Welcome

Please be seated by 9:20 a.m.

The teleconference will go live at 9:30 a.m.

Patient-Centered Outcomes Research Institute

Assessment of Prevention, Diagnosis, and Treatment Options

Advisory Panel Meeting

January 13, 2015

Patient-Centered Outcomes Research Institute

Welcome and Introductions

David Hickam, MD, MPH

Program Director
Clinical Effectiveness Research
PCORI

Housekeeping

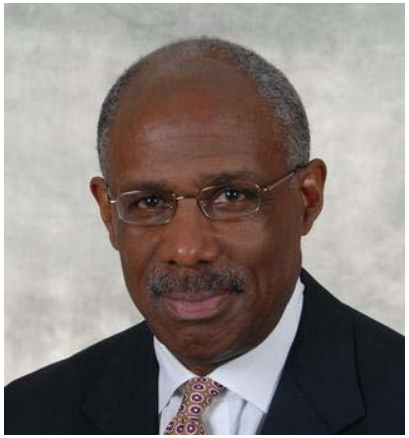
- Today's teleconference is open to the public and is being recorded
  - Members of the public are invited to listen to this teleconference
  - Meeting materials can be found on the PCORI website
  - Comments may be submitted via email to advisorypanels@pcori.org; no public comment period is scheduled
- For those in the room, please remember to speak loudly and clearly into a microphone
- Where possible, we encourage you to avoid technical language in your discussion
- Conflict of Interest Statement

Advisory Panel Members

Not pictured: Sara Hohly, Denise Kruzikas

Thank You for Your Service

Sara Hohly, BFA



Mark S. Johnson, MD, MPH

Ronald F. Means, MD

Denise Kruzikas, PhD, MPH

Clinical Effectiveness Research Team


David Hickam, MD, MPH


Yen-Pin Chiang, PhD


Harold Sox, MD


Diane Bild, MD, MPH


Anne Trontell, MD, MPH


Stanley Ip, MD


Danielle Whicher, PhD, MHS


Sandi Myers


Julie McCormack, MA


Jana-Lynn Louis, MPH


Katie Hughes, MA


Jackie Dillard


Jess Robb, MPH


Fatou Ceesay, MPH


Kim Bailey, MS


Marina Broitman, PhD


Cary Scheiderer, PhD

Advisory Panel Chairs

Alvin I. Mushlin, MD, ScM

Chair, Panel on the Assessment of Options

Chairman, Department of Public Health, Weill Cornell Medical College; Public Health Physician-in-Chief, New York Presbyterian Hospital/Weill Cornell Medical Center

Margaret F. Clayton, RN, PhD

Co-chair, Panel on the Assessment of Options

Associate Professor, College of Nursing and Co-Director of the PhD Program, University of Utah

Agenda Overview

Time	Agenda Item
9:30 – 9:45 a.m.	Welcome and Introductions
9:45 – 10:00 a.m.	Overview of the Agenda and Meeting Objectives
10:00 – 10:45 a.m.	Background and Status of Previous Topics
10:45 – 11 a.m.	BREAK
11 a.m. – 12:30 p.m.	Discussion: Genetic Testing in Rare Disease
12:30 – 1:30 p.m.	LUNCH
1:30 – 3:00 p.m.	Discussion: ICDs in the Elderly
3 – 3:15 p.m.	Break
3:15 – 4:45 p.m.	Discussion: Mindfulness-based Interventions
4:45 - 5 p.m.	Announcements and Next Steps
5 p.m.	Adjourn

Meeting Objective and Procedures

- Create a subset of specific questions for further consideration as priority research areas

- Procedures for Reviewing Topics
  - 3 CER topics will be reviewed
    - Senior Program Officer will do 5-10 minute introduction of topic
    - Approximately 1 hour and 30 minutes discussion per topic
    - Panelists will formulate 2-4 questions per topic that will be used as guidance for PCORI

