outcomes. While there is great potential for near-term research and innovation to boost patient safety, widespread implementation of today's evidence-based solutions will significantly reduce harms.

Given your passion for patient safety and deep respect for healthcare professionals, we believe you can bring strong federal leadership to a nationwide transformational initiative to support all hospitals and practitioners with implementing evidence-based solutions and accelerating efforts to better understand and address broader challenges with patient safety, including the harnessing of advances in computing technologies to boost patient safety. The goal is to move our healthcare systems expeditiously towards zero preventable harms, so that every American receives dignified and safe care.

Per your request, the following report contains our recommendations aimed at dramatically improving patient safety in our country for all Americans.

Sincerely,
Your President's Council of Advisors on Science and Technology

¹ Department of Health and Human Services (HHS). (2022 May 9). Adverse Events in Hospitals: A Quarter of Medicare Patients Experiences Harm in October 2018. *Office of Inspector General (OIG)*, OEI-06-18-00400. <https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf>

² Agency for Healthcare Research and Quality. (2022 October). 2022 National Healthcare Quality and Disparities Report. Rockville, MD. AHRQ Pub. No. 22(23)-0030. <https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqdr/2022qdr.pdf>

³ Bates, D. W., & Singh, H. (2018 November). Two Decades Since *To Err Is Human*: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs*, 37(11): 1736-1743. <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738>

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Executive Summary

Patient safety is an urgent national public health issue. According to recent data, approximately one in four Medicare patients experience adverse events during their hospitalizations, with many resulting in catastrophic outcomes. More than 40 percent of these events are determined to be due to preventable errors.⁴ Efforts to address this urgent problem are underway across federal agencies, but more must be done. This report seeks to empower existing and new efforts that will transform patient safety.

Harm from unsafe care occurs in all healthcare settings and affects all persons, from mothers and babies to seniors. Moreover, adverse outcomes of unsafe care disproportionately impact people experiencing social marginalization due to race, ethnicity, sexual orientation, gender identity, income, education, socioeconomic status, or physical and mental ability, resulting in health disparities.⁵ Examples of harms include, but are not limited to, medication errors, hospital-associated infections, surgical injuries, diagnostic errors and delays, medical device malfunctions, and “failure to rescue,” which is a failure to recognize and respond adequately to physiologic events that can cascade to death.

People enter the challenging and rewarding professions of healthcare because they are passionate about helping individuals to live healthy and fulfilling lives through delivering the best care possible. The organizations in which they work—hospitals, outpatient clinics, and small-practice offices, among others—are also committed to deliver lifesaving care every day. Despite commitments to quality care by practitioners and their organizations, alarmingly high rates of medical errors and patient injuries persist. There is much left to learn about how to make healthcare safer, but over the last two decades, progress has been made in understanding root causes of avoidable medical errors and evidence-based solutions have been developed to reduce many forms of injury. For example, evidence-based solutions have been developed for minimizing hospital-associated infections, pressure ulcers, medication errors, and surgical mishaps. Safety-enhancing protocols extend to “systems level” practices such as methods for boosting situational awareness that reduce errors due to discontinuities in care that occur during handoffs at changes of shifts of care teams⁶ and also with transitions of patients between care organizations.⁷

⁴ Department of Health and Human Services (HHS). (2022 May 9). Adverse Events in Hospitals: A Quarter of Medicare Patients Experiences Harm in October 2018. *Office of Inspector General (OIG)*, OEI-06-18-00400. <https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf>

⁵ Piccardi, C., Detollenaere, J., Vanden Bussche, P. & Willems S. (2018 August 7). Social disparities in patient safety in primary care: a systematic review. *International Journal for Equity in Health*, 17: No. 114. <https://equityhealthj.biomedcentral.com/articles/10.1186/s12939-018-0828-7>

⁶ Blazin, L.J., Sitthi-Amorn, J., Hoffman, J.M., & Burlison, J.D. (2020 July/August). Improving Patient Handoffs and Transitions through Adaptation and Implementation of I-PASS Across Multiple Handoff Settings. *Pediatric Quality and Safety*, 5(4): e323. https://journals.lww.com/pqs/Fulltext/2020/07000/Improving_Patient_Handoffs_and_Transitions_through.21.aspx

⁷ Earl, T., Katapodis, N., Schneiderman, S., Care Transitions. In: Hall, K.K., Shoemaker-Hunt, S., Hoffman, L., et al. (2020 March). Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices [Internet]. *Agency for Healthcare Research and Quality*, Report No.: 20-0029-EF. <https://www.ncbi.nlm.nih.gov/books/NBK555516/>

Despite significant efforts made by dedicated health professionals, agencies, and organizations, uniform, nationwide implementation of many of these known solutions has lagged.⁸ The Biden-Harris administration has already taken key steps to improve the quality of healthcare for every American. Now is the right time to renew our nation’s commitment to improving patient safety. Parallel to improvement of patient safety is the additional and closely linked aim of improving safety for the healthcare workforce. An additional benefit of widespread patient safety improvement will be substantial reductions in the total cost of healthcare in America.

All of this will become far more likely with strong and committed federal leadership to: (a) create a nationwide transformational initiative to support every hospital and practitioner in implementing known safety solutions for both patients and the workforce and sustaining them over time; and (b) create and maintain a robust national enterprise aimed at accelerating research, development, and deployment of technology and policies aimed at improving patient safety. The Biden-Harris administration can take bold action to advance health equity, improve the nation’s health and well-being, and avert suffering and death for hundreds of thousands of Americans each year.

Recommendations

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*. The *initiative* should commit to taking significant and tangible steps forward to solve the critical challenges with patient safety 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.

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

Recommendation 2: Ensure That Patients Receive Evidence-Based Practices 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 preventable harms, including “never events” that should never occur in healthcare. As many measures as possible should be generated from real-time automated electronic health data.

⁸ Bates, D. W., & Singh, H. (2018 November). Two Decades Since *To Err Is Human*: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs*, 37(11): 1736-1743.
<https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738>

- 2.A Identify and Address High-Priority Harms and Promote Patient Safety Through Incentivizing the Adoption of Evidence-Based Solutions and Requiring Annual Public Reporting Immediately and Quarterly Public Reporting Within 5 Years.**
- 2.B 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 Every American are Realized.**
- 2.C Advance Interoperability of Healthcare Data and Assure Access to the Tracking of Harms and Use of Evidence-Based Solutions.**
- 2.D Improve Safety for All Healthcare Workers and Their Patients Through Supporting a Just Culture of Patient and Clinician Safety in Healthcare Systems.**

Recommendation 3: Partner with Patients and Reduce Disparities in Medical Errors and Adverse Outcomes.

It is crucial to engage diverse stakeholders in the nation’s efforts to reduce the risk of harm from unsafe care. This should include partnering and collaborating with patients, families, and communities disproportionately 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:

- 3.A Implement a “Whole of Society Approach” in the Transformational Effort on Patient Safety.**
- 3.B 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.

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

A Transformational Effort on Patient Safety

Introduction

Patient safety is an urgent national public health issue. Considerable efforts have been undertaken across the US healthcare system to address the complex challenges that lead to unsafe care and, in too many cases, catastrophic outcomes.⁹

When Americans seek medical care, they trust that the health system and its clinicians will deliver safe, dignified, and effective care. Delivering high-quality, equitable healthcare is a complex endeavor. For example, in a hospital setting there are a range of critical factors that play a role in the care a patient receives and in their health outcome, with clinicians, practices and procedures, technology, medicines, physical infrastructure, and patients and their family members all playing important roles. The nature of and inter-relationships among these factors can influence the quality of care and likelihood of adverse outcomes.

Avoidable medical errors can occur at various points over the course of the patient experience, some resulting in severe, life-changing harms to the patient. This unacceptable situation continues to disproportionately impact people experiencing marginalization. The Biden-Harris administration has taken key steps to improve the quality of healthcare and access to healthcare for every American, which makes now a ripe time to renew our focus and commitment to improving patient safety.

A report by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that nearly 25 percent of Medicare beneficiaries were harmed during hospital stays during October 2018 and that more than 40 percent of those harm events could have been prevented with better care.¹⁰ More recently, a January 2023 article similarly reported that adverse events occurred in nearly one in four hospital admissions based on data collected from January to December 2018. One-third of those adverse events were serious, and one-fourth of the adverse events were preventable.¹¹ The authors of the study also noted that there is substantial undercounting of adverse events in U.S. hospitals due to reliance on voluntary reporting. They assert that measuring adverse events in a reliable and efficient way would be necessary to build understanding on the path to preventing these events. Taken together, these studies demonstrate that medical errors and resulting patient harms persist and many remain undetected, obfuscating the depth of the challenge and making learnings and improvement challenging.

Significant morbidity and mortality stems from misdiagnosis and inappropriate delays in care, including harmful delays in converging on diagnoses and delivering needed therapy after patients

⁹ Bates, D. W., & Singh, H. (2018 November). Two Decades Since To Err Is Human: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs*, 37(11): 1736-1743.

<https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738>

¹⁰ Department of Health and Human Services (HHS). (2022 May 9). Adverse Events in Hospitals: A Quarter of Medicare Patients Experiences Harm in October 2018. *Office of Inspector General (OIG)*, OEI-06-18-00400.

<https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf>

¹¹ Bates, D.W., Levine, D.M., Salmasian H. et al. (2023 January 12). The Safety of Inpatient Health Care. *New England Journal of Medicine (NEJM)*, 388: 142-153.

