

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL
ADVISORY COMMITTEE (PTAC)

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PUBLIC MEETING

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The Great Hall
The Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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Monday, June 15, 2026

PTAC MEMBERS PRESENT

TERRY L. MILLS, JR., MD, MMM, Co-Chair
SOIJANYA R. PULLURU, MD, Co-Chair
LINDSAY K. BOTSFORD, MD, MBA
LAWRENCE R. KOSINSKI, MD, MBA*
WALTER LIN, MD, MBA
KRISHNA RAMACHANDRAN, MBA, MS
DAVID C. TYSON, MA

PTAC MEMBERS IN PARTIAL ATTENDANCE

LAURAN HARDIN, MSN, FAAN*

PTAC MEMBERS NOT PRESENT

HENISH BHANSALI, MD, FACP
JAY S. FELDSTEIN, DO
JOSHUA M. LIAO, MD, MSc

STAFF PRESENT

MARSHA CLARKE, PhD, MBA, COR III, Designated
Federal Officer (DFO), Office of the
Assistant Secretary for Planning and
Evaluation (ASPE)
STEVEN SHEINGOLD, PhD, ASPE

*Via Zoom

A-G-E-N-D-A

Opening Remarks.....	3
Samuel Watters, Counselor, Immediate Office of the Secretary, U.S. Department of Health and Human Services Remarks.....	5
Abe Sutton, JD, Director, Center for Medicare and Medicaid Innovation (CMS Innovation Center), and Deputy Administrator, Centers for Medicare & Medicaid Services (CMS) Remarks...	13
Welcome and Co-Chair Update - Targeting Improvements in Patient Safety Through Alternative Payment Models Day 1.....	23
PTAC Member Introductions.....	26
PCDT Presentation: Targeting Improvements in Patient Safety Through Alternative Payment Models.....	31
Session 1: Approaches to Improve Patient Safety in Alternative Payment Models.....	63
- Susan E. Sheridan, MIM, MBA, DHL; Michelle Schreiber, MD; Susannah Bernheim, MD, MHS; Jason W. Mitchell, MD; and Dheerendra Kommala, MD	
Session 2: Measuring Patient Safety in Value- Based Care.....	142
- Jeffrey J. Geppert; Patrick S. Romano, MD, MPH; Commander Karen Chaves, MHS; and David C. Classen, MD, MS	
Session 3: Improving Patient Safety in Value- Based Care Through the Use of Health Information Technology and Data Analytics...	224
- Rollin J. (Terry) Fairbanks, MD, MS; Tejal Gandhi, MD, MPH, CPPS; Melissa Swanfeldt; and Aneesh Chopra, MPP	
Committee Discussion.....	297
Closing Remarks.....	315
Adjourn.....	315

P-R-O-C-E-E-D-I-N-G-S

(9:31 a.m.)

* CO-CHAIR PULLURU: Good morning and welcome to this meeting of the Physician-Focused Payment Model Technical Advisory Committee also known as PTAC. My name is Dr. Chinni Pulluru, and I'm one of the Co-Chairs of PTAC along with my colleague, Dr. Lee Mills.

Since 2020, PTAC has been exploring themes that have emerged from stakeholder-submitted proposals over the years. Previous PTAC themed discussions have focused on topics such as reducing barriers to participation in Alternative Payment Models and supporting primary and specialty care transformation, encouraging rural participation, using data and health information technology to transparently empower consumers and support providers, and improving multi-payer alignment and value-based care.

At this public meeting, we have brought together various subject matter experts to gain perspectives on targeting improvements in patient safety through Alternative Payment Models. We know that this topic is also of

1 interest to the Office of the Secretary at HHS¹
2 and the CMS² Innovation Center.

3 Before our first session of the day,
4 we are honored to have opening remarks from Mr.
5 Samuel Watters, Counselor in the Immediate
6 Office of the Secretary of HHS, and Mr. Abe
7 Sutton, Director of the CMS Innovation Center
8 and Deputy Administrator at CMS.

9 Mr. Watters' portfolio includes the
10 Center for Medicare and Center for Clinical
11 Standards and Quality, the Center for Program
12 Integrity, and the CMS Innovation Center, as
13 well as the Agency for Planning and Evaluation.
14 Guided by a commitment to patient safety, his
15 work at HHS centers on redesigning payment
16 incentives and coverage policies to drive
17 sustained investment in safety and quality
18 across health care settings.

19 Mr. Sutton, prior to assuming his
20 current role at CMS in January of 2025, served
21 as a principal at Rubicon Founders where he co-
22 founded two health service companies, Honest
23 Health, which focuses on enabling primary care
24 physicians, and Evergreen Nephrology, which

1 Health and Human Services

2 Centers for Medicare & Medicaid Services

1 focuses on enabling nephrologists. From 2017
2 to 2019, Mr. Sutton also served at the National
3 Economic Council, Domestic Policy Council, and
4 the Department of Health and Human Services.
5 In these roles, he coordinated health policy
6 across the federal government with the focus on
7 value-based care, increasing choice and
8 competition in health care markets, and
9 updating the federal government's approach to
10 kidney care.

11 First, we welcome Sam to speak, and
12 then we will move to Abe to share his remarks.

13 Sam?

14 * **Samuel Watters, Counselor, Immediate**
15 **Office of the Secretary, U.S.**
16 **Department of Health and Human**
17 **Services Remarks**

18 MR. WATTERS: Thank you very much.
19 Good morning, and thank you all for being here.
20 Thank you to the Committee and the Co-Chairs.
21 Thank you to Secretary Kennedy for allowing us
22 to move forward with this topic for a PTAC. I
23 had an opportunity to share a personal story
24 with him that I'll share with you all in a
25 moment that really resonated, and he's given me

1 agency to be able to move forward with
2 refocusing on this extremely important topic of
3 patient safety, as well as Dr. Mehmet Oz at the
4 Centers for Medicare & Medicaid Services, and
5 Abe Sutton as well. We've all had, I think,
6 really positive conversations about today's
7 meeting.

8 I want to thank Cyndi Goss in the
9 Assistant Secretary for Planning and Evaluation
10 Office for helping coordinate this, and Steve
11 Sheingold, as well, who put a tremendous amount
12 of effort into today's programming.

13 So as I said, before I begin, I want
14 to share a personal experience that brought the
15 issue of patient safety from the realm of
16 policy into something profoundly real for me.
17 This is the one part of the speech that I was
18 unable to write.

19 So Brianna Bauer was 25 years old.
20 We had been dating for a little over two years.
21 She was a third-year law student at Pepperdine
22 University. On November 15, 2024, she went in
23 for a very routine medical procedure, and due
24 to substantial problems and mistakes and every
25 breakdown that you can imagine happening from

1 the point the mistake was made on, she was
2 given way too much lidocaine, and she suffered
3 lidocaine toxicity. And they didn't catch it.
4 She started to have uncontrolled seizures. She
5 went into cardiac arrest, which they didn't
6 catch. When they transferred her to a
7 hospital, they hid the reality of the
8 situation. She didn't get the appropriate care
9 that she needed. She spent seven hours with
10 uncontrolled brain swelling, and they ended up
11 having to transfer her to UCLA³ just to save her
12 life. She suffered severe anoxic brain
13 injuries, and she is unfortunately in a
14 persistent vegetative state that I think she
15 will likely be in for the rest of her life.

16 I had the -- I was lucky to have
17 worked in the first Trump Administration at the
18 Agency for Healthcare Research and Quality, and
19 so I saw all the tremendous work that people
20 who are passionate about patient safety do.
21 But really until this happened just about a
22 year and a half ago, it had never hit home to
23 me as profoundly or as heavily as it did. That
24 drove me to want to come back into the

3 University of California, Los Angeles

1 department and make patient safety my North
2 Star. And I think many of you have had an
3 opportunity to have a conversation with me and
4 really have heard my passion for it and have
5 helped me advance this and drive this issue
6 forward. So I thank everybody really for being
7 here today, and I hope that we can make
8 something substantial out of this meeting
9 because unfortunately, stories like mine are
10 not rare.

11 More than 25 years ago, the
12 Institute of Medicine's landmark report *To Err*
13 *is Human* estimated that tens of thousands of
14 Americans were dying each year from preventable
15 medical errors. The report launched a patient
16 safety movement that has produced important
17 advances. We have better infection control
18 practices, stronger reporting systems, safer
19 surgical protocols, and a far greater awareness
20 that harm in health care is not inevitable.
21 And yet, if we're honest with ourselves, the
22 results have fallen short of the aspirations.

23 Today, patient safety remains one of
24 the most significant challenges facing American
25 health care. Recent evidence suggests that

1 preventable harm continues to affect millions
2 of patients, imposing enormous human and
3 financial costs. A major national study
4 published in *BMJ Quality and Safety* estimated
5 that approximately 795,000 Americans each year
6 suffer permanent disability or death because of
7 diagnostic errors alone. Diagnostic error
8 remains one of the leading causes of
9 preventable harm in the United States, yet it
10 is still inadequately measured and
11 insufficiently addressed.

12 At the same time, new reporting data
13 from the nation's largest patient safety
14 reporting database found that serious events
15 and high-harm events increased nearly 10
16 percent from 2023 to 2024. Other analyses
17 suggest that some of the gains achieved before
18 the pandemic have eroded under the pressure of
19 workforce shortages, burnout, growing
20 complexity, and fragmented systems of care.

21 The cost is measured not only in
22 lives altered and lost, preventable harm is
23 also a major contributor to health care waste
24 and inefficiency. We spent hundreds of
25 billions of dollars each year on care that does

1 not improve outcomes and in some cases actively
2 causes harm.

3 Every preventable infection,
4 medication error, misdiagnosis, fall, or
5 surgical complication represents both a human
6 tragedy and a failure of stewardship of public
7 resources. This reality should compel us to
8 ask a difficult question. Why, after a quarter
9 century of national effort, are we still
10 struggling to achieve meaningful reductions in
11 preventable harm?

12 Part of the answer is that our
13 approach has often been fragmented. We have
14 created reporting systems without learning
15 systems. We have created measures without
16 timely feedback. We've often focused on
17 compliance, rather than improvement, and too
18 frequently we have measured what is easy to
19 count, rather than what matters most to
20 patients.

21 Another challenge is that we have
22 sometimes created environments where fear of
23 punishment discourages transparency.
24 Accountability matters. Patients deserve
25 accountability. But patient safety advances

1 when organizations are willing to surface
2 problems, learn from them, and share lessons
3 broadly.

4 A system that is perceived as purely
5 punitive risks driving harm underground, rather
6 than bringing it into the light. We should
7 strive for a culture that balances
8 accountability with learning, transparency, and
9 continuous improvement. That is why this
10 moment presents such an important opportunity.

11 For the first time, we have
12 technologies capable of helping us detect harm
13 at a scale that was previously unimaginable.
14 Artificial intelligence, large language models,
15 and advanced analytics can help identify safety
16 events hidden within millions of clinical
17 records, uncover diagnostic errors, detect
18 emerging risks, automate quality measurement,
19 and dramatically reduce the burden of data
20 abstraction. AI⁴ can help level the playing
21 field so that sophisticated safety surveillance
22 is not limited to a handful of elite
23 institutions, but becomes available across the
24 health care system.

4 Artificial intelligence

1 We must also recognize that AI
2 itself introduces new risks. Algorithms can
3 miss critical information. AI-enabled
4 documentation tools can propagate inaccuracies.
5 Clinical decision support systems can create
6 new forms of error, and electronic records
7 themselves have become sources of patient harm
8 when poorly designed or poorly implemented.

9 As we embrace AI, we must apply the
10 same rigor to evaluating its safety that we
11 apply to evaluating any clinical intervention.
12 Our challenge, therefore, is not simply to
13 adopt technology, it is to build a modern
14 patient safety ecosystem that combines
15 transparency, measurement, culture, human-
16 centered design, and innovation.

17 Imagine a future where we can
18 identify harm in near real time; where patients
19 have a meaningful voice in safety reporting;
20 where quality measurement reflects actual
21 patient outcomes rather than outdated claim
22 space proxies; where hospitals are rewarded not
23 only for avoiding harm, but for how effectively
24 they recognize, disclose, and learn from
25 mistakes; and where every agency across HHS is

1 aligned around a single goal, moving the nation
2 toward zero preventable harm. That is the
3 opportunity before us.

4 The work of this Committee can help
5 shape payment models and policy frameworks that
6 move patient safety from aspiration to an
7 operational reality. We have the knowledge.
8 We have the technology, we have the evidence.
9 What we need now is the will to act with
10 urgency because behind every statistic is a
11 person, a family, and a story, and they deserve
12 a health care system that is committed to
13 safety as it is treatment. Thank you.

14 CO-CHAIR PULLURU: Abe.

15 * **Abe Sutton, JD, Director, Center for**
16 **Medicare and Medicaid Innovation**
17 **(CMS Innovation Center), and Deputy**
18 **Administrator, Centers for Medicare**
19 **& Medicaid Services (CMS) Remarks**

20 MR. SUTTON: Thank you and thank you
21 to the Co-Chairs, to the Committee, to the ASPE⁵
22 team for organizing this, and for everyone
23 listening in today for this important
24 conversation on the topic of patient safety.

5 Assistant Secretary for Planning and Evaluation

1 It's a privilege to join you all
2 today. I was last here in September, and I
3 spoke about the three strategic pillars that
4 guide our work at the Innovation Center,
5 touching on evidence-based prevention, touching
6 on choice and competition in health care
7 markets, and touching on empowering people to
8 achieve their health goals. The truth is that
9 patient safety is core to each of these three
10 pillars. Without safety and trust in the
11 health care system, it is hard to engage and
12 navigate and know where to turn.

13 Before I dive in, I just want to
14 recognize the incredible and inspirational work
15 that Sam Watters has done. It's a privilege to
16 be sitting with you here, Sam, and to get to
17 work with you to move forward this mission.
18 Your focus on patient safety has been
19 unwavering, and we would not be where we are
20 today, having advanced the ball without the
21 work and focus that you have gone. I know that
22 your story and your strength is an inspiration
23 to all of us in this work. And so truly thank
24 you, Sam.

25 Sam plays a critical role as a

1 counselor to Secretary Kennedy and giving
2 policy advice in that role. I know it's been an
3 incredible partnership where we work together
4 on advancing the ball in many Innovation Center
5 models, advancing the ball on the topic of
6 patient safety in our work, and really playing
7 a pivotal role in a number of areas, including
8 the Secretary's Nutrition Initiative. And so
9 it's a privilege to join to you today and to
10 join the PTAC today.

11 Patient safety and the Innovation
12 Center strategy, the truth is that patient
13 safety is really embedded in each of the
14 pillars. When I think about evidence-based
15 prevention, prevention includes preventing
16 harm. A foundational principle for doctors in
17 our health care system, do no harm. If we can
18 improve the efficiency and reduce unnecessary
19 utilization that may actively be harmful to
20 patients, that is a good thing to do. That is
21 the core philosophy behind our WISer⁶ Model
22 which focuses on areas of low-value care that
23 may actively pose a risk for harm and truly
24 embody waste in our system to prevent that

6 Wasteful and Inappropriate Service Reduction

unnecessary utilization. Attention on services where there is evidence of overutilization is critical. Patient safety concerns, inappropriate utilization, let's prevent them on the front end.

Turning to our second pillar on patient empowerment, patients have the information and the tools necessary to engage in safe care, to know where is a system that they can rely on, where are their safety records and track records? Where are the risks of infection? That information needs to be accessible, and we should try to eliminate the harm. Transparency and informed decision-making is the key principle behind this pillar.

I would highlight our LEAD⁷ Model and our ACCESS⁸ Model as two models that embrace us. I think about LEAD and its structure, Accountable Care Organizations, information accessible to people, and people choosing where to go in the system. Primary care physicians, partner innovations help them navigate with downstream providers in the system.

⁷ Long-term Enhanced ACO (Accountable Care Organization) Design

⁸ Advancing Chronic Care with Effective, Scalable Solutions

1 And then our ACCESS Model which is
2 geared really around patients choosing from
3 consumer-facing and technological solutions,
4 digital therapeutics, the one that is right for
5 them, the right that supports them will help
6 them navigate the system and achieve the
7 results they are looking to achieve within it.

8 Finally, choice and competition.
9 You should be able to choose providers and care
10 models that deliver the best outcomes.
11 Competition works best when patients,
12 providers, and payers have access to meaningful
13 information. You cannot get there if you do not
14 have safety results included in that. That has
15 to be part of every scorecard that you put
16 together. Now if there's a risk of infraction
17 or of a hospital-borne illness, that is not the
18 experience you're looking for in the system,
19 that poses a real risk of harm.

20 Now when creating the right
21 incentives for providers to read on value,
22 including patient outcomes, experience, and
23 safety, not simply volume, are part of the
24 equation. It changes the incentive structure
25 for providers as they engage with the health

1 care system.

2 The Innovation Center's authorities
3 go beyond allowing us to engage in the way that
4 the statute lays out based on how regulations
5 can implement the statute to support fee-for-
6 service incentive structures within our system,
7 so there's more flexible approaches, more
8 nuance in how we can design care pathways,
9 reacting to information as we see it. That's
10 important. That's one of our goals. That's
11 something we embrace.

12 As part of that, we monitor patient
13 safety outcomes. We monitor patients'
14 experiences as part of preparing model
15 evaluations. If there was a spike in sepsis as
16 part of the incentives we've designed for a
17 hospital system, that's something we need to
18 learn from, reflect, and redesign to ensure
19 that doesn't occur.

20 In the alternative, if we are
21 effective at resetting the quality incentive
22 because suddenly you're looking at avoiding
23 readmissions within 30 days post-discharge,
24 then we can see more of a focus on up-front
25 investment in avoiding these hospital-borne

1 illnesses.

2 We also are looking to test how
3 technology can reduce burden on providers and
4 increase patient quality. I mentioned the
5 ACCESS Model earlier. I can similarly mention
6 the ASPIRE⁹ Model, which is one that is going to
7 focus on Medicaid, on pediatric high-needs
8 populations and try and change the incentives
9 to interact with that population, including
10 giving them support 24/7 so that they avoid ED¹⁰
11 utilization.

12 How can we engage with populations,
13 meet them where they are, and prevent issues
14 from compounding as they engage with the health
15 care system? You go in for a routine visit,
16 and you come out with something much worse.
17 That's not the bargain we anticipate for when
18 we go into the hallowed halls of a medical
19 institution. Working to align incentives
20 around evidence-based care and patient outcomes
21 rather than volume is our mission at the
22 Innovation Center.

23 Now today's agenda highlights the

9 Accelerating State Pediatric Innovation Readiness and Effectiveness

10 Emergency department

1 importance of leadership accountability in
2 patient safety. Improving patient safety
3 requires active leadership engagement so that
4 resources and attention are focused on this
5 important issue. Clear accountability,
6 measuring the progress that is made and holding
7 oneself and one's team accountable or the lack
8 thereof or from what is improved, the
9 meaningful measurement aspects, and finally,
10 sustained investment to make progress on those
11 aspects in people, systems, and technology.

12 The truth is that we're at a moment
13 where more can be done in terms of measurement
14 than ever before. The cognitive ability to
15 track different aspects and see measurement and
16 prioritize and stratify between them has never
17 been more accessible. That's only true of some
18 systems though. And encouraging the deployment
19 of tools and measurements so that safety is
20 centered in the patient care experience is
21 critical, and we hope to set up the right
22 incentive structures to enable the adoption of
23 these tools and supports throughout the system.

24 Across our models, we will continue
25 to explore how payment and delivery can support

1 these goals, and I hope that the conversation
2 today and tomorrow will shape that approach
3 going forward.

4 Looking ahead, as we think about
5 patient safety, we think about better
6 measurement. How can we meaningfully measure
7 patient safety outcomes? What is the right
8 metric to focus on, and how do we draw the
9 right conclusions from it? What are the actual
10 metrics that matter to patients and providers
11 where change can be made quickly to drive
12 improvement? How can we use technology in a
13 smarter way? I mentioned the ACCESS Model, but
14 how can we scale payments with outcomes? What
15 would it look like if we think about remote
16 patient monitoring, and the right incentives
17 come into play in that space? What would it
18 look like to have earlier identification of
19 safety risks and opportunities for improvements
20 and to act on them and track that and reward
21 the action?

22 Finally, better incentives, models
23 that reward quality, continuity of care,
24 coordination, evidence-based care. The
25 partnerships that we have in the Innovation

Center with entities like AHRQ¹¹, with our colleagues in CCSQ¹², with the ASPE team and the PTAC, with clinicians serving patients, patient advocates, health care systems, and other stakeholders, really help ensure that we're focused on the right safety innovations in improvements that are transparent, so people can learn about them, see them, and understand it; measurable, so that we see, okay, this is real or this is not. And truly they are patient-centered, so that we are grounded in the experience of the patient as they engage with the system.

The PTAC is going to continue to play an important role in shaping physician-focused payment models, and we are grateful for the partnership and input that you provide to us. The key questions that I would pose for this group, where I'm hoping to get insight over the next two days, are how do we measure safety in value-based care? How can technology improve safety in ways where we see it as additive rather than as distracting from the care experience? And how should payment models

11 Agency for Healthcare Research and Quality

12 Center for Clinical Standards and Quality

1 create opportunities rather than risks as we
2 think about this question?

3 I look forward to learning from
4 today's discussion, and I know my team does as
5 well. Thank you.

6 CO-CHAIR PULLURU: Thank you, Abe,
7 for your thoughtful words and work in
8 developing policy to improve health care.

9 And thank you, Sam, for showing us
10 the importance of this and sharing a very
11 personal story in surfacing this for us today.

12 We appreciate your support and
13 engagement and look forward to collaborating
14 with the Office of the Secretary at HHS and the
15 CMS Innovation Center.

16 * **Welcome and Co-Chair Update -**
17 **Targeting Improvements in Patient**
18 **Safety Through Alternative Payment**
19 **Models Day 1**

20 CO-CHAIR PULLURU: For this public
21 meeting agenda, we will explore a range of
22 topics on targeting improvements in patient
23 safety through Alternative Payment Models that
24 include approaches to improve patient safety
25 and Alternative Payment Models; measuring

1 patient safety in value-based care; improving
2 safety in value-based care through the use of
3 health information technology and data
4 analytics; payment mechanisms and financial
5 incentives to encourage patient safety in
6 Alternative Payment Models.

7 This public meeting will focus on
8 examining how patient safety can be improved
9 through Alternative Payment Models and how the
10 development of new safety performance measures
11 and new technologies can help further improve
12 patient safety.

13 The background materials for this
14 public meeting, including the environmental
15 scan, can be found on the public meeting
16 registration site and will be posted online at
17 the ASPE PTAC website's meeting page.

18 Throughout the meeting, you will
19 hear from many esteemed experts with a variety
20 of perspectives. I also want to mention that
21 tomorrow morning, we will include a public
22 comment period. Public comments will be
23 limited to three minutes each. If you would
24 like to give an oral public comment tomorrow,
25 but have not yet registered to do so, please

1 email PTAC, ptacregistration@norc.org.
2 ptacregistration@NORC.org. Again, that's PTAC
3 registration.

4 The discussions, material, and
5 public comments from this public meeting will
6 inform a report to the Secretary of HHS on
7 targeting improvements in patient safety
8 through Alternative Payment Models. Over the
9 next two days, the Committee will discuss and
10 shape our comments for this upcoming report.
11 In April, we posted a Request for Input on the
12 ASPE PTAC website to give stakeholders an
13 opportunity to provide written comments to the
14 Committee on targeting improvements in patient
15 safety through Alternative Payment Models.

16 To date, we have received three
17 responses that the Committee may consider
18 during their discussion over the next two days.
19 I would also like to note, as always, the
20 Committee is ready to receive proposals on
21 possible innovative approaches and solutions
22 related to care delivery, payment, or other
23 policy issues from the public on a rolling
24 basis. We offer two proposal submission tracks
25 for submitters, allowing flexibility depending

1 on the level of detail of their payment
2 methodology. You can find information about
3 submitting a proposal on the ASPE PTAC website.

4 *** PTAC Member Introductions**

5 CO-CHAIR PULLURU: At this time, I
6 would like to invite my fellow PTAC members to
7 please introduce themselves. Please share your
8 name, your organization, and if you would like,
9 feel free to describe any experience you have
10 with our topic today.

11 I'll start. I'm Chinni Pulluru.
12 I'm a family physician by trade. Currently, I
13 am the Chief Medical Officer of Agentic
14 Healthcare, which is a vertically integrated
15 health tech company to deliver an individual
16 access promise, to provide patients with
17 agency, not only over their longitudinal health
18 records, but to deploy specialized AI agents to
19 take action on behalf of them and their
20 families.

21 Prior to that, I served as Chief
22 Clinical Executive at Walmart Health where I
23 led, among many things, the patient safety
24 organization for the pharmacies across Walmart,
25 as well as led health care operations between

1 Walmart Health and the tele-health platform.

2 And prior to that, I served as Chief
3 Clinical Executive for DuPage Medical Group, or
4 Duly Health and Care, where I led all things
5 clinical care delivery of which their risk
6 management platform was one, as well as their
7 patient engagement platform.

8 Now I'll hand it over to Lee.

9 CO-CHAIR MILLS: Good morning. I'm
10 Lee Mills. I'm also a family physician. I
11 currently serve as Chief Medical Officer of
12 Aetna Better Health of Oklahoma, one of the
13 state's three contracted Medicaid managed care
14 organizations. I came up through Medical Group
15 Integrated Health System and ACO operational
16 leadership and have the privilege of having led
17 and operated on both the provider side and the
18 health plan side through six CMMI¹³ models over
19 the years. In my current role, we're under the
20 interesting legislative and contractual mandate
21 to increase the total dollars spent under
22 value-based contracts to more than 50 percent
23 of all dollars spent through managed Medicaid
24 over the next three years in Oklahoma.

13 Center for Medicare and Medicaid Innovation

1 So next.

2 MR. RAMACHANDRAN: Thanks Lee. My
3 name is Krishna Ramachandran, Chief Information
4 Officer for United Health Care Operations
5 Experience. I've been in health care for 24
6 years in the technology provider and payer
7 perspective for the, in value-based care.

8 Lindsay?

9 DR. BOTSFORD: Thanks, Krishna.
10 Good morning. I'm Lindsay Botsford. I'm a
11 family physician in Houston, Texas, where I
12 continue to care for patients, including
13 Medicare beneficiaries. I also serve as a
14 Regional Medical Director with One Medical,
15 part of the Amazon Health Services family where
16 I support our practices across the Midwest and
17 Texas. I also chair the governing body of Iora
18 Health Network, which is our direct contracting
19 entity in ACO REACH for the last four years.

20 Prior to this, I've worked in large
21 health systems and teaching faculty roles in a
22 variety of VBC¹⁴ models, including Patient-
23 Centered Medical Homes and MSSP¹⁵.

24 David?

14 Value-based care

15 Medicare Shared Savings Program

1 MR. TYSON: Good morning. David
2 Tyson. I'm the Senior Director of Policy and
3 Regulatory Affairs at Novant Health, which is a
4 large, integrated delivery network spanning the
5 Carolinas. I help the system navigate all
6 things patient safety, quality, value-based
7 care regulations. And previously to my current
8 role, used to help lead our system ACOs and the
9 MSSP specifically.

10 Walter?

11 DR. LIN: Thanks, David. Good
12 morning, everyone. I'm Walter Lin, founder of
13 Generation Clinical Partners. We are a
14 medical provider group in the St. Louis area
15 focused on caring for the frail Medicare
16 beneficiaries living in senior living settings.
17 We have participated in a number of different
18 value-based care initiatives from bundled
19 payments to MSSP to institutional special needs
20 plans, PACE¹⁶ programs.

21 I currently serve also as the Chief
22 Clinical Strategy Officer for LTC ACO, which is
23 an MSP¹⁷ long-term care-focused ACO.

24 CO-CHAIR PULLURU: And now we'll go

16 Program for All-Inclusive Care for the Elderly

17 Medicare Secondary Payer

1 to our virtual members. Lauran and then Larry.

2 MS. HARDIN: Good morning. I'm
3 Lauran Hardin. I'm a nurse by training and
4 Chief Integration Officer for HC² Strategies.
5 HC² stands for Healthy Connected Communities,
6 and our work is deeply focused on building
7 coordinated approaches for complex populations,
8 also deeply involved in quality incentive
9 initiatives across the State of California with
10 health systems.

11 My background includes leading care
12 coordination in multiple ACOs and value-based
13 payment models, and I was part of the team that
14 established the National Center for Complex
15 Health and Social Needs, working with states,
16 communities, health systems, community-based
17 organizations and design of initiatives to
18 improve appropriate utilization quality and
19 safe care for complex populations.

20 DR. KOSINSKI: I'm Larry Kosinski.
21 I'm a gastroenterologist by training. I
22 practiced for 40 years in the Chicagoland area
23 and built the largest GI¹⁸ practice in Illinois,
24 the Illinois Gastroenterology Group. I also

18 Gastrointestinal

1 have significant experience on the hospital
2 side, having sat on a hospital board for 10
3 years. So patient safety is something I was
4 involved with at the ground level.

5 I'm also a serial entrepreneur,
6 having started a company named SonarMD, which
7 has built value-based care solutions for
8 gastroenterology and was one of the first PTAC-
9 recommended physician-focused payment models
10 back in 2017. I currently have a position as a
11 fractional CMO¹⁹ for an AI-powered microbiome
12 company named Jona. But most recently, most of
13 my energies are spent with my latest start-up
14 called VIOVOC, which is a company built around
15 an olfactory sensor for GI health.

16 I've been on this Committee for five
17 years. I look forward to today and tomorrow's
18 meetings.

19 *** PCDT Presentation: Targeting**
20 **Improvements in Patient Safety**
21 **Through Alternative Payment Models**

22 CO-CHAIR PULLURU: Thank you all.
23 Three of our Committee members, Dr. Henish
24 Bhansali, Dr. Jay Feldstein, and Dr. Joshua

19 Chief Medical Officer

1 Liao are unable to join us for this June
2 meeting, but we want to acknowledge their great
3 work on this Committee.

4 Now let's move to our introductory
5 presentation. PTAC members, you will have an
6 opportunity to share any comments or ask any
7 follow-up questions after the presentation.
8 Lee and I served on the Preliminary Comments
9 Development Team, or PCDT, and I've
10 collaborated closely with staff to prepare for
11 this meeting. As the PCDT lead, I will share
12 some of the findings from the analysis to set
13 the stage and goals for this meeting. So let's
14 begin.

15 Good afternoon today. Thank you for
16 joining us on this theme-based discussion on
17 patient safety and its relationship to
18 Alternative Payment Models. Patient safety is
19 one of the most fundamental obligations in
20 health care. Every interaction between a
21 patient and the health care system carries both
22 opportunity and risk. While medicine has
23 achieved extraordinary advances, preventable
24 harm remains one of the most persistent
25 challenges facing our health care system.

1 Today, we will explore not only prevalence and
2 cost of patient harm, but also how payment
3 models, measurement strategies, technology, and
4 organizational design can help us create safer
5 systems of care.

6 I'd like to thank the PCDT team, my
7 Co-Chair, Dr. Lee Mills, NORC, as well as ASPE,
8 for bringing together this presentation and
9 helping with these two days.

10 Our discussion today follows five
11 themes. First, we'll establish a common
12 understanding of patient safety. We'll review
13 the prevalence and economic burden of patient
14 harm. We'll examine the underlying causes of
15 safety failures and opportunities for
16 improvement. Fourth, we'll discuss how patient
17 safety can and should be measured. And
18 finally, we'll explore how Alternative Payment
19 Models can accelerate meaningful and
20 sustainable improvements in patient safety.

21 Our objective is not simply to
22 describe this problem. Our goal is to identify
23 actionable opportunities over the next two
24 days. Specifically, we'll examine how
25 Alternative Payment Models can create stronger

1 incentives for safety, where our current
2 measurement systems may be inadequate, how
3 emerging technologies can improve reliability
4 and fidelity to patient safety, and what
5 payment methodologies might best reward
6 organizations that prevent harm rather than
7 merely reacting to it.

8 Patient safety is already deeply
9 embedded in PTAC's work. PTAC has received 36
10 proposals, of which 28 physician-focused
11 payment model proposals were reviewed in public
12 meetings. Twenty-three were found to meet
13 Criteria 9 related to patient safety. This
14 tells us that stakeholders recognize that
15 patient safety is essential. However,
16 recognizing safety and systematically improving
17 it are not the same thing, and today's
18 discussion will focus on how we move from
19 intention to measurable impact.

20 For today's discussion, we are using
21 a practical working definition. Patient safety
22 is freedom from errors that could cause patient
23 harm during the delivery of health care.
24 Errors may be errors of commission, in which an
25 incorrect action was taken, or more

1 importantly, and sometimes even more
2 frequently, errors of omission, in which case a
3 correct action was not taken. This distinction
4 between commission and omission is critical
5 because many of the current safety
6 opportunities in modern health care stem not
7 from what was done, but from what was missed.

8 The economic burden of patient harm
9 is staggering. Across OECD²⁰ countries,
10 preventable harm is estimated to cost more than
11 \$600 billion annually. In the United States
12 alone, direct medical costs exceeds billions of
13 dollars each year. Yet the true burden extends
14 far beyond health care spending. Patient harm
15 affects productivity, family stability,
16 caregiver burden, workforce participation,
17 disability, as well as quality of life. In
18 many cases, the societal costs exceed the
19 direct medical costs. Patient safety is
20 therefore not only a clinical imperative, it's
21 an economic one.

22 The prevalence of harm is equally
23 sobering. More than one in 10 patients
24 globally experiences medical harm. Half of

20 Organisation for Economic Co-operation and Development

1 that harm may be preventable. Among
2 hospitalized Medicare beneficiaries,
3 approximately one in four experiences a harm
4 event, which may be even -- what may be even
5 more concerning is that nearly half of patient
6 harm events may never be captured by what are
7 existing reporting systems. This means that
8 the visible problem may only represent part of
9 the true burden of patient safety.

10 More than 25 years ago, a landmark
11 report, *To Err is Human*, fundamentally changed
12 the national conversation around patient
13 safety. The report estimated that tens of
14 thousands of Americans were dying each year
15 from preventable medical errors. It catalyzed
16 a generation of safety initiatives. However,
17 recent evidence suggests that improvement has
18 slowed if not stalled in recent years. The
19 reality today is that despite enormous effort
20 in the past, preventable harm remains
21 remarkably persistent in our health care
22 system.

23 Safety and quality are intertwined.
24 However, they're often discussed separately.
25 In reality, safety is one of the six

foundational dimensions of health care quality as spelled out in STEEEP²¹ quality domains. The STEEEP quality domains include safe care, timely, efficient, equitable, and patient-centered. When safety fails, however, every other dimension of quality is compromised. Therefore, it's very important that we consider safety be a part of the entire quality continuum. Without safety, quality cannot truly exist.

This slide provides perhaps one of the most important frameworks in the presentation. Patient harm does not occur in isolation. It is a systems problem. Systems, human factors, organizational culture, and technology all contribute to safety errors. This encompasses omission errors and commission errors, which result in altered patient outcomes. These factors interact to create opportunities to correct error.

Fortunately, mitigation strategies also exist. However, they are significantly underutilized. Communications, standardizing protocols, care coordination, training,

²¹ Safe, Timely, Effective, Efficient, Equitable, and Patient-Centered

1 improving technology to enable safety,
2 improving patient engagement, and most
3 importantly, a culture of safety, all
4 contribute to the mitigation factors.
5 Improving safety requires strengthening these
6 protective layers simultaneously and not in
7 isolation.

8 Patient safety errors occur across
9 virtually every aspect of the health care
10 delivery system. These include medication
11 errors, which account for a large chunk of
12 errors, particularly in transitions. It also
13 encompasses diagnostic lab and testing errors,
14 surgical and procedural ones. Outcomes such as
15 health care-related errors include infections,
16 falls, pressure injuries. Communication
17 failures are also categorized as safety issues.

18 Historically, health care has
19 focused heavily on commission errors because
20 they're easier to identify. However, omission
21 errors may be more common and more difficult to
22 detect, and this is where incentives can play a
23 role.

24 The adverse events framework. This
25 framework helps distinguish several important

1 concepts. It is important to note that not all
2 adverse events are preventable. These are
3 termed as non-controllable adverse events.
4 These occur despite appropriate care. Even
5 with non-controllable events, however, there is
6 an opportunity to rescue the situation and
7 follow up or regain the patient's trust that is
8 missed to lack of supportive systems.

