NIH Pragmatic Trials Collaboratory Steering Committee Meeting
April 21, 2022

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This presentation is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference

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No financial conflicts to disclose

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 29, 2011 VOL. 365 NO. 26

Liberal or Restrictive Transfusion in High-Risk Patients after Hip Surgery

Jeffrey L. Carson, M.D., Michael L. Terrin, M.D., M.P.H., Helaine Noveck, M.P.H., David W. Sanders, M.D., Bernard R. Chaitman, M.D., George G. Rhoads, M.D., M.P.H., George Nemo, Ph.D., Karen Dragert, R.N., Lauren Beaupre, P.T., Ph.D., Kevin Hildebrand, M.D., William Macaulay, M.D., Courtland Lewis, M.D., Donald Richard Cook, B.M.Sc., M.D., Gwendolyn Dobbin, C.C.R.P., Khwaja J. Zakriya, M.D., Fred S. Apple, Ph.D., Rebecca A. Horney, B.A., and Jay Magaziner, Ph.D., M.S.Hyg., for the FOCUS Investigators*

Supported in part by grants from the National Heart, Lung, and Blood Institute (U01 HL073958 and U01 HL074815).

RE GAIN

regional vs. general anesthesia for promoting independence after hip fracture surgery

- Pragmatic RCT of standard-care spinal versus standard-care general anesthesia for hip fracture surgery
  - PI: Mark Neuman, MD, MSc, University of Pennsylvania
- Enrollment dates 2/2016-2/2021
- 1,600 patients 45 centers in US & Canada
- Primary outcome: recovery of independence in walking at 60 days
- Secondary outcomes: complications, delirium, pain, opioid use; in-hospital to 365 days
- Funding: Patient Centered Outcomes Research Institute, 1406-18876
- ClinicalTrials.gov number NCT02507505

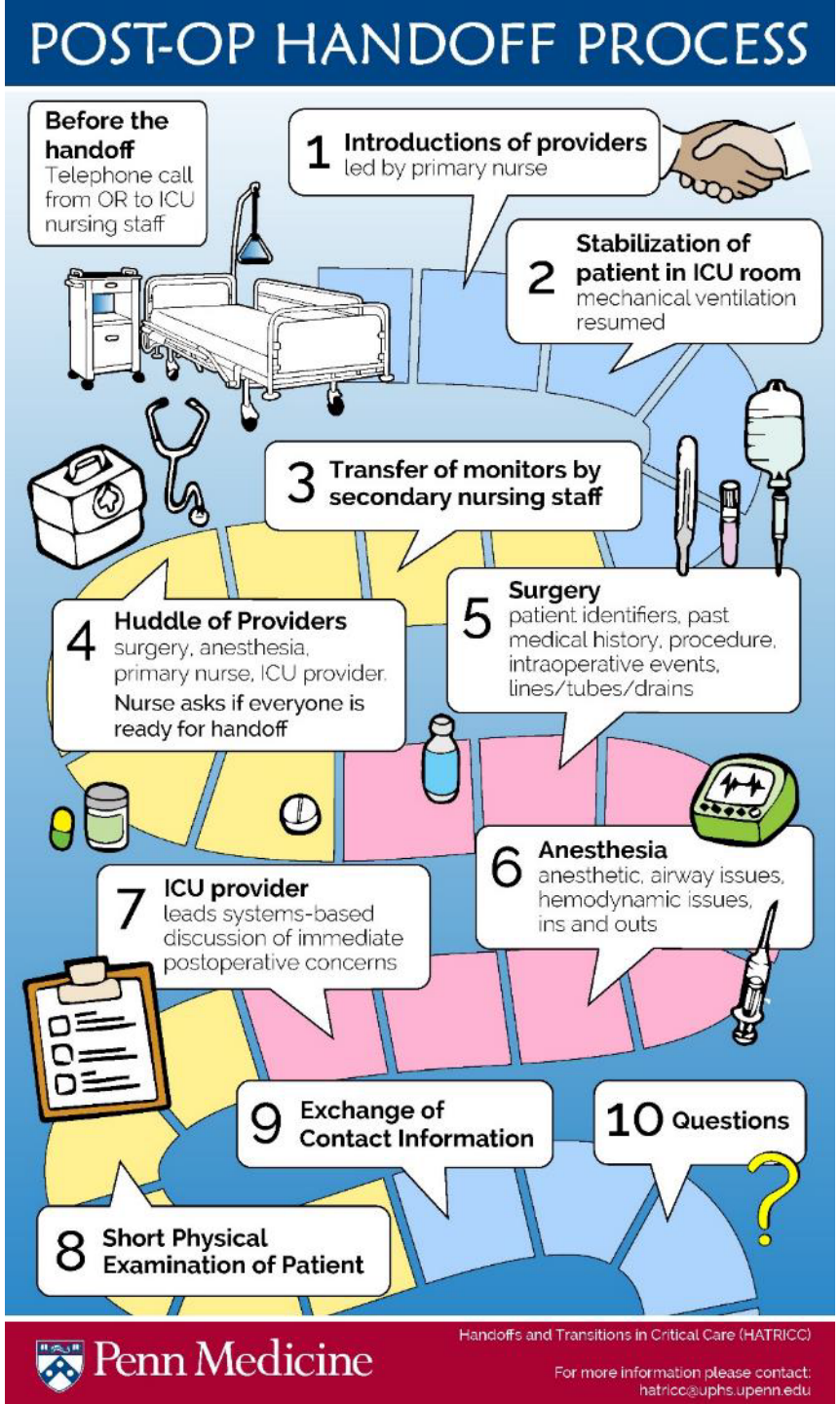
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Spinal Anesthesia or General Anesthesia for Hip Surgery in Older Adults

M.D. Neuman, R. Feng, J.L. Carson, L.J. Gaskins, D. Dillane, D.I. Sessler, F. Sieber, J. Magaziner, E.R. Marcantonio, S. Mehta, D. Menio, S. Ayad, T. Stone, S. Papp, E.S. Schwenk, N. Elkassabany, M. Marshall, J.D. Jaffe, C. Luke, B. Sharma, S. Azim, R.A. Hymes, K.-J. Chin, R. Sheppard, B. Perlman, J. Sappenfield, E. Hauck, M.A. Hoeft, M. Giska, Y. Ranganath, T. Tedore, S. Choi, J. Li, M.K. Kwofie, A. Nader, R.D. Sanders, B.F.S. Allen, K. Vlassakov, S. Kates, L.A. Fleisher, J. Dattilo, A. Tierney, A.J. Stephens-Shields, and S.S. Ellenberg, for the REGAIN Investigators*

A new handoff process developed iteratively with clinician input



Lane-Fall et al. *Joint Commission Journal,* 2018.