Status of Previous Topics

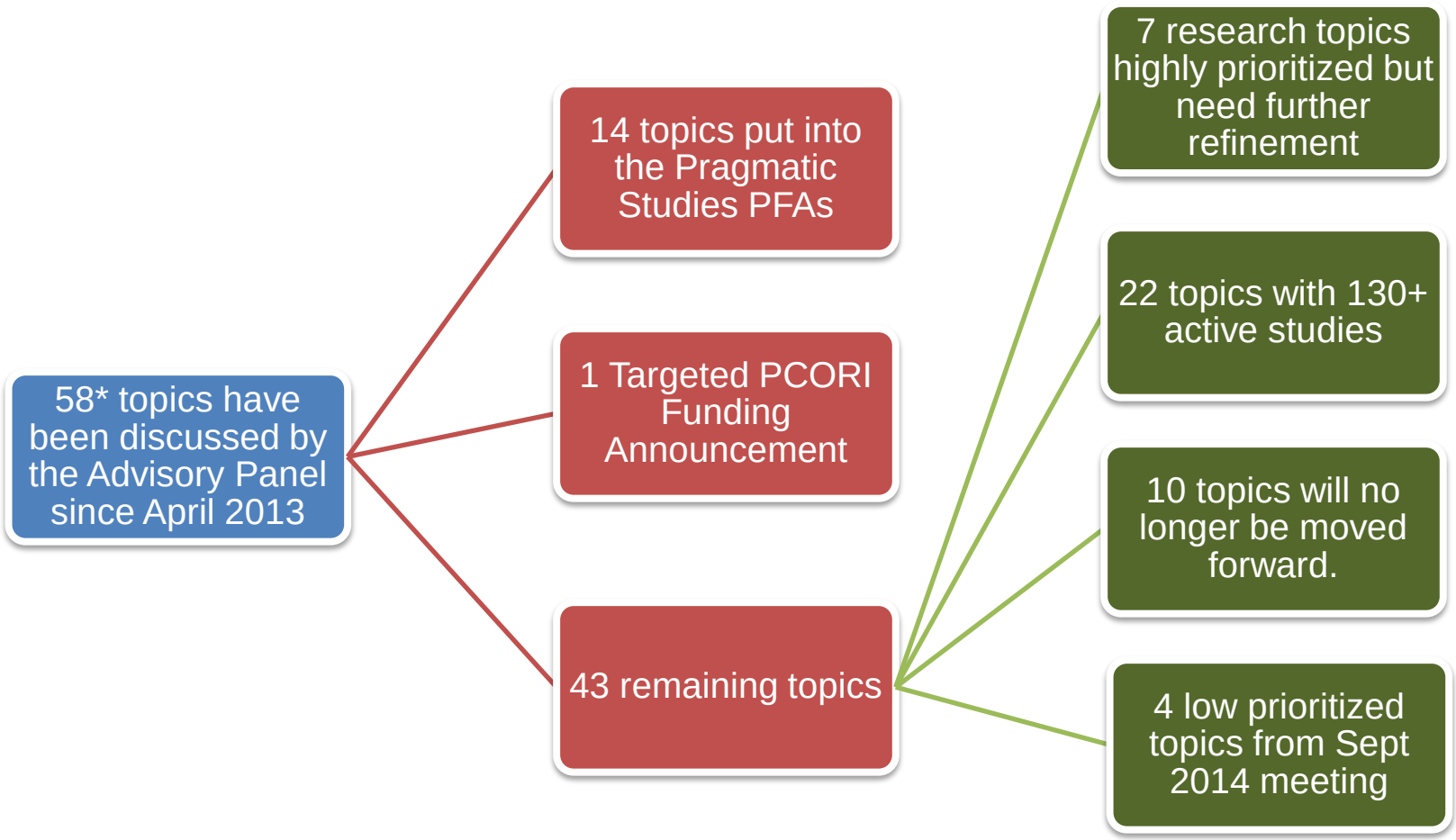
David Hickam, MD, MPH

Program Director
Clinical Effectiveness Research
PCORI

Past Approach to Topic Prioritization by the Advisory Panel

- Topic nominations from general public and clinical organizations (including NIH, AHRQ, IOM)
- Development of topic briefs
  - Brief background documents
  - High level evidence gaps
- Brief discussion of each topic by advisory panel
- Prioritization through a voting process
- Decision by PCORI about disposition of each topic
  - Pragmatic studies priority topics
  - Targeted funding announcements
- Further scoping of some topics
  - Retire topic due to large volume of current research
  - Input from stakeholders
  - Re-evaluation by panel

Status of Prioritized Topics



**Two topics were discussed twice (hearing loss and multiple sclerosis)*

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Status of Prioritized CER Topics

April 2013 Ranking	January 2014 Ranking	April 2014 Ranking
•1. Ductal Carcinoma in Situ	•1. Lung Cancer	•1. Inflammatory bowel disease
•2. Osteoarthritis	•2. Opioid Substance Abuse	•2. Atrial fibrillation
•3. Migraine Headache	•3. Autism Spectrum Disorder	•3. Major depressive disorders
•4. Bipolar Disorder	•4. Multiple Sclerosis**	•4. Mindful-based interventions
•5. Chronic Kidney Disease	•5. Proton Beam Therapy	•5. Management strategies for community-dwelling individuals with dementia
•6. Coronary Artery Disease	•6. Pelvic Floor Mesh Implants	•6. Renal Replacement Therapies
•Attention Deficit Hyperactivity Disorder	•7. Biomarker Testing	•7. Posttraumatic stress disorder
•Hip Fracture	•8. Psoriasis	•8. Intermittent claudication
•Carotid Artery Disease	•9. Hearing Loss**	•9. Nonsurgical treatment for cervical disc and neck pain
•Cerebral Adrenoleukodystrophy	•10. Hypercholesterolemia	•10. Periodontal disease
•Gestational Diabetes	•11. Robotic Surgery for Urologic and Gynecologic Cancers	•11. Primary open-angle glaucoma
•Eczema	•12. Mesh for the Management of Inguinal and Abdominal Hernia	•12. Eye disease
•Epilepsy	•13. Pemphigus Vulgaris	•13. Imaging technologies in cancer
•Generalized Anxiety Disorder	•14. Arrhythogenic Right Ventricular Dysplasia	•14. Detecting mild cognitive impairment
•Liver Cancer		•15. Managing serious emotional disorders in children and teens
•Macular Degeneration		•16. Concussion management
•Melanoma		
•Obstructive Sleep Apnea		

