The Imperative To Move To Value-Based Cardiovascular Care

Nihar R. Desai, MD, MPH
Associate Professor of Medicine, Yale School of Medicine
Vice Chief, Section of Cardiovascular Medicine
Investigator, Center for Outcomes Research and Evaluation
Disclosures

• Support from the Centers for Medicare and Medicaid Services to develop and maintain performance measures that are used for public reporting and payment programs.

• Research support and consulting from Amgen, Astra Zeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, CSL Behring, Cytokinetics, Merck, Novartis, SC Pharmaceuticals, Vifor.

• Medical review committee for Anthem.
First Things First

• We are in the midst of a remarkable period of scientific, technological, and therapeutic advances.
There Are Signs of Progress Everywhere
There Are Signs of Progress Everywhere

- 1958: Coronary arteriography developed (Sones)
- 1962: First beta-blocker developed (Black)
- 1969: First description of CABG (Favaloro)
- 1976: First HMG CoA reductase inhibitor described (Endo)
- 1961: Risk factors defined
- 1961: Coronary care unit developed (Julian)
- 1972: NHBPEP
- 1976: First implantable cardioverter-defibrillator developed (Mirowski)
- 1979: Coronary angioplasty developed (Grüntzig)
- 1980: First description of CABG (Favaloro)
- 1985: TIMI 1
- 1983: CASS
- 1986: GISSI and ISIS-2
- 1985: NCEP
- 1992: SAVE
- 1993: Superiority of primary PCI vs. fibrinolysis in acute MI noted
- 2002: ALLHAT
- 2007: Benefit of cardiac resynchronization therapy in heart failure demonstrated
- 2009: Genomewide association in early-onset MI described
- 2009: Deep gene sequencing for responsiveness to cardiovascular drugs performed
- 2002: Efficacy of drug-eluting vs. bare-metal stents determined
- 2009: Left-ventricular assist device as destination therapy in advanced heart failure shown to be effective
- 2009: Benefit of cardiac resynchronization therapy in heart failure demonstrated

Deaths per 100,000 Population

Year


1954 First open-heart procedure (Gibbon)
1961 First coronary care unit developed (Julian)
1958 Coronary arteriography developed (Sones)
1972 NHBPEP
1961 Risk factors defined
1980 First description of CABG (Favaloro)
1969 First description of CABG (Favaloro)
1976 First HMG CoA reductase inhibitor described (Endo)
1979 Coronary angioplasty developed (Grüntzig)
1985 TIMI 1
1983 CASS
1985 NCEP
1992 SAVE
1993 Superiority of primary PCI vs. fibrinolysis in acute MI noted
2002 ALLHAT
2007 Benefit of cardiac resynchronization therapy in heart failure demonstrated
2009 Genomewide association in early-onset MI described
2009 Deep gene sequencing for responsiveness to cardiovascular drugs performed
2002 Efficacy of drug-eluting vs. bare-metal stents determined
2009 Left-ventricular assist device as destination therapy in advanced heart failure shown to be effective
The Other Side of the Coin

• We are in the midst of a remarkable period of scientific, technological, and therapeutic advances.
• We are in the midst of a remarkable period of payment and delivery reform catalyzed by substantial variation in quality and outcomes as well as rising health care expenditures.
Sobering Gaps in Care

A Patients who achieved LDL-C levels <70 mg/dL and <55 mg/dL

- Achieved LDL-C level of 55-69 mg/dL
- Achieved LDL-C level of <55 mg/dL

Cannon CP et al. JAMA Cardiol. 2021
Readmissions: Prevalent, Costly, (Preventable)

Cumulative Percentage of Patients Rehospitalized

1 Month: 21.1%
3 Months: 36.6%
6 Months: 47.9%
1 Year: 59.4%

Disparities in Care

National crude hospitalization rate by race/ethnicity and sex

National age-standardized hospitalization rate by race/ethnicity and sex

Pt. Pacific Islander.
Substantial Variation in CV Outcomes

Spiraling Health Care Costs

Total U.S. health spending (public and private) is projected to rise to nearly one-fifth of the economy by 2025.

National Health Expenditures (% of GDP)

- 1980: 9%
- 1990: 12%
- 2000: 13%
- 2010: 17%
- Projected: 18% in 2020, 19% in 2025

Source: Centers for Medicare and Medicaid Services, National Health Expenditures, March 2020.
Where Do We Want To Go?

