Public Meeting of the

President's Council of Advisors on Science and Technology (PCAST)

July 27-28, 2023

Meeting Minutes

MEETING PARTICIPANTS

PCAST MEMBERS

1. Frances Arnold, Co-Chair
2. Arati Prabhakar, Co-Chair
3. Maria T. Zuber, Co-Chair
4. Dan E. Arvizu
5. Dennis Assanis
6. John Banovetz
7. Frances Colón
8. Lisa A. Cooper
9. John O. Dabiri
10. William Dally
11. Sue Desmond-Hellmann
12. Inez Fung
13. Andrea Goldsmith
14. Laura H. Greene
15. Paula Hammond
16. Eric Horvitz
17. Joe Kiani
18. Jon Levin
19. Steve Pacala
20. Saul Perlmutter
21. William Press
22. Jennifer Richeson
23. Vicki Sato
24. Lisa Su
25. Kathryn Sullivan
26. Terence Tao
27. Phil Venables
28. Catherine Woteki

PCAST STAFF

1. Lara Campbell, Executive Director
2. Reba Bandyopadhyay, Deputy Executive Director
3. Bich-Thuy (Twee) Sim, Assistant Director for Transformative Medicine and Health Innovation
4. Karin Saoub, AAAS Science and Technology Policy Fellow
5. Kimberly Lawrence, Administrative Assistant
6. Maya Millette, EOP/OSTP Intern

START DATE AND TIME: THURSDAY, JULY 27, 2023, 11:10 A.M. Eastern Time

LOCATION: Virtual Meeting via Zoom.gov

WELCOME

PCAST Co-chairs: Frances Arnold, Arati Prabhakar, Maria Zuber

The PCAST co-chairs—Frances Arnold, California Institute of Technology; Arati Prabhakar, Assistant to the President for Science and Technology; and Maria Zuber, Massachusetts Institute of Technology—called the meeting to order. Prabhakar noted that September's PCAST meeting would be held in person in Washington, DC. Prabhakar turned to Zuber to introduce the discussion of a letter to the President.

SESSION: DISCUSSION AND CONSIDERATION FOR APPROVAL OF PCAST LETTER TO THE PRESIDENT ON ADVANCING PUBLIC ENGAGEMENT WITH THE SCIENCES

Zuber introduced the session by noting that science communication plays a crucial role in today's world as scientific advancements and discoveries are constantly shaping our lives and the future of our society. Effective science engagement involves conveying complex or unfamiliar concepts in an understandable manner to audiences that include policymakers, the general public, and other stakeholders. For example, accurate and up-to-date information contributes to decision-making in areas such as public health and safety, environmental regulation, semiconductors, artificial intelligence (AI), and more. Conveying scientific concepts clearly and transparently builds public trust and facilitates adoption of science-based outcomes that could improve or even save lives. For all these reasons, science communication is of great interest to the members of PCAST. Zuber then introduced the co-leads of the science communications working group, Phil Venables, Vicki Sato, and Saul Perlmutter, who summarized the Letter to the President on *Advancing Public Engagement with the Sciences* and answered questions from PCAST members.

VICKI SATO

Sato said it is important to understand how to communicate more effectively with the public on matters of deep importance to individuals, families, and communities given that the language of science can be complex and that the nature of scientific understanding is that it is not static. Historically, Americans have had confidence that science and scientists will act in the public's best interests. Today, the rapidly changing information landscape, driven by modern technology, the continuing legacies of social inequities and abuse, and an overall decline of trust in institutions have negatively affected that confidence.

Americans want and deserve to have their values and priorities considered in decisions that affect their lives, said Sato. Therefore, it is important to create public polices informed by accurate scientific understanding and community values. The working group believes that the scientific community must provide access to accurate scientific information and facilitate a more vibrant dialogue between experts, communities, and the government agencies responsible for research and development.

Sato said the working group learned in talking to stakeholders that it is not enough to refine how the scientific community talks to the public. Rather, it is important to listen and create opportunities for community dialogue and incorporate the fruits of that dialogue into policies that better reflect the community's needs and values. The working group found examples from the past half century of community-informed science policy that have been rich, informative and constructive, and occasionally contentious. The letter to the President includes examples of community dialogue.

What is needed now, said Sato, is to shine a brighter light on this kind of dialogue, which led the working group to highlight in its letter to the President the importance for the nation's world-class science and technology agencies to amplify their engagement with the public. This letter is supported by research conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM), and engagement initiatives conducted by the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS). Research shows that enhanced community engagement done skillfully and transparently can be an important force for improving engagement with communities and conveying scientific advances, changes, and challenges to the public.

