Improving Healthcare Systems Program

Advisory Panel Meeting
April 19-20, 2013

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Patient-Centered Outcomes Research Institute
Affordable Care Act (ACA) 2010 says PCORI shall fund research that:

- Discovers new information
- Allows patients/families/clinicians and health system leaders to make better decisions between alternative approaches
- Leads to better patient-centered outcomes of care
The ACA also says that PCORI’s research must be conducted by scientists who are engaged with patients and stakeholders (such as clinicians, executives of provider organizations, administrators of insurance companies, and representatives of manufacturers).

Significant engagement extends throughout the research process.
# National Priorities for Research and Research Agenda

## Assessment of Prevention, Diagnosis, and Treatment Options
- Comparisons of alternative clinical options to support personalized decision making and self-care
- Identifying patient differences in response to therapy
- Studies of patient preferences for various outcomes

## Improving Healthcare Systems
- Improving support of patient self-management
- Focusing on coordination of care for complex conditions and improving access to care
- Comparing alternative strategies for workforce deployment

## Communication and Dissemination Research
- Understanding and enhancing shared decision making
- Alternative strategies for dissemination of evidence
- Exploring opportunities to improve patient health literacy

## Addressing Disparities
- Understanding differences in effectiveness across groups
- Understanding differences in preferences across groups
- Reducing disparities through use of findings from PCOR

## Accelerating PCOR and Methodological Research
- Improving study designs and analytic methods of PCOR
- Building and improving clinical data networks
- Methods for training researchers and patients to participate in PCOR
- Establishing methodology for the study of rare diseases
What Is a Healthcare System?

Through the patient’s lens—all the providers of the care I receive, as well as my insurer

Through the provider’s lens—all the providers with whom I interact, as well as the insurers

Through the insurer’s lens—all the providers I pay to care for my insured lives

Through the economist’s lens—all the patients, providers, and insurers in a geographic area

Through your lens?
How Can Healthcare Systems Be Improved?

- Changes in the deployment of personnel
- Changes in the use of information
- Changes in operating policies
- Changes in patients’ behaviors
- Changes in payment policies
- Changes in linkages to community agencies
- Other changes?
Vision

PCORI’s IHS program will produce new scientific information to:

- Transform the quality and efficiency of critical components of the US healthcare system
- Improve health-related outcomes that matter most to Americans
How Can Patients Benefit?

- **Processes**—Engagement in self-care, coordination of care, improved access to care, better quality of care
- **Outcomes**—Improved quality of life, greater satisfaction with care, greater functionality in life roles
IHS’s Traditional Path for Selecting Topics for Research Contracts

Figure 1: Traditional Process

Investigator-Generated Research Just One Part of the Process

PCORI issues broad funding announcements

Researchers partner with stakeholders to generate questions

Researchers, stakeholders apply review criteria in their applications

Peer review prioritizes applications by level of alignment with criteria

Diverse Research Portfolio answering key questions for patients and clinicians
IHS’s Novel Path for Selecting Topics for Research Contracts

Patient/Stakeholder-Led Approach

PCORI and stakeholders generate and prioritize questions based on review criteria

PCORI issues specific, funding announcements for highest priority topics

Researchers and stakeholders develop responsive proposals

Peer review prioritizes applications by level of alignment with criteria

Diverse Research Portfolio answering key questions for patients and clinicians
PCORI’s IHS program enters into contracts under which selected organizations perform specified health systems–related research, and PCORI pays them an agreed amount.
Engaged patients and stakeholders:

- Participate in the formulation of the research questions to be answered
- Help define essential characteristics of study participants, the comparators, and the outcomes to be measured
- Help monitor the conduct and the progress of the study
- Help disseminate the study’s results
Patient-centered outcomes (PCOs) are outcomes people care about, for example:

- Symptoms
- Unwanted events
- Health
- Quality of life
- Function
- Safety
- Survival
What Kinds of Features Should Be Studied?

- Deployment of personnel
- Information technology (IT)
- Incentives
- Special programs, such as navigators who link medical care to community services that promote patient self-management
- Others?
Outline for Our Topic Brief Discussion

- Primary discussant(s) briefly describes the topic to orient the panel ~2 minutes
- Secondary discussant(s) can add any other information ~1 minute
Review of Agenda

- 2:00-3:30 PM: Topics 1–7
- 3:30 BREAK
- 3:45-5:15 PM: Topics 8–15
Rating Topics Using Criteria

Highest (Meets criteria)

Lowest (Does not meet criteria)
Criteria for Research Prioritization

Patient-centeredness
- Is the research of specific interest to patients and caregivers?

