Donner Conference Room - Tahoe Forest Hospital

10976 Donner Pass Rd, Suite 3, Truckee CA 96161

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Meeting Book - 2024-05-07 Board Quality Committee Meeting

TAHOE
FOREST
HOSPITAL
DISTRICT

QUALITY COMMITTEE
AGENDA

Wednesday May 07, 2024 at 12:00 p.m.
Donner Conference Room – Tahoe Forest Hospital
10976 Donner Pass Road, Suite 3, Truckee, CA 96161

1. CALL TO ORDER

2. ROLL CALL
Michael McGarry, Chair; Robert Barnett, Board Member

3. CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA

4. INPUT – AUDIENCE
This is an opportunity for members of the public to address the Committee on items which are not on the agenda. Please state your name for the record. Comments are limited to three minutes. Written comments should be submitted to the Board Clerk 24 hours prior to the meeting to allow for distribution. Under Government Code Section 54954.2 – Brown Act, the Committee cannot take action on any item not on the agenda. The Committee may choose to acknowledge the comment or, where appropriate, briefly answer a question, refer the matter to staff, or set the item for discussion at a future meeting.

5. APPROVAL OF MINUTES OF: 02/28/2024 .... ATTACHMENT

6. CLOSED SESSION
 6.1. Hearing (Health & Safety Code § 32155)
    Subject Matter: Case Review
    Number of items: One (1)
 6.2. Approval of Closed Session Minutes
    6.2.1. 02/28/2024 Closed Session Board Quality Committee

7. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION
 7.1. Informational Reports
    7.1.1. Patient & Family Centered Care
       7.1.1.1. Patient & Family Advisory Council (PFAC) Update............................... ATTACHMENT
          Quality Committee will receive an update related to the activities of the Patient and Family Advisory Council (PFAC).
    7.1.2. Patient Safety
       7.1.2.1. BETA HEART Program Progress Report .... ATTACHMENT
          Quality Committee will receive a progress report regarding the BETA Healthcare Group Culture of Safety program.
 7.2. Safety First
 7.3. Quality Criteria for FY24 President & CEO Incentive Compensation .... ATTACHMENT
    Quality Committee will review the Care Compare Star rating concurrent bundles for the Fiscal Year 2024 President and Chief Executive Officer Incentive Compensation Plan metric.
 7.4. Leading a Culture of Safety .... ATTACHMENT

Quality Committee will discuss the key questions about our organization's capabilities and processes related to *Establishing organizational behavior expectations*, including foundational and sustaining strategies(page 25-29).

> American College of Healthcare Executives and IHI/NPSF Lucian Leape Institute. *Leading a Culture of Safety: A Blueprint for Success*. Boston, MA (2017) Downloaded on 3/9/22 from https://www.ihi.org/resources/Pages/Publications/Leading-a-Culture-of-Safety-A-Blueprint-for-Success.aspx

7.5. Board Quality Education .... ATTACHMENT
Quality Committee will review the educational articles listed below and discuss topics for future board quality education:

7.5.1. AHIMA. *Healthcare Data Governance*. Chicago, IL (2022). Downloaded on 10/20/23 from https://www.ahima.org/media/pmcb0fr5/healthcare-data-governance-practice-brief-final.pdf

7.5.2. Drazen, J.M., Kohane, I.S., Leong, T.Y. (2023). *Artificial Intelligence in U.S. Health Care Delivery.* New England Journal of Medicine, 389: 348-358.

7.5.3. Gallagher, T.H., & Kachalia, A. (2024) *Responding to Medical Errors – Implementing the Modern Ethical Paradigm.* New England Journal of Medicine, 390: 193-197.

8. REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS

9. NEXT MEETING DATE
The next committee date and time will be confirmed.

10. ADJOURN

*Denotes material (or a portion thereof) <u>may</u> be distributed later.

TAHOE FOREST HOSPITAL DISTRICT

QUALITY COMMITTEE
DRAFT MINUTES

Wednesday, February 28, 2024 at 12:00 p.m.
Donner Conference Room – Tahoe Forest Hospital
10976 Donner Pass Road, Suite 3, Truckee, CA 96161

1. CALL TO ORDER
Meeting was called to order at 12:02 p.m.

2. ROLL CALL
Board: Michael McGarry, Chair; Robert Barnett, Board Member

Staff in attendance: Harry Weis, President & CEO; Crystal Felix, Chief Financial Officer; Dr. Brian Evans, Chief Medical Officer; Jan Iida, Chief Nursing Officer; Janet Van Gelder, Director of Quality & Regulations; Dylan Crosby, Director of Facilities Management & Construction; Ashley Davis, Patient Safety Officer; Trent Foust, Director of Nursing; Kate Cooper, Surgical Manager; Martina Rochefort, Clerk of the Board

3. CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA
No changes were made to the agenda.

4. INPUT – AUDIENCE
No public comment was received.

5. APPROVAL OF MINUTES OF: 11/07/2023
Director Barnett moved approval of the Board Quality Committee minutes of November 7, 2023, seconded by Director McGarry.

Open Session recessed at 12:04 p.m.

6. CLOSED SESSION
  6.1. Hearing (Health & Safety Code § 32155)
      Subject Matter: Case Review
      Number of items: One (1)
Discussion was held on a privileged item.

  6.2. Approval of Closed Session Minutes
      6.2.1. 11/07/2023 Closed Session Board Quality Committee
Discussion was held on a privileged item.

Open Session reconvened at 12:25 p.m.

Director of Facilities, OR Manager and Director of Nursing departed during Closed Session. Medical Director of Quality joined during Closed Session.
Kevin Ward, PFAC Member, joined the meeting at 12:25 p.m.

7.   ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION

7.1. Informational Reports

7.1.1. Patient & Family Centered Care

7.1.1.1. Patient & Family Advisory Council (PFAC) Update

No discussion was held.

7.1.2. Patient Safety

7.1.2.1. BETA HEART Program Progress Report

No discussion was held.

7.2. Safety First

Harry Weis, President and Chief Executive Officer, shared a safety first about recent cyberattacks on Change Healthcare.

7.3. Potential Quality Criteria for FY24 President & CEO Incentive Compensation

Quality Committee discussed potential quality criteria for the Fiscal Year 2024 President and Chief Executive Officer Incentive Compensation Plan.

The criteria are a shift from outcome measures to process measures. Baselines have not yet been established.

The following were identified as areas for improvement:

1.   OP-35: Emergency Visits after Outpatient Chemotherapy
2.   HAI-6/C-Diff
3.   Sep-1/Sepsis
4.   Falls
5.   Surgical Site Infections
6.   OP-10: Abdomen CT Use of Contrast
7.   Total Joint Replacements
8.   Hospital-Wide All Cause Unplanned Readmissions

The process measures put the District on the path to know if we are on the right track with the data lag on the star rating.

The current placeholder for the measures is 90%. Once the baseline is determined, the goals can be adjusted.

7.4. Quality Assessment Performance Improvement (AQPI-05)

Quality Committee reviewed the annual Quality Assessment/Performance Improvement Plan (AQPI-05).

The plan will move forward to the full board in March after the Medical Executive Committee approves it.

Quality Committee reviewed performance improvement initiatives. Discussion was held.

On the development of a data governance strategy, President & CEO shared the Health System is planning to hire a Director of Business Intelligence.

CFO clarified that leadership is breaking down the silo approach to data and moving toward an organizational approach so there is one place for everyone to go.

Quality Committee recommended to add "enterprise wide" to item 10.

7.5. Leading a Culture of Safety

American College of Healthcare Executives and IHI/NPSF Lucian Leape Institute. *Leading a Culture of Safety: A Blueprint for Success*. Boston, MA (2017) Downloaded on 3/9/22 from https://www.ihi.org/resources/Pages/Publications/Leading-a-Culture-of-Safety-A-Blueprint-for-Success.aspx

No discussion was held.

7.6. Board Quality Education

Quality Committee reviewed the following articles related to Business Intelligence/Data Governance and Artificial Intelligence:

7.6.1. AHIMA. *Healthcare Data Governance*. Chicago, IL (2022). Downloaded on 10/20/23 from: https://www.ahima.org/media/pmcb0fr5/healthcare-data-governance-practice-brief-final.pdf

7.6.2. Drazen, J.M., Kohane, I.S., Leong, T.Y. (2023). *Artificial Intelligence in U.S. Health Care Delivery*. New England Journal of Medicine, 389: 348-358.

Dr. Brian Evans, Chief Medical Officer, is working on Dr. Dhaliwahl coming to speak as part of the Hobday Lectureship.

CEO shared the District does not want to be alpha in the AI space. CMO added that AI needs to be vetted. There has to be a way to leverage scale on vetting AI vendors. CFO added that in order for these vendors to help us we have to have a standard of work. Leadership recognized that the Vizient work on standard workflows would help us to step into AI easily. The risk is huge when you have not done the work on the front end. It would make more sense to piggy back on the larger companies that will have the AI available.

Director Barnett asked if the District has an internal taskforce looking at AI solutions. The District does not currently have an AI taskforce. Leadership will lean on the new Business Intelligence department to do some of that. The District will have to partner with others to get that done. Epic will definitely be a partner, possibly Microsoft. CFO noted it could be possible to leverage the Sierra Health Collaborative for some of this.

Director McGarry inquired how the Health System is thinking about data and AI. A major question is what are the major challenges that will be faced in 3-5 years. We are talking about fundamentally transforming the way we work. CMO shared the management systems work that is going on now is focused on how we make decisions, leadership, etc. The Health System will need to look big picture and it is happening rapidly. CFO stated what we talk about in the next two years will help lay the foundation for what we do in the future.

8. REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS
-QAPI Plan will go to the full board.

9. NEXT MEETING DATE
The next committee date and time will be determined at a later time.

10. ADJOURN
Meeting adjourned at 1:36 p.m.

Patient and Family Advisory Council (PFAC) Summary Report

January 2024 – June 2024

Alix Crone, DC, CPXP – Clinical Patient Experience Specialist

Summary of Monthly Topics

January – Kat Sigafoose, Director of Patient Access, discussed our current customer service training/expectations of our registration staff and identified improvement opportunities through a "Secret Shopper" program. We elicited input from the PFAC with regard to evaluation criteria and process for implementation. Emphasized that positive experienced should be shared/reinforced with the involved staff to help incentivize. Discussed a proposed "Disruptive Patient" agreement and policy that has come about in response to increased incidents of disruptive and aggressive patients. Proposed new messaging/wording of signs displayed to notify patients of behavior expectations. Suggested de-escalation training for all staff to be considered as a requirement.

February – Jonathan Lowe, NP, a Behavioral Health provider, presented on Spravato (aka esketamine) treatment for chronic depression. This is the first FDA-approved psychedelic treatment, though the Covid pandemic halted/slowed its use. It is used primarily for treatment-resistant depression and so far over 750 treatments have been administered at TFH with a very high patient-reported success rate. Currently limited due to lack of a "buy and bill" system which would allow us to collect better reimbursement and cut out the need for using specialized pharmacies in other states outside of our health system. Jonathan discussed other current needs for our community to include more therapists, more space and expanded services, such as group therapy.

March – Heather Hiller, Clinical Quality Analyst, presented about the prevalence and warning signs of sepsis, and elicited input from PFAC with regard to spreading community education/awareness. Sepsis is the leading cause of death in US hospitals as well as the leading cause of hospital readmissions. TFH has implemented sepsis "bundles" that are utilized for initial intervention. TFH also initiated a Multidisciplinary Sepsis Committee 2 years ago, performs sepsis drills, and identifies awards for staff with great recognition/care for sepsis on a quarterly basis. We are well above the National and State compliance rate benchmarks for our CMS Core Measure that tracks Severe Sepsis/Septic Shock at 92.3% as of last year. Ideas on improving education/awareness through our local news outlets (Moonshine Ink), links to videos online, education through the Rec Center during "Golden Hour" sessions, and on our internet page or collaboration with our Marketing Department.

April – Alix Crone, Clinical Patient Experience Specialist, reviewed our current Patient Satisfaction scores from Press Ganey for our main service lines. We discussed the survey process and reviewed the questions asked on the surveys. We looked for potential factors and explanations into trends and changes occurring over the last couple of years to current. We discussed how scores and comments were shared with leadership, and improvement opportunities stemming from the feedback. One member recommended exploring use of ChatGPT to help organize feedback and identify immediate trends/themes within.

May – Ellie Cruz, Manager of Labor and Delivery, will be presenting on doula and home birth services.

Current Overview

- Ongoing goal is to have PFAC identify ways to help educate community on all services offered by TFHS, as well as provide input and feedback on current and future processes and systems.

- Plan for 2024 is to receive updates from the ongoing topic/concern of patient access, and to be at forefront of upcoming changes and plans to the health system's services offered.

- PFAC meets every month, 9 months in the year. We do not meet during the months of July, August, or December.

- Next PFAC meeting is May 21, 2024

Current Members and Start Date

Name	Start Date	Name	Start Date
Kevin Ward	9/20/2018	Carina Toledo	11/17/2022
Sandy Horn	9/5/2019	Cris Valerio	12/1/2022
Violet Nakayama	10/31/2019	Jane Rudolph-Bloom	1/1/2024
Alan Kern	2/20/2020	Amber Mello	5/1/2024

Beta HEART Progress Report for Year 2024
(April 2024)

Beginning in 2020, Beta Healthcare Group changed their annual Incentive process to be "Annual", meaning that each year the five (5) domains have to be re-validated each year to be eligible for the incentive credit. General updates for 2024:

- Beta HEART Validation Survey completed May 9, 2023; validated in all 5 domains with a total cost savings of $152,971
- Beta HEART Validation Survey planned for May 22, 2024, including SCOR Culture of Safety Survey in March 2024

Domain	History of Incentive Credits (2% annually)	Readiness for next Validation	Goal	Comments
Culture of Safety: A process for measuring safety culture and staff engagement (Lead: Ashley Davis, Beta HEART Lead)	Validated 2023: $30,594.20	100%	-Greater than 60% completion rate for Culture of Safety Survey Pulse Check-In -Achieve Tier 2 in Zero Harm (OB & ED)	• Pulse check-in version of SCOR Culture of Safety survey was completed in March 2024 with 76% response rate (974 completions). Results to be shared and debriefings to start in May 2024. • TFHD Women & Family Center and Emergency Departments were recognized for achieving Tier 2 in Zero Harm (highest level of recognition for Beta) in 2023; goal to achieve same in 2024. • 5 leaders attended February 2024 workshop in Palm Desert, CA; topics include Culture of Safety and Rapid Event Response and Analysis.
Rapid Event Response and analysis: A formalized process for early identification and rapid response to adverse events that includes an investigatory process that integrates human factors and systems analysis while applying Just Culture principles (Lead: Janet Van Gelder, Ashley Davis)	Validated 2023: $30,594.20	100%	-75% or greater response time for event analyses within 45 days of event reported -75% or greater response time for closure of action items within 90 days of event reported	TFHD incorporates the transparent and timely reporting of safety events to ensure rapid change in providing safer patient care. All investigations utilize "just culture" and high reliability principles and encourage accountability. The Reliability Management Team reviews all action plans to address strength of action items. • 5 leaders attended February 2024 workshop in Palm Desert, CA; topics include Culture of Safety and Rapid Event Response and Analysis.
Communication and transparency: A commitment to honest and transparent communication with patients and family members after an adverse event (Lead: Janet Van Gelder, Ashley Davis)	Validated 2023: $30,594.20	100%	75% or greater response time for closure of event within 60 days	Disclosure checklist updated and refined as we update process and leaders trained to respond to events. • 10 leaders to attend April 2024 workshop in La Jolla, CA; topics include Communication & Transparency and Care for the Caregiver.
Care for the Caregiver: An organizational program that ensures support for caregivers involved in an adverse event (Lead: Stephen Hicks, Peer Support Lead)	Validated 2023: $30,594.20	100%	75% or greater response time for peer supporter deployment made in 0-12 hours	Ongoing training and quarterly peer support and steering committee meetings. Currently have 40 peer supporters available to all staff. New peer supporters attended onsite training in April 2024. One peer supporter is now trained in Critical Incident first aid and plans for more peer supporters to go through this training. Plan for train-the-trainer education in 2024 so we can train new peer supporters in-house. • 10 leaders to attend April 2024 workshop in La Jolla, CA; topics include Communication & Transparency and Care for the Caregiver.
Early Resolution: A process for early resolution when harm is deemed the result of inappropriate care or medical error (Lead: Janet Van Gelder, Ashley Davis)	Validated 2023: $30,594.20	100%	75% or greater response time for closure of event within 60 days	12 leaders to attend Early Resolution workshop in Huntington Beach, CA in September 2024.

Tahoe Forest Hospital
Standard Work Bundles
2024

We have developed the following concurrent quality metric bundles:

1. **OP-35: Emergency Visits after Outpatient Chemotherapy**
   a. Stakeholders: Kelley Bottomley, Derek Baden
   b. Standard work items
      i. Initial prevention
      ii. Symptomatic patients during treatment
         1. Evaluations and referrals
   c. Numerator-Chemo patients with validated chemo teach
   d. Denominator-New start chemo patients
   e. **Goal = ≥ 92%**
2. **HAI-6/C-Diff**
   a. Stakeholders: Trent Foust, Nicole Becker
   b. Standard work items
      i. Testing- call MD before
      ii. Enteric contact precautions
      iii. If C-Diff positive- PPE present, private room, hand hygiene observed
   c. Numerator-Patients with bundle items done
   d. Denominator- Patients with 3 or more loose stools in 24 hrs
   e. **Goal ≥ 90%**
3. **Sep-1/Sepsis**
   a. Stakeholders: Trent Foust, Nicole Becker, Ellie Cruz
   b. Standard work items
      i. 3 hour bundle
      ii. 6 hour bundle
   c. Numerator- Sepsis patients with 3 and 6 hour bundles verified
   d. Denominator- Sepsis admissions or new sepsis developed
   e. **Goal ≥ 90%**
4. **Falls**
   a. Stakeholders: Trent Foust, Nicole Becker
   b. Standard work items
      i. Fall risk bundle in place
      ii. Ambulation status posted (ICU/MS)
   c. Numerator- High fall risk patients with all bundles in place
   d. Denominator- Fall risk patients reviewed
   e. **Goal ≥ 90%**
5. **SSI**
   a. Stakeholders: Calley Corr, Kate Cooper
   b. Standard work items

          i. Pre-op hair removal

          ii. CHG Pre-op

          iii. Nasal Decolonization

          iv. Oral Decolonization

          v. Vanco MRSA Positive only

          vi. Normo-thermia pre-op

    c. Numerator- TJR patients with all bundles

    d. Denominator- Elective TJR patients

    e. Goal ≥ 90%

6. **OP-10: Abdomen CT Use of Contrast**

    a. Stakeholders: Sadie Wangler, Shayna Vosburgh

    b. Standard work items

          i. Exclusion diagnosis present

          ii. Verified with Provider correct order

    c. Numerator- Appropriate combined abdomen CT orders

    d. Denominator- Combined abdomen CT orders

    e. Goal ≥ 90%

7. **Total Joint Replacements**

    a. Stakeholders: Danielle Moran, TBD

    b. Standard work items

          i. Medical and social clearance

          ii. Patient education

          iii. Monitoring/follow-up

               1. Sub-items within each category

    c. Numerator- TJR patients with all bundles

    d. Denominator- Elective TJR patients

    e. Goal ≥ 90%

8. **Hospital-Wide All Cause Unplanned Readmissions**

    a. Stakeholders: Karyn Grow, Anna McGuire

    b. Standard work items

          i. TCM referral

          ii. Follow-up with PCP within 14 days

    c. Numerator- High risk discharges with bundle items

    d. Denominator- High risk discharges, score ≥3

    e. Goal ≥ 90%

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Tahoe Forest Hospital
Standard Work Bundles
2024

The concurrent bundles are for internal tracking and not reportable to CMS. Previously we have tracked outcome measures, showing noncompliance with the quality metric. The concurrent bundle is being proactive to ensure compliance with the process measure to avoid a negative outcome. We are focused on standard work and adhering to it every time to ensure the best outcome for our patients. Tracking the bundles will be reported out in the form of a numerator (number of patients with quality metric bundle completed) and denominator (total number of patients being measured).

3

Vision

Behavior Expectations

Trust, Respect, and Inclusion

ZERO HARM to Patients, Families, and the Workforce

Just Culture

Board Engagement

Leadership Development

Leading a Culture of Safety: A Blueprint for Success

American College of HealthcareExecutives
for leaders who care ®

THE NATIONAL PATIENT SAFETY FOUNDATION'S
LUCIAN LEAPE INSTITUTE

Contents

Leading a Culture of Safety: A Blueprint for Success

American College of Healthcare Executives

The American College of Healthcare Executives is an international professional society of 40,000 healthcare executives who lead hospitals, healthcare systems, and other healthcare organizations. Its mission is to advance its members and healthcare management excellence. ACHE offers its prestigious FACHE® credential, signifying board certification in healthcare management. Its established network of 78 chapters provides access to networking, education, and career development at the local level. In addition, ACHE is known for its magazine, *Healthcare Executive*, and its career development and public policy programs. Through such efforts, ACHE works toward its vision of being the preeminent professional society for healthcare executives dedicated to improving health. **The Foundation of the American College of Healthcare Executives** was established to further advance healthcare management excellence through education and research. The Foundation of ACHE is known for its educational programs — including the annual Congress on Healthcare Leadership, which draws more than 4,000 participants — and groundbreaking research. Its publishing division, Health Administration Press, is one of the largest publishers of books and journals on health services management, including textbooks for college and university courses.

For more information, visit www.ache.org.