SAUL PERLMUTTER

Perlmutter presented the working group's recommendations. The first recommendation is to issue a clarion call to federal agencies to make science and technology communication and public engagement a core component of their mission and strategy, reflecting a concern the working group heard from multiple parties. An essential component of this effort will be ensuring that agency senior-level policy development and decision-making processes include experts in participatory public engagement.

Perlmutter said the working group also heard about advances in understanding how to reach and work with communities and statistically representative publics, and that specific expertise is necessary for determining how to do this type of engagement in the context of federal rules, e.g. the Paperwork Reduction Act. This need led to the working group's second recommendation to establish a new office to support federal agencies in their continuing efforts to develop and build participatory public engagement and effective science and technology communications. This office should consist of individuals with a range of expertise who can partner with or be deployed to agencies and who can assist agencies in using social science-informed techniques for participatory engagement and cutting-edge digital technologies. Two useful models for this proposed office are the U.S. Digital Service in the Office of Management and Budget and the 18F office in the General Services Administration.

The overall response to the letter and its shorter format was enthusiastic, said Perlmutter. Feedback included the suggestion to consider changing the "included in" wording to "have input to" policy development in the first recommendation, but the working group felt that a stronger imperative is needed to move from one-way, top-down "science communications" to two-way, participatory "science engagement." Another concern was the desire for a strong mandate for agencies to have the capacities that the second recommendation envisions rather than have that expertise in a new office that could siphon resources from in-house agency efforts. Addressing this concern is why the first sentence of the second recommendation emphasizes this new office should supplement and not supplant agency efforts. It can be difficult for agencies to build the necessary expertise. The proposed office could help by recruiting to meet its mandate and potentially providing a way for other agencies to not only find this support but also eventually recruit those experts.

Perlmutter concluded his remarks by quoting from the last paragraph of the letter to the President: "In part because of the historic leadership of the United States in innovation, in medicine, energy, digital technology, space exploration, and many other areas, we are recognized as a country of almost unlimited possibilities. These advances can not only be inspiring but also empowering for all Americans, offering tools for identifying problems and inventing solutions, but only if our communities understand that they own these tools as key participants in the decision-making process."

After the working group co-leads' presentation, discussion among PCAST members followed.

ZUBER MODERATED THE Q&A AND DISCUSSION BETWEEN PCAST MEMBERS AND VENABLES, SATO, AND PERLMUTTER

Zuber asked if the working group collected information or received input on the best way to structure the individuals who work on engagement within the agencies, whether having them within a single office within an agency or embedding those working in an area who will engage with the public. Venables replied the U.S. Digital Service is a good model because it balances providing a central capability that enables the development of expertise without supplanting the needed expertise and capability within the agencies. As agencies grow and integrate this function across their teams, they can call on this central service to supplement their activities. One core element of success in agencies and private sector organizations that drive this type of communication is to have a central set of experts but also have leaders engaged in all parts of a department or agency's activities. This is why the first recommendation calls for elevating those with public engagement expertise to be connected to agency activities as early as possible.

Arnold asked if the working group envisions this new office detailing people to the agencies and if the working group could provide a concrete example of the expertise that would be provided to the agencies. Sato answered it is important for this office to have the flexibility to be current regarding its expertise in the rapidly changing field of digital technologies and in the rapidly changing social sciences. She asked Lisa Cooper to provide examples from HHS where current practices and thinking in the social sciences are shaping interactions with the public.

Cooper said a good example is the Community Engagement Alliance Against COVID-19, where there was expertise at the level of one of the federal agencies leading this effort—the National Institutes of Health (NIH). There is broad representation of stakeholders in this partnership and bidirectional communication at every level for communicating research findings rapidly to the public. Before disseminating information, community partners provide input about the format of the materials, the presentation, the messaging, the appropriate vehicles for communication, and the appropriateness of the language. This is an excellent model because the partnership here provides ongoing engagement with the people, who have a voice and who have concerns related to the work being done. Another example is the office of communications at the National Heart, Lung, and Blood Institute, which provides expertise and a consultation service for its researchers that other federal scientists can access.

Jennifer Richeson added that involving the broader social sciences community, especially people with expertise in sampling, is required to understand what different communities think about different emergent technologies. Getting that information requires people with a different expertise than those who are communication experts.

Arnold asked if Richeson envisions this office having a staff of such experts that would be detailed to agencies on request for a specific project. Richeson said yes, and that it could be teams of experts detailed depending on the particular project and the messaging needed. Arnold wondered if there are other mechanisms to engage the broader community of social scientists rather than have a dedicated staff, and Richeson said probably not in a problem-focused manner given the subject matter expertise required. Perlmutter added it would be possible to hire outside contractors for specific expertise, and Venables pointed out that engagement can range from small consultation to seek advice to full-scale deployment

for extended periods to build capacity in an agency. Sato said that U.S. Digital Services has a renewing roster of fellows that serve as a broader community of experts across a variety of skillsets.