*Topics in **RED** included in Pragmatic Trials PFA*
*Topics in **GREEN** included in August 2014 'Rescued Topic' Webinar*
*Topics in **GRAY** will no longer be moved forward*
*Topics in **BLUE** will have meetings to better refine the research question*

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Status of Prioritized CER Topics

August 2014 Ranking*	September 2014 Ranking	January 2015 Ranking
•1. Carotid Artery Disease •2. Nonsurgical treatment for cervical disc and neck pain •3. Coronary Artery Disease •4. Hip Fracture •5. Pelvic Floor Mesh Implants •6. Gestational Diabetes •7. Eczema •8. Periodontal Disease •9. Concussion Management •10. Intermittent Claudication •11. Cerebral Adrenoleukodystrophy •12. Pemphigus Vulgaris •13. Hypercholesterolemia •14. Arrhythmogenic Right Ventricular Dysplasia •15. Mesh Management of Inguinal and Abdominal Hernias	•1. Hepatitis C •2. Open-Angle Glaucoma •3. Statin Therapy for Atherosclerotic Disease •4. Regional v General Anesthesia for Orthopedic Procedures •5. Genetic Testing for Select Rare Diseases •6. Implantable Cardiac Defibrillators in Elderly •7. Inferior Vena Cava filters for Acute Venous Thromboembolism •8. Exercise and Physical Therapy for Tendinopathies •9. Cognitive Decline •10. Sjögren's Syndrome	

**Rescued topics previously prioritized during April 2013, January 2014, and April 2014 meetings*
*Topics in **RED** included in Pragmatic Trials PFA*
*Topics in **GRAY** will no longer be moved forward*
*Topics in **BLUE** will have meetings to better refine research question*
*Topic in **PURPLE** will have targeted funding announcement*

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Multiple Sclerosis topic

Diane Bild, MD, MPH
Senior Program Officer,
Clinical Effectiveness Research

Patient-Centered Outcomes Research Institute

Brief history of the topic

- APDTO Advisory Panel discussed multiple sclerosis in January 2014
  - Ranked it 4 out of 14
- PCORI included the topic in its first PFA for Large Pragmatic Studies
  - *Treatment options for patients with multiple sclerosis. Compare management options for modifying disease progression. These might include FDA-approved disease-modifying agents; behavioral interventions, including exercise and physical therapy; and complementary medicine alternatives.*

Brief history of the topic, continued

- PCORI received many letters of intent over three LPS cycles; however, no investigators were invited to submit a full application due to small sample sizes and other concerns.
- PCORI convened a preliminary stakeholder meeting on October 30, 2014 to ask:
  - Can comparative effectiveness research make a useful contribution at this point in time, addressing questions that matter to patients, their caregivers, and clinicians?
  - Answer was “yes.”

PCORI plans for this topic

- Commission an evidence review to expand on the previous topic brief, to address:
  - What is the comparative effectiveness of disease-modifying therapies (DMTs) on symptoms in MS?
  - What is the comparative effectiveness of symptomatic treatments in MS?
  - What are the most important subgroups of MS patients to consider, in terms of symptoms, disease course, and patient preferences, for CER of symptom management?
- Convene informal meetings with the pharmaceutical and biotechnology industries and payers to discuss their views of the most important CER questions in MS.
- Convene a larger stakeholder meeting in April 2015 in conjunction with the annual American Academy of Neurology in Washington, DC.