The National Patient Safety Foundation's Lucian Leape Institute

Established in 2007, the NPSF Lucian Leape Institute is charged with defining strategic paths and calls to action for the field of patient safety, offering vision and context for the many efforts under way within healthcare, and providing the leverage necessary for system-level change. Its members are national thought leaders with a common interest in patient safety. Their expertise and influence are brought to bear as the Institute calls for the innovation necessary to create significant, sustainable improvements in culture, process, and outcomes that are critical to safer healthcare.

For more information, visit www.npsf.org/LLI.

The National Patient Safety Foundation at the Institute for Healthcare Improvement

The Institute for Healthcare Improvement (IHI) and the National Patient Safety Foundation (NPSF) began working together as one organization in May 2017. The newly formed entity is committed to using its combined knowledge and resources to focus and energize the patient safety agenda in order to build systems of safety across the continuum of care. To learn more about our trainings, resources, and practical applications, visit ihi.org/PatientSafety.

Letter from the Project Co-chairs

Dear Colleagues:

Healthcare is one of the most complex industries in our world. Amid all of the pressing priorities, we must remember that the elimination of harm to our patients and workforce is our foremost moral and ethical obligation. In our roles as healthcare leaders, we have numerous responsibilities for ensuring the quality of care provided within our organizations, including patient and family experience, improving the health status of our communities, and maintaining the financial sustainability of our organizations. However, one of the most critical roles we must fulfill is ensuring the safety of patients who entrust their lives to our care, as well as ensuring the safety of a workforce—both clinical and non-clinical—that entrusts their livelihoods to our organizations. It is the ultimate duty of leaders to ensure the safety and prevention of unnecessary harm to these individuals and their loved ones. Healthcare executives must address the need to create sustainable cultures of safety throughout a healthcare system full of daunting challenges.

As our organizations aim to continually improve the reliability and safety of care, we can look to resources and successful practices to assist us, our Boards, our executive colleagues, our healthcare professionals, and the entirety of our workforce. The American College of Healthcare Executives (ACHE) and the National Patient Safety Foundation's Lucian Leape Institute (NPSF LLI) have partnered to collaborate with some of the most progressive healthcare organizations and globally renowned experts in leadership, safety, and culture to develop *Leading a Culture of Safety: A Blueprint for Success*. This document is an evidence-based, practical resource with tools and proven strategies to assist you in creating a culture of safety—an essential foundation for achieving zero harm. It is our hope that this guide will inspire and motivate, while providing approaches and tactics leaders can implement in driving cultural change, with the goal of elevating healthcare into the realm of recognized industries that have succeeded in reducing error and harm.

ACHE and NPSF LLI stand ready to assist you on this journey. We invite you to use this guide in both a strategic and tactical manner to direct your efforts in creating and sustaining a culture of safety, and to evaluate your success along your journey to zero harm.

Sincerely,

Gary S. Kaplan, MD, FACMPE
Co-chair

Charles D. Stokes, RN, BSN, FACHE
Co-chair

Acknowledgments

Culture of Safety Roundtable Participants

Gary Kaplan, MD, FACMPE*
Chairman and CEO
Virginia Mason Health System
Project Co-Chair

Charles Stokes, RN, BSN, FACHE*
Senior Vice President and Chief Operating Officer
Memorial Hermann Health System
Project Co-Chair

Jason Adelman, MD, MS
Chief Patient Safety Officer,
Associate Chief Quality Officer
New York-Presbyterian Hospital
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Timothy Anderson, RN
Patient Safety Supervisor
Harry S. Truman Memorial Veterans' Hospital

Peter Angood, MD, FRCS(C), FACS, MCCM
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KentuckyOne Health

Christine Candio, RN, FACHE
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St. Luke's Hospital

Pamela Cipriano, PhD, RN, FAAN
President
American Nurses Association

Carolyn Corvi, MS
Former Vice President and General Manager
The Boeing Company

Teresa Edwards, FACHE
President
Sentara Leigh Hospital

Derek Feeley*
President and CEO
Institute for Healthcare Improvement

David Fox*
President
Advocate Good Samaritan Hospital

Vicki Good, RN, MSN, CENP, CPPS
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Deborah Grubbe, PE, CEng
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DuPont Sustainable Solutions
Owner and President
Operations and Safety Solutions, LLC

Helen Haskell, MA
President
Mothers Against Medical Error

John Haupert, FACHE
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Grady Health System

Mark Jarrett, MD, MBA, MS
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Cheryl Knapp, MBA, RN, CPPS, CPHQ
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Physician Lead, Hawaii Safer Care

John Lynch III, FACHE*
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Main Line Health

David Marx, JD, BS
President and CEO
Outcome Engenuity

Michael Leonard, MD
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Safe & Reliable Healthcare

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Doron Schneider, MD
Chief Safety and Quality Officer
Abington Jefferson Health

Roger Seaver, FACHE
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Henry Mayo Newhall Memorial Hospital

Lisa Shannon, MBA
Chief Operating Officer
KentuckyOne Health

Jack Silversin, DMD, DrPH
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Sara Singer, PhD, MBA
Professor of Healthcare Management and Policy
Harvard School of Public Health

Maureen Swick, PhD, RN, MSN, NEA-BC
CEO
American Organization of Nurse Executives
Senior Vice President, Chief Nursing Officer
American Hospital Association

Beth Daley Ullem, MBA
Patient Advocate and Governance Expert

Kerry Watson
President
Arnot Ogden Medical Center
Chief Operating Officer
Arnot Health

Sam Watson, MSA, MT(ASCP), CPPS
Executive Director
Senior Vice President, Safety and Quality
MHA Keystone Center

Nicolas Wolter
Former CEO
Billings Clinic

Gary Yates, MD
Partner, Strategic Consulting
Press Ganey Associates, Inc.

Raul Zambrano, MS, MD, FAAFP, FACHE
Chief Medical Officer
Aurora Health Care's Southeast Market

*Participated in both Culture of Safety Roundtable meetings (May and December 2016)

The Culture of Safety Imperative

Harm to Patients and the Workforce

In 1999, the Institute of Medicine (IOM) Committee on Quality of Health Care in America estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors (IOM 1999). More recent estimates place this number closer to 200,000 deaths per year (James 2013). Though deaths due to medical error are notoriously difficult to measure, if this number is accurate within 100,000 deaths, medical error kills four times more Americans each year than motor vehicle accidents. It is important to note that these statistics, while disconcerting on their own, do not account for serious temporary or permanent physical and psychological harm caused by medical error, and they do not include harm to the healthcare workforce. Regardless of the measurement or estimation used, the rate of error and harm in healthcare is astounding, and sweeping, system-wide changes are imperative.

Moreover, when patients experience harm, clinicians find themselves negatively impacted as well. Being involved in an error that results in the harm or death of a patient is devastating for an individual who is committed to serving those who are sick. At its worst, this devastation can lead to self-harm, depression, isolation, and even suicide. The desolation that often results from causing harm is compounded for clinicians who work in organizations without supportive systems. Based on the 2016 Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture's hospital comparative database, only 64% of staff respondents felt that reported mistakes led to positive changes in their organization. Even fewer members of the workforce, only 45%, responded positively to questions related to their organization's non-punitive response to error (AHRQ 2016).

Considering the impact described above, every healthcare executive should prioritize enhancing the safety of patients and the workforce. As an industry, healthcare has taken steps in improving quality and patient safety. However, these small-scale, incremental improvements are not enough. Our immediate work requires a focus on safety not just as a key improvement initiative but as a core value that is fully embedded throughout our organizations and our industry.

In every healthcare organization, the ultimate responsibility for system-based errors and their resulting costs rests with the CEO and Board of Directors. CEOs and Boards will be held increasingly responsible for harm and death caused by error. In the long run, patient and workforce safety will not only be a moral imperative but will likely be critical to sustainability and essential to delivering on value.

Based on data from James and the American Hospital Association, an average, 100-bed hospital committed errors in care that caused the death of 23 patients in 2013. Such statistics indicate that each organization contributed to the preventable death of almost one patient every other week (AHA 2014, James 2013).

The Business Case for Safety

While the business case for patient safety continues to expand and to change with new regulatory and reimbursement requirements, the general consensus within the healthcare research community is that organizational costs for error and harm are high and will likely increase in the coming years. In addition to the increase in direct cost of care for the impacted patient and family following an error, organizations must also consider personnel costs, regulatory costs, and resource costs including investigation of errors, pursuit of legal defense, and payment of settlements. Perhaps most important to consider are the potentially immense costs related to repairing reputation after a catastrophic event has occurred and been publically reported (Weeks and Bagian 2003). When each of these costs is considered on top of the direct cost of patient care, the business case for improving safety becomes abundantly compelling.

A Case Study in Culture:

Mr. Jones is a previously healthy 55-year-old man, with a recent history of shortness of breath that is related to exercise. He has been referred by his primary care physician for a cardiology consultation, at which a stress test is ordered. The results of the stress test indicate a positive finding for potential heart disease. These results are not communicated back to his primary care provider, and although they are sent to the referring cardiologist, he is away at a conference. Mr. Jones receives no communications about the results of his test. One week later, Mr. Jones presents to the emergency department with chest pain and is diagnosed with an acute myocardial infarction. Upon further review of his medical records, the care team reviews his past test results and learns about the positive stress test. Mr. Jones requires placement of a stent to open his coronary artery, and requires rehabilitation prior to discharge to his home due to reduced cardiac function. One week after discharge from inpatient rehabilitation, Mr. Jones returns to his primary care physician, who realizes that Mr. Jones is not taking one of the new cardiac medications that was ordered by his inpatient team.

A Tale of Two Organizations: Which is more like yours?

ORGANIZATION A:

The inpatient team notifies the patient safety department about the missed test result, and a root cause analysis is performed to determine why Mr. Jones' critical test result was not communicated to either him or his cardiologist. Action steps from the root cause analysis focus on re-educating the stress test department about the policy for communication of abnormal test results.

The lessons from the root cause analysis are not shared beyond the safety team. The action plan is not presented to the leadership team or the Board for approval, and does not include metrics for sustainability. The CEO and Board hear about the event only as a statistic presented quickly at the end of a quarterly Board meeting.

Mr. Jones is not informed about either the missed stress test result or the root cause analysis.

The primary care provider writes a new prescription for the cardiac medication. Mr. Jones ultimately misses several weeks of work.

ORGANIZATION B:

The inpatient team notifies the patient safety department about the missed test result, and a root cause analysis is performed. Action steps include designing a new process for communication of test results that includes an escalation policy when it is not immediately possible to communicate critical test results to the ordering provider and/or the patient.

The primary care provider ensures that Mr. Jones begins taking the cardiac medication and also notifies the risk management/patient safety department about the delay in medication use. An additional root cause analysis is conducted, with a clear tracing of the breakdown during transition from hospital to rehabilitation and rehabilitation to home, and how and why it may have occurred.

The results of both RCAs, including strong action plans for improvement and metrics for sustainability, are presented to the organization's leadership team for review and approval. The CEO presents the case and action plan at the next quality and safety meeting.

Mr. Jones' care team informs him about these breakdowns in communication, and how they may have contributed to his myocardial infarction and could cause future health issues. His care team extends an apology, as well as an offer for early resolution and compensation that helps Mr. Jones pay for his medical bills, his time away from work, and the additional costs associated with the need for his family to care for him.

Six months later, an assigned member of the leadership team follows up with the frontline care team involved in the event to evaluate and reassess the action plan and review improvement metrics. These results are presented at the next Board meeting.

DEBRIEF

Many organizations report that their response to handling Mr. Jones' situation is more similar to Organization A than to Organization B. This example is but one of many that illustrate why healthcare must create and improve systems that are committed to zero harm to patients and our workforce.

Introduction

Dr. Lucian Leape, widely regarded as the father of the modern patient safety movement, has repeatedly stated that "the single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes." By prioritizing, developing, and sustaining an organizational culture focused on safety, we can drive the future of healthcare to a place where patients and those who care for them are free from harm. It is not only one of many priorities, but is the overriding ethical imperative for all leaders.

AHRQ defines a culture of safety as one "in which healthcare professionals are held accountable for unprofessional conduct, yet not punished for human mistakes; errors are identified and mitigated before harm occurs; and systems are in place to enable staff to learn from errors and near-misses and prevent recurrence" (AHRQ PSNet Safety Culture 2014). The leaders of organizations must set and, more importantly, demonstrate the behaviors and expectations essential to a safe and transparent culture.

To help healthcare leaders achieve their mission of total system safety, ACHE and LLI have partnered to develop this guide, which is intended to assist leaders in creating, shaping, and sustaining the type of culture needed to advance patient and workforce safety efforts. It is designed to inspire, motivate, and inform you as you lead your organization on its journey to zero harm.

The information in this guide comes from industry leaders and experts who have had success in transforming their organizations into system-wide cultures of safety. It is designed for you and your team members to adapt to your organization, wherever you may be on your journey.

Cultures of Safety Across the Continuum

Because error and harm happen across the continuum, it is imperative that all improvement initiatives also encompass all care settings. While some of the tactics and recommendations throughout this document will be more relevant in certain environments than others, the key principles developed throughout the six domains are applicable to all who oversee the delivery of care—not just hospital settings. This work is intended to be adapted as needed to enhance applicability for all organizations. However, the key concepts—building trust, respect, and enthusiasm for improvement through behaviors and principles that focus on ameliorating systems issues while requiring fair and inclusive practices—are critical to safe care in all settings.

This resource is organized into six leadership domains that require CEO focus and dedication to develop and sustain a culture of safety:

Vision

Establish a compelling vision for safety. An organization's vision reflects priorities that, when aligned with its mission, establish a strong foundation for the work of the organization. By embedding a vision for total patient and workforce safety within the organization, healthcare leaders demonstrate that safety is a core value.

Trust, Respect, and Inclusion

Build trust, respect, and inclusion. Establishing trust, showing respect, and promoting inclusion — and demonstrating these principles throughout the organization and with patients and families — is essential to a leader's ability to create and sustain a culture of safety. In order to achieve zero harm, leaders must ensure that their actions are consistent at all times and across all levels of the organization. Trust, respect, and inclusion are non-negotiable standards that must encompass the Board room, the C-suite, clinical departments, and the entire workforce.

Board Engagement

Select, develop, and engage your Board. Governing Boards play a vital role in creating and maintaining safety cultures. CEOs are responsible for ensuring the education of their Board members on foundational safety science, including the importance of and processes for keeping patients and the workforce safe. Boards must ensure that metrics that meaningfully assess organizational safety and a culture of safety are in place and systematically reviewed, analyzed, and the results acted upon.

Leadership Development

Prioritize safety in the selection and development of leaders. It is the responsibility of the CEO, in collaboration with the Board, to include accountability for safety as part of the leadership development strategy for the organization. In addition, identifying physicians, nurses, and other clinical leaders as safety champions is key to closing the gap between administrative and clinical leadership development. Expectations for the design and delivery of relevant safety training for all executive and clinical leaders must be set by the CEO and subsequently spread throughout the organization.

Just Culture

Lead and reward a just culture. Leaders must possess a thorough understanding of the principles and behaviors of a just culture, and be committed to teaching and modeling them. Human error is and always will be a reality. In a just culture framework, the focus is on addressing systems issues that contribute to errors and harm. While clinicians and the workforce are held accountable for actively disregarding protocols and procedures, the reporting of errors, lapses, near-misses, and adverse events is encouraged. The workforce is supported when systems break down and errors occur. In a true just culture, all workforce members—both clinical and non-clinical—are empowered and unafraid to voice concerns about threats to patient and workforce safety.

Behavior Expectations

Establish organizational behavior expectations. Senior leaders are responsible for establishing safety-mindfulness for all clinicians and the workforce and, perhaps even more importantly, modeling these behaviors and actions. These behaviors include, but are not limited to, transparency, effective teamwork, active communication, civility, and direct and timely feedback. These cultural commitments must be universally understood and apply equally to the entire workforce, regardless of rank, role, or department.

The journey toward patient and workforce safety requires vigilance and the highest level of dedication. Safety cannot be merely a strategic priority, but must be a core value that is woven into the fabric of our organizations. A culture of safety demands the involvement and commitment of the full healthcare team, from patients to clinicians to the rest of the workforce. However, an organization cannot be what its leader is not. It is both the obligation and the privilege of every healthcare CEO to create and represent a compelling vision for a culture of safety: a culture in which mistakes are acknowledged and lead to sustainable, positive change; respectful and inclusive behaviors are instinctive and serve as the behavioral norms for the organization; and the physical and psychological safety of patients and the workforce is both highly valued and ardently protected.

A Note about Disparities in Care

Across the United States, individuals experience great differences in life expectancy and other health outcomes based on social determinants that may include ethnicity, religion, socioeconomic status, geographic location, sexual orientation, and gender identity, among others. It is impossible to envision an organization driving toward zero harm that is not also consciously focused on addressing these disparities.

Professor Margaret Whitehead, head of the World Health Organization (WHO) Collaborating Centre for Policy Research on the Social Determinants of Health, defines equity in health this way: "Ideally everyone should have a fair opportunity to attain their full health potential and, more pragmatically, no one should be disadvantaged from achieving this potential, if it can be avoided" (Whitehead and Dahlgren 2006). The reality of healthcare today is that quality and safety cannot be achieved without equity. Healthcare organizations have the power to address disparities at the point of care and to make an impact on many of the determinants that create these disparities (Institute for Healthcare Improvement 2016). Because equity in health is essential to quality and safety, mitigation of health disparities must be prioritized across the six domains for developing a culture of safety. Not only is creating health equity part of the safety imperative, but it requires many of the same mechanisms recommended throughout this document.

A Note about Learning Systems

The IOM describes a learning healthcare system as one in which "science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families are active participants in all elements, and new knowledge captured as an integral by-product of the care experience" (IOM 2013).

While this guide focuses on developing and sustaining a culture that drives patient and workforce safety outcomes, a CEO's accountability for developing and supporting a learning system is equally important. Change implementation is a vast interdisciplinary undertaking that requires all aspects of a safety culture, from safety science knowledge, to trust, respect, and visionary leadership (Friedman 2015). The design of learning systems may vary—from high reliability to Six Sigma™ to the Toyota Production System and other Lean methodologies—but the key characteristics are the same. Zero harm to patients and the workforce is only possible with both a robust culture of safety and an embedded organizational learning system.

Recommendations for Use of This Guide

This guide was developed for CEOs and other executive leaders in order to provide a useful tool for assessing and advancing an organization's culture of safety. It can be used to help determine the current state of your organization's journey, inform dialogue with your Board and leadership team, and help you set priorities. The six domains are intended to be discussed with your Board, your leadership team, your workforce, and your community. These domains are interdependent, and each domain is an essential element that must be addressed along your journey. This guide contains recommendations for developing and evaluating plans to flourish in each of the six domains, and resources for helping you move forward and make measurable progress in your journey.

The high-level strategies and practical tactics in this guide are divided into two levels: foundational and sustaining. The foundational level provides basic tactics and strategies essential for the implementation of each domain. The sustaining level provides strategies for spreading and embedding a culture of safety throughout the organization. However, it is important to note that the journey to zero harm is more complex than this simple two-level structure. Each organization will be at a different place on the spectrum from developing the foundation of a culture of safety to embedding and sustaining these principles. An organization may work on strategies and tactics across the two levels, or may be at various levels of progress across each of the domains. In organizations that lack an empowering vision statement or trust and respect among leadership, clinicians, and the workforce, it may be most effective to begin improvement initiatives in these two domains. The keys to developing and sustaining a culture of safety are honest and transparent evaluation of your organization's current state, identification of gaps and goals, and an action plan that engages all members of the Board, leadership team, and workforce.

Whether an organization is just beginning the journey to a culture of safety or is working to sustain its safe culture, the following steps are recommended:

✓ Share this document with your Board Chair and leadership team.

✓ Complete the self-assessment with input from your Board, leadership team, clinicians and the frontline workforce, and patient and family representatives, as appropriate.

✓ Develop action plans based on an understanding of the current state of your organization. Use assessment results to frame discussions with your leadership team and the Board that focus on identifying ways to close gaps and aligning the direction of your organization with key safety and culture initiatives.

✓ Share the outcomes of the assessment, action plans, and progress with your senior leadership team, the Board, your workforce, and your patients and families, as appropriate and helpful.

✓ Ask for periodic feedback from your Board, your leadership team, and the workforce.

✓ Refer to this guide as a resource for systematic check-ins and adjustments, as needed.

A Culture of Safety: The Six Domains

Leading for Safety

Vision

Behavior Expectations

Trust, Respect, and Inclusion

Zero Harm
to Patients, Families, and the Workforce

Just Culture

Board Engagement

Leadership Development

ORGANIZATIONAL LEARNING — CONTINUOUS IMPROVEMENT

Measurement • Analysis and interpretation • Change implementation • Feedback

Vision

Establish a Compelling Vision for Safety

GOAL: COMMIT TO DEVELOP, COMMUNICATE, AND EXECUTE ON AN ORGANIZATIONAL VISION OF ZERO HARM TO PATIENTS, FAMILIES, AND THE WORKFORCE.

To engage and inspire all clinical and non-clinical healthcare professionals and the public, an organization's vision should reflect long-term, aspirational goals. This vision must be clearly aligned with the organization's mission, which establishes the foundation of what an organization does.

A compelling vision enhances performance, promotes change, motivates individuals, and provides context for decision making (Lipman 1996). Clearly articulated, a strong vision addresses the why, the how, and the when of the aspirational goal (Lipman 2003). Many CEOs of healthcare organizations strive to include safety among their top strategic priorities, and this objective must be clearly reflected as a core value in the vision and mission statements. The CEO is responsible for launching the critical first step of establishing safety as the most important part of what everyone does, every day.