1R01HL153735-01 | National Heart, Lung, and Blood Institute
9/2020 - 7/2025

	Aim 1	Aim 2	Aim 3	Aim 4
	Exploration	**Preparation**	**Implementation & Sustainment**	**Toolkit**
Questions to be answered	What determines whether ICUs will **adopt** and **use** a handoff protocol for patients with cardiopulmonary failure?	How should a handoff protocol be **customized to best fit** each ICU? Which **implementation strategies** address each ICU's context?	How does **implementation strategy tailoring** effect implementation and effectiveness outcomes?	**How can we operationalize** context characterization, intervention customization, and implementation for widespread dissemination?
Approach	**Contextual inquiry** through observations, interviews, focus groups, surveys, document review	**Customization** using participatory design; **Implementation mapping** based on Aim 1 determinants	**Tailored implementation** based on Aim 2 mapping; Type 2 hybrid design, stepped wedge with randomized roll-out	**Human-centered design** with facilitated stakeholder meetings, think-aloud exercises
Outcomes* & deliverables	**Implementation determinants for each ICU**	**Customized versions of HATRICC for each ICU**	**Implementation:** Fidelity (co-primary) **Effectiveness:** Incident organ failure in ICU (co-primary)	**Digital implementation toolkit for dissemination, scientific manuscripts, lay press publications**

HATRICC-US
HANDOFFS AND TRANSITIONS IN CRITICAL CARE
UNDERSTANDING SCALABILITY

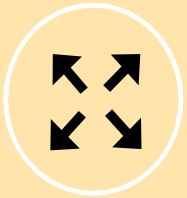
CMS Strategic Pillars

ADVANCE EQUITY

Advance health equity by addressing the health disparities that underlie our health system

EXPAND ACCESS

Build on the Affordable Care Act and expand access to quality, affordable health coverage and care



ENGAGE PARTNERS

Engage our partners and the communities we serve throughout the policymaking and implementation process

DRIVE INNOVATION

Drive Innovation to tackle our health system challenges and promote value-based, person-centered care

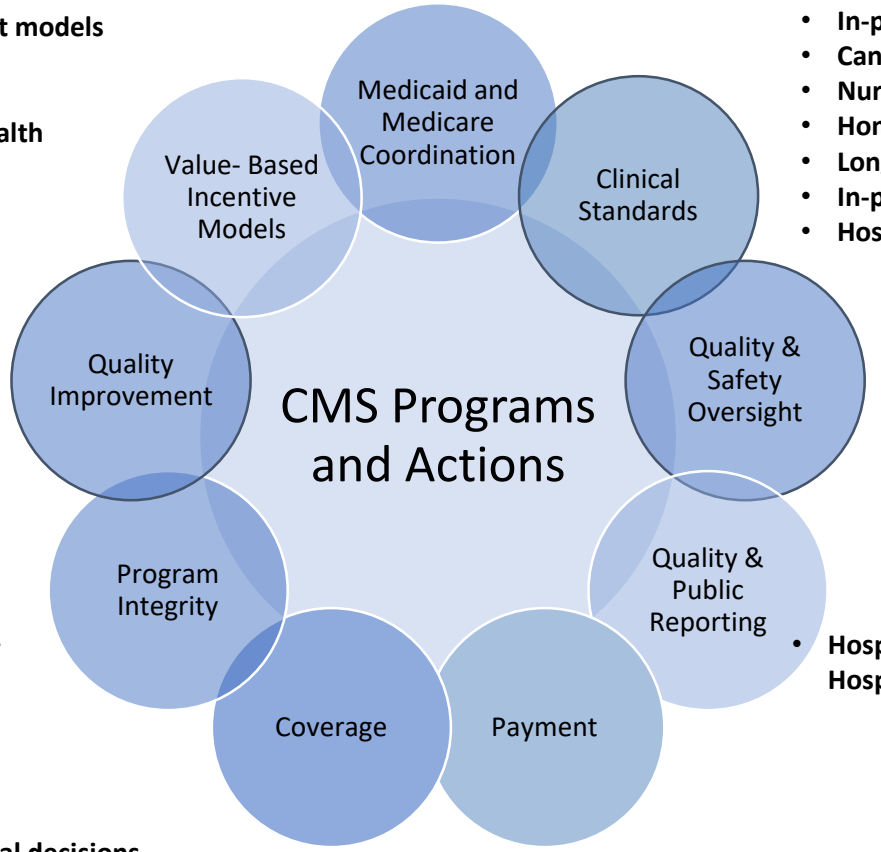
PROTECT PROGRAMS

Protect our programs' sustainability for future generations by serving as a responsible steward of public funds

FOSTER EXCELLENCE

Foster a positive and inclusive workplace and workforce, and promote excellence in all aspects of CMS's operations

CMS Authorities & Programs



- **1115 Waivers**
- **Demonstration programs**
- **Innovation Accelerator Program**

- **Hospital Inpatient Quality**
- **Hospital Outpatient**
- **In-patient psychiatric hospitals**
- **Cancer hospitals**
- **Nursing homes**
- **Home Health Agencies**
- **Long-term Care Acute Hospitals**
- **In-patient rehabilitation facilities**
- **Hospices**

- **Advanced Alternative payment models**
- **ACOs, PCMH, Bundles**
- **Multi-payer State agreements**
- **Prevention and Population Health**
- **Rapid Cycle Evaluation**

- **Quality Improvement Organizations**
- **Hospital Innovation & Improvement Networks**

- **CLIA**
- **Target surveys**
- **Quality Assurance Performance Improvement**

- **Provider Enrollment**
- **Fraud, Waste & Abuse Prevention & Detection**
- **Medical Review**
- **Audits and Investigations**

- **Hospitals, Home Health Agencies, Hospices, ESRD facilities**

- **National & Local decisions**
- **Mechanisms to support innovation (CED, parallel review, other)**

- **Part D**
- **VBP hospitals, SNF, HHA, ESRD**
- **Payment adjustments HAC, hospital RRP**
- **Physician Quality Payment Program (QPP)**

Vision: What's to Come Over the Next 10 Years

To read the white paper, visit innovation.cms.gov

How are we defining value in this strategy?