9 Controllable adverse event
10 represents failures that could potentially have
11 been avoided. Within this group, the most
12 serious are sentinel events and never events.
13 Never event is a very serious preventable
14 sentinel event that should never happen in
15 health care, such as wrong side surgery or
16 foreign object left in a patient.

17 When we think about patient harm, we
18 often focus on adverse outcomes. What we miss
19 are near misses. But near misses may be
20 equally valuable, if not more, in patient
21 safety. A near miss is when no harm occurred
22 to the patient. However, there was a potential
23 for harm and, by chance or timely intervention,
24 that harm did not occur. Detection systems and
25 near misses are foundational to any patient

1 safety foundation.

2 Near misses reveal vulnerabilities
3 before a patient is injured and are the events
4 that occur, per se, below the waterline.
5 They're not seen often in institutions and
6 structures. However, they're paramount
7 importance to safety, and reporting mechanisms
8 in a safety culture for near misses is very,
9 very important, particularly in systems that
10 have large hierarchical organizations.

11 Organizations with strong safety
12 cultures often learn as much from near misses
13 as they do from actual harm events. This
14 reporting culture tends to lend itself to what
15 are called high reliability cultures.

16 Patient safety has been
17 traditionally supported by a very extensive
18 ecosystem: CMS, AHRQ, CDC²², the FDA²³, the Joint
19 Commission, NCQA²⁴, Leapfrog, and IHI²⁵.
20 Specifically, CMS ensures mandatory minimum
21 safety standards, conditions of participation
22 in both Medicare and Medicaid. CMS also
23 publicly reports safety data through the Care

22 Centers for Disease Control and Prevention

23 Food and Drug Administration

24 National Committee for Quality Assurance

25 Institute for Healthcare Improvement

1 Compare tool of some of the analytics that we
2 will be seeing later in the presentation.

3 CMS also has administrative
4 Alternative Payment Models that promote patient
5 safety, such as the Hospital-Acquired Condition
6 Program. AHRQ is the primary federal agency
7 conducting patient safety research, developing
8 safety measure resources and tools. AHRQ also
9 oversees quality and safety review system to
10 track hospital adverse events.

11 An important component to patient
12 safety today is this hospital adverse event
13 reporting system. Each organization
14 contributes differently. However, together
15 they have created a regulatory measurement
16 research and accountability infrastructure that
17 supports safer care, and we can use this
18 mechanism and ecosystem to further the stalling
19 that has happened with patient safety.

20 Moving on to the cost and prevalence
21 of harm events, one of the most important
22 themes emerging in patient safety is a shift
23 beyond hospitals. Historically, safety events
24 have focused primarily on inpatient care.
25 However, much of health care now occurs in

1 ambulatory settings. The data shows that
2 preventable adverse events occurs in both
3 environments. Analysis of 11 Massachusetts
4 hospitals found that one in four of inpatient
5 admissions involved at least one adverse event.
6 One in four.

7 While on the outpatient side,
8 analysis of 11 sites found that 7 percent of
9 patients had at least one adverse event. Of
10 these events, a quarter were preventable, but
11 17.4 percent of them were deemed serious
12 events.

13 The data also points that patient
14 safety does not equally affect all segments of
15 the population. Patients over 65, those with
16 multiple chronic conditions, non-white
17 patients, and patients who are on Medicaid or
18 are uninsured being the most affected.
19 Improvements have occurred due to a variety of
20 factors, including mandatory hospital adoption
21 of standardized safety practices, such as hand
22 hygiene protocols and security checklists,
23 financial penalties through value-based care
24 incentive programs, such as CMS Hospitals
25 Readmission program. Future patient safety

1 strategies and further payment models must
2 address the entire continuum of care, which
3 currently leaves out the outpatient care
4 situations and include diversity of
5 populations.

6 The next few slides show a
7 remarkable data story. There has been
8 measurable improvement in several safety
9 indicators over time. The chart here shows
10 infection rates across five hospital
11 performance quintiles for major health care-
12 associated infections. The key message being
13 that large differences in hospital-acquired
14 infections exist between the best and the
15 worst-performing hospitals. The best-
16 performing hospitals consistently achieved
17 dramatically better outcomes than the worst-
18 performing hospitals.

19 These findings emphasize the
20 importance of stronger infection prevention and
21 quality improvement initiatives targeting
22 higher-risk hospitals. This variation matters
23 because it demonstrates that better performance
24 is possible.

25 Next, we see data from the hospital

1 safety results from the CMS Safety Compare
2 tool. The key messages here, as described, is
3 that many patient safety categories improved
4 between 2010 and 2019. There was a blip during
5 the COVID years. However, most indicators have
6 remained relatively stable in recent years.
7 We're starting to now see a decline post-COVID
8 to the norm. However, patient safety events
9 still remain elevated. The importance of this
10 is that, while we have put safety guardrails
11 and processes in place, and we have seen
12 incremental gains, overall, there has not been
13 drastic improvement when the health care system
14 is viewed in aggregate.

15 As we see in this slide, large and
16 persistent performance gaps exist across
17 hospitals. There's substantial difference in
18 scores between the top and the bottom
19 performers. Top-performing hospitals achieve
20 outcomes approximately 25 percent better than
21 expected. The lowest-performing hospitals
22 perform roughly 40 percent worse than expected.
23 These findings highlight substantial variation
24 in quality and opportunity for improvement
25 across hospital systems. This is observed

1 versus expected, so it has been risk-adjusted.

2 A large share of hospitals with poor
3 performance showed limited improvement over
4 time. Nearly half, or 44 percent, of poorly-
5 performing hospitals remained in the bottom
6 tertile throughout the study period. However,
7 approximately one in four hospitals improved
8 substantially and moved to the top tertile. A
9 substantial portion of high-performing
10 hospitals maintained strong performance over
11 time. However, approximately 20 percent of
12 initially high-performing hospitals declined to
13 the bottom three deciles over time.

14 The key message here in these
15 findings suggests that, while performance
16 challenges persist, meaningful performance is
17 achievable. However, maintaining high patient
18 safety performance can be challenging over
19 time, and these results highlight the
20 importance of sustained quality improvement
21 efforts and continuous monitoring, as well as
22 measurement, to preserve these gains in
23 performance and not see slippage.

24 Moving on to patient safety
25 challenges and opportunities. There is no

1 single explanation for causes of safety errors.
2 It is very multifactorial. Health care
3 organizations face competing priorities.
4 Measurement systems are retrospective and often
5 lag behind reality. Workforce burnout is a
6 huge problem, and staffing shortages introduce
7 additional risk. Transparency across health
8 care organizations remain inconsistent, and
9 many safety systems that are retrospective and
10 designed to identify harm after it occurs do
11 not account for near misses or preventing harm
12 before it occurs. The future of patient safety
13 must be increasingly proactive, predictive, and
14 preventive.

15 When we examine root causes, a
16 consistent pattern emerges. Most patient harm
17 originates not from a single individual
18 failure, but a broader system vulnerability.
19 Poor workflows, fragmented communication,
20 physician and care team burnout, resource
21 constraints, and technology challenges. This
22 insight shifts our focus from blame towards
23 system redesign that can be incentivized, and
24 it incorporates improvement across all of these
25 domains when we look at alternative payment

1 mechanisms.

2 One example of a common illustration
3 of health care safety mechanisms is the Swiss
4 cheese model. The Swiss cheese model may be
5 the most recognizable framework today. No
6 single safeguard is perfect. Every layer
7 contains weaknesses. Patient harm occurs when
8 these weaknesses align. The lesson here is
9 powerful. Safer health care is built not by
10 expecting perfection from any individual or
11 system, but by designing multiple systems that
12 anticipate human imperfection.

13 Fortunately, we do know many
14 interventions that work. Standardization and
15 operations, including protocols, structured
16 communication, care coordination, improving
17 patient engagement and patient reporting tools,
18 and safety cultures, particularly with
19 leadership leading safety culture and data
20 analytics.

21 We have to pay particular attention
22 to using the advances in technology as spoken
23 to earlier by both Sam and Abe. Technology can
24 include data analytics, remote monitoring,
25 predictive models that use AI to target high-

1 risk patients -- we know who high-risk patients
2 are -- and surveillance monitoring.

3 The last and perhaps most important
4 improvement strategy is culture. Encouraging a
5 just culture where reporting is encouraged, not
6 punished, and is applauded is important in
7 capturing both adverse events, as well as near
8 misses. The challenge here is creating
9 incentives and infrastructure necessary to
10 scale these interventions consistently, which
11 leads us to technology.

12 Technology occupies a very unique
13 and more and more important place in patient
14 safety. Technology can be the cause of harm.
15 There can be direct malfunction. It can
16 contribute to harm, such as non-monitored
17 defaults, burdensome documentation,
18 overdependence on technology, especially with
19 the implementation of AI. We do risk the
20 burden of overdependence and workforce
21 interventions that are technological without
22 oversight.

23 However, on a more optimistic note,
24 technology can prevent harm. Artificial
25 intelligence, predictive analytics, remote

1 monitoring, clinical decision support, and
2 interoperability that brings data that's
3 relevant to one place, all create opportunities
4 to identify risk before adverse events occur
5 and mitigate them. The question is not whether
6 technology will shape patient safety. The
7 question is how will we deploy it thoughtfully,
8 and how will we incentivize it through advanced
9 payment mechanisms?

10 Here I'll speak to two challenges
11 that deserve special emphasis. First,
12 outpatient safety. The IOM²⁶'s 1999 report
13 focused on medical errors on hospitals, but the
14 volume of care currently is far higher in
15 outpatient settings. Particularly with more
16 surgical procedures shifting to outpatient,
17 tracking safety and creating systems that track
18 safety in the entire health care continuum is
19 very important.

20 Second, but not least, errors of
21 omission. This is where the use of technology
22 can perhaps be deployed to surface pertinent
23 medical information that is time-consuming with
24 high potential for error at the point of care.

26 Institute of Medicine

1 Medication errors commonly account for omission
2 errors. This represents errors such as lack of
3 patient receipt of medication or duplicate
4 medications in transition. Technology can
5 solve these issues in real time, and this
6 deployment is critical.

7 Both of these represent errors where
8 current measurement systems remain
9 underdeveloped, and there's an opportunity for
10 improvement. This opportunity can play out
11 with Alternative Payment Models which may be
12 uniquely positioned to drive this improvement
13 not just episodically but over periods of time.

14 Now we look at measurement. As safe
15 care is one of the STEEEP measures, we must
16 encompass quality to measure the components of
17 patient safety, including never events, adverse
18 events, and safety processes. What gets
19 measured gets improved. Currently, the gold
20 standard is to do a retrospective chart review.
21 However, automating surveillance using
22 mandatory reporting mechanisms and safety
23 surveys could perhaps get better measurement,
24 particularly patient-related safety surveys.
25 Patient safety measurement must move beyond

1 counting adverse events, and we need a balanced
2 portfolio that includes outcomes, processes,
3 structures, and culture.

4 The strongest safety measures not
5 only measure harm, but the conditions that
6 predict harm. The most common measures used is
7 AHRQ's Patient Safety Indicators, or PSIs, that
8 assess potentially adverse events in hospitals.
9 There are 26 indicators, including 18 provider-
10 level indicators.

11 New measures that exist today are
12 CMS' Patient Safety Structural Measure and ECO²⁷
13 surveys. That shift from retrospective
14 measurement to predictive measurement may be
15 one of the most important advances in patient
16 safety that we've made.

17 Other opportunities for patient
18 safety measurements are CMS' eQOMs²⁸, use of
19 data directly extracted from EHRs²⁹ and HIEs³⁰,
20 such as pressure injuries, and reported through
21 the Hospital Inpatient Quality Reporting Tool,
22 or IQR program, and the Medicare Promoting
23 Interoperability Program. CMS has plans to add

27 Errors of Care Omission

28 Electronic clinical quality measures

29 Electronic health records

30 Health Information Exchanges

1 two additional measures, as well.

2 The CDC's National Healthcare Safety
3 Network is also creating electronic and
4 automated safety measures called dQMs³¹. These
5 build on eQMs and are meant to improve
6 validity and decrease reporting burden and will
7 be reported using HL7³² FHIR³³ standard APIs³⁴.

8 Even with these mechanisms, there
9 are challenges that contribute to this being
10 one of the largest problems in health care.
11 How do we determine when an adverse event was
12 preventable? Differences in definition of
13 errors, which perhaps represents an opportunity
14 for standardization. Lack of standardized
15 measures. Immature safety measures for
16 outpatient settings. A lag in safety measure
17 information due to reliance on administrative
18 data and minimal availability of measures of
19 omission.

20 Inclusion of patient-reported
21 measures represents great opportunity. The
22 U.S. results from the 2023 Paris and Medicare
23 Current Beneficiary Survey revealed 13 percent

31 Digital quality measures

32 Health Level Seven

33 Fast Healthcare Interoperability Resources

34 Application programming interfaces

1 of primary care patients reported that
2 something went wrong over the course of their
3 care in the last 12 months. This is perhaps
4 one of the greatest opportunities for us to
5 identify errors of omission.

6 Moving on to what the Committee has
7 worked to advocate for. Over the next three
8 slides, we detail eight CMS programs or
9 initiatives that have linked performance,
10 including patient safety performance to
11 payment. The Premier Hospital Quality Incentive
12 Demonstration is one. It saw positive results
13 with quality scores increasing almost 19
14 percent from 2003 to 2006. One of the
15 programs, the Hospital Readmissions Reduction
16 Program, saw readmission rates decrease,
17 particularly for certain conditions as acute
18 myocardial infarction, heart failure, and
19 pneumonia.

20 Next, we see that the MIPS, or the
21 Merit-Based Incentive Program, CMS-based
22 payment to providers on performance across four
23 categories. Patient safety is a MIPS high-
24 priority category, the results of which showed
25 that safety net specialists were more than 30

1 percent likely to receive positive payment
2 adjustments than non-safety net specialists.

3 The BPCI-A³⁵ Model resulted in
4 savings. This model also included safety and
5 resulted in savings to Medicare by year four.
6 What this shows us is that when safety is
7 embedded within quality and included within
8 alternative payment mechanisms, not only do we
9 see improvements in quality, improvements in
10 safety, we also see improvements in savings.

11 TEAM³⁶ is a new CMS model that will
12 report on specific patient safety measures and
13 will adjust payments based on performance of
14 these measures.

15 In the next two days, we will
16 explore approaches to patient safety in
17 Alternative Payment Models, measuring patient
18 safety in value-based care, improving value-
19 based care through the use of health
20 information technology and data analytics,
21 payment mechanisms and financial incentives to
22 encourage patient safety measures in
23 Alternative Payment Models.

24 I'll close with three observations.

35 Bundled Payments for Care Improvement - Advanced

36 Transforming Episode Accountability Model

1 First, preventable patient harm remains one of
2 health care's most significant challenges.
3 Second, the evidence clearly demonstrates that
4 safer care is achievable. And, third,
5 Alternative Payment Models offer a unique
6 opportunity to align financial incentives with
7 prevention, reliability, transparency, and
8 accountability. The ultimate goal is not
9 simply fewer errors. It's creating a health
10 care system where every patient can trust that
11 safety is embedded into every process, every
12 decision, and every encounter.

13 PTAC members, do you have any
14 follow-up comments or questions for Lee and I?
15 To indicate that you have a comment or
16 question, please flip your name card on its
17 side. For our virtual Committee members,
18 please raise your hand on Zoom. And, Sam,
19 you're welcome to participate, as well.

20 No questions, huh? Larry.

21 DR. KOSINSKI: You know I always
22 have something.

23 CO-CHAIR PULLURU: Of course.

24 DR. KOSINSKI: Chinni, great
25 presentation. I really enjoyed it, but I just

1 want to expand on a couple of your comments.
2 First of all, technology needs to be utilized
3 better to decrease errors. We need to move our
4 EHRs beyond just documentation tools. They
5 need to help minimize human errors. We need
6 many, many more CDS³⁷ tools that become part of
7 our process of care.

8 I like your comment about omission
9 errors being more harmful than commission
10 errors. In my experience, they truly are.
11 Errors in misdiagnosis, AI can be an effective
12 tool to help expand our diagnosis and to help
13 us avoid familiarity bias. If we don't think
14 of it, we'll never diagnose it. Communication
15 issues, technology can help us greatly with
16 communications as providers slip in and out of
17 hospitals depending on their schedules.

18 But one of the things that I think
19 needs to be focused on today is that we need to
20 help providers practice up to the level of
21 their licensure. We, today, have a very
22 heterogeneous provider profile. We have
23 specialists, we have primary care doctors, we
24 have mid-levels, we have coaches, we have

37 Clinical decision support

1 functional doctors, chiropractors, and
2 naturopaths. There's a spectrum of providers
3 today.

4 Then later, on top of that, the fact
5 that some are employed by hospital systems
6 where we can build processes into them versus
7 the majority of physicians on hospital staffs
8 being independent and really not part of the
9 employee team. We need to build processes so
10 that we can deploy them and minimize the
11 differences among the heterogeneity of the
12 providers.

13 CO-CHAIR PULLURU: Thank you, Larry.
14 Sam.

15 MR. WATTERS: Thank you, and thank
16 you for that presentation. I think one of the
17 reasons I'm so excited to hear about the
18 recommendations from this PTAC is that a
19 payment model structured the right way can lead
20 to the type of long-term sustained improvements
21 that you've mentioned are sometimes lacking.

22 I would like us to consider that we
23 have a system right now that penalizes for a
24 failure or penalizes for a mistake, and can we
25 consider a model that penalizes for failure to

1 correct? And it's a minor nuance, but I think
2 when we are purely punitive, when we see a
3 penalty, when we measure something specific, we
4 find failure at the system, and we just
5 penalize them and downwardly adjust. It leads
6 to bad behaviors. It leads to hiding, or it
7 leads to focusing on one specific area where
8 we're being asked to improve. Meanwhile, we
9 may have an entire system that is failing
10 behind us.

11 If we can focus on something that
12 says we've identified that you have failure,
13 now you have an opportunity to fix it, and if
14 you don't take steps to fix it, you're leaving
15 money on the table, that will speak, I think,
16 to the financial incentives that leaderships at
17 systems look for, that will make it actually
18 desirable to invest, especially for systems
19 that maybe are just used to being penalized
20 over and over and over again and find
21 themselves in that bottom quartile.

22 I think you pointed out a major gap
23 between the best-performing systems and the
24 worst-performing systems. So how do we bring
25 the worst-performing systems to the table? How

1 do we get them out of that basement that they
2 feel stuck in because they're being penalized
3 over and over again and maybe they just have no
4 reason to adopt a culture of patient safety or
5 there's not an incentive to do it, they're not
6 focusing on it? Let's find ways to get them
7 out of that, and I'm really excited to hear
8 about some of the ideas that are being
9 presented for that.

10 So I appreciate your presentation.
11 I think there's a lot we can focus on here.

12 CO-CHAIR PULLURU: Thank you, Sam.
13 Lee.

14 CO-CHAIR MILLS: Thanks so much,
15 Chinni. In our investigation of this topic,
16 one of the most fascinating things for me has
17 been the -- I mean, we've all recognized, of
18 course, that there's both commission and
19 omission, and different sites of care have
20 different proportions of that. In ambulatory
21 care, where I've spent most of my career, it's
22 things that you should have done that you
23 didn't do that wind up hurting a patient that
24 are really safety errors.

25 But the really kind of aha moment

1 for me that I'm not sure I've heard talked
2 about any other places, that the circles of
3 patient safety and the circles of quality and
4 care conversations really are the same thing.
5 They're flip sides of the same coin. Any gap
6 in care, talk about Stars or HEDIS³⁸
7 performance, any gap in care is a potential
8 safety error of omission. And the whole
9 organization of whether it's a near miss or a
10 controlled adverse event or a never event or
11 sentinel event, all that tracks, you know,
12 colorectal screening -- a screen that should
13 have happened that didn't happen is a
14 potentially controllable adverse event, all the
15 way down to a late cancer identified with
16 patient harm is a never event, and we don't
17 often talk about them.

18 The financial approach to each, the
19 management approach to each, are often
20 completely disconnected in most payer and
21 provider systems, and I just wonder what that
22 means if we think about a new way to turn over
23 a new leaf in this in the country.

24 CO-CHAIR PULLURU: And I'll add

38 Healthcare Effectiveness Data and Information Set

1 that, as we were doing the data for this
2 presentation and having been involved deeply in
3 risk management in the past, one of the things
4 that often gets overlooked is patient-reported
5 events. And, you know, from the days when I was
6 at DuPage, now Duly Health and Care, we had two
7 mechanisms. We had one where a patient picked
8 up the phone, called us, and complained. That
9 often is not that many because most people
10 won't pause their time, they move on,
11 especially when there's not been harm, right.
12 So you typically only get that when something
13 has happened. People aren't reporting near
14 misses.

15 But we had implemented a patient
16 survey system where one out of five patients
17 got surveyed when they left our offices. And
18 looking through those survey comments, we would
19 actually review them weekly with the risk
20 management team. And when you reviewed those
21 survey comments, there was a host of near
22 misses that came from that, that we then could
23 investigate, and it led to significant changes
24 in our systems and automating them.

25 So I think that patient-reported

1 surveys or passive reporting of comments is
2 really important part of any safety culture
3 because patients will often tell you the doctor
4 almost missed this or this almost happened or I
5 almost got the wrong report. And those are
6 important.

7 I think we're ready for break, so
8 let's adjourn for break, and we will have a
9 break till 10:40 Eastern time. Oh, is it
10 10:40? Okay. I guess we'll take 10 minutes
11 over. Please join us then as we welcome a
12 great group of experts for our first session,
13 Approaches to Improve Patient Safety in
14 Alternative Payment Models.

15 (Whereupon, the above-entitled
16 matter went off the record at 10:40 a.m. and
17 resumed at 10:53 a.m.)

18 DR. LIN: Welcome back, PTAC
19 members. Chinni and Lee laid the foundation
20 for this public meeting and some of the
21 questions we wanted to explore.

22 I am excited now to welcome five
23 esteemed experts to share their perspectives on
24 approaches to improve patient safety in
25 Alternative Payment Models. You can find the

1 full biographies and slides posted on the ASPE
2 PTAC website and the public meeting
3 registration site.

4 Welcome to our three in-person
5 session participants. And for our remote
6 participants, please go ahead and turn on your
7 video if you haven't done so already. After
8 all experts have presented, the Committee will
9 have time to ask questions and engage in what
10 we hope will be a robust discussion.

11 First, we are pleased to welcome in-
12 person Ms. Susan Sheridan, President and Chief
13 Executive Officer for Patients for Patient
14 Safety US. Sue, welcome.

15 * **Session 1: Approaches to Improve**
16 **Patient Safety in Alternative Payment**
17 **Models**

18 MS. SHERIDAN: Thank you. Good
19 morning to all. And I really want to share my
20 appreciation to those of you who actually
21 invited me to present today. I don't know how
22 often you hear from patients or the patient
23 community, but I'm extremely appreciative, and
24 this means an awful lot to me and to millions
25 of patients in our nation.

1 As mentioned, I'm with Patients for
2 Patient Safety US. We're a national
3 organization. We're a large convener of
4 patients, health care systems, HHS agencies,
5 specialty societies, to really address patient
6 safety. We have over 200 patient
7 organizations, community-based organizations,
8 consumer organizations that work with us. Our
9 mission, of course, is laser-focused on patient
10 safety.

11 So you can see here that, you know,
12 I'm with Patients for Patient Safety US.
13 Currently, I'm also the Co-Chair of the
14 National Academy of Medicine's Patient Safety
15 in the Era of AI Initiative. So that's
16 probably another dialogue but an important area
17 to look at regarding patient safety. I was a
18 director at the Society to Improve Diagnosis in
19 Medicine. I was an advisor at CCSQ at CMS. I
20 was a director at PCORI, the Patient-Centered
21 Outcomes Research Institute, around patient
22 engagement. And I also led, I was the external
23 lead at WHO³⁹ on their global Patients for
24 Patient Safety program.

39 World Health Organization

1 But what brings me here today? Cal
2 and Pat bring me here today. You can see them
3 on the screen. Lightning struck twice to my
4 family. Two diagnostic errors in one family.
5 Now, you were talking about errors of omission.
6 These were two errors of omission. They're
7 both now considered never events.

8 Cal was born a normal, healthy
9 newborn in 1995, but he suffered brain damage
10 at five days old from the failure to test and
11 treat his newborn jaundice. He has a condition
12 known as kernicterus. Cal today is 31. He is
13 hearing impaired, speech impaired, and mobility
14 impaired. He's funny, he's super smart, but he
15 has challenges he should never have had.

16 You know, what I learned is that Cal
17 was born during the HMO⁴⁰ area, the managed care
18 area, and they did not give him a bilirubin
19 test until day five, and it was too late. And
20 what I learned that broke our hearts was that
21 there were actual incentives to the clinicians
22 to withhold routine tests. The bilirubin test
23 cost a dollar.

24 Six years later -- you can see Pat

40 Health maintenance organization

1 up here -- Pat died also from a diagnostic
2 error when his malignant pathology of synovial
3 cell sarcoma got lost in the health care system
4 and never communicated to the neurosurgeon or
5 to us. It metastasized. It killed him when he
6 was 45 years old. Cal was six, and we had a
7 little girl during that time, Mackenzie. She
8 was four when Pat died.

9 I was widowed at 42 with two little
10 kids and \$300,000 in debt because we had passed
11 Pat's insurance limit. This was back in 2002.
12 As you can imagine, I was terrified. But what
13 haunted me more than anything of these two
14 errors was the invisibility of what happened to
15 Cal and Pat. There were no mechanisms
16 collecting that information. That data landed
17 nowhere. And in my attempts to report it, I
18 realized there were no mechanisms for patient-
19 reported experience and outcomes related to
20 safety. What I can say with absolute certainty
21 is that patients expect learning and immediate
22 improvement from our losses.

23 So the problem, Sam and the
24 Chairwoman, Chinni -- you know, went through
25 the problem, so I don't want to dwell on that,

1 except I do want to highlight the diagnostic
2 errors part of this, that diagnostic errors are
3 the most common, the most costly, and the most
4 catastrophic, and the most underreported harms
5 in our health care system. It is estimated
6 that it's costing our country annually \$200
7 billion. And it disproportionately impacts our
8 vulnerable populations, including my son.

9 I also want to focus on the last box
10 down there that current APMs⁴¹ do not directly
11 measure patient or diagnostic safety from our
12 perspective, missing tremendous nuggets of
13 information regarding diagnostic and patient
14 safety, coordination of care and delays in
15 diagnosis, and other issues.

16 What we know is if you can't measure
17 it, you can't improve it. We know that. What
18 we also know that CMS and CDC are calling on
19 health care systems to directly learn from
20 patients and families to improve our outcomes
21 regarding patient and diagnostic safety. That
22 is evident in CMS' new Patient Safety
23 Structural Measure. And we've also learned
24 through research that patients are actually

41 Alternative Payment Models

1 very good detectors and reporters of harm, and
2 I encourage you to take a look at some of that
3 data.

4 So taking all this into account, my
5 organization launched Project PIVOT⁴². It is to
6 improve patient and diagnostic excellence,
7 especially in vulnerable populations, through
8 the creation of patient-reported outcome and
9 experience measures. We brought together over
10 a hundred patient organizations, community
11 organizations, patients, and families, and over
12 149 professional stakeholders, including key
13 agencies that you'll see in a few minutes.
14 Together, we ended up with quite a big bolus of
15 potential survey questions or questions that
16 patients wanted to be asked.

17 But we brought together a large
18 stakeholder group. You can see up there: CMS,
19 HRQ, Press Ganey, Geisinger, ECRI⁴³, all who are
20 speaking at this event, were part of this
21 prioritization. And what patients really want
22 to see -- now, these are six questions.
23 They're currently in a process with Press
24 Ganey. They're getting piloted and validated

42 Patients Involved in deVeloping Outcomes Together

43 Emergency Care Research Institute

1 this year. We also have in the pipeline
2 several other questions specifically around
3 diagnostic safety that we're launching in
4 September.

5 But you can see that patients want
6 to be asked about their experience of
7 unexpected harm, both physical, psychological,
8 emotional, and financial harms. They want to
9 report when they're treated differently. Now,
10 this was especially true for older adults
11 because we have an older adult group in this
12 project. During the hospitalization, did you
13 feel that any of your concerns were dismissed,
14 as my concerns were dismissed when I was
15 reporting to the health care system Cal's
16 symptoms and that he was changing before my
17 eyes. They want to report if they were
18 informed how to report a concern about patient
19 safety.

20 Also of importance is were they
21 informed how to escalate care or get a second
22 opinion, and they also wanted to be asked if
23 they were given a list of pending test results
24 upon discharge. Now, all of these questions,
25 Press Ganey has refined also to apply to the

1 ambulatory care.

2 So why are patient-reported
3 experience measures, patient-reported safety
4 measures so important? First is value. This
5 measures what matters to patients. Second is
6 transparency. This makes hidden harms and near
7 misses visible, measurable, and actionable.
8 Preventive. Real-time patient-reported
9 measures can identify safety risks before harm
10 occurs.

11 Learning health systems. Patient-
12 reported measures are available immediately,
13 and we don't have to wait for claims data to
14 take action and make change. Accountability
15 creates C-suite accountability for patient and
16 diagnostic safety and integrity, patient-
17 reported outcomes are harder to gain.

18 So based on those questions that I
19 showed, patient-reported experience measures,
20 and the current ACOs that we have, you know,
21 our first proposal and the nearest-term
22 proposal is why not integrate these patient-
23 reported measures into current ACOs? Now, I
24 just put LEAD and the MSSP up there as
25 examples. The benefit of this is that we

1 already have an ACO infrastructure. It's a
2 minimal burden, and I'll talk about this
3 tomorrow at the last session, where this can
4 all be, you know, we can use AI to collect,
5 analyze, and report patient-reported outcomes.

6 This will bring patient-centeredness
7 to the ACOs, a safety lens. It promotes
8 diagnostic excellence, which is really missing
9 in most payment models, and it will reduce
10 cost.

11 So, tomorrow, I will be speaking
12 about the PIVOT Earn-Back Value Model where
13 this is a proposed model that, instead of
14 penalties, this is actually withholding if
15 benchmarks aren't achieved. It's a withhold of
16 money, like Sam said earlier. There's money on
17 the table, and they need to show improvement,
18 and they can earn back that money.

19 So, I mean, patients rarely want to
20 see health care systems actually penalized.
21 The number one thing we want is learning,
22 continuous learning.

23 So, in closing, regarding patient-
24 reported measures of safety, patients and
25 families have always been the earliest

1 detectors of safety breakdowns and the clearest
2 judges of whether care was truly safe. The
3 question before us is not whether their voices
4 matter. The question is whether we will
5 finally value those voices enough to measure
6 them, to learn from them, and reward health
7 systems that respond to them.

8 What patients experience is not
9 peripheral to safety. It is safety. Thank
10 you.

11 DR. LIN: Thank you, Sue, for the
12 passionate presentation. We are saving all
13 questions from the Committee until the end for
14 all presentations.

15 Next, we are excited to welcome back
16 in person Dr. Michelle Schreiber, who is the
17 Deputy Director of the Center for Clinical
18 Standards and Quality and the Director of the
19 Quality Measurement and Value-Based Incentive
20 Group at CMS. Welcome, Michelle.

21 DR. SCHREIBER: Thank you, and thank
22 you for the invitation. It's really a pleasure
23 to be here. I am a general internal medicine
24 physician by background. I've been a Chief
25 Medical Officer, a Chief Medical Informatics

1 Officer, a Chief Quality Officer, and I've been
2 deeply engaged in patient safety and quality
3 for most of my career. As a matter of fact,
4 it's one of the reasons that led me to CMS.

5 Doing no harm is the fundamental
6 principle of health care, and we're very
7 excited that you're considering a model that
8 will really focus on patient safety. I think
9 you already know about the patient safety being
10 a public health urgent model -- this was
11 certainly outlined by Sam and Chinni in their
12 excellent presentations -- and that you also
13 know that there is a cause for optimism and
14 that the results have been getting better
15 because during the pandemic, the safety metrics
16 of this country plummeted. That wasn't just
17 because of the cause of the pandemic, and
18 people were really scurrying to try and
19 understand COVID and how to deal with it. I
20 think it's a reflection that the systems of
21 safety that we have put in place were not
22 strong enough to withstand such a burden and
23 that we really need to focus on building our
24 systems of safety.

25 And while our numbers are getting

1 better, they're just now recovering to pre-
2 pandemic levels. They're not continuing to
3 improve.

4 At CMS, we have a number of safety
5 levers that we have been employing. But I do
6 want to say that, as was pointed out earlier,
7 this remains a fragmented system. Even our own
8 programs, try as we may to bring them together
9 and integrate them, which we are trying to do,
10 still remains somewhat fragmented. But you can
11 see we have many of them. A large ecosystem
12 has been put together in this country. It is
13 not only CMS. We work closely with CDC and
14 AHRQ and FDA and ONC⁴⁴.

15 But you can see just within CMS, we
16 have several, including the conditions of
17 participation, which establishes the floor for
18 quality and safety. However, here the penalty
19 is so great, in other words, if you fail the
20 conditions of participation, you cannot
21 participate in CMS payment, which means that
22 they're not invoked very often because the
23 penalty is so severe.

24 We have coverage and payment

44 Office of the National Coordinator for Health Information
Technology

1 decisions. We have audits and evaluation. We
2 have survey and certification, largely to the
3 conditions of participation. The Quality
4 Improvement Organization is one of the largest
5 quality improvement organizations in the
6 country, and they do focus on improving safety,
7 largely focusing their efforts in skilled
8 nursing facilities, small clinician practices,
9 and smaller hospitals. And they have shown
10 improvement.

11 In quality measurement, it is true
12 that CMS maintains a portfolio of quality
13 measures, and we are transitioning those
14 measures to digital measures, which we think
15 will provide near real-time data, not just for
16 CMS, but for organizations themselves to learn
17 how to use their data real-time to create
18 learning health systems. These measures are
19 used within 27 value-based programs. Some are
20 pay-for-reporting, some are pay-for-
21 performance, and they cover virtually every
22 health care setting in the United States. And,
23 finally, and I know Susannah will be talking
24 about this, the payment and innovative advanced
25 payment models.

1 I did mention that we work closely
2 with our sister agencies across HHS and
3 external to HHS, in particular the VA⁴⁵ and the
4 Department of Defense. The measures, Chinni,
5 that you had pointed out that CDC is putting
6 forward are collaborative measures between CDC
7 and CMS, as are many of the other measures,
8 even with AHRQ.

9 CMS has done a number of things
10 recently to advance accountability. You've
11 already spoken of transparency, and, as a
12 matter of fact, you showed some of those
13 results on Care Compare, where we publish all
14 of our data transparently to the public. We
15 empower patients to make informed decisions
16 based on this, and we empower providers and
17 health care systems, really, to see how they're
18 doing.

19 You may recognize that, most
20 recently, CMS finalized that we will reduce
21 Star ratings by one star for any facility who
22 ranks in the lowest quartile for patient
23 safety, because we did not feel that someone
24 should have a five-star CMS sort of seal of

45 Department of Veterans Affairs

1 approval if they were the worst in patient
2 safety. That affected 14 hospitals this year;
3 and when we do this with all hospitals next
4 year, it will affect approximately 450
5 hospitals.

6 We are deeply committed to
7 technology and data, as I pointed out,
8 transitioning to digital technology for all of
9 our measures, but in particular, our electronic
10 clinical quality measures that are digital
11 through FHIR, as are CDC's, for safety, so that
12 organizations, again, can use these in real
13 time. We're also looking at AI to sit as a
14 layer on top of electronic medical records to
15 be able to use large language models to pull
16 more information, especially around patient
17 safety, so that that can be used as
18 supplemental information. It is also a
19 potential source of looking at the incident
20 reporting systems of most organizations because
21 these are separate in many organizations, and
22 we don't have insight into them.

23 The culture of safety that has been
24 alluded to is extremely important. It really
25 provides support for reporting. And, Sam, I

1 would only say one thing to your comment where
2 you said we should be penalizing for failure to
3 improve. I would add to that penalizing for
4 failure to report because, many times, these
5 episodes go unreported.

6 And, finally, payment. We are
7 talking about that today in terms of a model,
8 but we have also been exploring whether or not
9 the Center for Medicare has any levers to use
10 for non-payment of error. We are limited by
11 the regulations of the Deficit Reduction Act,
12 but are still learning what we can do for
13 payment.