Strategies *Overarching strategies for implementation at the CEO level*	**Foundational**	**Sustaining**
	✓ CEO takes responsibility for educating himself/herself on how to develop vision and lead a culture of safety ✓ CEO communicates and models a shared vision of zero harm to patients, families, the community, and the workforce ✓ CEO communicates genuine, clear messages about vision, conveying purpose of safety culture to everyone, in all settings, repeatedly and for the long term ✓ CEO communicates how vision is critical to organizational success ✓ CEO prioritizes measurement, gap analysis, and improvement of culture of safety as foundational for vision ✓ CEO gains additional understanding of safety by participating in full harm investigation, including disclosure and apology and root cause analysis	✓ CEO and leadership team provide consistent, personalized messaging about the importance of safety and zero harm ✓ CEO relays importance and urgency of safety vision to both internal and external audiences ✓ CEO practices transparency and shared accountability between Board and leadership team regarding vision and relevant measurement and reporting

Establish a Compelling Vision for Safety

A compelling vision with patient and workforce safety as a core value is essential to achieving safe care. Zero harm is the aspirational "North Star." Healthcare CEOs demonstrate their belief that safety is a primary, non-negotiable goal by working with their Board, clinical leadership, and workforce to develop such a vision, to embed it in their organization, and to demonstrate their commitment and energize frontline workers through direct involvement in safety activities (NPSF 2015).
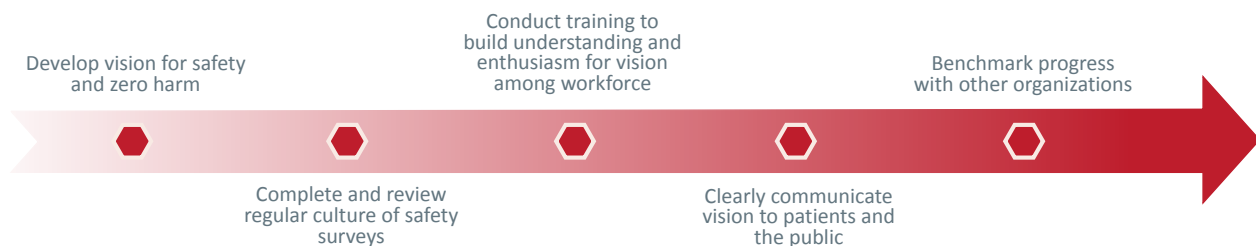
The first step for a CEO in creating this vision is to understand, acknowledge, and communicate the current state of their organization. A successful vision statement may be developed by top management and shared with the organization, or created in partnership with the workforce. The key is that the vision statement must encompass all organizational interests and engage the entire workforce. Visions that offer long-term perspective and include a degree of difficulty or stretch are often the most powerful. Finally, a vision statement should be clear and concise, allowing it to be easily remembered, repeated, and communicated (Kantabutra and Avery 2010).

Leaders must work with their teams, in direct partnership with physicians, nurses, and other clinical and non-clinical leaders, to assess the internal and external landscape of their organization. They must consider safety metrics, clinicians' attitudes and perceptions, patient and family experiences, and current practices, as well as trends and events that affect or might affect the healthcare industry. Landscape analysis is often accomplished through tactics including focus groups, safety culture surveys, safety rounds, analysis of safety metrics and reporting, and other diagnostic approaches. As one team of management researchers tell us, "The best way to lead people into the future is to connect with them deeply in the present" (Kouzes and Posner 2009). Understanding and communicating the current state enables leaders to connect and work with their teams and clinical experts to create a shared vision that can inspire everyone within the organization and the community.

While it is important to get input and buy-in from all levels when developing a vision, CEOs must be the ones to define and model the vision. Leaders at every level need to be visible in their commitment to patient and workforce safety and vocal about supporting actions that align with the organizational vision.

A clear and aspirational vision inspires the workforce and the public. The CEO works with the Board, leadership team, clinicians, and workforce to develop and embed this vision.

Develop vision for safety and zero harm

Conduct training to build understanding and enthusiasm for vision among workforce

Benchmark progress with other organizations

Complete and review regular culture of safety surveys

Clearly communicate vision to patients and the public

Vision

Establish a Compelling Vision for Safety

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization:** ✓ Work with select individuals throughout the organization to develop understanding of key organizational interests and goals ✓ Work with leadership team to develop aspirational end state (e.g., zero harm) that will be incorporated into vision ✓ Communicate the definition and importance of a culture of safety ✓ Build awareness of current state through culture surveys, observations, and focus groups, and communicate this throughout the organization ✓ Include zero harm vision in all communications from leaders at all levels, and keep this communication simple, consistent, and repetitive ✓ Include equity of care as part of vision statement and communicate the definition and importance of health equity ✓ Conduct training and information sessions for all employees to build understanding and enthusiasm for the vision ✓ Spend time on all floors and units communicating the connection of culture of safety and vision to the work of the frontline	**To engage your organization:** ✓ Clearly articulate your vision to the workforce and the public ✓ Benchmark culture progress and best practices with other similar organizations (e.g., participate in collaboratives) ✓ Develop and implement a recognition program for leaders, clinicians, and the workforce based on growth and adherence to vision ✓ Establish organizational goals that address safety and disparities in care **To engage clinical leaders:** ✓ Include physician, nursing and other clinical leaders in development of vision statement and strategic plan **To engage patients and families:** ✓ Clearly communicate the vision statement and values to patients ✓ Incorporate patient and family stories, along with statistics, when discussing vision at the Board level ✓ Include patient feedback in the development of vision statement
Assessing Execution *List of questions that should be asked to further assess and measure progress*	**YES / NO** ☐ ☐ Are the CEO and leadership team able to clearly communicate the vision to all parties, in both internal and external interactions? ☐ ☐ Can all members of the organization articulate the vision for safety and how it relates to their individual work? ☐ ☐ Is a patient safety and quality dashboard (which includes safety culture metrics) utilized and regularly reviewed in the context of organizational vision?	

Trust, Respect, and Inclusion

Value Trust, Respect, and Inclusion

GOAL: ESTABLISH ORGANIZATIONAL BEHAVIORS THAT LEAD TO TRUST IN LEADERSHIP AND RESPECT AND INCLUSION THROUGHOUT THE ORGANIZATION REGARDLESS OF RANK, ROLE, OR DISCIPLINE.

Trust, respect for others, and inclusion are essential to creating environments that are both physically and psychologically safe. Building trust involves managing conflict and making the environment safe for communicating bad news. It also involves practicing honesty, inclusion, transparency, and respect with everyone. Each member of the workforce must feel compelled and empowered to uphold mutual accountability and speak up for safety. Healthcare leaders develop trust within their organizations by having authentic relationships and conversations. For example, undertaking humble inquiry, asking questions to which you do not already know the answer, and building relationships based on genuine curiosity and interest all help leaders find information that might otherwise elude them (Schein 2013).

	Foundational	Sustaining
Strategies *Overarching strategies for implementation at the CEO level*	✓ CEO recognizes the critical importance of trust, respect, and inclusion in shaping organizational culture ✓ CEO creates expectation for trust, respect, and inclusion, and models these through his or her interactions with every individual at every level of the organization ✓ CEO holds the leadership team accountable for modeling trust, respect and inclusion ✓ CEO directs policies that empower the workforce to first and foremost act within the guidelines of trust, respect, and inclusion when making decisions ✓ CEO establishes the expectation that learning from failures and improving systems is a part of daily organizational activity	✓ CEO establishes expectations and accountability for formal program focusing on trust, respect, and inclusion that includes patients and is implemented across the organization ✓ CEO and organization have clear, visible expectations of acceptable behavior and consequences for behaviors that do not meet standards of trust, respect, and/or inclusion ✓ CEO establishes transparent practices with the Board, senior leadership, workforce and community, as appropriate ✓ CEO takes ownership of partnering with similar organizations, through Patent Safety Organizations (PSOs) or other collaboratives, to share learning and best practices

Trust, Respect, and Inclusion

Value Trust, Respect, and Inclusion

The actions of leaders must be consistent over time and throughout the organization. Behavioral standards and expectations should apply to everyone, without exception. Respect for others—be they patients, family members, peers, or subordinates—is essential for creating and sustaining trust. Developing and holding all leaders and the workforce accountable to codes of conduct or code of ethics can help to solidify the practices and behaviors that encourage trust and respect (Chassin and Loeb 2013).

Beyond modeling behaviors of respect themselves, leaders may need to institute ongoing education for volunteers, students, clinicians, and the workforce about appropriate behavior, and continue to actively encourage changes designed to increase fairness, transparency, collaboration, inclusion, and individual responsibility (Leape et al., 2012).

In pursuing safety as a core value, trust, respect, and inclusion are fostered by CEOs who make and keep commitments to the workforce, who communicate when a problem cannot be fixed immediately, who consistently display a sense of fairness, and who engage in and encourage reciprocal, helping behavior throughout the organization.

CEOs must also display their trust in others. Creating a strong team enables leaders to have confidence in delegating decisions and authority, though trust does not mean believing nothing will ever go wrong. Leaders can expect to continually work on building, sustaining, or repairing trust.

Cultural Diversity and Respect in the Workplace

It is imperative that CEOs understand the cultural makeup of both the community and the organization in which they serve. Implementing and modeling behaviors that reflect a respectful and inclusive environment is essential to a culture of safety. This should include placing a high value on the positive impact of greater diversity and inclusion among leadership as well as the workforce. It should also include efforts to evaluate and eliminate disparities in patient care. Unleashing the potential of workforce diversity depends on the establishment of inclusion, the building of trust and respect, and training in skills and behaviors that support an inclusive and respectful organization. With this approach, cultural diversity can be an effective resource for creative problem solving and organizational learning, and can help to identify and ameliorate disparities of care. (EU-OSHA 2013)

Trust, Respect, and Inclusion

Value Trust, Respect, and Inclusion

Trust, respect, and inclusion are the foundation of a culture of safety. The CEO develops trust and respect with individuals at all levels of the organization, and, with the Board, holds leaders, clinicians, and the workforce accountable for policies and behaviors that reflect these values.

Provide education and training on respect, diversity, and inclusion

Encourage, recognize, and reward reporting

Develop and share patient and provider compacts

Implement workforce safety programs, addressing both physical and psychological safety

Implement communication and resolution programs

Participate in full transparency with the public around harm events and action plans for improvement

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization:** ✓ Commit to implementing and holding all leaders and the work force accountable for processes and policies related to respect for people, just culture, and managing disruptive behavior ✓ Encourage and promote open discussion of safety issues via leadership rounds and reporting systems, and ensure follow-up and feedback ✓ Ensure that the workforce has dedicated time to devote to patient safety and safety culture work ✓ Implement workforce safety programs to reduce physical and psychological harm to the workforce ✓ Clearly define and encourage behaviors that show deference to expertise rather than hierarchy or title	**To engage your organization:** ✓ Aim for total transparency, but explain situations in which the organization is unable to be completely transparent ✓ Publicly share available information about events of harm, and plans for managing associated risks ✓ Ensure follow-up and feedback on identified safety issues, and be transparent if an issue cannot be resolved promptly ✓ Create compacts for leaders that clearly define expected behaviors in trust and transparency as they relate to other leaders, peers, and subordinates ✓ Build metrics for respect and trust (e.g., workforce psychological safety, error reporting) into the evaluation process for all leaders

Trust, Respect, and Inclusion

Value Trust, Respect, and Inclusion

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization (cont):** ✓ Recognize and reward reporting with the goal of reducing and eventually eliminating anonymous reporting ✓ Provide education and training on diversity and inclusion at every level of the organization ✓ Track employee engagement and turnover as a metric to evaluate trust, inclusion, and respect ✓ Include care disparity metrics on regularly reviewed patient safety dashboards ✓ Translate tools and resources for both patients and the workforce into a variety of languages, keeping in mind cultural context and linguistic idiosyncrasies ✓ Adopt communication and resolution/reconciliation programs for patients and families after events of preventable harm ✓ Establish patient and family advisory councils	**To engage clinical leaders:** ✓ Provide training for physicians, nurses, and other clinical leaders around patient engagement and communication ✓ Provide cultural competency training for all clinical leaders that is relevant to the patient populations they serve **To engage patients and families:** ✓ Encourage and enable patients and families to speak up if they notice a risk to safety ✓ Ensure that crisis plans address how to communicate with patients and families in the event of an error, regardless of degree of harm ✓ Commit to shared decision making and consider patient preferences in all treatment plans ✓ Engage patients and families in creating and disseminating patient compacts that include what patients can expect from the organization, their care providers, and the workforce
Assessing Execution *List of questions that should be asked to further assess and measure progress*	**YES / NO** ☐ ☐ Are all clinicians and workforce members provided with training in communicating with patients, including disclosure and apology? ☐ ☐ Are measures of respect included in all performance assessment tools? ☐ ☐ Is a formal program for respect and trust in place and evaluated regularly? ☐ ☐ Is there systematic training on diversity and inclusion for both the clinical and non-clinical workforce? ☐ ☐ Do the Board and leadership team regularly create and evaluate improvement plans for addressing disparities in patient care?	

Board Engagement

Select, Develop, and Engage Your Board

GOAL: SELECT AND DEVELOP YOUR BOARD SO THAT IT HAS CLEAR COMPETENCIES, FOCUS, AND ACCOUNTABILITY REGARDING SAFETY CULTURE.

Boards of healthcare organizations oversee the fiduciary performance, reputation, and key performance outcomes of an organization, including those related to quality, safety, and culture. The accountability for safety is shared between the CEO and the Board. The CEO is responsible for guaranteeing Board education on the importance of safety, ensuring that the Board understands quality and safety metrics, and recommending the appropriate representation of safety expertise on the Board, which could mean a safety expert from another field. In line with the CEO's responsibilities, the Board is responsible for making sure the correct oversight is in place, that quality and safety data are systematically reviewed, and that safety receives appropriate attention as a standing agenda item at all meetings. It is imperative that safety be a foundational factor in how healthcare Boards make decisions, so that patient and workforce safety culture is a sustainable focus for the organization.

	Foundational	Sustaining
Strategies *Overarching strategies for implementation at the CEO level*	✓ CEO guarantees Board education on importance of safety, the meaning of quality and safety metrics, and safety culture principles and behaviors ✓ CEO ensures Board membership includes clinical, safety, and patient/family representation ✓ CEO provides adequate agenda time for review and discussion of safety culture metrics and issues ✓ CEO sets up quality and safety committee(s) with Board representation ✓ CEO ensures each Board agenda includes time designated for Chief Medical Officer or Chair of Quality and Safety Committee to present safety and quality data ✓ CEO develops a robust Board-level patient and workforce safety dashboard that includes culture of safety metrics	✓ CEO works with the Board to set direction, goals, metrics, and systems of mutual accountability for zero harm to both patients and the workforce ✓ CEO provides for the appropriate level of oversight of the credentialing and re-credentialing process, including elements of quality and safety ✓ CEO works with the Board and/or compensation committee to align executive compensation with patient and workforce safety and culture metrics ✓ CEO leverages patient stories and presentations to educate the Board ✓ CEO provides opportunities for Board member representation on appropriate safety committees

Board Engagement

Select, Develop, and Engage Your Board

In recruiting new Board members, considerable thought should be given to the competencies, skills, experiences, and diversity needed to create and sustain a culture of safety. These skills may include specific competencies related to leading culture improvement efforts, as well as clinical and safety competencies. Ensuring that there is robust clinical expertise in the Board room is critical to incorporating frontline perspective into all conversations and initiatives, and allows for collaborative leadership in safety efforts throughout the organization (Goeshel et al. 2010). These decisions should also include measures of diversity that ensure the board is representative of the community and workforce it serves. Finally, leaders may encourage Boards or relevant committees to include a patient and family representative and safety experts from relevant industries. These recommendations should be made at the appropriate level based on each unique organization's needs.

A well-rounded and diverse Board empowers and supports the work of the CEO in creating and sustaining a culture of safety. The importance of Board education and training in safety science fundamentals, including just culture, human factors, and systems engineering cannot be overemphasized (NPSF 2015). There is real power in support for the CEO from the Board regarding issues of safety, allowing this focus to cascade to leadership and, ultimately, throughout all levels of the organization.

Effective Patient and Family Representation on Boards and Committees:

CEOs should consider the following characteristics of effective representation, while keeping in mind the appropriate voice and level of representation of patient/family member(s) to meet the needs of their organization and community:

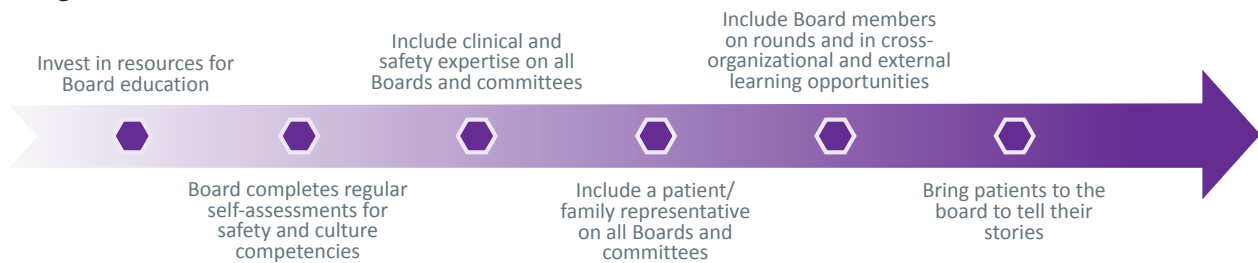1. Culture of the Board encourages total engagement and involvement of patient/family member(s)

2. Patient/family member(s) are representative of the community the organization serves

3. Patient/family member(s) have representation on quality and safety committee(s) and other committees, as appropriate

4. Patient/family representative is provided with ongoing learning opportunities in safety science and safety culture

Board Engagement

Select, Develop, and Engage Your Board

An engaged Board plays a key role in organizational culture and safety. The CEO encourages Board competencies and commitment regarding safety, while providing a transparent line of sight between the Board and the rest of the organization.

Invest in resources for Board education

Include clinical and safety expertise on all Boards and committees

Include Board members on rounds and in cross-organizational and external learning opportunities

Board completes regular self-assessments for safety and culture competencies

Include a patient/family representative on all Boards and committees

Bring patients to the board to tell their stories

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization:** ✓ Establish Board Quality and Safety Committee with oversight responsibility for culture change, safety, and performance improvement ✓ Include an individual with safety and culture expertise on Board and appropriate committees, or ensure an advisor with these skills is available to the CEO and the Board ✓ Begin each Board meeting with a slide detailing the number and names of patients and staff who experienced harm since last meeting, and include a story about at least one of these individuals ✓ Regularly share and discuss a dashboard that includes patient and workforce safety and culture metrics ✓ Utilize a Board self-assessment that includes inquiry on safety culture knowledge to determine educational opportunities ✓ Identify a list of required Board competencies specific to leading culture improvement	**To engage your organization:** ✓ Encourage the Board to link executive compensation to safety outcomes, while ensuring metrics chosen do not discourage safety efforts ✓ Include Board members on guided leadership rounds ✓ Align Board dashboards to show safety and quality metrics as segmented by categories related to disparities in care ✓ Ask Board members to participate in events to show their support during Patient Safety Awareness Week and to be present at major quality, safety, and culture-related events ✓ Bring frontline teams to Board meetings to share their success stories and receive recognition ✓ Consider a rotating position on the Board or Quality and Safety Committee reserved for the frontline workforce ✓ Request that Board members spend time on all floors and units communicating and supporting the safety agenda

Board Engagement

Select, Develop, and Engage Your Board

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization (cont):** ✓ Discuss whether Board reflects the community your organization serves and implement action plan to address any gaps ✓ Invest in resources for Board education, including patient safety science and quality ✓ Create a matrix of Board competency needs and seek candidates with those skills in mind ✓ Regularly review accreditation survey results with the Board ✓ Encourage ample clinical expertise, including physicians and nurses on the Board and/or on Board committees ✓ Include a presentation on a current organizational safety culture issue by an expert in safety and quality at each Board meeting ✓ Educate Board members on issues of disparities in care	**To engage your organization (cont):** ✓ Provide Board members with opportunities to learn from Boards and leaders of outside organizations and industries ✓ Require Board approval on resolutions to all serious safety events **To engage clinical leaders:** ✓ Involve physicians, nurses, and other clinical leaders to present clinical and quality improvement efforts regularly to the Board ✓ Bring clinical leaders dedicated to culture to Board meetings to share their experience and receive recognition **To engage patients and families:** ✓ Create positions for patient/family representatives on your Board and on your quality/safety committee(s) ✓ Present patient stories at Board and appropriate committee meetings ✓ Invite patients to attend Board meetings and personally share their stories and experiences (both positive and negative)

Assessing Execution

List of questions that should be asked to further assess and measure progress

YES / NO

- ☐ ☐ Does the Board conduct regular self-assessments related to knowledge and understanding of culture of safety?
- ☐ ☐ Are programs in place to build competencies in culture improvement for Board members?
- ☐ ☐ Is the amount of time spent on quality and safety during each Board meeting tracked and at least comparable to time spent on finance and other items?
- ☐ ☐ Do performance assessments for the CEO include the organization's safety activities and measures of culture?
- ☐ ☐ Do patient safety and quality leaders participate in at least a portion of all Board meetings?
- ☐ ☐ Is a patient and/or workforce story presented at each Board meeting?

Leadership Development

Prioritize Safety in Selection and Development of Leaders

GOAL: EDUCATE AND DEVELOP LEADERS AT ALL LEVELS OF THE ORGANIZATION WHO EMBODY ORGANIZATIONAL PRINCIPLES AND VALUES OF SAFETY CULTURE.

Healthcare CEOs, in collaboration with the Board, are responsible for establishing the direction and accountability for the design and delivery of their organization-wide leadership development strategy. Within this strategy, it is imperative that safety is part of the education for both current and emerging leaders. It is the responsibility of the CEO to establish the priority for safety and culture in the development of leaders at all levels and in all departments across the organization.