- Value **for all people with Medicare.**
  - **Care that is the highest quality**
    - **Safe with best outcomes**
    - **Patient-centered**
    - **Equitable**
  - **And also affordable**

Looking Back, Looking Forward – Building a Strategy

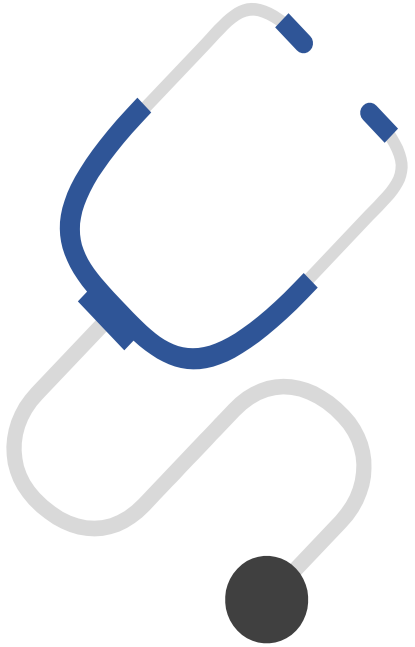
EMBED HEALTH EQUITY IN EVERY MODEL	
ISSUES and CHALLENGES: • Full diversity of beneficiaries in Medicare and Medicaid is not reflected in many models • Models have not systematically evaluated impacts across beneficiaries with different demographic characteristics	**NEXT STEPS:** • Design models to target and increase participation among providers that care for underserved populations • Require a deliberate and consistent approach to assess model impacts on underserved populations and close disparities in care and outcomes
STREAMLINE MODEL PORTOLIO	
ISSUES and CHALLENGES: • Complex payment policies and model overlap rules can result in conflicting incentives for providers • Participants face difficulty in joining or continuing in models due to investment and administrative burden	**NEXT STEPS:** • Create a cohesive strategy for model development and evolution and ensure hierarchy of models is rational • Make model parameters, requirements, and other critical details as transparent and easily understandable as possible

Looking Back, Looking Forward – Building a Strategy

SUPPORT CARE DELIVERY TRANSFORMATION	
ISSUES and CHALLENGES: • Accepting downside risk is challenging if providers lack tools to manage care and risk • Significant infrastructure investments are often needed to participate in models	**NEXT STEPS:** • Make actionable data, learning collaboratives, and payment flexibilities available to participants • Send strong and consistent signals and expectations about CMS' commitment to value-based care for participants
MODEL DESIGN MAY NOT ENSURE BROAD TRANSFORMATION	
ISSUES and CHALLENGES: • Model design features, including in some cases voluntary participation, can lead to selection bias • Multi-payer models designed for Medicare providers have not attracted Medicaid and commercial payers	**NEXT STEPS:** • Reduce selection bias by improving model design (*e.g.*, benchmarking, risk adjustment, and transformation supports) • Consider multi-payer alignment opportunities earlier in model design process

CMS Mission: Promoting Evidence-based Care

- Evidence-based coverage underpins the HHS / CMS value mission
- CMS is uniquely positioned to establish evidence-based care standards
- CMS may extend coverage to an item or service that is considered "reasonable and necessary" as defined under the Social Security Act
- CMS is evaluating items and services to ensure they are 1) safe and effective, 2) not experimental or investigational, and 3) appropriate for Medicare beneficiaries



FDA and CMS Authorities

"Responsible for protecting the public health by ensuring the **safety, efficacy, and security** of … drugs, biological products, and medical devices."[1]

Authority to determine whether a particular medical item or service is "**reasonable and necessary**"[2] **for the treatment of an illness or injury**.

[1]https://www.fda.gov/about-fda/what-we-do; [2]*Heckler v. Ringer*, 466 U.S. 602, 617 (1984).

CMS Coverage Options for both Routine and Emerging (Breakthrough) Technologies

National Level

National Coverage Determination (NCDs) +/-

Coverage with Evidence Development

- 3 - 4 completed annually, on average
- Timing driven by available resources, priorities, and external factors
- Finalized 9 months after opening
- Current waitlist

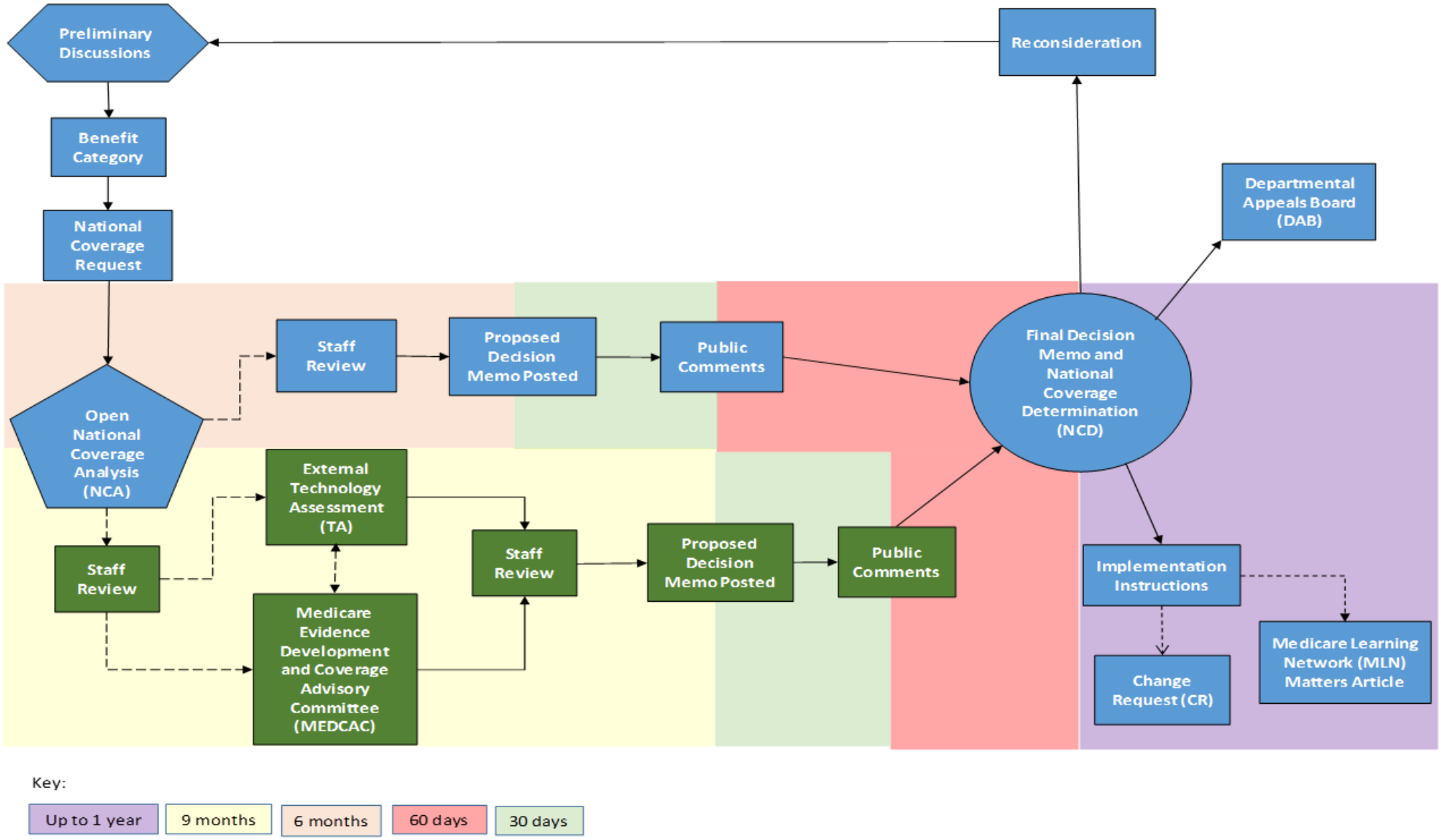
Local (MAC) Level

Local Coverage Determination (LCDs)