Impact of the condition on individual/population health
- Prevalence, incidence, morbidity, productivity, mortality

Options for addressing the issue
- What could new research contribute toward patient-centered outcomes?

Likelihood of implementing research results into practice
- How likely are study findings to change clinical practice?

Durability of information
- How long will the information resulting from this research be valuable?
#1 Compared to usual care, what are the effects of accountable care organization care on patient-centered outcomes among patients with chronic conditions?

| Introduction: | • The accountable care organization (ACO) model is patient-centered, with quality measures falling into four domains outlined by CMS: patient experience, care coordination and patient safety, preventive health services, and attention to at-risk populations  
• ACOs are designed to change practice patterns by aligning incentives |
| Burden: | • Chronic conditions affect >50% of US population  
• Accounts for >75% of healthcare spending  
• Seven out of 10 deaths in the US are related to chronic disease  
• Prevalence of chronic conditions in younger people has increased  
• Chronic conditions account for disability and diminution in quality of life |
| Options for addressing issue: | • ACOs  
• There are no guidelines or systematic reviews that address the impact of ACOs on patient-centered outcomes (PCOs)  
• The steps each is taking to implement an accountable care model are varied |
| Potential for new information to improve care and PCOs rapidly: | • Identifying best practices for assigning patients to ACOs  
• Developing measures to assess ACOs with respect to PCOs  
• Creating a taxonomy of implementation strategies and critically assessing the merits of each |
#2 What are the relative effects of different models of chronic care on PCOs?

## Introduction:
- Much of the occurrence and many of the complications of chronic diseases are also preventable
- Failures of the disease management approach have led to an increased focus on patient-centered management, which includes individualized treatment

## Burden:
- Chronic conditions affect >50% of US population
- Account for >75% of healthcare spending
- Seven out of 10 deaths in the US are related to chronic disease
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- Chronic conditions account for disability and diminution in quality of life

## Options for addressing issue:
- Traditional medical model: disease management focusing on single condition
- Newer models have focused on individual patients and their multiple needs
- Outcomes that extend beyond clinical outcomes
- A multidisciplinary team that extends beyond medical care

## Potential for new information to improve care and PCOs rapidly:
- Identifying best models and the relative effects of those models on PCOs
- Identifying which models maximize PCOs in various patient groups
- Identifying elements of a model that make it more or less successful
- Identifying the appropriate PCOs being evaluated
- Target model selection to the correct patients to maximize PCOs
#3 Compared to usual care, what is the effect of care management (designed to optimize care coordination and continuity) on PCOs among patients with COPD?

<table>
<thead>
<tr>
<th>Introduction:</th>
<th>COPD includes chronic bronchitis and emphysema</th>
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<tbody>
<tr>
<td></td>
<td>Patients have diverse needs arising from the disease itself</td>
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<td>Practice guidelines offer little guidance for these patients with complex and variable needs</td>
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<table>
<thead>
<tr>
<th>Burden:</th>
<th>&gt;12 million Americans affected</th>
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<td>Fourth leading cause of morbidity and mortality in the United States</td>
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<td>Direct cost estimated to be $30 billion in United States and indirect $20 billion</td>
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<td>Evidence shows practitioners adhere poorly to guideline recommendations</td>
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<table>
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<tr>
<th>Options for addressing issue:</th>
<th>&gt;40 guidelines released in last five years focusing on diagnostic strategies and treatment recommendations</th>
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<tbody>
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<td>The failure of traditional approaches suggests the need for management strategies that are patient-centered and include individualized treatment</td>
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<table>
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<tr>
<th>Potential for new information to improve care and PCOs rapidly:</th>
<th>Benefits of specialists, co-management, or referral for different patient groups</th>
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<td>Structure of provider teams</td>
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<td>How to structure care management in solo or small practices</td>
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<td>Care management to reduce ED usage, hospitalizations, and readmissions</td>
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Introduction:  
- Common approach is based in clinical practice guidelines, focusing on diagnostic criteria and treatment recommendations  
- Treatment must also manage the patient’s individual needs arising from associated comorbidities and treatment complications