<https://www.nejm.org/doi/full/10.1056/NEJMsa2206117>

first engage with the medical system.^{12, 13, 14, 15} Delays in diagnosis and treatment have further been linked to socioeconomic disparities.^{16, 17}

A National Academies report released in 2015 estimated that errors in diagnosis contribute to approximately 10 percent of patient deaths and account for six to 17 percent of hospital adverse events.¹⁸ The report included data from a 2018 report estimating that over 12 million Americans¹⁹ are impacted by diagnostic error each year and that the cost of diagnostic errors to the U.S. healthcare system may be over \$100 billion annually.²⁰ A national survey in 2017 revealed that diagnostic errors were the most commonly reported type of medical error experienced by patients, accounting for 60 percent of all medical errors.²¹ A December 2022 Agency for Healthcare Research and Quality's (AHRQ) study found that nearly 6 percent of patients coming to emergency departments receive incorrect diagnoses and 2 percent result in adverse events, leading to an estimated 7.4 million

¹² Sterling, S.A., Miller, W.R., Pryor, J., Puskarich, M.A., & Jones, A.E. (2015 September 1). The Impact of Timing of Antibiotics on Outcomes in Severe Sepsis and Septic Shock: A Systematic Review and Meta-Analysis. *Critical Care Medicine*, 43(9): 1907-1915.

https://journals.lww.com/ccmjournals/Abstract/2015/09000/The_Impact_of_Timing_of_Antibiotics_on_Outcomes_in.16.aspx

¹³ Sekoranjana, L., Griesser, A.C., Wagner, G., et al. (2009 July 11). Factors influencing emergency delays in acute stroke management. *Swiss Medical Weekly (SMW)*, 139(27-28):393-9.

<https://smw.ch/index.php/smw/article/view/993/990>

¹⁴ Alrawashdeh, A., Nehme, Z., Williams, B., Smith, K., Brennan, A., Dinh, D.T., Liew, D., Lefkovits, J., & Stub, D. (2021 April 16). Impact of emergency medical service delays on time to reperfusion and mortality in STEMI. *Open Heart*, 8(1): e001654. <https://openheart.bmj.com/content/openhrt/8/1/e001654.full.pdf>

¹⁵ De Luca, G., Suryapranata, H., Ottervanger, J.P., & Antman, E.M. (2004 March 4). Time delay to treatment and mortality in primary angioplasty for acute myocardial infarction: every minute of delay counts. *Circulation*, 109(10): 1223-5.

<https://www.ahajournals.org/doi/epub/10.1161/01.CIR.0000121424.76486.20>

¹⁶ Miller, A.L., Simon, D., Roe, M.T., Kontos, M.C., Diercks, D., Amsterdam, E., & Bhatt, D.L. (2017 April 15). Comparison of Delay Times from Symptom Onset to Medical Contact in Blacks Versus Whites with Acute Myocardial Infarction. *The American Journal of Cardiology*, 119(8): 1127-34.

<https://www.sciencedirect.com/science/article/abs/pii/S0002914917300395?via%3Dihub>

¹⁷ Lim, B., Chauhan, D., Schultz, M.L., Levine, D., Loumiotis, I., Friedmann, P., Parides, M.K., Forest, S.J., DeRose, J.J. (2022 March 5). Relation of Community-Level Socioeconomic Status to Delayed Diagnosis of Acute Type A Aortic Dissection. *The American Journal of Cardiology*, 170: 147-54.

<https://www.sciencedirect.com/science/article/abs/pii/S000291492200090X?via%3Dihub>

¹⁸ National Academies of Sciences, Engineering, and Medicine, Institute of Medicine. (2015 September). Improving Diagnosis in Health Care. *Washington, DC: National Academies Press (NAP)*.

<https://nap.nationalacademies.org/catalog/21794/improving-diagnosis-in-health-care>

¹⁹ Singh, H., Meyer, AND., & Thomas, EJ. (2014 August 12). The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. *BMJ Quality & Safety*, 23: 727-731. <https://qualitysafety.bmj.com/content/23/9/727>

²⁰ Society to Improve Diagnosis in Medicine (SIDM), & Coalition to Improve Diagnosis (CID) Policy Committee. (2018 February 7). The Roadmap for Research to Improve Diagnosis, Part 1: Converting National Academy of Medicine Recommendations into Policy Action. *SIDM Policy Roadmap for Research to Improve Diagnosis*.

https://www.improvediagnosis.org/wp-content/uploads/2018/10/policy_roadmap_for_diagnosti.pdf

²¹ NORC at the University of Chicago & Institute for Healthcare Improvement National Patient Safety Foundation (IHI/NPSF) Lucian Leape Institute. (2017 September 28). Americans' Experiences with Medical Errors and Views on Patient Safety. *Cambridge, MA: Institute for Healthcare Improvement and NORC at the University of Chicago*.

https://www.ihl.org/about/news/Documents/IHI_NPSF_NORC_Patient_Safety_Survey_2017_Final_Report.pdf

misdiagnoses and 2.6 million adverse events per year in the U.S.²² A July 2023 study reported that over 500,000 Americans are permanently disabled or die per year because of misdiagnosis and that misdiagnoses of 15 diseases account for about 50 percent of all serious harms, and nearly 40 percent are accounted for by the top five conditions, including stroke, sepsis, pneumonia, venous thromboembolism, and lung cancer.²³ Although findings vary across studies, many of these reports have documented disparities in harms experienced by patient based on age, sex, gender, race, and ethnicity.²⁴

Leadership Needed Now for Dramatic Improvements in Patient Safety

Fortunately, over the last two decades progress has been made in understanding the root causes of many types of medical errors, and tested or evidence-based solutions have been developed to address these challenges. We now need federal government leadership to create a nationwide transformational initiative on patient safety to support every hospital and practitioner with implementing these solutions and sustaining them over time. In addition, we need federal leadership to further advance the scientific knowledge base for healthcare safety so that errors and injuries considered unavoidable today become preventable in the future.

It should be the policy of the Biden-Harris Administration, through both federal action and public-private partnership, to immediately, dramatically, measurably, and continually reduce healthcare-associated injuries to patients and workplace injuries to the healthcare workforce. Healthcare professionals grapple with the risk of physical harm,^{25, 26} such as exposure to infectious disease, musculoskeletal injuries, and violence,²⁷ and mental health challenges,²⁸ including exhaustion, sleep

²² Newman-Toker, D.E., Peterson, S.M., Badihian, S. et al. (2022 December 15). Diagnostic Errors in the Emergency Department: A Systematic Review No. 258. Comparative Effectiveness Review. *Rockville, MD: Agency for Healthcare Research and Quality (AHRQ), Effective Health Care Program*, No. 22(23)-EHC043. https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/ce-258-diagnostic-errors-research.pdf

²³Newman-Toker, D.E., Nassery, N., Schaffer, A.C., et al. (2023 July 17). Burden of serious harms from diagnostic error in the USA. *BMJ Quality & Safety*.

<https://qualitysafety.bmj.com/content/early/2023/07/16/bmjqs-2021-014130>

²⁴ Thomas, A., Krevat, S., & Ratwani, R. (2022 February 25). Policy Changes To Address Racial/Ethnic Inequities In Patient Safety, *Health Affairs Forefront*.

<https://www.healthaffairs.org/doi/10.1377/forefront.20220222.128111>

²⁵ Harolds, L., & Hurst, H. (2016 February 12). Preventing Workplace Injuries Among Perinatal Nurses. *Nursing for Women's Health*, 20(1):99-108.

<https://www.sciencedirect.com/science/article/abs/pii/S1751485115000057?via%3Dihub>

²⁶ Aljabri, D., Vaughn, A., Austin, M., White, L., Li, Z., Naessens, J., & Spaulding, A. (2020 January 26). An Investigation of Healthcare Worker Perception of Their Workplace Safety and Incidence of Injury. *Workplace Health Safety*, 68(5):214-25.

https://journals.sagepub.com/doi/10.1177/2165079919883293?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%20pubmed

²⁷ Odes, R., Lee, S.J., Hong, O., & Jun, J. (2023 February 10). The effect of COVID-19 on workplace violence in California's hospitals: An interrupted time series analysis. *Journal of Advanced Nursing*, 79(6):2337-2347.

<https://onlinelibrary.wiley.com/doi/10.1111/jan.15588>

²⁸ Murray, E., Kaufman, K.R., & Williams, R. (2021 August 19) Let us do better: learning lessons for recovery of healthcare professionals during and after COVID-19. *BJPsych Open*, 7(5): e151.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8376907/#>

deprivation, and burnout.²⁹ All proposed actions must incorporate and empower the voices and participation of patients, families, communities experiencing marginalization, and community-based organizations to leverage their lived experience and expertise to influence patient safety policy and practice to be more patient-centered.

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

Through public statements and a series of linked Executive Orders, the President should bring immediate and sustained attention to the urgent need to reduce harm to patients from unsafe care and improve healthcare workforce safety as a national priority. The President should establish a **White House-led Transformational Effort on Patient Safety**, that commits to more comprehensively engage all relevant government agencies to help solve the critical challenges in both the public and private sectors.

This transformational effort should include both immediate actions to address the crisis and actions that ensure lasting change, recognizing that incremental change has not been adequate and a radical redirection of approach is required.