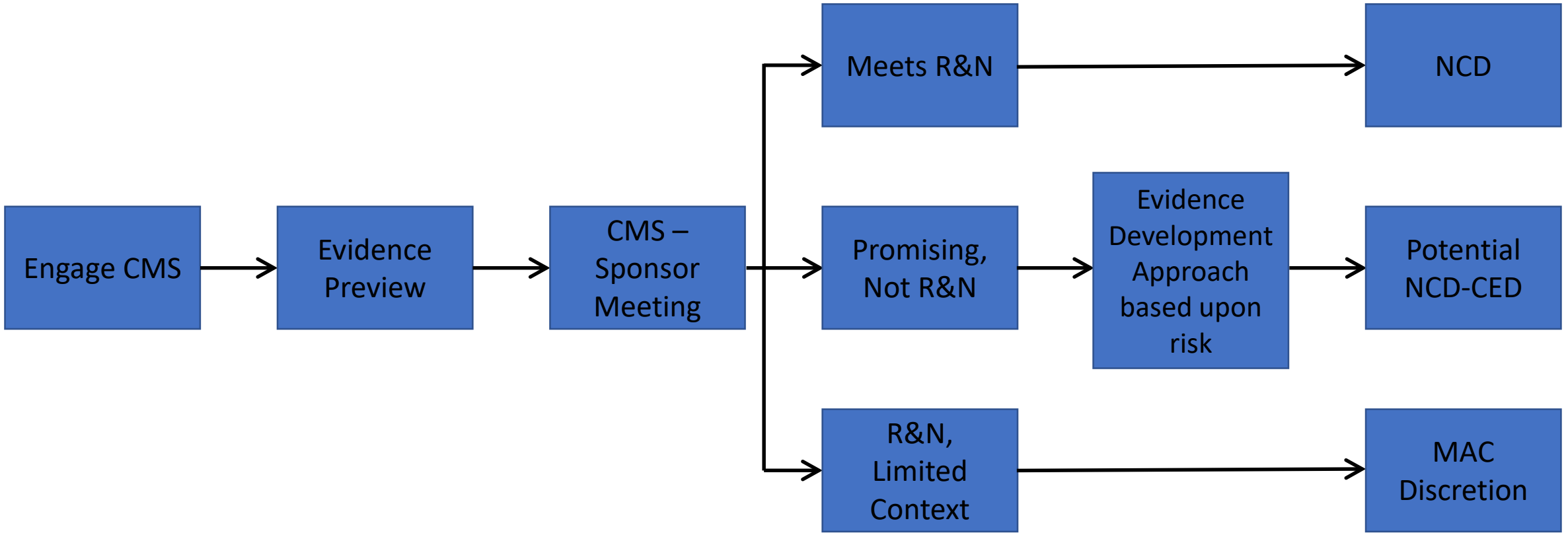
- 37 unique LCDs annually, on average
- May vary by jurisdiction, less so for lab tests and durable medical equipment
- Effective ~ 9 months after opening

Individual Claim Determination

- No NCD or LCD
- Coverage based on individualized MAC assessment


Preliminary Discussions
Reconsideration
Benefit Category
National Coverage Request
Departmental Appeals Board (DAB)
Staff Review
Proposed Decision Memo Posted
Public Comments
Final Decision Memo and National Coverage Determination (NCD)
Open National Coverage Analysis (NCA)
External Technology Assessment (TA)
Staff Review
Staff Review
Proposed Decision Memo Posted
Public Comments
Implementation Instructions
Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)
Change Request (CR)
Medicare Learning Network (MLN) Matters Article
Key:
Up to 1 year
9 months
6 months
60 days
30 days

Future State for Emerging Technologies: Mapping a Potential Coverage Process



Legend: Evidence Preview = current evidence vs. reasonable and necessary standard; R&N = Reasonable and Necessary; Evidence Development Approach = Collaborative Evidence Development Plan; NCD = National Coverage Determination; NCD-CED = NCD including Coverage with Evidence Development; MAC = Medicare Administrative Contractor.

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Drivers of change

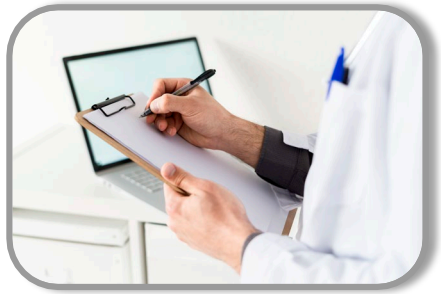
Assessment

Highest-Quality, Best-Value, and Patient-Centered Care within a Resilent System framework

$

Payment Models

Elevator: Quality improvement



Assessment: Quality measures

Minimum for all individuals

Conditions of Participation

Survey and enforcement

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Pragmatic Trials and Improving Long-Term Care: Recommendations From a National Institutes of Health Conference

TABLE 1 Recommendations to Improve Pragmatic Trials and Achieve Evidence-Based Change in Long-Term Care Practice and Policy: Revamp, Respond, Reframe, Reach

1. *Revamp* the academic mindset and enterprise
   - Develop practice-based evidence
   - Change the academic mindset and academic process to one of quality improvement
   - Maximize nimble funding opportunities
2. *Respond* to what is known about content and process
   - Draw from existing knowledge regarding the topic *in the context of* implementation
   - Think systemically when implementing a new intervention
   - Build the knowledge base related to the topic in the context of implementation
3. *Reframe* the partnership paradigm
   - Be purposeful in identifying partners
   - Begin the collaboration before the proposal is written
   - Collaborate to change care practices that are not pragmatic
4. *Reach* 3 key parties toward 3 key goals when communicating
   - Communicate to organizations to change care
   - Communicate to the public to drive awareness and create urgency
   - Communicate to academics to promote science

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CMS NATIONAL QUALITY STRATEGY

A Framework to Advance Quality and Safety in American Healthcare

Building and Evolving Quality

Traditional Quality

- Safe
- Timely
- Effective
- Efficient
- Equitable
- Patient Centered

Re-Envisioned Quality

- Safer Systems
- Global Metrics
- EQUITY
- Patient Directed and Reported
- Resilient
- Workforce
- Digital
- Aligned

Patient Centered Care: The CMS National Quality Strategy

- Aims to promote the highest quality outcomes and safest care for all individuals. Quality is integral to highest value.
- Focuses on a person-centric approach as individuals journey across the continuum of care and across payer type.
- Incorporates lessons learned from the COVID-19 Public Health Emergency to inform both short and long-term direction for our health care system.
- Supports creation of a more equitable, safe, and outcomes-based health care system for all individuals.