William Press asked if the working group considered guardrails that would prevent an administration from applying political pressure to miscommunicate science and engage with the public in a biased manner with a predetermined outcome. Sato replied the proposed office would be a nucleus for credibility, transparency, and neutrality that could survive different administrations. Perlmutter said the working group designed the office to have more capacity to listen to communities, rather than just speaking.

Andrea Goldsmith asked about the role of universities as partners with federal agencies in terms of how to engage the public and how to engage the best science communicators, such as Isaac Asimov and Stephen Hawking. Sato replied that universities are an important part of the communication ecosystem and many universities have established outward-facing science presentations about discoveries within their institution and on topics of general interest. Universities can also serve as a place where scientific integrity and responsibility to the public get instilled, and they can provide a broad range of independent voices. Perlmutter said agencies are seeking permission to develop programs with universities and other grantees to accomplish some of their communication goals.

Venables noted that as individual agencies develop effective practices for engaging the public, the central office can capture that, develop toolkits for those practices, and then promulgate them. This is something the U.S. Digital Service does. In the same way, the office could also promulgate effective methods for engaging universities.

Paula Hammond asked if the working group envisioned how to address misinformation that influences how a community receives or understands science without losing trust, and if the new office would have skillsets in this area. Perlmutter replied that having a dialogue in process before confronting misinformation makes a difference in how people react to learning they have been receiving incorrect information and whether they are receptive to changing their minds. Sato noted that the scientific community does not always do a good job communicating about the fluid nature of science.

Prabhakar said that President Biden, soon after taking office, issued a memorandum to all federal agencies and departments on scientific integrity and evidence-based policymaking because he sees it as fundamental for the public to have trust in government. The recommendations in the letter to the President should lay the groundwork for engaging more effectively in two-way communication to the benefit of science and society.

Eric Horvitz pointed out there are digital tools that can provide more rigorous and extensive information about different populations than traditional small surveys do. The new office could start leveraging novel ways to listen to understand where the American people are to help improve engagement. Perlmutter added it is important to clearly state that listening activities are intended to help understand what the public needs to hear to raise awareness in the agencies about the public's goals and interests.

Zuber remarked that one of NASA's original mandates was to engage the public, which it does exceptionally well. Part of NASA's approach has been to stress education and to use teams of ambassadors who are largely science teachers, but also workers in science museums, libraries, and other institutions where education is important. Given there are people who do not want to believe the government but tend to believe their children, having a strong focus on educating young people on good

scientific practices and results can have a secondary effect of educating parents and grandparents. Catherine Woteki added that the cooperative extension system, which has educators from land-grant universities engaging with the public in almost every U.S. county, is another effective model with important lessons.

With the discussion concluded, PCAST voted unanimously to accept the letter to the President on science engagement.

SESSION: DISCUSSION AND CONSIDERATION FOR APPROVAL OF PCAST REPORT TO THE PRESIDENT ON THE SEVENTH QUADRENNIAL ASSESSMENT OF THE NATIONAL NANOTECHNOLOGY INITIATIVE

Arnold introduced the session by noting that the National Nanotechnology Initiative (NNI) was established in the 1990s to help the United States stay at the forefront of the exciting new field of nanotechnology and nanoscience. Since then, scientists have learned to manipulate matter at the nanoscale, resulting in discovery of new phenomena and new products making it to the market, and much of the vision for the NNI has been realized. She then introduced the co-leads of the PCAST working group to assess the NNI, Lisa Su and William Dally, who summarized the report's findings and recommendations and answered questions from PCAST members.

LISA SU

Su said nanotechnology research has been critical to U.S. innovation and is now essential to many industries. Liquid nanoparticles, for example, were the crucial delivery vehicle for over 676 million doses of mRNA COVID-19 vaccines administered in the United States, and nanomaterials have become important for developing next-generation energy technologies. Some 3,700 companies identifying as nanotechnology enterprises generated $42 billion in revenue and employed 171,000 workers in 2017. Many more companies employ nanotechnology as part of their broader business portfolio, making nanotechnology a substantial contributor to the U.S. economy.

Su reviewed the history of the NNI, which Congress authorized through the 21st Century Nanotechnology Research and Development Act of 2003. She noted the role of the National Science and Technology Council's (NSTC) Nanoscale Science, Engineering, and Technology (NSET) Subcommittee and the National Nanotechnology Coordination Office (NNCO) as the governance infrastructure that coordinates activities that support nanotechnology research and funding.