Emphasis on safety education can also help close the gap between administrative and clinical leadership, providing all leaders with the shared goal of driving toward a culture of safety for the betterment of the organization and the patients they serve. Identifying and developing physician, nursing, and other clinical leaders as champions for safety is a key responsibility of the CEO. Numerous studies indicate the positive impact clinical leaders can have on culture and safety, particularly in an era when healthcare leaders are often in a position to make decisions that affect care at the frontlines. Clinical leaders have extensive understanding of healthcare's "core business" of patient care, and are therefore in a unique position to connect administration with the clinical workforce, and to garner support for safety and culture initiatives. In addition to safety education, CEOs can commit to developing effective physician, nursing, and other clinical leaders by providing and encouraging training in non-clinical skills, including professionalism, emotional intelligence, team building and communication, and basic business principles (Angood 2014).

	Foundational	**Sustaining**
Strategies *Overarching strategies for implementation at the CEO level*	✓ CEO sets expectations and accountability for the design and delivery of the organization's leadership development strategy ✓ CEO ensures he/she and the leadership team receive necessary safety education, and provides the appropriate level of safety education throughout the rest of the organization ✓ CEO identifies physicians, nurses, and other clinical leaders as champions for safety	✓ CEO serves as a mentor for other C-Suite executives ✓ CEO establishes expectation that quality and safety performance and competence are required elements for evaluating current and potential leaders for promotion and succession planning ✓ CEO assigns accountability for measurable outcomes of safety education as part of leadership development strategy ✓ CEO ensures patient and workforce safety are key parts of the organization's reward and recognition system

Leadership Development

Prioritize Safety in Selection and Development of Leaders

The selection process for both current and emerging leaders should be predicated on their understanding of, dedication to, and alignment with the organization's vision for patient and workforce safety, communication skills, and modeling of expected safety behaviors. Safety can be a topic for individual professional development as well as organization-wide succession planning to ensure that the commitment to safety is sustainable throughout all levels and functional areas. Many organizations already have a process in place for identifying individuals with high potential to succeed as leaders, into which a safety and culture program can be integrated (Garman and Anderson 2014).

Finally, it is critically important to provide regular feedback to both current and developing leaders that is valuable to them, whether that is a 360-degree review model or another structured review (Garman and Anderson 2014). Feedback should clearly define, communicate, and embody required leadership competencies in safety culture, and safety development plans should be reviewed at regularly scheduled check-ins. CEOs are responsible for not only setting this direction, but also participating in these reviews from the perspective of gathering feedback about their own competence in safety culture and behaviors, and sharing input for members of their leadership team.

A well-developed leadership team that is dedicated to a culture of safety provides a catalyst for the evolution of the organization. The CEO, in collaboration with the Board, is responsible for establishing the direction and accountability for the design and delivery of an organization-wide leadership development strategy.

Define organizational leadership competencies

Provide continuing education opportunities in safety science and culture

Provide opportunities for cross-departmental training

Define processes for leadership development at all levels

Develop systems for training, coaching, and mentoring current and prospective leaders

Provide opportunities for learning from outside organizations and industries

Leadership Development

Prioritize Safety in Selection and Development of Leaders

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization:** ✓ Define and develop organizational leadership competencies in safety culture and safety behaviors and ensure that all current and future leaders and the frontline workforce receive education in selected competencies ✓ Define cultural roles and expectations for all leaders within the organization, including clinical leaders ✓ Create systems to support leaders in culture work at all levels of the organization through training, coaching, and mentoring ✓ Consider safety expertise and credentialing along with leadership potential when considering emerging leaders ✓ Discuss whether leadership team reflects the community the organization serves and develop plan to address any gaps ✓ Create systems that ensure regular reporting on leadership development measures ✓ Develop and employ a talent review process that is candid and transparent ✓ Conduct gap analysis of CEO and leadership for knowledge, skills, and attitudes around patient safety and culture	**To engage your organization:** ✓ Build an incentive program into leadership reviews that is focused on reporting performance on key culture of safety metrics ✓ Provide continuing learning opportunities in safety and culture, with a focus on experiential learning ✓ Tie measures and performance on safety and culture to leadership development priorities, talent management reviews, and succession planning ✓ Provide opportunities and expectations for leaders to learn outside of the organization, both with similar organizations and outside industries ✓ Build a guiding coalition of champions, including clinicians and frontline workforce members, that provides candid and honest feedback to the CEO ✓ Incorporate leadership development into organizational people strategy ✓ Define talent as an organizational resource and allow for interdepartmental training and mobility ✓ Ensure leaders are trained to teach and coach their employees ✓ Recommend that each senior executive participate in communication and apology to patients and families who have experienced harm

Leadership Development

Prioritize Safety in Selection and Development of Leaders

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization (cont):** ✓ Ensure all executives can clearly articulate how a culture of safety applies in their department, and that all leaders can do the same ✓ Develop systems that encourage deference to expertise rather than hierarchy or title in issues of safety	**To engage clinical leadership:** ✓ In leadership development programs, incorporate opportunities for clinical leader advancement **To engage patients and families:** ✓ Ensure leaders have competencies in how to partner effectively with patients at all levels of care ✓ Include patient and family representatives in leadership recruitment and hiring process
Assessing Execution *List of questions that should be asked to further assess and measure progress*	**YES / NO** ☐ ☐ Do all leaders receive training in patient safety science and safety culture? ☐ ☐ Is at least one member of the executive leadership team a Certified Professional in Patient Safety or a safety expert? ☐ ☐ Are leadership development plans reviewed annually? Do they include measures of key safety culture competencies? ☐ ☐ Do leadership development programs include cultivation of a robust skill set in communication, engagement, listening, performance improvement, and emotional intelligence, as well as business acumen?	

Just Culture

Lead and Reward a Just Culture

GOAL: BUILD A CULTURE IN WHICH ALL LEADERS AND THE WORKFORCE UNDERSTAND BASIC PRINCIPLES OF PATIENT SAFETY SCIENCE, AND RECOGNIZE ONE SET OF DEFINED AND ENFORCED BEHAVIORAL STANDARDS FOR ALL INDIVIDUALS IN THE ORGANIZATION.

Healthcare organizations that are successful in improving safety and eliminating harm have leaders who understand and commit to the principles of just culture. A just culture "focuses on identifying and addressing systems issues that lead individuals to engage in unsafe behaviors, while maintaining individual accountability by establishing zero tolerance for reckless behavior. Just organizations focus on identifying and correcting system imperfections, and pinpoint these defects as the most common cause of adverse events. Just culture distinguishes between human error (e.g., slips), at-risk behavior (e.g., taking shortcuts), and reckless behavior (e.g., ignoring required safety steps), in contrast to an overarching 'no-blame' approach" (PSNet Safety Primer 2016).

	Foundational	**Sustaining**
Strategies *Overarching strategies for implementation at the CEO level*	✓ CEO encourages commitment to just culture framework as an essential business philosophy ✓ CEO communicates and models the use of just culture principles in all decisions and actions as part of daily responsibilities and interactions, including root cause analysis ✓ CEO educates Board and leadership team on principles of just culture and role models these principles	✓ CEO employs just culture principles throughout organization and communicates that rules apply to all, regardless of rank, role and discipline ✓ CEO sets expectations for accountability for anyone interacting with the healthcare organization to commit to utilizing just culture principles in every day practice and decisions ✓ CEO ensures just culture principles are implemented in all interactions

A just culture is not a blame-free environment; clinicians and the workforce are still held accountable for following protocols and procedures. The vast majority of errors are not a result of individual failures, but are the result of systems that are inherently flawed and create environments of risk. A just culture acknowledges that punishing people for mistakes discourages reporting, fails to correct problems in the system, and sets up the likelihood of recurrence. Just culture also emphasizes the importance of the affected workforce after events occur, and focuses on support and peer-to-peer counseling for affected clinicians and the workforce.

When clearly defined, articulated, and implemented by leadership, a just culture approach encourages the reporting of errors, lapses, near-misses, and adverse events. It is through reporting and event analysis that the organization learns what went wrong, or could have gone wrong, and how to prevent it from happening again.

Just Culture

Lead and Reward a Just Culture

The hard work of establishing a just culture, however, goes well beyond agreeing to the concept itself. It involves incorporation of expertise in human factors engineering and systems design, full support and resources from the CEO and all leadership, and full engagement of departments such as Human Resources and Organizational Development. It also requires robust reporting systems with mechanisms in place to provide timely feedback to the workforce about not only what went wrong, but why it went wrong. This feedback also includes strong action plans to prevent future occurrence. Developing a just culture policy is just the first step, and organization-wide, systemic implementation is key.

While training of leaders and the patient safety workforce on just culture is vital, everyone at all levels of the organization must consistently integrate just culture principles as an organizational norm. The CEO's role in ensuring that just culture principles are understood and implemented across the organization is fundamental to success. If one individual within the organization is punished for a system flaw, just culture efforts can be severely undermined. Leaders must be transparent with the Board, physicians, the workforce, and the public about the organization's approach, so that when something does go wrong, the response is expected, practiced, and applied uniformly throughout the organization.

Just Culture Principles

Human behaviors within a just culture can be described as follows:

⬡ **HUMAN ERROR =** An inadvertent slip or lapse. Human error is expected, so systems should be designed to help people do the right thing and avoid doing the wrong thing.

   Response: Support the person who made the error. Investigate how the system can be altered to prevent the error from happening again.

⬡ **AT-RISK BEHAVIOR =** Consciously choosing an action without realizing the level of risk of an unintended outcome.

   Response: Counsel the person as to why the behavior is risky; investigate the reasons they chose this behavior, and enact system improvements if necessary.

⬡ **RECKLESS BEHAVIOR (NEGLIGENCE) =** Choosing an action with knowledge and conscious disregard of the risk of harm.

   Response: Disciplinary action.

(PSNet Safety Primer 2016)

Just Culture

Lead and Reward a Just Culture

A just culture that focuses on identification and resolution of systems issues supports clinicians and the workforce when these systems break down. CEOs ensure that the principles of a just culture are implemented organization-wide and that they inform every action and decision.

Develop just culture policy and align across systems and departments

Utilize just culture principles in all event reviews and decisions

Treat gaps in culture as adverse events

Educate Board, leadership, and workforce

Develop metrics for just culture and hold workforce accountable

Involve the media to explain errors, data, and decisions to the public

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization:** ✓ Educate Board, leadership, and workforce about just culture through integrated training programs ✓ Develop and implement a decision-making process and application of just culture that is behavior-based, rather than harm-based ✓ Ensure organization-wide leadership commitment to frameworks of just culture and accountability that are aligned across all departments ✓ Create an interdisciplinary just culture champion team to review organizational policies, provide training, and ensure policies are being followed at all levels ✓ Identify metrics to track performance on just culture implementation	**To engage your organization:** ✓ Educate organization to be responsive to and transparent about actions related to professional discipline ✓ Implement a peer support program ✓ Hold workforce accountable for implementing just culture principles in daily practice and decision-making ✓ Include actual and mock scenarios on meeting agendas that demonstrate application of just culture principles ✓ Involve the media as a way to explain errors, decisions, and data to the public ✓ Treat and respond to gaps in culture and expected safety behaviors as adverse events ✓ Expect that leaders utilize just culture tools in all situations, even those not significant or punishable, to ingrain principles and use into organizational norms

Just Culture

Lead and Reward a Just Culture

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization (cont):** ✓ Align systems and standards for just culture across all organizational departments, including Human Resources ✓ Ensure employees are well-trained in just culture algorithm and tools and utilize them in daily activities and decisions ✓ Publicly reward positive examples of just culture	**To engage clinical leadership:** ✓ Include clinical leaders in the development of just culture policies ✓ Provide training for physicians, nurses, and other clinical leaders in just culture to build understanding and enthusiasm **To engage patients and families:** ✓ Ensure that patients and family members who serve on Board and committees are educated on just culture principles ✓ Include patients and families in mediation committees/tribunals to assist in resolving conflicts between departments
Assessing Execution *List of questions that should be asked to further assess and measure progress*	**YES / NO** ☐ ☐ Do Board, leadership, and workforce development programs include training on just culture? ☐ ☐ Is there one set of defined behavioral standards for all individuals within the organization, including leadership, physicians, and the workforce? ☐ ☐ Is compliance with the established just culture framework part of regularly reviewed performance reviews, including career development plans, for leaders and the workforce? ☐ ☐ Does the organization use, evaluate, and define action plans related to measures of just culture on employee surveys? ☐ ☐ Is there an existing measure that is regularly evaluated for assessing frontline knowledge of just culture algorithm?	

Behavior Expectations

Establish Organizational Behavior Expectations

GOAL: CREATE ONE SET OF BEHAVIOR EXPECTATIONS THAT APPLY TO EVERY INDIVIDUAL IN THE ORGANIZATION AND ENCOMPASS THE MISSION, VISION, AND VALUES OF THE ORGANIZATION.

Much of the work involved in creating a culture of safety in healthcare is intrinsically linked to the everyday behaviors that characterize an organization (PSNet Patient Safety Primer: Safety Culture 2016). In fact, culture is often defined as "the way we do things around here." CEOs set the tone and have the power and responsibility to establish behaviors, set expectations, and promote accountability for these behavioral norms for everyone, including both employed and non-employed individuals. It is essential for Board members, the CEO, and leaders at every level to model the behaviors they aim to cultivate throughout the organization.

Strategies *Overarching strategies for implementation at the CEO level*	**Foundational**	**Sustaining**
	✓ CEO creates, communicates, and models an organizational climate of personal and professional accountability for behavior	✓ CEO prioritizes resources for professional accountability framework and programs to ensure and sustain behavioral excellence
	✓ CEO establishes systems to recognize and reward desirable behaviors	✓ CEO ensures that succession planning and talent management programs prepare future leaders with competencies in organizational behavior and accountability
	✓ CEO activates organization to develop, implement, and evaluate programs that address and improve personal, professional, and organizational behavior and accountability	✓ CEO works with licensing bodies and medical executive committees, where applicable, to ensure behavioral expectations and accountability practices are consistent
	✓ CEO engages Board by sharing metrics and dashboards related to organizational behavior	✓ CEO and leaders at all levels of the organization encourage questions, increasing the likelihood that the right question will be asked at a critical time
	✓ CEO engages and holds all leaders and workforce accountable for defined behaviors	

Behavior Expectations

Establish Organizational Behavior Expectations

Chief among the behaviors that contribute to an environment of physical and psychological safety are transparency, effective teamwork, active communication, just culture, respect, and direct and timely feedback. Each of these can be learned, and the workforce should be educated about what is expected and why. For example, educating health professionals in effective communication with patients and families, whether disclosing an error, seeking informed consent, or practicing shared decision making, is a key part of cultivating teamwork, communication, and respect.

One of the first responsibilities of a CEO is to understand the current accepted behaviors within the organization. One way to achieve this understanding is through use of validated surveys of patient safety culture, which can help identify areas of strength as well as areas for improvement at organizational, departmental, and unit levels. Surveys can also reveal the strength or weaknesses of organizational culture and "subcultures," and provide leaders a better sense of where they may need to focus attention. In this manner, leaders are able to better connect with the frontline workforce on a regular basis, whether through leadership rounding, safety huddles, briefings/ debriefings, or other tactics, so they can hear about challenges firsthand. A Board, leadership, physician and other clinical professional, and workforce "credo" or compact also helps to communicate behavioral expectations. Such a compact can frame discussions and maintain accountability when someone violates the standard behavioral code (Webb et al. 2016).

It is also important to have a mechanism for escalating concerns when behavioral codes are violated and for dealing with disruptive and unsafe behaviors. Everyone within the organization should understand what that procedure is, and that it will be applied consistently across the organization, regardless of rank, department, revenue, or other considerations. It is essential to remember that the process of changing behavioral norms across an organization or system can be a long and challenging one. That is why it is equally important to ensure that there is also a system to reward individuals who are identified as modeling desired behavior. True progress can be accomplished with the dedication of a highly engaged, unwavering, and courageous CEO.

Importance of Physical and Psychological Safety of the Workforce

An environment that protects the physical and psychological safety of the workforce is fundamental to a culture of safety. Yet many healthcare workers suffer from harm, including bullying, burnout, and physical injury and assault, during the course of providing care. Under these conditions, it is difficult for care providers to find joy and purpose in their work, and patient safety is jeopardized. The prioritization of safety behaviors including respect, transparency, and teamwork is at the foundation of safety for the workforce, and therefore for patients. The workforce needs to know that their safety is an enduring, non-negotiable priority for the CEO and Board. This commitment is demonstrated when action plans are developed and implemented to ensure the workforce feels valued, safe from harm, and part of the solution for change (NPSF LLI 2013).

Behavior Expectations

Establish Organizational Behavior Expectations

Organizational safety behavior expectations are the daily demonstration of a true culture of safety. CEOs work with leaders and the workforce to develop these expectations and to personally demonstrate expected behaviors, while holding the leadership team accountable for doing the same.

Define organization-wide required processes and expected behaviors

Encourage open reporting and safety discussions and provide transparent feedback

Recognize and reward workforce engaging in defined safety behaviors

Define organizational response to disrespectful or disruptive behavior

Hold all leaders and workforce accountable for organization-wide expected behaviors

Engage patients in all team activities and communication processes

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization:** ✓ Complete culture of safety surveys every 12-18 months and review with Board, leadership team, and workforce; set targets for improvement and take deliberate action to achieve them ✓ Stratify and track culture and safety metrics by sociodemographic variables that are important to the organization's community and develop plans to address any gaps ✓ Develop required processes for teamwork, communication, and handoffs among the workforce and with patients, using tools like SBAR, read back, "stop the line," briefings, and de-briefings ✓ Require, participate in, and give context for existing safety processes, including safety huddles and operational briefings, and use these opportunities as forums to build better teamwork and safety culture	**To engage your organization:** ✓ Require annual signatures on compacts for Board members, leaders, and the workforce that clearly define expected professional accountability behaviors ✓ Educate and explain to your organization and the public what you will be transparent about, and what limits may exist on transparency ✓ Design and implement a crisis communications policy and plan for both internal and external audiences ✓ Align and integrate organizational safety and respectful behaviors with all departments across the organization ✓ Provide feedback to employees when they report a safety issue, closing the loop and demonstrating how frontline callouts improve safety ✓ Recognize and reward individuals and teams for demonstrating positive safety behaviors and reporting

Behavior Expectations

Establish Organizational Behavior Expectations

Organizational Readiness Level	Foundational	Sustaining
Tactics *Examples of tactics that may be implemented to create change at each of these levels*	**To engage your organization (cont):** ✓ Define organizational safety behavior expectations and respectful behaviors, as well as the organizational response to disrespectful behavior and conflict ✓ Proactively promote and encourage teamwork by implementing a formal team training program ✓ Break down hierarchical policies and systems for reporting, and encourage reporting without fear of punishment or retribution ✓ Break down power gradients by communicating and rewarding a policy that requires all staff to speak up for safety concerns ✓ Develop and abide by leadership behaviors, including appreciative or humble inquiry ✓ Celebrate and recognize individuals and teams who excel at key safety behaviors ✓ Work with key stakeholders to clearly communicate and enforce the same behavioral standards for both employed and non-employed practitioners and staff	**To engage your organization (cont):** ✓ Ensure the existence of measurement tools and/or report cards for individual performance ✓ CEO requires and accepts notification of any serious safety events within 24 hours, without exception ✓ SBAR for all serious safety events is shared with full administrative and clinical leadership teams and with the Board ✓ Leadership distributes awards for teams and organizations based on culture of safety metrics **To engage clinical leaders:** ✓ Recognize and reward physicians, nurses, and other clinical leaders who actively participate in teamwork and communication initiatives ✓ Create (and require signatures on) physician and leadership compacts that clearly define behavioral expectations ✓ Commit to and train the workforce on communication and resolution programs **To engage patients and families:** ✓ Include patients in the development of required processes for communication with patients, using tools like AskMe3® and shared decision making ✓ Encourage and enable patients and families to report safety concerns, and follow up with families who have reported ✓ Ensure that safety behavior expectations are centered around the patient, and involve patients in setting these expectations ✓ Create, supply, and use understandable tools for patient involvement and shared decision making ✓ Invite patients to utilize versions of communication and reporting tools (e.g., SBAR) and to participate in team processes ✓ Have a designated team available to provide support to patients, families, and the workforce when an error has occurred

Behavior Expectations

Establish Organizational Behavior Expectations

Organizational Readiness Level	Foundational	Sustaining
Assessing Execution *List of questions that should be asked to further assess and measure progress*	**YES / NO** ☐ ☐ Does the organization have a clearly defined reporting system and measure utilization of this system (including follow-up and feedback processes)? ☐ ☐ Are organizational behavior expectations, such as use of huddles and briefings, with follow-up plans and identified owners of action items, implemented and reviewed regularly? ☐ ☐ Are professional accountability standards (e.g., a process to address disruptive behaviors) in place, used, and regularly evaluated? ☐ ☐ Are specific tools to encourage teamwork and clear communication in place, used, and regularly evaluated? ☐ ☐ Are communication and resolution/reconciliation programs in place, utilized, and regularly evaluated?	

Appendix

Key Terms Related to Patient Safety and a Culture of Safety

Based on AHRQ PSNet Glossary [nd], Runciman et al. 2009, and others as noted.

Adverse Event: Any injury caused by medical care. An undesirable clinical outcome that has resulted from some aspect of diagnosis or therapy, not an underlying disease process. Preventable adverse events are the subset that are caused by error.

Clinician: A health professional qualified in the clinical practice of medicine, such as a physician, nurse, pharmacist, or psychologist who is directly involved in patient care, as distinguished from one specializing in laboratory or research techniques or in theory.

Error: An act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome.

Harm: An impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability, and death. Harm may be physical, social, or psychological, and either temporary or permanent.