14 I've spoken of some of these
15 accomplishments already, but CMS has put
16 forward the birth-friendly designation. This is
17 in support of maternal safety; the Patient
18 Safety Structural Measures, which has been
19 alluded to. Important information on this is in
20 the appendix of these slides so that you can
21 review them for details if you wish.

22 The age-friendly structural measure
23 is also one around safety, especially in the
24 elderly. The Quality Improvement Organization
25 13th Statement of Work. And I spoke about the

1 Stars in our suite of digital measures, and we
2 are starting with several new measures for
3 diagnostic safety.

4 In terms of quality measurement, you
5 can see we have over 400 measures, and 122 of
6 them are dedicated to patient safety, of which
7 a large number are actually external to
8 hospitals, although the major focus has largely
9 been in hospital programs. The new focus is
10 not only medication safety complications,
11 health care-acquired infections, but also
12 organizational capacity, which is really what
13 the Patient Safety Structural Measure was, and
14 diagnostic safety.

15 These are the five domains of the
16 Patient Safety Structural Measure. And I do
17 want to emphasize, although it has been stated
18 before, the vital importance of leadership and
19 governance when it comes to patient safety. It
20 is truly that as a fundamental commitment to
21 patient safety being the North Star that will
22 help an organization really make gains in
23 patient safety. And we see this across the
24 board, and we see some organizations fail
25 because their leaders have left.

1 One of the things that really needs
2 to happen, and we're very excited about this
3 being considered a payment model, is that the
4 C-suite, including the Chief Operating Officer
5 and the Chief Financial Officer, have
6 frequently seen this as a penalty that they're
7 willing to take, rather than investing, because
8 safety is the North Star, investing in patient
9 safety and making that better. I also want to
10 highlight what Sue has been talking about, the
11 vital importance of patients and family
12 engagement, the ability of patients to report
13 directly, the ability of their voice to be
14 heard.

15 We do have a suite of digital
16 measures, you can see them here, and as you
17 heard, partnering with the CDC to bring forward
18 more. Again, the goal here is real-time
19 reporting that a facility can use to make
20 continuous improvement.

21 I think many of the successes and
22 the shortfalls were really covered by Chinni in
23 your really wonderful presentation. So thank
24 you. I won't spend time on this. But I do
25 want to just highlight a few future

1 considerations.

2 We've talked about the use of
3 artificial intelligence, the reporting of harm.
4 Many of you know that there is actually a
5 national patient safety organization movement.
6 There are about 100 patient safety
7 organizations in the country, and they are, in
8 theory, supposed to report to a national
9 database that is maintained by AHRQ, which
10 would give us national information around
11 patient safety. Of the 100 patient safety
12 organizations, only about five actually report,
13 and I think that is another opportunity for us
14 to have more national information around
15 patient safety.

16 We spoke about digital advance. So
17 in thinking through a model, I just want to
18 close with a couple of things. One is the hope
19 that there will be one, and, Sam, I want to
20 thank you really for your tireless commitment
21 to patient safety. You and I have spoken on
22 multiple occasions, and I think your leadership
23 has been instrumental.

24 Two, focus on capabilities. Ensure
25 that the system has the capabilities, such as

1 governance, the ability to use data real-time
2 to drive improvement, and the culture that
3 allows speaking up and reporting in a safe
4 environment. Include training in everything
5 that you do because a lot of organizations may
6 think they have capabilities such as high
7 reliability, but really, when they think about
8 it, they don't necessarily have it.

9 Patient engagement, there's a
10 tremendous opportunity, I think, to reframe and
11 re-ask patients around their experience for
12 safety. And technology offers us a lot of
13 opportunities for the future, such as wearable
14 devices, or monitoring, or predictive
15 analytics, and artificial intelligence to gain
16 more information.

17 But in the end, I think the most
18 important thing is willpower. If we can create
19 the will to change and to truly accelerate
20 patient safety, there's no doubt that we can
21 make tremendous progress and that patients will
22 not be harmed. Thank you.

23 DR. LIN: Thank you, Michelle.
24 Next, we are also happy to welcome back in
25 person Dr. Susannah Bernheim, Chief Medical

1 Officer for the CMS Innovation Center.
2 Susannah, please go ahead.

3 DR. BERNHEIM: Thank you, Walter.
4 Thank you. I'm really happy to be here this
5 morning to speak with all of you and to be on a
6 panel with colleagues who have just committed
7 so much of their life's work to promoting
8 patient safety. It's really an honor.

9 Michelle covered a lot of the work
10 around patient safety at CMS. I feel like my
11 job here today is to talk a little bit
12 specifically about the CMS Innovation Center,
13 what some of our authorities are and our
14 opportunities, and give you just a few examples
15 of places where patient safety has shown up in
16 our models to sort of spark the Committee's
17 thinking about where we could go from here.

18 And I want to really appreciate and
19 acknowledge Sue's concrete recommendation for
20 us about ACOs, and where we could go there.
21 And, Sue, I've heard your stories before, but
22 it sort of stops the room. Anyway, I'm sorry,
23 and I appreciate you sharing them.

24 Okay. To put the bottom line up
25 front about how I think about the Innovation

1 Center and our opportunities, if you look at
2 the CMMI portfolio today, we don't have a
3 patient safety model. But across the
4 portfolio, you'll see efforts to use the levers
5 we have, the distinctive levers we have in the
6 Innovation Center to advance fundamental
7 changes in health care. And a lot of those
8 particularly should drive care coordination.

9 And, in fact, one of the main themes
10 that came out of a 2023 study about common
11 findings across different models was this
12 common focus on driving coordination. And if
13 you think about what leads to poor patient
14 safety, coordination is critical tool for
15 improvement. Coordination and communication
16 between primary care doctors and specialists,
17 between ambulatory care and acute care, between
18 patients and clinicians. So I think that is a
19 key opportunity for us.

20 And the heart of the Innovation
21 Center work is a requirement that our models
22 both drive lower costs and improve quality.
23 Improving safety is fundamental to the success
24 of our models. As many will point out, adverse
25 safety events and experiences are not only

1 terrible for patients, they're also costly for
2 the system. And care coordination is a key gap
3 that models can help address and is really
4 crucial for safety.

5 So I'm going to step into a short
6 overview of this Innovation Center's
7 priorities. I'm going to talk about the
8 authorities that we have that can drive safety,
9 give you a couple of examples from the
10 ambulatory space. You'll see me really
11 focusing on some of our ambulatory models
12 because Michelle has done such a nice job
13 thinking about the hospital space. And then
14 really just hope to think about the
15 opportunities in front of us. That was my
16 agenda.

17 Okay. So this is an image of how we
18 framed the priorities for the Center. And
19 because Abe mentioned a bunch of this, I'm just
20 going to take a moment on this. We have these
21 three pillars around prevention, patient
22 empowerment, choice and competition. And as
23 Abe noted, all of these have meaningful
24 connections to patient safety.

25 But I just wanted to say a word

1 about our patient empowerment pillar, that one
2 in the middle. I think, following on Sue's
3 remarks, there's been really important advocacy
4 from patient safety experts about the need for
5 us to empower patients and beneficiaries as a
6 part of our efforts. In the Innovation Center
7 right now, we're addressing patient empowerment
8 primarily by focused on how can we give people
9 more information, support, and incentives to
10 take a more active role in their health, that
11 equipping patients with the tools to understand
12 their health status, set goals, make informed
13 decisions is important. But I think this idea
14 around surfacing information to beneficiaries
15 is a really important and synergistic with the
16 work to advance patients' voice in the health
17 system, as both are really about the advocacy
18 for patients' engagement and partnership.

19 I'm going to just switch now to
20 talking a little bit about where I see our
21 opportunities in ambulatory care, but I can't
22 resist saying just one word about the hospital
23 models because I think they have been
24 tremendous opportunities to strengthen the
25 incentives already in use in CMS.

1 In TEAM, which is a mandatory
2 Transforming Episode Accountability Model,
3 we're focusing on surgical bundles. This will
4 be mandatorily in hospitals across the country,
5 and it lets us not only incorporate the patient
6 safety measures that Michelle's team used, but
7 crank up the financial accountability for those
8 measures. And it's really about driving
9 coordination from the hospital through the
10 outpatient space and holding hospitals
11 accountable for those outcomes. And if you
12 want to lower the costs of procedure-based
13 bundles and reduce use of acute care and
14 maintain good outcomes for beneficiaries,
15 coordination and avoidance of complications are
16 critical. And we've seen the success of bundle
17 payments preventing decrements in patient
18 safety in our CJR⁴⁶ Model as well. We could not
19 have proposed to expand that model had we not
20 had results that showed that these bundle
21 payments could be successful. So that's my
22 quick word on the hospital measures as I pivot
23 to ambulatory.

24 So this slide is just a reminder

46 Comprehensive Care for Joint Replacement

1 about some key ambulatory safety priorities and
2 the opportunities that they afford us to try to
3 improve safety. Here, like in the hospital
4 setting, but even more, we see the importance
5 of communication, medication safety, care
6 coordination, failures, and the fact that
7 patients need to be centered in their care.
8 And this gives us, these kinds of failures
9 influence medication management, fall
10 prevention, diagnostic safety.

11 So I think there's a lot of
12 opportunity in the Innovation Center and in
13 advanced payment models to focus on
14 interoperability, to focus on medication
15 management, which we'll talk about an example
16 of, coordination, as I've mentioned before, our
17 communication systems, especially, again,
18 echoing Sue, hearing from patients and engaging
19 with them. And I note, as recommended by many,
20 that we really focus on patients who are most
21 high-risk.

22 So as we turn to thinking
23 specifically about Alternative Payment Models,
24 I think it's useful to ground in what the
25 Innovation Center's authorities are. So this

1 is, you know, I don't even know what all these
2 sections refer to, but a reminder that what's
3 sort of distinctive about what we can do in
4 CMMI and what this Committee can help us think
5 about is the ability to waive existing
6 requirements to test new approaches that can
7 help us advance safety. And I wanted to give
8 examples of the ways we do that again in the
9 spirit of sort of sparking the Committee's
10 recommendations.

11 So, for example, in some of our
12 models, we waive the three-day rule. This
13 allows participants in the models to identify
14 patients that would benefit from skilled
15 nursing care without going through a costly
16 high-risk hospital stay. In other cases, we
17 allow for case management through a home visit
18 waiver, so for people to come into patients'
19 homes. And in a third example, and I'll give
20 an example of how we're using this, we allow
21 for payment arrangement across participants
22 that can really encourage and build that
23 systemic coordination.

24 We also obviously use tools such as
25 quality measurements tied to financial payment,

1 and we often create specific requirements for
2 care management to sort of instill certain
3 changes in the way care is given in our models.
4 And I'm going to use the example of our GUIDE⁴⁷
5 Model to highlight this, and then I'll talk
6 briefly also about a particular example in our
7 LEAD Model just to show sort of how we can
8 embed some of these authorities inside of our
9 models to drive safety.

10 And I'll be brief because these are
11 just meant to be examples, but here's an image
12 related to how in GUIDE, which is an ambulatory
13 model focused on improving the care of patients
14 with dementia that has many features to it that
15 are really focused on supporting caregivers.
16 But we also, within this, given the risk of
17 polypharmacy for dementia patients, have a
18 number of different factors in place just to
19 focus on attending to medication management.
20 So we have requirements for the physicians to
21 review and reconcile medicines. We have
22 quality measures that have financial incentives
23 particularly focused on high-risk medicines.
24 We have support for communication across the

47 Guiding an Improved Dementia Experience

1 teams. We have the use of case care
2 navigators. So you see how we can start to
3 build many pieces that you need to really drive
4 something like avoidance of polypharmacy.

5 I'm talking a little fast, but I've
6 got just one more example. LEAD is our newest
7 ACO model, which launches in 2027. And there's
8 lots that we could talk about in LEAD, but I
9 just want to highlight one aspect that brings
10 in an example of how our models can distinctly
11 support patient safety. In LEAD, we're testing
12 what are called CMS-administered risk
13 arrangements, and this creates infrastructures
14 for ACOs to be able to contract directly with
15 specialists. And one of those specific
16 mechanisms in LEAD is called RISE, which stands
17 for Resilience and Independence in a Safe
18 Environment to age in place episode. RISE is
19 much easier to say than all of those words.
20 But this is a distinct opportunity where ACOs
21 can build actually on what folks may have known
22 of as the CAPABLE⁴⁸ Model from some time ago, so
23 they can contract directly to bring
24 occupational therapists and nurses into

48 Community Aging in Place - Advancing Better Living for Elders

1 patients' homes and focus on fall prevention.

2 And when we create an opportunity
3 like this for the ACOs, we're tying that also
4 to a requirement that they have a new
5 prevention intervention that we are tracking,
6 and we're encouraging them to consider this as
7 a piece of their particular prevention
8 interventions.

9 Okay. So I just want to also
10 highlight the impact because, in the Innovation
11 Center, we also test what happens with our
12 models. So here are a few examples of CMMI
13 evaluations, again, in models that weren't
14 proclaimed to be patient safety models but
15 where we had the opportunity to understand an
16 impact.

17 So I already talked about our
18 episode-based payment models and how important
19 it was, as we're driving down post-acute care
20 use and costs, to build in looking at things
21 like complications of care as a guardrail and
22 the success of CJR in maintaining quality while
23 reducing costs. That's an important feature of
24 our safety models.

25 In our Oncology Care Model, we had

1 an embedded multidisciplinary, multidimensional
2 safety framework that looked at things like
3 unanticipated ED visits and late-stage chemo
4 use, and those results showed an overall
5 improvement in quality and safety. So, again,
6 an evaluation showing that the model led to
7 improvements. And a favorite is the
8 Partnership for Patients, which was an early
9 model where patient safety was really front and
10 center, and this is credited with a lot of
11 improvements nationally in things such as
12 health care-acquired conditions.

13 Okay. So, in sum, I hope this is
14 helpful for the Committee to consider the range
15 of tools that we have to advance patient safety
16 in the Innovation Center throughout our models,
17 whether or not we label them as patient safety
18 models. And we can continue to use these
19 authorities and are eager to hear the
20 Committee's recommendations for how to do so,
21 especially interested in how we can build on
22 the coordination functions that are so
23 important for safety and have been found to be
24 a feature of many models and the incorporation
25 of patient voice in this coordination. And

1 there's a special opportunity when we advance
2 safety in the CMMI models to do these at formal
3 tests that we evaluate and, therefore, can
4 expand when they're successful.

5 Thank you.

6 DR. LIN: Thank you, Susannah.
7 Next, we are excited to welcome virtually Dr.
8 Jason Mitchell, who is Executive Vice President
9 and Chief Medical Officer at Geisinger.
10 Welcome, Jason.

11 DR. MITCHELL: Thank you all so
12 much. It really is a privilege to be here. I
13 am a practicing family physician, as well as
14 CMO at Geisinger, and so this is near and dear
15 to my heart.

16 Going to the next slide. The truth
17 is safety matters, period, and zero harm is
18 possible. And I think with all of us
19 cumulatively in this room representing who we
20 represent, so CMS, health systems, clinicians,
21 we can get to zero harm. And I just wanted to
22 begin with that.

23 Next slide. And I wanted to start
24 with some of the great things that have been
25 done. And so we use these models, we

1 participate in these models, and there's a ton
2 of opportunity here. And so it was really fun
3 to hear you all talking about them because I
4 think they've really moved the ball forward.

5 I think there's also opportunities
6 which I'd like to highlight. The first is most
7 of the CMS-driven Alternative Payment Models
8 really don't have a full incentive framework
9 for safety on its own. It's mixed in other
10 pieces. And we still have a focus in these
11 models on utilization, admissions,
12 readmissions, those type of things, which are
13 really, really important, but safety goes far
14 beyond that.

15 I would say probably the strongest
16 of these models, and we've heard about this, is
17 the CMS TEAM Model, which really begins to dig
18 into key safety metrics, and it's important.
19 And as I think about the opportunities for this
20 to go forward and think of these past
21 presentations that we've just presented, this
22 was in there, medication events are huge in
23 safety, right? Whether you're in the hospital,
24 in the home, in clinic, medication is huge.

25 Post-discharge falls. When you

1 think about what begins that cycle for our
2 patients, they get into many admissions, it
3 will be a fall, repeated falls. Post-discharge
4 complications. So far beyond some of the
5 bundles we've seen in the past but really think
6 about all admission types. And then ambulatory
7 safety. Generally, people are not in our
8 hospitals, and they're not in our clinics,
9 they're at home. And so how can we begin to
10 address their needs at home? And so as I think
11 about the current models, which have done a lot
12 of great good for the people they serve, I
13 think about here's the pieces we could be going
14 to.

15 Next slide. So I think it's not
16 just obviously CMS' job to do this, it's our
17 job as health systems to do this, right? We
18 have to do this in partnership, we have to be
19 pushing forward. This is an example of what
20 Geisinger has done, where we're actually
21 warranting some of our procedures. We are
22 going personally at risk for any bad outcomes
23 to ensure that we are aligned with the best
24 outcomes 100 percent of the time. And this is
25 an example of some of the work in ProvenCare,

1 which is a warranty in heart surgery. And it
2 really, as CMS puts people at risk, we put
3 ourselves at risk with different payers as
4 well.

5 Next slide. And in doing so, you
6 really have to change your organization. And I
7 want to share a little bit about what Geisinger
8 has done as a health system because I think
9 this can play into what CMS can do in
10 integrating your models. But if you want to
11 eliminate harm and get to zero harm, if you
12 want to improve safety, you have to be highly
13 reliable. You can't be great 95 percent of the
14 time, you have to be great 99.999 percent of
15 the time, right? You have to be that perfect.
16 And to do that, you have to have systems to
17 support you.

18 For us, we are all in on high-
19 reliability organization principles. And I
20 want to share a little bit about this and then
21 how they impact what we do.

22 There are really five principles to
23 high reliability. The first sections are
24 anticipate safety threats. The second is
25 respond and adapt. So in that anticipate

1 section, it's a preoccupation with failure,
2 which sounds terrible, right? You don't want
3 to be preoccupied with failure; but, in fact,
4 it's amazing. And it's what we do as
5 clinicians every day. We're always worried.
6 What could go wrong? What's happened with my
7 patient? What can I do to preempt it? And
8 it's getting that mindset for every individual
9 that touches the patient to preempt and
10 prevent.

11 The second is reluctance to
12 simplify. Health care is complex, and it's
13 never just, oh, we could just do X, Y, or Z,
14 and that fixes it. You have to dig in,
15 understand root cause analysis, and truly get
16 to the cause.

17 The third is sensitivity to
18 operations, meaning the people at the frontline
19 understand what's going on better than the
20 people who are not at the frontline. And so
21 you have to understand and ask and be present
22 to really solve for these safety issues.

23 And respond and adapt in the HRO⁴⁹
24 system, it's a commitment to resilience,

49 High Reliability Organization

1 knowing that failures occur and, when they
2 occur, how do you bounce back and prevent them
3 again. You have to have that resilience.

4 And then the fifth concept is
5 deference to expertise. So as we are making
6 decisions, as we are designing for patient
7 safety, you defer to expertise. And the people
8 most expert are the patients and the
9 clinicians, the nurses, the doctors, the
10 advanced practice clinicians taking care of
11 them. And so having that deference to
12 expertise and including them in the
13 conversation and co-designing gives you a much
14 better product.

15 These are the principles that we use
16 every day at Geisinger so that we can work to
17 zero harm, both in the inpatient and ambulatory
18 setting.

19 Next slide. To do this, you have to
20 really change how you lead, and you have to
21 make it part of the fundamental culture so that
22 everyone's involved. As I mentioned, it's all
23 about reliability, which is a consistency.

24 There's things that you can do.
25 What we do is we start every meeting with a

1 safety moment, every single meeting with a
2 safety moment. And even if it's our health
3 plan meeting, if it's an administrative
4 meeting, IT meeting, it's with a safety moment
5 because it all ties back to care. And that
6 keeps people focused on how what work they do
7 ties back to it.

8 We encourage and protect those that
9 speak up. You've got to have a psychologically
10 safe environment and transparency so people
11 feel safe saying, hey, this didn't go right, or
12 people pull the line when something's not right
13 and stop something before it starts. You have
14 to have a no-blame culture, and you have to
15 celebrate when you find the harm, because now
16 you can find it, identify it, do root cause and
17 prevent it in the future. So a very different
18 way of thinking about it within a just culture.

19 And then you have to link decisions
20 to safety. In every decision you make, you
21 have to think how does this impact the patients
22 that we serve, how will it change their safety,
23 and how do we create reliability that we do
24 this every single time? So those are the
25 concepts as leaders that allow us to use those

1 principles.

2 Next slide. And so with that,
3 that's how we work towards it. And I want to
4 share some of the things that I believe that we
5 could do as a health system, that CMS can do,
6 and APM models, that will advance us forward.

7 The first is really advancing
8 patient safety metrics to directly reward harm
9 prevention. So adding the safety composite
10 score for ACOs, considering a safety-gated
11 financial incentive so it's hard to get savings
12 if you haven't also had safety. And I heard
13 some other withholding concepts in the previous
14 conversation. This is more of just a gating
15 for the benefits of safety.

16 And then beginning to think about
17 bundled payments that include post-acute safety
18 measures far beyond readmissions because
19 there's a lot of other important things that
20 happen to create safety for patients prior than
21 just readmissions and so including a more
22 comprehensive look. I think the second piece
23 of this is aligning financial outcomes with
24 zero harm, so can we anchor outcome-adjusted
25 payments to safety. So really episode

1 guarantees like we have done with ProvenCare,
2 can we do that and go beyond just the basics,
3 just the bread-and-butter diagnosis of
4 populations.

5 Another piece is rewarding bundle
6 adherence. So bundle adherence is a leading
7 indicator to harm avoidance, and some
8 organizations have to ramp up to prevent harm.
9 And so how do you create systems that align
10 that allow people to ramp up with adherence and
11 eventually outcomes measures so that they have
12 that time to do that?

13 And then the other piece is really,
14 and you heard about this earlier, integrating
15 patient-reported outcomes and safety measures
16 because what really matters is what the
17 patients feel, what people feel, what people
18 experience. And we can say all we want, we can
19 show all the numbers we want, but we need to
20 know what they are experiencing. And as we
21 ramp this up, we'll get a better sense of what
22 our patients need, what we need, what our
23 families need, and so including those.

24 And then, finally, and you heard
25 little bits and pieces of this in the

1 conversations, but really deploying models to
2 support ambulatory safety because that's where
3 patients are. That's where people are in their
4 homes, at work. They're not in the hospitals
5 very much. They're out in the community, and
6 that's where we can have a huge amount of
7 impact.

8 Probably the most important thing is
9 getting an established framework. What are the
10 unified metrics and outcomes in ambulatory
11 safety? Let's get a framework we can all align
12 to, we can put incentives to, and move forward
13 as a nation. I think that would be critical
14 for us.

15 I think the second piece is a focus
16 on frailty and fall prevention. When I step
17 back and actually look at hospital metrics
18 nationally, locally, that frailty of that
19 individual is a huge predictor to something bad
20 happening to that patient. And if we can
21 understand that, we can improve the nutrition,
22 we can prevent the falls, you can fundamentally
23 reduce harm for those individuals. And so that
24 is a place where we have ripe opportunity that
25 we've probably not taken advantage of as a

1 nation to improve the health outcomes of
2 people.

3 And then, finally, medications
4 reduce harm from medications. There are so
5 many ways that medications can do amazing
6 things for us. There's so many ways they harm.
7 Polypharmacy can be harmful. Confusion as to
8 what medications to take. Lack of access to
9 get their medications. Confusion around
10 benefits of medications. And so as a big
11 category that can reduce harm, especially in
12 the ambulatory setting, it's another place to
13 look.

14 And so really I wanted to be brief.
15 I wanted to share safety matters. We are all
16 about zero harm. We've put a lot of effort
17 into it. We don't call it preventable harm.
18 We call it all harm. All harm is preventable.
19 And even if you can't figure out how to prevent
20 it today, tomorrow you're probably going to.
21 So I really want to put that stake in the sand
22 and then share some of these key opportunities
23 with you all and looking forward to questions
24 at the end of this.

25 DR. LIN: Thank you, Jason.

1 Finally, we are delighted to welcome virtually
2 Dr. Dheerendra Kommala, Chief Medical Officer
3 at ECRI. Please go ahead, Dheerendra.

4 DR. KOMMALA: Thank you so much for
5 the invitation. It's a privilege to be here.

6 If we can go to the next slide,
7 please. Excited to represent the 250 passionate
8 people who work at ECRI to really improve
9 safety and quality in health care. Our mission
10 and our vision is to reduce harm. We are a
11 federally qualified patient safety
12 organization. We are also an evidence practice
13 center designated by AHRQ, one of the only
14 organizations that is a combination of both.

15 We've been a testing lab for almost
16 60 years now, testing medical devices and
17 equipment. We also have as a sister
18 organization ISMP, Institute for Safe
19 Medication Practices. That is the premier
20 organization in reduction of medication errors.
21 And most recently, we acquired a company called
22 The Just Culture Company, which is all about
23 non-punitive culture to transform workplaces.
24 We, as you can see here, serve a significant
25 part of the ecosystem in many different ways.

1 Can you go to the next slide,
2 please? Thank you. Many of these topics have
3 been talked about in the beginning parts of the
4 presentations. We continue to make some
5 progress through the different innovative
6 models that CMS has proposed, but there still
7 is significant areas of improvement. We
8 continue to see one in four patients observing
9 adverse events, 50 percent underreporting, if
10 not more. There's a significant area of
11 improvement for us, which is we need to really
12 change our patient safety outcomes and really
13 implement continuous learning systems because
14 the only way we will get better is learning
15 from things that have happened and implementing
16 them.

17 What I have done for this
18 presentation is look at the last 10,000 events
19 that we actually have been reported to us and
20 gain some insights and make some
21 recommendations.

22 If you could go to the next slide,
23 please. Okay. So the concept here is all
24 about near misses. And I think Sam pointed out
25 that it's about, once we learn about something,

1 we need to make sure that they're implemented
2 appropriately. And it's not being punitive at
3 the stage where events are being reported.

4 So we looked at the 10,000 events
5 that were submitted to us, and over 1,000 of
6 those events were what are called near misses.
7 As an example, a pharmacist was conducting
8 rounds and found a heparin drip that a patient
9 was on. There was no monitoring labs for almost
10 48 hours. Labs were ordered after 48 hours.
11 This is a very classical case of a near miss
12 where significant harm could have befallen the
13 patient. But this kind of behavior is not
14 incentivized where this pharmacist in
15 particular reported the potential that this
16 could have caused a harm.

17 So this is a recommendation that I
18 will talk about later, which is let's reward
19 safety signals. Let's reward near misses so
20 that this becomes a culture for us. In
21 addition to, obviously, if people are not
22 implementing the right steps, then there should
23 be disincentives.

24 Next slide, please. One of the
25 pieces that we consistently see is medication

1 reconciliation problems. In particular, these
2 transitions happen at admission, during
3 inpatient care, and at discharge. Some of the
4 earlier presenters have talked about this.
5 Almost 73 percent of these events that we've
6 seen are taking place during care transitions.

7 As an example, six medications that
8 the patient was on was completely omitted at
9 the time for admission and was caught at the
10 time of discharge. These are medications like
11 aspirin, thyroid supplements, et cetera, which
12 actually, as you can all understand, is
13 problematic that there was no recognition of
14 that.

15 So transition failures do not have
16 an accountable owner, and we need to set that
17 up, and we need to incentivize the correct
18 reporting here, as well.

19 Next slide, please. There's a big
20 role for technology to play, I think. And I
21 agree with earlier presenters that it could
22 change the safety paradigm. But the issue is
23 that there's almost 1,500 new devices that have
24 been cleared through 2025. About 97 percent of
25 them, a significant portion of them, are

1 cleared by the 510(k) process. And if you look
2 at the recalls, there's almost 43 percent of AI
3 devices that have been recalled over the last
4 one year.

5 The point here is we absolutely need
6 to utilize new innovative technologies, but it
7 should be connected with outcomes. It should
8 be connected with value-based frameworks. We
9 are also supportive of enabling digital health
10 access.

11 Next slide, please. We've looked at
12 sepsis as an event in the last 10,000 safety
13 events, and we observed 88 sepsis-related
14 events, 15 of them being severe. One thing
15 which caught my mind is there was almost an
16 eight-hour delay from the time the patient
17 actually came into the hospital all the way to
18 the antibiotic being administered. Now,
19 there could be many reasons for it, but, as we
20 see this consistently, we see system design
21 failures in the context of order sets being
22 ambiguous, IV⁵⁰ access barriers, antibiotic
23 scheduling, and competing clinical priorities.

24 So the point here is this is just a

50 Intravenous

1 tip-of-the-iceberg problem where there's a need
2 for us to really look at systems design and
3 even factors engineering to really address some
4 of these systematic problems, and that needs to
5 be incentivized, as well.

6 Next slide, please. Okay. So very
7 quickly then, recommendations. Safety signals
8 should be utilized, and in particular near
9 misses to adverse events. So you want a health
10 system to decrease their adverse events and
11 increase their near misses so that they
12 actually get the right culture and the
13 continuous learning system.

14 We need to start incentivizing
15 utilization of technology, but in a value-based
16 framework, and outcomes should be an important
17 parameter that we are actually measuring them
18 on. Patient care transitions continue to be a
19 problem, particularly in high-risk points, and
20 we need accountability. We need payment
21 structures that actually take into account
22 patient care transitions. It's not just the
23 acute care system anymore. It is the alternate
24 care sites, and it's the whole.

25 And, finally, we need to start

1 thinking about human factors engineering and
2 design of care delivery. It's an important
3 factor that goes from reactive to proactive.

4 I want to end by saying the patient
5 has to be at the center of all we do. Sue
6 Sheridan, I'm completely supportive of the
7 concept that you put forth. Thank you for your
8 time. I'm glad to take questions.

9 DR. LIN: Thank you, Dheerendra.
10 And, thank you to all our experts for these
11 great informative presentations.

12 Now, let's move to the discussion
13 portion of the session. At this time, PTAC
14 members, please flip your name card up, or for
15 our virtual Committee members, please raise
16 your hand on Zoom if you have questions for our
17 guests.

18 Additionally, we want to encourage
19 our experts to ask each other follow-up
20 questions. You can signal that you have a
21 question by flipping your name card up or
22 raising your hand on Zoom.

23 In the interest of ensuring balance
24 across different perspectives and questions, we
25 encourage experts to keep each response to a

1 few minutes.

2 All right. So, Sue.

3 MS. SHERIDAN: No, I'm just learning
4 so much in this, and I have a question actually
5 for Susannah. Susannah, you mentioned that,
6 you know, at CMMI, you don't really have any
7 innovation models that focus just on safety.

8 Could there be models that focus
9 just on safety?

10 DR. BERNHEIM: Absolutely. I mean,
11 that's the short answer. You want short
12 answers?

13 MS. SHERIDAN: Great.

14 DR. BERNHEIM: I would just say the
15 one thing I'll add is like, I would not want
16 that to distract us from building it into other
17 models.

18 MS. SHERIDAN: Yes.

19 DR. BERNHEIM: Because, you know,
20 the ability to expand models if they don't have
21 a patient safety focus, if it's not that one
22 that gets expanded, so yeah.

23 MS. SHERIDAN: Thank you.

24 DR. LIN: Thank you. I think
25 David's next.

1 MR. TYSON: Okay. I think I was
2 last to put it up. But, that's totally fine
3 too. So, I actually want to go back to a point
4 that Sam raised in his opening remarks, but I
5 think kind of came up in a lot of what you all
6 were talking about.

7 And, I don't direct this to one
8 person individually. So, whoever wants to sort
9 of popcorn in, please feel free.

10 But, how do we engage the low
11 performers? How do we bring them along?

12 I think the point is well taken that
13 anybody that's going to voluntarily participate
14 in a CMMI model, or watch a PTAC recording, are
15 probably the folks that are not the ones that
16 we need to focus on.

17 So, is it focusing on improvement
18 trajectory? How do we keep them engaged from
19 the initial point of intervention and then the
20 actual outcome, which sometimes can take years
21 to sort of see that improvement play out?

22 So, I don't know who wants to take
23 that first. But, how do we engage low
24 performers?

25 DR. SCHREIBER: I can start. I will

1 tell you in the quality improvement
2 organization network, we target low performers.

3 And, we look at what their scores
4 are and reach out. It's also a voluntary
5 program, so they don't have to.

6 But, we specifically target low
7 performers. And, I think any other kind of
8 model or payment system could do the same.

9 MS. SHERIDAN: I'd like to add what
10 onto what Michelle said, tomorrow I'm
11 presenting the earn-back model, the incentives
12 kind of conceptual model.

13 And, something that we're seeing
14 that if those who do not reach their
15 performance measures, their benchmarks, that
16 this is where we see a great opportunity for
17 the QIOs⁵¹ to come in as consultants to help
18 those lower performers rise up and then earn
19 back their, you know, what was withheld.

20 So, we're trying to weave in many of
21 the CMS levers into the earn-back payment
22 model.

23 DR. BERNHEIM: And, the only thing
24 I'll add, I think I was going to say both of

51 Quality Improvement Organizations

1 these things, that there's ways to do it with
2 the financial, there's ways to do it with
3 quality improvement. Often the measures reward
4 improvement, right?

5 So, we have a complicated thing in
6 ACO REACH called CI/SEP⁵². But, part of the
7 idea is that if you're not achieving, if you
8 get rewarded for improvement.

9 And then, the last thing I'll say is
10 that this is an issue with voluntary models,
11 and you will see we are increasingly thinking
12 about mandatory models so that you get a more
13 representative set of participants.

14 DR. MITCHELL: Just one other
15 thought on here is, you know, meet people where
16 they are. Let's assume that everyone wants to
17 be high-quality, and they've got barriers to
18 that.

19 And so, I think providing glide
20 paths, sometimes providing incentives up front
21 so if they need to invest, they can, is
22 important. And so, let's assume good
23 intentions, figure out the barriers, you know,
24 avoid simplifying, and then give them pathways

52 Continuous Improvement/Sustained Exceptional Performance

1 that work.

2 And, I know there's many CMS models
3 that do that, right? There's different tiers,
4 there are different timings.

5 So, I think that's the best way to
6 match the low performers.

7 DR. KOMMALA: If I can jump in. We
8 meet with all CEOs⁵³ and C-suite folks of both
9 high-performing and low-performing
10 organizations.

11 The ability to connect safety and
12 quality to financials is a gap. And, there
13 needs to be some level of education there.

14 If you're safer as a hospital,
15 you'll actually end up being better from a
16 financial outcome standpoint. But, that piece,
17 I think, is lacking.

18 And then, the second piece really is
19 around absolutely incentivizing the right
20 behaviors and providing the right financial
21 output for the right behaviors that are being,
22 and the right outcomes that they are achieving.
23 Moving up levels, whether it's Leapfrog score
24 or otherwise, they should be incentivized to do

53 Chief Executive Officers

1 that.

2 MS. SHERIDAN: Yeah. Just I'm kind
3 of giving away my presentation tomorrow. But,
4 I'm just thinking about that, the earn-back
5 model. And, I'll go much more into detail
6 tomorrow.

7 But, we actually see it, the PIVOT
8 Earn-Back Model as a continuous learning system
9 within a payment model. And so, for low
10 performance, what we envision as people don't
11 make their benchmarks and reinvest, you know,
12 their withheld money into safety, and there's
13 actual learning and improvement, that that gets
14 shared with other hospitals.

15 So, almost like a partnership or
16 patients kind of concept. So, there could be a
17 learning collaborative that's going on as
18 hospitals are learning how to improve in
19 safety.

20 So, it would help those lower
21 performers.

22 DR. LIN: Great. Thank you for all
23 those responses. I'm going to go to Larry and
24 then Lauran.

25 DR. KOSINSKI: Thank you, Walter.

1 Great discussion. But, as always happens here
2 when we listen to our SMEs⁵⁴, the gears in my
3 head are just flying.

4 But, thinking about what the
5 commonalities are amongst the four
6 presentations, one of the things I was very,
7 very pleased to hear, is a focus on ambulatory
8 safety. So much of what CMS and CMMI have done
9 in the past has been focused on the hospital
10 side.

11 But, that's actually putting the
12 cart in front of the horse, because the errors
13 in safety, the errors in diagnosis, the
14 misdiagnoses, they occur in the outpatient
15 setting predominantly. And, by the time the
16 patient reaches the hospital in potentially an
17 avoidable complication, we've really missed our
18 opportunity.