WILLIAM DALLY

Dally said it was clear from the working group's discussions with various agency representatives and external experts working in the field that nanotechnology has evolved and matured in the 20 years since the NNI began, with today's work in nanotechnology focused more on the development and applications across materials. Given that, the machinery put in place when nanotechnology was an emerging field—the NNCO and NSET—is no longer the right machinery for a technology in its mature phase. Biennial reviews by PCAST and the National Academies are no longer needed, and it is not clear that a coordination office is needed for this now mature field. Therefore, the working group considered how federal coordination of nanotechnology research should be continued to best serves the science and the American people.

The working group's first recommendation, said Dally, is for the President to work with Congress to sunset or revise substantially the 21st Century Nanotechnology Research and Development Act. However, nanotechnology remains important to the United States economy, and the federal government should continue to support research and development, infrastructure, education, and research in this area.

Dally said the second recommendation calls for the director of OSTP to work with the executive director of the NSET Council to direct the NSET subcommittee to continue leading federal coordination of nanotechnology strategic planning, implementation, and outreach. The working group concluded that the NSET subcommittee is the right body to continue doing this job under whatever streamlining or sunsetting occurs as a result of the first recommendation.

The third recommendation, said Dally, calls for the NSET subcommittee to enhance experiential learning programs for nanotechnology students and scientists to become the collaborative, multidisciplinary workforce needed for nanotechnology and other advanced technologies.

After the working group co-leads' presentation, discussion among PCAST members followed.

ARNOLD MODERATED THE Q&A AND DISCUSSION BETWEEN PCAST MEMBERS AND SU AND DALLY

Dally explained the primary function of NSTC's NSET subcommittee is to coordinate with different federal agencies involved in nanotechnology so that their work dovetails well together, is not duplicative, and does not leave gaps. Prabhakar added that NSTC is a long-standing coordination body with various committees and subcommittees that span federal research and development activities and serve as a platform for coordination.

Greene asked how the working group envisioned the NSET subcommittee working to coordinate various applications and ensure that science is not lost as it goes across agencies. She also asked how the federal government would repurpose or make use of the well-established nanotechnology centers the federal government has supported. Dally replied that the working group is not recommending sunsetting the infrastructure and shared research and development facilities or that there be less research and development in nanotechnology. Those facilities are getting good use and delivering good value to the scientific community, and the NSET subcommittee is doing a good job of coordination. The underlying technology has become mature and the real action now is in applying that technology, which means the coordinating structure needs to evolve to best focus resources on applications. Su added the recommendations are about the mechanics of how the federal government invests in nanotechnology.

Desmond-Hellman asked how the working group feels about the state of maturity regarding the safety of nanotechnology manufacturing and discarding nanomaterials. Hammond said how nanomaterials interact with cells in the human body depends on the composition of the nanomaterial, so there is no single generalized set of rules or ideas around toxicity that encompasses all nanomaterial systems. While the science of nanomaterial safety has advanced to where there is a large body of data and good understanding, efforts should continue to understand toxicity issues. In nanomedicine, there has been extensive work looking at how safe nanoparticles are in the body, where they circulate and distribute, and what long-term impacts might be. Those studies exist in other areas of nanotechnology, which the Food and Drug Administration (FDA) and other regulatory agencies should continue to fund.

Zuber commented that in reviewing the report's examples of outstanding achievements in nanotechnology, she felt it is the right time to make the working group's recommendations.

Goldsmith asked if there are any examples of effective programs featuring multidisciplinary coursework across high schools, community colleges, universities, and industry. She also asked about the partnerships the NSET subcommittee would need to effectively train a workforce across all four of those dimensions of the education ecosystem. Dally said the third recommendation was aimed at graduate-level education with the intent for students to become "multilingual" in different specializations. Su added that when the working group interviewed people in academia, the main suggestion was to encourage graduate students to take the time to be multidisciplinary versus becoming narrowly focused on a field. The NSET subcommittee has been considering how coordination can help broaden a multidisciplinary approach.

Sato asked if there will be a mechanism in the proposed coordinating structure to ensure that work in specific areas continues to get the financial and research support required to fund the next generation of advances and products. Prabhakar replied that those kind of decisions cannot come out of a consensus, information-sharing process. Rather, they must come from the federal research and development agencies that are deeply aware of where the research frontiers and big problems are. She expects that to continue. Dally explained the working group is suggesting changing the coordination function so that if multiple agencies were sponsoring similar projects or projects with overlapping technology needs, the coordination structure would get involved to connect people across agencies and ensure those efforts are harmonized.

Steve Pacala noted the possibility that generative AI might accelerate the exploration and production of new nanomaterials and asked if the working group discussed that possibility with respect to its recommendations. Dally replied there is a separate PCAST working group on generative AI that should look closely at that possibility.