Inclusion: Positively striving to meet the needs of different people and taking deliberate action to create environments where everyone feels respected and able to achieve their full potential (National Institute for Health Research 2012).

Just Culture: A culture that recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A just culture also recognizes that many individual or "active" errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts "no blame" as its governing principle, a just culture does not tolerate blameworthy behavior such as conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated).

Patient Safety: Patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events.

Psychological Safety: Individuals' perceptions about the consequences of interpersonal risks in their work environment. These perceptions include taken-for-granted beliefs about acceptable interactions with co-workers, superiors, and subordinates, and how others will respond when one puts oneself on the line, such as by asking a question, seeking feedback, reporting a mistake, or proposing a new idea (Edmondson 2011).

Respect: The treatment of others with deference in daily interactions, weighing their values, views, opinions and preferences (Sergen's Medical Dictionary 2012).

Safety Culture/Culture of Safety: The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the characteristics of the organization's health and safety management. Organizations with a positive safety culture are characterized by communications based on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures (Health and Safety Commission 1993).

Total Systems Safety: Safety that is systematic and uniformly applied (across the total process) (Pronovost et al. 2013). A systems approach can help with the design and integration of people, processes, policies, and organizations to promote better health at lower cost.

Trust: The collective expectations by the public and other clinicians that health care providers will demonstrate knowledge, skill, and competence, and will act in the best interest of both patients and colleagues with beneficence, fairness, and integrity (Calnan 2008).

Workforce: Health professionals and all other workers employed in health service or other settings, including but not limited to clinicians, administrators, medical records personnel, and laboratory assistants.

Workforce Safety: Healthcare workforce safety refers to freedom from both physical and psychological harm for all those who work with patients as well as those who oversee or provide non-clinical support for those who work with patients.

Zero Harm/Free from Harm: The total absence of physical and psychological injury to patients and the workforce.

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Self-Assessment Tool

Culture of Safety Organizational Self-Assessment

Please Note: *The questions in this self-assessment represent a selection of elements from the report, "Leading a Culture of Safety: A Blueprint for Success." This brief assessment may not accurately represent the full environment or state of each organization. It is recommended that teams review all strategies, tactics, and information in the full document for additional clarity and guidance.*

Instructions:

1 **Select** a diverse team to lead the safety culture review and improvement process. It is recommended that this team include key C-Suite executives, clinical leadership, patient safety leadership, and a patient and family representative.

2 **Share** the guide, *Leading a Culture of Safety: A Blueprint for Success* with your team. Review the full document as a team or independently.

3 **Ask** each team member to complete this self-assessment independently. Conduct a series of meetings to:

A) Review self-assessment responses and scoring for each category as a team, and finalize your organizational score.

B) Develop action plans, metrics/dashboard, for assessment, and follow-up plans for low scoring domains (Refer back to *Leading a Culture of Safety: A Blueprint for Success* for assistance)

Note: *if your team records low scores in Establish a Compelling Vision for Safety or Value Trust, Respect, and Inclusion, it is recommended that you begin with action plans for improvement in these domains.*

C) Review improvement metrics, revisit action plans, and make adjustments as necessary. You should include additional team members and/or consultants where applicable.

Notes on Scoring:

Each statement should be scored on a scale of 1-5 based on the following:

1 – Never true for my organization

2 – Rarely true for my organization

3 – Sometimes true for my organization

4 – Almost always true for my organization

5 – Always true for my organization

If you are **unsure** of the response, please check the box titled unsure. When adding responses for a total score, this box should be recorded as a **0**. For any item where a member of the leadership team is unsure of the response, it is recommended that he or she spend time speaking with frontline staff and other appropriate individuals in the organization to determine the best answer.

Reviewing Responses:

The **total score** is the sum of the response for each of the three questions. The total score will correlate with one of the three ranges in the boxes below, $0 - 4$, $5 - 9$, or $10 - 15$. Confirm that the **organizational state** box accurately describes the current state of your organization. If it does not, you may need to reevaluate your responses, or speak with additional individuals to better understand the current state of your organization.

Use the **recommended next steps** box in the column that correlates with your total score as a quick reference when developing action plans for improvement. For additional information and recommendations, refer to *Leading a Culture of Safety: A Blueprint for Success*.

Scoring:

1 – Never true for my organization
2 – Rarely true for my organization
3 – Sometimes true for my organization

4 – Almost always true for my organization
5 – Always true for my organization
0 – Unsure of the response

Establish a compelling vision for safety

MEASURABLE ELEMENTS	SCORE						OBSERVATIONS
Key questions to ask about your organization's capabilities and processes.	1	2	3	4	5	Unsure 0	*Please provide a brief description of why you chose this score, considering all parts of each question.*
1. My organization's safety vision statement and aspirational end state are clear and consistently communicated.							
2. My organization completes and reviews culture of safety surveys every 12 – 18 months with evidence of improvement.							
3. My organization's CEO and leadership team effectively build enthusiasm for and understanding of my organization's safety vision statement.							

Total Score = _____

	Score: 0 – 4	Score: 5 – 9	Score: 10 – 15
Organizational State *Brief description of current state of the organization*	Organization's vision statement does not reflect an end state of zero harm and is not regularly communicated to the workforce. Leaders and staff may have a difficult time understanding or communicating how their daily work contributes to advancement of the vision statement.	Organization has a defined vision with a clear, aspirational end state. Leaders communicate this vision consistently to the workforce, and understand how their work fits into the organizational vision statement. All members of the workforce are able to effectively communicate the vision statement.	Leaders and the workforce effectively communication the organization's vision to patients, families, and the public. The workforce is motivated by the vision statement and can clearly tie their daily work to the advancement of this vision. Metrics to benchmark progress toward vision are in place and regularly evaluated.
Recommended Next Steps *Recommended next steps for improvement and implementation are based on domain and included in Leading a Culture of Safety: A Blueprint for Success*	*Begin with review of Foundational tactics* Develop a vision statement with a clear end goal; Educate leaders and the workforce on the meaning of safety culture and zero harm; Host information sessions to build understanding and enthusiasm for the vision	*Review Foundational and Sustaining tactics* Encourage leader visibility on front lines and communication about how daily work advances vision; Hold leaders accountable for regularly and consistently communicating vision to all units and departments	*Review Foundational and Sustaining tactics* Share vision and action plans for change transparently with patients, families, and the public; Benchmark progress towards zero harm and share goals and strategies with similar organizations; Develop and support programs that recognize growth and adherence to vision

Scoring:

1 – **Never** true for my organization   4 – **Almost always** true for my organization

2 – **Rarely** true for my organization   5 – **Always** true for my organization

3 – **Sometimes** true for my organization   0 – **Unsure** of the response

Value trust, respect, and inclusion

MEASURABLE ELEMENTS	SCORE						OBSERVATIONS
Key questions to ask about your organization's capabilities and processes.	1	2	3	4	5	Unsure 0	*Please provide a brief description of why you chose this score, considering all parts of each question.*
1. My organization uses and regularly evaluates formal respect programs that provide education and support to patients and the workforce.							
2. My organization implements workforce safety programs to reduce physical and psychological harm to the workforce.							
3. My organization transparently shares information and metrics around harm events and action plans for improvement across our organization.							

Total Score = _____

	Score: 0 – 4	Score: 5 – 9	Score: 10 – 15
Organizational State *Brief description of current state of the organization*	CEO and organizational leaders understand the criticality of trust, inclusion, and respect, but may not model these values in all situations. The workforce fears punishment from reporting and disclosing errors to patients. Hierarchies based on rank and role exist throughout the organization.	Formal respect and teamwork programs are in place across the organization, and all staff participate in regular trainings. The workforce reports errors and close calls anonymously and without fear of retribution. Leaders across the organization embody behaviors that focus on trust, respect, and inclusion in all interactions.	Open and honest reporting is standard across the organization, and includes defined feedback cycles. Both patients and the workforce are empowered to speak up about safety concerns. Robust communication and support programs are in place for patients, families, and the workforce.
Recommended Next Steps *Recommended next steps for improvement and implementation are based on domain and included in Leading a Culture of Safety: A Blueprint for Success*	*Begin with review of* ***Foundational*** *tactics* Develop organization-wide respect for people programs; Train all leaders, staff, and clinicians on respect program; Develop, implement, and train on anonymous reporting systems; Establish a patient and family advisory council	*Review* ***Foundational*** *and* ***Sustaining*** *tactics* Educate leaders and workforce on inclusion, diversity, and communication with both patients and co-workers; Develop and implement disclosure and apology program; Include metrics for trust, respect, and inclusion as part of annual review process for all leaders	*Review* ***Foundational*** *and* ***Sustaining*** *tactics* Publically share information about harm events and plans to prevent recurrence; Enable and encourage patients and families to speak up for safety through available tools and education programs; Provide cultural competency training for leaders and workforce; Regularly evaluate metrics on disparities in patient care

Scoring:

1 – **Never** true for my organization
2 – **Rarely** true for my organization
3 – **Sometimes** true for my organization

4 – **Almost always** true for my organization
5 – **Always** true for my organization
0 – **Unsure** of the response

Select, develop and engage your Board

MEASURABLE ELEMENTS	SCORE						OBSERVATIONS
Key questions to ask about your organization's capabilities and processes.	1	2	3	4	5	Unsure 0	*Please provide a brief description of why you chose this score, considering all parts of each question.*
1. At all Board meetings in my organization, the amount of time spent reviewing and discussing a transparent dashboard on safety and culture is equal to or greater than time spent reviewing financial performance.							
2. My organization's Board members are required to complete regular self-assessments and education related to safety culture and quality principles.							
3. Performance assessments and incentives for my organization's leadership are inclusive of safety culture metrics and performance.							

Total Score = _____

	Score: 0 – 4	Score: 5 – 9	Score: 10 – 15
Organizational State *Brief description of current state of the organization*	Organization's Board members have strong financial backgrounds, but lack quality and safety expertise. Safety metrics are presented briefly at each Board meeting, and few questions are asked. The majority of the meeting focuses on financial review.	Organization has a quality and safety committee that reviews all serious harm events, but these are rarely presented to the full Board. Time spent on safety during Board meetings includes a story of harm told by the safety/quality manager, and some questions are asked about the event. Board meetings prioritize financial review over safety review.	Organization's Board and committees include experts in safety, clinicians, and a patient and family representative. Patients are invited to meetings to present their experiences directly to the Board. Safety is a top priority and Board members understand how safety impacts the bottom line and feel empowered to ask questions.
Recommended Next Steps *Recommended next steps for improvement and implementation are based on domain and included in Leading a Culture of Safety: A Blueprint for Success*	*Begin with review of Foundational tactics* Provide educational opportunities in safety science and culture for all Board members; Include a safety expert on the Board; Develop a patient and workforce safety dashboard for regular review; Establish a quality and safety committee	*Review Foundational and Sustaining tactics* Consider including a patient/family representative on Board and all committees; Provide opportunities for all Board members to participate on guided leadership rounds; Share all serious safety events and action plans with the full Board	*Review Foundational and Sustaining tactics* Link CEO compensation and bonuses to performance on safety and culture metrics; Provide opportunities for Board members to learn from other organizations and industries; Bring frontline teams to Board meetings to tell their stories and be recognized for exemplary performance

Scoring:

1 – **Never** true for my organization   4 – **Almost always** true for my organization

2 – **Rarely** true for my organization   5 – **Always** true for my organization

3 – **Sometimes** true for my organization   0 – **Unsure** of the response

Prioritize safety in the selection and development of leaders

MEASURABLE ELEMENTS	SCORE						OBSERVATIONS
Key questions to ask about your organization's capabilities and processes.	1	2	3	4	5	Unsure 0	*Please provide a brief description of why you chose this score, considering all parts of each question.*
1. All leaders in my organization receive education and review opportunities in safety science and safety culture.							
2. My organization has defined roles, safety competencies, and development programs for leaders at all levels.							
3. My organization allows leaders opportunities for learning across departments and from outside organizations and industries.							

Total Score = _____

	Score: 0 – 4	Score: 5 – 9	Score: 10 – 15
Organizational State *Brief description of current state of the organization*	Organization's leaders are considered for development opportunities and promotion based on business and financial competencies. Leader development programs focus on executive leadership. All leaders have semi-regular reviews that focus on financial performance.	Organization's executive leaders are provided basic safety science and culture educational opportunities. Leadership development programs are in place at all levels and throughout the organization. Both current and emerging leaders have access to peer coaching and mentoring programs.	Leaders at all levels of the organization are required to complete safety culture training. Regular reviews for all leaders include safety and culture metrics. Leaders are provided opportunities to learn from outside organizations and industries and are able to transfer among departments and units based on interest and organizational needs.
Recommended Next Steps *Recommended next steps for improvement and implementation are based on domain and included in Leading a Culture of Safety: A Blueprint for Success*	*Begin with review of Foundational tactics* Define required leadership competencies in culture and safety; Conduct regular gap analyses for CEO and senior leader competencies in safety culture; Develop and implement an organization-wide leadership development program	*Review Foundational and Sustaining tactics* Provide continuing education opportunities in safety and culture for both new and emerging leaders; Develop systems that support leaders at all levels, including opportunities for cross-departmental training	*Review Foundational and Sustaining tactics* Provide leaders at all levels opportunities for learning outside the organization; Define talent as an organizational resource; Tie performance on safety culture to leadership development priorities and promotional opportunities

Scoring:

1 – **Never** true for my organization

2 – **Rarely** true for my organization

3 – **Sometimes** true for my organization

4 – **Almost always** true for my organization

5 – **Always** true for my organization

0 – **Unsure** of the response

Lead and reward a just culture

MEASURABLE ELEMENTS	SCORE						OBSERVATIONS
Key questions to ask about your organization's capabilities and processes.	1	2	3	4	5	Unsure 0	*Please provide a brief description of why you chose this score, considering all parts of each question.*
1. My organization uses a defined just culture policy during all review processes and decisions (e.g. not just harm event review).							
2. My organization regularly reviews metrics for just culture education and understanding and defines improvement opportunities.							
3. My organization has one set of defined and employed behavior standards and accountability guidelines in place for all individuals, regardless of department, rank, or role.							

Total Score = _____

	Score: 0 – 4	Score: 5 – 9	Score: 10 – 15
Organizational State *Brief description of current state of the organization*	Organization may have just culture policy but it is not robust or embedded in decisions and processes across the organization. Patient safety and risk management professionals are systematically trained in just culture principles.	Organization has a robust just culture policy that is well-communicated internally and utilized in processes and departments across the organization and/or system. All staff are trained on just culture principles and use of just culture algorithm.	Just culture algorithm is embedded in all reviews and decisions across all departments. The Board, leaders, and the workforce are held accountable for utilizing the just culture policy. Patients and the public are educated on just culture and transparency around events through their providers and use of the media.
Recommended Next Steps *Recommended next steps for improvement and implementation are based on domain and included in Leading a Culture of Safety: A Blueprint for Success*	*Begin with review of* ***Foundational*** *tactics* Develop a robust just culture policy; Educate the Board, leadership team, and workforce on just culture principles and the daily use of the just culture algorithm; Ensure utilization of just culture principles in all event reviews	*Review* ***Foundational*** *and* ***Sustaining*** *tactics* Work with the Board and organizational leaders to align just culture policies across all professions and departments; Develop and review metrics for just culture; Hold workforce accountable for the utilization of just culture algorithm	*Review* ***Foundational*** *and* ***Sustaining*** *tactics* Treat gaps in culture as adverse events requiring review with the just culture algorithm; Educate providers on transparent communication of errors; Work with the media to educate and inform the public about just culture and plans for improvement

Scoring:

1 – **Never** true for my organization   **4** – **Almost always** true for my organization

2 – **Rarely** true for my organization   **5** – **Always** true for my organization

3 – **Sometimes** true for my organization   **0** – **Unsure** of the response

Establish organizational behavior expectations

MEASURABLE ELEMENTS	SCORE						OBSERVATIONS
Key questions to ask about your organization's capabilities and processes.	1	2	3	4	5	Unsure 0	*Please provide a brief description of why you chose this score, considering all parts of each question.*
1. My organization uses and regularly reviews a formal training program and defined processes for teamwork and communication.							
2. Professional accountability standards, including processes to address disruptive behavior and disrespect, are implemented uniformly across my organization.							
3. My organization has a program for recognition and celebration when individuals or teams excel at key safety behaviors and culture metrics.							

Total Score = _____

	Score: 0 – 4	Score: 5 – 9	Score: 10 – 15
Organizational State *Brief description of current state of the organization*	Behavior expectations vary across the organization, often based on department, unit, or role. Leaders and the workforce are not aware of defined standards of respectful behavior or consequences for disrespectful behavior. Best practices and standard processes also vary.	Behavior expectations are consistent across care providers, but organizational response to disruptive behavior may vary. Non-clinical departments, including finance and human resources, may not utilize common behavioral standards. Leaders are held accountable for modeling expected behaviors.	All members of the organization are held accountable for the same behavior expectations and have the same consequences for disrespectful behavior. Organization provides transparency of these expectations through patient/ provider compacts. Leaders and the workforce are rewarded for exceptional teamwork and communication.
Recommended Next Steps *Recommended next steps for improvement and implementation are based on domain and included in Leading a Culture of Safety: A Blueprint for Success*	*Begin with review of Foundational tactics* Implement a formal team training program; Develop and communicate organization-wide behavioral expectations; Develop and implement standard processes for teamwork and communication	*Review Foundational and Sustaining tactics* Measure implementation and compliance of teamwork and communication programs; Develop compacts detailing behavior expectations for signature by leaders and the workforce; Ensure measurement tools and report cards for individual performance exist and are utilized	*Review Foundational and Sustaining tactics* Work with key stakeholders to ensure identical processes for employed and non-employed clinicians and staff; Develop required processes for communication and teamwork with patients and families; Develop standard tools for patient and family involvement in teamwork and communication processes

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Healthcare Data Governance

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Healthcare Data Governance (DG) is not a new topic but is still challenging for many healthcare organizations to implement and achieve. With the increase in technology and specifically the electronic health record (EHR), the amount of data available has grown exponentially. Additionally, the focus on providing higher quality care in a more efficient way has increased awareness that data is a strategic asset that needs to be managed. An organization's data can consist of master data (e.g., shared data), reference data (e.g., classifications, standards, mappings), and metadata (e.g., data about other data).

This Practice Brief outlines the healthcare data governance structure/framework, guiding principles, organization-wide applications, and best practices/recommendations surrounding healthcare data.

AHIMA's Definition of Data Governance:

> The overall administration, through clearly defined procedures and plans, that assures the availability, integrity, security, and usability of the structured and unstructured data available to an organization. (AHIMA, 2020)

Healthcare data governance programs include the people, processes, and systems used to manage data throughout the data lifecycle as noted in Figure 1, allowing data to benefit the organization.

1

Figure 1 –AHIMA Data Lifecycle

AHIMA Data Lifecycle

CAPTURE — Recording data in health Information systems

PROCESS — Series of actions taken to create a product and/or service.

USE — Access, sharing and analysis

STORE — Maintaining and archiving

DISPOSE — Destruction per retention schedule
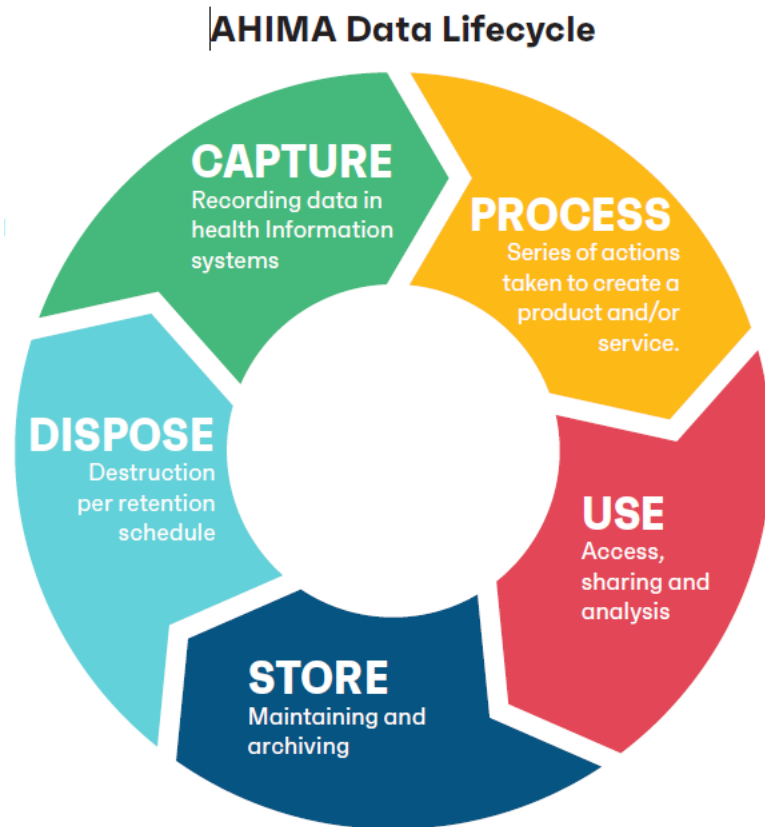
The quality of healthcare data is vital. Ensuring data quality is often a goal of an organization's healthcare data governance program. Data quality is determined based on a set of data characteristics as summarized below.

DATA QUALITY CHARACTERISTICS

AHIMA defines Data Quality and Integrity as "the extent to which healthcare data are complete, accurate, consistent and timely throughout its lifecycle including collection, application (including aggregation), warehousing and analysis.