19 So, I was very, very pleased to hear
20 several of you speak about proactive patient
21 engagement, especially in symptomatic high-risk
22 chronic diseases. This has been something
23 that's been near and dear to my heart for the
24 last 10 years with my Sonar work.

54 Subject matter experts

1 And so, I'd love to hear some
2 granularity from you as how you have built
3 PROMs⁵⁵ and patient safety measures in the
4 ambulatory space. I'd love to hear some
5 granularity here.

6 MS. SHERIDAN: And, I think that
7 question was directed to me, Sue Sheridan.

8 DR. KOSINSKI: Yeah, any of you.
9 But, yes, Sue, go ahead. Go ahead.

10 MS. SHERIDAN: I'll jump in. So,
11 the PROMs and PREMs⁵⁶ that we have developed
12 around patient safety and diagnostic safety was
13 really we created a new methodology where we
14 brought in over 100 patient organizations,
15 community-based organizations. We brought in
16 three separate populations, mothers of color,
17 people with disabilities, and older adults.

18 And, together over a series of nine
19 different engagement events, we created the
20 PREMs and PROMs that mattered to the patients
21 and family members. And, they went through a
22 very systematic and rigorous qualitative
23 analysis of those.

24 And then, we mapped them onto

55 Patient-Reported Outcome Measures

56 Patient-Reported Experience Measures

1 national initiatives, patient safety
2 initiatives such as CMS, CDC, HRQ initiatives.
3 And, we narrowed it down to a set of 18, and
4 then the stakeholder groups and the patients
5 prioritize them.

6 So, we have come up with probably
7 one of the first sets of patient-reported
8 outcome and experience measures around safety
9 and diagnoses, and we have more in the
10 pipeline.

11 DR. KOSINSKI: And, how do you
12 deploy them?

13 MS. SHERIDAN: Well, right now
14 they're getting piloted and validated by Press
15 Ganey. And so, they're under, you know, a
16 validation process right now. And then, we
17 hope to deploy them through payment models.

18 We hope to integrate them into the
19 HCAHPS⁵⁷. And so, we hope to put them in play,
20 work with CMS, and incorporate them as
21 performance measures.

22 So, we see several pathways for the
23 PREMs and PROMS around safety.

24 DR. KOSINSKI: Anybody else want to

57 Hospital Consumer Assessment of Healthcare Providers and Systems

1 comment on that? Anybody from the CMS CMMI
2 side?

3 DR. SCHREIBER: Actually, I still
4 think we have a lot of opportunity to have more
5 insights into the ambulatory side.
6 Statistically speaking, there really is
7 probably a lower percentage of errors, because
8 there's not, you know, an acute change in
9 patient's condition as it is in the hospital
10 setting.

11 But, we have started looking at
12 diagnostic errors. CMS has introduced two
13 diagnostic errors, one around timeliness of
14 mammography, making sure that abnormal
15 mammograms are followed completely and on time.
16 Same thing for colonoscopy, because we know
17 that that is an area of real challenge.

18 So, we are starting to incorporate
19 this. We have a commitment to look at patient
20 safety measures and incorporate them in all of
21 our value-based programs.

22 In other words, those 27 value-based
23 programs that extend into all care facility
24 types.

25 DR. KOSINSKI: Are you following up

1 on the positive first line colon cancer
2 screening tests?

3 Because we're seeing dismal follow-
4 ups for colonoscopy, following someone who has
5 a positive FIT⁵⁸ or a positive Cologuard,
6 because it's not part of the HEDIS measures,
7 it's not part of the Star rate.

8 DR. SCHREIBER: That's exactly
9 what's in one of the new measures that's being
10 investigated.

11 DR. KOSINSKI: Wonderful. Thank
12 you.

13 DR. LIN: All right, Laurant.

14 MS. HARDIN: First, I think I'm
15 freezing. I'm going to have to turn off my
16 camera. Apologies, I'm having Wi-Fi with
17 weather here.

18 I just want to commend all of you.
19 Your presentations were all excellent in a lot
20 of different directions. And, specifically
21 Sue, I just want to commend you for
22 transforming what happened with your family
23 into advocacy for millions of people.

24 I really have some specific

58 Fecal immunochemical test

1 questions. I've worked for more than 20 years
2 in complex populations and hospitals, as well
3 as in the ambulatory setting, definitely
4 serving complex medical conditions, also
5 children with complex needs.

6 But, another population that comes
7 up in that field is those with behavioral
8 health conditions. I was part of the National
9 Academy of Medicine High Cost, High Needs
10 collaborative, which really teased out the
11 impact of behavioral health on high cost, high
12 needs.

13 I'm just curious if each of you
14 might comment on how do these measures apply,
15 and how are they being looked at in the
16 behavioral health population, which experiences
17 the same complications with transitions in care
18 failures, lack of evidence-based care, or
19 overprescribing, and also unnecessary high
20 utilization?

21 DR. BERNHEIM: It's a great area of
22 focus. I'll say just a quick word about our
23 Innovations in Behavioral Health Model, the
24 IBH⁵⁹ Model at CMMI.

59 Innovation in Behavioral Health

1 You know, one of the things we're
2 thinking about there, which touches on some of
3 what you're talking about, so first, one of the
4 key things about that model that I think is
5 important, is that it's really about how do you
6 integrate the physical health care with the
7 behavioral health care?

8 And, that alone, I think, creates a
9 little bit of a safety net for the kinds of
10 things that can happen in a setting if you
11 don't. You know, often patients with SMI⁶⁰
12 don't necessarily have as a good as system for
13 their physical health.

14 So, that's just an underlying
15 feature. But, maybe more importantly to your
16 point, is thinking about incorporating the
17 patient voice in that model, and how to think
18 about patient's own goals as a feature of the
19 care that is being required in that model.

20 It's not exactly what you were
21 asking about, but that's the place in the
22 Innovation Center where we've most focused on
23 some of the behavioral health needs recently.

24 DR. MITCHELL: Yeah. I'd like to

60 Serious mental illness

1 comment. I think we have a huge opportunity
2 with BH⁶¹, and you can't separate behavioral
3 health from physical health, right? We're all
4 one human.

5 And, if you look at this, spend and
6 utilization, if you have a BH diagnosis and any
7 medical diagnosis, you're going to have about
8 two to three times the utilization for that
9 medical diagnosis when there's a common BH.

10 And so, you can improve someone's
11 health overall, both mentally and physically,
12 if you treat it. We will never have enough
13 psychiatrists, psychologists, therapists to
14 treat all the folks with BH diagnosis, if we
15 don't get more people doing the bread and
16 butter, depression, anxiety, and substance use
17 disorder.

18 And so, as I think for the
19 opportunities, if we could get more of the
20 ambulatory clinicians that are not BH, to treat
21 depression and anxiety and SUD⁶², it frees up
22 the BH resources to do more complex things.

23 And, I think, that would be
24 transformational. Otherwise, you have a lot of

61 Behavioral health

62 Substance use disorder

1 folks with treatable illness that just can't
2 get care.

3 And so, for us, we focus on
4 collaborative care models. We focus on broad
5 use of primary care clinicians and special
6 clinicians to engage in BH diagnosis, both
7 diagnosis and treatment for simple things. We
8 engage clinical pharmacists to support us.

9 But, it really is creating a network
10 for those simpler diagnosis that any of us can
11 treat, let's treat them. And, they are not
12 just BH, and they're not just psychiatry.

13 If you have a heart attack or a
14 stroke, there's a great increased chance of
15 depression afterwards, right? We know it's
16 there. It's part of these processes. Let's
17 treat it.

18 If you look at postpartum
19 depression, it's super common and part of
20 pregnancy. Let's diagnose and treat it in
21 those specialties.

22 So, we've got to have specialists
23 engaged in their specialty also treating it.
24 And, I think, that's how we get from here to
25 there on a lot of the BH conditions that we

1 see.

2 DR. KOMMALA: If I can comment,
3 Lauran, as well. Yeah, so, we see events
4 related to lack of timely follow-up post-
5 discharge. We see the same issues as in other
6 faculties of medicine, which is our med
7 reconciliation.

8 I think for us to think about making
9 sure that there are incentives for timely
10 follow-up. Jason brought up postpartum
11 depression, I mean, one of the issues there is,
12 can we have timely follow-up so that we detect
13 it appropriately and treat it appropriately?

14 Med reconciliation is another big
15 issue. And, it is obviously pervasive across
16 all kinds of discharge. And, in this aspect
17 really, patient and family education is very
18 critical to identify sort of the red flags that
19 actually they're probably going to see.

20 And so, yeah, we need to look at
21 this systematically across all these domains
22 and ensure that they're appropriately
23 incentivized.

24 MS. SHERIDAN: I'll just add, this
25 is Sue. I'll just endorse what you just said

1 about the importance of patient and family
2 inclusion in identifying what matters most of
3 the patients, and also what could those PREMs
4 and PROMs look like from the behavioral mental
5 health point of view.

6 Now, some of the questions that are,
7 we call them PIVOT questions, address some of
8 that. But, we would like to, down the road,
9 you know, we're creating a pipeline, we would
10 like to do something around behavioral and
11 mental health specific because we think some of
12 those questions will be nuanced.

13 So, we hope to put those into the
14 pipeline.

15 MS. HARDIN: Thank you all.

16 DR. LIN: So, I'd like to turn to
17 Krishna. Thank you for your patience.

18 MR. RAMACHANDRAN: No worries.
19 Thank you. And, excellent comments,
20 discussions by all there. This is a question
21 for Michelle, but open for other panelists as
22 well.

23 Michelle, you mentioned sort of the
24 role of AI for identification and deeper
25 understanding of harm. I definitely believe in

1 the potential of AI and certainly some of the
2 risks as well that Dheerendra mentioned.

3 Could you elaborate on sort of CMS'
4 thinking about it? How can it come to life
5 safely and responsibly from a care delivery
6 perspective?

7 DR. SCHREIBER: Thanks for the
8 question. I think there are a lot of
9 opportunities. One of the things that we're
10 doing is again, looking at if there's an AI
11 engine on top of a facility's electronic
12 medical record, can they be using a large
13 language model and pulling information from
14 text-based documents for radiology reports, for
15 example, pathology reports, the clinical notes?

16 Because, there's so much information
17 that is there, but it's not just coded data
18 information, it's unstructured data. And,
19 that's where a lot of information is.

20 So, I think there's a tremendous
21 opportunity there. But, of course, we have to
22 make sure that the AI systems are correct and
23 are pulling that appropriately.

24 I think one of the other challenges
25 in safety, and I alluded to it, is that the

1 incident reports, for example, in most
2 organizations are not directly under the
3 purview of many of the quality organizations.
4 Some are seen as risk and risk management, and
5 that is directly distinct from quality and
6 quality management, and we don't always see
7 that.

8 So, I think AI is an opportune time
9 to look at that as well. In addition, I think
10 AI is going to be helpful when it comes to
11 predictive models, monitoring, like you can
12 monitor an entire unit, for example, looking
13 for early warning signs and then intervening
14 early on patients who may need it.

15 So, I think it is going to really
16 present a lot of opportunities. I do want to
17 make one comment though, and that's, you know,
18 we've spoken of digital measures and digital
19 measures so that people can use them in real
20 time in a facility.

21 We actually aligned our initial
22 digital measures with ECRI, thank you very
23 much, on the most common types of harm. The
24 problem is, as we start turning those on across
25 organizations, and I think you're going to hear

1 this from David Classen later when he speaks,
2 is that you suddenly get this overwhelming
3 volume of errors that you find out, to the
4 point that some organizations that have started
5 doing this have turned these systems off,
6 because they don't know how to deal with the
7 quantity of information that they're getting.

8 Which leads to what I had spoken of
9 earlier, the capability in a system to be able
10 to process this. And, I think AI is going to
11 help with that as well.

12 So, if you're getting all of these
13 volume of events, can you use AI to help you
14 evaluate them and prioritize them? Because I'm
15 very concerned that again, some very big
16 systems have turned these off.

17 DR. KOMMALA: If I can add to that
18 as well. There is an opportunity for us to
19 capture near misses in this manner that maybe
20 we will not be able to capture if there's no AI
21 overlay, so using LLM⁶³.

22 So, I think it's all about the
23 continuous learning system for the ability to
24 capture it. But, Michelle's right. If we are

63 Large Language Model

1 capturing a lot of information, we need to
2 decipher it and make sure what is relevant and
3 important is actually captured and acted upon.

4 But, the near miss concept can also
5 be captured through AI overlays.

6 DR. MITCHELL: Yeah. Just to add
7 onto this. You know, the democratization of
8 information to the point of care is critical,
9 and it's something that a human brain can't
10 always do.

11 So, I'm a family doc. I can't read a
12 thousand things in the chart. I can't read
13 every hospital admission. I can't read every
14 study and know it all at once. We do the best
15 we can. That's how we operate.

16 With AI and chart synthesis, it
17 should give me a better picture than I could
18 ever do on my own. And, if you begin to give
19 that tool not just to your doctors and your
20 advanced practice clinicians, but every nurse
21 for phone triage, every time someone calls at
22 the help desk, every time someone calls anyway,
23 and they now have a bigger picture, it should
24 help us identify and prevent the harm before it
25 happens and to see those near misses.

1 And so, I think there's a huge
2 opportunity here. And, I am all about, let's
3 go to the big level, let's throw it over the
4 whole system and find it as a system.

5 But, if we get every clinician,
6 every nurse, everyone on the phone working to
7 prevent harm because they have the tool at
8 their fingertips, I think that's how you really
9 move the ball. And, that's the structure you
10 need to deal with, probably the amount that's
11 out there that we haven't seen.

12 MS. SHERIDAN: I would add another
13 person to your list that you just mentioned. I
14 would add the patient.

15 The patients are becoming extremely
16 super users of AI. And, we have the
17 opportunity to contribute to safety.

18 So, just imagine if patients were
19 in, you know, let's say in a health care
20 system, let's say in a hospital, they had, you
21 know, access to let's say a bot, you know,
22 reaches out to them every night at the hospital
23 to ask them five questions about safety. You
24 know, that could immediately give, you know,
25 immediate feedback and alerts to light

1 deterioration, or being dismissed, or seeing
2 unsafe care.

3 And so, the opportunity to automate
4 and use AI to capture from the patient what is
5 going on, it could definitely feed into a safer
6 health care system.

7 And, Michelle was talking about
8 predictive analytics. Now, if there is an
9 engine operating the background, you know,
10 think about Cal. Had there been AI operating
11 in the background, they would have seen a
12 neonate at 16 hours already jaundiced. That is
13 a red flag. It should have set off alarms.

14 And, you know, at discharge, head to
15 toe jaundice, 33 hours old discharged. AI
16 should have set off alarms.

17 But, what if it set out alerts to
18 Mom? What if on my cell phone I got from this
19 AI system, Mom, your child is in danger of, you
20 know, elevated jaundice, don't leave without a
21 bilirubin test?

22 So, you think of all these really
23 creative opportunities to engage not just the
24 doctors and nurses, administrators, but the
25 patients.

1 DR. LIN: Thank you for those
2 responses. Lindsay.

3 DR. BOTSFORD: Yeah, thanks. I
4 don't know, we are riding the AI enthusiasm.
5 So, I almost feel like I'm taking away from
6 that. But, maybe the answer can incorporate
7 some of it.

8 You know, when we think about other
9 challenges, certainly in the physician world
10 and everywhere, administrative burden,
11 reporting burden is still very top of mind.
12 You layer that onto flat payments.

13 And so, I've heard a couple
14 different ways to fund these improvements in
15 safety. I heard, you know, thinking about, or
16 ways to accomplishment, I should say.

17 So, Susannah, you highlighted the
18 idea of promoting process measures that improve
19 safety, medication reconciliation, proven
20 things along the way that maybe don't have a
21 cost, but the measurement is a little bit
22 easier.

23 I also heard people talk though
24 about penalties, and withholds, and my worry to
25 maybe David's leading question is, when we

1 think about the people with the biggest
2 opportunity to improve, and we're talking about
3 mechanisms like withholds or, you know, even
4 just penalties for safety, I'm worrying about
5 again, if we're hitting the most vulnerable
6 with more potential reporting costs and burdens
7 and potential reductions in payment.

8 And so, I guess as you think about
9 the different ways to accomplish the goal of
10 safety through funding mechanisms, I heard kind
11 of incentivizing process measures, which
12 already exists, that support safety. I heard
13 maybe paying for new tools, AI or otherwise,
14 that support safety.

15 But, then, I also heard kind of the
16 more traditional penalties and withhold. And,
17 I'm just kind of curious as we think about
18 where we go, do we think that penalties in
19 reducing payments or increasing the burden of
20 reporting is enough?

21 Or, are there other ways to support
22 this goal outside that?

23 DR. MITCHELL: I will comment on
24 that as a health care system. You know, I
25 think shared savings was great. We know

1 quality and safety reduces the cost of care,
2 which reduces the cost to CMS and to us as a
3 national community.

4 And so, when we reduce harm, there
5 should be savings, and we can measure it, and
6 we can show that savings back with the systems
7 to do it.

8 If you take systems that are
9 struggling today on CMS metrics, and if they
10 have mostly Medicare and Medicaid and can't
11 make ends meet, doing a withholding and
12 expecting them to invest is unlikely to be
13 successful, and certainly if it's a voluntary
14 model, no one's going to participate. If it's a
15 mandatory model, you just gave them a pay cut
16 to someone that's having challenges.

17 So, I think really if we could get
18 more into a shared savings, and say, look,
19 every time you prevent a readmission, every
20 time you prevent a fall, every time you just
21 stop the hip fracture, there's shared savings,
22 and it's real money, then that's how everybody
23 wins, because it decreases overall utilization.

24 And so, as a hospital system, yes,
25 we have less people harmed in the hospital,

1 less rate, and it shifts that funding that
2 would be spent in hospitalizations to fund
3 these programs.

4 So, I really would like us not to do
5 a withhold from fee-for-service, but actually a
6 shared savings on what you could do through
7 quality and safety.

8 DR. BERNHEIM: The only thing I'll
9 add is that I think Michelle has said this a
10 couple of times, but as an agency, we're
11 thinking a lot about, you know, the way
12 measures can function and be good, but are not
13 the be-all, end-all of improvement, right?

14 And so, this concept that Michelle
15 was talking about is sort of, how do we support
16 capabilities? How do we assess and reward
17 capabilities, is one way of starting to sort of
18 build that fundamental layer.

19 And, that can look different if
20 you're talking about a hospital versus an
21 ambulatory setting. But, I think that's an
22 important direction that we are thinking about
23 a lot.

24 And, the other thing, in the models,
25 the other tool we have and in many of them we

1 use these, there are sort of ways of doing
2 prospective or early payment, including some of
3 the models having multiple years of pre-
4 implementation where we're really supporting.
5 And, this happens like in the state models with
6 Medicaid, where we're really supporting some of
7 the system transformation that has to happen
8 before those sort of incentive pieces come into
9 play.

10 So, just two thoughts that I think
11 are important.

12 DR. SCHREIBER: A couple of things.
13 I would say even in the traditional Medicare
14 models where there is a withhold, paying back
15 if there's improvement, right?

16 So, there has to be a way of being
17 able to, what Sue was talking about, earn those
18 dollars back.

19 The second I would say is in
20 reducing the burden of some of these programs.
21 Part of the gist of the transition to digital
22 measures is that they are 1/20th of the burden
23 that's been shown in a couple of evidence-based
24 studies.

25 And then, the timeliness of

1 information which allows for real-time learning
2 and improvement I think becomes payback at that
3 point.

4 DR. MITCHELL: But, the prequel to
5 all of that is, if all the EMR⁶⁴ vendors must
6 have eCQMs built into their workflows, it makes
7 it easier for systems to do that.

8 And, even the smaller vendors. So,
9 you have all the independent doctors and
10 smaller practices that don't have the Epics
11 that can participate as well.

12 And so, there may be another piece
13 to consider in the recommendations on, you
14 know, what's expected of these EHR vendors to
15 facilitate this work.

16 DR. LIN: Well, great. Thanks for a
17 really robust discussion. We are five minutes
18 past the official end time. But, we got
19 started late, so we'll just call it even there.

20 I'd like to thank all five of our
21 experts for joining us today. You helped us
22 cover a lot of ground during this session.
23 And, you're welcome to stay and listen to as
24 much of the meeting as you'd like.

64 Electronic medical record

1 At this time, we have a break until
2 1:10 p.m. Eastern time. Please join us then.
3 We have a great set of experts for our second
4 session, which focuses on measuring patient
5 safety and value-based care.

6 (Whereupon, the above-entitled
7 matter went off the record at 12:16 p.m. and
8 resumed at 1:11 p.m.)

9 MR. TYSON: All right. Welcome
10 back. Hopefully everybody had a good lunch
11 break. My name is David Tyson. I'm one of the
12 PTAC members.

13 At this time, I'm happy to welcome
14 four remarkable experts for our second session
15 focusing on measuring patient safety and value-
16 based care. You can find their full biographies
17 and slides posted on the PTAC website and the
18 public meeting registration site.

19 So, first, I want to welcome our in-
20 session participants. And also, for those that
21 are here remotely, please go ahead and turn on
22 your videos if you haven't done so already.

23 After all four experts have
24 presented, our Committee members will have
25 plenty of time to ask questions.

1 First up, we are glad to welcome in
2 person Mr. Jeffrey Geppert, a senior research
3 leader at Battelle.

4 So, Jeff, please lead us off.

5 * **Session 2: Measuring Patient Safety**
6 **in Value-Based Care**

7 MR. GEPPERT: Thank you very much.
8 And, good afternoon and thank you for the
9 opportunity to speak with you today.

10 So, as David said, my name is
11 Jeffrey Geppert. I'm a Senior Research Leader
12 at Battelle Memorial Institute and a Measure of
13 Science Team Lead in our health unit.

14 Battelle is a CMS-certified
15 consensus-based entity under Section 1890 of
16 the Social Security Act. And, as the
17 consensus-based entity, Battelle launched the
18 Partnership for Quality Measurement, a
19 membership comprising over 1,200 health care
20 stakeholders.

21 And, together with PQM⁶⁵, Battelle
22 currently supports three consensus-based entity
23 processes, endorsement and maintenance, which
24 is the review of the scientific acceptability

65 Partnership for Quality Measurement

1 of measures for general accountability use.

2 And, with our colleagues at CMS, we
3 support the pre-rulemaking measure review,
4 which is the review of measures under
5 consideration for recommendations for adding
6 measures to CMS quality and payment programs.

7 And then, finally measure set
8 review, which is a review of measures in the
9 current CMS portfolio for recommendations for
10 continued use of measures in CMS quality and
11 payment programs.

12 So, how do you know if a patient
13 safety measure is fit for purpose for an
14 accountability use such as an Alternative
15 Payment Model?

16 First, because quality measurement
17 is different than quality improvement, the
18 measure of purpose ought to be oriented towards
19 structural and system change rather than
20 behavioral change.

21 However, for many measures, often
22 the structural and system change goal or
23 purpose is not explicitly stated, which can be
24 challenging for measure implementers to know
25 what to do.

1 Second, because quality measurement
2 is not the solution to every quality problem,
3 and quality measurement is time- and resource-
4 intensive, measures should be linked to
5 material outcomes to patients. The benefit of
6 measurement should outweigh data collection,
7 reporting, and use burden, and any adverse
8 effects associated with measure use should be
9 identified and mitigated.

10 However, in many cases, the actual
11 difference between the better performer and the
12 worse performer on many measures is potentially
13 maybe two or three cases, two or three
14 numerator events, which really calls into
15 question whether the burden of measurement is
16 really generating value, whether it's really
17 exceeding the benefit of the measurement.

18 And, oftentimes for many of these
19 measures, the causal link between the measure
20 focus or the numerator of the measure and the
21 material outcomes to patients can be highly
22 attenuated across the system and over time,
23 further potentially challenging importance.

24 Third, the measure must be feasible
25 to collect, report, and act upon. And,

1 implementers are often challenged with this,
2 because often the patient safety measures rely
3 on data, as we've talked about, in unstructured
4 fields or in data systems that are outside the
5 HR⁶⁶, like laboratory, or pathology, or
6 radiology.

7 And, this is especially true in the
8 diagnostic excellence space and is an important
9 consideration for future development of
10 patient-reported outcomes.

11 Fourth, the measure must demonstrate
12 consistent performance relative to a benchmark,
13 stable performance across subpopulations and
14 over time, and resilient performance under
15 various sort of perturbations.

16 However, while patient safety
17 measures may be common across the entire
18 system, any particular clinician or hospital
19 may experience few such adverse events, or the
20 target population may be small, making
21 consistent performance challenging to
22 demonstrate.

23 Fifth, for accountability, the
24 entity must be really the primary cause of the

66 Health record

1 measure focus or the patient safety event.

2 However, often the causal evidence
3 presented is usually not particularly
4 compelling. Often the associations that are
5 relied upon are not very strong, they're
6 relatively weak. There's very little mechanism
7 data that's collected to show a causal
8 association.

9 So, such inferences about causality
10 are prone to the ecological fallacy with other
11 competing causes and counteracting mechanisms
12 often predominant. And, use of the measure
13 then in this circumstance generates some risk
14 both for entities and for patients, which is
15 often not necessarily acknowledged or directly
16 mitigated.

17 Finally, the measure of barriers to
18 improvement must be identified and mitigated,
19 or the measure of facilitators of improvement
20 must be identified and emulated.

21 However, often the case is that how
22 the patient safety measure works for whom and
23 exactly in what circumstances, again, is not
24 explicitly stated or only superficially
25 examined, which again presents a challenge for

1 measure implementers.

2 The other fitness to purpose
3 considerations we often think about are
4 appropriateness of scale. Oftentimes we
5 measure everybody all the time, everywhere,
6 instead of focused measurement for impact.

7 And, the second consideration is
8 time to value realization, which really
9 considers whether the measure is generating
10 value now or will in the future as things
11 evolve.

12 So, we've already heard, and we'll
13 hear again throughout today and tomorrow, there
14 are many emerging approaches that address some
15 of these challenges, including interoperability
16 and AI composites, structural measures, and
17 patient-reported outcomes. And, we can return
18 to these topics in the discussion.

19 However, what I would like to focus
20 on, is a potential reframing and switch from a
21 compliance-based accountability to a more goal-
22 oriented accountability for Alternative Payment
23 Models and patient safety.

24 Traditional patient safety remains
25 essential. The measures help detect harm,

1 benchmark performance, support system
2 incentives and transparency, but as care
3 delivery becomes increasingly dependent on AI,
4 interoperability, automation, and complex
5 sociotechnical workflows, a retrospective
6 measurement alone may not be sufficient to
7 establish that systems are acceptably safe.

8 Other safety critical industries
9 have addressed a very similar problem such as
10 an autonomous vehicles, oil and gas, nuclear
11 industries, and they address this challenge
12 with something called an assurance case, which
13 is basically a structured evidence-based
14 argument that explicitly identifies the hazards
15 involved, explains the safety controls, and
16 continuously evaluates that residual risk in
17 light of current evidence.

18 The opportunity is not necessarily
19 to replace quality measures, but to combine
20 them with assurance cases so that Alternative
21 Payment Models can move from simply measuring
22 harm, toward prospectively assuring safety in
23 complex systems.

24 Traditional patient safety
25 measurement tells us whether the harm occurred.

1 Assurance cases help determine whether the
2 system is credibly safe before the harm occurs.

3 So, in closing, a few takeaways.
4 So, as we have seen, quality measurement in
5 general, and patient safety measurement in
6 particular, is faced with inferential
7 challenges when used to support accountability
8 claims.

9 But, there are some practical proven
10 ways in which we might address that challenge.
11 First, we can complement patient safety
12 measures with assurance or safety cases as a
13 governance infrastructure for accountability.

14 Second, new AI tools make any
15 science more predictive, more mechanism-based,
16 more evidence-informed. And, we can leverage
17 this mechanism-based reasoning to focus and
18 target our measurement and accountability
19 resources on the patient safety domains and
20 context where we know with some certainty in
21 advance whether the measures are most likely to
22 work.

23 And, we've talked a lot today about
24 various counterfactuals, omissions, near
25 misses, and mechanism-based reasoning is

1 particularly adept at addressing those kinds of
2 counterfactuals.

3 Finally, we can focus our financial
4 resources on pay for transformation, which is
5 based on three transformation finance
6 principles: community engagement, generating
7 value, and establishing value progressively
8 through an understanding of how entities
9 actually change and transform.

10 So, strategically, there's an
11 opportunity to reframe the patient safety
12 measurement discussion and accountability, to
13 elevate the discussion from better metrics to
14 better reasoning about safety, to directly
15 address the accountability and legitimacy, to
16 connect naturally to AI governance and
17 sociotechnical systems, to explain why current
18 quality measure debates persist despite decades
19 of metric development.

20 And then, finally, it positions
21 assurance cases as a potential complimentary
22 governance infrastructure, rather than just
23 another reporting burden.

24 Thank you, and I look forward to the
25 discussion.

1 MR. TYSON: All right. Thank you,
2 Jeff. So, next we are pleased to welcome Dr.
3 Patrick Romano, a Professor in the Divisions of
4 General Medicine and Pediatrics at the
5 University of California, Davis.

6 Dr. Romano, welcome.

7 DR. ROMANO: Good afternoon. Thank
8 you, it's a pleasure to be here from UC Davis
9 Health in Sacramento, California.

10 I am supposed to provide some
11 provider perspectives, but I am an unusual
12 provider. I'm a general internist, as well as
13 a general pediatrician by training.

14 I do have broad experience across
15 the domains of internal medicine practice.
16 Currently, my practice is focused in team-based
17 primary and urgent care.

18 I'm a fellowship-trained health
19 services researcher, a member of all the
20 appropriate professional societies, but not
21 speaking for them. I've been heavily engaged
22 on the academic side, served as co-editor-in-
23 chief of the academic journal *Health Services*
24 *Research* or *HSR*. And, more recently for six

1 years as Co-EIC⁶⁷ for AHRQ's Patient Safety
2 Network or PSNet.

3 But, most of my effort has really
4 been around measurement. I've been most of the
5 last 20 years a clinical lead for the AHRQ
6 Quality Indicators Program and the Patient
7 Safety Indicators, in collaboration with
8 colleagues at Battelle, Stanford University,
9 and Mathematica.

10 More recently, I've also partnered
11 with CMS to serve as clinical lead for the
12 eQMs for Eligible Clinicians contract in the
13 QPP⁶⁸ Program. And, I worked for five years on
14 the Hospital Harms development as well in the
15 Inpatient Quality Reporting Program, those
16 efforts in collaboration with the American
17 Institutes for Research.

18 Finally, I've been deeply engaged
19 with the Leapfrog Group as a member of their
20 hospital safety grade TEP⁶⁹ since its inception.
21 So, I'm not a typical provider.

22 I've spent most of my life working
23 on developing, testing, validating, refining,

67 Editor-in-Chief

68 Quality Payment Program

69 Technical Expert Panel

1 and implementing health care quality measures,
2 particularly focused on patient safety. And,
3 much of this work, of course, is built on the
4 framework of the IOM or NAM⁷⁰, recognizing that
5 really equity and value are cross-cutting
6 dimensions, so we can't talk about value
7 without talking about effectiveness, safety,
8 timeliness, patient-centeredness,
9 accessibility, and efficiency.

10 So, these concepts very much tie
11 together, and of course this concept is also
12 reflected in CMS' Meaningful Measures framework
13 with safety being one of six core components.

14 Now, just building a little bit on
15 PTAC's working definition for patient safety,
16 freedom from errors that could cause patient
17 harm. I would just encourage maybe a little
18 bit of broadening of the phrase during the
19 delivery of health care.

20 Many of us prefer associated with
21 health care, or resulting from health care,
22 because in many cases, the harms that we
23 observe become apparent after the patient has
24 transitioned to a different setting of care, a

70 National Academy of Medicine

1 different provider, different organization.

2 We are focused on zero preventable
3 harm as others have said before, recognizing
4 the causes that we can identify, we can modify,
5 consistent with evidence.

6 So, of course, much of our work
7 builds on the work of Avedis Donabedian and the
8 quality framework. The idea that stronger
9 structures with better material and human
10 resources, more robust organizations will
11 enable better processes of care, better
12 adherence to best practices, which in turn will
13 lead to fewer preventable errors and better
14 outcomes, that goal of zero preventable harm.

15 But, we've discovered over the
16 decades that this concept may be too linear.
17 In fact, process improvement often drives
18 structural change.

19 Structures may be important
20 mediators of the effects of processes on
21 outcomes, and even the best structures only
22 facilitate better care. They don't actually
23 represent better care or lead directly to
24 better care.

25 Outcomes are really what matters to

1 our patients, their families, the communities,
2 all our stakeholders. And, particularly
3 important from my perspective, outcomes reflect
4 not just what was done, but how well we did it,
5 right?

6 So, if we're thinking about what
7 happens at the bedside, whether the nurses have
8 picked up complications early, communicated
9 that information, whether physicians have
10 educated patients well, motivated them to take
11 their medications, and to adhere with the
12 program of care, all of these things, it's
13 about how well things are done. And,
14 traditional structural and process measures
15 don't capture these well.

16 Now, we do have some conceptual
17 challenges here, particularly in targeting
18 improvements in patient safety through
19 alternative physician payment models. Safe
20 care is really an ethical and a legal
21 imperative.

22 We teach all our medical students,
23 primum non nocere, first do no harm. We are,
24 of course, surrounded by tort liability when we
25 make mistakes.

1 The professional ethics demand our
2 attention to patient safety. Indeed, they
3 create distress, even burnout when we make
4 mistakes.

5 So, you might argue, do we really
6 need financial rewards or penalties to provide
7 safe care in addition to what is embedded in
8 the professional culture?

9 We also have to recognize that,
10 well, sometimes things haven't worked out quite
11 right. And, this is an example of one
12 Alternative Payment Model, it was designed by
13 Congress, so nobody here is responsible for it.

14 But, it's the Hospital-Acquired
15 Condition Reduction Program. It was part of
16 the ACA⁷¹, the 1 percent Medicare fee-for-
17 service penalty for the bottom quartile of
18 hospitals based on six measures, including the
19 PSI 90 composite patient safety and adverse
20 events that Jeff and I helped develop, as well
21 as five health care-associated infection
22 measures. What did that get right?

23 Well, it has many meaningful outcome
24 measures from diverse sources. They're

71 Affordable Care Act

1 balanced, so there's not undue attention on any
2 one measure. They do force hospitals to attend
3 to patient safety, and the attribution is
4 essentially undeniable, because hospitals have
5 reported these events themselves.

6 But, there's some problems. This
7 two-bin design stabilizes the total penalty.
8 It was designed as a pay for in the ACA, but it
9 doesn't reward improvement.

10 It doesn't recognize huge variation
11 within those two bins. It can be sensitive, as
12 Jeff has pointed out, to relatively small
13 numbers of events.

14 The thresholds are unpredictable
15 from year to year. There could be a prediction
16 market where people could bet on whether
17 they'll be above or below the threshold in any
18 given year.

19 It has been shown to disfavor
20 teaching or safety net hospitals, partially
21 because two-thirds of the measures don't have
22 patient-level risk adjustment. They do
23 incentivize underreporting to some extent.

24 And, when you look at exogenous
25 data, there's really little evidence of impact.

1 So, what do we learn from these experiences?

2 Well, I would say that a better
3 approach, perhaps building somewhat on what
4 Jeff has described, a better approach would
5 first recognize these attribution challenges.

6 To realize from the provider
7 perspective, we work in teams. And, those
8 teams include lots of other professionals who
9 we depend heavily on, nurses, assistants,
10 therapists, techs.

11 We often don't choose our team
12 members. We may split our time across multiple
13 teams. The harm events are rare. They have
14 many causes. That's why we do root cause
15 analysis or failure mode effects analyses.

16 They have many patient-level risk
17 factors. They may manifest after the measured
18 episode. So, all those holes have to be
19 aligned in the Swiss cheese for the event to
20 reach the patient.

21 So, there are some attribution
22 challenges. Fortunately, the ACO structures
23 provide some mechanisms for handling those
24 attribution challenges.

25 I think increasingly we're

1 interested in linking outcomes or intermediate
2 outcomes and processes that complement and
3 balance each other, to help create those
4 insurance cases.

5 So, for diabetes management, for
6 example, let's look at CMS' at hypo and
7 hyperglycemia together, so we can see both ends
8 of how patients with diabetes are managed in
9 hospitals.