CMS National Quality Strategy: Goals

Embed Quality across the Care Journey

Advance Health Equity

Foster Engagement with Stakeholders Focused on Person & Family-Centered Care

Promote Safety to Achieve Zero Preventable Harm

Strengthen Resiliency in the Healthcare System

Embrace the Digital Age

Incentivize Scientific Innovation & Technology

Increase Alignment to Promote Seamless and Coordinated Healthcare

The QIO Program's 14 Quality Innovation Network-QIOs (QIN-QIOs) bring Medicare beneficiaries, providers, and communities together in data-driven initiatives that increase patient safety, make communities healthier, better coordinate post-hospital care, and improve clinical quality. By serving regions of two to six states each, QIN-QIOs are able to help best practices for better care spread more quickly, while still accommodating local conditions and cultural factors.

One Classic Example: Isolated Systolic Hypertension (ISH) in the elderly

Article

June 26, 1991

Prevention of Stroke by Antihypertensive Drug Treatment in Older Persons With Isolated Systolic Hypertension

Final Results of the Systolic Hypertension in the Elderly Program (SHEP)

JAMA. 1991;265(24):3255-3264. doi:10.1001/jama.1991.03460240051027

Using Measures to Drive Improved Performance

- Measures drive improved performance
  - Should support ongoing performance improvement
  - May be used in incentives or penalties
  - Most programs start as incentives, or pay to report, and then transition to pay for performance
- Measures are used in incentive based payment programs in order to incentivize/penalize for performance
- Link performance to payment as opposed to just pay for volume = VALUE
- CMS goal – to have all healthcare payments in advanced value payment models (value = quality + safety + experience / cost)
- How do measures move us in a direction of advanced value payment models, and what measures are most valuable in this payment world

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CMS Quality Incentive Programs

Hospital IQR – Inpatient Quality	MIPS - Clinician	Post Acute Care – SNF QRP
Hospital – Readmissions Reduction	MSSP Clinician Reporting	Expanded SNF VBP
Hospital Value Based Purchasing	Advance Payment Models	Hospice Quality Reporting
Hospital Acquired Conditions	Support Act – eRX of Opioids	Home Care Quality Reporting
Hospital Promoting Interoperability	Medicare C& D Stars Rating	Inpatient Rehabilitation Facility
Cancer Exempt Hospital	Hospital Stars	Long Term Care Hospital
Inpatient Psychiatric Hospital	Nursing Home Stars	Medicaid Adult Core Set
Hospital Outpatient	Home Health VBP	Medicaid Child Core Set
Ambulatory Surgery Program	Rural Emergency Hospitals	
ESRD QIP	Marketplace Quality Reporting	

NQF MAP Process not used for Medicaid, Marketplace or CMMI models; different processes used

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

FEBRUARY 17, 2022

Health Care Safety during the Pandemic and Beyond — Building a System That Ensures Resilience

Lee A. Fleisher, M.D., Michelle Schreiber, M.D., Denise Cardo, M.D., and Arjun Srinivasan, M.D.

The health care sector owes it to both patients and its own workforce to respond now to the pandemic-induced falloff in safety by redesigning our current processes and developing new approaches that will permit the delivery of safe and equitable care across the health care continuum during both normal and extraordinary times. We cannot afford to wait until the pandemic ends.

udio interview
Dr. Fleisher is
e at NEJM.org

Measure Domain: Safety

Domain Category (Goals): SAFETY	Domain Indicator (Measurable Objectives)
National Serious Safety Events	Healthcare Associated Infections
	Healthcare Associated Complications
	Diagnostic Accuracy/Error
	Medication Error
	EMR Safety
Safety Culture	Culture of Safety
	Reliability/Resiliency
	Preparedness
Workforce Safety	Workforce Resiliency
	Staffing
	Burnout and Turnover
Safety for Special Populations	Maternal Safety
	Pediatric Safety
	Elder Care/Geriatrics/Nursing Home Residents
	Vulnerable Populations (at risk from equity/social determinants)

Traditional MIPS Reporting

Performance Category	Submission Type	Collection Type	Measures/Requirements
 Quality	• Direct • Sign-in and Upload • Medicare Part B Claims *(small practices)*	• eCQMs • MIPS CQMs • QCDR Measures • Medicare Part B Claims Measures *(small practices)* • CAHPS for MIPS Survey *(groups only)* • Web Interface *(groups only)*	• 12-month reporting • You select **6** individual measures ▪ 1 must be an outcome measure OR a high-priority measure (if an outcome is not available) • **Or** you report **all 10** CMS Web Interface measures *(groups only)*

 Cost	• No data submission required	N/A	• 12-month reporting
			• No reporting
			• Measures include:
			  ▪ Medicare Spending Per Beneficiary Clinician (MSPB-C) measure
			  ▪ Total Per Capita Cost (TPCC) measure
			  ▪ 18 episode-based measures

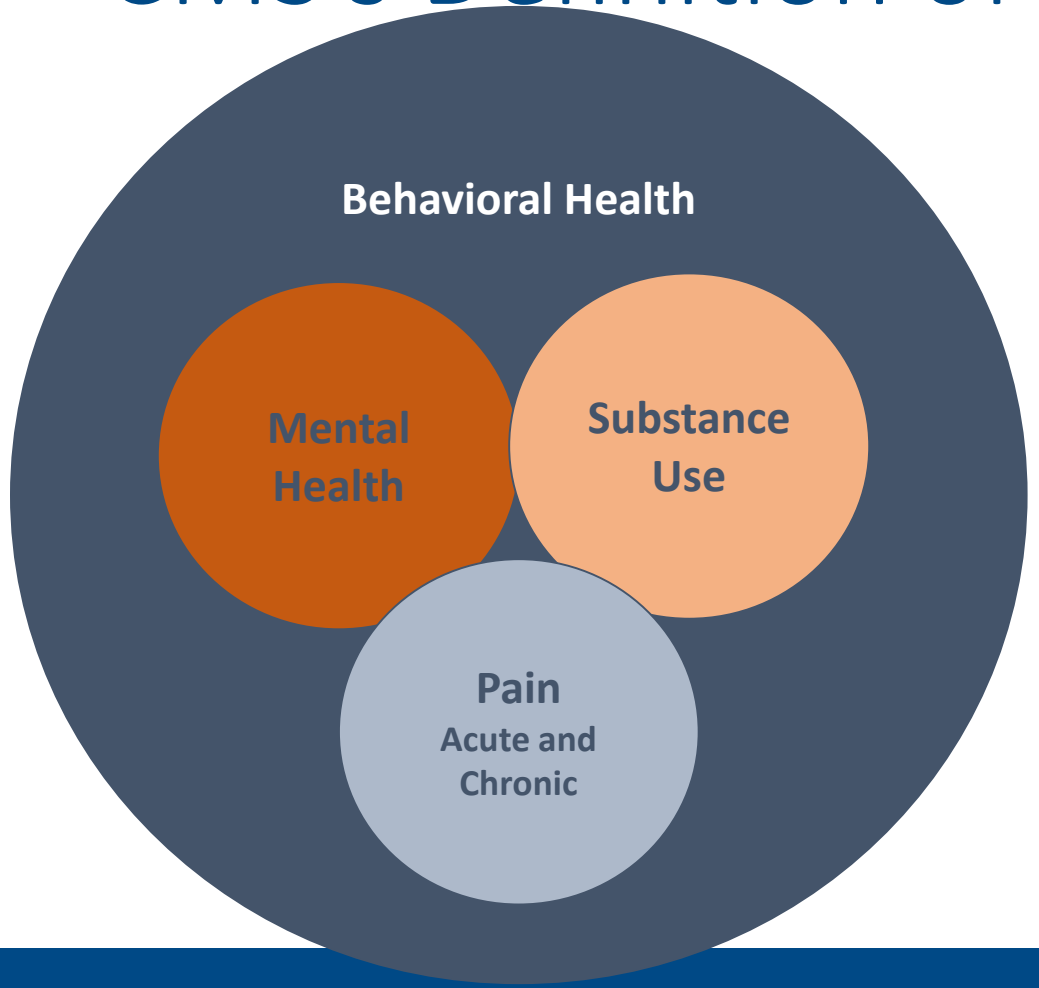
 Improvement Activities	• Direct
	• Sign-in and Upload
	• Sign-in and Attest
		N/A	• 105 activities
			• 90-day reporting
			• The maximum score is 40 points; each activity contains a weight:
			  ▪ Medium – worth 10 points
			  ▪ High – worth 20 points