The President should immediately establish clear leadership, with lines of accountability across HHS for long-term and lasting success over a horizon of 10 years, aimed at making healthcare safer by minimizing injuries to patients and healthcare workers and reducing disparities in patient safety, dramatically, measurably, and sustainably by 2030. The transformational effort should focus on leveraging knowledge about safety science, human factors, advances in information technology, including data analytics and fast-paced developments in AI, and via establishing new forms of participatory engagement with patients and their families. The President should call on the nation to work collaboratively and urgently to prioritize and vastly improve safety. This work should engage patients, family members, community organizations, and healthcare professionals and organizations, all while prioritizing the reduction of inequities and disparities in healthcare delivery and health outcomes.

Recommendation 1.A

Appoint a Patient Safety Coordinator, Reporting to the President, on Efforts to Transform Patient Safety Among All Relevant Government Agencies.

The President should create a new Patient Safety Coordinator role in the White House, reporting directly to the President, to help coordinate effective patient safety improvement efforts at the federal level, as well as engaging with non-government stakeholders. The Patient Safety Coordinator will work closely with the Secretary of HHS, who will remain the leader for implementation of patient safety, enhancing systems and structures at HHS to facilitate long-term impact. The Patient Safety Coordinator will work with the Secretary of HHS to convene federal agency leadership on a regular basis, including working with the Office of Management and Budget (OMB) to identify resources and funding for these activities, and engaging with critical stakeholder groups including hospitals, clinicians, patient groups, and more, to help support implementation of these recommendations.

²⁹ Kelley, M.M., Zadvinskis, I.M., Miller, P.S., Monturo, C., Norful, A.A., O'Mathúna, D., Roberts, H., Smith, J., Tucker, S., Zellefrow, C., & Chipps, E. (2022 August). United States nurses' experiences during the COVID-19 pandemic: A grounded theory. *Journal of Clinical Nursing*, 31(15-16):2167-2180. <https://onlinelibrary.wiley.com/doi/10.1111/jocn.16032>

Reflecting a “whole-of-government” approach, the Patient Safety Coordinator should convene and oversee coordination of patient safety initiatives across federal agencies and regularly account for progress through public reporting to the President. The coordination strategies should align with and further efforts on addressing disparities in patient safety, directing the allocation of resources, and specifying the goals and timeline for implementing this bold patient safety agenda.

The President should charge the HHS, DoD, DoJ, and VA Secretaries with providing a timeline and specific goals for improving patient safety outcomes, based on the high-priority-harms (see Recommendation 2.A), including working with the White House Patient Safety Coordinator to deliver at least annual reporting to the President on the progress in improving patient safety and implementation of (recommended or specific) actions. The public annual report will also be published, similar to the transportation safety national reports, detailing progress toward eliminating harms identified as highest priority.

Box 1: A coordinated federal effort should include special focus advisory groups:

Patient and family group to ensure regular and formal input from a diverse set of patient, family, and community voices, especially those from groups who have experienced harm from unsafe care.

Healthcare workforce group (representing physicians, nurses, technicians, pharmacists, and other healthcare professionals), to ensure appropriate input from the healthcare workforce and to ensure that any new recommendations work to prevent and reduce unnecessary administrative or regulatory burdens that are placed on health workers, and to optimize the use of technologies that support health workers, while minimizing technologies that inhibit clinical decision-making.

Safety science group comprised of highly qualified experts in safety science and human factors engineering, drawn from healthcare and other high-hazard industries, healthcare equipment manufacturers, healthcare legal experts, and technology experts in the field of bioinformatics, AI, medical device safety, and health economics.

*All teams should include people with a diversity of lived experiences and people with expertise in structural and social determinants of health.

Recommendation 1.B

Establish a Multidisciplinary National Patient Safety Team, Including Those Most Affected.

The President should direct the Secretary of HHS to establish a dedicated, independent, healthcare safety investigation body, the *National Patient Safety Team* (NPST). The NPST should examine and analyze safety issues and opportunities for mitigating and addressing safety challenges with healthcare delivery independently, issuing non-punitive, non-binding, and learning-focused safety recommendations that support system-wide improvements.

The NPST should compose and operate a public-private partnership team, similar to the Commercial Aviation Safety Team (CAST),³⁰ comprised of multidisciplinary clinical, informatics, technology/AI,

³⁰ The Commercial Aviation Safety Team (CAST). (1997). <https://www.cast-safety.org/apex/f?p=102:1>

data science, safety science, and human-factors experts, and go one step further to include insights from patients and families.

The NPST should fully engage to gain an understanding of perspectives of clinicians and of patients and families. Thorough engagement will require that the NPST take steps to specifically ensure that patients and families, as well as health professionals, especially those belonging to groups that experience the most social and economic marginalization, are represented. Non-punitive protections should be included for healthcare professionals and others who provide information to the NPST.

The NPST should focus on system-level solutions including, but not limited to, threat and error management (e.g., eliminating confusing names, labels and containers for medications where errors can be catastrophic), eliminating potential single-point failures, leveraging lessons from human factors to improve the safety of healthcare facilities, devices and systems, addressing team communication and collaboration failures, and including opportunities for the effective and responsible use of AI technologies.

The NPST should make recommendations to AHRQ to develop patient safety reporting and learning systems for patients, families, and clinicians to report experiences or observances of harm. These systems must be independent from the organization where harm may have occurred, should empower learning, be non-punitive and ideally be part of the regular public reporting by the White House Patient Safety Coordinator recommended in 2.A. Any data collected should enable disparity stratification efforts by race, ethnicity, primary language, and other socio-demographics, when possible. The NPST's recommendations should be made public. While non-binding, federal and state agencies that accredit healthcare organizations should consider using the NPST's recommendations in their assessments.

Determining the Scope of the Problem

The federal government should establish a robust and transparent mechanism to quantify the degree of harms in the U.S. healthcare system overall, including for the most vulnerable populations, and to monitor progress in reducing harm. Transformational improvement of patient safety requires ensuring more effective use of incident reporting at the national and local levels and supplementing these data with other ways to measure adverse outcomes as well as threats to patient safety including enhanced monitoring for adverse events via signals from electronic health record systems and medical devices and predictive analytics to assess the risk of harms. The federal government will need multiple ways to assess and prevent the root causes of harms, including understanding of rates of adverse outcomes and how they differ by demographic groups.

Numerous methods can be employed to measure harms to patients and, unfortunately, these methods often present conflicting inferences about the magnitude of the problem and progress in mitigating harm. Quantifying the scope and severity of medical errors is challenging and recent studies note that the true rate of harms may be underestimated due to underreporting.³¹ The US can, and should, develop better measures for major causes of harm, and threats of harm, for a larger set of causes of harms. Today such measures of threats are derived from incident reports, although these are not adequately standardized, are prone to bias, and under-report harms especially in populations

³¹ Shojania, K.G. & Dixon-Woods, M. (2017 April 18). Estimating deaths due to medical error: the ongoing controversy and why it matters. *BMJ Quality & Safety*, 26: 423-28.
<https://qualitysafety.bmj.com/content/26/5/423>

that are socially marginalized.^{32, 33} There is concern that the health systems that put patients at greatest risk for unsafe care often report the least, paradoxically making them appear safer.

Recommendation 2: Ensure That Patients Receive Evidence-Based Practices for Preventing Harm and Addressing Risks.

Researchers and practitioners in healthcare have made substantial progress over the past two decades in learning how to reduce many forms of medical error and patient injuries. Specific interventions have been identified and demonstrated to be effective, including, among others, using checklists (such as in operating rooms before surgery), standardizing procedures reliably to conform to the best science (such as correctly managing respirator machines, intravenous catheters, and urinary catheters), communicating structured information about patients to enhance situation awareness when care teams transition (reporting on illness severity, action lists, and contingency plans, etc.), and creating “just cultures” in which all staff and patients feel safe and supported to report hazards and errors that they observe. Some hospitals have driven to nearly zero significant hospital-associated infections, pressure ulcers, and certain types of surgical mishaps for extended periods of time.

Unfortunately, progress on patient safety too often remains spotty and local, rather than permeating the American health system. As a result, far too many patients do not benefit from these evidence-based practices. It is time to create and act on a guarantee: that every American will experience care that corresponds to the leading safety practices. This can and should begin with a national focus on high-priority conditions for which mitigations have been developed, then designing incentives and supports for all hospitals and healthcare settings to achieve gains that have been demonstrated elsewhere. At the same time, we need to double down as a nation on pushing on the science and technology to develop new understanding, practices, and technologies to address adverse outcomes more broadly, including those that do not yet have satisfactory mitigations.

Healthcare is unique among high-risk industries in not fully measuring or understanding the magnitude of harms, not substantively mitigating recognized harms, and not ensuring transparency and shared accountability for making progress. To remedy this, the healthcare ecosystem must move toward more effective learning and deeper accountability on patient safety. We recommend that the White House Patient Safety Coordinator work with HHS to facilitate the creation of an ecosystem that learns and is accountable to materially reducing harms and threats of harm for every American. Such an ecosystem would be inclusive, involve diverse stakeholders including those suffering harms, healthcare delivery organizations, technology companies, professional organizations, and regulators.

Recommendation 2.A

Identify and Address High-Priority Harms and Promote Patient Safety Through Incentivizing the Adoption of Evidence-Based Solutions and Requiring Annual Public Reporting Immediately with an Aspiration of More Frequent Reporting in the Future.