Hepatitis C Targeted PFA

Danielle Whicher, PhD, MHS
Program Officer,
Clinical Effectiveness Research

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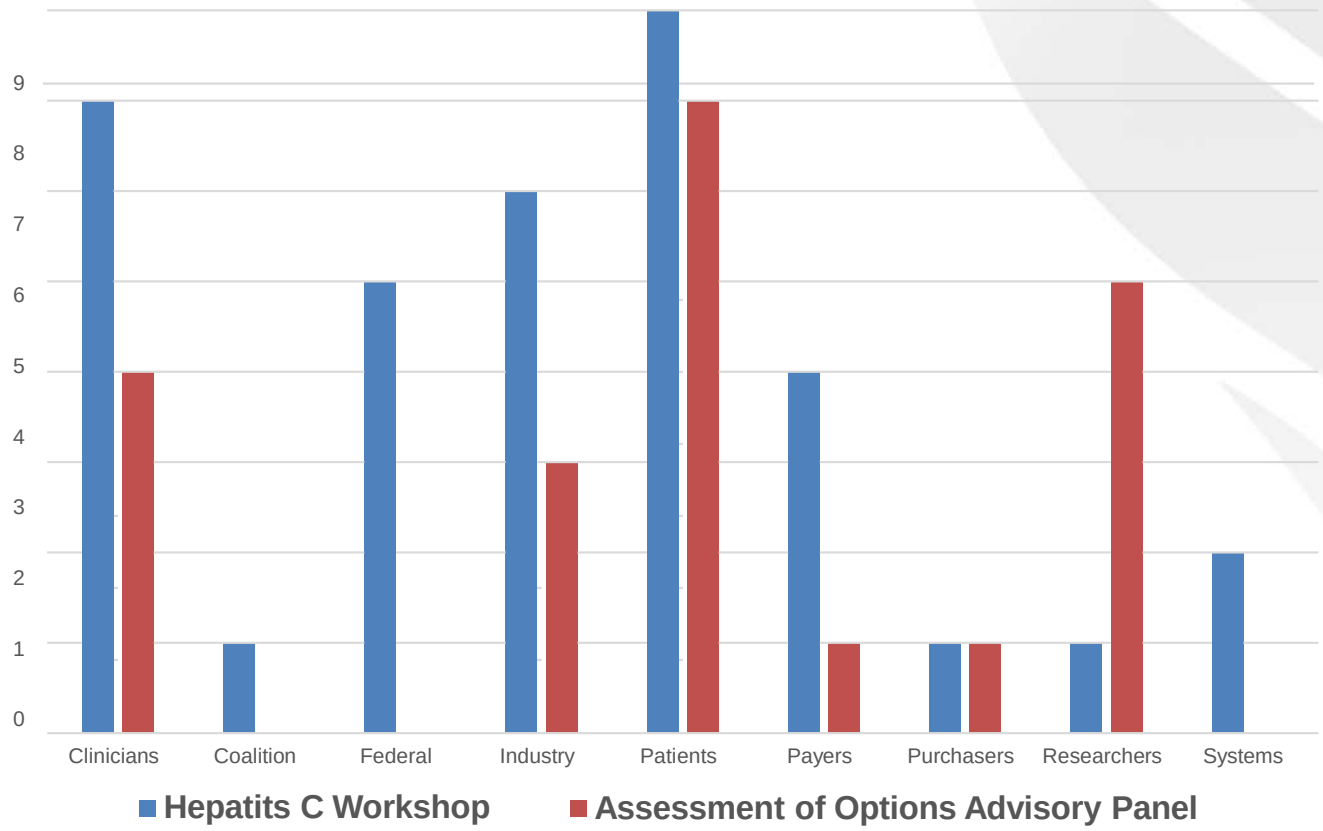
Stakeholder Input

- **Assessment of Options Advisory Panel** met September 19th
  - Panelists ranked hepatitis C #1
- **Multi-Stakeholder workshop** held October 17th
  - **40 invited stakeholder's attended in person**
    - Meeting was open to the public via teleconference and webinar
  - **Discussed:** whether CER can help answer questions about hepatitis C screening, diagnosis, and treatment

Stakeholder Meeting Attendees



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Hepatitis C Funding Announcement

- Four research topic areas received strong support in a multi-round voting process
- PCORI proposes to commit up to **$50 million in total costs to fund** large clinical studies to test the comparative effectiveness of alternative approaches to diagnosis, treatment, and management of Hepatitis C
- The maximum length of these studies will be 5 years

Four Priority Questions

- What are the trade-offs between long-term virologic response and adverse effects for different regimens of oral antiviral medications for the treatment of hepatitis C infection?
- What are the comparative benefits and harms of treating patients with hepatitis C infection early versus waiting to treat only those patients who show progression of liver disease or other manifestations of hepatitis C infection?
- Which screening methods and testing strategies, in which settings, lead to the best detection rates?
- What approaches for linking primary care physicians with specialty teams are most effective in accurately diagnosing and effectively treating patient with hepatitis C, who are clinically complex, hard to reach, or difficult to treat?