2

AHIMA characteristics of data quality are as follows:

1. Accuracy: The data should be free of errors, is correct.
2. Accessibility: Proper safeguards established to ensure data is available when needed.
3. Comprehensiveness: The data contains all required elements
4. Consistency: The data is reliable and the same across the entire patient encounter.
5. Currency: Data is current and up to date
6. Definition: All data elements are clearly defined.
7. Granularity: The data is at the appropriate level of detail.
8. Precision: The data is precise and collected in their exact form.
9. Relevancy: Data is relevant to the purpose it was collected
10. Timeliness: Documentation is entered promptly, is up-to-date and available within specified and required time frames (AHIMA 2020)

Many healthcare organizations have given some thought to data governance but perhaps are unsure where to start or how to achieve a robust data governance program. An obstacle to implementing organizational healthcare data governance may be a lack of understanding of data as an asset by key stakeholders which may lead to data silos and delays in the formation of an organizational wide program.

Healthcare data governance should be organization-wide and include interdisciplinary teams consisting of subject matter experts. A key purpose of healthcare data governance is to establish an organizational culture that ensures data is secure, reliable, and available to those who should have access to it. If the entire organization is engaged, a data governance culture is formed, leading to the organization's robust program.
A healthcare data governance culture may be achieved by starting data governance in small steps to demonstrate the value.

The first step in any healthcare data governance plan or program is to define data governance and scope. Organizations must establish the basic framework of collection, retention, use, accessibility and sharing of healthcare data. This framework may consist of policies, procedures, standards, ownership, decision rights, roles and responsibilities and accountability related to the data. Organizations should create a Data Governance Management Team (or similarly titled team) with the Chief Data Officer (or similar position

3

and title) working with the Chief Medical Information Officer to establish healthcare data governance plans or programs.

GOVERNANCE STRUCTURE

Organizations need to establish an operational framework to determine the major DG components and their relationship to each other. High-level DG components may include structure, oversight, responsibilities, culture, regulation compliance, and infrastructure.

CHARTER

The purpose of the charter is to establish the Data Governance program and scope. It describes at a high level what the program will have oversight for and describes the operational framework and decision-making accountabilities required to enforce and socialize new healthcare data policies and standards.

SCOPE

The scope defines what the Data Governance program will include such as:
- Organizational structure
- Authorities
- Councils and roles

PROGRAM GUIDING PRINCIPLES

Examples of healthcare Data Governance program guiding principles include the following:

- Data is a strategic asset that has value and risk.
- Data related decisions should be made at the lowest level possible.
- Not all data will be treated equally; data will be valued and governed/managed based on business impact, stakeholder needs and applicable policy/regulation (e.g., protected health Information (PHI)).
- Data definitions, standards, processes, and policies will be developed and maintained with an organization-wide approach.

4

- Data stewards define the business terms and definitions, approve data values, data relationships, business rules, data quality standards and monitor data quality and data asset value, while IT maintains the systems that capture and manage data through their lifecycle.
- Individuals who create or acquire data are accountable for the quality of that data and must record it in accordance with its definition.
- Data quality and integrity will be addressed by the individuals that create the data and who are closest to the data, understand its meaning and business implications to the specification of the data stewards, with support from the central Data Governance program.

Figure 2 Hierarchy of Data Governance roles

5
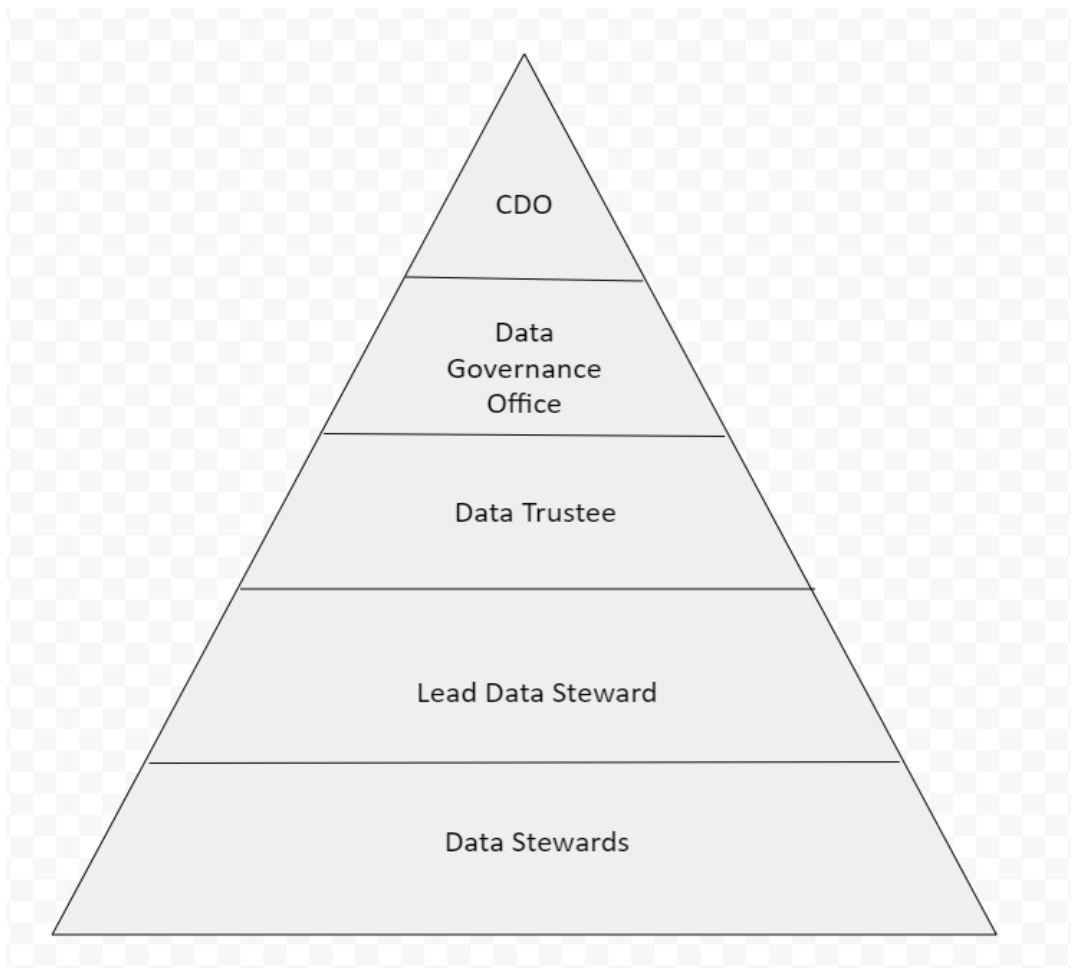
KEY ROLES WITHIN THE OPERATIONAL FRAMEWORK

- Chief Data Officer (CDO)
- Chief Analytics Officer or other sponsor of the Data Governance Office or Steering Committee.
- Data Trustee
- Lead Data Steward
- Data Stewards

DATA STEWARD ROLE AND RESPONSIBILITIES

Data Steward: The Data Steward has overall accountability for data and reporting by responsibly managing data assets, data lineage, and data access, supporting sound data analysis and rationalizing information strategy. This role requires focus on data strategy, execution, and support for projects, programs, application enhancements, and production. The Data Steward defines standards and best practices for data analysis, modeling, and queries; and works collaboratively with business owners in assisting them in the accurate, timely, and complete documentation and data collection. (AHIMA, 2017) Some specific examples of responsibilities are below.

- Coordinate with organizational units and business systems to review and give input within their data domain or subdomain to the following (all which are applicable):
- Data quality and accuracy
- Data profiling
- Data queries
- Data mapping
- Business terms and synonyms
- Business definitions
- Business rules
- Conceptual data models
- List of allowable values
- Process changes
- Data standards

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- Review data quality reports to ensure data is fit for the different business purposes across source systems and critical data assets.
- Act as advocates for the data and serve as the central voice representing their various stakeholder perspectives.
- Work with the Lead Data Steward in maintaining the Business Glossary in the Data Governance Platform.
- Map business terms from local systems captured within the data catalog.
- Support the dissemination and understanding of data in a data domain or subdomain both within specific jurisdiction and across the enterprise.
- Maintain an end-to-end knowledge of data and related business processes for a data domain or subdomain.
- Assign data classification, identify and document sensitive and confidential data for data elements within their data domain or subdomain.
- Provide input on data classification of data assets that contain elements from their data domain or subdomain.
- Evaluate and consult on the processes for making changes to the data model, business definitions, master data and reference data.
- Identify the value of data by liaising with stakeholders for critical business decisions
- Define data quality dimensions (timeliness, accuracy, consistency, conformity) in the source systems based on data usage.

LEAD DATA STEWARDS ROLE AND RESPONSIBILITIES

The Lead Data Stewards are data domain or subdomain specific and have deep knowledge of how data is used within the organization from a business perspective. Specifics related to this role:

- Formally appointed by the Data Trustees or the Chief Data Science Officer (owner of Analytic Data Assets).
- The appointment is reviewed annually.
- Act as an agent of the Data Trustee or the Analytic Data Asset Owner.
- Lead and coordinate efforts for associated Data Stewards within the data domain, subdomain or for an analytic data asset.
- Represent the collective of associated Data Stewards for their data domain or subdomain.

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- Escalate issues to Data Stewardship Council, as appropriate, for resolution.
- Ensure policy and standards are followed, with a focus on improvement of data quality and the protection of sensitive data.
- Evaluate existing processes, controls, data flows, documentation, procedures, data lineage, and governing routines to identify gaps and/or data issues for remediation.
- Maintain all necessary artifacts needed to manage their data domain, subdomain, or analytic data asset.

DATA ANALYTICS ROLE AND RESPONSIBILITIES

The Data Analytics role oversees the creation and lifecycle management of analytic data assets. Some specific examples include the following:

- Manage and measure value creation attributed to analytic data assets.
- Ensure data use adheres to facility ethical standards and regulatory requirements (e.g., HIPAA, etc.).
- Grant access and authorization to analytic data assets.
- Adhere to definitions of data elements as defined by the Data Trustees/Lead Data Stewards for all data sourced to create analytic data assets.
- Define and manage business terms, definitions, value sets for all derived data elements and maintain them in the Business Glossary.
- Define and manage the technical metadata for all derived data elements and maintain it in the enterprise Data Catalog.
- Resolve any discrepancies with Data Trustees/Lead Data Stewards when derived data definitions are misaligned with source data elements.
- Provide training and guidance on interpretation and use of analytic data assets or visualizations/reports created from these assets.

THE DATA TRUSTEES ROLE AND RESPONSIBILITIES

The Data Trustees (Owners) are senior leaders with deep knowledge and authority of the data domain or subdomain and are accountable for how data is defined and used within the facility from a business perspective. Specifics related to this role:

- Formally appointed by the Data Governance Steering Committee.
- The appointment is reviewed annually.

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- Resolve conflicts escalated to the Data Trustee.
- Provide support, champion resources, and provide authority to act.
- Ensure adoption of Data Governance decisions at a national, ministry, and subsidiary levels.
- Author or contribute to key Data Governance policies.
- Identify and standardize the use and governance of data in support of the business strategy and compliance requirements.
- Approve business terms in the business glossaries and other data definitions.
- Ensure the accuracy of data as used across the organization.
- Work with other Data Trustees to resolve data issues and dissonance across business units.
- Provide input to the Steering Committee on software solutions, policies or regulatory requirements that impact their data domain.

CHIEF DATA OFFICER ROLE AND RESPONSIBILITIES

The Chief Data Officer (CDO) provides vision and strategy for all data management activities, including healthcare data system lifecycles. The CDO takes the lead in global data management, governance, quality, and vendor relationships across the enterprise. Key responsibilities may include:

- Establish data policies and standards
- Lead data organization
- Master business intelligence
- Enforce organization information management concepts (AHIMA, 2017)

POLICIES AND PROCEDURES/ STANDARD OPERATING PROCEDURES

Organizations may have one overall Data Governance policy or separate policies for each key area of Data Governance. Examples of key areas to address:

DATA INTEGRITY POLICY: The purpose of a healthcare data integrity policy is to ensure that organizational data have integrity so that management and employees may rely on that data for decision making purposes. Data integrity refers to the reliability, accuracy, and

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validity of data which requires consistent definitions for each data element and an understanding of the business processes underlying the data.

Data Access Policy: The purpose of a data access policy is to ensure that employees have appropriate access to organizational data. The value of data is increased through appropriate access. Security measures will protect data and ensure proper use of data when accessed.

Data Privacy and Usage Policy: The purpose of a data usage policy is to ensure that data are used as appropriate and according to any applicable laws. Employees may only access and use data as required for their job.

Data Sharing Policy: The purpose of a data sharing policy is to detail how internal and external data requests are inventoried, tracked, and managed and ensures data is being shared securely and efficiently. Examples would include registry data, Health Information Exchange (HIE), and research data.

Data Retention Policy: The purpose of a data retention policy is to specify how long data must be retained to meet regulatory and/or organizational needs, and what should be done to the data after retention requirements have been met. Organizations may choose to delete/destroy or archive data once retention requirements have been met.

Data Dictionary

Generally, the data dictionary is a descriptive list of the names, definitions, and attributes of data elements to be collected in an information system or database whose purpose is to standardize definitions and ensure consistent use. It supports consistent use of data, documents the source and update frequency. The data dictionary content may differ according to each organization. Basic elements are names and definitions, specific details of the data such as type, length, primary and foreign keys, and the source. The data dictionary ensures standardization and quality of the data.

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Data Dictionary Example:

Field Name	Table	Description	Data Type	Field Length	Key	Valid Values	Data Source	Data Created	Field Term Date	Update Frequency
Charge Master Item	CDM	Supply Code	Text	25	Primary	Alphanumeric	Finance Office	1/1/1999		Annual
Rev Code	CDM	Rev Area	Text	4	Foreign	Digits	Finance Office	1/1/2000		Annual
HCPCS Code	CDM	HCPCS/CPT	Text	5	Foreign	Alphanumeric	Coding/HIM	1/1/2000		Annual
Charge	CDM	Charge per unit	Currency	12		>$0.00	Finance Office	1/1/2000		Annual

BUSINESS GLOSSARY

A business glossary is a compendium of business terms and definitions, which have been approved by stakeholders and are maintained and governed. The language representing the data should be aligned with the language of the business.

Consistent terms and definitions, with corresponding metadata, are essential to managing patient demographic data across its lifecycle in the context of meaning. Agreement about term names and definitions is essential to ensure that all stakeholders who supply or consume the data understand it the same way without ambiguity. If common understanding of terms for shared data is lacking, business processes are negatively affected.

The business glossary represents agreement among key stakeholders on the language and associated meaning pertaining to patient data needed to support quality care, efficient payments, and patient safety. If business terminology is not uniquely named and defined, confusion and inefficiencies may cause issues. (The Office of the National Coordinator for Health Information Technology, n.d.)

Definitions of terms within a healthcare organization may differ by department or division. If these terms are addressed in the Business Glossary with the naming conventions and itemized by department, this will help alleviate disparities. For example: LOC may be used in

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the clinical record as loss of consciousness. LOC in the surgical department may be used to identify the length of case as noted in the table below.

Application/Department/Domain	Abbreviation	Definition
Clinical Information System	LOC	Loss of Consciousness
Surgical Information System	LOC	Length of Case

All data elements within the domains of an enterprise should be included in the business glossary. Elements may overlap domains for example:

Finance

- Payer
  - Insurance Plan
    - Contract

Patient

- Location
  - Patient Type
    - Payer
      - Insurance Plan
        - Length of Stay (LOS)

Clinical Information System

- Patient Type
  - Location
    - Length of Stay (LOS)
      - Discharge Disposition

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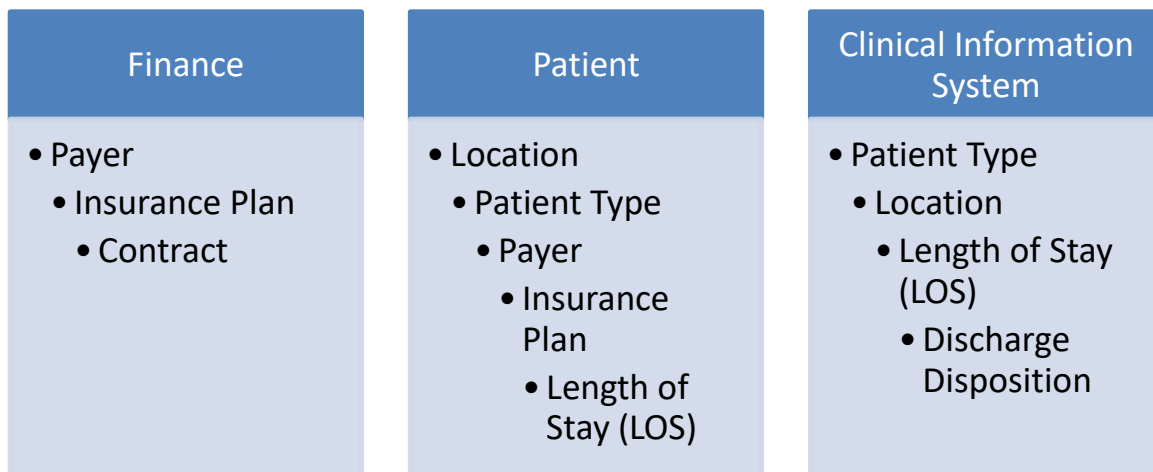
Best Practices/Recommendations

Following are some best practices and lessons learned from organizations that have implemented Healthcare Data Governance.

- **Establish program priorities.** Establishing program priorities helps focus Data Governance efforts to achieve results. One way to do this is to prioritize critical data elements for the organization. For example, patient demographics such as date of birth or race/ethnicity may be important as they are used in numerous ways. Key measures such as case mix or length of stay can be important to address as they are often used by multiple departments for reporting. It is important to consider where these critical data elements are used and how defined as well as the entire data lifecycle (e.g., data creation, collection, use, and destruction).

- **Ensure accountability.** It is important to have a Data Governance structure that helps to drive accountability. The best way to do this is to have clearly defined roles and responsibilities (e.g., sponsors, data stewards, domain owners, technical leads, etc.) -- outlining who is responsible for what and when. Having a governance structure in place allows the organization to address questions or issues as they arise as well as work toward the required goals.

- **Demonstrate the value by defining key metrics.** Results of the Data Governance work need to be measured and clearly demonstrate a value proposition. There should be key metrics tied to program goals. For example, key metrics may be tied to data quality (e.g., data accuracy, data completeness), risk or cost reduction (e.g., reduction in rework), or process improvement (e.g., data issues corrected). There can also be value in tracking data literacy across the organization (e.g., knowledge of data management principles; adherence to data management standards, policies, and procedures; published data definitions; attendance at trainings, etc.).

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- **Support collaboration.** Those in Data Governance roles should have opportunities to collaborate, discuss challenges, and share best practices. Utilizing a Data Governance platform and applications can help support this effort.

Remember, establishing healthcare Data Governance is an iterative, learning process. The program will adapt and evolve over time as progress is made.

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AI IN MEDICINE

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Artificial Intelligence in U.S. Health Care Delivery

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THE ADOPTION OF ARTIFICIAL INTELLIGENCE (AI) AND ITS IMPACT ON business sectors happen in phases. The use of AI is advanced in many areas, including reinventing how a financial institution provides investment advice and products to its customers, offering "recommendation engines" that suggest the next retail product to buy for a consumer who has just bought one item, and developing driverless cars. In health care delivery, however, AI remains in the early stages.

AI adoption in health care delivery lags behind the use of AI in other business sectors for multiple reasons. Early AI took root in business sectors in which large amounts of structured, quantitative data were available and the computer algorithms, which are the heart of AI, could be trained on discrete outcomes — for example, a customer looked at a product and bought it or did not buy it. Qualitative information, such as clinical notes and patients' reports, are generally harder to interpret, and multifactorial outcomes associated with clinical decision making make algorithm training more difficult. Another challenge is embedding AI output into the already complex clinical workflow. Furthermore, in our experience, the environment in which some health care organizations operate often leads these organizations to focus on near-term financial results at the cost of investment in longer-term, innovative forms of technology such as AI. Health care organizations that prioritize innovation link investment decisions to "total mission value," which includes both financial and nonfinancial factors such as quality improvement, patient safety, patient experience, clinician satisfaction, and increased access to care.

We think that the need for AI to help improve health care delivery should no longer be questioned, for many reasons. Take the case of the exponential increase in the collective body of medical knowledge required to treat a patient. In 1980, this knowledge doubled every 7 years; in 2010, the doubling period was fewer than 75 days.[1] Today, what medical students learn in their first 3 years would be only 6 percent of known medical information at the time of their graduation. Their knowledge could still be relevant but might not always be complete, and some of what they were taught will be outdated. AI has the potential to supplement a clinical team's knowledge in order to ensure that patients everywhere receive the best care possible. Bringing that potential to reality has not been easy, but there are some successes.

There are signs of increased adoption. Economies of expertise — or the development of more robust AI algorithms from more data — have become a key accelerant for a new subindustry, referred to as health care services and technology (e.g., software and platforms, data analytics, and payment services), which has the

potential in the next few years to be as large monetarily as the entire payer subindustry is today.[2] The coronavirus disease 2019 (Covid-19) pandemic has also been a catalyst, prompting organizations to accelerate plans to digitalize and deploy AI. At the management and board levels of organizations, the recent public awareness of generative AI has increased conversations regarding AI. In addition, the adoption of AI can have second-order effects, such as alleviating part of the ongoing shortage of physicians and nurses.

In this article, we discuss the emerging use of AI in health care delivery, which is defined as direct and supportive functions related to the provision of health care. By way of full disclosure, we are both employed by a company that provides consulting services for public and private organizations in this area. We also examine the use of AI in the domains of reimbursement, clinical operations, and quality and safety. Finally, we discuss the challenges that health care organizations are facing in deploying AI.