³² McDonald, C.J., Weiner, M. & Hui, S.L. (2000 July 5). Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report. *Journal of the American Medical Association (JAMA)*, 284(1): 93-95.

<https://jamanetwork.com/journals/jama/fullarticle/192843>

³³ Brennan, T.A. (2000 April 13). The Institute of Medicine Report on Medical Errors — Could It Do Harm?. *New England Journal of Medicine (NEJM)*, 342:1123-25.

https://www.nejm.org/doi/10.1056/NEJM200004133421510?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

The President should direct the HHS Secretary, in collaboration with the DoD, VA and DoJ where relevant to require the appropriate federal agencies to develop a list of high-priority harms, as well as evidence-based practices and system-level mitigation strategies to eliminate those harms. This will require more effective and widely used measures of harms, with as many measures as possible generated from real-time automated electronic health data. A list of high-priority harms should likely include, but not be limited to, medication adverse outcomes, surgical adverse outcomes, diagnostic errors, hospital-associated infections, falls, pressure injuries, deep vein thrombosis and pulmonary embolus, and failure to rescue. Tracked and publicly reported events should include particularly serious avoidable events, referred to as “never events”—adverse events and outcomes that should never occur in healthcare. Such events include sets of surgical or procedural events, product or device events, patient protection events, care management events, environmental events, radiologic events, and criminal events.^{34, 35, 36, 37} HHS should prioritize efforts, such as those currently being implemented by the Agency for Healthcare Research and Quality,³⁸ to identify and dedicate resources to support those hospitals which serve populations disproportionately affected by harms.

The Secretary of HHS should require that the Centers for Medicare and Medicaid Services (CMS) develop, implement, and continually evaluate mechanisms to incentivize hospitals to employ evidence-based patient safety solutions, especially those directed at the identified high-priority harms. Incentives and penalties should include organizations not being reimbursed for the primary and harm-associated care if evidence-based practices are not in place. Conversely, if the evidence-based patient safety solutions are in place and the patient is harmed, the hospital should be reimbursed for not only the primary care, but also the harm-associated care. Other approaches to incentivizing patient safety include employing an expanded list of adverse events tracked in the Hospital-Acquired Conditions program for payment reductions.³⁹ Incentives should specifically reward excellent quality and safety performance for underserved populations, and HHS should provide additional support to hospitals that lack adequate resources such as safety-net hospitals and those serving disproportionately affected populations.

Financial penalties have the potential to exacerbate disparities along race and class lines and across hospitals; therefore, the impact of these incentives and penalties on safety-net and other hospitals caring for populations with greater medical and/or social needs should be closely monitored to avoid unintended consequences. Additionally, consideration should be given to incentivizing hospitals engaged in efforts to expand access to underserved populations and/or to reduce disparities in

³⁴ Serious Reportable Events in Healthcare: A Consensus Report. (2002). Washington, DC. *National Quality Forum*. Summary: https://www.qualityforum.org/projects/hacs_and_sres.aspx#t=1&s=&p= Accessed: August 2023.

³⁵ Kizer, K.W. & Stegun, M. B. (2005 February). Serious Reportable Adverse Events in Health Care. Henriksen, K., Battles, J.B., Marks, E.S., Lewin, D.I. (eds). *Advances in Patient Safety: From Research to Implementation (Vol. 4: Programs, Tools, and Products)*.

³⁶ Serious Reportable Events in Healthcare 2011. (2011 December) *National Quality Forum*. https://www.qualityforum.org/Publications/2011/12/Serious_Reportable_Events_in_Healthcare_2011.aspx

³⁷ Never Events. (2019 September 7). *Patient Safety Network, Agency for Healthcare Research and Quality*. <https://psnet.ahrq.gov/primer/never-events>, Accessed: August 2023.

³⁸ Patient Safety and Quality Improvement. *Agency for Healthcare Research and Quality*. <https://www.ahrq.gov/patient-safety/index.html> Accessed August 2023

³⁹ Waters, T. M., Daniels, M. J., Bazzoli, G. J., et al. Effect of Medicare’s Nonpayment for Hospital-Acquired Conditions: Lessons for Future Policy. (2015 March). *JAMA Intern Med*. 2015;175(3):347-354. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2087876>

care.⁴⁰ CMS should also require mandatory and public reporting (at least annually and moving to more frequently) of high-priority harms by individual healthcare organizations (not aggregated systems). CMS should use the list of high-priority harms and associated evidence-based solutions to inform its pay for performance program. While positive incentives may be more desirable than penalties, strong tools, such as Condition of Participation (CoP), may be necessary to accelerate adoption of timely reporting.

Regular reporting will help ensure accountability, and public reporting ensures transparency with the public that is served. The goal is for reporting to be rapid enough that solutions can be implemented as problems develop but also an accurate reflection of the safety status of hospitals. Annual reporting should become more frequent as reporting systems improve and automated reporting grows.

Recommendation 2.B

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 Every American are Realized.

The pain of the families and communities of those who have experienced harm from unsafe care is magnified when personal and system-wide accountability and transparency are lacking, and when solutions to prevent harms are not implemented. To increase board and executive accountability for safety and quality oversight, CMS should add metrics and perform surveys that relate to healthcare organizations' executive leadership and board accountability for patient safety, expanding similar tools like AHRQ's Survey on Patient Safety Culture.^{41, 42} To ensure standards for timely communication to patients and families of harm events and immediate root cause analysis of the harm - with dissemination of the findings internally and with appropriate medical bodies, CMS should require within five years that hospitals demonstrate their efforts to communicate with families and appropriate medical bodies after future adverse events as a Condition of Participation. Hospitals should consider, as a model, prior efforts aimed at communication and resolution, including the Communication and Optimal Resolution Program (CANDOR)⁴³ and Communication Resolution Program (CRP)^{44, 45, 46}

⁴⁰ Shakir, M., Armstrong, K., & Wasfy, J.H. (2018 April). Could Pay-for-Performance Worsen Health Disparities? *J Gen Intern Med.* 2018 Apr;33(4):567-569. <https://pubmed.ncbi.nlm.nih.gov/29302881/>

⁴¹ Agency for Healthcare Research and Quality (AHRQ). Surveys on Patient Safety Culture. <https://www.ahrq.gov/sops/index.html>

⁴² Agency for Healthcare Research and Quality (AHRQ). AHRQ's Making Healthcare Safer Reports: Shaping Patient Safety Efforts in the 21st Century. <https://www.ahrq.gov/research/findings/making-healthcare-safer/index.html>

⁴³ Agency for Healthcare Research and Quality (AHRQ). Communication and Optimal Resolution (CANDOR). <https://www.ahrq.gov/patient-safety/settings/hospital/candor/index.html>

⁴⁴ Mello, M.M., Boothman, R.C., McDonald, T., Driver, J., Lembitz, A., Bouwmeester, D., Dunlap, B., & Gallagher, T. (2014 January 1). *Health Affairs*, 33: No. 1 https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.0828?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

⁴⁵ University of Washington Medicine. Communication & Resolution Programs. *The Collaborative for Accountability and Improvement: A Program of UW Medicine.* <https://communicationandresolution.org/communication-and-resolution-programs/>

⁴⁶ American Medical Association (AMA). (2017). Communication and resolution programs. *AMA Advocacy Resource Center.* <https://www.ama-assn.org/system/files/2019-01/ama-issue-brief-communication-and-resolution-programs.pdf.pdf>

We note that CMS has stated a condition of participation (CoP) that references the important role of boards in an institution’s quality assessment and performance improvement (QAPI) plan. In March 2023, CMS issued guidance on this CoP, requiring hospitals to maintain and demonstrate evidence of its QAPI program for review by CMS, as part of their efforts to deliver safe, quality patient care and prevent adverse events and patient harm (42 CFR 482.21).^{47,48} Given the availability of evidence-based practices and new computing tools, the boards of healthcare institutions should commit to improving health outcomes and ensure that strategies, goals, and resources are appropriately directed to that core mission. We recommend that a diverse expert panel be created to develop a roadmap for boards that defines the key strategies that should be part of all hospitals’ operational plans. Boards should consider using the latest computing applications to enhance the implementation of their strategies, free up more workforce capacity, and to limit workforce burnout, while ensuring the strategies / applications have taken algorithmic biases into account.

The Patient Safety Coordinator and HHS should collaborate to develop a learning ecosystem and shared accountability system to ensure these promising strategies for hospital operations are implemented and harms are being reduced. Shared accountability means that HHS and health systems work together to realize safety goals. CMS should consider revising its CoPs to ensure that hospitals have an annual rather than every three-year survey and that the surveyors evaluate policies and practices to reduce harms, ensuring clinicians are using evidence-based solutions and new promising and proven practices. They will also review rates of top harms and require corrective action plans for those not realizing goals. In addition, surveyors will meet with the hospital board chair, CEO, and representative of patients who have been harmed to review progress in reducing rates of adverse outcomes.

The Patient Safety Coordinator should create a learning ecosystem, to ensure goals for reducing patient harms are realized and each of these components is working optimally. As part of this effort, HHS should also highlight interventions that most effectively reduce harm to marginalized populations. This ecosystem should include all relevant federal agencies, patients, and families harmed from healthcare, technology companies, states, health systems, regulators, and professional organizations. The goal of this ecosystem is to more rapidly share what is working both horizontally and vertically among the multitude of partners needed to reduce harm and to help ensure that no group gets left behind in the efforts to reduce harm.