Timeline

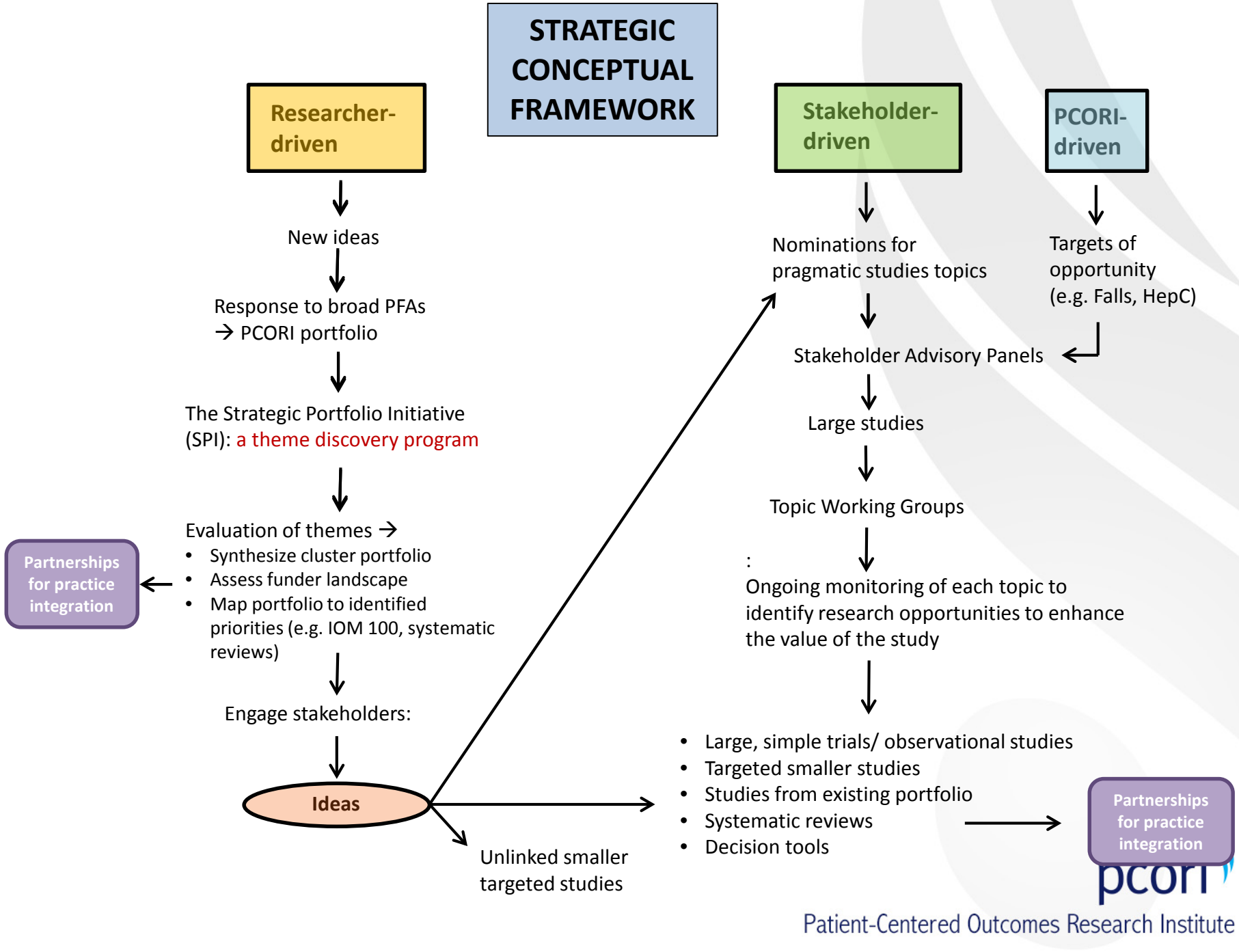
Action	Date
Release Date	February 5, 2015
PCORI Online System Opens	February 5, 2015
Applicant Town Hall Session (Webinar)	February 15, 2015
Letter of Intent Due	March 6, 2015 by 5:00 PM (EST)
Application Deadline	May 5, 2015 by 5:00 PM (EST)
Merit Review	Week of August 4, 2015
Awards Announced	September 2015

An Outline of a Proposed Selection Process for the Topics for Large Studies

Harold Sox, MD
Director,
Research Portfolio Development

Patient-Centered Outcomes Research Institute

STRATEGIC CONCEPTUAL FRAMEWORK



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Outline of process

1. Developing the initial list of topics
2. Identifying the evidence gaps: topic briefs
3. Initial triage
4. Defining the research questions
5. Advisory Panel meeting
6. Funding Announcement

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Developing the initial list of topics

- Using current procedures and criteria, program officers will review a list of topic nominations and identify 10 of them for further consideration using the current PCORI process.
- Sources of topics include:
  - Nominations from stakeholders
  - Topics identified from study of PCORI's existing portfolio of funded topics

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Identifying the evidence gaps: topic briefs

- PCORI will commission topic briefs on the 10 topics. These briefs will address the topic selection criteria, evidence gaps, and potential research questions.

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Initial Triage by Advisory Panel

- The Advisory Panel members will review the materials off-line and vote individually by email.
- The top four vote getters (the high priority topics) will advance to the next stage.

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Defining the research questions

- For each finalist topic, PCORI will convene 3-4 content experts and several stakeholders to identify key research questions within the short-list topics.
  - For clinical topics, the experts will have a reputation for excellence in clinical care and deep knowledge of the field
    - invited speakers on a clinical topic at a national meeting
    - clinical program director in a subspecialty.
  - The stakeholder would typically be a medical director of a payer organization or health care system.