Burden:  
- Cancer affects >1 million Americans  
- Cancer is the second leading cause of mortality in the United States  
- Direct costs of cancer were $124 billion in 2010  
- Incidence rates have remained stable or risen slightly in the last 10 years

Options for addressing issue:  
- Hundreds of cancer guidelines have been issued in the last five years, focusing on diagnosis and treatment  
- Guidelines on screening and early diagnosis exist for some cancers; however, adherence is low  
- Survivorship care plans exist to address the needs of cancer survivors, but lack evidence on whether they improve patient outcomes

Potential for new information to improve care and PCOs rapidly:  
- Impact of new developments in diagnostics and treatment on patients  
- How to facilitate the transition to life after cancer  
- Little research has been done on fear of recurrence
#5 Compared to usual care, what is the effect of care management (designed to optimize care coordination and continuity) on PCOs among patients requiring palliative care?

| Introduction: | • Palliative care is patient- and family-centered care with the goal of optimizing quality of life, by focusing on pain and symptom management, communication about goals and care planning, and psychosocial and spiritual support  
• PCOs may extend to family-caregiver–centered outcomes |
| --- | --- |
| Burden: | • Despite the benefits, hospice care usually does not occur in the United States  
• As much as 1/3 of healthcare utilization occurs at the end of life  
• Disparities exist related to race and income in areas such as pain management, communication, and use of hospice care |
| Options for addressing issue: | • Care management is one type of palliative care intervention  
• Moderate evidence for the effectiveness of palliative care interventions, but results vary depending on the outcomes, population, and settings  
• Limited evidence for other types of interventions, such as advance care planning, quality improvement, and policy initiatives |
| Potential for new information to improve care and PCOs rapidly: | • Larger, more inclusive, better quality studies that include a comprehensive range of patient populations, types of conditions, and outcomes to target and prioritize outcomes, increase access to care, and reduce disparities  
• Impact of improving communication about goals and care planning in settings other than intensive care units |
#6 Compared to usual care, what is the effect of care management (designed to optimize care coordination and continuity) on PCOs among pregnant women?

| Introduction: | • Care management models include expanding the scope of prenatal care beyond prevention of adverse outcomes to include emphasis on quality of care, continuity of care, maternal education, and social support  
• These models generally rely on the addition of nurses and other trained personnel to the care team |
|---|---|
| Burden: | • Maternal mortality has increased in recent years (13 deaths/100,000 births)  
• Adverse infant outcomes may lead to long-term health consequences and may pose a financial and emotional burden to caregivers |
| Options for addressing issue: | • Standard care: aims to optimize medical outcomes by providing regular screening and medical care  
• Care management: seeks greater continuity, more communication, and more pregnancy education, while minimizing delays in screening and treatment  
• Care management models are generally individual to institutions and difficult to generalize |
| Potential for new information to improve care and PCOs rapidly: | • Determine the impact of care management on clinical and patient-centered outcomes  
• Identify which models deliver the best outcomes  
• Determine whether care management helps with the early identification and care for high-risk pregnancies |
#7 Compared to usual care, what is the effect of care management (designed to optimize care coordination and continuity) on PCOs among patients with multiple chronic conditions?

| Introduction: | • Patients with two or more chronic conditions are said to have multimorbidity or multiple chronic conditions (MCCs) |
| Burden: | • 75 million people have MCCs  
• MCC patients are more likely to take multiple medications, have a higher rate of adverse events, more psychological distress, more rates of disability, and poorer quality of life than the rest of the population |
| Options for addressing issue: | • There are no standard management options for people with MCCs  
• Application of multiple single-condition clinical practice guidelines (common, but not optimal)  
• Individualized treatment plans, focused on the patient and his or her needs, with the patient an active participant in his or her own care  
• Effects of care management on PCOs for MCCs are not well understood |
| Potential for new information to improve care and PCOs rapidly: | • Optimal mix of providers structure of the teams providing care management  
• Optimal frequencies and modalities of interaction with care management team  
• Which PCOs should be targeted for improvement with care management  
• Determining whether approaches to care management need to be modified based on the intended outcomes |
Compared to care management provided by insurance companies, what is the effect of care management provided by medical homes on PCOs among patients with MCCs?