10 Let's look as Leapfrog is, at
11 handwashing practices together with health
12 care-associated infection rates. Let's look at
13 fall prevention, improving patient mobility,
14 functional status, and injurious falls as an
15 outcome.

16 And, in the emerging realm of
17 diagnostic excellence, let's look at the
18 diagnostic process, as well as the outcomes of
19 timely diagnosis, timely initiation of
20 treatment.

21 So, just two examples, of course,
22 from the work that I've been fortunate to be
23 involved in. These are the CMS Hospital Harms,
24 which Dr. Schreiber alluded to earlier.

25 All of these are now in the program

1 at various stages for implementation. And, all
2 of them come out of the structured fields and
3 electronic health records.

4 And, with the diagnostic process
5 building on NASEM⁷²'s work on understanding the
6 diagnostic process, we're now, I think, working
7 across the agency, across the Department of
8 Health and Human Services really, to focus on
9 the diagnostic process. And, how we
10 communicate diagnostic information, how we act
11 quickly on that information so that treatment
12 can be initiated in a timely manner.

13 So AHRQ is now in the process of
14 testing and implementing the three measures on
15 the left of timely follow-up after abnormal
16 breast cancer screening, colorectal cancer
17 screening, and lung cancer screening.

18 CMS is also in the process of
19 implementing two of these measures as we've
20 discussed, and eventually we hope that these
21 measures will lead to fewer late stage
22 diagnoses and more timely presentations of
23 cancer.

24 So, my takeaways, proceed cautiously

72 National Academies of Science, Engineering, and Medicine

1 and deliberately. Recognize that payment
2 models really don't have a strong track record
3 for improving patient safety. We have to
4 recognize that intrinsic motivation for us as
5 health care providers may be as strong or more
6 important than extrinsic motivation.

7 Transparency is essential. I'm a
8 big believer in transparency, but it can
9 proceed with or without financial rewards and
10 penalties.

11 Accountability and actionability
12 must be linked to the entity level. So, the
13 entity or organization that we hold accountable
14 must also be the entity that can act on those
15 results to improve patient safety and
16 subsequently improve and reduce harms.

17 We build, we want to build on the
18 foundations of professionalism, CQI⁷³, the
19 culture of safety, learning health systems
20 align with what's important to patients and
21 caregivers, as well as purchasers.

22 And, we have to expect unintended
23 consequences. If we rely on provider-reported
24 events, there will be some underreporting. We

73 Continuous quality improvement

1 have to audit and monitor that.

2 There will be some risk avoidance if
3 high-risk patients aren't appropriately handled
4 through risk adjustment.

5 There may be undertesting or
6 overtesting depending on how testing impacts
7 performance on the measure. So, we have to be
8 alert to these consequences and continuously
9 monitor.

10 So, thank you for the opportunity to
11 present, and I look forward to the discussion.

12 MR. TYSON: Thank you, Dr. Romano.
13 So, next we are happy to welcome virtually
14 Commander Karen Chaves, who is the Director of
15 the Division of Quality Measurement and
16 Improvement at the Center for Quality
17 Improvement in Patient Safety at the Agency for
18 Healthcare Research and Quality and an Officer
19 in the United States Public Health Service
20 Commission Corps.

21 So, Karen, please go ahead.

22 COMMANDER CHAVES: Thank you so
23 much. Thank you everyone, thank you for having
24 me. It's a privilege to be here.

25 And, it's fitting that I'm following

1 Dr. Romano. He has been instrumental in our
2 Quality Indicators Program over the years.
3 And, I learn so much every time we meet and
4 talk about patient safety.

5 I lead the Division of Quality
6 Measurement and Improvement at AHRQ or ARC as
7 we like to call ourselves. My background is in
8 health policy and administration.

9 I've had the privilege of working at
10 AHRQ for most of my federal career alongside my
11 colleagues in the Center for Quality
12 Improvement and Patient Safety. Today I'm
13 going to focus my remarks on our measurement
14 activities specifically.

15 And, I'm also glad to introduce Dr.
16 Judy George, who will be joining me for the Q&A
17 portion as well. She leads the AHRQ Quality
18 Indicators Program. Next slide, please.

19 Okay. Oops, one second. I lost my
20 notes. I'm going to start with a quick
21 introduction to the Quality Indicators Program.

22 The program's aim is to produce
23 scientifically sound measures and software for
24 health care users, to identify the potential
25 for quality improvement. This aligns with our

1 role as a federal agency focused on research
2 and in our center, specifically on patient
3 safety research, as we are fundamentally a
4 research agency, not a regulatory agency, which
5 distinguishes us from the other federal
6 agencies like CMS, and FDA, and other agencies
7 in HHS.

8 As a research agency, we have
9 developed about 70 Quality Indicators organized
10 into six modules for which we maintain the
11 technical specifications and continue to
12 conduct refinements and produce open access
13 software on an annual basis.

14 In this program, we continuously
15 test and validate our measures to respond to
16 user feedback, and working with our federal
17 partners who use our Quality Indicators to
18 ensure that the measures we produce are
19 scientifically sound and produce meaningful
20 data for quality improvement.

21 And, as a research agency, our work
22 in the Quality Indicators Program in the
23 development of measures is conducted before
24 they are adopted and used for implementation in
25 quality improvement for public reporting and

1 for payment models and other related
2 activities. Next slide, please.

3 This is important to keep in mind,
4 because as you see here on the slide, our
5 Quality Indicators have a broad set of users
6 with various perspectives and varying access to
7 resources for analyzing and reporting data.
8 They come to our Quality Indicators for the
9 underlying measure specifications, standards of
10 measurement, and access to the software tool
11 that is open and available to all users.

12 Our users include hospitals and
13 health care systems, hospital associations and
14 health plans, and third-party vendors, as
15 you're familiar with like EHR vendors, data
16 analytic companies, and other non-profit
17 quality improvement organizations, and of
18 course, our federal agencies partners and
19 federal payers.

20 These known use cases range widely
21 across quality improvement and performance
22 measurement, and our research cuts across all
23 of these. Our Quality Indicators focus on
24 broad use or quality improvement, and not
25 specifically designed for accountability.

1 But, we do work together with the
2 implementation partners of our measures to
3 address the scientific basis for these
4 measures. Next slide.

5 So, to address some of the questions
6 posed to our panel today, I will focus on the
7 findings from the Patient Safety Indicators Gap
8 Analysis Report, which was conducted over the
9 past year and concluded in December of 2025.

10 The patient indicators, as you are
11 all familiar with, are one of six modules of
12 Quality Indicators that we produce. We
13 maintain and refine the technical
14 specifications for PSIs for a broad set of
15 users, and the PSI module focuses on
16 potentially avoidable safety events, which
17 include in-hospital complications and adverse
18 events following surgeries, procedures, and
19 childbirth.

20 As you are all aware, PSIs are high-
21 visibility due to use in multiple pay-for-
22 performance and public reporting initiatives,
23 including those for CMS. And so, we coordinate
24 our development processes together with these
25 partners and our colleagues.

1 The measure specifications and
2 technical resources from PSIs are also relevant
3 to other national initiatives for measuring and
4 preventing harm in health care settings, such
5 as those at CDC. In this gap analysis study,
6 we worked together with our CMS colleagues to
7 conduct extensive literature review.

8 We utilized public comments and
9 conducted listening sessions with carefully
10 selected stakeholders that represented patient
11 safety perspectives from across provider types,
12 health care organizations, and patient advocacy
13 groups. Next slide.

14 I want to highlight a few of the
15 themes we considered in our study. First,
16 acknowledging that the field of quality
17 measurement has grown a great deal since the
18 landmark IOM report, as mentioned this morning,
19 crossing the quality chasm.

20 Since then, there has been a
21 proliferation of measures, each organization
22 developing some for specific purposes and
23 slightly different before the same condition
24 oftentimes, and resulting in some overlap
25 across measures. Just a few examples, the AHRQ

1 PSIs, CDC's NHSN⁷⁴ measures, CMS' PSIs, which
2 are mostly adapted from the AHRQ PSIs, NCQA's
3 HEDIS measures as well.

4 We understand the burden of
5 measurement when we have far too many measures
6 being used. But, we also acknowledge that
7 there are still areas that we don't have good,
8 standardized measures for, and I'll be
9 discussing some of these in the next few slides
10 here.

11 We also discussed a lot of
12 challenges in data throughout our findings.
13 What are the potential sources of data that
14 could inform quality improvement beyond those
15 from the traditional data sources as Jeff had
16 mentioned? Next slide.

17 Thank you. This is the guiding
18 framework from the preventable harm measurement
19 framework and taxonomy used in CMS' Meaningful
20 Measures 2.0. We use this framework to help
21 visualize the opportunities to expand PSIs
22 within the domains outlined.

23 You see here are the stages of care,
24 prevention, diagnosis, treatment, and outcomes

74 National Healthcare Safety Network

1 reflecting the full spectrum of care, the
2 patient's care journey, and to the outcomes
3 important to patients.

4 The subdomains are the logical
5 groupings of preventable harm within each
6 domain. And, further divided by those with
7 existing PSIs that we have and those without
8 existing PSIs.

9 At the bottom of the figure are
10 cross-cutting issues impacting preventable
11 harm, safety culture breakdowns, resource and
12 technology limitations, care transitions, and
13 communication problems. This framework has
14 helped us to organize our discussions and
15 findings in the report. Next slide.

16 And, this is a list of the
17 conditions I will touch on today. Let's move
18 to the next slide.

19 One of the areas that the study
20 identified as a gap in the PSIs was in
21 diagnostic safety. This aligned well with the
22 work that we have in our agency and with our
23 other HHS partners in diagnostic excellence.

24 Currently, the PSI module does not
25 have measures that specifically address

1 diagnostic safety. But, as Patrick alluded to,
2 we are working on expanding our modules to
3 include diagnostic excellence.

4 In the report, the gaps identified
5 in this area were on missed labs, imaging, and
6 other test results that lead to delayed or
7 misdiagnoses, and inappropriate follow-up care,
8 which could be examined for measurement
9 opportunities.

10 In the report, it also discussed
11 challenges in this area in terms of how to
12 capture missed and wrong diagnoses due to long
13 timeframes, thresholds and clinical judgment,
14 the differences in diagnoses made by
15 generalists versus specialists.

16 Also, the challenges in using
17 traditional sources of data such as billing
18 information, and the fact that diagnoses often
19 occur in outpatient settings where it is
20 difficult to capture and track this
21 information. Also, the report discussed the
22 considerations for rural communities that lack
23 access to diagnostic tools and technology.

24 So, an area of opportunity
25 identified and we continue to discuss is in

1 proxy measures such as late-stage diagnoses
2 that could be evaluated for their accuracy in
3 reflecting true missed diagnoses. And, we are
4 pursuing this in the area of cancer care
5 treatment. Next slide.

6 The next topic in the study was on
7 adverse drug events, which is the highest and
8 most common form of patient harm in the United
9 States. The PSI module does not include adverse
10 drug events currently, but there are other
11 measures in use from HEDIS and NCQA.

12 Adverse drug events may include
13 medication errors, drug-drug interactions,
14 medication reactions with errors, and delays in
15 administration, posing safety risks in
16 inpatient post-acute care and ambulatory
17 outpatient settings.

18 The input we received on this topic
19 were related to the need to more clearly define
20 adverse drug events as not all adverse drug
21 events relate reactions to medications are
22 necessarily preventable.

23 And so, focusing on serious adverse
24 drug events may be more helpful to reduce
25 reporting burden, and also having definitions

1 that distinguish between medication errors and
2 preventable adverse reactions could help
3 improve current measures.

4 The input we received also suggested
5 focusing on high-alert medications such as
6 opioids, anticoagulants, and insulin. There
7 are many data challenges identified in the
8 study for this area.

9 We noted that claims data does not
10 have adequate information on adverse drug
11 events necessarily. And, for example,
12 medication reconciliation, wrong dose, and
13 excessive dose don't appear in claims data that
14 we used.

15 And, it was also suggested in the
16 feedback we got that patient-reported data
17 might be considered as a way to capture this
18 information as an opportunity to explore. Next
19 slide.

20 The next topic was on health care-
21 associated infections. HAIs are the second
22 most common outpatient adverse safety event.

23 These can be product- or device-
24 related such as catheter-associated urinary
25 tract infections. They can be surgery-related

1 such as surgical site infections. And, some
2 are not related to either of these, such as C.
3 diff infection, or non-ventilator-acquired
4 pneumonia, and sepsis.

5 Current PSIs address central venous
6 catheter-related bloodstream infection rate,
7 which is our PSI-7, and postoperative sepsis
8 rate PSI-13. In the study, we discussed
9 opportunities for measuring other common HAIs
10 such as C. diff, ventilator and non-ventilator
11 associated pneumonia, hospital-onset bacteremia
12 and fungemia, as well as for catheter-
13 associated urinary tract infections, or SSIs⁷⁵
14 among cardiovascular and colorectal surgeries
15 specifically.

16 We do note that CDC's National
17 Healthcare Safety Network and HSN offers
18 providers extensive support in tracking and
19 measuring HAIs. So, we are careful not to
20 duplicate measures.

21 Instead, we're considering retiring
22 PSI-07, and at the same time maintaining and
23 perhaps expanding our PSI-13. Next slide.

24 Health care-associated conditions,

75 Surgical site infections

1 these are surgical and procedural events that
2 are third most common source of patient harm.
3 Our PSI module does include many of these, PSI-
4 3 for pressure ulcers, PSI-5 surgical items,
5 unretrieved device fragments, for example, also
6 PSI-8 hip fracture, postoperative respiratory
7 failure rate PSI-11, and many others, including
8 birth injury, birth trauma injury, and two
9 obstetric trauma measures PSI 18 and 19.

10 It is noted that these are all
11 inpatient, so there is opportunity to expand
12 the specifications for several of these
13 measures into different settings. For example,
14 fall and pressure ulcers to long-term care
15 settings would be a gap to explore further.

16 The study also discussed several
17 considerations for expanding our PSIs into
18 ambulatory care settings. We acknowledge that
19 CMS have outcome measures in ambulatory care
20 settings.

21 There is increasing volume and
22 complexity of procedures in ambulatory care
23 settings, and at the same time, lack of
24 comparable quality oversight relatively
25 speaking in ambulatory care centers, and the

1 lack of resources and technology within this
2 setting, all point to the need for more
3 attention and focus in measurement in
4 ambulatory settings.

5 The study also identified anesthesia
6 and perioperative care as gaps in measurement
7 across inpatient and ambulatory care settings.
8 So, this was a really interesting find for us.

9 And also, really importantly, is the
10 study identified the gap in the HACs⁷⁶
11 measurement to really look at maternal care,
12 which could have a large impact on reducing
13 preventable harms that occur during pregnancy
14 and infancy leading to early death of mothers
15 and infants.

16 Some examples of this exploratory
17 area is sepsis among obstetric patients, severe
18 bleeding, and births and VTEs⁷⁷, diagnosis in
19 maternal populations for behavioral health and
20 also for hypertension.

21 And, this is an area that we have
22 worked a lot in more recently, and I'll share
23 with you more in the last few slides. Next
24 slide, please.

76 Hospital-acquired conditions

77 Venous thromboembolisms

1 And also, in the topic of mortality,
2 preventable deaths continue to be an issue
3 within health care delivery in the U.S. And,
4 an estimated approximately 3 percent of health
5 care-related deaths are preventable. Our
6 current PSIs include two PSIs, PSI-2 low
7 mortality diagnosis-related groups, and death
8 rate among surgical patients with serious
9 treatable conditions PSI-4, for acute settings.

10 We recognize there are opportunities
11 to refine these specifications to account for
12 baseline risk factors such as frailty, and to
13 adjust for procedural volume for these
14 measures.

15 The other opportunities identified
16 in the study in mortality were to look at a
17 more expansive view of preventable death in
18 non-acute settings, or mortality attributed to
19 chronic diseases among younger populations, and
20 potentially leveraging novel data sources such
21 as using vital sign monitoring systems and AI
22 tools. Next slide, please.

23 So, just to summarize from our gap
24 analysis study, four recommendations
25 highlighted here. They were one, to review

1 existing PSIs to eliminate overlap with other
2 federal agency federal safety measures.

3 Two, to expand PSIs to ambulatory
4 surgical centers and develop measures for
5 perioperative care. Three, to broaden our
6 maternal and neonatal safety measures to care
7 settings beyond the hospital such as birthing
8 centers, and develop perinatal safety
9 indicators to better quantify preventable harms
10 in these populations.

11 And then, four, to continue efforts
12 to identify sources for measures of preventable
13 harm from diagnostic errors, and exploring.
14 Some examples are exploring data sources as
15 well, other data sources.

16 And, just to touch on some of the
17 current activities underway, Patrick has
18 already alluded to our diagnostic excellence
19 measures in cancer-related conditions, our
20 maternal health measures that we have a beta
21 module for, and our outpatient surgery work
22 that we are currently exploring.

23 I will cede the time to the rest of
24 the panel. But, just note that we do have
25 slides in the slide deck that you can turn to

1 later on for more information.

2 Thank you very much.

3 MR. TYSON: Thank you, Karen. So,
4 next we're going to go welcome virtually Dr.
5 David Classen, Professor of Medicine at the
6 University of Utah, Lead of the Utah Center for
7 Health AI and the Health IT Safety Program, and
8 Senior Advisor for Pascal Metrics. David,
9 welcome.

10 DR. CLASSEN: Yes, thank you very
11 much for having me, everyone. And I'm going to
12 talk from the PSO⁷⁸ perspective, the patient
13 safety organization perspective, about what
14 safety measurement can look like in the future
15 when it's enabled with AI and advanced
16 analytics.

17 And my background is I'm basically
18 an IT and medical informaticist at the
19 University of Utah. I also work part-time for
20 Pascal Metrics, a PSO. I also Chair the AHRQ
21 Common Formats PSO Committee.

22 I also run Leapfrog's EHR safety
23 standard, which now is part of the safer guides
24 and a part of CMS standards as a standard that

78 Patient Safety Organization

1 looks at the safety of functioning EHRs. We
2 started on the inpatient and moved to the
3 outpatient, and now we're moved to med recon,
4 choosing wisely and preventing hospital
5 complications.

6 We're just about to add a module on
7 sepsis detection, AI programs that detect
8 sepsis, but we're expanding well into all of
9 the AI vendors as well. The VA is currently
10 implementing what we've developed so far.

11 So, today what I'd like to talk
12 about is what does safety look like, safety
13 measurement look like in the era of AI and
14 advanced analytics?

15 I'm on the new National Academy of
16 Medicine committee that's very focused on what
17 patient safety is going to look like in the era
18 of AI, and we're very focused on measurement,
19 and a lot of the issues we've discussed here
20 today we're really struggling with. What's the
21 value of retrospective measures when we have
22 EHR data with AI and we could do prospective
23 measures?

24 So, I think that's why what I'm
25 going to share with you is probably fairly

1 relevant, but we're really struggling with
2 these issues at the National Academy of
3 Medicine. Next slide, please? Great.

4 At the Institute for Healthcare
5 Improvement, we've been running safety
6 collaboratives around the world for a long
7 time, and we were never happy with the existing
8 patient safety measures. A lot of hospitals
9 use voluntary reporting.

10 A lot of hospitals use the AHRQ PSI
11 administrative codes to measure safety, and
12 when we looked into that, we just think, we
13 thought those areas were missing a lot of
14 safety problems, so we developed our own tool
15 called the IHI Global Trigger Tool.

16 Roger Resar, and I, and Fran Griffin
17 and all developed that, and that became our
18 standard measure throughout all of our IHI
19 initiatives, and basically, it was a measure of
20 all-cause harm.

21 And everywhere we went in all of our
22 initiatives in the United States, Europe, Asia,
23 when we would implement this tool to measure
24 safety, we would find that safety events were
25 occurring in one-quarter to one-third of all

1 hospital patients.

2 And we noticed this over and over
3 again for more than a decade, so we were fairly
4 comfortable that the frequency of harm was
5 somewhere around a quarter to a third of all
6 hospital patients.

7 David Bates took our methodology and
8 applied it in a study he published in the *New*
9 *England Journal* back in 2023 and showed exactly
10 the same result. About one in every four
11 patients in four teaching hospitals, in 11
12 teaching hospitals in the Harvard system, were
13 having harm.

14 So, we've been working on safety for
15 a long period of time. As you know, since *To*
16 *Err is Human*, our new report from the National
17 Academy of Medicine I'm viewing as *To Err is*
18 *Human 2*, and we'll probably be issuing that in
19 the end of 2027.

20 But I think the bottom line in all
21 of this is we're struggling with the fact that
22 our current measurement systems pick up only a
23 fraction of all of the harm that we pick up at
24 IHI with our Global Trigger Tool, and how do we
25 resolve that issue?

1 Well, after the Global Trigger Tool
2 had been well-established in a number of
3 places, we took a whole team to three famous
4 hospitals in the United States, one in Boston,
5 one in St. Louis, and one in Salt Lake City.

6 These were IHI reviewers, and we
7 came in, and we applied the Global Trigger Tool
8 to their medical records. Now, that was
9 retrospective, and we basically found a whole
10 lot of harm. Next slide, please?

11 If you look on the left, we found
12 354 adverse events at these three hospitals
13 using IHI's Global Trigger Tool review team.
14 In that same patient population, the AHRQ
15 Patient Safety Indicators only picked up 35
16 adverse events.

17 And the hospital reporting systems,
18 which were very, these were all very
19 sophisticated hospitals, only picked up four,
20 and so we found the main way hospitals measure
21 harm, either the PSIs or the volunteer
22 reporting system, was missing 90 percent of
23 harm, and we believed at the time -- that's one
24 reason we're making a whole lot of progress in
25 patient safety is because our measurement

1 systems were missing 90 percent of it.

2 Now, what are the latest numbers
3 that we know about safety based on more modern
4 techniques to measure it? We know about
5 400,000 patients probably get killed every year
6 from safety events. We know that about 10
7 million people get injured.

8 We know there are about 800,000
9 diagnostic injuries, and we know that one in
10 four hospital patients experiences harm, and
11 basically, about 7 percent of outpatients
12 experience harm every year.

13 So, many ask why aren't we getting
14 better in safety? It's because our measurement
15 systems that most hospitals employ miss 90
16 percent of harm. So, how can we go beyond
17 that?

18 And so, we got a lot of pushback at
19 IHI that our chart review base measurement was
20 retrospective like all of these other measures,
21 and what a lot of people said was what good
22 does it measure a safety event after it's
23 occurred? Why can't we use electronics to
24 create safety measures that are real-time, and
25 we can help the patient while they're in the

1 bed?

2 So, we took the IHI Global Trigger
3 Tool, and we automated it. We automated about
4 50 triggers in all of the leading EHRs, whether
5 they be in Epic, Cerner, MEDITECH, or
6 Allscripts, and what did we find?

7 About a quarter of the patients at
8 hospitals were having harm that we could pick
9 up in real time with electronic systems, but
10 not only could we pick it up in real time, we
11 could actually go a step further. Next slide,
12 please?

13 So, Don Berwick and I wrote an
14 editorial, and it said we've demonstrated
15 technically we can automate the Global Trigger
16 Tool, we can detect much more harm, and we can
17 do it in real time. We can help the patients
18 in the beds.

19 So, why shouldn't we go down this
20 road of moving safety electronic measures as
21 safety measures into the electronic world and
22 make them real-time when we can help patients?
23 And that's exactly -- next slide, please?

24 And there's a video that goes along

1 with that. You can find it on the ACP⁷⁹
2 website. Don made a great video with a plea.
3 Why don't we move to a new way to measure
4 safety prospectively in real time?

5 And indeed, this is where CMS has
6 gone, which is to pick up eCQMs and develop
7 them in safety, and I've had the pleasure of
8 working with Patrick on many of these events.

9 These events, these nine really, I
10 think, are the future of safety measurement.
11 And although CMS doesn't require them to be
12 real-time, at Leapfrog, I think we're going to
13 go down the road to make that a requirement for
14 our high-functioning hospitals.

15 We'll see, but they easily could be.
16 There's no technical reason you can't measure
17 every single one of these in real time when you
18 can help the patient in their bed. And the two
19 I've highlighted in red are required this year
20 by CMS.

21 Next slide, please? But what if you
22 could automate 50 safety eCQMs in real time?
23 And this is what the PSO has done.

24 So, this PSO has basically automated

79 American College of Physicians

1 up to 50 of these things in real time,
2 implemented in more than 100 hospitals, and the
3 view you get of safety when you do it in real
4 time when you can help the patients is very
5 different than the way we've managed safety in
6 the past.

7 And this has worked with Epic,
8 Cerner, MEDITECH, and Allscripts, and it works
9 with current levels of interoperability, so you
10 don't need any fancy new tools or anything
11 else. And this is one of the things we're
12 considering at the National Academy of
13 Medicine.

14 If this can be done technically, why
15 shouldn't it be done? And so, one of the
16 things that this particular program does, next
17 slide, please, is allow you to do this at
18 multiple levels in health systems.

19 So, this PSO did it at a health
20 system level where they automated all safety
21 measurement. They did it at a hospital level.
22 They did it at a regional level. They did it
23 at a unit level.

24 They did it at a team level, and
25 then they did it at the patient level, perhaps

1 the most interesting experiment in all of this.
2 Why shouldn't we give this information to
3 patients in real time? Next slide.

4 And this is the way it works. Real-
5 time data streams out of EHRs in all of these
6 different hospitals, goes into a PSO database
7 where real-time analytics and algorithms fire,
8 detect safety problems as they occur, allow
9 them to be reviewed immediately, and then it
10 can lead to interventions to help patients
11 while they're experiencing their safety event,
12 or it can feed big quality improvement
13 initiatives.

14 And basically, what hospitals found
15 who do this is they increase the amount of harm
16 they detect by 25-fold, and suddenly, they not
17 only can look at harm at the hospital level,
18 they can look at harm in all of the different
19 unit levels.

20 And guess what they find? Harm
21 varies in both frequency and type across
22 different units in the same hospital, and yet
23 our safety initiatives are for the whole
24 hospital. So, what this allows hospitals to do
25 is to start focusing their efforts on adverse

1 events in different units in different ways,
2 and that's a big change, and that's something
3 at the NAM we're obviously very interested in.

4 What if we could focus our safety
5 efforts differently on different units and do
6 it in real time or prevent it ahead of time?
7 Next slide.

8 And one of the challenges when you
9 do this using EHR data is you get so much
10 noise, so many false positives, and that's
11 where a lot of efforts in this area have
12 failed, is hospitals turn on these automated
13 triggers, and they get so many, so many hits,
14 they can't manage it.

15 So, what the PSO did is use both
16 experience and then AI to markedly decrease the
17 noise in the system and get it down to events
18 that are really likely to have occurred, very
19 high PPVs⁸⁰.

20 And when you do that, you can create
21 a real-time safety monitoring system that can
22 monitor every patient, every day, and in a 300-
23 bed hospital, you can do it with one FTE⁸¹, the
24 power of AI, and advanced analytics.

80 Positive predictive values

81 Full-time equivalent

1 So, that was another
2 transformational event in this which allowed us
3 to move to real-time safety monitoring at every
4 patient in the hospital. Next slide? And so,
5 what happens when you compare this new real-
6 time prospective safety monitoring system to
7 existing?

8 So, here was a health system that
9 was doing the manual IHR⁸² chart review for
10 adverse events, the Global Trigger Tool chart,
11 and then they compared it to the new automated
12 system, and I think you can see the difference.

13 When you put in automated
14 prospective systems and you compare them to the
15 old IHI manual chart review, the difference is
16 astounding in how much harm you pick up. Next
17 slide?

18 And then this was a similar idea. A
19 hospital puts in one of these prospective
20 safety systems to detect adverse events using
21 EHR data and compare how many adverse events it
22 detected in that in the same population.

23 And we looked to see how many of
24 those adverse events were in a hospital's

82 Individual health record

1 voluntary reporting system. You can see the
2 difference, 147 in the hospital's voluntary
3 reporting system versus 3,740 with the new
4 automated system.

5 And we've also done studies
6 comparing PSIs to these automated systems, and
7 once again, they detect very few events
8 compared to the automated systems. Next slide?

9 What this does is enable hospitals
10 to test out many strategies for reducing
11 adverse events because they have a good
12 measurement system to see if their intervention
13 actually works, a system that can pick up
14 almost 95 percent of all the harm, do it in an
15 automated fashion.

16 And this hospital tried several
17 different interventions to decrease its adverse
18 events related to oversedation, and they used
19 the measurement system to decide which one
20 works. Then they implemented it, and they had
21 a dramatic drop in safety problems.

22 So, I think as we look at this at
23 the NAM, these focused approaches to really
24 measuring safety in detail may allow us to
25 understand what interventions work and what

1 don't.

2 Because we've been working on this
3 for 25 years, and we still have an awful lot of
4 harm. I would argue it's because we just didn't
5 have good measurement systems to see which
6 interventions worked and which didn't. Next
7 slide?

8 Going a step further here, and this
9 PSO created a huge database of
10 hospitalizations, adverse events, positive
11 triggers, and everything else into the
12 millions, and then could develop an AI-enabled
13 prediction system that could predict harm up to
14 72 hours before it occurred in the patients.

15 This is a real-world case with all
16 of the numbers scrambled so you can't find it,
17 but it was a patient who came into the hospital
18 with a ruptured appendix, got operated upon,
19 initially got better and then started to get
20 worse, and then went on to experience and
21 intra-abdominal hemorrhage and then intra-
22 abdominal abscesses. This is a real-world
23 case.

24 And as they started to get worse, if
25 you clicked on this little button here, you'd

1 be referred to a model with 275 indicators in
2 it. You're referred to the elements of the
3 model that were really high.

4 And you can see hematocrit had
5 fallen, white count was up, platelet count was
6 up, clearly an indication that something intra-
7 abdominally was going on, but I think this is
8 where the power of safety measurement will be
9 changed completely, I think, by the world of
10 AI. Next slide?

11 Robert Wood Johnson saw all of this
12 and said why are you just sharing this AI
13 safety information with health care workers?
14 Why don't you share it with patients, and
15 families, and caregivers?

16 So, they funded us, next slide, to
17 do a project where we actually created real-
18 time safety dashboards that included both real-
19 world safety events and safety risks.

20 Patients designed this completely
21 themselves, and basically, patients loved the
22 risk predictor because they said that's one I
23 can get more interested in, but they can click
24 on any of these dots and not only see what
25 their risk of having a safety problem is, but

1 also the exact safety problems and risks they
2 have now.

3 And they wanted to know. Put it in
4 language I can understand. You got bacteria in
5 your urine. Tell me what questions about this
6 problem I can ask my care team, tell me what
7 things I can do to manage this, and then give
8 me a place where I can get more information
9 about this. Next slide?

10 And they wanted it on every
11 technology platform, so we made this system,
12 this dashboard work on desktops, laptops,
13 iPads, and iPhones, and a lot of patients, and
14 family, and caregivers accessed patient
15 information about a loved one of theirs in the
16 hospital offsite using their iPhone.

17 So, what did we find when we did a
18 clinical trial of this? Next slide. Robert
19 Wood Johnson insisted we do a whole battery of
20 evaluations on this, and the primary outcomes
21 for patients hospitalized who used this system,
22 they had lower 30-day readmissions and lower
23 30-day mortality.

24 They also had higher patient
25 activation scores, and that's a Robert Wood

1 Johnson-funded measure, but we looked at the
2 secondary outcomes and there were no problems
3 here.

4 So, I do think, as we think about
5 value-based care, if every Medicare patient had
6 access to this kind of system as part of their
7 care, we could make a huge dent in patient
8 safety. Next slide, please?

9 And finally, what the PSO was
10 focused on, if we're doing these automated
11 triggers and detecting in a prospective safety,
12 surveillance, and monitoring system, the stuff
13 on the left side, why shouldn't we at the same
14 time not apply this to risk management and use
15 this approach to detect potentially
16 compensatory events in real time?

17 And that's what the PSO did. And
18 they set up a system working with Lloyd's of
19 London and a big malpractice insurer in a big
20 health system to see if they could detect
21 potentially compensatory events in a short
22 period of time, and guess what?

23 They could detect almost 90 percent
24 of them in 36 hours versus 50 days for this
25 health system for normal detection, and that

1 means they could complete investigation quickly
2 and start intervening, and what did that mean?

3 They could significantly reduce
4 payouts. And I think the return on investment
5 on this side will be much greater than the
6 return on investment that we've seen on the
7 clinical slide. Next slide, please?

8 So, with that, I'll stop and ask any
9 questions? But I think my advice is we should
10 be bold about thinking about measurement in the
11 future that's driven by AI advanced analytics
12 that's real-time when we can actually help
13 patients.

14 And the technical barriers of this
15 have already been overcome. You can do this
16 right now with the current version of Cerner,
17 Epic, MEDITECH, or Allscripts. The challenges
18 here are getting organizations to adopt it
19 because most of them invested heavily in
20 voluntary reporting and PSIs, and they don't
21 want to give up that infrastructure. So, I will
22 stop there, and thank you for your time.

23 MR. TYSON: Thank you, and thank you
24 to everybody, all of our experts here, for your
25 great presentations.

1 So, now we're going to move to our
2 open discussion with our Committee members.
3 So, PTAC members, please flip your name card up
4 if you have a question, or for our virtual
5 Committee members, please raise your hand on
6 Zoom if you have any questions for our guests.

7 Additionally, we want to encourage
8 our experts to ask each other follow-up
9 questions. You can signal that you have a
10 question also by flipping your name card up or
11 raising your hand.

12 We'll just say in the interests of
13 ensuring balance across different perspectives
14 and questions, we encourage experts to keep
15 each response to a few minutes. So, with that,
16 I'll open the floor to questions. Krishna?

17 MR. RAMACHANDRAN: Sure, yes, David,
18 but certainly open for others as well. So, I
19 love the sort of global trigger evolution to
20 automated EHR, the power of AI. I think it's
21 really cool to see that progress in a really
22 meaningful, measurable sort of manner, so
23 excellent work there to make this real.

24 Really, the question for you is in
25 the spirit of trying to scale this systemwide,

1 nationwide, like you mentioned one of the
2 barriers. I guess, what advice or asks would
3 you have of Committee members like us, or CMS,
4 or Medicare? How would we scale this idea
5 nationwide at scale?

6 DR. CLASSEN: It's a great question,
7 and this has been scaled across more than 100
8 hospitals in the United States and Australia,
9 so it's technically scalable. We could do it
10 right now.

11 I mean, and this is the issue we're
12 focused on at NAM. If this is not technically
13 limited, why aren't we doing it? And I can
14 just talk about some of the barriers as we've
15 observed to do this, but there are no technical
16 barriers. You could do all that I've showed you
17 right now.

18 Big barriers to do this, a lot of
19 health systems have existing safety measurement
20 structures in place they don't want to give up,
21 invested heavily in voluntary reporting
22 systems, which is how a lot of them measure
23 safety currently, and they've built a big
24 infrastructure around this.

25 I know of one health system that

1 gets about 100,000 safety reports in their
2 voluntary reporting system, this is a hospital,
3 big hospital, every year. They have a whole
4 fleet of staff analyzing those reports non-
5 stop, running RCAs⁸³ and everything else to deal
6 with them.

7 When you look into detail how many
8 of those 100,000 voluntary reports of safety
9 actually caused harm to the patient, it's a
10 teeny fraction. Why is that? Because the
11 voluntary reporting systems were set to contain
12 any possible error that could occur, and that's
13 exactly where people went with reporting.

14 And we all know not all errors are
15 created equal. Most errors never occur, if you
16 will, in any harm to patients, so you could
17 build a whole measurement system that reduces
18 your errors by 95 percent and have little
19 impact on your harm. That's the challenge here.

20 Another challenge organizations had
21 is they're scared to death of putting in a
22 prospective electronic safety measurement
23 system that would markedly increase the amount
24 of harm they detect. Why? They worry about

83 Root cause analyses

1 malpractice risk, that we're going to put
2 ourselves at risk for malpractice problems.

3 Number two, they worry about
4 reputational risk. It might get out, if they
5 start measuring, that they're having a whole
6 lot of harm. Three, they may be caught not
7 being able to deal with all of these safety
8 problems like dealing from a fire hose.

9 So, there are a lot of reasons that
10 organizations institutionalize their current
11 patient safety measurement approaches that have
12 nothing to do with technical limitations or
13 anything else, and I get that. I get that
14 entirely.