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Advisory Panel meeting

- A clinician from the panel of experts in each of the four high priority topics will present the research questions identified by the panel and lead a discussion with the Advisory Panel.
  - The goal of the discussion will be to incorporate the thinking of the Advisory Panel members into the formulation of the research questions.
- The panel will vote on the research questions for each topic (rank ordering within topic, not across topics).

Funding Announcement

- PCORI staff will choose the research questions based partly on
  - The Advisory Panel vote
  - The feasibility of addressing the research question
  - Fit with PCORI's mission.
- Review by the Science Oversight Committee of the Board and approved by the Board of Governors
- List the high priority research topics and, within each topic, the research questions.

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Break
10:45 a.m. – 11:00 a.m.

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Genetic Testing in Rare Disease

Introduction:

Diane Bild, MD, MPH

Senior Program Officer, Clinical Effectiveness Research

Experts:

Marshall Summar, MD

Division Chief, Genetics and Metabolism

Margaret O'Malley Chair of Molecular Genetics

Uday Deshmukh, MD, MPH, CPE, FACP

Senior Medical Director of Clinical Operations, Florida Blue

Genetic Testing in Children in Whom a Rare Genetic Disease is Suspected

Diane Bild, MD, MPH
Senior Program Officer
Clinical Effectiveness Research

Patient-Centered Outcomes Research Institute

Genetic Testing - Background

- Genetic testing is increasing in availability and use.
- Over $5 billion was spent on genetic testing in 2010 in the US[1].
- There are currently 1,000-1,300 tests available.
- Genetic testing in children can be used for screening, diagnosis, predicting the risk of future events, and informing treatment decisions.
- Genetic testing has value and promise but also risks.

[1] http://www.unitedhealthgroup.com/~/media/UHG/PDF/2012/UNH-Working-Paper-7.ashx

Topic Brief: Genetic Testing in Children in Whom a Rare Genetic Disease is Suspected

- Topic history at PCORI:
  - April 2014 – Rare Diseases Advisory Panel chair proposed this topic.
  - July 2014 – PCORI commissioned topic brief from Duke on Genetic testing for rare diseases among children.
  - September 2014 – APDTO Advisory Panel discussed the topic and ranked it 7 out of 10 topics.
  - December 2014 – PCORI commissioned Duke to expand on topic brief, bring in stakeholder input, and prioritize research needs.
  - January 2015 – Today's discussion

Duke's process

- Shown in detail in Figure 1.
  - Appraised recent systematic reviews
  - Identified important evidence gaps
  - Transformed gaps into research questions
  - Engaged stakeholders to identify additional gaps and to prioritize research needs or questions
  - Scanned recently published and ongoing studies

Stakeholder priorities

- Stakeholders prioritized evidence gaps relating to 4 primary areas of uncertainty:
  1. Patients' and families' experiences of genetic testing;
  2. Provider strategies for supporting patients undergoing genetic testing;
  3. Shared decision-making regarding genetic testing; and
  4. Patient-centered outcomes for clinical care and research in genetic testing

Top 9 ranked questions

1. What is the value of genetic testing for children in whom a rare disease is suspected (and their caregivers), and how can we best measure this value? 17 cohort studies, 2 RCTs
2. What support tools, training, and resources best enable providers to optimally care for children in whom a rare disease is suspected (and their caregivers)? 7 systematic reviews, 13 cohort studies, 2 guidelines
3. What are the most important patient-centered outcomes relating to genetic testing for children in whom a rare disease is suspected (and their caregivers)? 10 cohort studies, 1 RCT, 1 guideline
4. How does the diagnostic odyssey experienced prior to clinical consultation influence perceptions of genetic testing and testing decisions for children in whom a rare disease is suspected (and their caregivers)? 4 cohort studies, 1 RCT
5. What are the comparative benefits and risks of formal genetic counseling prior to and following genetic testing among children in whom a rare disease is suspected (and their caregivers)? 1 SR, 4 RCTs, 4 cohort studies, 2 guidelines

Questions on page 12 of Topic Brief

Top 9 ranked questions, continued

6. How can children in whom a rare disease is suspected (and their caregivers) become better prepared to process relevant health and psychosocial information, understand limitations of this information, decide how to act on this information, and stay informed beyond their initial decision? 4 RCTs, 7 cohorts
7. What strategies are most effective in informing shared decision-making with regard to the benefits and risks of pursuing genetic testing in children in whom a rare disease is suspected (and their caregivers)? 3 RCTs, 12 cohorts, 1 guide
8. How does the composition of the care team (e.g., genetic counselors, medical geneticists or other specialist providers, generalist providers, other clinicians) influence outcomes for children receiving genetic testing (and their caregivers)? 2 SR, 2 RCTs, 6 cohort studies
9. How do shared decision-making processes for genetic testing and patient-centered outcomes differ depending on the types of tests available (e.g., targeted testing for mutations vs. broader approaches like whole-exome or whole-genome sequencing (including the recommendation to analyze and report on the 56 'medically actionable genes')? none

