The Role of Personalized Medicine in Improving American Healthcare

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Personalized Medicine Coalition
March 13, 2014
Discussion

- Our Goals and Early Results
- Quality Measurement and Value-based purchasing
- Center for Medicare and Medicaid Innovation
- Coverage
- Future and Opportunities for collaboration
Delivery system and payment transformation

**Current State –**
- Producer-Centered
- Volume Driven
- Unsustainable
- Fragmented Care
- FFS Payment Systems

**Future State –**
- People-Centered
- Outcomes Driven
- Sustainable
- Coordinated Care

**New Payment Systems (and many more)**
- Value-based purchasing
- ACOs, Shared Savings
- Episode-based payments
- Medical Homes and care mgmt
- Data Transparency
The “3T’s” Road Map to Transforming U.S. Health Care

Key T1 activity to test what care works

Clinical efficacy research

Basic biomedical science ↔ Clinical efficacy knowledge ↔ Clinical effectiveness knowledge

Key T2 activities to test who benefits from promising care

Outcomes research
Comparative effectiveness research
Health services research

Key T3 activities to test how to deliver high-quality care reliably and in all settings

Quality Measurement and Improvement
Implementation of Interventions and health care system redesign
Scaling and spread of effective interventions
Research in above domains

Improved health care quality & value & population health

• At least six components
  – Quality measurement
  – Aligned payment incentives
  – Comparative effectiveness and evidence available
  – Health information technology
  – Quality improvement collaboratives and learning networks
  – Training of clinicians and multi-disciplinary teams

Source: P.H. Conway and Clancy C. Transformation of Health Care at the Front Line. JAMA 2009 Feb 18; 301(7): 763-5
Early Example Results

• Cost growth leveling off - actuaries and multiple studies indicated partially due to “delivery system changes”

• But cost and quality still variable

• Moving the needle on some national metrics, e.g.,
  – Readmissions
  – Line Infections

• Increasing value-based payment and accountable care models

• Expanding coverage with insurance marketplaces
Results: Medicare Per Capita Spending Growth at Historic Lows

Source: CMS Office of the Actuary

*Medicare Part D prescription drug benefit implementation, Jan 2006
Medicare All Cause, 30 Day Hospital Readmission Rate

Source: Office of Information Products and Data Analytics, CMS
National Bloodstream Infection Rate

Over 1,000 ICUs achieved an average 41% decline in CLABSI over 6 quarters (18 months), from 1.915 to 1.133 CLABSI per 1,000 central line days.

Quarters of participation by hospital cohorts, 2009–2012
Hospital Acquired Condition (HAC) Rates Show Improvement

- 2010 – 2012 - Preliminary data show a 9% reduction in HACs across all measures
- Many areas of harm dropping dramatically (2010 to 2013 for these leading indicators)

<table>
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<th>Ventilator-Associated Pneumonia (VAP)</th>
<th>Early Elective Delivery (EED)</th>
<th>Obstetric Trauma Rate (OB)</th>
<th>Venous thromboembolic complications (VTE)</th>
<th>Falls and Trauma</th>
<th>Pressure Ulcers</th>
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<td>55.3% ↓</td>
<td>52.3% ↓</td>
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<td>12.0% ↓</td>
<td>11.2% ↓</td>
<td>11.2% ↓</td>
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Beneficiaries Moving to MA Plans with High Quality Scores

Medicare Advantage (MA) Enrollment Rating Distribution

- 2-Star
- 3-Star
- 4-Star
- 5-Star

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<td>2014</td>
<td>1%</td>
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- 4 or 5 Stars
- 2 or 3 Stars

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<td>2014</td>
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Discussion

• Our Goals and Early Results
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The Six Goals of the National Quality Strategy

1. Make care safer by reducing harm caused in the delivery of care
2. Strengthen person and family engagement as partners in their care
3. Promote effective communication and coordination of care
4. Promote effective prevention and treatment of chronic disease
5. Work with communities to promote healthy living
6. Make care affordable
CMS framework for measurement maps to the six national priorities

- Measures should be patient-centered and outcome-oriented whenever possible
- Measure concepts in each of the six domains that are common across providers and settings can form a core set of measures

**Clinical quality of care**
- HHS primary care and CV quality measures
- Prevention measures
- Setting-specific measures
- Specialty-specific measures

**Person- and Caregiver-centered experience and engagement**
- CAHPS or equivalent measures for each setting
- Shared decision-making

**Care coordination**
- Transition of care measures
- Admission and readmission measures
- Other measures of care coordination

**Efficiency and cost reduction**
- Spend per beneficiary measures
- Episode cost measures
- Quality to cost measures

**Population/ community health**
- Measures that assess health of the community
- Measures that reduce health disparities
- Access to care and equitability measures

**Safety**
- Healthcare Acquired Infections
- Healthcare acquired conditions
- Harm
Value-Based Purchasing

• Hospital:
  • Value-based purchasing, readmissions, healthcare acquired conditions, EHR Incentive Program and Inpatient Quality Reporting

• Physician/clinician
  • Physician value-based modifier, physician quality reporting system, EHR incentive program

• End stage renal disease bundle and quality incentive program
Value-Based Purchasing

• Goal is to reward providers and health systems that deliver better outcomes in health and health care at lower cost to the beneficiaries and communities they serve.