 Promoting Interoperability	• Direct • Sign-in and Upload • Sign-in and Attest	N/A	• 90-day reporting • Must use Certified EHR Technology (CEHRT) • 4 Objectives: 1. e-Prescribing; **2.** Health Information Exchange; 3. Provider to Patient Exchange; **4.** Public Health and Clinical Data Exchange

MIPS Clinical Trial Improvement Activities

COVID-19 Clinical Data Reporting with or without Clinical Trial	1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or 2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research.
MIPS Eligible Clinician Leadership in Clinical Trials or CBPR	Lead clinical trials, research alliances, or community-based participatory research (CBPR) that identify tools, research, or processes that focus on minimizing disparities in healthcare access, care quality, affordability, or outcomes.

CMS's Definition of Behavioral Health



Behavioral health encompasses a beneficiary's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental disorders and substance use disorders.

"Whole-person care" encompasses the whole of a beneficiary's needs including physical health, behavioral health, oral health, long-term services and supports, and health-related social needs.

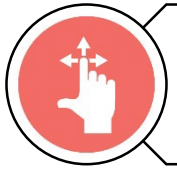
CMS Behavioral Health Strategy

Mission: To make high quality, affordable, effective, equitable, and data-informed behavioral health, mental health, substance use disorders, and pain care services available to CMS consumers.

Vision: Consumers receive person-centered behavioral health, mental health, substance use disorders, and pain care services that successfully address their needs and foster healthy lives characterized by independence, self-determination, hope, dignity, and meaning.

CMS Behavioral Health Strategy Goals

Strengthen Equity & Quality in Behavioral Health Care



Improve Access to Substance Use Disorder Prevention, Treatment and Recovery Services

Ensure Effective Pain Treatment and Management

Improve Access to and Quality of Mental Health Care and Services

Utilize Data to Inform Effective Actions and Measure Impact on Behavioral Health

Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014

- Bill passed on September 18, 2014, and signed into law October 6, 2014
- **The Act requires the submission of standardized patient assessment data elements by:**
  - Long-Term Care Hospitals (LTCHs): LCDS
  - Skilled Nursing Facilities (SNFs): MDS
  - Home Health Agencies (HHAs): OASIS
  - Inpatient Rehabilitation Facilities (IRFs): IRF-PAI
- **The Act specifies that data** "… be **standardized and interoperable** so as to allow for the **exchange of such data among such post-acute care providers and other providers** and the use by such providers of such data that has been so exchanged, including by **using common standards and definitions** in order to provide access to **longitudinal information** for such providers to **facilitate coordinated care** and **improved Medicare beneficiary outcomes**…".

Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014

Post-acute Care Assessment Content

- **Administrative Content**
  - Patient Name
  - Date of Birth
  - Race/Ethnicity
  - Marital status
  - Admission/Discharge dates
  - Admit from/Discharged to locations
  - Reason for admission
  - Provider NPI, CCN, Medicaid Provider #

- **"SPADEs"**
  - Function (e.g., self care and mobility)
  - Cognitive function (e.g., express & understand ideas; mental status, such as depression and dementia)
  - Special services, treatments & interventions (e.g., need for ventilator, dialysis, chemotherapy, and total parenteral nutrition)
  - Medical conditions and co-morbidities (e.g., diabetes, heart failure, and pressure ulcers)
  - Impairments (e.g., incontinence; impaired ability to hear, see, or swallow)
  - Other categories

- **Clinical Content**
  - Diagnosis/medical conditions
  - Mental/Cognitive Status (memory, orientation, consciousness, delirium, mood, behavior)
  - Communication (express needs, understanding verbal/non-verbal content, hearing and vision)
  - Functional Status (Self-care/ADLs, Mobility, Use of assistive devices)
  - Bladder and Bowel continence
  - Falls
  - Pressure ulcers and other skin conditions
  - Surgery
  - Nutritional and swallowing status
  - Medication information
  - Special treatments, procedures & programs
  - Height and Weight
  - Patient preferences and goals of treatment
  - Pain
  - Vaccinations
  - Therapy- PT, OT, SLT
  - Living arrangements/support availability
  - Care planning

Patient _____ Identifier _____ Date _____

Section J Health Conditions

J0510. Pain Effect on Sleep

Enter Code

Ask patient: "Over the past 5 days, ***how much of the time has pain made it hard for you to sleep at night?"***

0. **Does not apply – I have not had any pain or hurting in the past 5 days** → *Skip to K0200, Height and Weight*
1. **Rarely or not at all**
2. **Occasionally**
3. **Frequently**
4. **Almost constantly**
8. **Unable to answer**

J0520. Pain Interference with Therapy Activities

Enter Code

Ask patient: "Over the past 5 days, ***how often have you limited your participation in rehabilitation therapy sessions due to pain?"***