Questions on page 12 of Topic Brief

Addition question asked of stakeholders to identify specific genetic tests or conditions:

- "Are there specific genetic tests and/or rare genetic diseases in children that you believe would be appropriate 'test cases' to use for further exploration of potential evidence gaps?"
- Considerations include:
  - conditions with reliable, validated testing options vs. conditions with less reliable options;
  - condition that are untreatable vs. treatable vs. treatable only with experimental therapies;
  - conditions with severe symptoms vs. less severe symptoms;
  - conditions with shortened lifespan vs. normal lifespan.

Stakeholders suggested exemplars

- Hereditary cancer syndromes
- Duchenne Muscular Dystrophy
- Autism
- Resistant epilepsy
- Fragile X Syndrome
- Huntington Disease
- Lysosomal storage disorders (including treatable diseases, e.g., Type I Gaucher, vs. less treatable diseases, e.g., Tay Sachs or Type II Gaucher)
- Spinal Muscle Atrophy

Discussion

- Among these topics, which ones should PCORI pursue?
- Should we focus on specific conditions or tests?
  - If so, how shall we identify those?
- What steps might we take next?

Lunch
12:30 p.m. – 1:30 p.m.

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ICDs in the Elderly

Introduction:

Stanley Ip

Senior Program Officer, Clinical Effectiveness Research

Experts:

Gillian D. Sanders-Schmidler, PhD

Director, Duke Evidence-Based Practice Center

Associate Professor of Medicine, Duke University

Sana Al-Khatib, MD, MHS

Associate Professor of Medicine, Duke University

The Use of Implantable Cardioverter-Defibrillators (ICD) in the Elderly

Stanley Ip, MD
Senior Program Officer
Clinical Effectiveness Research

Patient-Centered Outcomes Research Institute

Implantable Cardioverter-Defibrillator (ICD)

- A battery operated device that can sense arrhythmia and deliver electric shock
- Use to break fast arrhythmia as in ventricular tachycardia (VT)/fibrillation (VF)
- First line treatment for the secondary prevention of sudden cardiac death (SCD) in patients with prior events due to suspected VT/VF
- Primary prevention in populations at high risk for VT/VF

Other treatments for VT/VF

- Anti-arrhythmic drugs
- Ablation by surgery or via catheter
- Cardiac transplant

Sudden Cardiac Death (SCD)

- Cardiac death within 1 h of onset of symptoms
- 300,000 to 400,000 deaths per year
- 5 to 6% of patients survive SCD
- SCD is often the first manifestation of coronary artery disease
- ICD is currently the most effective therapy in patients at risk

2013 ACCF and HRS Guidelines

- ICD and/or CRT implantation is appropriate in general when the expected value in terms of survival and/or other health benefits (symptoms, functional status, and/or quality of life) exceed the potential adverse health consequences relating to the acute procedural risk and the long-term consequences of living with an implanted device (*http://www.hrsonline.org/Practice-Guidance/Clinical-Guidelines-Documents/Appropriate-Use-Criteria-for-ICDs-and-CRT#axzz3OAWIm0sz*)

Considerations in the elderly

- SCD increases with age
- >500,000 Medicare beneficiaries eligible for ICD
- Data from trials typically have few elderly patients
- Trial patients commonly younger than patients in everyday practice
- Comorbidities might attenuate the benefit of ICD

Nominator's interest in ICD in the elderly

- Effects on elderly with comorbidities
- Beyond survival
  - Inappropriate shocks (20 to 24% of patients)
  - Psychological outcomes
  - Health resource utilization
  - Device reliability and side effects
  - Battery replacement (every 4 to 6 years) is not risk free
  - Limitations on getting MRIs
  - End-of-life circumstances and decisions

Previous Panel Discussion

- Focus on treatment heterogeneity in patients with different baseline risk of SCD
- CER of ICDs vs. other treatment options in older patients with and without multiple comorbidities

Research priorities in expanded topic brief

- Safety and effectiveness of ICDs in older patient subgroups not well-represented in clinical trials
- Predictors of SCD
- Impact of ICD use (e.g., shocks, complications) on QoL and survival
- Use of shared decision making
- Disparities in ICD referrals by sex, race, or ethnicity
- Risk stratification strategies beyond the use of Left Ventricular Ejection Fraction
- Patient preferences (i.e., improved survival from ICDs at the cost of comorbidities/complications/suffering)
- Effect of ICD use on geriatric outcomes like QoL, physical activity, independence, fatigues, and frailty
- Distribution of modes of death in older patients eligible for ICD (e.g., heart failure death, noncardiac death, sudden death, other cardiac death, unknown death)
- Comparative safety and effectiveness of different devices (single chamber, dual chamber, etc.) based on age, underlying heart disease, and the presence of other diseases

Discussion

- What scientific information do an elderly patient and her/his providers need in order to help make a decision of whether to have an ICD?
- 7/12 areas have more than a dozen recent or ongoing studies (e.g., predictors of SCD mortality, risk stratification strategies, impact of ICD use on QoL and survival, safety and effectiveness in subgroups)
- Which topics fit well into a CER framework?
- Which research questions are feasible to answer within a relatively short time frame?
- Feasibility of randomization in the elderly

Break
3:00 p.m. – 3:15 p.m.