15 And indeed, there are some hospitals
16 who put in this type of automated safety
17 system, increased their detection of harm by
18 20- or 25-fold, and then turned it off. So, I
19 think it's a great question. The barriers here
20 are not technical. They're organizational and
21 cultural.

22 MR. RAMACHANDRAN: I think we were
23 chatting about that this morning too, right,
24 this, like, failure to correct aspect that
25 Samuel had brought up too, so they are great

1 points. Thank you.

2 DR. CLASSEN: Thank you.

3 MR. TYSON: Other questions?

4 DR. CLASSEN: The only thing I might
5 add to this is one big HMO let me study safety
6 events in their hospitals and then track
7 patients for a year afterwards, and what we
8 found is, of course, when you're in the
9 hospital and you have a safety event, that
10 increases your mortality, and your length of
11 stay, and everything else. What we didn't know
12 is what happens outpatient.

13 Well, this was a big HMO that kept
14 track of all of that, and what we found out is
15 that after you left the hospital, your risk of
16 readmission was the highest of any patient
17 population in the organization at 30 days, but
18 it didn't stop at 30 days.

19 Your risk of readmission lasted for
20 a year, your risk of increased mortality lasted
21 for a year, and you had a marked higher use of
22 outpatient resources. So, these safety events
23 don't stop at the hospital door. They go all
24 across the continuum of care, and I think
25 that's something we didn't appreciate before.

1 MR. TYSON: Yeah, Jeff, please chime
2 in.

3 MR. GEPPERT: It was more of a
4 comment than a question, and it's -- the
5 infrastructure to assure these AI tools are
6 doing what we expect them to do is emerging and
7 evolving.

8 So, one thing to note is that
9 agentic AI is, it's non-determinative, meaning
10 very small changes in inputs can result in very
11 large changes in outputs. And so, what this
12 means is that agent-based systems demonstrate a
13 lot of these same kind of human factor errors
14 that we're used to with evaluating systems.

15 So, for example, there's a lack of
16 communication. There's a lack of teamwork.
17 There's a lack of assertiveness. There's
18 complacency. There's fatigue. There's stress.
19 There's lack of knowledge. There's lack of
20 resources.

21 There's lack of awareness. There's
22 distractions. There's pressures. There's
23 norms, all of the things we worry about when
24 dealing with humans in safety-critical
25 situations applied to these AI agents.

1 And the second thing I'll mention is
2 that right now we're talking about sort of, you
3 know, we're looking at models, like the
4 individual models, like, you know, an AI-
5 enabled global trigger tool or something, but
6 that's not how AI is sort of manifesting itself
7 in health care.

8 We have individual models, but then
9 we have these models that are being run by
10 agents, and then we have multiple agents
11 running multiple models, and then we have
12 agents that are acting autonomously, and then
13 we have agents that are acting enterprise wide.

14 And so, the errors in this sort of
15 AI chain tend to bubble up from the bottom.
16 Like I said, small errors in the model inputs
17 manifest themselves into potentially large
18 errors at the institutional level.

19 Whereas, our control mechanisms go
20 exactly the opposite direction. We tend --
21 what we're talking about when we talk about AI
22 controls is we're talking about AI governance
23 and how organizations are managing, you know,
24 the implementation of their AI resources.

25 So, that's just to say, you know,

1 right now, you know, I don't know that we
2 should be building Alternative Payment Models
3 on an AI foundation. If tools like that work,
4 I think you need to ask yourself, well, what's
5 the point of value-based purchasing? What's
6 the point of value-based payment? Is it just
7 to recognize and reward value?

8 You know, then as tools like that
9 become sort of well-established, evidence-
10 based, then you just pay people to adopt them,
11 right? I mean, it's like it's just you know
12 what works, and they implement what works, but,
13 you know, for the most case, we don't have that
14 degree of certainty in terms of what works.
15 There's a lot of other things that get in the
16 way.

17 And that's where value-based payment
18 still has a role in terms of, you know, trying
19 to figure things out like, you know, how is it
20 that all of these AI tools sort of put
21 together, and how is it that they ultimately
22 result in outcomes that are better for
23 patients?

24 There's a lot of unknowns there that
25 I think value-based purchasing and value-based

1 payment models could help us sort of uncover.

2 DR. CLASSEN: So, Jeff, this is
3 David Classen. I just want to echo your point.
4 The AI stuff I showed you, we used AI
5 techniques. We didn't use anybody else's AI
6 model, and I don't think we will because the AI
7 model is not predictable enough to understand
8 how it would impact things.

9 Separately, through our Leapfrog EHR
10 safety standard, we've seen AI algorithms start
11 to make their way into EHRs. And one
12 particular scenario, we were studying -- about
13 3,000 hospitals every year use our Leapfrog EHR
14 safety standards, basically a simulated group
15 of patients that allows you to check and make
16 sure your system is picking up known safety
17 risks.

18 We were testing it at one hospital,
19 and we happened to admit a patient, a test
20 patient, and then we had them administer a
21 medication to that test patient, as we always
22 do, and then we usually have them order a
23 dosage, a frequency, and a duration of that
24 test medication.

25 In this hospital, we put the patient

1 in, we put the medication in, and before we
2 could put the dose, frequency, and duration in,
3 the AI program filled it all in. We had never
4 seen this before because in rule-based systems,
5 that doesn't happen.

6 Then we ran the same scenario 10
7 times, and AI gave us six different answers.
8 One of them was just a fatal overdose. So,
9 that gets back to your point. These systems
10 are very dynamic, and in clinical care, you
11 have no idea what they're going to recommend.

12 MR. TYSON: So, Larry, I see you
13 have your hand raised. We'll go to you next.

14 DR. KOSINSKI: Yeah, I probably
15 ought to leave my hand up all the time because
16 I always have a comment.

17 This is really, really thought-
18 provoking, and I'm tying together comments that
19 have come from a number of you, and I'm struck.
20 This is really cultural. I think the most
21 powerful issue we're dealing with here is a
22 cultural one.

23 It looks like, from the basis of
24 what David said, these are measurable. These
25 are quantifiable. These are categorizable. We

1 can do this. This is no different than when
2 police body cameras were started, or nurse
3 navigation systems were initiated, and today,
4 we even have electronic umpires in sporting
5 events.

6 The technology is leading the way
7 towards our ability to identify human, I don't
8 want to use the word error, but variability in
9 the human performance of tasks, and this is
10 cultural.

11 And I think from this Committee, our
12 approach has to be that we embrace the culture,
13 and we try to help move this entire thing
14 forward, but I have a specific question, and
15 I'm going to tie together something David said
16 and something Patrick said.

17 I'm intrigued about the team issue
18 here because Patrick brought up the fact, I
19 think it was him, that care is team-based,
20 errors are team-based oftentimes, and so how do
21 we measure the systems-based errors and bring
22 them down to the team, and affect it really
23 from a team level rather than an individual
24 level?

25 Whoever can answer it, answer it.

1 I'm thinking we're never going to get to this
2 unless we can get into that structure and try
3 to unravel it.

4 DR. CLASSEN: I can address it.
5 When we first started doing these automated
6 triggers, we were sending the emails to the
7 frontline provider, your patient may have this
8 problem, and the frontline providers were so
9 overwhelmed with everything else, they couldn't
10 acknowledge it. So, we learned we had to build
11 a team to manage these issues, and we couldn't
12 just rely on the frontline provider to do it.

13 And I think over time, that team-
14 based approach to deal with these issues,
15 analyze them, and decide what needs to happen,
16 supporting the frontline providers, but not
17 relying on them to handle it, I think has been
18 a big learning here, but we tried so many ways
19 to just send it to the frontline provider,
20 doctor or nurse, and have them deal with it.
21 It never worked.

22 DR. ROMANO: I'll just say that
23 perhaps an advantage that we have in thinking
24 about Alternative Payment Models is that there
25 is an entity or organization that has

1 volunteered, that has agreed to participate in
2 that Alternative Payment Model, and in so
3 doing, they are taking some accountability for
4 the value and the outcomes of care that they
5 provide.

6 So, as CMMI and others look at how
7 those entities are structured, I think ideally
8 those entities would have internal structures
9 that really reflect the teams that provide
10 care, so that when we are told collectively,
11 let's say, in our ACO, that we're
12 underperforming on a particular metric, that we
13 can socialize that information across providers
14 in the organization and figure out what each of
15 our relative contributions is to fixing the
16 problem.

17 So, I worry though when I see
18 structures that are taking accountability
19 without having that foundational structure of
20 providers who are fully engaged, right?
21 Because sometimes it just seems like a way to
22 get easy money, right?

23 And that's not going to do the job,
24 right? So, there has to be a structure where
25 people are actually collaborating and working

1 together, and taking responsibility for the
2 outcomes, and have some ability to intervene
3 based on the results.

4 MR. TYSON: All right, so I know we
5 have a few more questions, but before we get to
6 those, we're going to expand our panel a little
7 bit.

8 I'm going to actually invite
9 Michelle Schreiber back up to join us again.
10 She was one of the experts from our first
11 discussion today. Michelle is the Deputy
12 Director of the Center for Clinical Standards
13 and Quality, and Director of the Quality
14 Measurement and Value-Based Incentives Group at
15 CMS. So, Michelle, we have a planted question
16 for you here from the information --

17 DR. SCHREIBER: So, that's why I'm
18 here, right, planted questions?

19 (Laughter.)

20 MR. TYSON: From the information
21 that our session experts have shared with us
22 already and the discussion we've been having
23 here, are there any comments or additional
24 observations you'd like to offer from your
25 perspective?

1 DR. SCHREIBER: Thank you. First of
2 all, I've worked with everyone here, and this
3 is the direction that CMS has really taken as
4 well, as you heard me this morning, by
5 transforming our measures to digital, which can
6 do several things.

7 One, it helps with the data
8 standardization that not only we need for the
9 measures, but we need to train AI models,
10 because AI models have to be trained on some
11 standardized data around this.

12 Number two, David is absolutely
13 right. Although CMS may not get these real-time
14 or provide feedback real-time, there is nothing
15 that stops the organization from learning how
16 to use these real-time in their units, on their
17 floors, and creating real-time feedback
18 monitoring systems and ongoing learning systems
19 for change.

20 We spoke already about AI this
21 morning, and again this afternoon, about what
22 you can do to kind of look at this huge volume
23 of data that's coming through to make sense of
24 it, and to have it in a manageable way that you
25 can act upon it.

1 And I think that's extremely
2 important, but it's equally important to make
3 sure that we're following our AI systems as
4 they're learning and make sure that they're
5 learning the correct things. That being said, I
6 think the last comment that Patrick made, and
7 Jeff, is really important.

8 CMS can mandate, you know, that
9 every facility implement one of these. It
10 won't go over very well because, I'm looking at
11 Sam, because it will be burdensome, and it will
12 be expensive, which is why I think a model is
13 so valuable.

14 Because a model can take this and
15 really evaluate it, and evaluate if this works,
16 and evaluate if we then want to translate it to
17 national participation. So, we need to study
18 it, I think, first, and I think that's really
19 what we're talking about here today. Thanks.

20 MR. TYSON: So, Walter?

21 DR. LIN: Fascinating discussion.
22 Thank you, everyone, for just great
23 presentations. I couldn't help but think that
24 so much of our discussion, both in this panel
25 and the previous one, was focused on inpatient

1 patient safety measures, and just a couple of
2 questions around that.

3 I think I know the reason why, but
4 I'd love to hear kind of the panelists just
5 educate us all on why that's been the focus of
6 the patient safety body of work writ large over
7 the past few decades.

8 I think, Michelle, you said it
9 earlier, that the patient safety error rate is
10 probably much lower in the outpatient setting,
11 but just given most of the care happens in the
12 outpatient setting, I have to think that the
13 number of errors and patient safety events
14 outnumber in the outpatient versus the
15 inpatient setting.

16 And then kind of a follow-up
17 question would be are there emerging approaches
18 to rectify this imbalance? What is being done
19 to help address outpatient safety events?

20 DR. SCHREIBER: So, I'll start it
21 first if I may. I think we started in the
22 hospital because our health care system is very
23 hospital-centric, and traditionally, that's
24 where most care was provided.

25 In addition, the care changes

1 frequently, right? You give a drug, and you
2 see its effect immediately, whereas in the
3 ambulatory setting, you don't see that. You
4 know the patient is at home. They're not in
5 front of the provider to be able to see the
6 immediacy of it.

7 That being said, health care is
8 changing, as you and everybody else has pointed
9 out. More and more surgery is actually now
10 done ambulatory.

11 As a matter of fact, the majority of
12 hip replacement or joint replacement surgery is
13 done ambulatory, something that none of us
14 would have thought possible five or 10 years
15 ago.

16 Those are what the statistics are
17 now, and I think we need to look at this a
18 little bit differently, but you're right. If
19 you consider the traditional harm, right, like
20 a fall with injury, that's more common in a
21 setting in a facility, in a hospital, than it
22 is at home.

23 It really wasn't until the whole
24 topic of diagnostic excellence really started
25 coming to the foreground that we started really

1 thinking about ambulatory harm, because I think
2 that's going to be the majority of the
3 ambulatory harm that we see, and we're just at
4 the surface of doing that.

5 AHRQ actually had started a lot of
6 that work. CMS is just introducing some of the
7 measures, but we're just starting to see it.
8 So, I think that we just have to transform and
9 recognize that our health care system is
10 shifting ambulatory.

11 And I would say more than just
12 shifting ambulatory, it's going to shift to
13 local patient control too, and making sure the
14 patients have this information, and the
15 patients are making that decision is going to
16 be yet another step.

17 MR. GEPPERT: Just from a purely
18 measurement perspective, ambulatory is a lot
19 harder because the numbers get small fast, and
20 so accountability essentially is about
21 causality, and establishing causality when
22 patients are coming to the ambulatory setting
23 from lots of different pathways and leaving the
24 ambulatory setting on lots of different
25 pathways, it's much more difficult to

1 demonstrate and to show, and the evidence base
2 is much more sparse. It hasn't been studied as
3 much.

4 MR. TYSON: All right, Lindsay?

5 DR. BOTSFORD: All right, well, I
6 have a question for Dr. Romano, but others may
7 have an opinion as well.

8 You had a provocative statement in
9 there that payment models do not have a very
10 good track record at improving patient safety,
11 and I guess the question is, is it just they
12 haven't been good in the past and we need to
13 make them better, or is there something
14 inherently flawed by thinking that a payment
15 model is the way to improve patient safety?

16 And I guess maybe the follow-on as
17 to your following statement was, you know,
18 transparency alone is maybe the best
19 intervention, and so I'm curious around what
20 are the models that would just encourage that
21 transparency along the way?

22 DR. ROMANO: Well, right, my
23 statements were a little bit deliberately
24 provocative, so you can take it with a grain of
25 salt, but, you know, I think that, again, much

1 of what we've learned is from the hospital
2 programs, and we discussed earlier the
3 hospital-acquired condition detection program,
4 the hospital value-based purchasing program,
5 clearly -- the hospital readmission reduction
6 program for that matter.

7 I mean, clearly these programs have
8 had some impact in reducing readmissions,
9 reducing reported events, but have they truly
10 improved care?

11 I think that's been much harder to
12 demonstrate because, frankly, on the provider
13 side, we're creative, and we figure out ways to
14 make our performance look better sometimes,
15 even when we haven't actually improved care --

16 DR. SCHREIBER: It's called gaming
17 the system.

18 DR. ROMANO: Gaming the system, yes,
19 and there is -- you know, so that's why I
20 think, you know, there's a mixed record,
21 because we've maybe focused on a few things,
22 and we can say, well, yes, we've prevented some
23 readmissions, but, you know, many of those
24 readmissions have just been converted to
25 observation stays, so does it make any

1 difference from the patient's perspective if
2 they were in for 48 hours for readmission or
3 for an observation stay?

4 So, it's these kinds of problems, I
5 think, that we've encountered, so I think we
6 have to get smarter about how we do it. I'm
7 not saying that it's hopeless, but I think we
8 have to get smarter, and part of that is really
9 by building on maybe some of the work that
10 we've been doing with composites, by building
11 on ways of linking processes and outcomes
12 together.

13 I alluded to that. Jeff alluded to
14 that in terms of those assurance cases.
15 David's alluded to it in terms of how we
16 implement systems within organizations.

17 And obviously, you know, Leapfrog,
18 David and I have both worked extensively with
19 Leapfrog, and there have been some twists and
20 turns in that journey, but I think Leapfrog's
21 focus has been on transparency.

22 And ultimately, we want people to
23 pay attention to measures. We want everybody,
24 all of the stakeholders to pay attention to
25 measures, but when we put too much money on the

1 line, sometimes that may motivate us in the
2 wrong way, you know, to pay more attention to
3 how do we reduce the number of events from five
4 to three versus how do we build more robust
5 systems that prevent not just these errors, but
6 errors like this that affect a larger number of
7 patients? So, those were just a few thoughts,
8 but I'm sure my colleagues have more.

9 DR. SCHREIBER: It gets back to, I
10 think, what we've all been speaking of, and
11 that's this isn't a technology issue. This is
12 a willpower issue. We know how to do things.
13 We know how to make it better.

14 Industry certainly knows how to do
15 this. It knows how to make things better.
16 They've led the way in high reliability, and
17 has health care adopted it? No, not
18 particularly. And so, I think it's willpower.
19 So, how do you create the will? Is it a
20 payment model? It kind of depends.

21 I mean, if you think about it, the
22 Medicare Advantage Stars rating, for example,
23 which has an enormous amount of money tied to
24 it, yet when you saw measures change with that,
25 you also saw them gamed probably a lot, but you

1 could see change, but it was really large
2 amounts of money.

3 Most of the value-based programs
4 that we have are fairly small amounts of money
5 that are tied to it, and I would say then it
6 becomes a business decision in many respects,
7 if people would rather just take the penalty
8 than put in the work to really change the
9 capabilities. If I had a dime for every CFO⁸⁴
10 that told me that it was cheaper to take the
11 penalty, I'd be very rich.

12 So, I think the real question is how
13 do we create the will in this country to get
14 organizations to change? I think that's what
15 Sam is really telling us and trying to do.

16 How do we create the will to change?
17 And that really is cultural, and that is all of
18 us, from the government, to the commercial
19 payers, to all of us sort of speaking from the
20 same book on how important this is.

21 In the end, high-quality health care
22 is our product in health care, and it doesn't
23 feel that way. It feels like profit is our
24 product, you know, and that conversation, until

84 Chief Financial Officer

1 that turns, I think that's part of the
2 challenge.

3 MR. TYSON: Any final thoughts from
4 the group? Oh, sorry, yes?

5 CO-CHAIR PULLURU: I'll keep it
6 brief, although it was a relatively diffuse
7 question I had. You know, as I saw this
8 conversation play out, and the conversation
9 earlier today play out, what struck me most is
10 the fact that payment, when attached to
11 initiatives, when I look back at success,
12 right, and think about meaningful use of
13 success in getting EMR adoption, it worked.

14 Think about BPCI⁸⁵ in getting joints
15 to be less expensive. It worked, and higher
16 quality, by the way, are moved to the
17 outpatient, so I see these large-scale
18 initiatives that have worked.

19 And as I was reflecting, Michelle,
20 on taking away Stars from hospitals, I'm
21 thinking, I was thinking why would a hospital
22 CMO care? Because there's indirect costs
23 attached to Stars measures, not like MA⁸⁶ where
24 it actually, you know, 0.5 is what, \$1,000

85 Bundled Payments for Care Improvement

86 Medicare Advantage

1 PMPM⁸⁷?

2 So, you know, as you think about it,
3 and I would ask our Committee to think about
4 this in incentives, is it almost has to play
5 into something. We're not where we can do
6 mandatory, you know, mandatory APMs, but there
7 are mandatory things like MIPS, you know.

8 And so, I think we have to embed
9 this into the DNA or the infrastructure of how
10 payment cuts across all lines in order for it
11 to be relevant, and we've done it before, and
12 so that would just be my comment.

13 DR. KOSINSKI: Chinni, it's not a
14 question of if. It's a question of how and
15 when.

16 MR. WATTERS: Yeah, I would love to
17 see us find a way to make it impossible for
18 leadership in a system not to invest in patient
19 safety, and that may mean saying that you are
20 leaving money on the table.

21 If we have a system now where you
22 make a mistake, and we penalize you, maybe a
23 hospital says it's worth it to take the
24 penalty. If we create a system that says

87 Per member per month

1 you've made a mistake, now you have money
2 available, of your own money, that you can only
3 get back if you devote to improving in your
4 system.

5 And you can leave that money on the
6 table, and you can walk away, and that's fine,
7 or you can take it, and you can try to improve.
8 You can see that it works, or if it doesn't
9 work, you can try again the next time if you
10 continue to perform poorly.

11 But it's the type of leaving the
12 money on the table so that you would be
13 derelict in your duty as a leader of your
14 system if you didn't invest, that's what I'd
15 like to see us try to explore, because that's
16 how you're going to find that it becomes then
17 the responsibility of the leadership to adopt
18 the culture of patient safety that we know will
19 lead to the systemwide change.

20 And if we're too narrow, and we
21 define one or two issues to focus on, you've
22 just given a target for somebody to hyperfixate
23 on, get better at, hit your metrics and move
24 on, and then meanwhile, a patient is dying of
25 something else, so let's create a more flexible

1 system.

2 Let's create something that leads to
3 continuous improvement. Let's create something
4 that encourages transparency, right? We want
5 to see that.

6 Maybe it's something where we have
7 an automated system of reporting on all of
8 these different metrics, and it passes through
9 a PSO, through some of type of reform so that,
10 you know, they're not afraid of the penalties
11 that David mentioned some hospitals were
12 fearful of when they turned these systems on.

13 And then let's create a system of
14 continuous, real-time feedback so that we know
15 what interventions work, and then allow money
16 on the table for expenditures on practice
17 improvement activities so that, you know,
18 you've got 500 hospitals testing out 500
19 different things all of the time and figuring
20 out what works in real time.

21 I think there are ways that we can
22 do it. I think it is extremely accurate to say
23 that in the past, we've made a couple of
24 mistakes, or we've had sort of suboptimal
25 models, and I think we can certainly learn from

1 those. So, I'm so excited about all the
2 different pieces that I've heard from these
3 different people because I think we can make it
4 happen.

5 MR. TYSON: That feels like a pretty
6 good place to end things. So, I want to thank
7 everybody for your time and your expertise this
8 afternoon, or in Michelle's case, also this
9 morning. Maybe you can come back for the next
10 one and get the hat trick.

11 DR. SCHREIBER: Tomorrow, I will be
12 here all day.

13 (Laughter.)

14 MR. TYSON: So, at this time, we're
15 going to take a 10-minute break. Please join
16 us for our next session, our third and final
17 session today, with experts discussing
18 improving patient safety in value-based care
19 through the use of health IT and data
20 analytics. Thank you.

21 (Whereupon, the above-entitled
22 matter went off the record at 2:46 p.m. and
23 resumed at 2:57 p.m.)

24 * **Session 3: Improving Patient Safety**
25 **in Value-Based Care Through the Use**

**of Health Information Technology and
Data Analytics**

MR. RAMACHANDRAN: All right, welcome back. I'm Krishna Ramachandran, one of the PTAC members.

In our third session this afternoon, improving patient safety in value-based care through the use of health information technology and data analytics, we will hear from four distinguished experts. You can find their full biographies and slides posted on the ASPE PTAC website and the public meeting registration site as well.

Welcome to our three in-person, in-person session participants, also passionate, I'm sure, and also for our one remote participant. Please go ahead and turn on your video. I see you've already done so. Thank you.

After all four experts have presented, our Committee members will have plenty of time to ask questions.

First up, we're happy to welcome in person Dr. Terry Fairbanks, Senior Vice President and Chief Quality and Safety Officer

1 at MedStar Health, and Professor of Emergency
2 Medicine at Georgetown University. Welcome,
3 Terry.

4 DR. FAIRBANKS: Great, thank you.
5 Thanks, everybody, for having me. It's really
6 great to be here.

7 And what I'm going to talk about
8 today as the panel, kind of introduce a deep
9 safety science perspective and then talk about
10 how it impacts us as a health system in a way
11 that I think will really help the Committee as
12 they think about this.

13 So, we were asked to supply an About
14 Me and About MedStar Health. This is listed.
15 What I'm going to do is I'm just going to say
16 the narrative that I think matters in this is
17 that I had three phases to my career.

18 My first phase, I was a safety
19 engineer. I was not in health care. I have a
20 master's degree in safety engineering with a
21 focus on human factors engineering.

22 And during this decade, I was a
23 pilot. I had a general aviation pilot's
24 license, but my research was in other high-risk
25 industries. I did not do any work in health

1 care.

2 Then the second phase of my career
3 was I went into medical school to become an
4 emergency physician, and I realized that what I
5 saw was health care had not heard all of the
6 things that I saw as really relevant in helping
7 the other high-risk, safety-critical industries
8 that I had worked in.

9 So, I spent a decade kind of as a
10 deep academic physician. I worked clinically
11 in the ER⁸⁸ through this whole time and
12 continued to beyond, and I wrote papers, and
13 did grants, and developed a program of how do
14 we bring safety science and safety engineering
15 into health care?

16 I started the National Center for
17 Human Factors in Healthcare, which is based at
18 MedStar Health. And I heard Dr. Schreiber,
19 others talking about investment. Really proud
20 of the deep investment that MedStar Health has
21 made over the last two decades in really trying
22 to do everything right from a safety
23 standpoint.

24 Then in my third decade, I had to

88 Emergency room

1 put my money where my mouth was after
2 researching, and consulting, and say how do we
3 be safer, and I became MedStar Health's, eight
4 years ago, MedStar Health's Chief Quality and
5 Safety Officer, where I'm responsible for
6 quality, safety, health equity, and infection
7 prevention.

8 So, that's me, and I'll just say
9 briefly about MedStar Health, it's the largest
10 health system in the Washington, D.C., and
11 Baltimore area, with 10 hospitals, about 500
12 outpatient sites now, and 35,000 associates.

13 We have prioritized safety for two
14 decades. So, what I'm going to tell you about
15 now from a safety science standpoint is how do
16 we get to the next level for the people that
17 really do invest in this and really are trying
18 to do things right?

19 In the last discussion, I think
20 there was some focus on the bottom dwellers,
21 who I acknowledge are out there. There are
22 health systems who are not trying to do this
23 right and who don't get it, and I want to give
24 the perspective on for those who are trying to
25 do it right.

1 So, we have had this safety first
2 approach. We do follow the quality metrics as
3 closely as we can, but safety first. Keeping
4 our patients safe is where we've been for 20
5 years.

6 We have innovation in risk
7 management, with open and honest communication
8 with family, no deny and defend. We have early
9 discussions with family when things go wrong,
10 and that creates this open culture that helps
11 prevent -- helps support our caregivers.

12 We have just culture that makes sure
13 that people are comfortable telling us about
14 what goes wrong and where the risks and hazards
15 are, deep patient and family engagement, and we
16 have deep human factors integration.

17 Our National Center for Human
18 Factors in Healthcare, which was invested in by
19 MedStar Health, is as many as 20 to 25 human
20 factors and safety engineers embedded in the
21 health system.

22 So, with that perspective, we, a few
23 years ago, I was asked to do a talk at a
24 national meeting about why we're not moving
25 faster in health care and safety. So, I

1 thought, you know, there's controversy. Are we
2 getting safer since the IOM report? I think we
3 can all agree that we're not getting safer fast
4 enough.

5 So, we brought -- I did 30
6 qualitative interviews with deep safety
7 experts, people who had true safety science
8 credentials, PhDs or master's degrees in the
9 safety industry, who knew how other industries
10 did it, and interviewed them, did a qualitative
11 assessment, also did a social media inquiry on
12 that and included that in there.

13 And there were five emerging themes
14 from this that I think are relevant to what
15 your Committee is considering as you think
16 about how to regulate in a way that helps our
17 health systems become safer.

18 So, those five are, one, avoid the
19 conflation of quality and safety. I'm going to
20 spend a minute talking about that in a minute,
21 and I think it's critical. Deliberately infuse
22 true safety science into what we do. Preempt
23 harm with a proactive focus.

24 Dr. Classen was bringing the
25 important point of when we know where harm can

1 occur, we need to monitor, trigger, find it,
2 and he also brought up the importance of safety
3 hazard reporting is understanding where the
4 near misses and risks occur and trying to
5 mitigate those before a patient's injured. We
6 have to create incentives for systems to do
7 that.

8 And then finally, really important
9 is engage the whole health care industry in the
10 systems approach, and I'm going to give a
11 couple examples where, when you talk about the
12 best systems in the country at safety, people
13 really trying to do it right and investing in
14 it right, right now, in the current national
15 structure, we cannot get to zero because so
16 many that are --

17 It's such a complex system, EHR
18 designers, medical device companies, all the
19 many people that interact with our folks need
20 to be at the table with us as partners to
21 ensure that we're as safe as we can be.

22 So, really quickly, how do we tell
23 the difference between quality and safety? We
24 use the idea that quality metrics are things
25 where patients say how does my care measure up

1 against the best practice?

2 It's quantitative. It's a metric.
3 Sometimes there's a safety event that happens
4 so often it becomes a quality metric, but what
5 we are here to really do is to have no harm to
6 patients, and that's safety.

7 We say in our health system when
8 we're furthering safety, we're saying from the
9 patient's perspective, please don't harm me,
10 and this takes a very different skill set.

11 The people that are really good at
12 optimizing quality metrics have competencies
13 like Kaizen, Standard Work, Lean Six Sigma, the
14 industrial engineering approaches, because they
15 know if these six things go into the process
16 every single time, then you'll get this good
17 outcome every single time.

18 Safety is much more nuanced, much
19 more qualitative, understanding human factors,
20 safety design, team training, psychological
21 safety. How do you create a culture that
22 doesn't cause inhibition of people talking
23 about where their risks and near misses were?

24 But if you think about how complex
25 it is, when there's a frontline provider who

1 encounters a risk or hazard, you need them to
2 be comfortable telling you about it and not
3 feel like it's going to count against them.
4 That is really nuance, and we've worked really
5 hard on creating that kind of a culture.

6 I'll just now move to this piece
7 about infused true safety science, and I'm not
8 going to make it a full human factors
9 engineering lesson, but when we look at the
10 three types of human error that we know occur,
11 the most common in health care errors is skill-
12 based error.

13 Skill-based comes from James Reason
14 and Rasmussen literature. It's not medical
15 literature. We think of this as technical
16 skills. That's not what they mean here.

17 It's not like IVs and intubation.
18 They mean what I call automaticity errors, the
19 things that we do every single day. Those are
20 the things that we need to mitigate.

21 And I'm going to give you a really
22 easy example that we all experience every day.
23 Defibrillator design, this is a study that
24 showed defibrillator design where, when
25 somebody needed to defibrillate a patient --

1 And for the clinicians in the room,
2 you know that when somebody goes into cardiac
3 arrest, they're usually in a rhythm that, if
4 you shock them right away, you have a high
5 chance of resuscitating them back to life.
6 Every minute that goes by, you have a 10
7 percent lower chance of success of
8 resuscitation, so every minute counts in this.

9 If you have a defibrillator that's
10 charged up, ready to shock, you say clear, and
11 you press the on button, if you look at that
12 picture, instead of the red shock button by
13 mistake, a human error, it just turns the
14 defibrillator off.

15 So, I want you to compare that to
16 your knowledge of the common slide projector,
17 PowerPoint slide projector, and think about
18 what happens if you accidentally make an error
19 and go to turn that off when you're about to
20 give a presentation. All of the manufacturers
21 in the country stop and say, wait, do you
22 really want to turn this device off? Press
23 again if yes.

24 So, I ask you, why does a lifesaving
25 device not do that? Why does it just turn off?

1 If you have a person that's just died in front
2 of you, you can resuscitate them, and it allows
3 you to make an error.

4 And this is a critical piece because
5 the consumer electronics company has
6 acknowledged that there's human error. They
7 call it use error in the use of their product,
8 and they have mitigated it.

9 The defibrillator company has not --
10 and the reason they haven't, I submit to you,
11 is because we believe that in health care, we
12 will become safer by telling people not to make
13 errors.

14 Be conscientious. Be careful. Take
15 a minute and think about what you're doing.
16 This was mentioned in the last panel. We need
17 system design, safe design of everything we
18 interact with to get to zero.

19 We have a huge responsibility. We
20 have to make sure we hire trained people, make
21 sure they have the right culture, make sure
22 that they do everything to optimize their work,
23 and we need help from everybody to help bring
24 in the safe pieces.

25 So, with this defibrillator story,

1 when we brought this to the defibrillator
2 company, they said yes, we're aware of this.
3 We do have labeling that helps do it.

4 So, this brings to the safety
5 science piece, does labeling help fix a skills-
6 based error? And the answer is no, it doesn't
7 really have any effect on skills-based error.
8 And to do that, I just want you to -- this was
9 supposed to be animated, so I'm sorry.

10 What's in this picture is a door
11 that has a pull handle, and it has a big sign
12 that says push, and all of you would approach
13 that door and you would pull, and the reason
14 you would pull is because human factors
15 engineering tells us you're not thinking about
16 opening the door and the steps to it.

17 You are following the process, and
18 it's the design of the door that leads you to
19 push, or to pull, I'm sorry, instead of push.
20 You don't read the sign.

21 That door that's showing right there
22 is the perfect design mitigation for that,
23 because a push plate, if you replace a push
24 plate with the handle that's telling your brain
25 to pull, it not only tells you to do the right

1 thing, but it makes it really hard to do the
2 right thing, or to do the wrong thing, sorry.

3 And those are the two concepts of
4 basic safety engineering. Know where the risks
5 and hazards are and mitigate them in a safety
6 science-based actual solution. So, it's more
7 than Dr. Classen's pieces of the trigger tool.
8 It's also understanding where the risks and
9 hazards are, and that's why reporting becomes
10 so important.

11 Why am I saying that to you?
12 Because where this Committee could go wrong is
13 make incentives that reduce or inhibit
14 reporting. You have to think about the safety
15 culture and making sure that we create an
16 environment where, when people do go up and
17 pull on that door but don't injure a patient,
18 I'm talking analogy here, that they take a
19 minute, and they say they want to report it
20 without feeling like errors are counting
21 against them.

22 In safety-critical industries, like
23 aviation, they have become ultra-safe, not from
24 trying to reduce errors, but from trying to
25 understand the human error and mitigate the

1 design around it so that they reduce adverse
2 events. It's a critical nuance to understand
3 as we regulate safety.

4 Lots of examples of this. I want to
5 yield my time. I think I'm near the end here,
6 but I will say in health care, we put our
7 providers out front every day to tiptoe around
8 these hazards that we're putting in front of
9 them, with poorly designed systems that do not
10 actually bring us to a place where it's easy to
11 be safe.

12 So, bottom line, we have to use
13 hazard, risk, and error data. We need to
14 understand where the near misses are. We can't
15 just count errors and believe that that's going
16 to be what makes us safer. We have to
17 encourage reporting and study the errors before
18 they injure a patient.

19 We have to be sophisticated in how
20 we respond. We need people with PhDs and
21 master's degrees in safety engineering.
22 Medical school and nursing school do not teach
23 you how to lead safety. You have to have the
24 extra training.

25 Encourage and expand the collection

1 of data, and the data has to be the facilitator
2 of change, not a disincentive to change. Take
3 a health system like us, that for 20 years has
4 invested heavily in safety, and we're not to
5 zero yet.

6 So, it's not as easy as just being
7 conscientious and caring. It is complex and
8 hard to do, and we need great collaboration in
9 order to do this together. Thank you.

10 MR. RAMACHANDRAN: Thank you, Terry.
11 Great comments. We're saving all the questions
12 in the Committee until the end of our
13 presentations. Next up, we are excited to
14 welcome virtually Dr. Tejal Gandhi, who is
15 Chief Safety and Transformation Officer, Press
16 Ganey Associates. Go ahead, Tejal.

17 DR. GANDHI: Thanks so much. Thank
18 you so much for having me. Can you hear me
19 okay?

20 MR. RAMACHANDRAN: We do.

21 DR. GANDHI: Okay, great. All
22 right. So, I'm going to move us -- so, first of
23 all, double down on everything Terry said. We
24 absolutely need to think about people, process,
25 technology, systems, human factors, all of

1 those things. And I'm going to go a little
2 deeper into the technology side, given our
3 discussion today, and really go into artificial
4 intelligence.