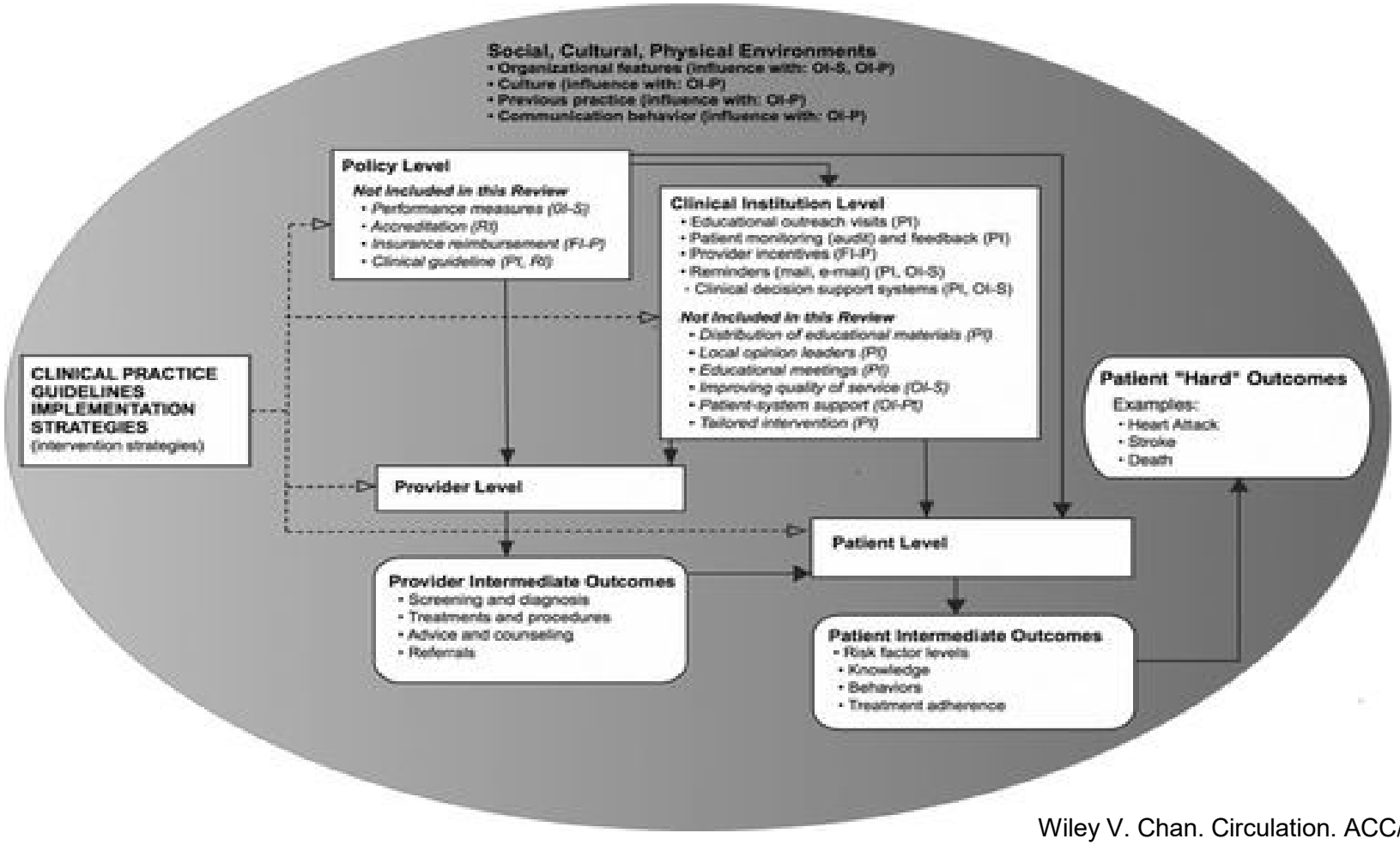
0. **Does not apply – I have not received rehabilitation therapy in the past 5 days**
1. **Rarely or not at all**
2. **Occasionally**
3. **Frequently**
4. **Almost constantly**
8. **Unable to answer**

J0530. Pain Interference with Day-to-Day Activities

Enter Code

Ask patient: "Over the past 5 days, ***how often have you limited your day-to-day activities (excluding rehabilitation therapy sessions) because of pain?"***

1. **Rarely or not at all**
2. **Occasionally**
3. **Frequently**
4. **Almost constantly**
8. **Unable to answer**



Wiley V. Chan. Circulation. ACC/AHA Special Report: Clinical Practice Guideline Implementation Strategies: A Summary of Systematic Reviews by the NHLBI Implementation Science Work Group, Volume: 135, Issue: 9, Pages: e122-e137

Healthcare 8 (2021) 100432

Contents lists available at ScienceDirect

Healthcare

journal homepage: www.elsevier.com/locate/healthcare

Accounting for quality improvement during the conduct of embedded pragmatic clinical trials within healthcare systems: NIH Collaboratory case studies*

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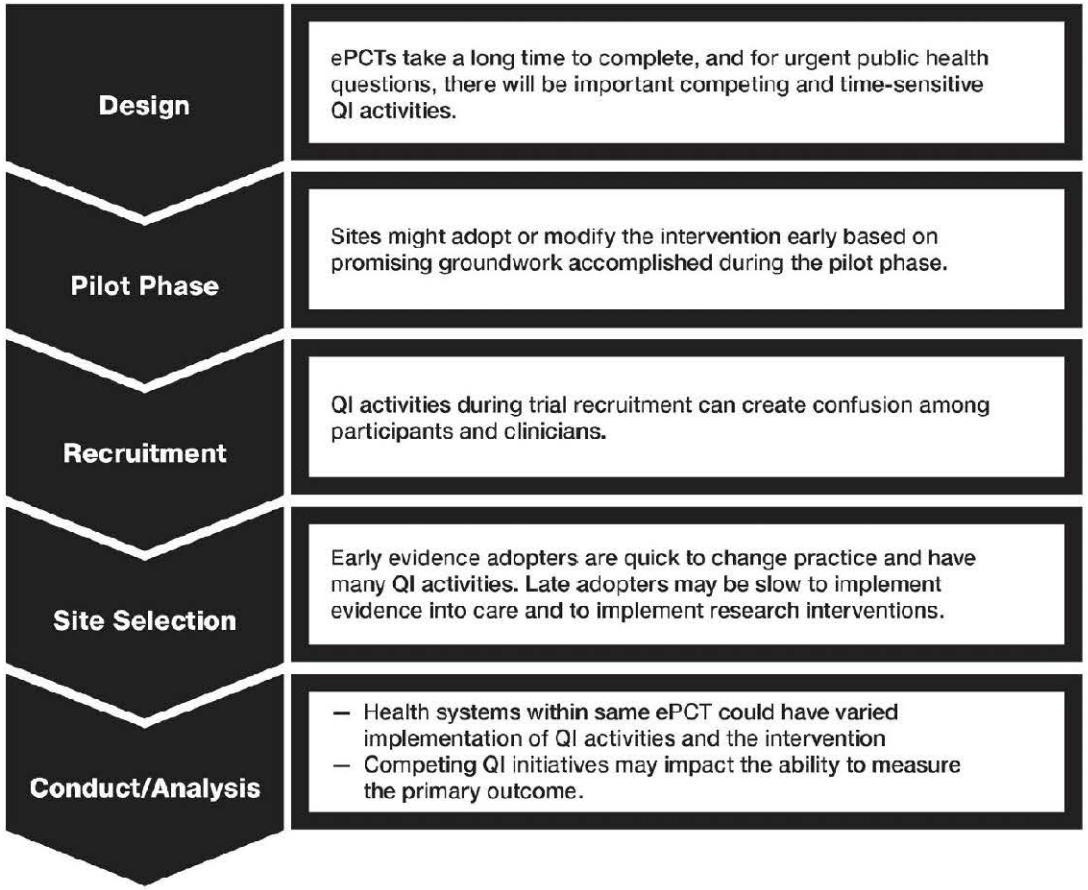


Fig. 1. Challenges that arose from QI activities by phase of the ePCT.