The learning ecosystem and shared accountability system must ensure a balance between learning from harm and accountability for mitigating harm for every American. It is a blight upon the US government that, decades after knowing the scope of patient harm, the US lacks a valid monitoring and learning system that can reduce harm. With these recommendations, the Biden-Harris

⁴⁷Centers for Medicare & Medicaid Services (CMS). (1996 October). Condition of participation: Quality assessment and performance improvement program 42 CFR 482.21. Code of Federal Regulations. <https://www.ecfr.gov/current/title-42/section-482.21>

⁴⁷Centers for Medicare & Medicaid Services (CMS). (1996 October). Condition of participation: Quality assessment and performance improvement program 42 CFR 482.21. Code of Federal Regulations. <https://www.ecfr.gov/current/title-42/section-482.21>

⁴⁸Centers for Medicare & Medicaid Services (CMS). (2023 March 9). Revision to State Operations Manual (SOM), Hospital Appendix A - Interpretive Guidelines for 42 CFR 482.21, Quality Assessment & Performance Improvement (QAPI) Program. CMS Quality, Safety & Oversight. <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-states/revision-state-operations-manual-som-hospital-appendix-interpretive-guidelines-42-cfr-48221-quality>

Administration can create an inclusive and transparent learning and accountability system that eliminates harm for everyone.

Recommendation 2.C

Advance Interoperability of Healthcare Data and Assure Free Access to the Tracking of Harms and Use of Evidence-Based Solutions.

Steady progress toward safer care requires seamless integration of data and easy access to information by all parties, including patients, with appropriate privacy protections. Relevant federal agencies, led by the Office of the National Coordinator for Health Information Technology (ONC), should develop a comprehensive strategy to improve the interoperability of healthcare data to support improvements in patient safety and healthcare quality, including the collection of demographic data to specifically support understandings of patient safety, healthcare quality, and equity. Healthcare data should include demographic and social determinants of health (SDOH) data, to facilitate understanding of healthcare disparities in patient safety. CMS, ONC, and other relevant federal agencies should encourage all healthcare information companies and medical technology companies to allow interoperability with easy access to data feeds via standard interfaces. Also, data from devices should be available for research on patient safety when in compliance with federal regulations such as HIPAA. The federal government should consider incentives, e.g., a tax credit, for such data philanthropy.

The safety associated with the use of medical devices would be improved with better data, including tracking of devices and their performance. Mandated inclusion of Unique Device Identifiers (UDI) in claims and in Electronic Health Records would dramatically improve data availability. In addition, the FDA should consider defining a risk rating system for medical devices that provides specific guidance for devices in accordance with levels of risk and requires routine post-marketing surveillance and evaluation for those devices, especially when a new technology is being deployed clinically. It would be valuable to include in public reporting the quality and performance measures for surgeries or other procedures that involve medical devices designated as high risk.

Box 2: Example of future agency collaboration

Building upon existing work by AHRQ to collect data from Patient Safety Organizations (PSOs), HHS, DoD, and VA could establish mandatory reporting to a national repository for patient safety events data which could support access to and interoperability of healthcare data as well as enable disparity stratification efforts.

Recommendation 2.D

Improve Safety for Every Healthcare Worker Through Supporting a Just Culture of Patient Safety and Clinician Safety in Healthcare Systems.

Results in safety science and experiences to date in other industries suggest that it will be difficult to improve patient safety substantially without simultaneous attention to improving the safety of the healthcare workforce. An unsafe, insecure, or fearful workforce cannot offer safe care. The National Patient Safety Team, with input from the healthcare workforce group as described in **Box 1**, should be tasked to identify and disseminate evidence-based, systems level solutions to keep the workforce

safe from harm during the course of their work, including harms such as needle stick injury, back injury, falls, radiation, and psychological and physical burnout. In addition, the NPST should identify and encourage implementation in healthcare organizations of mechanisms and processes that promote openness, feedback, psychological safety, reporting, and, where necessary, whistleblowing protections, for healthcare workers seeing or facing challenges with patient and workforce safety. The whistleblowing protection should also apply to hospitals that are not reporting all patient harms, or where they have not yet implemented evidence-based solutions despite stating they have.

Recognizing Disproportionate Burden on Marginalized Groups

Preventable medical errors and their downstream effects directly contribute to and exacerbate health disparities. System-wide approaches are needed to address these disparities. People experiencing marginalization are more likely to suffer harms as a result of medical errors, inadequate testing and treatment, and inaccurate diagnosis,^{49, 50, 51, 52} and they may lack the resources to adequately address harms once they have occurred. Unconscious race and class biases, in particular, can shape how clinicians perceive patients and communicate with them,⁵³ which has the potential to

⁴⁹ Metersky, M.L., Hunt, D.R., Kliman, R., Wang, Y., Curry, M., Verzier, N., Lyder, C.H., & Moy, E. (2011 May). Racial Disparities in the Frequency of Patient Safety Events: Results from the National Medicare Patient Safety Monitoring System. *Medical Care*, 49(5): 504–10. https://journals.lww.com/lww-medicalcare/Abstract/2011/05000/Racial_Disparities_in_the_Frequency_of_Patient.11.aspx

⁵⁰ Shen, J.J., Cochran, C.R., Mazurenko, O., Moseley, C.B., Shan, G., Mukalian, R., & Neishi, S. (2016 July 21). Racial and Insurance Status Disparities in Patient Safety Indicators among Hospitalized Patients. *Ethnicity & Disease*, 26(3):443-52. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4948813/>

⁵¹ Piccardi, C., Detollenaere, J., Vanden Bussche, P. & Willems S. (2018 August 7). Social disparities in patient safety in primary care: a systematic review. *International Journal for Equity in Health*, 17: No. 114. <https://equityhealth.biomedcentral.com/articles/10.1186/s12939-018-0828-7#citeas>

⁵² Bell, S.K., Dong, J., Ngo L., McGaffigan, P., Thomas, E.J., & Bourgeois, F. (2022 February 4). Diagnostic error experiences of patients and families with limited English-language health literacy or disadvantaged socioeconomic position in a cross-sectional US population-based survey. *BMJ Quality & Safety*, Published Online. <https://qualitysafety.bmj.com/content/early/2022/02/03/bmjqs-2021-013937>

⁵³ Cooper, L.A., Roter, D.L., Carson, K.A., Beach, M.C., Sabin, J.A., Greenwald, A.G., & Inui, T.S. (2012 March 15). The associations of clinicians' implicit attitudes about race with medical visit communication and patient ratings of interpersonal care. *American Journal of Public Health* 102(5): 979-87. <https://pubmed.ncbi.nlm.nih.gov/22420787>

negatively impact healthcare quality and patient safety.^{54, 55, 56, 57} Additionally, outcomes measures and algorithmic tools used in medical settings can have unintended biases that can exacerbate healthcare challenges for marginalized groups.^{58, 59} Community challenges can compound these disadvantages, since people living in under-resourced areas often lack access to medical care^{60, 61} and receive care from hospitals that, due to longstanding structural inequities, may not have the necessary staffing or resources to implement best practices for ensuring patient safety.⁶² As such, improving patient safety throughout the healthcare system, with a special focus on patients from socially marginalized groups, is critical to advancing health equity.^{63, 64}

⁵⁴ Cohen, R. G., Cooke, D. T., Erhunmwunsee, L., Krohn, C., Sudarshan, M., Wallace, A., & Moffatt-Bruce, S. (2022 October 29). Cultural Diversity, Bias, and Patient Safety: A Case-Based Discussion. *The Annals of Thoracic Surgery*, 115(3): 555-61. [https://www.annalsthoracicsurgery.org/article/S0003-4975\(22\)01389-3/fulltext#articleInformation](https://www.annalsthoracicsurgery.org/article/S0003-4975(22)01389-3/fulltext#articleInformation)

⁵⁵ Howell, E.A., Brown, H., Brumley, J., Bryant, A.S., Caughey, A.B., Cornell, A.M., Grant, J.H., Gregory, K.D., Gullo, S.M., Kozhimannil, K.B., Mhyre J.M., Toledo, P., D’Oria R., Ngoh, M., & Grobman, W.A. (2018 April 23). Reduction of Peripartum Racial and Ethnic Disparities: A Conceptual Framework and Maternal Safety Consensus Bundle. *Journal of Obstetric, Gynecologic & Neonatal Nursing*, 47(3): 275-89. [https://www.jognn.org/article/S0884-2175\(18\)30064-9/fulltext](https://www.jognn.org/article/S0884-2175(18)30064-9/fulltext)

⁵⁶ Haider, A.H., Schneider, E.B., Sriram, N., Scott, V.K., Swoboda, S.M., Zogg, C.K., Dhiman, N., Haut, E.R., Efron, D.T., Pronovost, P.J., Freischlag, J.A, Lipsett, P.A., Cornwell, E.E., MacKenzie, E.J., & Cooper, L.A. (2015 June). Unconscious Race and Class Biases among Registered Nurses: Vignette-Based Study Using Implicit Association Testing. *Journal of the American College of Surgeons*, 220(6): 1077-86. https://journals.lww.com/journalacs/Abstract/2015/06000/Unconscious_Race_and_Class_Biases_among_Registered.20.aspx