**Introduction:**
- Care management includes coordination of care and educational activities to help people with chronic conditions understand their condition and to achieve optimal health and quality of life.

**Burden:**
- 75 million people have MCCs
- Patients with MCCs are more likely to take multiple medications, have a higher rate of adverse events, more psychological distress, more rates of disability, and poorer quality of life than the rest of the population.

**Options for addressing issue:**
- Patient-centered medical homes (PCMHs): provide care management with a primary care physician as the leader of patient care and care coordination activities
- Care management by insurance companies: utilizes non-physician personnel, generally offsite, to coordinate care
- Insufficient evidence to compare clinical outcomes of care coordination in patients with MCCs in medical homes versus insurance companies

**Potential for new information to improve care and PCOs rapidly:**
- Effect of PCMHs on PCOs for patients with MCCs
- Implementation methods for PCMHs
- Identifying elements that have significant effect on outcomes on patients with MCCs
**Introduction:**
- PCMHs may be directed and staffed by providers other than physicians, such as physician assistants (PAs), nurse practitioners (NPs), nurses, or other specially trained staff

**Burden:**
- ~1/3 of current physicians practice primary care, but only 1/4 of current medical school graduates plan on careers in primary care
- Within 10 years, the deficit of primary care physicians will be 40,000

**Options for addressing issue:**
- The American College of Family Physicians has stated that PAs should be recognized as primary care providers in the PCMH model
- There is speculation that NPs could also fulfill roles as primary care providers
- No published trials have evaluated PCMHs led by PAs, NPs, nurses, or other non-physicians

**Potential for new information to improve care and PCOs rapidly:**
- Evaluate the effectiveness of PCMHs led and staffed by PAs and NPs on care quality and PCOs
- Identify elements required for rapid uptake of this model
#10 Compared to primary care alone, what is the effect of primary care co-located with mental health services on mental health symptoms, medication use, and other PCOs?

<table>
<thead>
<tr>
<th>Introduction:</th>
<th>• WHO recommends integrating mental health care with primary care services and the promotion of mental health along with general health</th>
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| Burden:       | • Half of all Americans will develop some mental illness in their lifetime  
• 17% of US adults have both a physical and mental health condition  
• Mental illness is associated with diminished well-being, unhealthy behaviors, and reduced overall quality of life  
• Health disparities tend to be exacerbated for mental health care due to access and other social factors |
| Options for addressing issue: | • Collaborative care: includes mental health services in the primary care setting  
• Some evidence for improvement on specific outcomes, such as the mental condition itself, patient satisfaction, and quality of life  
• Lacking evidence on outcomes such as medication adherence, self-management, symptom burden, and clinical outcomes relevant to the medical condition |
| Potential for new information to improve care and PCOs rapidly: | • Comparison of different models: treatment by primary care physician, co-managed, or referred  
• Identifying the effect on a comprehensive range of patient outcomes  
• Optimal structure of provider teams  
• Identifying whether mental health disease also increases risk for other medical problems |
#11 Compared to direct transportation to a regional trauma center, what is the effect of stabilization at a local hospital (followed by transfer to a regional trauma center) on survival and other PCOs?

| Introduction: | • A trauma center is a hospital that has resources and equipment needed to care for severely injured patients  
• Local hospitals can provide initial assessment and treatment of trauma but are not designated as trauma centers if they do not have trauma surgeons and other necessary hospital resources |
| Burden: | • Injuries are the leading cause of death for children and adults ages 1 to 44  
• Nearly one in five (45 million) Americans live in regions without access to a Level I or II trauma center within one hour of where they are injured |
| Options for addressing issue: | • Trauma systems: includes both trauma centers and non-trauma centers for the care of injured individuals in a region  
• Inclusive system: all hospitals within a region participate in the trauma system  
• Exclusive system: all injured patients are preferentially sent to the few trauma centers |
| Potential for new information to improve care and PCOs rapidly: | • Optimal triage and management of patients within trauma systems  
• Effect of different triage models on PCOs |
#12 Compared to usual care, what is the effect of information technology (e.g., EHRs, PHRs, and decision support) on providers’ compliance with guidelines and chronically ill patients’ adherence to treatment plans?