What Makes a Good Measure

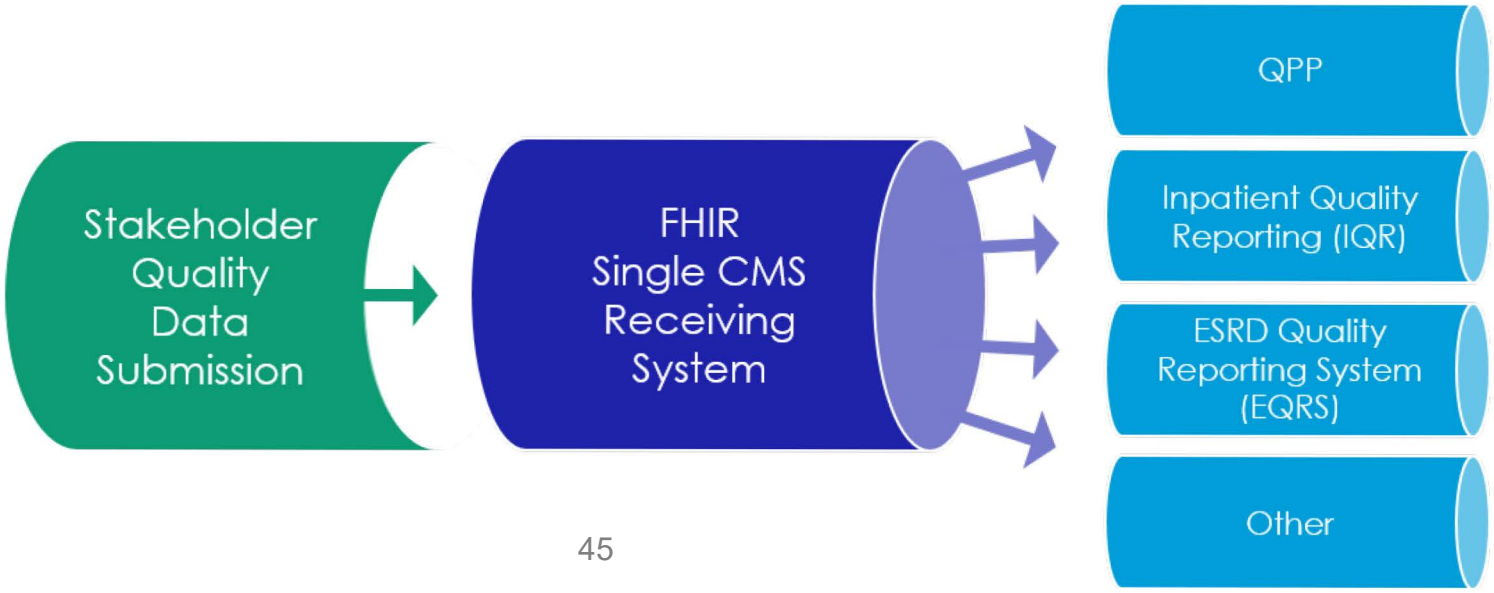
- High Impact
- Meaningful to patients and providers
- Supports Scientific Evidence and Best Practice
- No Unintended Consequences
- Valid and Reliable
- Feasible
- Appropriate Risk Adjustment – clinical, social determ
- Availability of Standardized Data Elements
- Low Burden
- Outcome/Patient reported outcome preferred over Process

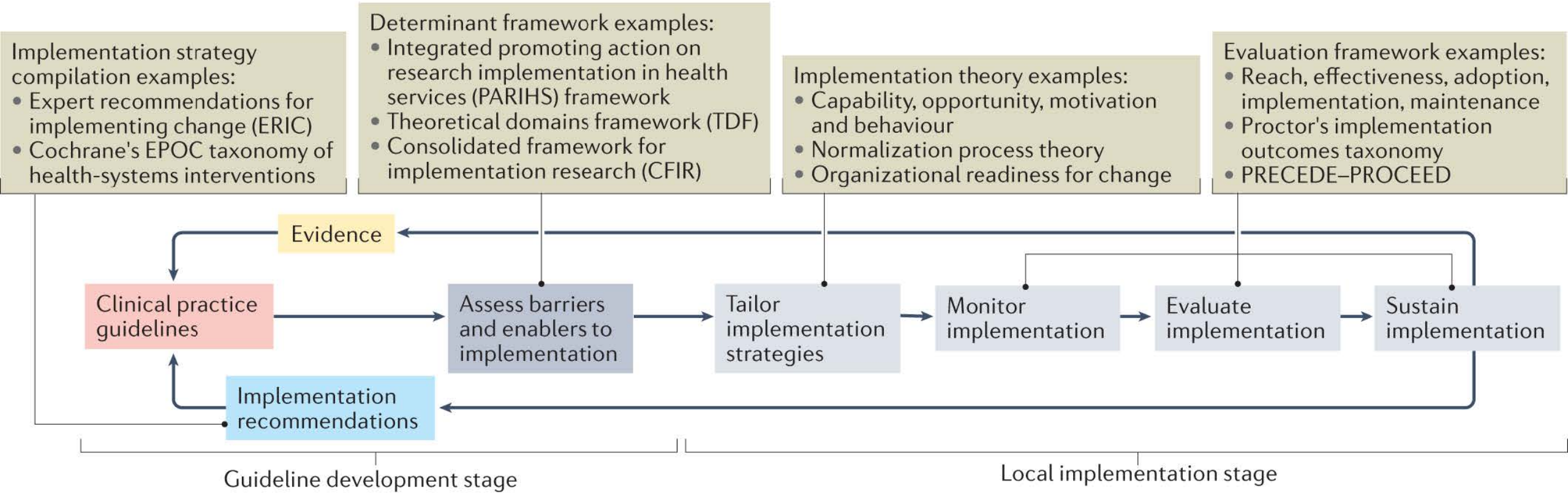
Measure Domain: Safety

Domain Category (Goals): SAFETY	Domain Indicator (Measurable Objectives)
National Serious Safety Events	Healthcare Associated Infections
	Healthcare Associated Complications
	Diagnostic Accuracy/Error
	Medication Error
	EMR Safety
Safety Culture	Culture of Safety
	Reliability/Resiliency
	Preparedness
Workforce Safety	Workforce Resiliency
	Staffing
	Burnout and Turnover
Safety for Special Populations	Maternal Safety
	Pediatric Safety
	Elder Care/Geriatrics/Nursing Home Residents
	Vulnerable Populations (at risk from equity/social determinants)

FHIR Pilot: Future State Submissions

A successful FHIR pilot leads the way for stakeholders to submit to a centralized submission solution for quality reporting. The receiving system can then do the measure calculations and exchange data and results with applicable quality programs, removing the burden from the submitter.





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Thank you!

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