⁵⁷ Haider, A.H., Schneider, E.B., Sriram, N., Dossick, D.S., Scott, V.K., Swoboda, S.M., Losonczy, L., Haut, E.R., Efron, D.T., Pronovost, P.J., Freischlag, J.A, Lipsett, P.A., Cornwell, E.E., MacKenzie, E.J., & Cooper, L.A. (2014 September). Unconscious race and class bias: Its association with decision making by trauma and acute care surgeons. *Journal of Trauma and Acute Care Surgery*, 77(3): 409-16. https://journals.lww.com/jtrauma/Abstract/2014/09000/Unconscious_race_and_class_bias_Its_association.3.aspx

⁵⁸ The White House. (2022 October). Blueprint for an AI Bill of Rights: Making Automated Systems Work for the America People. *Office of Science and Technology Policy*. <https://www.whitehouse.gov/wp-content/uploads/2022/10/Blueprint-for-an-AI-Bill-of-Rights.pdf>

⁵⁹ Krumholz, H.M., & Bernheim, S.M. (2014 December 2). Considering the Role of Socioeconomic Status in Hospital Outcomes Measures. *Annals of Internal Medicine*, 161(11):833-4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5459391/>

⁶⁰ U.S. House of Representatives. (2020 July). Left Out: Barriers to Health Equity for Rural and Underserved Communities. *Report of the Committee on Ways and Means Majority*. <https://sharenm.s3.amazonaws.com/library/U4ReG3RcofVn9WlAe04qsxK8et2upq0UMtvEVZjz.pdf>

⁶¹ Lam, O., Broderick, B., & Toor, S. (2018 December 12). How far Americans live from the closest hospital differs by community type. *Pew Research Center*. <https://pewrsr.ch/2L2nthb>

⁶² Viscardi, M.K., French, R., Brom, H., Lake, E., Ulrich, C., & McHugh, M.D. (2022 January 5). Care Quality, Patient Safety, and Nurse Outcomes at Hospitals Serving Economically Disadvantaged Patients: A Case for Investment in Nursing. *Policy, Politics, & Nursing Practice*, 23(1):5-14. https://journals.sagepub.com/doi/10.1177/15271544211069554?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

⁶³ Chin, M.H. (2021 April 19). Advancing health equity in patient safety: a reckoning, challenge and opportunity. *BMJ Quality & Safety*, 30: 356-61. <https://qualitysafety.bmj.com/content/30/5/356>

⁶⁴ Schulson, L.B., Thomas, A.D., Tsuei, J., and Etchegaray, J.M. (2022 August 8). Identifying and Understanding Ways to Address the Impact of Racism on Patient Safety in Health Care Settings. *Santa Monica, CA: RAND Corporation*. https://www.rand.org/pubs/research_reports/RRA1945-1.html

Recommendation 3: Partner with Patients and Reduce Disparities in Medical Errors and Adverse Outcomes.

It is crucial to engage relevant stakeholders in the nation’s effort to reduce harm from unsafe care. This should include partnering and collaborating with the 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 collaborating with those communities that have experienced long-standing disparities. For example, disparities in receiving timely, effective care for hypertensive disorders of pregnancy and post-partum complications such as cardiomyopathy, hemorrhages, and pulmonary emboli, substantially contribute to disparities in maternal morbidity.⁶⁵ These symptoms require careful, urgent, and non-biased assessment, which Black patients and people from other marginalized groups are less likely to experience. The issue of healthcare disparities is longstanding and complex, and the recommendations below should not be considered as comprehensive. Rather, they may serve as a complement to other ongoing efforts, including a National Academies committee that conducted an analysis of federal policies that contribute to health disparities⁶⁶ and an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine that is examining the current state of racial and ethnic healthcare disparities in the U.S., including barriers to successful implementation of evidence-based solutions.⁶⁷ To partner with patients and reduce and eliminate disparities in patient safety, the President should direct the following activities.

Recommendation 3. A

Implement a “Whole of Society Approach” in the Transformational Effort on Patient Safety.

All relevant federal agencies, committees, and advisory groups should establish policies, structures, budgets, and training for diversifying input on patient safety performance, advancing information at all levels, and implementing evidence-based solutions for tangible progress in advancing healthcare equities for all Americans. Federal agencies should seek meaningful and robust participation of experts in racism and intersectionality; diverse healthcare workers, patients, family members, and patient and community organizations, including people who have experienced harm from unsafe care, patients from communities who experience marginalization; and people who have experienced higher rates of harm such as people with severe mental illness, physical and neurocognitive disabilities, and degenerative conditions such as Parkinson’s disease, frontal-temporal dementia, and Alzheimer’s disease. Patients, families, and community members should be involved in the development (“co-production”) of all phases of patient safety planning, programming, assessment, monitoring and evaluation. There should be a meaningful and transparent process for frontline healthcare workers, patient advocates, family members, and patient and community organizations to participate in all actions related to patient safety. Specifically, community members with lived experiences should be encouraged and or incentivized for sharing their expert advice in this process, such as with financial reimbursements for time and effort. HHS, DoD, DoJ, and VA should establish

⁶⁵ The Joint Commission. (2022 July 27). Diagnostic Overshadowing Worsens Health Disparities. *Blog: Advancing Health Care Equity*. <https://www.jointcommission.org/resources/news-and-multimedia/blogs/advancing-health-care-equity/2022/07/diagnostic-overshadowing-worsens-health-disparities/#.ZCbh1hXMK5e>

⁶⁶ National Academies of Sciences, Engineering, and Medicine (2023). *Federal Policy to Advance Racial, Ethnic, and Tribal Health Equity*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26834>

⁶⁷ *Unequal Treatment Revisited: The Current State of Racial and Ethnic Disparities in Healthcare*. Accessed: 2023 August). National Academies of Sciences, Engineering, and Medicine. <https://www.nationalacademies.org/our-work/unequal-treatment-revisited-the-current-state-of-racial-and-ethnic-disparities-in-healthcare>

competitive awards and other incentives for capacity building for patients, family members, and patient or community organizations to enable diverse input into the co-development of patient safety solutions.

Recommendation 3.B

Improve Data and Transparency to Reduce Disparities.

To improve data and transparency to reduce disparities, the President should direct the Secretary of HHS to require AHRQ to lead the development and validation of new questions focused on racial/ethnic bias and patient safety in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, allowing CMS to require collection of patient perceptions of racial/ethnic bias and patient safety through existing surveys. CMS should incentivize healthcare facilities to collect self-reported patient race/ethnicity information as part of their safety improvement efforts. AHRQ should encourage patient safety organizations (PSOs) to collect, analyze, and disseminate information on racial and ethnic disparities in patient safety. The Secretary of HHS should draft a national patient safety rights charter that includes concepts such as patient rights to safety, respect, autonomy, reliable care, information and transparency, and promotes the concept of safe, respectful care as a patient's right.

Root Causes, Successes, and Ongoing Challenges

Over the past 20 years, patient safety experts have developed effective evidence-based practices such as practices to reduce some hospital acquired infections and increase medication safety, but uniform, nationwide implementation of these strategies is lacking.⁶⁸

Hospitals that have implemented evidence-based solutions, however, have markedly reduced patient harm and death due to medical errors. For example, the implementation of evidence-based solutions in local hospitals, including solutions for central line-associated bloodstream infection (CLABSI)⁶⁹ and surgical site infections,⁷⁰ have been successful in reducing harm to patients. However, systemic improvements in quality of care—which depend on various factors including institution type and

⁶⁸ Bates, D. W., & Singh, H. (2018 November). Two Decades Since *To Err Is Human*: An Assessment Of Progress And Emerging Priorities In Patient Safety. *Health Affairs*, 37(11): 1736-1743.

<https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.0738>

⁶⁹ Berenholtz, S.M., Lubomski, L.H., Weeks, K., Goeschel, C.A., Marsteller, J.A., Pham, J.C., Sawyer, M.D., Thompson, D.A., Winters, B.D., Cosgrove, S.E., Yang, T., Louis, T.A., Lucas, B.M., George, C.T., Watson, S.R., Albert-Leshner, M.I., St. Andre, J.R., Combes, J.R., Bohr, D., Hines, S.C., Battles, J.B., & Pronovost, P.J. (2014 January). Eliminating Central Line-Associated Bloodstream Infections: A national patient safety imperative. *Infection Control & Hospital Epidemiology*, 35(1): 56-62. <https://pubmed.ncbi.nlm.nih.gov/24334799/>

⁷⁰ Schaffzin, J.K., Harte, L., Marquette, S., Zieker, K., Wooton, S., Walsh, K., & Newland, J.G. (2015 November). Surgical Site Infection Reduction by the Solutions for Patient Safety Hospital Engagement Network. *Pediatrics*, 136(5): e1353-60. <https://publications.aap.org/pediatrics/article-abstract/136/5/e1353/33788/Surgical-Site-Infection-Reduction-by-the-Solutions?redirectedFrom=fulltext>

leadership,⁷¹ hospital resources,⁷² staffing,⁷³ training and wellness,⁷⁴ and workplace culture⁷⁵—have proven difficult to bring to scale on a volunteer basis, or to sustain.⁷⁶ PCAST’s recommendations propose solutions for accelerating the adoption of evidence-based solutions, while providing hospital systems and staff with the resources necessary to do so.