Clinical & Policy Objectives

- Reduce Hospitalization & Readmissions
- Reduce Length of Stay
- Reduce Spending & Increase Value
- Improve Quality & Outcomes of Care
How Do We Actually Get There?

- **Clinical & Policy Objectives**
  - Reduce Hospitalization & Readmissions
  - Reduce Length of Stay
  - Reduce Spending & Increase Value
  - Improve Quality & Outcomes of Care

- **Transformative therapeutics**
- **Timely quality & performance measures**
- **Innovative technology and remote monitoring platforms**
Rapidly Expanding Therapeutic Armamentarium

FIGURE 1  Timeline of Completed and Ongoing LDL Cholesterol-Lowering Cardiovascular Outcome Trials

Placebo-controlled statin trials
- AFCAPS/TexCAPS
- WOSCOPS
- 4S
- CARE
- LIPID
- ALERT
- PROSPER
- HPS
- CARDS
- SPARCL
- JUPITER
- ASCOT-LLA
- IMPROVE-IT
- CORONA
- ASPEN
- GISSI-HF
- GIANT
- STAREE
- HOPE-3

Statin vs. Usual/standard care
- ALLHAT-LLT
- GISSI Prevenzione
- A to Z
- TNT
- IDEAL
- PROVE-IT
- SEARCH

Ezetimibe trials
- SEAS
- SHARP
- CLEAR Outcomes
- Bempedoic acid trial

Statins dose comparison trials
- SPIRE
- SEARCH
- ODYSSEY OUTCOMES
- ORION-4
- PCSK9 inhibitor/synthesis inhibitor trials
The Fundamental Problem

Sobering Gaps in Care

A Patients who achieved LDL-C levels <70 mg/dL and <55 mg/dL

- Achieved LDL-C level of 55-69 mg/dL
- Achieved LDL-C level of <55 mg/dL

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline (n=4951)</th>
<th>Year 2 (n=4218)</th>
<th>Baseline (n=537)</th>
<th>Year 2 (n=519)</th>
<th>Baseline (n=2626)</th>
<th>Year 2 (n=2235)</th>
<th>Baseline (n=1788)</th>
<th>Year 2 (n=1464)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td></td>
<td></td>
<td>Baseline (n=537)</td>
<td>Year 2 (n=519)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort taking PCSK9i</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort with LDL-C level of 70-99 mg/dL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohort with LDL-C level ≥100 mg/dL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cannon CP et al. JAMA Cardiol. 2021
How Do We Actually Get There?

- Transformative therapeutics
- Timely quality & performance measures
- Innovative technology and remote monitoring platforms
- Renewed patient and community engagement efforts
- Novel care delivery and clinical operations
Use of ongoing data to drive health system improvement
Focus on iterative and ongoing learning
All stakeholders participate

Key Areas of Synergy

- Evolution of evidence base for precision medicine and implementation science
- Recognition of underuse and overuse of interventions
- Management of abundance of data

Optimal integration of effective diagnosis, prevention, and treatment

Understanding of multilevel content

Theories and strategies to drive health care improvement

Key Areas of Synergy

- Support for implementation of effective practices
- Contextually sensitive
- Improvement of practices

Adapted from Chambers DA et al. JAMA. 2016;315:1941-1942.

Optimal use of data to drive clinical care and patient decision making
Ongoing development of the evidence base, novel therapies
Improved phenotyping of complex diseases

Key Areas of Synergy

- Refresh cycle of evidence base
- Determination of degree of achievable personalization of care
One Part of the Solution…
Reconfigure Clinical Operations

Green, LW. American Journal of Public Health, 2006
Evidence Generation in Heart Failure

**Current Paradigm**

- National Registries
- Publications
- Practice Insights

**Proposal**

- Live EHR-based Registry at Integrated Health Care Systems
- Cross-Sectional and Longitudinal Examinations
- Interventions Aimed at Quality Improvement
- Practice Insights

**Advantages**

- Inexpensive
- Automated
- Adaptable
- Allows Feedback
- Allows Interventions

Figure. Our proposal on how integrated health care systems can play a key role in addressing the challenges of heart failure research today that requires a far more cost-effective and rapid innovation-implementation cycle.
PROMPT-Lipid: Study Schema

**Study Flow**

- **Cardiology and Internal Medicine providers within the Yale New Haven Health System**