EMERGING HIGH-VALUE USES OF AI

AI is broadly defined as a machine or computing platform that is capable of making intelligent decisions. Two types of AI have generally been pursued in health care delivery: machine learning, which involves computational techniques that learn from examples instead of operating from predefined rules, and natural language processing, which is the ability of a computer to transform human language and unstructured text into machine-readable structured data that reliably reflect the intent of the language.[3,4]

In health care delivery, the role of AI in improving clinical judgment has garnered the most attention, with a particular focus on prognosis, diagnosis, treatment, clinician workflow, and expansion of clinical expertise. Specialties such as radiology, pathology, dermatology, and cardiology are already using AI in the process of image analysis.[1,5-7] In radiologic screening, for example, up to 30% of radiology practices that responded to a survey indicated that they had adopted AI by 2020, and another 20% of radiology practices indicated that they planned to begin using AI in the near future.[8]

The potential of AI, however, extends much further. We have found that uses of AI are emerging in nine domains of health care delivery (Fig. 1).

However, most uses of AI in health care delivery have not been subject to randomized, controlled trials. Therefore, the usual level of evidence required for medical decision making may be lacking. We indicate where there is ample evidence and where it is absent. We still aim to provide a perspective based on our conversations with dozens of health care leaders, but we understand that this is not a substitute for a randomized, controlled trial.

Our discussions with U.S. health care leaders suggest that AI adoption in the nine health care domains has been met with varying degrees of success. Newer forms of technology, such as blockchain and generative AI, have not played a major role. Some health care leaders argue that unlocking the potential of AI will require the use of these types of technology, but our experience suggests otherwise. Overall, most organizations are still in the pilot phase of AI adoption and are attempting to validate the benefits. Here, we focus on uses of AI in three domains of health care delivery: reimbursement, clinical operations, and quality and safety.

REIMBURSEMENT

Reimbursement — an area of checks and balances between payers and providers — is key to the financial health of a health care organization. Uses of AI in this domain are both common and among the most advanced uses, with a higher-than-average total mission value (Fig. 1). In what has been termed "the coding wars," AI not only has become an important tool for stakeholders to monitor one another but also has been simplifying and reducing difficulty in the patient's experience with medical payments.

Providers refer to the processing of claims that payers should reimburse (Fig. 2) as revenue-cycle management. This is one of the provider's tasks that is often performed by persons who review a health care professional's billing and provide guidance regarding the completion of the bill in a manner that aligns with the services provided so that the amount actually paid to the organization will be appropriate. With the use of this system, more than 10% of claims are denied or delayed because of eligibility issues and missing data, but up to 85% of those denied claims could have been avoided.[10]

One large health system recognized that AI — specifically predictive analytics — could gen-
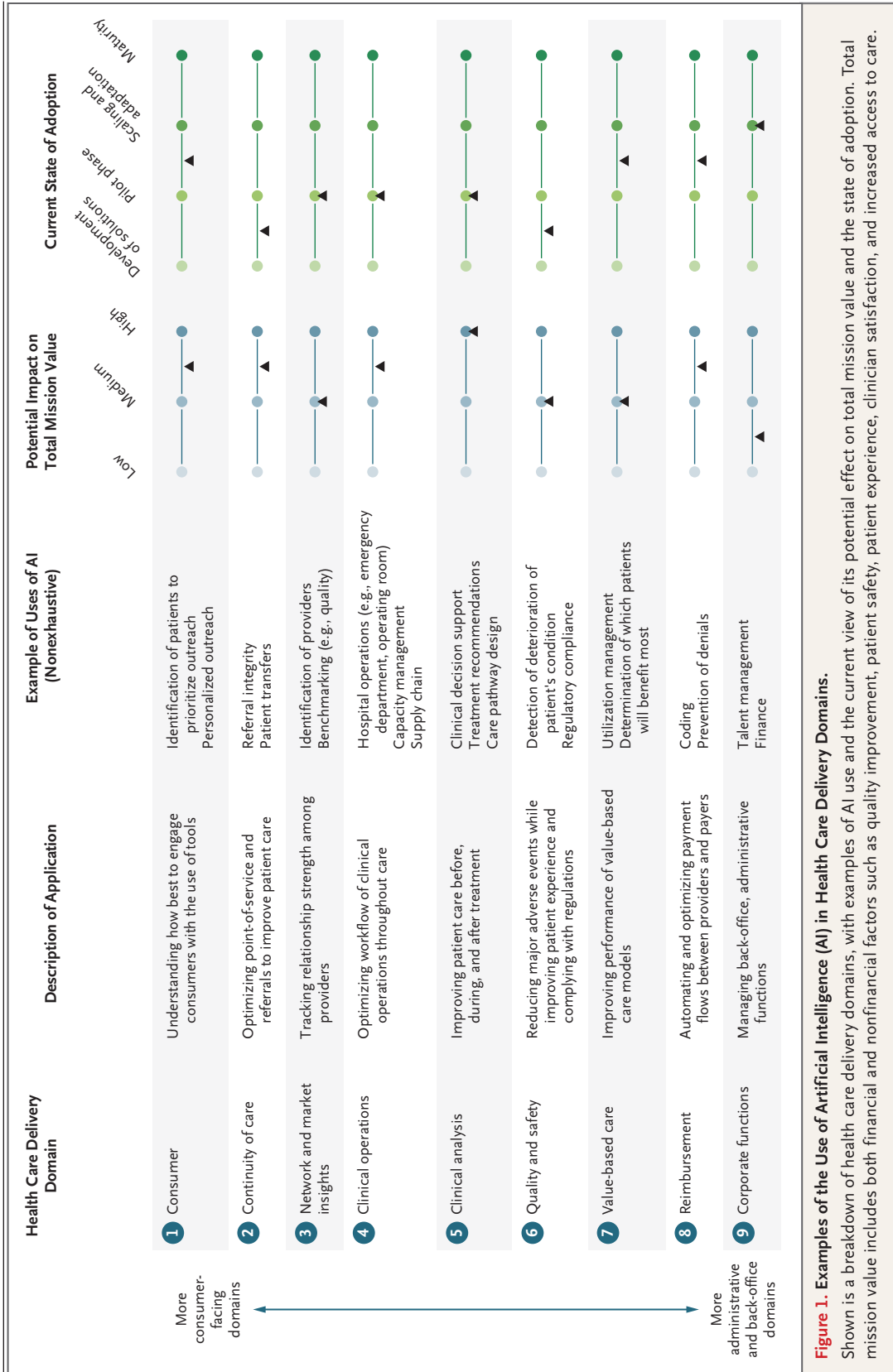
Figure 1. Examples of the Use of Artificial Intelligence (AI) in Health Care Delivery Domains.

Shown is a breakdown of health care delivery domains, with examples of AI use and the current view of its potential effect on total mission value and the state of adoption. Total mission value includes both financial and nonfinancial factors such as quality improvement, patient safety, patient experience, clinician satisfaction, and increased access to care.

Direction of domains: More consumer-facing domains ↔ More administrative and back-office domains

Health Care Delivery Domain	Description of Application	Example of Uses of AI (Nonexhaustive)
1 Consumer	Understanding how best to engage consumers with the use of tools	Identification of patients to prioritize outreach; Personalized outreach
2 Continuity of care	Optimizing point-of-service and referrals to improve patient care	Referral integrity; Patient transfers
3 Network and market insights	Tracking relationship strength among providers	Identification of providers; Benchmarking (e.g., quality)
4 Clinical operations	Optimizing workflow of clinical operations throughout care	Hospital operations (e.g., emergency department, operating room); Capacity management; Supply chain
5 Clinical analysis	Improving patient care before, during, and after treatment	Clinical decision support; Treatment recommendations; Care pathway design
6 Quality and safety	Reducing major adverse events while improving patient experience and complying with regulations	Detection of deterioration of patient's condition; Regulatory compliance
7 Value-based care	Improving performance of value-based care models	Utilization management; Determination of which patients will benefit most
8 Reimbursement	Automating and optimizing payment flows between providers and payers	Coding; Prevention of denials
9 Corporate functions	Managing back-office, administrative functions	Talent management; Finance

Potential Impact on Total Mission Value (Low, Medium, High)

Current State of Adoption (Development of solutions, Pilot phase, Scaling and adaptation, Maturity)

Claims Creation
After a member receives a service, the provider fills out a detailed claim form, typically electronically

Claims Submission
Provider sends the form to a payer; typically >90% of claims are submitted electronically

Auto-adjudication
Claim comes into payer's inbound systems; typically >80% of claims are auto-adjudicated

Manual Adjudication
Approximately 20% of claims that must be manually adjudicated are generally resolved by claims processors or claims specialists; a claim that is rejected is sent back to the provider

Examples of Uses of AI (nonexhaustive)
Improve auto-adjudication by looking for specific markers or variables resulting in manual review
Assess utilization management records and electronic health records to support adjudication
Support manual processing by presenting supplemental information
Use bots for pricing and claim cleaning to automate tasks that are largely manual

Payment
A claims tool determines whether the claim is going to be paid, and reimbursement is initiated

Claims Tracking
The provider and member can track a claim statement online; the statement can be received through an online portal or through mail; either the provider or member may dispute the claim

Audits, Grievances, and Appeals
Claims excellence and adjustments team audits claims on a monthly or quarterly basis to reduce errors and improve accuracy; team also handles grievances and appeals

Examples of Uses of AI (nonexhaustive)
Determine root cause of audit, grievance, or appeal
Identify issues early to avoid appeal process

Figure 2. Use of AI in Claims Processing.
In the reimbursement domain, AI can be used at specific points in the processing of a typical claim. The information in this figure is from Sahni et al.[9]

erate cost savings and improve not only cash collection and yield but also the patient's experience. The effort began with a large data set (12 months of claims data representing millions of payer interactions), with a focus on more than 100 claims attributes. The system ran the data through a re-gression model to find those that correlated most closely with a denied billing claim. With this new predictive model, unsubmitted claims were then prerun, increasing the number of claims identified as likely to be denied by 33%, as compared with a retrospective baseline. In addition, the

model identified the most likely root causes of claims denial, such as National Drug Code denial or a specific payer's policy. That health system now has a pilot program that uses the top 10 root causes to flag claims and address them before submission. Over time, the goal is to further develop the model to generate claims-specific root causes of denial and prevent billings from moving forward if they harbor these flaws. This could further improve the denied-claims record of the health system and potentially reduce the administrative spending needed for claims processing and reprocessing, all while improving the patient's experience by reducing the number of frustrating denials.

On the payer side, a large managed-care organization used AI to move from a traditional, labor-intensive model to an AI-based model, with the goal of eliminating upstream errors in a way that could reduce the need for manual claim adjudication. Thus, the organization trained a model that identified and weighted the factors that led to the need for manual intervention, such as specific procedure codes. The model continuously generated output that was based on relative manual effort. With the use of AI by the managed-care organization, the percentage of complex claims that were processed without denial increased from less than 80% to more than 90%. This reduced associated administrative spending by 30% and improved patient experience and clinician satisfaction.

AI is also being used in prior authorization, a process that involves substantial manual labor, with only 21% of prior authorizations automated.[9] The process can be costly because it requires doctors and registered nurses to review requests for authorization. From the payer's perspective, the objective is to ensure that patients are receiving clinically appropriate treatment. Therefore, prior authorization is meant to be a check on what the provider has ordered.

In an attempt to reduce friction in the system, one payer created an integrated, clean database with a sample that included member eligibility and benefits information, historical medical and pharmacy claims, and historical prior authorization requests with clinical decisions, appeals, and outcomes. These data were then fed into a triage engine that categorized requests into four levels of complexity on the basis of such factors as the level of detail shared, the plan member's clinical history, and the knowledge gained from processing similar requests. AI has already begun to reduce the number of steps in the process, as compared with traditional manual workflows, and the majority of low- and medium-complexity prior authorization requests are automatically approved. This has led to reduced turnaround times, more consistent clinical outcomes, and better overall experiences for patients and clinicians. With this foundation in place, the payer's long-term vision is to apply AI to further accelerate decision making.

CLINICAL OPERATIONS

Clinical operations is another health care delivery domain with expanding AI use. Although AI adoption is not as advanced in clinical operations as it is in reimbursement, the total-mission-value potential is similar, and AI has been an area of intense research in clinical operations (Fig. 1). Consider the operating room, one of the most critical assets for clinical care in a health system. The demand for operating rooms is traditionally high, so a missed surgical slot could result in a substantial increase in wait time, not to mention loss of revenue. Scheduling delays owing to surgeries that run longer than anticipated could also have a nonfinancial effect, such as a worse experience for patients and their families as they wait for an operation to end or for a procedure to begin. In health systems in the United States, more effective use of operating-room capacity can increase access to care, which is especially important today because of surgical backlogs and clinician shortages.

In our experience, operating-room optimization can occur in three steps: improving operating-room management, predicting operating-room use, and using operating-room analytics in real time (Fig. 3). Each step has the potential to provide an incremental benefit, but the final two steps are still in development, and their potential benefit is difficult to quantify.

The first step uses descriptive analytics, such as a histogram showing the distribution of operating-room times over the previous 30 days, to identify variations in scheduling. Health systems have used this approach successfully for many years.[11,12] This step has not traditionally involved AI use, nor has it been needed.

In the second step, AI starts to play a central role by predicting operating-room use. Preopera-

	Improving Operating-Room Management	Predicting Operating-Room Use	Using Operating-Room Analytics in Real Time
Level of AI Use	Limited		Predominant
Analytics Approach	Descriptive	Predictive	Prescriptive
Description of Analytics	Analyses of historical operating-room performance to identify and address variation	Predictions regarding preoperative cancellations, in-surgery risk, and postoperative complications	Models that translate predictions into systematic action, including real-time scheduling and reporting
Examples (Nonexhaustive)	Measured key operating-room statistics such as start time, surgical incision time, room turnover time, and patient turnover time (University Hospital, 1994) Measured key operating-room statistics such as start time, turnover, and unavailability (Medical University of South Carolina, 1998)	Predicted operations with high risk of cancellation (West China Hospital, 2018) Predicted risk of death during cardiac surgery (unidentified academic institution, 2020) Predicted duration of elective surgery (Gold Coast Hospital, 2017) Predicted postoperative major complications and death (University of Florida Health, 2019)	Simulated improvement in utilization by 19% and reduction of overtime by 10% (Mayo Clinic, 2015) Simulated reduction in post-anesthesia care unit holds without decreasing operating-room utilization (Lucile Packard Children's Hospital Stanford, 2018)

Figure 3. Use of AI in the Operating Room.

In the clinical operations domain, AI has been adopted for use in the operating room. Sources of information are Mazzei et al.,[11] Overdyk et al.,[12] Luo et al.,[13] Killic et al.,[14] Shahabikargar et al.,[15] Bihorac et al.,[16] Ozen et al.,[17] and Fairley et al.[18]

tive prediction analytics are focused on reducing cancellations and estimating mortality.[13,14] During surgery, predictions generally focus on the duration of the procedure and potential complications while it is being performed.[15,19] Finally, predictions about likely postoperative outcomes aim to identify major complications.[16]

The third step, using operating-room analytics in real time, can turn prediction into action. For example, AI would be used to build prediction of the duration of a procedure into precise scheduling, allow for the coordination of multiple operating rooms being used simultaneously, and integrate predictions such as likely surgery cancellations into operating-room optimization.[20] Organizations such as the Mayo Clinic and Lucile Packard Children's Hospital at Stanford have estimated that utilization would potentially be improved by 15 to 20% if AI were implemented.[17,18] However, this step remains largely in the pilot phase, and whether the improvements will be realized is not known.

Another use of AI in clinical operations is tackling clinician burnout.[21] Physicians now spend more than 50% of their time updating electronic health records (EHRs), and this use of time is a documented contributor to burnout.[22,23] Multiple providers are piloting natural language processing to reduce this burden. If these efforts are successful, natural language processing could turn unstructured data such as clinicians' notes into the structured data needed for the EHR as well as for other uses, such as documenting quality metrics or filling in appropriate Current Procedural Terminology codes. This application of AI would give clinicians more time to spend with patients and on tasks that require human judgment.

QUALITY AND SAFETY

Quality and safety constitute a domain in which a substantial portion of value comes from nonfinancial factors. The current level of adoption of AI in this domain is limited (Fig. 1), as is the evidence on the broad effect of AI on quality and safety, but two uses of AI, focused on patient safety and patient experience, show potential.
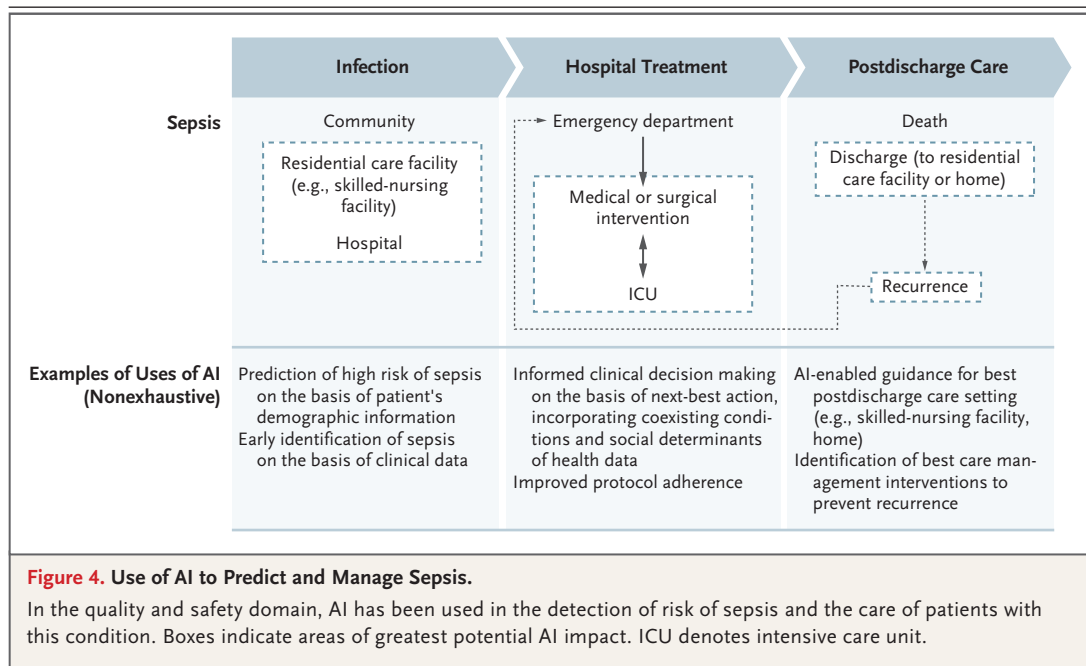
In the first use of AI, the objective with re-

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gard to patient safety is to reduce major adverse events — specifically, in cases in which current evidence-based methods are less useful in preventing and addressing complications and in which integration of complex, unstructured data with measurable metrics could help in making predictions. Adverse drug events, decompensation, and diagnostic errors have been identified as problems with the greatest potential for improvement with AI.[7] Tackling these problems requires the generation of actionable information. This process uses data from types of sensing technology, including vital-sign monitoring, wearables such as insoles in shoes, pressure sensors, and computer vision, to embed clinical alarms and reports in the workflow.[4]

For example, sepsis has become an area of focus in recent AI efforts, given the high mortality associated with this condition and the importance of early action (Fig. 4). One AI algorithm used EHR data in combination with blood pressure and heart rate measures to predict whether a given patient in the intensive care unit (ICU) might have sepsis.[24] A health system has used AI to monitor data such as vital signs and nursing reports. The AI output then links with clinical workflows to quickly alert hospital staff if a patient could be in trouble and appropriate clinical steps need to be taken to reduce risk. Over a period of 5 years beginning in 2014, this monitor-

ing had reportedly saved approximately 8000 lives across the network of the health system.[25] Another approach used a broader predictive algorithm for clinical deterioration in the ICU; this algorithm reduced mortality in 21 hospitals.[26] In addition, a recent study showed that when a provider confirms an alert, mortality is further reduced.[27]

The second use of AI — to improve patient experience — can involve Consumer Assessment of Healthcare Providers and Systems (CAHPS), a program of the Agency for Healthcare Research and Quality that measures how patients experienced or perceived key aspects of their care, not how satisfied they were with their care. CAHPS scores are also tied to "star ratings" (a five-star scale, with one star representing poor performance and five stars representing excellent performance) for Medicare Advantage plans. One regional payer sought to identify its most dissatisfied members and to understand why they were dissatisfied. The payer used measures traditionally inferred from a variety of encounter, survey, and operational data, as well as assembled member-level data such as claims, enrollment information, call-center contacts, appeals and grievances, monthly member-survey data, and care management data. After identifying proxy variables for dissatisfaction, the payer ran regressions to determine variable significance and relationships.

	Infection	Hospital Treatment	Postdischarge Care
Sepsis	Community Residential care facility (e.g., skilled-nursing facility) Hospital	Emergency department Medical or surgical intervention ICU	Death Discharge (to residential care facility or home) Recurrence
Examples of Uses of AI (Nonexhaustive)	Prediction of high risk of sepsis on the basis of patient's demographic information Early identification of sepsis on the basis of clinical data	Informed clinical decision making on the basis of next-best action, incorporating coexisting conditions and social determinants of health data Improved protocol adherence	AI-enabled guidance for best postdischarge care setting (e.g., skilled-nursing facility, home) Identification of best care management interventions to prevent recurrence

Figure 4. Use of AI to Predict and Manage Sepsis.
In the quality and safety domain, AI has been used in the detection of risk of sepsis and the care of patients with this condition. Boxes indicate areas of greatest potential AI impact. ICU denotes intensive care unit.

AI algorithms were then built to assess the likelihood of disenrollment and the sentiment score for all members. Members were clustered into similar segments and further assessed to understand important dissatisfaction variables in each cluster. This information was then used to prioritize and inform outreach, which improved members' experiences through better identification and resolution of their issues. Overall, the use of AI led to improved allocation of outbound call resources while addressing member challenges. CAHPS scores also improved, contributing to a four-star rating by the Centers for Medicare and Medicaid Services.