Prabhakar noted that accomplishments tend to be counted based on the start of new things, but new things cannot start without stopping activities that started a few decades ago and have done what they needed to do. These recommendations are important for celebrating the work that has been accomplished while making room for the next generation of research.

With the discussion concluded, PCAST voted unanimously to accept the report to the President on the seventh assessment of the NNI.

PUBLIC MEETING ADJOURNED: THURSDAY, JULY 27, 2023, 18, 2:30 P.M. EASTERN TIME

MEETING RESUMED: FRIDAY, JULY 28, 2023, 11:05 A.M. EASTERN TIME

SESSION: DISCUSSION AND CONSIDERATION FOR APPROVAL OF PCAST REPORT TO THE PRESIDENT ON A TRANSFORMATIONAL EFFORT ON PATIENT SAFETY

Prabhakar opened the session by noting that patient safety has been the subject of concern and a great deal of work by PCAST. She then introduced the co-leads of the PCAST working group on patient safety,

Eric Horvitz and Joe Kiani, who summarized the report's findings and recommendations and answered questions from PCAST members.

ERIC HORVITZ

Horvitz said adverse events include but are not limited to misdiagnosis and delayed diagnosis, infections, bleeds, medication reactions, organ injuries, and falls. Despite well-intentioned patient safety incentive programs that the Centers for Medicare and Medicaid Services (CMS) has established, numerous studies have suggested these programs have fallen short of their intended objectives.

Horvitz mentioned four recent studies that provide a compelling snapshot of where the nation stands regarding preventable adverse events.

- A May 2022 report from the HHS Office of the Inspector General said adverse outcomes affected 23 percent of hospitalized Medicare patients, half of which better care could have prevented. The estimated cost to the nation was in the hundreds of millions of dollars. This report specifically criticized CMS's incentive programs as not applying to the majority of harm events patients experience.

- A December 2022 study by the Agency for Healthcare Research and Quality (AHRQ) found that approximately 6 percent of emergency department patients receive incorrect diagnoses. In all settings, 7.4 million misdiagnoses and 2.6 million adverse events linked to misdiagnoses occur each year in the United States.

- A January 2023 study conducted by investigators at Harvard Medical School found that adverse outcomes affected 23.6 percent of admissions, of which 22.7 percent were preventable and 9 percent were severe or catastrophic.

- A July 2023 study from researchers at the Johns Hopkins School of Medicine estimated that over 500,000 Americans are permanently disabled or die annually because of misdiagnosis. This study found that 15 diseases account for approximately 50 percent of all serious misdiagnosis harms, with stroke, sepsis, pneumonia, venous thromboembolism, and lung cancer accounting for some 40 percent of serious misdiagnosis harms. The Johns Hopkins team expressed hope that directing technical advances and refining practices to help physicians make more accurate diagnoses for these five disorders would result in significant progress on reducing adverse events from misdiagnoses.

The Harvard team, said Horvitz, emphasized that despite stunning advances in medical science, there are still important gaps in patient safety and noted that U.S. hospitals rely solely on voluntary reporting of adverse events, resulting in substantial undercounting. They also described the considerable variability they saw among hospitals in adverse event rates, with some sites showing adverse outcomes in over 40 percent of patient visits. They recommended identifying adverse events in electronic health records using computerization of triggers and leveraging AI.

Horvitz said the working group outlined four focus areas for recommendations to move the needle on improving patient safety. These include: (1) implementing reliable and efficient methods for measuring adverse events; (2) standardizing strategies to identify and mitigate preventable adverse events; (3)

highlighting crucial organizational elements such as promoting a culture of safety, encouraging participation and coordinating efforts on safety and quality; and (4) actively pursuing avenues for integrating technical advancements into clinical practices.

The working group's first overarching recommendation, said Horvitz, calls for establishing and maintaining federal leadership for improving patient safety as a national priority. Toward that end, the working group proposed that the President should establish a White House-led transformational effort on patient safety. The initiative should foster a comprehensive collaboration of government agencies to address critical patient safety challenges across both public and private sectors. The goal is to achieve long-term, tangible success by 2030 and to significantly, measurably, and sustainably minimize avoidable injuries to patients and health care workers and reduce disparities in patient safety.