One bright spot has been the successes resulting from learning health networks that have convincingly reduced harm rates. Successful examples include CMS’s [Partnership for Patients](#), which helped to prevent 20,500 hospital deaths between 2014-2017,⁷⁷ and regional networks such as Solutions for Patient Safety, a national consortium of children’s hospitals who voluntarily share data and ideas to reduce harm.⁷⁸ PCAST celebrates these efforts and offers recommendations for expanding their reach and effectiveness. At the same time, PCAST recognizes that the healthcare organizations’ executive leadership, Boards, and culture will be critical to the success in any endeavor that seeks to reduce patient harm.

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 and evidentiary foundations for safe healthcare, so that errors, injuries and healthcare disparities are minimized. Promising directions include harnessing new practices and

⁷¹ Longo, D.R., Hewett, J.E., Ge, B., Schubert, S., & Kiely, R.G. (2007 May/June). Hospital Patient Safety: Characteristics of Best-Performing Hospitals. *Journal of Healthcare Management*, 52(3): 188-204; discussion 204-5. <https://www.proquest.com/docview/206738804?pq-origsite=gscholar&fromopenview=true>

⁷² Encinosa, W.E., & Bernard, D.M. (2005 February). Hospital Finances and Patient Safety Outcomes. *INQUIRY: The Journal of Health Care Organization, Provision, and Financing*, 42(1): 60-72. https://journals.sagepub.com/doi/10.5034/inquiryjrnl.42.1.60?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

⁷³ Shekelle, P.G. (2013 March 5). Nurse-patient ratios as a patient safety strategy: a systematic review. *Annals of Internal Medicine*, 158(5): 404-09. https://www.acpijournals.org/doi/full/10.7326/0003-4819-158-5-201303051-00007?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org

⁷⁴ Trockel, M.T., Menon, N.K., Rowe, S.G., Stewart, M.T., Smith, R., Lu, M., Kim, P.K., Quinn, M.A., Lawrence, E., Marchalik, D., Farley, H., Normand, P., Felder, M., Dudley, J.C., & Shanafelt, T.D. (2020 December 7). Assessment of Physician Sleep and Wellness, Burnout, and Clinically Significant Medical Errors. *Journal of the American Medical Association (JAMA) Network Open*, 3(12): e2028111. <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2773777>

⁷⁵ Weller, J., Boyd, M., & Cumin, D. (2014 January 7). Teams, tribes and patient safety: overcoming barriers to effective teamwork in healthcare. *Postgraduate Medical Journal*, 90(1061):149-54. <https://academic.oup.com/pmj/article-abstract/90/1061/149/6992009?redirectedFrom=fulltext>

⁷⁶ Toor, H., Farr, S., Savla, P., Kashyap, S., Wang, S., Miulli, D.E. (2022 March). Prevalence of Central Line-Associated Bloodstream Infections (CLABSI) in Intensive Care and Medical-Surgical Units. *Cureus*. 2022 Mar 3;14(3):e22809. doi: 0.7759/cureus.22809c. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8976505/>

⁷⁷ Department of Health and Human Services (HHS). (2019 January). AHRQ National Scorecard on Hospital-Acquired Conditions Updated Baseline Rates and Preliminary Results 2014–2017. *Agency for Healthcare Research and Quality (AHRQ), Healthcare-Associated Infections Program, National Scorecard Reports*. <https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/hacreport-2019.pdf>

⁷⁸ Lyren, A., Brill, R.J., Zieker, K., Marino, M., Muething, S., & Sharek P.J. (2017 August 16). Children's Hospitals' Solutions for Patient Safety Collaborative Impact on Hospital-Acquired Harm. *Pediatrics*, 140(3): e20163494. <https://publications.aap.org/pediatrics/article-abstract/140/3/e20163494/38408/Children-s-Hospitals-Solutions-for-Patient-Safety?redirectedFrom=fulltext>

technologies for assisting with medication selection and management, as well as diagnosis, monitoring, and predictions about treatment effectiveness based on individual characteristics.

Recommendation 4.A

Develop a National Patient Safety Research Agenda.

HHS through CDC, NIH, and other relevant agencies should develop a ten-year research and development program to harness advances in human factors, safety science, computer science, and health technologies to address health care safety challenges including those linked to healthcare disparities. Safety science, as well as tools and technologies available today in prototype form and in limited deployments hold promise to rapidly increase the ability to predict risk of adverse outcomes, track harms, provide alerts in advance of potential errors, and to, more generally, guide decision making to enhance healthcare quality and reduce unsafe care. Safety enhancing technologies that make use of automated electronic health records as well as data available from devices and sensors touching the patient can enhance patient safety and healthcare quality and reduce the time and effort burden of data collection on health care teams. Special attention should be given to the potential for these advances to exacerbate existing disparities, and appropriate monitoring and safeguards for unintended consequences should be put in place.

Beyond component targeted solutions, more holistic and systems focused studies are needed to understand and address systems-level failures. Leveraging knowledge and experience from the commercial air-transport industry safety efforts, system-level approaches should include empowering hospitals and other elements of the health care system with safety-critical methods, transparency, and a culture of safety. Additionally, studies should focus on improved understanding of disparities, e.g., through stratification of outcomes by demographic and other factors such as geographic-level and hospital characteristics, and reduction of disparities, e.g., through the deployment of interventions focused on mitigating the effects of structural and social barriers and addressing biases in healthcare delivery. Given the challenge of predicting the effects over time of introducing new programs and interventions to healthcare organizations and to the larger U.S. healthcare system, explicit research and reporting of results should be focused on monitoring the influences of recommended mitigations, with a special focus on progress on mitigating disparities in healthcare delivery.

Recommendation 4.B

Harness Revolutionary Advances in Information Technologies.

Multiple information technologies hold great opportunity for enhancing patient safety, including new forms of event capture from logs, non-invasive sensing and monitoring, data analytics tools, and AI methods for diagnosis, prediction, and generation in healthcare.

As mentioned under recommendation 4.A, advances in information technologies can decrease the data collection burden on front-line healthcare workers while also providing rapid insights into risks of adverse outcomes via visualizations and summaries that can help to guide mitigations.

AI methods for performing diagnosis and prediction from findings in patient data are particularly ripe for being harnessed to boost the accuracy and timeliness of diagnosis and therapy. Applications of AI to date are largely research prototypes with limited deployments. While special care and caution are needed to validate performance on different tasks and effort is needed to integrate AI advances into operational services, including the development of effective designs for human practitioner-AI

interaction,⁷⁹ much more can be done on research, validation, and in the maturation of applications.⁸⁰ AI, particularly the rapid developments in machine learning, when carefully honed, integrated, and leveraged in healthcare environments, hold opportunity to significantly address patient safety challenges in both hospital and outpatient settings. These tools can effectively support clinicians in decision-making, providing advice (e.g., differential diagnoses, ideal testing, information gathering), reminders (e.g., alerts about potentially overlooked evidence-based practices for safety), summaries (e.g., initial drafts of I-PASS reports in support of team transitions), and focusing attention through their capabilities in diagnosis, prediction, treatment planning, and language-based analysis.^{81,82,83,84,85} Prominent among the emerging technologies are traditional *supervised machine learning* and the more recent *self-supervised technologies*. The latter include recent developments with general-purpose *foundation* models, also referred to as *large language models* (LLMs). These models and their applications in healthcare are nascent yet show early promise for being leveraged in administrative tasks and, with careful testing and validation, with assisting with clinical decision making.^{86, 87, 88, 89,}^{90, 91} While there is opportunity ahead with the harnessing of recent developments with LLMs in

⁷⁹ Fogliato, R., Chappidi, S., Lungren, M., Fisher, P., Wilson, D., Fitzke, M., Parkinson, M., Horvitz, E., Inkpen, K., & Nushi, B. (2022 June 20). Who Goes First? Influences of Human-AI Workflow on Decision Making in Clinical Imaging. *2022 Association for Computing Machinery (ACM) Conference on Fairness, Accountability, and Transparency*, 1362-74. <https://dl.acm.org/doi/abs/10.1145/3531146.3533193>

⁸⁰ Coalition for Health AI (CHAI). (2023 April 4). Blueprint for Trustworthy AI Implementation Guidance and Assurance for Healthcare. <https://www.coalitionforhealthai.org/papers/blueprint-for-trustworthy-ai-V1.0.pdf>

⁸¹ Bayati, M., Braverman, M., Gillam, M., Mack, K.M., Ruiz, G., Smith, M.S., & Horvitz, E. (2014 October 8). Data-Driven Decisions for Reducing Readmissions for Heart Failure: General Methodology and Case Study. *PLOS One Medicine*, 9(10): e109264. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0109264>

⁸² Henry, K.E., Hager, D.N., Pronovost, P.J., & Saria, S.A. (2015 August 15). A targeted real-time early warning score (TREWScore) for septic shock. *Science Translational Medicine*, 7(299): 299ra122. <https://www.science.org/doi/abs/10.1126/scitranslmed.aab3719>

⁸³ Wiens, J., Campbell, W.N., Franklin, E.S., Gutttag, J., & Horvitz, E. (2014 July 15). Learning Data-Driven Patient Risk Stratification Models for Clostridium difficile. *Open Forum Infectious Diseases Advance Access*, 1(2): ofu045. <https://academic.oup.com/ofid/article/1/2/ofu045/1462831>

⁸⁴ Hauskrecht, M., Batal, I., Valko, M., Visweswaran, S., Cooper, G.F., & Clermont, G. (2013 February). Outlier detection for patient monitoring and alerting. *Journal of Biomedical Informatics*, 46(1): 47-55. <https://www.sciencedirect.com/science/article/pii/S1532046412001281>