• Hospital value-based purchasing program shifts approximately $1 billion based on performance

• Five Principles
  - Define the end goal, not the process for achieving it
  - All providers’ incentives must be aligned
  - Right measure must be developed and implemented in rapid cycle
  - CMS must actively support quality improvement
  - Clinical community and patients must be actively engaged

VanLare JM, Conway PH. Value-Based Purchasing – National Programs to Move from Volume to Value. NEJM July 26, 2012
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The purpose of the [Center] is to test innovative payment and service delivery models to reduce program expenditures…while preserving or enhancing the quality of care furnished to individuals under such titles.

- *The Affordable Care Act*
CMS Innovations Portfolio: Testing New Models to Improve Quality

**Accountable Care Organizations (ACOs)**
- Medicare Shared Savings Program (Center for Medicare)
- Pioneer ACO Model
- Advance Payment ACO Model
- Comprehensive ERSD Care Initiative

**Primary Care Transformation**
- Comprehensive Primary Care Initiative (CPC)
- Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration
- Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration
- Independence at Home Demonstration
- Graduate Nurse Education Demonstration

**Bundled Payment for Care Improvement**
- Model 1: Retrospective Acute Care
- Model 2: Retrospective Acute Care Episode & Post Acute
- Model 3: Retrospective Post Acute Care
- Model 4: Prospective Acute Care

**Health Care Innovation Awards**
- Partnership for Patients
- Community-Based Care Transitions
- Million Hearts

**State Innovation Models Initiative**

**Initiatives Focused on the Medicaid Population**
- Medicaid Emergency Psychiatric Demonstration
- Medicaid Incentives for Prevention of Chronic Diseases
- Strong Start Initiative

**Medicare-Medicaid Enrollees**
- Financial Alignment Initiative
- Initiative to Reduce Avoidable Hospitalizations of Nursing Facility Residents

**Capacity to Spread Innovation**
Innovation is happening broadly across the country
Accountable Care Organizations (ACOs)

• An ACO promotes coordinated care and population management
• Over 350 ACOs serving over 5 million Medicare beneficiaries
• Over $380 million of savings combined year 1 of MSSP and Pioneers
• Pioneer model with early promising results
  – Generated shared savings and low cost growth (0.3%)
  – Outperformed published benchmarks on 15/15 clinical quality measures and 4/4 patient experience measures
GOALS:

• Partner with states to develop broad-based State Health Care Innovation Plans
• 6 Implementation and 19 Design/Pre-testing States
• Plan, Design, Test and Support of new payment and service and delivery models
• Utilize the tools and policy levers available to states
• Engage a broad group of stakeholders in health system transformation
• Coordinate multiple strategies, payers, and providers into a plan for health system improvement
• Plan to announce round 2 soon
GOAL: Test new innovative service delivery and payment models that will deliver better care and lower costs for Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) enrollees.

• Test models in four categories:
  1. Reduce Medicare, Medicaid and/or CHIP expenditures in outpatient and/or post-acute settings
  2. Improve care for populations with specialized needs
  3. Transform the financial and clinical models for specific types of providers and suppliers
  4. Improve the health of populations
Partnership for Patients: Over 3500 Hospitals Reducing Harm and Improvement Accelerating
We’re Focused On

• Implementation of Models
• Monitoring & Optimization of Results
• Evaluation and Scaling
• Integrating Innovation across CMS
• Portfolio analysis and launch new models to round out portfolio
Possible Model Concepts

• Outpatient specialty models
• Practice Transformation Support
• Health Plan Innovation
• Consumer Incentives
• ACOs version 2.0
• Home Health
• SNF
• More.....
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Diagnostics

State of Diagnostic Testing

• Rarely therapeutic
• May expose a patient to specific short- or long-term risks
• The benefits & some potential harms accrue via its ability to inform downstream clinical management of the patient.
• The balance of risk and harm should consider the acuity and severity of the patient’s condition.