SLOW ADOPTION OF AI IN HEALTH CARE DELIVERY

The examples noted above from three domains show that the use of AI in health care delivery is developing and that in some situations, the technology has proved to be effective. Yet health care remains among the business sectors that have been slow to adopt AI.[28] Why is this so?

To answer this question, it is important to understand technology adoption. Generally, it follows an S curve: starting with the development of solutions, then piloting, followed by scaling and adaptation, and finally reaching maturity. In several business sectors, such as banking, AI is already reaching the maturity part of the S curve. In contrast, most of the domains in health care delivery are still developing solutions (quality and safety) or piloting them (clinical operations).

Adoption of AI in health care delivery is lagging behind for several reasons. First, given the many different sources and types of health care data needed, they are known to be more heterogeneous and variable than data in other business sectors (e.g., data to make a movie recommendation in Netflix).[29] This creates challenges in applying AI. Another major reason is the fee-for-service model of payment as compared with a value-based payment model. The latter payment structure would fund measures that improve care or make it safer, which is where the benefit of AI in health care delivery could be of substantial importance. Under a fee-for-service model, these incentives are substantially less prominent or absent altogether. Other documented reasons for the slow adoption of AI in health care delivery are lack of patient confidence, including concerns

about privacy and trust in the output; regulatory issues such as Food and Drug Administration approval and reimbursement; methodologic concerns such as validation and communication of the uncertainty of a given AI-based recommendation or decision; and reporting difficulties such as explanations of assumptions and dissemination.[3,6,30-32] These factors will have to be addressed before long-term adoption of AI and full realization of the opportunity that it provides.

Issues within health care organizations may also account for the slow adoption of AI. These challenges must be addressed if AI deployment (a type of digital transformation) is to be successful.[33] We have found that this effort involves six categories encompassing strategic vision, key enabling factors, and implementation, each with specific health care delivery challenges to overcome, as shown in Figure 5.

For example, starting with a strategic vision, one of the greatest challenges is properly defining the costs and benefits of deploying AI. Historically, the decision to invest in AI has been based on financial return. This calculation should be expanded to include nonfinancial factors as well. Otherwise, AI adoption could continue to lag in certain domains in which a large portion of its effect is nonfinancial, such as quality and safety.

Organizations may underestimate the importance of data management, one of the most critical factors enabling successful AI adoption. Data management includes preparing data for use in the information technology system, addressing information gaps, setting up information so that biases are prevented, and ensuring enough availability to achieve scale. Addressing this challenge is not "one and done" but instead requires approaches for continuous testing and validation across multiple providers, geographic locations, and disease use cases.

Finally, implementation is critical for AI adoption within an organization. This category takes the most time and effort, and it is often short-changed by organizations. One challenge is change management. For example, there may be agreement to move to prescriptive scheduling in the operating room, but the implications of this decision are quite different for a hospital administrator, the chief of surgery, individual surgeons, and the operating-room team. Thus, successful AI adoption is likely to require intentional actions that both help to effect behavioral change and

Categories of Successful AI Deployment	Goal	Challenges
Strategic Vision — ① Mission-led road map	Ensure a clear view of where the value is going to be and a road map to get there	**Part of the Solution:** Ongoing belief that AI is a "silver bullet" rather than part of a broader solution **Transformative Potential:** Focusing only on the "incremental" opportunity rather than reimagining for the "transformative" potential **Total Mission Value:** Focusing only on financial factors rather than accounting for nonfinancial factors such as quality improvement, patient safety, patient experience, clinician satisfaction, and increased access to care **Focus:** Pursuing many domains rather than 1 or 2 "priority" domains with multiple uses of AI **Timing to Impact:** Misconception that AI is a "quick win" rather than a process that is implemented over multiple years
Key Enabling Factors — ② Talent	Ensure that the correct skills and capabilities are available to execute and innovate	**Skills:** Missing skill sets in workforce to implement and manage AI **Talent Road Map:** Lack of long-term plan for workforce hiring, upskilling, and reskilling as AI use expands **Education:** Underinvestment in making workforce AI-literate
③ Agile delivery	Increase the speed at which teams are able to deliver work	**Culture:** Negative attitude toward AI or lack of consensus **Funding:** Limited ongoing funding to deploy AI
④ Technology and tooling	Allow the organization to move quickly, with flexibility and resiliency	**Technology Infrastructure:** Inability to integrate AI into legacy systems, secure AI, or provide necessary computing power **Data Preparation:** Underinvestment in tools to properly prepare data
⑤ Data management	Use data intelligence to derive a competitive advantage	**Completeness:** Inability to address data gaps with the use of internal or external sources **Unbiased Data:** Lack of awareness of inherent biases in data, such as data that are limited to one health system site **Availability:** Missing scale in the number of data points to train AI **Data Governance:** Governance to manage data is not formalized
Implementation — ⑥ Change in operating model of the organization	Develop business processes, employee skills, and structures to realize total mission value	**Change Management:** Lack of recognition that translating strategic vision requires different behavior changes for everyone in the workforce, as well as coaching **Workflow Integration:** Failure to integrate AI into clinical workflow to minimize the behavior change needed **Cross-functional Teams:** Not creating fully cross-functional teams, such as clinicians, technologists, and operations professionals **Transparency:** Inability to overcome "black box" nature of AI, such as quantification of assumptions **Interpretable Output:** Not providing easy-to-understand output with relevant information to enhance decision making **Operational Governance:** Not creating a formal governance structure to oversee all aspects of implementation and ongoing management

Figure 5. Examples of Challenges to AI Adoption in Health Care Delivery Organizations.

A breakdown of categories of successful AI deployment and common challenges that organizations experience are shown. Sources of information are Rajkomar et al.,[3] Bates et al.,[6] Shaw et al.,[30] Singh et al.,[31] He et al.,[32] and Carey et al.[33]

address the details holistically, such as creating AI output visualizations that make interpretation easy for clinicians.

Another implementation challenge is workflow integration. The use of AI in clinical operations is more successful when it is treated as a routine part of the clinical workflow.[6,27] In essence, AI output is more effective when viewed as a member of the team rather than as a substitute for clinical judgment.

Although the challenges to successful AI deployment within an organization are real, they

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can be overcome. Efforts that can help include introducing demonstration projects that test many AI applications focused in a few domains, establishing a balance between building in-house capabilities and partnering with AI technology vendors to access economies of expertise, quantifying the total mission value, and aligning incentives to increase adoption. Investment will be required to achieve these ends. Across business sectors, the higher performers in AI adoption spend 30 to 60% more on AI than the lower performers. In addition, unlike the lower performers, the higher performers expect to continue to increase their AI adoption budgets as implementation takes place.[34]

CONCLUSIONS

AI adoption in health care delivery has lagged behind adoption in other business sectors, but the past few years have shown the potential and promise of AI, which has already begun to shape the operations of payers and providers in some areas. If the promise of AI is realized, the quality of and access to health care delivery will be improved. The promise remains, but realizing it in practice has not been easy.

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Perspective

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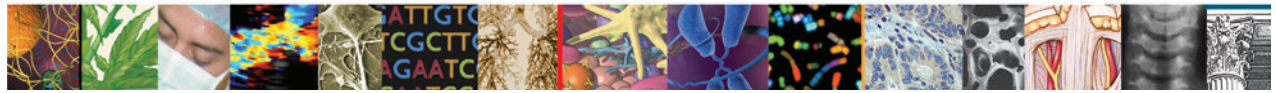
FUNDAMENTALS OF MEDICAL ETHICS

Responding to Medical Errors — Implementing the Modern Ethical Paradigm

Thomas H. Gallagher, M.D., and Allen Kachalia, M.D., J.D.

Ms. Z. is a 45-year-old woman recently diagnosed with breast cancer. Seven months ago, she reported a breast lump to Dr. C., her primary care physician. The physician noted a cystic area, but since Ms. Z. was starting her menstrual cycle, Dr. C. recommended reexamination. Dr. C. then went on leave, and Dr. B. assumed the patient's care. Ms. Z. saw Dr. B. several times for high blood pressure but did not mention the breast lump, and Dr. B. had not noticed this problem in her medical record. Last month, with her blood pressure now controlled, Ms. Z. asked Dr. B. about the breast lump, noting that it was growing. She was subsequently diagnosed with cancer and has returned to talk with Dr. B.

Responding to a medical error is daunting. Clinicians in Dr. B.'s situation experience the emotions every human feels when something has gone wrong: remorse, frustration, embarrassment, and fear. Perfectionism can also increase clinicians' reluctance to confront problems.

Traditionally, recommendations regarding responding to medical errors focused mostly on whether to disclose mistakes to patients. Over time, empirical research, ethical analyses, and stakeholder engagement began to inform expectations — which are now embodied in communication and resolution programs (CRPs) — for how health care professionals and organizations should respond not just to errors but any time patients have been harmed by medical care (adverse events). CRPs require several steps: quickly detecting adverse events, communicating openly and empathetically with patients and families about the event, apologizing and taking responsibility for errors, analyzing events and redesigning processes to prevent recurrences, supporting patients and clinicians, and proactively working with patients toward reconciliation. In this modern ethical paradigm, any time harm occurs, clinicians and health care organizations are accountable for minimizing suffering and promoting learning. However, implementing this ethical paradigm is challenging, especially when the harm was due to an error.

Historically, the individual physician was deemed the "captain of the ship," solely accountable for patient outcomes. Bioethical analyses emphasized the fiduciary nature of the doctor–patient relationship (i.e., doctors are in a position of greater knowledge and power)

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and noted that telling patients like Ms. Z. about harmful errors supported patient autonomy and facilitated informed consent for future decisions. However, under U.S. tort law, physicians and organizations can be held accountable and financially liable for damages when they make negligent errors. As a result, ethical recommendations for openness were drowned out by fears of lawsuits and payouts, leading to a "deny and defend" response.

Several factors initiated a paradigm shift. In the early 2000s, reports from the Institute of Medicine transformed the way the health care profession conceptualized patient safety.[1] The imperative became creating cultures of safety that encouraged everyone to report errors to enable learning and foster more reliable systems. Transparency assumed greater importance, since you cannot fix problems you don't know about. The ethical imperative for openness was further supported when rising consumerism made it clear that patients expected responses to harm to include disclosure of what happened, an apology, reconciliation, and organizational learning.

In 2001, the Joint Commission began requiring health care organizations to adopt policies to inform patients of "unanticipated outcomes." The Lexington Veterans Affairs Healthcare System and the University of Michigan generated interest in CRP adoption after reporting early successes with their programs.[2,3] The Agency for Healthcare Research and Quality catalyzed progress by funding research on responding to harm and developing the Communication and Optimal Resolution toolkit.

Two features of CRPs' vision of the ethics of accountability are noteworthy. First, this conceptualization emphasizes that after harm occurs, all clinical team members (e.g., technicians, nurses, doctors) and health care organizations have a duty to make choices that minimize its impact. The suffering that patients and families experience from the harmful error itself is compounded, and often exceeded, when they do not receive a transparent, compassionate, and accountable response.[4] Second, this paradigm acknowledges that enacting these choices is challenging. At their core, CRPs codify the concept that after a clinician or organization has made a harmful error, they have a duty to help patients understand what happened, support them in coping, and prevent recurrences, recognizing that this obligation is fundamental to the respect and dignity owed to every patient. When clinicians and organizational leaders appreciate the values underlying CRPs, they may be motivated to take these uncomfortable steps.

Research has been critical to CRP expansion. Several studies have demonstrated that CRPs can enjoy physician support and operate without increasing liability risk. Nonetheless, research also shows that physicians remain concerned about their ability to communicate with patients and families after a harmful error and worry about liability risks including being sued, having their malpractice premiums raised, and having the event reported to the National Practitioner Data Bank (NPDB).[5] Successful CRPs typically deploy a formal team, prioritize clinician and leadership buy-

in, and engage liability insurers in their efforts. The table details the steps associated with the CRP model, the ethical rationale for each step, barriers to implementation, and strategies for overcoming them.

The growth of CRPs also reflects collaboration among diverse stakeholder groups, including patient advocates, health care organizations, plaintiff and defense attorneys, liability insurers, state medical associations, and legislators. Sustained stakeholder engagement that respects the diverse perspectives of each group has been vital, given the often opposing views these groups have espoused.

As CRPs proliferate, it will be important to address a few key challenges and open questions in implementing this ethical paradigm.

First, organizations will have to ensure that CRP implementation is aligned with ethical principles and their own stated mission. Incomplete CRP implementation is ubiquitous. Faithfully implementing CRPs is especially difficult in environments with limited resources (e.g., safety-net hospitals or freestanding outpatient clinics), urban areas where the liability risk is higher than average, complex cases such as those in which it's unclear whether the error caused harm, and cases of delayed diagnosis (e.g., the unknown extent of Ms. Z.'s harm would make the conversation with her more difficult and complicate reconciliation). Incomplete implementation fuels critics' concerns that CRPs are merely claims-management programs for obvious harmful errors. Health care organizations' boards of directors and adminis-

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CRP Model for Responding to Harmful Medical Errors.*				
CRP Step	**Ethical Rationale**	**What Should Happen in the Case of Ms. Z.**	**Common Barriers**	**Organizational Strategies to Address Barriers**
Clinician immediately reports event to organization	Unknown errors cannot be fixed Every clinician is obligated to improve the system	PCP reports delay to a designated office (e.g., patient safety), triggering CRP	Clinicians' fear of punitive consequences for themselves or others Inadequate follow-up on safety reports	Adoption of a just culture (no punishment for human error, discipline for intentional actions) Better loop closure
Prompt, honest, and empathetic communications with patient	Empathetic and honest information sharing is essential to patient autonomy and informed decision making	CRP team works with PCP to arrange conversation with Ms. Z. to acknowledge delay, apologize, promise follow-up, and answer her questions	Fear that conversation will increase liability Not knowing what to say	Just-in-time support from CRP team to ensure and guide open, empathetic conversations
Support for all needs of patients, including psychological and logistic support	The responsibility to minimize patient suffering after harm includes supporting patient needs however possible	CRP offers and helps Ms. Z. find short- and long-term psychological and other support resources	Belief that patient needs are limited to disclosure, apology, and financial compensation	CRP offers and helps find necessary supports for patients
Psychological support for clinicians	Organizations are obligated to support clinicians' psychological well-being	CRP team offers (and provides) psychological support for PCPs and anyone else involved	Shame, concern that seeking help is a sign of weakness, and fears about confidentiality	CRP ensures involved clinicians receive offers of support (often provided by clinical leadership), including access to confidential peer-support programs
Event analysis and prevention planning	Delivering safe health care requires learning from mistakes to prevent recurrences	Organization investigates what happened and takes steps to reduce the likelihood of a repeat event (e.g., if Dr. C.'s automated reminders in the electronic health record were not visible to Dr. B., provide a software fix)	Expertise and resources are required for timely investigation Effective improvements are often difficult to design and implement	CRP informs patients how organization will prevent similar events in future Development of safety and risk teams with necessary expertise on investigations and intervention design
Reconciliation	When error causes harm, justice and equity principles call for proactive efforts (e.g., not waiting for a claim) toward reconciliation	If the investigation uncovers a harmful error, organization apologizes and works with Ms. Z. to determine what she needs (e.g., compensation, prevention) If the investigation determines there was no harmful error, organization provides full details of the results	Traditional deny-and-defend approach Belief that if patients want financial compensation, they will ask for it	CRP proactively coordinates with liability insurers and seeks reconciliation with patients

* Tools to help organizations implement high-fidelity communication and resolution programs (CRPs), including a communication tip sheet, are available at https://communicationandresolution.org/tools-and-resources/. PCP denotes primary care physician.

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trative leaders should prioritize and provide adequate resources for their CRPs, including training for executives, program leaders, and risk managers. Whether organizational leaders will demonstrate the commitment required to ensure that CRP implementation is principled and consistent remains an open question.

A second key challenge is interfacing with the medical liability system. It's encouraging that several liability insurers now support CRPs. However, a strong barrier to CRPs has been fear of liability risk and difficulty changing longstanding claims-management processes, even among insurers that say they're enthusiastic about this approach. For example, an important function of insurers is to defend claims. Whose perspective should prevail if a provider believes a harmful error was made but the insurer believes the event is defensible? In addition, CRPs may appropriately settle cases on behalf of an organization for a systems failure, obviating the requirement to report a particular physician to the NPDB. Is this approach reasonable, even though it could make it more difficult to identify physicians who are repeatedly involved in substandard care? Finally, patients may be more likely to receive greater compensation when represented by legal counsel, but such representation can be costly and hard to find. What role should CRPs play in encouraging patients to seek representation and helping them find an attorney?

Third, organizations need to figure out how to balance commitment to transparency with protective privileges and agreements. It is somewhat paradoxical that

An audio interview with Thomas Gallagher is available at NEJM.org

although CRPs are rooted in a commitment to transparency, investigations into possible errors may be shrouded in secrecy. Quality improvement, peer review, and attorney–client privileges create "safe spaces" for organizations to examine quality-of-care challenges, but these privileges can inhibit the flow of information to patients and the public. Moreover, many liability settlements are accompanied by nondisclosure agreements, which may severely limit what, if anything, patients and families can say about the event that affected them. These restrictions, in turn, can both exacerbate patients' distress and inhibit prevention of errors at other organizations, running counter to the greater goals of CRPs. How public should the investigatory findings and ultimate resolution of a CRP case be?

A fourth challenge is ensuring that programs aimed at promoting transparency do not lead to unintended consequences. Open communication with patients is fundamental to CRPs. However, well-meaning clinicians sometimes rush to be open with patients but fail to prepare, and they may end up sharing information that is inaccurate and speculative, or they are perceived as lacking empathy. Patient trust that is lost during these first conversations is almost impossible to regain. How can organizations strike the right balance between encouraging both openness and discipline in communications about harm with patients and families without causing clinicians to question the sincerity of their organization's CRP?

Despite these challenges, CRPs are increasingly recognized as the standard for responding to errors. Recently, the President's Council

of Advisors on Science and Technology (PCAST) Working Group on Patient Safety publicly presented its recommendations to PCAST for "A Transformational Effort on Patient Safety." The working group recommended that the Centers for Medicare and Medicaid Services require the implementation of CRPs in order to achieve resolution in cases of patient harm (https://www.youtube.com/watch?v=oc7b5Ut5dwQ). Regulatory mandates that organizations deploy evidence-based CRPs and demonstrate reliable implementation seem inevitable.

Medicine exists as a public trust, with the expectation that the profession will self-regulate. Today, in the wake of all harmful errors, bioethical principles require that clinicians and health care organizations demonstrate transparency, compassion, and accountability and proactively meet patient needs. These steps cannot only increase trust in the health care system, but also help it improve.

From the Collaborative for Accountability and Improvement, the Division of General Internal Medicine, Department of Medicine, and the Department of Bioethics and Humanities, University of Washington Medicine, Seattle (T.H.G.); and the Armstrong Institute for Patient Safety and Quality and the Division of General Internal Medicine, Department of Medicine, Johns Hopkins Medicine, Baltimore (A.K.).

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Looking AHEAD to State Global Budgets for Health Care

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Fourteen years after the passage of the Affordable Care Act (ACA), the value-based care movement is facing hard truths. An evaluation of 49 of the first payment and care-delivery models implemented by the Center for Medicare and Medicaid Innovation (CMMI), which was established by the ACA, showed that the vast majority haven't achieved the goal of reducing health care spending.[1] The Congressional Budget Office (CBO) reported that, despite its initial projection that these models would result in nearly $3 billion in net savings between 2011 and 2020, CMMI actually increased federal spending by $5.4 billion over its first decade.[1] Although this analysis excluded the Medicare Shared Savings Program — a signature initiative that has produced moderate savings — the findings are sobering.

In the wake of these disappointing results, CMMI is advancing new approaches. In September 2023, the Centers for Medicare and Medicaid Services (CMS) announced an ambitious model — States Advancing All-Payer Health Equity Approaches and Development (AHEAD). The AHEAD model moves toward population-based payment at the state level and has three goals: curbing cost growth, improving population health, and advancing health equity. States can now apply to participate in this voluntary model, with a preimplementation period beginning in 2024 and a performance period of 8 to 9 years, lasting through 2034. AHEAD will employ several strategies to achieve its goals, each of which has both promising features and limitations.

First, AHEAD will use global budgets as the primary strategy for curbing cost growth. Under this payment scheme, health systems are assigned budgets to finance the full range of medical services for a specified patient population. Hospitals will receive biweekly payments from Medicare that are based on historical revenue and their patients' medical needs. If these payments exceed the costs of providing care, hospitals will keep the excess revenue. Conversely, if hospital expenditures exceed the payments, hospitals will absorb the additional costs. The rationale for this model is that fixed budgets — which are independent of the volume and type of services provided — create incentives to reduce unnecessary utilization and to shift investment away from high-intensity services and toward primary and preventive care. Global budgets also present an opportunity to control the growth of health care spending. Capping annual budget increases at the rate of inflation could slow spending growth, thereby generating savings for Medicare and state governments. AHEAD builds on the experiences of Vermont, Pennsylvania, and especially Maryland, which experienced slower spending growth in some areas after implementing global budgets for its hospitals in 2014.[2]

Second, AHEAD seeks to improve population health by elevating primary care. Global budgets theoretically encourage investment in preventive services because reducing avoidable hospitalizations will be financially beneficial. In Maryland, however, global budgets weren't consistently associated with increases in primary care use, which suggests that implementing global budgets alone may be inadequate to shift care patterns.[4] AHEAD invests in primary care more directly by offering enhanced payments to outpatient practices (including federally qualified health centers and rural health clinics) that make advances in areas such as behavioral health integration, care coordination, and screening for social needs. CMS expects these payments to average $17 per patient per month, which could drive hundreds of thousands of dollars in

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