  **Randomization**

  - **Intervention Provider**
  - **Control Provider**

  **Patients with very high risk ASCVD**
  and LDL-C > 70 mg/dL

  **Informational Alert**

  **Usual Care**

  **Outcome Assessment**

*Based on 2018 ACC/AHA/Multisociety Lipid Guidelines*
PROMPT-LIPID Alert

Key Technical Elements:
1. Patient ID
2. LDL-C timing relative to medication changes
3. Medication assessment

Key Alert Attributes:
1. User Designed
2. Real-time
3. Targeted
4. Tailored
5. Embedded Ordering Capability
PROMPT-LIPID Order Set

1. High Intensity Statins
   - Usage: Patient not on high-intensity statin
     - atorvastatin 40 mg tablet
     - atorvastatin 80 mg tablet
     - rosuvastatin 20 mg tablet
     - rosuvastatin 40 mg tablet

2. Ezetimibe
   - Usage: Patient already on high-intensity statin and LDL still >70mg/dL
     - ezetimibe 10 mg tablet

3. PCSK9i
   - Usage: Patient already on high dose statin and LDL still >70mg/dL
     - evolocumab 140 mg/mL pen injector
     - evolocumab 420 mg/3.5 mL wearable injector
     - alirocumab 75 mg/mL Pen Injector
     - alirocumab 150 mg/mL Pen Injector

4. Follow-up Labs
   - 90 Day Lipid Panel w/ Hyperlipidemia HCC Dx
     - Hyperlipemia (E78.5) Select Specific Diagnosis
     - Lipid panel

PROMPT-LIPID: Rapid Enrollment Across Yale New Haven Health System
PROMPT-LIPID Results

OR 2.33 (1.48, 3.66), p = 0.0004
Number Needed to Alert = 9

p = 0.008

p = 0.01

21.2%
How Do We Actually Get There?

- Transformative therapeutics
- Timely quality & performance measures
- Innovative technology and remote monitoring platforms
- Renewed patient and community engagement efforts
- Novel care delivery and clinical operations
- Alternative payment models
### Medicare Payment Policy

<table>
<thead>
<tr>
<th>Alternative Payment Model</th>
<th>P4P (HRRP, HVBP, MIPS)</th>
<th>Bundled Payments</th>
<th>Accountable Care Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview</td>
<td>Focus on specific measures and specific quality domains</td>
<td>One payment per defined episode—movement away from simple utilization-based reimbursement</td>
<td>Population-based care (payment not triggered by service delivery) rewarding integration, quality, outcomes, and efficiency</td>
</tr>
</tbody>
</table>

**Payment Models…They Are A Changin’**

- **IPPS/FFS**
- **P4P**
  - HRRP
  - HVBP
  - MIPS
- **Bundled Payments**
  - BPCI
  - BPCI-Advanced
- **Accountable Care Organizations**
  - MSSP
  - NextGen ACO

---

Cardiology Is In The Thick Of It…

Medicare Payment Policy

<table>
<thead>
<tr>
<th>IPPS/FFS</th>
<th>P4P</th>
<th>Bundled Payments</th>
<th>Accountable Care Organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HRRP, HVBP, MIPS</td>
<td>BPCI, BPCI-Advanced</td>
<td>MSSP, NextGen ACO</td>
</tr>
</tbody>
</table>

### Alternative Payment Model

<table>
<thead>
<tr>
<th>Cardiology Focus</th>
<th>P4P (HRRP, HVBP, MIPS)</th>
<th>Bundled Payments</th>
<th>Accountable Care Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology Focus</td>
<td>30-day readmission and mortality for AMI, HF Process Measures for CAD, HF</td>
<td>Cardiac Care is among the most frequently selected clinical episode service line groups in BPCIA</td>
<td>Given the prevalence of chronic cardiovascular conditions (CAD, HTN, HF, etc) and their associated health care utilization, ACOs necessarily have to focus on these conditions/patients.</td>
</tr>
</tbody>
</table>

A Summary & A Look Ahead

• Despite deeper understanding of the physiology and pathobiology of heart failure and an expanding therapeutic arsenal, we find ourselves with significant gaps in performance, evidenced by suboptimal quality, disparities in care, variation in outcomes, and spiraling costs.
• We must continue to invest in innovation and foster development of novel therapies.
• Alternative payment models will be essential to fully aligning the interests of patients, providers, payers, and policymakers.
• To fully realize its potential, the transition to value-based care must be met with a realignment, reconfiguration, and reimagination of clinical care including novel approaches to care delivery, patient engagement, and policy.