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Mindfulness-Based Interventions

Introduction:

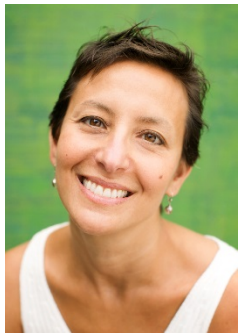
Anne Trontell, MD, MPH

Senior Program Officer, Clinical Effectiveness Research

Experts:

Madhav Goyal, MD, MHS

Department of Medicine, Johns Hopkins University



Regina Dehen, ND, L*Ac*

Chief Medical Officer, National College of Natural Medicine

Mindfulness-Based Interventions for the Treatment of Anxiety, Depression, and Pain

Anne Trontell, MD, MPH
Senior Program Officer
Clinical Effectiveness Research

Patient-Centered Outcomes Research Institute

What is Mindfulness?

https://www.youtube.com/watch?v=NbizmVKHdgs

Background: 2014 AHRQ Evidence Report on Meditation Programs for Psychological Stress and Well-Being

- Examined mindfulness and mantra meditation techniques, not movement-based approaches like yoga
- Outcomes: anxiety, depression, pain, and others
  - stress/distress, well-being/ positive mood, QoL, attention, and stress-related behaviors (substance abuse, sleep, eating, weight)
- Found moderate SOE vs. nonspecific active controls for improving anxiety, depression, and pain with effect sizes ranging from 0.22 to 0.43 at time points from 4 wk to 6 mo.
- CE analysis found no evidence of superiority to any specific comparative therapies

Background to Mindfulness-based Interventions (MBI) Topic Brief

- Topic brief scope: MBSR, MBCT,Vipassana, Zen, qui gong, tai chi, and yoga with mindfulness meditation component
- Standard approach to evidence gap and research questions
- Evidence gap themes of 21 identified (7 from stakeholders)
  - MBI vs pharmacologic, behavioral, & other therapies
  - MBI as adjunctive therapy to existing ones
  - Training and sustaining MBI

Also raised issue of measurement of MM

Stakeholder-Prioritized List of Research Needs of MBI in Depression, Anxiety, or Pain

- Which MBIs are most effective?
- Do MBIs decrease healthcare utilization, such as medication use?
- Which MBIs are effective adjuncts to existing therapies? E.g. to reduce frequency or severity of subsequent disease episodes?
- Which MBIs are associated with favorable clinical outcomes? Are these effects maintained over time?
- Are MBIs equivalent in safety/effectiveness to standard care e.g. pharmacologic or non-pharmacologic care?
- Do MBIs have different safety/effectiveness relative to standard care?
- Does CE of MBI differ by mode of delivery or pt practice?
- Does CE of MBI differ by dose/frequency/nature of sessions?

Stakeholder-Prioritized List of Research Needs: Existing & Ongoing Research

- CER of different MBI
- Impact of MBI on healthcare utilization
- Adjunctive use of MBI
- Which MBIs are associated with favorable clinical outcomes?(N=77)
- Are MBIs equivalent in safety/effectiveness to standard care?(N=26)
- Do MBIs have different safety/effectiveness relative to standard care? (N=28)
- Differential effectiveness by delivery method or patient practice
- Differential effectiveness by dose & frequency of MBI

Very limited data

High-level Summary Points of Topic Brief

- Mindfulness-based interventions hold promise for patient-centered outcomes related to depression, anxiety, and pain
- Relatively inexpensive and safe
- Research exploring the effects of MBI is in its infancy
  - MBI are diverse
  - Anxiety, depression, and pain are themselves heterogeneous
  - Stronger study designs are needed

Questions

- Are the characteristics of one or more mindfulness-based interventions sufficiently well-described and characterized to allow them to be studied in a CER framework for depression, anxiety, or pain?
- Which research questions are most promising for consideration?
  - Specific mindfulness-based interventions?
  - Specific mental health or physical conditions?
- Is randomization to a behavioral vs. medical intervention likely to e feasible?

Next Steps and Adjourn: 4:45 p.m.

- Next in-person meeting will occur on May 27 and/or May 28, 2015 in Washington, DC.
- Reminder: Please complete the Post Event Survey by June 12, 2015.

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Thank you for your participation.

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