| Introduction: | • Clinical decision support (CDS) systems enhance compliance to clinical practice guidelines (CPGs) by providers and increase adherence to treatment by patients  
• ACA provides large incentives for adoption of CDS-enabled electronic health records (EHRs) and provides patient health records (PHRs) to patients |
|---|---|
| Burden: | • <50% of Americans receive the recommended treatment based on CPGs  
• Due to poor communication across systems and providers, patients with chronic conditions, especially those with multiple conditions, are at risk of having duplicated tests and more adverse events |
| Options for addressing issue: | • Health information technology (HIT) solutions (e.g., EHRs and PHRs) that are CDS-linked  
• Patient-focused guidelines directly implemented in the PHR |
| Potential for new information to improve care and PCOs rapidly: | • New HIT tools (e.g., CDS)  
• Strategies for implementing CDS-linked HIT systems  
• Proper application of CPGs in planning a treatment while considering patient-centered preferences and outcomes  
• Effect of HIT tools on provider compliance and patient adherence |
**#13 What are the relative effects of different quality improvement strategies on the quality of preventive services, acute care, chronic care, and rehabilitative services—and on PCOs—for adults and children?**

| Introduction: | • According to the Institute of Medicine, high-quality care is care that is safe, effective, patient-centered, timely, efficient, and equitable  
• Applications of quality improvement (QI) have spanned all components of care, including preventive, acute, chronic, and rehabilitative services |
| Burden: | • ~1/2 of patients receive suboptimal or unsatisfactory care  
• An estimated 1/3 of total healthcare expenditures in the United States represent waste  
• Deficiencies in the quality of care lead to excess morbidity and mortality |
| Options for addressing issue: | • Good evidence for QI strategies to address preventive and chronic care  
• Some evidence for a variety of different multimodal interventions for specific acute conditions in different contexts  
• Insufficient data for strategies for QI efforts for rehabilitative services |
| Potential for new information to improve care and PCOs rapidly: | • Research on the effectiveness of QI for acute and rehabilitative care  
• Rigorous evaluation of QI efforts (e.g., using randomized designs, comprehensive outcomes, and generalizable populations)  
• Implementation strategies (including developing local leadership and capacity for management and measurement) |
#14 What are the relative effects of different insurance features (e.g., benefit designs, utilization management, cost sharing) on chronically ill patients’ access to care, quality of care, and PCOs?

| Introduction: | • Fee-for-service payment models are often costly for both the insurer and the patient, and they can reward the provision of unnecessary care  
| | • Recently, new insurance options have been developed, and their benefits and risks for the chronically ill remain to be seen |
| Burden: | • Chronic conditions affect >50% of US population  
| | • Accounts for >75% of healthcare spending  
| | • Nearly 2/3 of Medicare beneficiaries have two or more chronic conditions  
| | • Copays and premiums are often unaffordable for chronically ill individuals, and medical bills contribute importantly to personal debt and bankruptcy |
| Options for addressing issue: | • Alternatives to fee-for-service insurance designs  
| | • Value-based insurance design: co-payment inversely related to proven benefit  
| | • “Consumer-directed health plan”: offers financial incentive for consumers to become involved in purchasing decisions for their own health care  
| | • Little evidence for these plans on access, quality, and outcomes |
| Potential for new information to improve care and PCOs rapidly: | • Determine whether different insurance features reduce payments for medical services while preserving the health of their beneficiaries  
| | • Experiment through voluntary participation in alternative designs in Medicare, Medicaid, and private insurance  
| | • Effect of different designs on access, quality, and PCOs |
#15 Compared to usual care, what are the effects of different models of transitional care on patient safety and other PCOs?

<table>
<thead>
<tr>
<th>Introduction:</th>
<th>• Transitional care: strategies designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care</th>
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</table>
| Burden:       | • Transitioning from inpatient to outpatient care, as well as transitioning to higher intensity care, are both periods of increased risk for adverse events  
• ~20% of patients have adverse events after discharge, half of which are considered preventable  
• Deficiencies in transitional care are felt largely through costs due to hospital readmissions |
| Options for addressing issue: | • Transitional care involves three basic elements to guarantee continuity of care and quality: communication, medication reconciliation, and education  
• The evidence to support these interventions is fairly robust |
| Potential for new information to improve care and PCOs rapidly: | • How to best implement evidence-based transitional care strategies in real-world settings  
• Effective tools and processes to improve transitions  
• Effect of different models and tools on outcomes |