In addition, said Horvitz, this recommendation charges the Secretary of HHS with the responsibility to coordinate these efforts across agencies with accountability to the President for progress and suggests the Secretary to report quarterly to the President to ensure sustained focus on these issues. It also calls for appointing a patient safety coordinator in the White House who reports to the President on efforts to transform patient safety across all relevant government agencies and engage non-government stakeholders in this work, thereby complementing cross-agency and cross-sector efforts, much like the coordinator for the Cancer Moonshot program. The working group also proposed that the President instruct the HHS Secretary to establish a dedicated, independent multidisciplinary National Patient Safety Team (NPST). NPST, modeled after the Commercial Aviation Safety Team, would study avoidable patient safety challenges and issue nonbinding, learning-focused safety recommendations. NPST would include people from populations most affected by adverse events as well as multidisciplinary clinical expertise, informatics and AI experts, data scientists, safety scientists, human factors experts, and insights from patients and their families.

Horvitz said the second overarching recommendation centers on ensuring that all patients receive evidence-based solutions for preventing harm and addressing risk. This recommendation advises the President to 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. It also suggests that CMS should revise its patient safety incentive program to only pay for the additional cost of certain hospital-acquired conditions if the hospital employed relevant evidence-based practices. Sub-recommendations call for:

- Identifying and addressing high-priority harms and promoting patient safety by incentivizing the adoption of evidence-based solutions and requiring annual public reporting immediately and quarterly public reporting within five years. Current programs only tackle some 2 to 5 percent of avoidable harms, even though researchers have made significant strides in formulating evidence-based solutions over the last two decades.

- Creating a learning ecosystem and shared accountability system in which HHS and health systems would work together to ensure that evidence-based practices are implemented and goals for reduced harms and risks of harm for all Americans are realized. To increase board and executive accountability for safety and quality oversight, CMS should add metrics and perform surveys that relate to health care organizations' executive leadership and board accountability for patient

safety. CMS should also promote implementing the Communication and Optimal Resolution Program to achieve resolutions in cases of patient harm.

- Advancing interoperability of health care data and ensuring free access to harms tracking data, within the constraints of the Health Insurance Portability and Accountability Act and use of evidence-based solutions.

- Improving safety for all health care workers and their patients by supporting a culture of patient and clinical safety in health care systems. The working group suggested that HHS, DoD, and VA work together to identify clinical workplace injuries, and that NPST should encourage implementing mechanisms that foster openness, feedback, psychological safety, reporting, and when necessary, whistleblowing protections.

The working group's third overarching recommendation, said Horvitz, is to partner with patients to reduce disparities and adverse outcomes. It is crucial to foster collaboration among stakeholders, including health care organizations and patients, families, and communities most affected by unsafe care, with special attention paid to studying and addressing long-standing inequities. To address these inequities, the working group called for implementing a "whole of society approach" for the transformational effort on patient safety. Federal agencies should seek meaningful and robust participation of diverse patients, family members, and patient and community organizations, including people who have experienced harm from unsafe care, patients from communities that experienced marginalization, and communities that have experienced higher rates of harm. In addition, HHS, DoD, and the VA should establish competitive awards for capacity building for patients, family members, and community organizations to enable diverse input to communication and co-development of patient safety solutions.

Horvitz said to advance data and transparency to reduce disparities, the working group recommends that the President direct the HHS Secretary to require AHRQ to develop and validate new questions for the Hospital Consumer Assessment of Healthcare Providers and System (HCAHPS) survey. HCAHPS, a patient satisfaction survey, should include assessments of racial and ethnic bias and safety, allowing CMS to gather data on patient perceptions of racial and ethnic bias. The working group also proposes that AHRQ should pursue and encourage efforts to collect, analyze, and disseminate information on racial and ethnic disparities in patient safety.

The working group's fourth recommendation, said Horvitz, calls for accelerating research and deployment of practices, technologies, and exemplary systems of care to minimize errors and injuries. Promising directions include harnessing new practices and technologies for assisting with medication selection and management, improving accuracy of diagnosis, shortening time to diagnosis, monitoring, and predicting treatment effectiveness based on individual characteristics. Sub-recommendations include:

- Developing a national patient safety research agenda for which HHS, CDC, NIH, and other relevant agencies should develop a 10-year research and development program to leverage computing, information, and health technologies to address health care safety challenges, particularly for marginalized populations.

- Harnessing revolutionary advances in information technologies, such as event capture from electronic health records, non-invasive monitoring, data analytics, and AI for diagnosis and

prediction. This should include developing an AI for patient safety program through relevant HHS agencies, collaborating with FDA to share best practices, patient safety datasets, and information on technology integration with hospital workflows.

- Pushing for fast-paced advances in federal health care delivery system capacities and showcasing results in those systems as exemplars for safer health care. DoD and the VA are well positioned to develop federal health care delivery systems as prototypes for safer health care.

Horvitz said the working group called for the Secretaries of Defense, HHS, and VA to demonstrate their commitment to patient safety by facilitating implementation of PCAST's recommendation to prioritize dramatic improvements in patient and workforce safety in their respective health care delivery systems and to measure systematic progress and results for regular reports to the President. The aim is to make the military health system and the veterans' health care system outstanding, instructive examples of safer care for both the nation and internationally over the next five years.