Individualized Response (e.g. in oncology)

• Drugs (anti-cancer) therapeutic agents are generally toxic, and are given at doses near those that produce adverse effects.
• Individuals vary widely in how they respond to anticancer agents.
• Ideally, treatment with would be guided toward optimizing net benefit (relative to harm) to patient.
• Companion diagnostics can inform how to best tailor therapy
Genetic & Pharmacogenomic Testing: Coverage Challenges

• The topic is very broad
• The science is evolving and questions are:
  • Is evidence sufficient?
  • Applicable to the Medicare population?
• Use of the information generated?
• The influence on health outcomes?
• CMS is willing to engage industry, FDA, and other stakeholders on considering best approach to a myriad of complex issues
ACCE Criteria and Coverage

• To ‘earn’ coverage, a genetic test’s sponsors should be able to demonstrate, based on published results, the following:
  • Analytical validity (for example: analytic accuracy; reproducibility)
  • Clinical Validity (for example, clinical sensitivity and specificity)
  • Clinical Utility (for example, improved outcomes due to selecting or excluding patients for therapy)
  • Ethical, legal and social concerns are appropriately met
Provide adequate evidence that...

- The **incremental information** obtained by new diagnostic technology compared to alternatives
- Changes **physician/clinician** recommendations
- Resulting in **changes in therapy**
- That **improve clinically meaningful health outcomes**

- A **treatment strategy** using the new therapeutic technology compared to alternatives
- Leads to **improved clinically meaningful health outcomes**
Pharmacogenomic Testing & Cancer Treatment Strategy

• Is there sufficient evidence that pharmacogenomic testing (PGT) provides information to make decisions that improve health outcomes for patients with cancer?

• Are PGT results informative concerning:
  – Diagnosis;
  – Prognosis; and/or
  – Predicting Response to Therapy?
Examples of Local Coverage

• Specific gene markers for hereditary cancer syndromes

1. Only a covered benefit for a Medicare beneficiary with a personal history of an illness, injury, or signs/symptoms thereof (i.e. clinically affected).

2. In the absence of past or present illness in the beneficiary, screening tests are not generally covered under national Medicare rules. For example, Medicare currently does not cover genetic tests based on family history alone.

3. A covered genetic test must be used to manage a patient who is a Medicare beneficiary [i.e., a genetic test is not covered for family planning; nor risk assessment of other family members; nor in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary].

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician.
5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:
   - Meets appropriate CLIA regulations;
   - Participates successfully in ACMG/CAP inspection and survey program;
   - Maintains appropriate state licensure and credentialing of laboratory director and staff by the American Board of Medical Genetics (ABMG).
Example of National Coverage

- Cytogenetic Studies [NCD 190.3 (1998)]
  - Detects abnormal chromosome number or structure (e.g., trisomy; translocations)
- Covered for these indications:
  - Genetic disorders in a fetus;
  - Failure of sexual development;
  - Chronic myelogenous leukemia;
  - Acute leukemias: lymphoid, myeloid, and unclassified; or
  - Myelodysplasia
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The Future of Quality Measurement for Improvement and Accountability

- Meaningful quality measures increasingly need to transition away from setting-specific, narrow snapshots
- Reorient and align measures around patient-centered outcomes that span across settings
- Measures based on patient-centered episodes of care
- Capture measurement at 3 main levels (i.e., individual clinician, group/facility, population/community)
- Why do we measure?
  - Improvement

Source: Conway PH, Mostashari F, Clancy C. The Future of Quality Measurement for Improvement and Accountability. JAMA 2013 June 5; Vol 309, No. 21 2215 - 2216
Opportunities and Challenges of a Lifelong Health System

• Goal of system to optimize health outcomes and lower costs over much longer time horizons
• Payers, including Medicare and Medicaid, increasingly responsible for care for longer periods of time
• Health trajectories modifiable and compounded over time
• Importance of early years of life

Source: Halfon N, Conway PH. The Opportunities and Challenges of a Lifelong Health System. NEJM 2013 Apr 25; 368, 17: 1569-1571
Financial Instruments and models that might incentivize lifelong health management

- Horizontally integrated health, education, and social services that promote health in all policies, places, and daily activities
- Consumer incentives (value-based insurance design)
- “Warranties” on specific services
- Bundled payment for suite of services over longer period
- Measuring health outcomes and rewarding plans for improvement in health over time
- Community health investments
- ACOs could evolve toward community accountable health systems that have a greater stake in long-term population health outcomes
What can we do together?

• Focus on better health, better care, and lower costs
• Test new models of care delivery and payment
• Recognize that era of personalized medicine enables improved patient outcomes
• Tailor interventions to appropriate patient segments
• Value innovation and cover and pay appropriately for interventions that improve patient outcomes
• Remove barriers to personalized medicine and catalyze transformation focused on patient-centered care
• Relentless pursuit of improving health outcomes
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