5 And on the next slide, there is my
6 brief bio as well. I'll just give you a couple
7 of highlights that are relevant, which is, I
8 started my career as a health services
9 researcher, studying how technology can improve
10 quality and safety. This was back in the day
11 of prescription pads, so we've come a long way,
12 but we really do have a lot of opportunities,
13 and since then, I've been a Safety Officer at a
14 large academic medical center, a Chief Quality
15 Officer at a large system, and then was CEO of
16 the National Patient Safety Foundation, was at
17 the Institute for Healthcare Improvement, and
18 now, I'm at Press Ganey. Next slide.

19 So, I've been thinking a lot about
20 artificial intelligence and patient safety, and
21 have a lot of background in technology and
22 safety, as I mentioned, and a lot of background
23 around really what worked and didn't work well
24 with electronic medical record adoption back 20
25 years ago or so. And I've been framing it in

1 this way: these are the questions that we
2 really need to ask about technology, and the
3 first three really relate to governance. Is
4 the technology designed to be safe? Is it
5 being implemented safely and used safely? And
6 this ties entirely to what Terry was talking
7 about in terms of human factors, work-arounds,
8 all those kinds of things, and governance
9 structures and other things can really play a
10 role in making sure organizations are
11 addressing those questions, as well as systems
12 approaches, et cetera. But what I want to
13 focus on today is that fourth question, which
14 to me is really interesting, is and can the
15 technology improve patient safety?

16 So, on the next slide, I kind of
17 walk through what to me are maybe some of the
18 lower-hanging fruits around this. And, you
19 know, an overall theme around how AI could
20 improve safety is to decrease administrative
21 burden and cognitive load. We know that human
22 beings make errors, as Terry so eloquently
23 said, and we know that when there's cognitive
24 load, they're more likely to make errors. And
25 so, there is a really great potential for AI to

1 help reduce that cognitive load, and I'll talk
2 about that in a second.

3 But then, there's specific areas in
4 safety where I think AI really has opportunity
5 as well. First of all, around diagnosis
6 errors, which is arguably the biggest type of
7 safety issue we have, and we haven't made
8 progress, as much as we'd like, in this
9 particular area. Medication reconciliation. I
10 listened to some of the previous panels, not
11 all, unfortunately. I know med reconciliation
12 came up a lot, and AI has a really big
13 opportunity to help solve that issue, which is
14 one of these issues we've been worrying about
15 for 25 years and have not necessarily figured
16 out the way to solve. I think getting
17 predictive, upstream, and proactive, is a
18 really big opportunity. There's a big
19 opportunity, as David Classen spoke about,
20 about measuring harm, and I think as well,
21 analyzing harm and really making sure that we
22 are effectively learning from the harms that
23 are occurring. So, if we're increasing the
24 number of events we're pulling in, how do we
25 effectively analyze them so that we get to

1 strong actions coming out.

2 And then the last bucket is around
3 patient engagement. I know Sue Sheridan had
4 spoken earlier. There's a lot of opportunities
5 with, you know, for patients to engage with AI,
6 but also for us to leverage AI to better engage
7 with our patients. Next slide.

8 So, I'm going to quickly go through
9 some of the background on that list. You know,
10 many of you may have seen this study. I know
11 this came up in one of the previous comments,
12 that to expect a doctor to review the chart now
13 is basically like asking them to skim
14 Fahrenheit 451 before every clinic visit, which
15 is completely unrealistic. And so, really, we
16 need to address the data overload issue, and AI
17 is going to be a way to help us do that. Next
18 slide.

19 And so, these are the ways that AI
20 can reduce cognitive burden. It can help with
21 data gathering, data synthesis, help with
22 documentation, help us take appropriate action
23 based on the data in front of us, and help us
24 with some other asynchronous activities as
25 well. And so, you know, there's really -- I

1 want to emphasize how important this is,
2 because if we can free up that cognitive load,
3 it will just help in so many other ways. Next
4 slide.

5 The proactive piece, also, I really
6 want to highlight. Too often in safety, we are
7 reactive. Somebody gets harmed, and then we
8 analyze it, and we try to figure out how to
9 prevent it from happening again. And a
10 colleague of mine at IHI used to say, we are
11 measuring who falls through the ice, not the
12 thickness of the ice. So, we need to get
13 upstream and understand where there's risk in
14 addition to where harm is occurring, and I
15 think that's a big opportunity with artificial
16 intelligence. Next slide.

17 If we look at the literature around
18 this, most of the use cases around AI actually
19 are tied to these kinds of prediction models,
20 so we can predict who might be at risk for
21 adverse drug events, for sepsis, for falls, for
22 surgical complications, for decompensation, et
23 cetera. So, I mean, I think these tools are
24 really going to help us with that shift to
25 being proactive, though I do want to really

1 emphasize, it is not going to really have
2 benefit unless we can really tie it into
3 clinical workflows and actionability. It
4 doesn't help me to tell me someone's at risk.
5 It helps me to say why they're at risk, and
6 what action do I need to take to minimize that
7 risk, and do that in my workflow. And so,
8 that's going to be a critical piece for us to
9 really optimize the use of these tools. Next
10 slide.

11 You know, getting back to the topic
12 of chart summarization, the Fahrenheit 451
13 problem. We've all seen the exponential growth
14 of ambient AI and scribes and other things to
15 help with this cognitive burden. And so, I
16 will just say that, you know, from a technology
17 standpoint, this has probably been one of the
18 fastest adopted technologies out there. And I
19 think when organizations are seeing that value,
20 they are moving quicker than we've ever seen to
21 adopt some of these tools. Next slide.

22 I also want to talk about diagnostic
23 error. I mean, certainly reducing cognitive
24 load, chart summarization, all of those things
25 actually can help with reducing diagnostic

1 error. There's also the opportunity for AI to
2 help solve some of the nitty-gritty nuts and
3 bolts issues that have been in place forever
4 that we haven't been able to solve. I think of
5 med rec as one of those, and I think of test
6 result follow-up as another one. When you have
7 an abnormal test result, are we doing the
8 appropriate follow-up? And particularly in
9 areas like radiology and pathology, this has
10 come up over and over again that results fall
11 through the cracks, diagnoses are delayed,
12 patients are harmed. And so, we're starting to
13 see some studies that really show that
14 implementation of AI to help find these test
15 results and see if follow-up has happened and
16 flag if they haven't, and tie that into
17 processes that can do the follow-up, really
18 have opportunity and measurable impact on
19 reducing errors that are occurring. Next
20 slide.

21 The other thing that these large
22 language models can do is help us with the
23 improvement work. So, this was a study that
24 showed that you can use these large language
25 models to actually find out why there was

1 missed colon cancer screenings, so then you can
2 do the improvement work to reduce that. And it
3 helps actually optimize the work of the safety
4 and quality folks to be able to use these tools
5 to help do the chart reviews and do the deep
6 dive to understand where the gaps are or why
7 the gaps are occurring, so you can then design
8 those strong actions, as I mentioned. Next
9 slide.

10 And then, I just want to comment
11 briefly on patient engagement. You know, Sue
12 mentioned patients are using AI online and
13 other things, in many other ways. I think
14 health systems really need to start leveraging
15 AI for patient engagement overall, and
16 particularly, I think a way to start is really
17 to ask patients about safety. I know Sue
18 talked about that, and Project PIVOT, and you
19 know, we've been doing work with them to try to
20 do that. But also, you can ask those specific
21 questions, but the value is going to be in the
22 comments, and understanding safety themes from
23 patient comments. And you can look at patient
24 comments, patient complaints, you can look at
25 online websites, all these other places, and

1 pull safety themes out of there with tools such
2 as AI, and make it easier to find those themes
3 and trends. Next slide.

4 We've done this with patient
5 experience comments, and you can look at a
6 million patient care experiences and find the
7 safety-related comments out of those, and
8 again, find the themes that you can learn from
9 that. And it's far better and easier than
10 having to read through all of those comments.
11 Next slide.

12 We're also really working on direct
13 patient feedback for safety. So, leveraging
14 tools that can ask patients to report safety
15 concerns and have that feed directly into event
16 reporting systems. You know, Terry talked
17 about the importance of event reporting. We
18 want event reporting from our clinicians, but
19 it would be very, I think, valuable to also get
20 event reporting from patients, because what
21 patients report is different from what
22 clinicians report. So, making that easier for
23 patients to do, and having, again, the tools to
24 help analyze that information, is going to be
25 key.

1 So, I'm very positive about the
2 value of AI. I kind of walked through very
3 quickly all the positive ways that it can help
4 patient safety, and then there's a long list of
5 what to worry about. So, here's definitely not
6 a comprehensive list, but there's certainly
7 things to worry about, design, implementation,
8 and use. As I mentioned, about like the
9 governance piece, and how we have to make sure
10 we understand how it's designed, is it being
11 implemented well, is it being used the way we
12 want, is there a drift in its performance, does
13 it have bias, et cetera? Lots of things there.
14 And, really have to understand what the impact
15 of these tools are on the human beings that are
16 using the tools. So, is it leading to
17 deskilling, where we lose key skills? Is there
18 an automation bias, where we're trusting the
19 tool too much and ignoring potentially
20 important things that are occurring outside of
21 the technology? How do we need to teach and
22 train clinicians to use these tools well? So,
23 there's a lot of questions in all of these
24 buckets of how we make sure that we are
25 mitigating risk of these tools. Next slide.

1 And then, I will just say, and
2 there's studies coming up that are reinforcing
3 this. So, AI can have cognitive bias. Next
4 slide. AI can actually have errors that if we
5 expect human beings to find the errors in the
6 AI messaging, that is very challenging. It's
7 sort of a cop-out to say well, there's always a
8 human in the loop. Human beings are not good
9 at vigilance and overseeing things that AI is
10 going to produce. So, it's a high-risk
11 strategy to say our solution is the human in
12 the loop. So, we need to understand how to do
13 that better. Next slide.

14 And, you know, even back to the
15 cognitive burden. I'm very excited about
16 ambient AI summarizing the chart, et cetera,
17 but that review of what the AI is creating can
18 create additional cognitive burden on our
19 clinicians. So, we just have to really
20 understand that this is a balance, and there's
21 definite positives, and I'm much more positive
22 than negative, but we have to understand where
23 there can be negatives and mitigate those. Next
24 slide.

25 So, this is my last slide, and

1 really, as I think about it, going forward, we
2 need to detect risk, we need to act on it, and
3 we need to close the loop on things like test
4 results, and I think we need to incentivize
5 adoption of tools that augment safety across a
6 broad range of safety process and outcome gaps,
7 and some of the low-hanging fruit, I think, is
8 in test result management, med reconciliation,
9 adverse event detection, patient-reported
10 safety concerns. We need metrics to ensure
11 safety improvement across both process and
12 outcome measures for these kinds of tools. We
13 need to really focus on this proactive,
14 upstream, risk mitigation, as opposed to always
15 just focusing on people who have fallen through
16 the ice. And, I think we need metrics to
17 evaluate the clinician experience with
18 technology, to understand the impact on
19 cognitive burden on workflow and other pieces,
20 because we know there can be these unintended
21 consequences, and really overall have those
22 balancing measures to always monitor for the
23 unintended consequences.

24 You know, we learned this with
25 electronic medical records, 25 years ago, that

1 every new technology introduces new problems.
2 We have to be aware of that and measure for it,
3 and that doesn't mean we don't implement the
4 technology, but it means we do it in a smarter
5 and safer way. So, I will wrap up there, and
6 thanks for your attention.

7 MR. RAMACHANDRAN: Thanks, Tejal.
8 Appreciate the comments there. Next, we are
9 pleased to welcome in person Ms. Melissa
10 Swanfeldt, Senior Director of Quality and
11 Regulatory Compliance at MEDITECH. Welcome,
12 Melissa.

13 MS. SWANFELDT: Thank you, and thank
14 you to the Committee for allowing me to speak
15 today. So, I represent MEDITECH. We are the
16 oldest software company and oldest EHR in the
17 nation in regards to, we've been around for
18 over 55 years. The EHR we created 55 years ago
19 is not the same EHR that we have today, and I
20 would like to really talk about what those
21 technology opportunities are for patient
22 safety.

23 So, EHR technologies have been
24 supporting patient safety in a number of ways,
25 and I think many of the speakers throughout

1 today have mentioned some of these. You know,
2 certainly clinical decision support, and CPOE⁸⁹,
3 and med reconciliation, telehealth
4 technologies, and expanding access to care
5 remotely for patients, patient engagement, and
6 patients engaging in their safety in verifying
7 records and tracking history, real-time
8 surveillance and predictive analytics embedded
9 within clinical workflow, and really leveraging
10 interoperability. And I know a few of the
11 speakers have talked a bit about that.

12 So, some of the system-level
13 contributors to patient safety, and again, have
14 been addressed by a number of the presenters.
15 Disruption in workflow, alert fatigue,
16 cognitive overload, fragmented patient
17 histories, too much data. How do you sort of
18 synthesize what's relevant for that patient?
19 Communication gaps, variabilities, labor
20 shortages, lack of patient engagement, all
21 things that contribute to patient safety. So,
22 how can technology help? And really, how we
23 look at technology as an EHR company, is to
24 really try to improve the systems around the

89 Computerized Provider Order Entry

1 care team.

2 This should be augmenting their
3 workflows, it should be embedded in what
4 they're doing every day, and not something
5 extra. It shouldn't be just about checking a
6 box or going somewhere else to get at the data.
7 It needs to be embedded in what they're doing
8 every day. And it can do things like identify
9 risk early in the care process, standardize
10 care quality and interventions that are
11 happening in the health care system, support
12 decision-making for the clinicians and the
13 patients, personalize care, improve
14 communication engagement, and reduce burden. I
15 think Tejal spoke about this, but we have a ton
16 of data in health care. Meaningful use is over
17 20 years old, as has been mentioned throughout
18 today's session. Thirty percent of the world's
19 data is generated by the health care industry,
20 and 97 percent of it goes unused, and is not
21 usable in a meaningful way. Eighty percent of
22 current health care data is unstructured.

23 So, how do we use technology to
24 improve that data life cycle? We're looking at
25 it from three perspectives. Data capture, so,

1 using tools like ambient listening, computer
2 vision, smart sensors, and wearables, to
3 capture data and make that data capture easier
4 and cleaner. Utility, making the data more
5 useful. AI machine learning is excellent at
6 pattern recognition, and how do you really look
7 at the utility of the information that you're
8 using? Clinical decision support, care
9 prioritization. How do you identify that
10 patient that needs your attention first?
11 Including actionable insights and AI-generated
12 summaries.

13 Accessibility. Allowing the data to
14 be more accessible, but making it meaningful.
15 Not giving you all of those reams of data
16 coming from continuity of care documents, and
17 allowing you to be able to decipher through
18 that data through interoperability. FHIR and
19 FHIR APIs, I think, have a ton of promise.
20 We're seeing a lot of great work with the
21 health tech ecosystem pledge, and I am excited
22 to really see that continue to grow and be
23 leveraged in the safety space. Real-time
24 availability for that data, but the right data,
25 being able to serve up the right data to the

1 clinician. Workflow integration. As Tejal
2 mentioned, that's key. It can't be something
3 extra that the nurse or the provider needs to
4 go and do. It needs to be embedded in their
5 workflow every day. And then, leveraging
6 chatbots.

7 We see every day at MEDITECH our
8 customers using tools that make care safer and
9 better in improving outcomes. I picked just a
10 small few here, and I specifically picked these
11 organizations, because they're small rural
12 health organizations, and I think there's often
13 the underheard organizations across the country
14 today that are doing some fantastic work in
15 patient safety. North Country Healthcare in
16 New Hampshire, where I reside, has put in some
17 surveillance tools to improve tracking of
18 indwelling catheters. What they've seen in
19 just a few months is zero instance of CAUTI⁹⁰
20 over an eight-month period, and that is at the
21 start of the initiative, and that's continuing
22 today. Hundred percent compliance with CAUTI
23 documentation. I know there's been lots of
24 talk today over how valuable quality measures

90 Catheter-associated urinary tract infection

1 and quality reporting are, but that's what we
2 have today, and that's what these organizations
3 are aiming to.

4 One thing I will note is, a
5 reduction, significant reduction, in
6 administrative burden for the infection control
7 department. They don't have as much work to
8 have to do in order to report on this. They've
9 taken that work from 50 hours down to less than
10 four in what they need to do to be able to
11 report on these measures. Southern Ohio
12 Medical Center in Ohio has been doing a ton of
13 work with clinical decision support in
14 decreasing unnecessary cultures. Appalachian
15 Regional, a 10-hospital organization in
16 Appalachia, mostly supporting rural health
17 organizations, have implemented a number of
18 nurse-driven protocols to look at how do they
19 manage diabetes ketoacidosis, and have reduced
20 resolution time by 25 percent. And a number of
21 different -- another example at Southern Ohio
22 Medical Center, reduction in C-diff infection.

23 So, here, just want to talk a bit
24 about where data can be better leveraged
25 through the care journey. So, again, a number

1 of speakers today have mentioned pre-visits,
2 admission intakes, or what happens, how do we
3 understand what's happening with that patient?
4 If it's the first time I'm seeing this patient,
5 how do I get a good view of this patient so
6 that I can provide the best care possible? How
7 do we use the data to better do real-time
8 monitoring of patients, regardless of care
9 setting? Identifying predictive data, where
10 this patient may be at risk. Allowing AI to
11 enable clinical decision support. Wearables.
12 Sensors, ambient listening, which was mentioned
13 already, and surveillance alerts.

14 And those surveillance alerts for
15 patients that may be at high risk need to be
16 well timed and identified so they're not
17 disruptive and not ignored. Disruptive of
18 workflow and not ignored. Care transfers. You
19 know, there's been so much research done on how
20 outcomes and safety risks are during care
21 transitions. So, how do we use technology to
22 better manage that? We have some organizations
23 using AI-generated nurse handoffs, so as a
24 patient's moving from one care setting to
25 another, they're using AI to help augment and

1 ensure that the right information is provided
2 from one care setting to another. Identifying
3 predictive scores of who is at risk when
4 they're transitioning. Outreach and follow-up
5 education. Telehealth. AI-generated messaging.
6 Remote patient monitoring. All key areas where
7 data can continue to be leveraged.

8 AI has a lot of potential if
9 implemented in the right way, having all of the
10 right players at the table when an organization
11 is going about implementing AI technologies.
12 Here are some statistics from one of our early
13 sites that has adopted AI and ambient listening
14 tools to create AI-generated course summaries.
15 And 80 percent of the users reported that there
16 was a reduction in cognitive load when they
17 were doing their discharge documentation.
18 Twenty to 30 percent reduction on documentation
19 time and administrative tasks when using an
20 ambient listening tool. And a savings of 40
21 hours per month from the quality and infection
22 internal department on having to abstract data
23 out of the chart for quality measure reporting.

24 So, when we look at technology, we
25 can really think of it as a clinician force

1 multiplier. How can it augment that care team?
2 It can help them reclaim capacity. It can
3 augment their intuition as a clinician. What
4 do I need to be paying attention to to provide
5 the best care to this patient or the patient
6 population that I'm caring for? And extending
7 their app expertise, virtual nursing,
8 telehealth, and training simulations are some
9 examples.

10 But it's important, and I think
11 Tejal spoke about this as well, is, we have to
12 establish guardrails for responsible AI use in
13 health care. There needs to be trust and
14 transparency to the users when they're using
15 it, but to the patients as well. So,
16 disclosure when AI is being used in clinical
17 care, established processes for obtaining
18 patient consent, explainability standards,
19 standardized plain language model cards, as
20 well as privacy compliance for PHI⁹¹ and PII⁹²
21 protection of the data.

22 Mitigating bias and ensuring equity.
23 A formal bias testing across diverse
24 populations is important. Prioritizing high-

91 Protected health information

92 Personally identifiable information

1 quality representative training data.
2 Democratizing access to AI. As I mentioned
3 earlier, MEDITECH, we provide EHRs to a lot of
4 small and rural health organizations across the
5 country, and they need the same tools and
6 access to the same level of functionality that
7 the large teaching organizations have, and
8 being able to provide these types of tools to
9 rural health organizations are important.

10 Human autonomy. Human in the loop
11 was mentioned, so that's important. Preserving
12 the right to override AI decisions. And AI
13 cannot replace human or clinical judgment. To
14 mitigate risk related to that is vulnerability
15 testing and secure safeguards. Life-cycle-
16 based risk assessment, so continuing to go back
17 to the models to ensure they're still working,
18 right? Models, we know, anybody who's read up
19 on AI, you can have model degradation over
20 time. It's important that you're continually
21 monitoring that AI is still working and working
22 effectively. You can also use it to be able to
23 dial in to become more effective. Use that AI
24 to be able to dial in better care protocols for
25 patients. So, we're using it to drive for this

1 particular care, and we can use it to make the
2 care smarter over time, and then ensuring
3 regulatory alignment that we want, you know,
4 risk-based approach to AI. So, you know,
5 regulatory oversight should not be the same for
6 a low-risk AI use case versus something high-
7 risk that requires medical device clearance.

8 And then, just a bit on funding and
9 regulatory considerations for safety and
10 innovation. So, we would recommend continued
11 investment in technology-driven solutions for
12 chronic care management, investment in AI in
13 EHR upgrades that support safety, again,
14 especially for those rural health
15 organizations. Governance incentives, so
16 financial incentives for organizations meeting
17 high-safety governance standards as an
18 organization. And then, regulatory
19 collaboration would really, as an EHR vendor
20 and as an EHR vendor community would like to
21 see continued cross-agency collaboration on
22 regulatory requirements-related technology
23 adoption, especially when it comes to clinical
24 decision support and AI. One size does not
25 all, and you know, want to be able to see that

1 collaboration across federal agencies.

2 For example, the FDA has regulated
3 recently, with their recent guidance that they
4 released earlier this year, is any clinical
5 decision support, whether it's AI or not,
6 that's used to manage and support clinicians in
7 identifying high-risk patients for sepsis or
8 stroke, as well as sepsis care and stroke care,
9 is considered a medical device. Most health
10 care organizations probably don't know that,
11 because that's new guidance. My job at
12 MEDITECH is to watch what's happening at the
13 FDA. Most health care organizations do not
14 have people that are looking at if we turn on
15 this rule for clinical decision support, is
16 that a medical device, and then what kind of
17 oversight is there? And, so, just really
18 taking that risk-based approach to regulation,
19 I think is important. Thank you.

20 MR. RAMACHANDRAN: That's good. Thank
21 you, Melissa. Next up, we're happy to welcome
22 back Aneesh, Chair of Arcadia Institute. Great
23 to have you back.

24 MR. CHOPRA: I know we're falling
25 behind, so I'll do my best to kind of tighten

1 it up so we can get to questions.

2 MR. RAMACHANDRAN: We're good.

3 MR. CHOPRA: I'm going to do this in
4 three parts. I'm going to share context. I'm
5 going to provide you, like a sous chef in the
6 restaurant, some raw material that you could
7 use to cook up a model, and then with some
8 humility, I want to suggest to you what a model
9 might look like to consider as you're
10 evaluating what to do next.

11 So, a little bit of personal
12 context. I had the honor and privilege of
13 serving as Chief Technology Officer for
14 President Obama in the Obama Administration. I
15 was Virginia Secretary of Technology, and then
16 in the last decade, I founded a firm that grew
17 to be one of the largest researchers on CMS
18 data, sold that to a firm called Arcadia, where
19 I serve as Chair of the Arcadia Institute,
20 operating one of the larger longitudinal data
21 platforms focused on value-based care in the
22 country.

23 A little bit of a reminder, I'm
24 going to widen the aperture a little bit. All
25 of you are familiar with *To Err is Human*, you

1 likely are familiar with, but I don't know if
2 we've heard it much today, the 2023 PCAST⁹³
3 report on patient safety. I'm going to
4 highlight that report, because it emphasizes
5 the importance of longitudinal data sharing as
6 enabling infrastructure for getting safety
7 right. It also went so far as to say that we
8 should find a mechanism to encourage patients
9 to contribute data on the patient safety
10 journey. That last piece is a little bit of
11 the root cause problem that you're hearing
12 throughout, which is that we've been taking a
13 hospital-centric approach in patient data
14 approach, and not a patient-centered
15 longitudinal approach to measuring quality and
16 safety thus far, and we don't have to do that
17 anymore. We can have nice things.

18 Obviously, it's in the news, and I
19 don't mean to cause any personal attention to
20 this, but I did want to highlight the very
21 prominent sepsis journey from NASCAR earlier.
22 Again, I'm not an expert in the clinical
23 evidence of this story, just what's in the
24 media, to highlight the point that I think is

93 President's Council of Advisors on Science and Technology

1 relevant for this patient-centered view. The
2 SEP-1⁹⁴ measure today would have missed any of
3 the two weeks prior to the event where the
4 driver had communicated, I need to see a
5 doctor, I'm having issues. None of that
6 content is in the calculation for SEP-1. It
7 starts when they're admitted to the hospital.
8 No bueno. Even the new community onset eQOM
9 starts at admission and links to whatever is in
10 the hospital's EHR, not the longitudinal
11 journey of the patient. No bueno.

12 The goal, in the spirit of what the
13 PCAST called for, is to have a safety learning
14 network that has a full trajectory of the
15 patient's story from the time there were some
16 initial symptoms, to contact with any health
17 care professional, to and for this unfortunate
18 situation admission, and then of course an
19 unfortunate outcome. We miss the patient's
20 trajectory by design. We don't have any
21 mechanism to track it. None of our regulatory
22 measures, no quality measurement, nothing.

23 The great news is, after a decade of
24 meaningful use, and I would go even further

94 Severe Sepsis and Septic Shock Management Bundle

1 with President Bush's call in 2004, we have
2 with the Trump Administration, a meaningful
3 opportunity to finish what we all started 30
4 years ago. And that is, to bring forward a
5 unified, open data model, that brings payers,
6 providers, and patients on the same platform.
7 In this case, a CMS aligned network.

8 When we hear about data sharing, we
9 hear often acronyms like TEFCA⁹⁵. That largely
10 is for physician-to-physician treatment
11 purposes today. Payer access to that is
12 voluntary, so payers don't really get a chance
13 to participate. Consumer access is a little
14 bit getting better, but not yet where it needs
15 to be. My mom suffers from what's called
16 hyper-portal-itis. She sees lots of
17 specialists, and she's got lots of portal log-
18 ins, and she doesn't remember all those
19 accounts. Thanks to the health tech ecosystem,
20 now she can access the information through
21 Claude, she's got a cool Anthropic thing, she's
22 learning a lot about her conditions. Patients,
23 providers, and payers are on the same platform.

24 This, by the way, meets the heart of

95 Trusted Exchange Framework and Common Agreement

1 the Cures Act, which is overwhelmingly
2 bipartisan and called for this notion that
3 information should be accessible to all
4 stakeholders, "without special effort."
5 There's no reason why the patient safety
6 community can't benefit from these same
7 legislative principles in the Cures Act
8 embodied by what's being done in the health
9 tech ecosystem. So, like layup, your community
10 can build an Alternative Payment Model now,
11 assuming that we're going to have better data
12 sharing.

13 So, let's get into the three areas
14 where I want to highlight. Did I go too far?
15 Sorry. Three areas that I wanted to highlight
16 as raw materials for your consideration.
17 Number one. We have to move from proprietary
18 logic, hard coded into CQL⁹⁶ calculating
19 measures, because it assumes everything in a
20 doctor's clinical EHR is perfectly documented
21 with everything in the right code. And as
22 Melissa will attest, oh, yes. We've got that
23 nailed. Everyone's got everything properly
24 documented. You've got to be kidding me. And

96 Clinical Quality Language

1 making doctors, like, literally manually label
2 every piece of data is the dumbest idea on the
3 planet. So, we are not going to do that.

4 So, what that means is, we have to
5 move away from eCQM, unfortunately. I know
6 we're committing to it, and it's like a whole
7 thing, and Michelle was here, and CMS is all
8 over this, but it is the wrong technical
9 architecture. It is unfortunately proprietary
10 logic, transmitting very specific if/then CQL,
11 assuming beautifully documented information in
12 the EHR to reduce a response. Else, it breaks,
13 and we have to do a workaround. And we've seen
14 this in the Medicare ACO program. Poor
15 Michelle's heard me complain about this going
16 on five years, where even something as simple
17 as blood pressure reporting is only 60 percent
18 accurate, because when an externally sourced
19 blood pressure enters the EHR, it's like a
20 static PDF on the side. That sucks.

21 We're moving to digital quality
22 measures. Ish. We still need some help. But
23 the premise is, you move away -- one half of
24 the problem is, you move away from the hard
25 coded EHR to something that's a bit more

1 permissive, of an organization, an Accountable
2 Care Organization, to aggregate the information
3 and have all of that removed from the
4 physician's work and into the entity that is
5 accountable for the results. It could be a
6 payer, it could be an ACO, and that entity is
7 responsible for organizing the information such
8 that it can fire off this same problem of the
9 hard coded CQL logic.

10 I hope with AI we are moving to a
11 third generation. There is a new initiative
12 called COIN. Conversational Inter Op. It is,
13 I believe, the next generation of Cures Act
14 standard, post-FHIR. It allows for AI agents
15 to reason. So, say a bunch of clinicians wrote
16 a Word document that explained what it is they
17 were trying to do, rather than having software
18 developers hard code if/then logic into CQL. It
19 allows for a more reasoning approach to say
20 show me the evidence of the case against what
21 we're trying to find to see whether there's
22 been a match. And so, that reasoning to
23 reasoning layer moves us from raw data sharing,
24 where everything has to be tagged, to more
25 widely understood logic sharing. Here's what

1 I'm trying to get at, can you make the best
2 case, and let's figure that out together.

3 There is a wonderful team at UC San
4 Diego, the AI team called that notes are all
5 you need. So, instead of manually doing a
6 bunch of documentation headache for the
7 doctors, they used AI reasoning agents to do
8 SEP-1 reporting, basically, and they were able
9 to extract all the necessary information and
10 transmit it over to CMS for Star ratings,
11 without it annoying doctors for having to
12 micromanage the documentation. Okay, I'm being
13 a little bit hyperbolic for the sake of fun.
14 It's the afternoon, we've got to keep moving.
15 Okay.

16 Now, here's the flywheel that we're
17 finding ourselves in, and it's the most
18 important part of the health tech ecosystem.
19 We've had a supply side regulatory framework
20 for the last decade or so. Poor Melissa is
21 subject to ONC certification rules. She is the
22 supplier of the EHR. People are telling her
23 what she has to do to build the features and
24 functions, but they don't necessarily reflect
25 the full needs of the safety community, patient

1 community, payer community, take your pick,
2 clinical trials. Everyone who wants to use the
3 data downstream is invisible when a supply side
4 is sort of saying here's what you get, and you
5 get what you get, and you don't get upset.

6 We have the opportunity to move
7 towards a more use case-driven model, and
8 that's what CMS has done with the health tech
9 ecosystem. Organizations are pledging to be
10 early adopters. Early adopters test new
11 technical approaches to problems. Once there's
12 evidence of industry adoption, ONC and CMS can
13 standardize and scale what works through
14 existing authorities. U.S. policy on standards
15 requires evidence of industry adoption to name
16 them in regulation. It is the hard part of
17 getting evidence of industry adoption. AKA, if
18 only half a dozen organizations embrace a
19 better patient safety strategy, this body can
20 initiate the testing of that approach, and the
21 policymakers can scale without a change in
22 federal law. Not easy, but it requires us to
23 motivate those early adopters, which can be
24 done by voluntary means, like health tech
25 ecosystem, or a new Alternative Payment Model.

1 What are the three technical
2 abilities that -- Abe was here earlier today.
3 I hope he mentioned some of these. CMMI has
4 done a great job moving beyond just narrow risk
5 payment model structures to more tech
6 enablement capabilities. You may have heard
7 about the WISeR Model. By the way, as you
8 know, in January, Anthropic open sourced an AI
9 agent skill on all of CMS' published NCDs⁹⁷ and
10 LCDs⁹⁸. For free. All of us can have it. We
11 can have nice things. And this was released as
12 part of a commitment to the health tech
13 ecosystem.

14 So, WISeR takes those CMS criteria,
15 already proven coverage criteria, and just asks
16 physicians to say, generate the evidence that
17 you've met criteria. I know it's a political
18 fight, football, and Congress is all mad about
19 it, but at the end of the day, it's a technical
20 matter. It moves us away from the hard coded
21 CQL to a reasoning layer. Access, of course,
22 is going to bring a new capability, with
23 outcomes aligned payments. Another potential
24 area to bring tech-infused organizations to get

97 National Coverage Determinations

98 Local Coverage Determinations

1 to an outcome, like a better safety culture. I
2 trust Terry's words on all of this. The guy's
3 a legend. And then, CARA⁹⁹, where we're getting
4 CMS itself shipping software. That would allow
5 us to do something more, like programmatically
6 design how a specialist should get paid in the
7 context of a primary care practice, where we
8 could incorporate more of these patient safety
9 attributes in the payment model.

10 So, what's the ask? Here's the ask.
11 During my tenure, I had the pleasure of
12 releasing a CMMI program called the Healthcare
13 Innovation Challenge or the Healthcare
14 Innovation Awards. It was a big open
15 competition for any idea from the bottom up.
16 And while there were lots of -- like, anything.
17 Apples, pears, bananas, and grapes. Hundreds
18 of ideas were funded. Not all of them were the
19 greatest on the planet, but there were several
20 really hidden gems, and I wanted to highlight
21 one called the High Value Health Collaborative,
22 awarded to another godfather, Jim Weinstein at
23 Dartmouth. CEO of Dartmouth at the time. He
24 recruited the Cleveland Clinic, Providence,

99 CMS Administered Risk Arrangements

1 Intermountain and others, and said hey, let's
2 pool our EHR data, CMS contributed longitudinal
3 claims history, and the combined dataset could
4 be used to generate evidence. And they found a
5 better protocol for sepsis, and it had far
6 better results. They also looked at areas like
7 low back pain and avoiding surgery, so they
8 saved money on that front.

9 So, there is a construct here, an
10 idea for you to consider in the spirit of
11 access, to fund what I'm jokingly, referring to
12 as Star Alliances for safety. Remember the
13 Star Alliance has competitors who are
14 collaborators? So, put a MedStar together with
15 UC San Francisco, UCFS, and other rock stars,
16 and let them form a collaborative where they
17 pool their EHR data, we contribute payer data,
18 we get a longitudinal signal, patients can
19 contribute, back to the PCAST recommendation,
20 and we generate new evidence of what safety
21 looks like, and then disseminate that through
22 the clinical decision support standards that
23 Melissa has to already implement. And we've
24 got a flywheel that allows us to learn and
25 improve. And if there are savings measurable

1 along the way, you can either pour those
2 savings back into those organizations, or find
3 a way to flywheel more evidence generation as
4 more of an open platform.

5 Borrowing from the health tech
6 ecosystem, we can start with all risk-bearing
7 networks. ACOs are highly aligned to address
8 patient safety. Start with MSSP, REACH, LEAD,
9 et cetera. Bring the CMS FHIR API
10 infrastructure, the BCDA¹⁰⁰, which allows for
11 daily pre-adjudicated claims information, move
12 away from hard-coded, sorry Michelle, BCQM¹⁰¹
13 kind of hard code to more open COIN models, and
14 then use the pledge construct to get these Star
15 Alliance folks to collaborate, such that we can
16 learn, and then the regulators can scale what
17 works. Thank you. Let's have a good
18 discussion.

19 MR. RAMACHANDRAN: Thank you,
20 Aneesh. And thank you to all of our experts
21 for excellent conversations there. We'll open
22 the discussion now to our Committee members.
23 This time, PTAC members, flip your name card
24 up, or for our virtual Committee members,

100 Beneficiary Claims Data API

101 Beyond Care Quality Monitor

1 please raise your hand on Zoom. Do we have any
2 questions for our guests? Additionally, as
3 we've said before, we want to encourage our
4 experts to ask each of their follow-up
5 questions as well, and you can signal if you
6 have a question by flipping your name card up
7 as well, or raising your hand if you're on
8 Zoom. SO, in the interest of ensuring balance
9 across different perspectives and questions, we
10 encourage our experts to keep responses to just
11 a few minutes. So, with that, I will look for
12 some hands and name cards. I see Chinni, you
13 want to kick us off?

14 CO-CHAIR PULLURU: Yeah. One of the
15 things -- I was fascinated by the concepts that
16 Terry brought up in safety engineering. And I
17 had spent some time at Walmart during COVID, so
18 we did a lot of that. But, what I'd love to
19 understand from you is, what you've done in an
20 isolated system, how can that be scaled? And
21 how can that be incentivized? Because there's
22 tactical operations in what you've done, right?
23 And it leads to what Melissa and Aneesh and
24 everyone else and Tejal and all of them
25 function in a layer. But your layer is very

1 tactical. And so, how do you envision scaling
2 that across the country?