Horvitz said the four overarching recommendations form a foundation for a much-needed transformational initiative on patient safety. The overarching recommendations, complemented by their respective sub-recommendations, have the potential to amplify long-term endeavors by various agencies and organizations dedicated to reducing adverse outcomes in health care settings.

Horvitz highlighted several comments the working group received in feedback on the report. Some experts, for example, thought that conditions of participation (CoP) is too strong of a hammer and that it would be better to provide positive incentives. Responding to this comment, the working group put the ultimate decisions on the need or use of CoPs in the hands of the leaders of the proposed transformational effort. CoP already requires hospitals to track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms. The working group recommended reviewing and revising the definitions of preventable hospital-acquired conditions, creating new incentives processes and programs, and establishing accountability, reporting, and transparency requirements.

The working group, said Horvitz, sees evidence-based practices and these recommendations leading to large Medicare cost reductions given the hundreds of millions and perhaps billions of dollars wasted on preventable adverse events.

Another comment, said Horvitz, expressed concerns about the potential burden the recommendations might impose on small, safety net hospitals in poor financial circumstances. To address this concern, the working group introduced language that there should be coordination on the special needs of specific types of hospitals and that HHS should provide additional support to hospitals that lack adequate resources, such as safety net hospitals and those servicing disproportionately affected populations. It is expected there will be financial benefits to these hospitals by removing the CMS penalty of not paying for the cost of hospital-acquired conditions if they implement evidence-based practices. Given the data on inequities in quality of care, it is critically important to bring evidence-based practices to underserved communities.

A final comment was that quarterly reporting would be too difficult to implement and would lead to the report not being taken seriously. The working group changed the reporting requirement to yearly with the goal of shifting to quarterly reporting over five years.

After Horvitz's presentation, discussion among PCAST members followed.

PRABHAKAR MODERATED THE Q&A AND DISCUSSION BETWEEN PCAST MEMBERS AND HORVITZ AND KIANI

Dally commented that while the third recommendation mentions transparency in regard to reducing disparities, transparency could play a much larger role in getting systems to adopt evidence-based practices and reduce medical errors. As an analogy, he referred to the Insurance Institute publishing motor vehicle safety ratings and the effect that had on prompting manufacturers to make vehicles safer and achieve five-star safety ratings. Currently, there is no place to see which hospitals have a five-star patient safety rating and a larger or smaller than average incidence of medical errors. If available to the public, hospitals would be motivated to adopt those practices and improve their safety ratings.

Kiani replied that transparency is a big part of the recommendations as reflected by the call for hospitals to report preventable harms on their websites annually to start and eventually on a quarterly basis. Horvitz said there has been pushback on this idea, and the working group hopes that electronic tools will ease the burden of reporting. When asked if the working group envisioned any downsides to transparency, Kiani replied no based on the working group's discussions with experts who noted that public companies must report their sales and earnings quarterly to help investors decide where to make investments. While there is pushback, hospitals already do this internally since they review every adverse event on a much more regular basis than quarterly. Horvitz acknowledged that the recommendations must be monitored to understand their implications and effects on a complicated socio-technical system.

Terence Tao asked if there is a risk that hospitals or health care practitioners might have perverse incentives to maybe reclassify high-risk CoPs and other harms so they are less visible in their reports. Horvitz said the working group's report notes that leaders and coordinators must monitor this to understand the gaming that might occur, even inadvertently. Desmond-Hellman added that the culture and tone from the hospital chief executive officer is tremendously important for getting people to feel proud of reporting and working to improve if that is the expectation. Those who are enlightened will understand that the sooner they report a problem, the sooner they can enact a solution to avoid that problem. These errors rarely occur because of people acting badly, but rather because systems need improvement to avoid errors.

Cooper said she believes more in using incentives rather than disincentives because there is the potential for organizations such as safety net hospitals to be disadvantaged by policies that use disincentives. Prabhakar said there should be a healthy debate about which of those levers to use for safety net hospitals.

When asked about accountability, Kiani said the report focuses on action rather than results given there are evidence-based solutions that have proven to reduce medical errors. The accountability that the working group recommends is based on the idea that if someone gets harmed because an evidence-based solution was not implemented, the responsible party will not get paid. However, if an error occurs even if the responsible party has implemented an evidence-based solution, the incentive is that they will still be reimbursed.

Jon Levin asked how systems will be held accountable for errors when there is so much variability in the human body and across patients, which can make it hard to understand what went wrong in an individual

health episode. Horvitz replied the way the incentives work, partly in recognition of that variability, is there is no reimbursement penalty if evidence-based practices are in place. As far as comparing hospital performance, there is work on normalizing across hospitals to account for differences in the population for which a hospital might be responsible.