⁸⁵ Lee, D.H., Yetisgen, M., Vanderwende, L., & Horvitz, E. (2020 July). Predicting Severe Clinical Events by Learning about Life-Saving Actions and Outcomes using Distant Supervision. *Journal of Biomedical Informatics*, 107: 10425. <https://www.sciencedirect.com/science/article/pii/S1532046420300538>

⁸⁶ Singhal, K., Azizi, S., Tu, T., et al. (2023 July). Large language models encode clinical knowledge. *Nature* 620, 172-180 (2023). <https://doi.org/10.1038/s41586-023-06291-2>

⁸⁷ Nori, H., King, N., Mayer McKinney, S., et al. (2023 March). Capabilities of GPT-4 on Medical Challenge Problems, *arXiv*. <https://arxiv.org/abs/2303.13375>

⁸⁸ Lee, P., Bubeck, S., Petro, J. (2023 March). Benefits, limits, and risks of GPT-4 as an AI chatbot for medicine. *New England Journal of Medicine*. <https://www.nejm.org/doi/10.1056/NEJMSr2214184>

⁸⁹ Kanjee, Z., Crowe, B., Rodman, A. (2023 July 3). Accuracy of a Generative Artificial Intelligence Model in a Complex Diagnostic Challenge. *Journal of the American Medical Association (JAMA)*, 2023;330(1):78-80. doi:10.1001/jama.2023.8288. <https://jamanetwork.com/journals/jama/fullarticle/2806457>

⁹⁰ Dash, D., Thapa, R., Banda, J. M., Swaminathan, A., et al. (2023 May 1). Evaluation of GPT-3.5 and GPT-4 for supporting real-world information needs in healthcare delivery. *arXiv*. <https://arxiv.org/abs/2304.13714>

⁹¹ Strong, E., DiGiammarino, A., Weng, Y., et al. (2023 July 17). Chatbot vs Medical Student Performance on Free-Response Clinical Reasoning Examinations. *JAMA Intern Med*. doi:10.1001/jamainternmed.2023.2909 <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2806980>

healthcare applications, enthusiasm needs to be tempered with careful research and evaluation, and considerations of regulatory oversight with uses.⁹²

HHS, through its relevant agencies, including the National Library of Medicine (NLM), AHRQ, CDC, and NIH, in collaboration with the FDA should consider establishing a program of **AI for Patient Safety**, aimed at pooling and sharing best practices, specifying systems, collecting, and making available patient-safety datasets, sharing models and practices, and providing information on integration of technologies for sensing and monitoring, data analytics, and AI systems within current workflows of hospitals. The AI for Patient Safety Program suggested here should work to develop and deploy AI technologies as they are validated, particularly with fast-paced advances in machine learning, on promising directions for patient safety. These efforts should include the list of high-priority harms as an initial focus.

Box 3: Agency collaboration to organize federal healthcare datasets

The NIH, DoD, and VA should coordinate with one another to identify, catalogue, and digitize federal healthcare datasets for use in AI in health care research. For example, the pathology glass slide assets hosted at the Joint Pathology Center can be digitized and made available to unlock new powers of recognition and prediction for enhancing patient safety. That data and other anonymized, privacy-preserving research datasets can be made available to researchers for machine learning studies aimed at creating new technologies to advance excellence in diagnosis, treatment, planning, and disease management across health conditions.

While automated technologies leveraging AI tools hold significant promise when developed using health equity principles and practices, it is critically important to employ best practices, engineering principles, and monitoring methodologies to detect, characterize, and mitigate challenges with the safety and reliability of the systems and consider fairness, per biases arising in the data and downstream systems constructed from that data for patients of different backgrounds and demographics.^{93, 94}

Recommendation 4.C

Develop Federal Healthcare Delivery Systems' Capacities and Showcase Results as Exemplars for Safer Healthcare.

The DoD and VA are well positioned to develop federal health care delivery systems as leading prototypes for safer healthcare. The Secretaries of Defense, HHS, and VA should demonstrate their commitment to patient safety by facilitating implementation of PCASTs recommendations to prioritize dramatic patient safety and workforce safety improvements in their respective healthcare delivery systems, with measurements of systemic progress through regular, public reports to the

⁹² Meskó, B., & Topol, E. J., (2023 July 6). The imperative for regulatory oversight of large language models (or generative AI) in healthcare. *npj Digital Medicine*, 6:120. <https://doi.org/10.1038/s41746-023-00873-0>

⁹³ Parikh, R.B., Teeple, S., & Navathe, A.S. (2019 November 22) Addressing Bias in Artificial Intelligence in Health Care. *Journal of the American Medical Association (JAMA)*, 322(24): 2377-78. <https://jamanetwork.com/journals/jama/article-abstract/2756196>

⁹⁴ Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019 October 25). Dissecting racial bias in an algorithm used to manage the health of populations. *Science*, 366(6464): 447-53. <https://www.science.org/doi/10.1126/science.aax2342>

President. The aim should be bold and clear: Within the next five years, to make the Military Health System, and the Veterans Healthcare System outstanding, instructive examples of safer care for both the nation and internationally. The departments should provide forums to recognize exemplars in patient safety as well as share their best practices with other health systems with particular focus on supporting hospitals serving marginalized populations.

Building on Biden-Harris Administration Efforts

The Biden-Harris administration has taken key steps to improve the quality of healthcare for all Americans. These efforts have focused on tackling cancer,⁹⁵ the maternal health crisis,⁹⁶ expanding health insurance coverage,⁹⁷ lowering healthcare costs,⁹⁸ addressing algorithmic discrimination,⁹⁹ and advancing health equity.¹⁰⁰ In addition, federal agencies have made important progress in addressing patient safety through research, education and training, stakeholder engagement, and strengthening standards for healthcare quality. These efforts have been distributed across multiple Departments, including HHS, the Veterans Health Administration (VA), the Department of Defense (DoD), and the Department of Justice. Most recently, HHS launched the National Healthcare System Action Alliance, a learning community comprised of healthcare systems, federal partners, patients and families, and other stakeholders focused on advancing patient safety and healthcare worker safety.¹⁰¹

The combination of all of these measures has provided a critical foundation for improving health and healthcare access for all Americans. The Biden-Harris Administration's momentum makes now the right time to renew our focus and commitment to improving patient safety. The next step to ensure benefits are shared by all Americans is to solidify leadership around patient safety at the national level while also ensuring strong roots of support for hospitals and practitioners who are working along all points in the spectrum from the federal to the local level. To that end, PCAST's recommendations suggest actions that can be taken to reduce medical errors and the harms that they cause. We are confident that these recommendations promote long-term strategies to leverage new

⁹⁵ The White House. Cancer Moonshot. <https://www.whitehouse.gov/cancermoonshot/>

⁹⁶ The White House. (2022 June 22). White House Blueprint for Addressing the Maternal Health Crisis. <https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf>

⁹⁷ The White House. (2021 January 28). Executive Order on Strengthening Medicaid and the Affordable Care Act. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/28/executive-order-on-strengthening-medicare-and-the-affordable-care-act/>

⁹⁸ The White House. (2022 April 5). FACT SHEET: Biden Harris Administration Proposes Rule to Fix “Family Glitch” and Lower Health Care Costs. <https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/05/fact-sheet-biden-harris-administration-proposes-rule-to-fix-family-glitch-and-lower-health-care-costs/>

⁹⁹ The White House. (2022 October). Blueprint for an AI Bill of Rights: Making Automated Systems Work for the America People. *Office of Science and Technology Policy*. <https://www.whitehouse.gov/wp-content/uploads/2022/10/Blueprint-for-an-AI-Bill-of-Rights.pdf>

¹⁰⁰ The White House. (2021 November 10). FACT SHEET: Biden Administration Announces New Investments to Support COVID-19 Response and Recovery Efforts in the Hardest-Hit and High-Risk Communities and Populations as COVID-19 Health Equity Task Force Submits Final Report. <https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/10/fact-sheet-biden-administration-announces-new-investments-to-support-covid-19-response-and-recovery-efforts-in-the-hardest-hit-and-high-risk-communities-and-populations-as-covid-19-health-equity-task/>

¹⁰¹ Agency for Healthcare Research and Quality (AHRQ). (2022). The National Healthcare System Action Alliance to Advance Patient Safety. <https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html>

methods to reduce medical errors along with recent advances in technology, human factors science, data science, and AI to achieve the goal of dramatically, measurably, and sustainably reducing patient harms from errors by 2030.

Even though measuring deaths and other harms linked to healthcare delivery is challenging and our aligned incentives recommendations are bold, audacious action is needed to diminish the large burden on patients and families resulting from medical errors, especially for groups that have been historically marginalized. We appreciate President Biden's keen interest to end suffering for American patients and the opportunity the President has given PCAST to provide recommendations that can dramatically reduce, if not eliminate, patient harm and suffering.

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Appendix A: External Experts Consulted

PCAST sought input from a diverse group of additional experts and stakeholders. PCAST expresses its gratitude to those listed here who shared their expertise. They did not review drafts of the report, and their willingness to engage with PCAST on specific points does not imply endorsement of the views expressed herein. Responsibility for the opinions, findings, and recommendations in this report and for any errors of fact or interpretation rests solely with PCAST.

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