3 DR. FAIRBANKS: Thanks for the
4 question. I think one thing has already been
5 done, and that is the patient safety structural
6 measures, which, I think Dr. Schreiber is still
7 here, that Dr. Schreiber and Patients for
8 Patient Safety U.S. really helped influence.
9 Incentivize or encourage other hospital systems
10 to do things that have served foundational for
11 us. For example, making sure that every single
12 time a patient is harmed from a medical event,
13 an adverse event, that the board is fully aware
14 of the deep details of that to create a
15 learning environment, so that basic structure
16 of leadership, accountability from the very
17 top, is the first piece.

18 The second piece is, what we haven't
19 done is, we haven't put a human factor safety
20 engineer in every environment that has learning
21 to do. What we've done instead is, we've
22 infused the concepts in the learning by
23 creating an infrastructure that encourages
24 proactive safety management. First of all, we
25 do reactive really well, and we prescribe how

1 to do reactive. All those things I said. When
2 something appears to be an unanticipated
3 outcome or occurrence, whether or not we know
4 yet there was an error, we require four things.
5 Care for the caregiver, early family
6 communication and honest communication with the
7 family, early reporting, and early learning
8 from a systems view. And that is something
9 that is disseminated to every single
10 leadership. It's expected of our leaders.

11 But the other important piece that
12 I'll end with is, we have a model where we
13 encourage people to be proactive. We have
14 three stages. Two of proactive and one of
15 reactive, that I just described. The first
16 proactive stage is, we expect all of our
17 leaders to integrate safety thinking into
18 everything new that they do, whether it's a new
19 process, a new implementation of an EHR or a
20 medical device, or anything new, they have to
21 look at it from a safety lens, and if it's high
22 risk, it has to have a proactive risk
23 assessment done.

24 The second piece, which there's been
25 a lot of discussion about today, is

1 understanding where our existing risks are, and
2 mitigating that. The way this can be scaled is
3 making sure that all leaders understand that's
4 what they're responsible for. It's not the
5 safety person at the hospital that should be
6 doing that. It's every single operational
7 leader that needs to be responsible for
8 proactive safety management in their own
9 environment.

10 CO-CHAIR PULLURU: Do the rest of
11 the Committee members, or do the rest of the
12 panel have any input into that? Would love to
13 hear your thoughts on scaling.

14 MR. CHOPRA: Can we just ask Terry,
15 does Maryland reimburse you better because of
16 the investments you've made on proactive and
17 reactive? Or is that embedded within, you've
18 found an operational way to do that expense
19 covered by savings elsewhere?

20 DR. FAIRBANKS: That's a really good
21 question, and I think it's why this Committee
22 is so important. Maryland reimbursement, like
23 CMS reimbursement, is based on quality metrics,
24 which are different than safety. So, the
25 Maryland reimbursement is because we do well in

1 our quality metrics, but that's very different
2 from injuring payments from adverse events.

3 Now, it's important to say that when
4 we as a health system in this country injure a
5 lot of patients from the same thing, Dr.
6 Classen talked about this, having trigger
7 tools. So, example might be VTE or blood clots
8 in the hospital setting, or HAPI¹⁰² skin ulcers
9 from not turning the patient enough or other
10 factors, then that becomes a quality metric
11 that we all need to get really, really good at.
12 But that's different than when human error or
13 device design or use error or implementation,
14 what we're here to talk about today,
15 implementation of health IT or AI in a way that
16 doesn't reduce or mitigate errors, but it
17 sometime may facilitate errors, is something
18 that's not counted by any of these metrics.
19 And that's the problem. It's the hidden,
20 uncounted issue.

21 DR. GANDHI: And I was going to just
22 add to what Terry said. I think that
23 organizations that have done what MedStar has
24 done have been led by leaders who really are

102 Hospital-acquired pressure injury

1 committed to this, despite the fact that it's
2 hard to do an ROI¹⁰³, but we need to move to a
3 world where it's really everybody doing it, and
4 it has been challenging, given the ROI piece.
5 I think the other piece, which Terry alluded
6 to, is safety has to be everybody's job, but we
7 do not train everybody on those safety
8 principles that Terry mentioned are different
9 from quality. So, you know, to expect
10 everybody to be doing this kind of safety and
11 systems work without those competencies is a
12 real problem, and those competencies have to be
13 across the board through an organization. And
14 so, I think the CMS structural measure starts
15 to get at this, but there needs to be a
16 fundamental change in how we are, you know,
17 training people, having them understand safety
18 science, et cetera.

19 And just to say one more thing about
20 that, I can't tell you how many times we want
21 to do, we're encouraging organizations to do
22 the disclosure, communication, and resolution
23 programs like Terry described to mitigate the
24 impacts of an adverse event, be transparent, et

103 Return on investment

1 cetera, and there's pushback because
2 organizations will say well, our risk and legal
3 folks won't let us do that. So, I mean,
4 there's huge barriers to doing the right thing,
5 which we have to get past.

6 DR. FAIRBANKS: If I can follow
7 Tejal's comment on, I think it's important you
8 brought up the liability piece. One thing
9 that's really important that we have shown,
10 there's not a financial incentive to doing
11 this, but we have definitely shown, as other
12 health systems over the years have shown, that
13 we are not financial punished by being honest
14 with patients and telling them when errors and
15 adverse events have occurred. So, that is an
16 important thing that is really, I think, a
17 fallacy out there, that in hospitals that still
18 have the deny and defend approach, they believe
19 that they'll be better that way. And I don't
20 think we've shown that to be the case.

21 MR. RAMACHANDRAN: Great
22 perspective. Larry, I see you have a question?

23 DR. KOSINKI: Yes. Something Tejal
24 said has been sticking with me, and that is
25 that she had a bullet on the provider

1 experience. And all day today we're talking
2 about errors and implying that we can make
3 better providers. The EHR should be a tool for
4 just that, and I'm old enough to remember the
5 early days of EHRs, where many of us were using
6 home-grown or customized EHRs, and we built CDS
7 tools that were in the process of care that
8 helped us physicians practice. And although we
9 all embraced meaningful use when it came out,
10 but what meaningful use has produced are
11 unwieldy EHRs that are designed to conform to
12 outside guidelines, and a lot of the internal
13 customization that we used to be able to do
14 before fairly easily, we cannot do today
15 anymore.

16 And so, I would like to ask Tejal
17 and whoever else wants to speak on this, how
18 can we make these EHRs minimize errors by
19 providing our providers with better tools,
20 especially in an environment where we have a
21 very heterogenous group of providers today? If
22 you go to a functional medicine meeting, the
23 MDs and DOs are in a minority, but they're all
24 providers. So, how do we minimize the
25 variation by improving the EHRs

1 customizability?

2 DR. GANDHI: I'll start, and I'm
3 sure Melissa has more that she would want to
4 add to this. I mean, I do think that we have to
5 design our EHRs to be user-centered. And
6 unfortunately, you know, 20 years ago or more
7 recently, they haven't been very user-centered,
8 and we've created a lot of extra work and
9 burden for folks. Now, on the other hand, I do
10 think that there is a balance in the sense that
11 I don't think we should be over customizing
12 either, because a lot of times we've seen
13 people are customizing everything and maybe to
14 the detriment of safety, because they're kind
15 of doing it 20 different ways when you really
16 should be doing it two different ways. So, I
17 do think there's a balance, but the fact that
18 we didn't start with a very user-centered
19 approach I think really burned us, and as we go
20 forward -- you know, that's what I was talking
21 about with these predictive models and other
22 things, like we can't just bombard with more
23 alerts and more this and that. It has to be in
24 the workflow. And so, I think, you know, I
25 think the EHR vendors understand that, but it's

1 still, I think, an evolving practice of really
2 making that the way everything is designed
3 today. But again, Melissa is at an EHR
4 company, so I don't want to step on her toes in
5 answering this.

6 MS. SWANFELDT: So, user-centered
7 design, extremely important. One of the things
8 that we do is we bring clinicians into our
9 development process so that they can be at the
10 table with our product developers to design
11 systems that really match their workflow and is
12 complementary to what they're doing, and not,
13 again, something extra. I think when EMRs
14 really got a bad rap during just after the
15 meaningful use error, where there was a lot of
16 information for things like clinical quality
17 measures, that were abstracted by somebody in
18 the back office for years, that they would read
19 through the chart and pull that information
20 out. That certainly wasn't an ideal situation,
21 but we took that process, that back-end
22 process, and we put it really on our clinicians
23 to have to capture data in a specific way
24 that's mapped to a specific ICD¹⁰⁴ code or

104 International Classification of Disease

1 SNOMED¹⁰⁵ code, or whatever it might be. And
2 then, that just made EMRs unwieldy over time.

3 And I think what we're, really, have
4 tried to do with new technologies and
5 surveillance tools is to, and being able to do,
6 like, automated data mapping to standards is to
7 take all of that away from that administrative
8 stuff and noise away from the clinician and try
9 to do some of that on the back end with
10 technology, versus having sort of an abstractor
11 that's sitting in a room to do that. But that
12 user-centered design is imperative to the
13 process, and that includes having everybody at
14 the table, right? If it's the EHR working with
15 the health system and the medical device that
16 it's interacting with, that's important to
17 ensure that everybody has a seat at the table
18 to make it the best engineered, safest system.
19 And then we need to continue to measure that to
20 ensure it doesn't need over time, you know,
21 that it goes through an early adopter or pilot
22 process to make that stronger.

23 DR. KOSINSKI: If I could follow up
24 on one point, we heard a wonderful example of

105 Systematized Nomenclature of Medicine

1 what happens when competitive health systems
2 come together to form a common project. When
3 are we going to see the EHR vendors come
4 together to break down this disparity that
5 we're dealing with?

6 MS. SWANFELDT: Well, I will say,
7 the EHR vendors do work together often. I am a
8 member of the Electronic Health Records
9 Association, which is an industry trade group
10 of all EHR vendors, all the large EHR vendors,
11 and small EHR vendors across the nation, work
12 together. You know, I'm at meetings with them
13 sometimes multiple times a week to specifically
14 look at that. How can we as a larger part of
15 the health care ecosystem work together to try
16 to influence policy, to try to engineer better
17 tools?

18 That's important, and then as Aneesh
19 mentioned, the health tech ecosystem. Many of
20 the EHR vendors are involved with that. That's
21 really trying to take technology to a different
22 level in regards to interoperability and making
23 that data more usable. And that should be
24 regardless of the vendor EHR that you're using.
25 So, I do think there have been a lot of strides

1 there. Is it perfect? No. Is there more work
2 we can all do together? Absolutely.

3 MR. CHOPRA: Just to briefly, Dr.
4 Kosinski, just to maybe put a finer point on
5 it, I don't really want the EHR vendors to
6 collaborate on this absent a demand signal from
7 the health systems who pay for their products.
8 When President Biden launched the cancer
9 moonshot, I helped voluntarily get MEDITECH and
10 Epic and others to voluntarily agree to map
11 cancer data, which is not in the USCDI¹⁰⁶.
12 Cancer stage is not standardized. To
13 voluntarily make that information available,
14 the EHR vendors largely collaborated and did
15 that, but to my knowledge, none of the health
16 systems actually adopted it.

17 So, part of the root cause problem
18 here is, if this body finds that there's some
19 capabilities that are needed, like we want to
20 reward people that use evidence-based medicine,
21 and maybe even generate the evidence, back to
22 the collaboration argument, if what you were
23 describing was that you're introducing
24 protocols that you no longer can "customize,"

106 United States Core Data for Interoperability

1 in air quotes, because the protocols are now
2 deferred to whatever the vendor ships out of
3 the box, that's a disaster. We absolutely need
4 you to be able to write your own protocols in
5 the CDS Hooks standard, which is just coming to
6 market in the next X months. I think 1/1/28,
7 or maybe 27. Anyway, it's coming.

8 That capability should give you the
9 ability to publish your own evidence
10 guidelines. And if this body created an
11 incentive program for health systems to both
12 publish, contribute guidelines, and then
13 consume and use and attest that they were
14 adopted, that would be a big demand signal to
15 the EHR vendors to collaborate and make that --
16 again, if you did it as a Star Alliance, we get
17 their early adopters, and then ONC could force
18 the EHRs who don't want to collaborate to do it
19 anyway in the future on this certification.

20 MR. RAMACHANDRAN: Great, thank you.
21 Chinni, you want to take the last question?

22 CO-CHAIR PULLURU: Yeah. This
23 question is for Aneesh and whoever else wants
24 to contribute. Aneesh, I love the Star
25 Alliance concept. I think it's awesome. How

1 would you think about, besides just a project
2 that's out there, how would you think about
3 funding it on a large scale? What chassis
4 would you use?

5 MR. CHOPRA: So, this is where CMMI
6 has a great deal of authority to do this today
7 without a change in statute. The High Value
8 Health Collaborative is a \$30 million one-time
9 grant for five years. Back in 2000 and
10 whatever. 12. So, if there was a call to fund
11 these models, these, call them six to eight,
12 then Terry would sign up, I hope. God bless
13 you. And we would have a bunch of health
14 systems collaborate and compete and ask for
15 that one-time funding.

16 Now, the ongoing savings could come
17 from improvements in actual incentive payments.
18 Your role is to recommend APMs. So, Chinni,
19 look at WISeR. WISeR said here's the evidence
20 from the CMS coverage programs. Deliver that
21 evidence to the point of care and get people in
22 traditional Medicare to adopt coverage in the
23 right way. Six organizations are picked to do
24 it in six states. So, there's already
25 precedent for doing a tech project within the

1 guise of CMMI.

2 Then, look at ELEVATE¹⁰⁷. I think
3 many of us are big believers in the MAHA¹⁰⁸
4 prevention -- like, it's kind of a dream for
5 many people, right? It's just not in the
6 traditional system. MAHA ELEVATE is seeding
7 small dollars, \$3 million here and there, to
8 generate evidence about what works. So,
9 between a \$30 million one-time grant to High
10 Value Health Collaborative, or a \$3 million
11 sprinkling it across the industry, and the
12 WISer analogy of picking six to go live in six
13 states, we have enough sous chef material.

14 So, you're not inventing a new
15 recommendation amongst your team. You're
16 basically saying safety is as important as
17 coverage, right? Coverage policy. Right now,
18 with the evidence for safety, what works is
19 like, eh, we need more Terrys to publish more
20 evidence, and then we have this human factors
21 thing, and it goes. And then, Melissa's job
22 would be attest that on this admission, that
23 this clinician evaluated the case against the

107 Enhancing Lifestyle and Evaluating Value-based Approaches
Through Evidence

108 Make America Healthy Again

1 evidence and attests that they met the
2 criteria. We can do that in our sleep. That's
3 the basic of CDS Hooks. No big engineering
4 problem. So, we can MacGyver our way to
5 prioritizing safety with existing authorities,
6 with modest funding from CMMI, and basically a
7 sustaining model that you have to study over
8 the next five years to say is there a better
9 quality not safety, Terry said it best, that we
10 can design, that does a flywheel to fund the
11 ongoing generation of evidence and monitoring
12 its use?

13 It's very achievable, and I'm
14 excited that this meeting, today, on the
15 shoulders of a successful health tech
16 ecosystem, means that you can do this. If it
17 was a year ago, or two years ago, you're sort
18 of making it up and dreaming and hoping, and
19 it's such a big lift, and how are we going to
20 get there? And the meeting, that was very
21 nice, nice people, but I don't know if we can
22 do anything. I'm telling you, you can do all
23 of this now with your authorities, without any
24 change in law.

25 MR. RAMACHANDRAN: That's a great

1 point. Phase three of the health tech
2 ecosystem. From prior auth to patient safety.

3 MR. CHOPRA: Why not?

4 MR. RAMACHANDRAN: Yeah. I like it.
5 Other thoughts, questions, from the panelists?
6 Or thoughts on Chinni's questions?

7 MR. GEPPERT: I just want to follow
8 up on the question, which, I also love the Star
9 Alliance concept, and I'm glad we picked up on
10 it. And I'll suggest kind of an addition to
11 that, and I'm about to use an aviation analogy,
12 so I just want to level the playing field,
13 because people always say we're different in
14 health care. Yes, we're very different in
15 health care, but basic safety engineering
16 concepts that have worked in other industries
17 do work in health care. We just have to adopt
18 them.

19 But in aviation, the NTSB¹⁰⁹ studies
20 and finds the risks and hazards, but then they
21 don't solve them. The NTSB then hands those
22 risks and hazards off to the CAST, the
23 Commercial Aviation Safety Team, that has
24 everyone at the table. Every airline, every

109 National Transportation Safety Board

1 big manufacturer. So, Boeing and Airbus are
2 there, American and United are there, the
3 pilots' union is there, the flight attendants'
4 union is there, the people that build Avionics
5 are there, the ATC¹¹⁰. Everyone involved in the
6 complex system is there, and they solve the
7 problem together. So, when we think of not
8 competing on safety, it's not just the health
9 systems -- and health systems don't compete on
10 safety. Our close competitors in this region,
11 Hopkins and University of Maryland, we don't
12 compete on safety. The Chief Quality and
13 Safety Officers and I talk a lot on those
14 systems, and we work together.

15 But all of those groups need to be
16 together at the table, not competing on safety,
17 in order to really get us to the next level in
18 a meaningful way. I don't know how this
19 Committee manages that, but I still thought it
20 was an important addition to the Star Alliance
21 concept.

22 DR. GANDHI: And I would add to that
23 as well, sorry. I agree, like, when you put
24 the data together, we can start identifying

110 Air traffic control

1 best practices more readily and all of the
2 things, but the implementation of those best
3 practices is where we often really fall down.
4 And I just don't want to lose sight of the --
5 this is going to take people, process, and
6 technology. And we can build a system. The
7 systems are really important, the technology is
8 really important, but as Terry started with,
9 when we did the National Action Plan for
10 Patient Safety, which really informed the CMS
11 patient safety structural measure, we talked
12 about the importance of leadership and
13 governance. And you know, I wish that we could
14 sort of not worry about that and just move into
15 just implementing stuff, but I just don't want
16 to undersell that that is really critical.
17 Because we have been trying to do patient
18 safety work for the last 30 years. It's been a
19 boulder we've been pushing up the hill.
20 Progress has been slow. And I think technology
21 will help, but we can't ignore that people and
22 process thing, and all the humans that are in
23 the system interacting with those processes and
24 technology.

25 MR. RAMACHANDRAN: Great points.

1 Well, thank you all. Fantastic discussion.
2 So, appreciate your time, appreciate the
3 insights there as well. Yeah. So, at this
4 time we'll have a 10-minute break, and the
5 Committee will come back to reflect on the day,
6 discussion potential comments and
7 recommendations for the report to the
8 Secretary. So, with that.

9 (Whereupon, the above-entitled
10 matter went off the record at 4:25 p.m. and
11 resumed at 4:38 p.m.)

12 * **Committee Discussion**

13 CO-CHAIR MILLS: Welcome back, I'm
14 Dr. Lee Mills, one of the Co-Chairs of PTAC.
15 As you may know, PTAC will be issuing a report
16 to the Secretary of HHS that will describe our
17 key findings from this public meeting on
18 targeting improvements in patient safety
19 through Alternative Payment Models.

20 We now have time for some -- the
21 Committee to reflect on what we've heard in
22 today's sessions and from the PCDT. We'll hear
23 more from other experts tomorrow in an
24 additional session, but we want to take time to
25 gather our thoughts before adjourning for the

1 day.

2 So, Committee members, please refer
3 to the potential topics for deliberation
4 document and your notes. To indicate a
5 comment, of course, please flip up your name
6 card. And for Larry online, I'm watching you,
7 so I'll know when you have a comment. And
8 let's try to cover the room thoroughly and get
9 comments out for our staff. So, who's first?
10 All right, Krishna.

11 MR. RAMACHANDRAN: I thought it was
12 a great day. It was just fantastic to hear the
13 perspectives and many sort of connected
14 thoughts as well. Like each speaker first
15 brought their own world views and perspectives,
16 but there was a thread that sort of kept coming
17 through, which I appreciated.

18 One, it was helpful, I think
19 Aneesh's example towards the end of modeling it
20 like the health tech ecosystem I think was a
21 great takeaway for us there. How do we sort of
22 leverage patient safety within the constructs
23 of other collaborations, recent collaborations,
24 recent in mind? I liked Susannah's point
25 around using the waivers to sort of even create

1 a model of the structure.

2 Loved some of the comments that came
3 about, about using AI, responsible AI, in order
4 to, you know, further the patient safety.
5 Whether it's to increase the reporting, as well
6 as to help the follow-up, I thought, you know,
7 some of these model features could incorporate
8 that.

9 And, then, some of the bright spots
10 that stood out, particularly Dr. David
11 Classen's work on the evolution of the trigger
12 tool to automate it, I think are good learnings
13 that we can even incorporate into these models
14 as well.

15 So, anyway, I thought that was the
16 connective tissue for me. A lot of good ideas
17 for us to formulate into a model that Abe and
18 team can incorporate with the folks in Patient
19 Safety.

20 CO-CHAIR MILLS: Thank you, Krishna.
21 David?

22 MR. TYSON: Yeah, I think one of the
23 things that I sort of picked up on was this
24 sort of, let's call it the to-model-or-not-to-
25 model tension today. I think we heard from

1 some folks that came down on the side of, we
2 sure need to adopt a safety in all policies
3 mentality, and sort of bake in patient safety
4 in all of these models in some form or fashion.

5 And, then, I think in the last
6 session we got more of a, no, patient safety is
7 distinct and should not be sort of lumped in
8 with quality, but be treated as something sort
9 of entirely separate, and worthy of its own
10 study and measurement.

11 And, so, I think for us as a group
12 in terms of making recommendations, I think
13 navigating that tension is going to be one of
14 the key challenges coming away from this of, do
15 we want to bake in additional patient safety
16 metrics and sort of approaches throughout a
17 litany of CMS programs, or do we want to
18 recommend that there needs to be a patient
19 safety model that comes out of this?

20 CO-CHAIR MILLS: Walter.

21 DR. LIN: Yeah, I agree. This was a
22 great day, a lot of substantive and informative
23 presentations and discussions. It really
24 reinforced to me that patient safety needs to
25 be embedded into APMs as a core objective or,

1 as David just said, maybe, perhaps be the
2 primary focus of a model. Although, I'm not
3 quite sure as to how that might work. But,
4 regardless though, I'm convinced even more so
5 that patient safety should not be treated as a
6 secondary afterthought in value-based care
7 models.

8 We heard repeatedly that safety is
9 broader than avoiding obvious adverse events,
10 but it also includes errors of omission,
11 diagnostic errors, communication failures, and
12 unsafe transitions of care across settings. A
13 lot of these things we've talked about before
14 in prior PTAC meetings.

15 Although, thinking about all the
16 unintentional harm inflicted upon vulnerable
17 patients by well-meaning clinicians can be
18 downright depressing. We heard many important
19 potential solutions and frameworks from our
20 SMEs that give me optimism.

21 Examples include Sue Sheridan's
22 reminder that patients and families often see
23 safety risks the system can miss, and that
24 PROMs and PREMs can serve as important safety
25 signals to providers. To Jason Mitchell's

1 description of Geisinger's work to become a
2 higher liability organization that enables them
3 to provide a warranty for heart surgeries. To
4 Tejal Gandhi's presentation on how AI has real
5 promise to improve safety by decreasing
6 cognitive burden, identify risk earlier, and
7 make safety problems more visible before they
8 become harm events by measuring the thickness
9 of the ice before the patient falls through it.

10 From a payment model perspective, my
11 big takeaway is that value-based care broadly
12 and the advanced payment models specifically
13 have a unique opportunity to make these risks
14 visible and actionable.

15 At the same time, I think one of the
16 most important cautions we heard today from
17 Patrick Romano is that payment models by
18 themselves do not have a strong track record of
19 improving patient safety, but rather this
20 depends on, heavily -- often depends heavily on
21 professionalism, continuous quality
22 improvement, a culture of safety, and a true
23 learning organization.

24 Several speakers also emphasized
25 that a strong safety culture depends on

1 transparency, psychological safety, encouraging
2 clinicians and organizations to report harm
3 events, near misses, unsafe conditions without
4 fear of blame.

5 So, I think -- kind of, as I think
6 about tomorrow and our discussion on payment
7 mechanisms, a key question is not simply how to
8 attach financial consequences to patient
9 safety, but how to design payment models that
10 reinforce, rather than undermine, the intrinsic
11 motivations and safety culture we need.

12 Approaches like no savings without
13 safety or shared savings withholds and earn-
14 backs may have promise, but I think in light of
15 some of the discussions we had this afternoon,
16 they need to be designed carefully so they
17 reward robust reporting, learning, corrective
18 action, and measurable improvement, and align
19 with what matters most to patients, families,
20 and purchasers without encouraging
21 underreporting, risk avoidance, or stinting on
22 care.

23 CO-CHAIR MILLS: Outstanding, thank
24 you, Walter. Lindsay?

25 DR. BOTSFORD: Yeah, good comments

1 by my peers already. I think -- one reflection
2 I've had in thinking through this is, we often
3 talk about, in payment models, how the total
4 cost of care is the gold standard or looking at
5 outcomes and not just process measures, but
6 some of what I heard today actually reflects
7 that maybe it's the process measures and
8 systems that are more important than the
9 outcomes, to drive that culture, ultimately, as
10 opposed to just penalizing for bad outcomes.

11 Another comment that struck me was
12 along the line of, you know, putting too much
13 money on the line can sometimes incentivize the
14 wrong things and encourage gaming. And as we
15 would think about how some of this fits in
16 payment models, I worry some of the same things
17 could come true when it's thought of as a
18 payment model as opposed to a different
19 approach.

20 So, inherently linking payment to
21 it, or a payment model that might try to
22 demonstrate it, might inherently subvert the
23 objectives we're trying to solve for. I think
24 -- I was also struck by the comment just
25 around, you know, payment models haven't done a

1 great job in the past, so we need to be
2 thoughtful of it. Yet in every presentation,
3 it is clear that funding or payment is needed.

4 I don't know if it's a payment model
5 or if it's a different type of investment in
6 tools and systems that support that culture of
7 safety. The things like the AI EHR investment
8 and human factors designs that could move the
9 needle more than payment models.

10 CO-CHAIR MILLS: Thank you, Lindsay.
11 Larry?

12 DR. KOSINSKI: Well, I've got my top
13 10 just like everybody else, I think, but, you
14 know, I don't want to be replicative of what
15 everybody said about structural measures and,
16 you know, we heard errors of omission, and we
17 actually said it in Chinni's presentation, are
18 probably more significant than those of
19 commission.

20 Heard clearly that we need to move
21 out of the hospital environment and the
22 ambulatory environment, so that we can get more
23 of a longitudinal view. We also heard that
24 this is going to be difficult to build
25 statistics from since the numbers fall very

1 rapidly, but the longitudinal care is really
2 what's going to be important.

3 An interesting comment from one of
4 the presenters was that the results of --
5 without a longitudinal, we're not going to find
6 some of these errors, because the results of
7 errors sometimes don't show up until quite a
8 bit later.

9 I like the comments around the fact
10 that we need to address the provider
11 experience. I think we need to stop using the
12 term error and try to build some type of a
13 positive, improving a safety quotient,
14 something like that. Because, as long as we're
15 punitive and negative on what we're finding,
16 we're going to kill the culture.

17 Because we -- I think our biggest
18 challenge here is to instill a culture of
19 change. You know, we could take some --
20 learning from the aerospace industry, I mean
21 the airlines, I mean, my god, nobody gets --
22 nobody is more scrutinized than the airline
23 industry, and they've accepted it.

24 But we're seeing it all around us.
25 You know, I mentioned police having, you know,

1 cameras and now we even have electronic
2 baseball umpires and, you know -- if technology
3 is affecting all of us all around, and I was
4 encouraged to hear from the presenters today
5 that the technology is there, promote and
6 sustain the change that we need. It's there.
7 We've got to build the culture to accept it and
8 inject AI into it, integrating it in, but
9 seriously monitoring it as we integrate it to
10 make sure it's not prone to its errors.

11 And maybe we need to learn from some
12 of these other industries and be incremental in
13 our deployment of this, so we don't get the
14 pushback that we would if we're too intrusive.
15 We need -- the providers need tools, they don't
16 need more regulation. They need things that
17 help them complete their work every day.

18 I like Chopra's suggestion, this
19 could be something that could, you know, be the
20 structure of our letter to -- of our report to
21 the Secretary, that we need to bring the EHR
22 vendors together, but we also need to bring
23 together those that are going to implement
24 those EHRs and those that are going to pay for
25 those EHRs, in order to build a solution that

1 we can incrementally deploy and build this
2 culture of change. Those were great sessions
3 today.

4 CO-CHAIR PULLURU: At the risk of
5 being somewhat repetitive, I'll try to go fast,
6 but I summarized the day for myself in a
7 structure that I thought about. The first
8 being -- it's vertical, and the first being
9 data on infrastructure. And Aneesh spoke to
10 needing to standardize it, make it easier for
11 people to access and not making -- and have CMS
12 really drive that, right, and have it be an
13 interoperable data layer. This comes up all
14 the time, just as important for safety.

15 The second was really in EHR and
16 being more provider- and patient-centric versus
17 just being a tool that adds more burden.
18 Because having increased documentation burden
19 also leads to safety risk, there's a cognitive
20 burden there. And I think that responsibility
21 needs to be a part of whatever we design.

22 The third is when Susan, really,
23 spoke about collaboration and how they're
24 designing structures under her watch of
25 coordination, care coordination, and

1 collaboration as a part of some of the work
2 that she's doing at CMS.

3 Fourth is, really, thinking about
4 how does the tactical culture of the provider
5 group. So, Tejal brought up leadership,
6 Michelle brought up training. I think we didn't
7 speak about the fact that we need to have an
8 incentive and structure around people being
9 trained in safety.

10 I loved Jason and how he brought up
11 the fact that -- I love his thought around, you
12 know, hey, don't punish the providers, let's
13 talk about shared savings. Let's just not have
14 them take a pay cut, because that's what this
15 looks like when you really think about
16 mandatory measures.

17 When we speak to measurement, you
18 know, I thought Classen hit it out of the
19 ballpark with the fact that, part of the
20 problem is, we are not measuring what needs to
21 be measured. And the current measures, we seem
22 to be improving but in aggregate we're not
23 improving. And maybe the problem why we're not
24 improving is that we have the wrong -- we're
25 not measuring what we need to, and it's only a

1 percentage, the PSI.

2 And Terry brought up systems
3 engineering, and I think, you know, every --
4 you know, how do we -- I mean, we as a
5 Committee need to really think about how we
6 incentivize that kind of tactical, on-the-
7 ground FTE, and how does that become a part of
8 what we create an incentive structure? We have
9 quality officers all over the country now. How
10 many people have safety officers?

11 And, so, the last and, I would say,
12 kind of the most important thing in my mind
13 that came out of all this, is that the patient
14 needs to be a big part of the reporting
15 structure.

16 And, you know, Press Ganey does this
17 really well, and back when I was at DuPage, we
18 looked at Press Ganey reports. And it's just,
19 patience, if you listen hard enough, will tell
20 you what the near misses are. And there's not
21 a systematize mechanism right now in our
22 infrastructure to pick up on that, measure it,
23 and react to it and have accountability for it.
24 And I think that that's important. So, I'll
25 stop here.

1

2

CO-CHAIR MILLS: Okay, great

3

comments and review. I've tried to pick out a

4

few items that haven't yet been picked up.

5

Some of them have.

6

First, to David's prior comment

7

about is safety, you know, part of mandatory,

8

every model, or is it a unique model, and I

9

think my response at the end of the day is,

10

it's a yes-and question, not an either-or

11

question. That we ought to bake safety, you

12

know, measurements and concepts across the

13

board into everything that CMS and CMMI do. But

14

there may be a place and a space, especially on

15

a pilot for new approaches for a specific

16

patient safety model, and so that has some

17

merit.

18

I really loved the parts about

19

adding PROM and PREMs to be expected to be a

20

standard part of the data set when you're doing

21

any type of experiencing measuring or quality

22

data reporting, and I think that makes good

23

sense. You know, we all are doing -- whatever

24

your vendor is, Press Ganey or any other, we're

25

all doing patient experience monitoring all the

1 time, and yet we're not using some of those
2 standardized questions that could get some of
3 those domains, and that would be valuable.

4 But I'm still in cognitive
5 dissonance about this idea that patient safety
6 is not quality. And I get it, from a pure
7 academic discipline, they have different
8 ramifications. And yet at the same time, if
9 you show me a patient safety problem, I'll show
10 you a low-value, low-quality care issue. And,
11 so, they really are the same.

12 And I think the hook, maybe, is for
13 most practicing clinicians, we spend a whole
14 lot of time thinking about improving clinical
15 quality, but never think of that in the same
16 vein as a overt safety issue. If you didn't
17 get, you know, those last 10 patients to have
18 their cancer screening, you hurt somebody just
19 as surely as if you mopped and didn't put out a
20 sign, and they fell and hit their head, right?
21 So, I think maybe that duality is more useful
22 with clinicians than with the wider audience.

23 We heard some about mechanisms that
24 Lindsay touched on that, you know, shared
25 savings may be a vehicle, there may be some

1 need for initial investment to increase process
2 and capability performance. That made sense.

3 In the second panel, we heard a lot
4 about that it's really important, that we have
5 to make it not cheaper to take the penalty than
6 it is to implement the safety program. And,
7 so, again, that's a great systems theory. You
8 got to make it hard to do the wrong thing and
9 easy to do the right thing. And if right now
10 it's just too easy for a CFO to say I'll take
11 the penalty and not build the systems, we've
12 got to change that incentive structure.

13 But that then led me to the 5,000-
14 foot level, and we've had this conversation
15 multiple times, that, really, we spend a lot of
16 time talking about models in metrics, and
17 measurement and incentives, in our minds all
18 thinking about making the pitch to practicing
19 clinicians to do these. And, actually,
20 sometimes the pitch is really to the
21 employment, CEOs and CFOs, that are running big
22 integrated health systems and employing
23 physicians across the country, right?

24 So, in a sense that this safety
25 issue is -- as most safety issues come up in

1 integrated health delivery systems now, they
2 often disappear into risk management and never
3 see the light of day. And, so, it makes me
4 think that we need the, you know, the chief
5 counsels, and the compliance officers and the
6 risk safety community to be part of the
7 conversation to solve this. That they've got
8 to have a different culture of how we take this
9 on.

10 And, then, lastly -- okay, and
11 lastly, what we heard loud and clear this
12 afternoon, which is kind of a first in six
13 years in the PTAC, is that it's not a
14 technology issue, it's not an information
15 issue, it's not a regulatory framework policy
16 or legal space issue, it's just a willpower
17 issue. All the preconditions we need to do
18 something really, really special already exist.
19 It's just a matter of lining up the dots, build
20 the system, and get it released. And that's an
21 exciting place to be for the group, so.

22 CO-CHAIR PULLURU: And not a funding
23 issue.

24 CO-CHAIR MILLS: Okay. Other final
25 comments or thoughts?

1 (No audible response.)

2 * **Closing Remarks**

3 CO-CHAIR MILLS: Okay. Well, at
4 this time I want to thank everybody for
5 participating today, both our wonderful session
6 experts, my PTAC colleagues, and all those who
7 joined us in the audience today both in-person
8 and online. Thank you for that.

9 We'll be back again tomorrow morning
10 at 9:00 a.m. Eastern Time where we'll be joined
11 by four incredible experts who will share their
12 perspectives during another expert session on
13 payment mechanisms and financial incentives, to
14 encourage patient safety and alternative
15 payment mechanisms.

16 There will be an opportunity for
17 public comments related to the meeting topic
18 tomorrow morning at approximately 10:50 Eastern
19 Time before the meeting concludes. And I
20 believe at this time we have four public
21 commenters signed up. Look forward to hearing
22 their comments.

23 * **Adjourn**

24 We hope you will join us then.
25 Thank you. And this meeting is adjourned for

1 the day.

2 (Whereupon, the above-entitled

3 matter went off the record at 5:00 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: PTAC Advisory Committee

Before: PTAC

Date: 06-15-26

Place: virtual meeting

was duly recorded and accurately transcribed under
my direction; further, that said transcript is a
true and accurate complete record of the
proceedings.



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