Zuber noted the recommendations call for providing additional help to safety net hospitals and those that serve disadvantaged communities, and she asked what happens if the additional resources are not available. Kiani replied that every one of the evidence-based practices the working group reviewed produces cost savings within a year of implementation. Quality and safety will help improve the bottom line of hospitals and payers such as Medicare. What will help is for CMS and HHS to help these hospitals identify and implement evidence-based solutions as a cost-saving measure. Horvitz added the report indicates it might be prudent to have carveouts for special case situations, such as financially strapped hospitals. Desmond-Hellman noted that, in developing its recommendations, the working group considered the undesirable outcome of hospitals closing. Cooper remarked that the working group needs to ensure the report has language addressing the concerns regarding disproportionate negative impacts on certain institutions.

Dally wondered if there is a need for an independent third party that would rate and report on data to ensure uniformity and consistency in reporting. Kiani replied that HHS, as it addresses preventable harms with evidence-based solutions, will develop a list of high-priority harms and how hospitals should report them. Achieving uniformity will take time, though.

When asked how to address the culture issues, Kiani said one thing CMS had done with CoP requirements is to ask boards, chairs, and chief executive officers to understand their hospitals' quality issues. The report recommends this, too. With both carrots and sticks, boards and executives should empower nurses and doctors to implement evidence-based solutions and create the right culture. An important part of creating a good culture, said Desmond-Hellman, is to engage everyone on staff, as well as patients and their families. Doing so creates a culture of patient-centric patient safety.

Dan Arvizu asked if there are additional incentives or perhaps mentorship programs that would help rural hospitals. Kiani replied there is a question whether the incentives and disincentives would be big enough to get them to implement evidence-based interventions given the cost-plus reimbursements these hospitals receive. However, interviews with safety net hospital leaders show they want to be as good at patient safety as big hospitals. What they are looking for is leadership. President Biden is a big advocate for patients, and directing HHS to make patient safety a priority could galvanize the country around this issue.

Andrea Goldsmith asked how the working group envisions its recommendations addressing the culture issue. Kiani replied the idea is that leadership from the President and HHS, this report, the dialogue the report will create, and the incentives and disincentives will make hospital administrators want to implement evidence-based solutions and establish the culture to support those solutions. This will not be an easy journey. However, discussions the working group had with hospital leaders made it clear that harm rates decreased significantly in hospitals that have implemented evidence-based solutions.

Cooper commented that although the working group did not do a deep dive into equity issues, it is an important and complex issue to address. The working group recognizes there will be issues arising that

disproportionately affect certain institutions and certain groups of people and that require further attention beyond the focus of this report. Horvitz noted the working group surveyed the literature on inequities, and it called out inequities as a critically important dimension to address. Kiani added that if every hospital implements evidence-based solutions, that will positively affect every race and gender. The report notes the importance of capturing data by race and ethnicity to identify inequities affecting marginalized people.

Pacala remarked that calling for independent auditing of hospital-generated data could have a big effect on culture, similar to how independent auditing of financial reporting affects corporate behavior. Auditing also enforces learning and can provide lessons on which evidence-based solutions work when scaled, for example. He asked if the working group searched for a way to anonymize audits to identify issues with implementation. Kiani replied that CMS already has a mechanism to audit hospitals, with some 5,000 surveyors that audit hospitals related to their CoPs. Once these evidence-based solutions are implemented and hospitals start reporting the results, the surveyors will be there to confirm the reported results. In addition, third-party accreditors, such as the Joint Commission, also audit hospitals, as does the HHS Office of the Inspector General.

With the discussion concluded, PCAST voted unanimously to accept the report to the President on a transformational effort on patient safety.

PUBLIC COMMENT

Sruthi Chilamakuri provided two minutes of public comment.

CLOSING COMMENTS

Arnold, Zuber, and Prabhakar thanked the members of PCAST and the PCAST staff for the months of research and hard work to develop the three reports. Prabhakar then adjourned the meeting.

PUBLIC MEETING ADJOURNED: FRIDAY, JULY 28, 2023, 12:10 P.M. Eastern Time

SUMMARY OF PREPARATORY MEETING

During the preparatory (closed) sessions, PCAST heard brief updates from its sub-committees and discussed the next steps for those efforts.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Frances Arnold, Ph.D.
Co-Chair
President's Council of Advisors on Science and Technology

Arati Prabhakar, Ph.D.
Co-Chair
President's Council of Advisors on Science and Technology

Maria Zuber, Ph.D.
Co-Chair
President's Council of Advisors on Science and Technology